Women, pregnancy and children – pharmacokinetics, injectables, endocrinology

PS1/2

Dolutegravir (DTG) use during pregnancy and birth outcomes: data from the Antiretroviral Pregnancy Registry (APR)

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Purpose: To describe maternal demographics, pregnancy and neonatal outcomes among infants with prenatal exposure to DTG using data from the APR.

Method: The APR is a voluntary, international, prospective exposure-registration cohort study, monitoring for early warning signals of major teratogenic effects of ART and collecting data on pregnancy and neonatal outcomes. Descriptive analysis with frequency tabulation of pregnancy and neonatal outcomes is reported.

Results: Through 31 January 2019, 522 pregnancies with exposure to DTG were prospectively reported to APR with 281 periconception exposures, 62 later during 1st trimester, 117 during 2nd trimester and 62 during 3rd trimester. Median age at conception was 29 years and 80.8% were from the United States. At enrolment, 45.4% had CD4 count>500 cells/µL, 32.6% had 200–499 cells/µL, 14.2% had<200 cells/µL and 7.9% unknown. The 522 DTG exposed pregnancies resulted in 537 outcomes: 491 (91.4%) live births (15 twin births), 7 (1.3%) stillbirths, 15 (2.8%) induced abortions, and 24 (4.5%) spontaneous abortions. Among live births, 17 (3.5%) reported birth

Table 1. Birth Defect Outcomes of Pregnant Women Exposed to DTG

Prospective Registry Cases with Follow-up Closed through 31 January 2019

<table>
<thead>
<tr>
<th>Total</th>
<th>Outcomes</th>
<th>Live</th>
<th>Births</th>
<th>Defect</th>
<th>NDS</th>
<th>CNS</th>
<th>NTD</th>
<th>Encephalocele</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>(n)</td>
<td>(n)</td>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
</tr>
<tr>
<td>Any InSIT</td>
<td>1487</td>
<td>1362</td>
<td>43</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure</td>
<td>[3]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periconception</td>
<td>834</td>
<td>725</td>
<td>21</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Later First</td>
<td>135</td>
<td>129</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trimester</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second/Third</td>
<td>516</td>
<td>506</td>
<td>20</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trimester</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any Dolutegravir</td>
<td>537</td>
<td>491</td>
<td>17</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure</td>
<td>[3]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periconception</td>
<td>289</td>
<td>248</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Later First</td>
<td>62</td>
<td>59</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trimester</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second/Third</td>
<td>186</td>
<td>184</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trimester</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: ART – antiretroviral therapy; CNS – central nervous system; NTD – neural tube defect. Note: Periconception is defined as any exposure 2 weeks prior to conception through 28 days gestational age; Later First Trimester is defined as any exposure in the first trimester that begins after 28 days gestational age. [1] NDS cases are a subset of CNS defects and are counted in both columns. [2] Encephalocele cases are a subset of CNS defects and are counted in both columns. [3] Includes cases with missing trimester of exposure. * Comparators for population expected rate of defects (2.72 – 4.17) 100 live births from MACDP and TBDR respectively. MACDP –Metropolitan Atlanta Congenital Defects Program; TBDR–Texas Birth Defects Registry
Table 2. Neonatal Outcomes (among Singleton, Live Births without Birth Defects)

<table>
<thead>
<tr>
<th>Neonatal Outcomes</th>
<th>Overall DTG Exposed</th>
<th>Earliest exposure to DTG - Periconception</th>
<th>Earliest exposure to DTG - Later 1st Trimester</th>
<th>Earliest exposure to DTG - 2nd/3rd Trimester</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Outcomes, N</td>
<td>447</td>
<td>226</td>
<td>57</td>
<td>164</td>
</tr>
<tr>
<td>Gestational Age*</td>
<td>398 (89.0%)</td>
<td>200 (88.5%)</td>
<td>48 (84.2%)</td>
<td>150 (91.5%)</td>
</tr>
<tr>
<td>37 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational Age*</td>
<td>48 (10.7%)</td>
<td>26 (11.5%)</td>
<td>9 (15.8%)</td>
<td>13 (7.9%)</td>
</tr>
<tr>
<td>37 weeks (Premature)</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>0</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Birth Weight*</td>
<td>382 (85.5%)</td>
<td>190 (84.1%)</td>
<td>49 (86.0%)</td>
<td>143 (87.2%)</td>
</tr>
<tr>
<td>Birth Weight*</td>
<td>54 (12.1%)</td>
<td>29 (12.8%)</td>
<td>8 (14.0%)</td>
<td>17 (10.4%)</td>
</tr>
<tr>
<td>Birth Weight*</td>
<td>10 (2.2%)</td>
<td>5 (2.2%)</td>
<td>2 (3.5%)</td>
<td>3 (1.8%)</td>
</tr>
<tr>
<td>Birth Weight*</td>
<td>11 (2.5%)</td>
<td>7 (3.1%)</td>
<td>0</td>
<td>4 (2.4%)</td>
</tr>
</tbody>
</table>

Note: DTG = Dolutegravir; LBW = Low Birth Weight. *Among singleton, live births without birth defects. Note: Periconception is defined as any exposure 2 weeks prior to conception through 28 days gestational age; Later First Trimester is defined as any exposure in the first trimester that begins after 28 days gestational age; Second Trimester begins at 14 weeks gestational age and Third Trimester begins at 28 weeks gestational age.

defects. For 1st trimester exposures, overall defect prevalence was 3.58% (11/307), 95% Ct: 1.8–6.32. One neural tube defect (NTD) case of anencephaly with periconception DTG exposure was reported. Among the 447 singleton, live births without birth defects, 48 (10.7%) were premature (<37 weeks of gestation); 54 (12.1%) had birth weight <2500 grams, and 10 (2.2%) <1500 grams.

Conclusion: APR data do not demonstrate an increased risk of overall birth defects with DTG use above the population expected rate of defects (2.72–2.17/100 live births from MACDP and TBDR respectively). The number of periconception outcomes is currently insufficient to refute or confirm an association of DTG with NTD. The Registry continues to closely monitor birth defects in pregnancies exposed to DTG and other integrase inhibitors, including NTDs with periconception exposure.

PS1/3

Prevalence and outcomes of pregnancies over a 20 year period: the EuroSIDA study


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Objectives: From a public health perspective it is important to evaluate time trends in prevalence and outcomes of pregnancies among HIV-positive women to ascertain equal access to care.

Methods: The EuroSIDA study collected pregnancy information 1996–2015 as annual cross-sectional audits of pregnancy and outcomes. Odds of pregnancy were modelled using logistic regression with generalized estimating equations accounting for repeated pregnancy information within women.

Results: Of 5535 women aged 16–50 years, 4217 (76.2%) had pregnancy information available. There were 1315 pregnancies reported in 912 women (21.6%). Of these, 319 (24.3%) occurred in 1996–2002, 576 (43.8%) in 2003–2009 and 420 (31.9%) in 2010–2015. The proportion of women with pregnancies were 28.1% (321/1143) in East Europe, 24.5% (146/596) in North, 19.8% (140/706) in West/Central, 19.3% (110/569) in Central Eastern and 16.2% (195/1203) in South. The proportion of women with a pregnancy decreased from 449 (17.3%) in 2003–2009 to 341 (12.6%) in 2010–2015, consistently across all regions. After multivariable adjustment, the odds of pregnancy were lower in 1996–2002, in South, Central-East and East Europe compared to West/Central Europe, in older women, in those with low CD4 counts or previously diagnosed with an AIDS-defining condition, and higher in those with a previous pregnancy or who were HCV positive (Figure).

Adjusted odds of pregnancy

Preparation outcomes were reported for 999 pregnancies in 1996–2014, with 690 live births (69%), of which 342 (49.5%) were HIV-negative, 23 (3.3%) HIV-positive and 325 (47.1%) of unknown HIV status. There were 7 stillbirths, 103 spontaneous and 199 medical abortions.

Conclusions: Pregnancy was reported for one in five women in EuroSIDA with a significant increase after 2002 when more effective cART became available. Substantial differences were seen between regions with higher prevalence in Eastern Europe, mainly due to differences in age and CD4 counts. Further surveillance of rates and outcomes of pregnancies among HIV-positive women in Europe is warranted.

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Does menopause affect treatment response in HIV-infected women? A multicenter cohort in Spain

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Purpose: The aim of this study was to compare the immunovirological response at 48 and 96 weeks from antiretroviral therapy (ART) initiation among premenopausal and postmenopausal HIV-infected women aged 45-60 years from the cohort of the Spanish HIV/AIDS Research Network (CoRIS).

Method: Linear regression was used to assess mean differences in CD4 T-cell count and CD4% changes and logistic regression to estimate odds ratios (ORs) for CD4/CD8 ratio normalization (≥1.0), achievement of Multiple T-cell marker recovery (MTMR - CD4 count≥500 + CD4%≥29% + CD4/CD8 ratio≥1) and virological suppression from ART initiation.

Results: Among 254 women included, 173 (68%) were premenopausal at ART initiation. Tenofovir disoproxil fumarate (TDF) + Emtricitabine (FTC) + Efavirenz (EFV) was the most frequent initial regimen, prescribed in 52 (30%) premenopausal and 23 (28%) postmenopausal women. Initial treatment regimens did not differ significantly between both groups. At ART initiation, there were no significant differences between premenopausal and postmenopausal women in CD4 counts (208 vs 183 cell/mm³; p=0.584), CD4 percentages (16.6% vs 15.0%; p=0.653) and CD4/CD8 ratio (0.30 vs 0.26; p=0.768), but premenopausal women had significantly lower viral loads than postmenopausal ones (4.7 vs 5.1 log copies/mL; p=0.021).

Conclusion: Among 254 women included, 173 (68%) were premenopausal at ART initiation. Tenofovir disoproxil fumarate (TDF) + Emtricitabine (FTC) + Efavirenz (EFV) was the most frequent initial regimen, prescribed in 52 (30%) premenopausal and 23 (28%) postmenopausal women. Initial treatment regimens did not differ significantly between both groups.

Discontinuation of neonatal postexposure prophylaxis in infants born to HIV-infected mothers with suppressed plasma viral load: safety and implementation of the new Swiss recommendations

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2. Institute of Medical Virology, University of Zurich, Zurich, Switzerland
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11. University Children's Hospital Zurich, Zurich, Switzerland
12. Children's Research Center, University Children's Hospital Zurich, Zurich, Switzerland

Purpose: New recommendations for prevention of HIV mother-to-child transmission (MTCT) have been issued by the Swiss Federal Office of Public Health (FOPH) in January 2016. For the first time in a high-income country neonatal post-exposure prophylaxis (neoPEP) is no longer recommended in HIV exposed newborns if maternal HIV plasma viral load (pVL) is fully suppressed in the last trimester. We aimed to investigate the implementation and safety of the new national recommendations in Switzerland.

Method: We evaluated data from the Swiss Mother and Child HIV Cohort Study (MoCHIV) and the linked Swiss HIV Cohort Study (SHCS) database. Children born between 2010 and 2018 were included if information on maternal pVL in the last trimester was available. We compared the frequency of neoPEP in infants born before and after the introduction of the recommendations. HIV-status of the children was assessed by PCR at 6 months of age.

Results: Maternal HIV pVL in the last trimester was <50 copies/mL in 363 of 383 (94.8%) children born during the study period. Of these, 264 of 267 (98.9%) children born before the guideline change in 2016 received neoPEP compared to 12 of 96 (12.5%) born afterwards (p<0.001, see Figure 1). NeoPEP was administered to all 20 infants with detectable maternal HIV pVL in the last trimester, including 5 infants born 2016 onwards. None of the 87 children that didn’t receive neoPEP was infected with HIV.

Conclusion: The new recommendations have been implemented rapidly in Switzerland. This indicates that treating physicians were well-informed and did accept the arguments provided. NeoPEP exposure was reduced by 86.4%, while no MTCT of HIV was observed. Our data suggests that neoPEP recommendations of other high-income countries should be reconsidered.
Social and implementation science

PS2/1
Empowering home visiting nurses as leaders in the response to the HIV epidemic in Central Asia

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Purpose: In Central Asia, people living with HIV (PLHIV) on antiretroviral treatment (ART), face many obstacles to retention in care and treatment. These include stigma, discrimination, lack of support from relatives, and opioid and alcohol abuse. Considering the need to reach the 90–90–90 goals, home-based care has the potential to reduce many of these barriers.

Method: In January 2018, ICAP launched "SUPPORT4HEALTH," an enhanced nurse-led home-based intervention to improve adherence and retention of PLHIV in care and treatment. Implemented in three countries (Kazakhstan, Kyrgyzstan, Tajikistan), the intervention focused on adult PLHIV who were newly initiated/restarted on ART and PLHIV on ART for six months or more with viral load >1000 copies/mL. The intervention includes eight home-visits and nine phone calls over a six-months period and is provided in addition to the standard of care. During each visit, nurse completes all information about performed activities into mobile application e-Nurse. ICAP uses this application for home visiting nurses’ mentoring and monitoring.

Results: This structured and systematized 6-month intervention using nursing home visits is now implemented at 28 sites in three countries and includes 56 home visiting nurses. During the home visits, the nurses conduct clinical TB screening, drug and alcohol surveys, pill counts, adherence assessments, counseling of patients’ partners and conversations with relatives to decrease stigma and discrimination. As of June 1, 2019, 3257 patients signed informed consent and were enrolled into the model. Among them, 1867 patients completed the model and 1530 (82%) achieved viral load suppression (<100 copies/mL).

Conclusion: Empowering home visiting nurses as leaders in the response to the HIV epidemic contributes to establishing trusting relationships and specific support for patients with a variety of complex health needs to improve adherence among ART patients. Improved adherence is improving health care outcomes for patients and their communities.

PS2/2
Extension of HIV treatment coverage in Ukraine through advocating access of dolutegravir generics to market

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Purpose: High price of the antiretrovirals (ARV) of the first line is deemed to be among the main barriers to achieve the 90–90–90 global targets for the low- and middle-income countries. In its recent recommendations, the World Health Organization (WHO) recommended dolutegravir (DTG) as the main first-line and second-line treatment. Ensuring access of generic medicines to market leads to decrease of medicines price and, respectively, secures increase of drug affordability.

Method: In 2016, price for the branded DTG for the Eastern European countries constituted more than 200 USD per monthly course. To decrease the price, All Ukrainian Network of People living with HIV (100 Percent Life) negotiated for extension of the license agreement for DTG for Ukraine. Upon receiving the license, 100 Percent Life facilitated the process of DTG inclusion into the procurement list of medicines. In 2017, 100 Percent Life held meetings with key stakeholders, which resulted in registration of the first generic DTG.

Results: In 2017, after the generic DTG entered the market the DTG price for monthly course decreased from more than 200 USD to 5 USD. Considering that 21 patients received ARV regimes with DTG in 2017 the state budget savings for annual course constituted 2730 USD. Decrease in prices enabled optimization of the ARV regimes in terms of scaling up towards DTG in accordance with WHO’s recommendations. As of June, 2019 Ukraine procured DTG regimes for 15218 patients. Procurement of the generic DTG comparing to the HIV epidemic in Central Asia with brands enabled savings of 1978340 USD.

Conclusion: The 100 Percent Life’s project demonstrates possibility to extend HIV treatment coverage by advocating access of DTG generics to the market. Funds allocated as a result of budget savings were used for procurement of additional prophylaxis, support and care services for key-groups as envisaged within the transition plan from the donors funding.

PS2/3
Assisted partner notification services to improve HIV case identification and linkage to antiretroviral treatment for sexual contacts of male and female sex workers in low-resource setting: findings from a key population program in Kenya

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Purpose: Female and male sex workers (FSW and MSW) continue to report high prevalence of HIV and contribute significantly to new infections in Sub-Saharan Africa. Currently, 29.3% for FSW and 18.2% of MSM/MSW are positive compared to 5% general population. A 2009 modes of transmission study indicated that 14% of all new infections in Kenya are directly attributable to sex workers. Identifying sexual contacts of sex workers is key in improving overall HIV case identification and linkage to treatment. Assisted partner notification (aPNS) is effective for increasing HIV case identification among discordant couples but its effectiveness in identifying contacts of FSW and MSW is unknown.

Methods: FSW and MSW followed through a key population (KP) HIV prevention program in Mombasa, Kenya were tested at five specialized sex worker clinics (drop-in centers). FSW and MSW who tested positive were offered aPNS; those who agreed were requested to provide contacts of sexual partners in the recent six months. Clinical staff at drop-in centers contacted the partners on phone and offered HIV testing either at the drop-in centers or at other locations.

Results: Between April and June 2019, 587 HIV positive FSW and 166 MSW were identified. aPNS was offered to 250 FSW and 143 MSW. 98 FSW (39%) and 133 MSW (93%) index partners accepted aPNS and provided contacts for 162 partners for FSW and 227 for MSW. Among the contacts 36 were known HIV positive and 28 (14%) were newly identified positive.

Conclusion: aPNS holds potential to increase HIV testing for sexual contacts of sex workers who are at high risks of HIV in African settings. aPNS also provides a targeted approach with relatively high yields and is more cost-effective compared to mass testing, especially in low-resource settings that experience occasional HIV test kit shortage.

Weight gain under integrase inhibitors: is this real?

PS3/1
Antiretroviral therapy and body weight in the START (Strategic Timing of Antiretroviral Treatment) trial

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Purpose: Obesity and HIV-infection are risk factors for cardiovascular disease making it important to understand how antiretrotherapy (ART) affects body weight. Contrary to other ART naïve trials, START suggested that ART was associated with lower weight gain (JAHA 2017, doi:10.1161). We explore possible predisposing factors of weight changes in START.

Method: In START, HIV-positive adults with CD4 counts>500 cells/µL were randomly assigned to initiate ART immediately or defer (until CD4<350 cells/µL or progression to AIDS). Weight was measured at baseline and follow-up visits. The mean treatment difference (immediate-deferred) in percent change...
in weight from baseline was estimated using repeated measures models for the full cohort and across 8 baseline-defined subgroups. 

Results: START randomized 4684 participants; median baseline weight was 74 kg (25th, 75th-percentile: 64, 83), median follow-up was 3.0 years. Compared to baseline, weight increased by 1.13% (95% confidence interval [CI]:0.86, 1.48) in the immediate and 1.92% (95% CI: 1.65, 2.19) in the deferred groups. The mean treatment difference in percentage change in weight was −0.79% (95% CI: −1.08, −0.50; p<0.001). This difference was larger among participants with low baseline HIV-RNA (subgroup x treatment interaction p=0.001; fig. 1a, fig. 2). High CD4 counts, female gender and living in mid-low-income regions were associated with lower weight gain in the immediate ART group (subgroup x treatment interaction p<0.001, p=0.048, p=0.019, respectively). Participants taking NNRTIs seemed to have less weight gain compared to other ART classes, however, differences across ART classes were not significant.

Conclusions: ART initiation at CD4>500 cells/µL resulted in less weight gain than deferral. This effect was pronounced among participants with low baseline HIV-RNA levels suggesting that the impact of ART among those with high levels was countered by weight gain due to reduction in viral replication. The impact of integrase inhibitors could not be assessed due to minimal use in the trial.

PS3/2

Effect of doravirine on body weight and body mass index in treatment naive adults with HIV-1

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Purpose: Studies suggest integrase strand-transfer inhibitors may cause more weight gain than protease inhibitors and non-nucleoside reverse transcriptase inhibitors in ART-naive patients. Female sex, black race, and disease stage have been associated with weight gain in some studies. We compared the effects of doravirine (DOR) on body weight and BMI with those of ritonavir-boosted darunavir (DRV+r) and efavirenz (EFV) using data from the Phase 2 (P007) and Phase 3 trials (DRIVE-FORWARD and DRIVE-AHEAD) in treatment-naive adults with HIV-1.

Method: Median change in weight was compared using the Wilcoxon rank-sum test, and proportions with≥5% weight gain were compared using the Miettinen-Nurminen method. The proportions whose BMI increased (change from underweight/normal to overweight/obese or from overweight to obese) were summarized, and the risk of BMI increase in each treatment group was estimated using a generalized linear model adjusting for region, gender, race, age, and baseline BMI, CD4 + T-cell count, and HIV-1 RNA.

Results: At 48 and 96 weeks, median weight change was statistically comparable between DOR and DRV+r but higher for DOR than EFV (table). The proportion with≥5% weight gain was comparable between DOR (26.5%) and DRV+r (23.1%) and higher for DOR than EFV (20.6%) at week 48 but was similar across all groups at week 96. The proportion with BMI increase was not significantly different for each comparison at both time points. Baseline CD4 + T-cell count and HIV-1 RNA predicted BMI increase at weeks 48 and 96, while race, age, and treatment group did not; sex predicted BMI increase at week 48 but not at week 96.

Conclusion: DOR and DRV+r had comparable effects on body weight and BMI. Median weight gain was statistically greater for DOR than EFV at both time points, while≥5% weight gain was greater at 48 weeks only. DOR and EFV had comparable effects on BMI.
Effects on Body Weight and BMI by Treatment Group (DOR, DRV+r, EFV)

<table>
<thead>
<tr>
<th>Combined DOR Group</th>
<th>DRV+r Group</th>
<th>DOR vs DRV</th>
<th>Combined EFV Group</th>
<th>DOR vs EFV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Body Weight (kg) from Baseline, Median (IQR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 48 N=751</td>
<td>1.00 (–1.0, 3.90)</td>
<td>N=316</td>
<td>0.59 (–1.9, 3.42)</td>
<td>p=0.117</td>
</tr>
<tr>
<td>Week 96 N=677</td>
<td>1.50 (–1.0, 4.94)</td>
<td>N=268</td>
<td>0.70 (–1.85, 5.10)</td>
<td>p=0.147</td>
</tr>
</tbody>
</table>

Proportion of Participants with ≥5% Weight Gain (kg) from Baseline

| Week 48 N=751 | 26.5% | N=316 | 23.1% | p=0.245 | N=402 | 20.6% | p=0.028 |
| Week 96 N=677 | 31.8% | N=268 | 32.8% | p=0.749 | N=362 | 32.0% | p=0.925 |

Proportion of Participants with Increased BMI

| Week 48 N=751 | 11.4% | N=315 | 11.1% | p=0.828 | N=402 | 7.9% | p=0.062 |
| Week 96 N=677 | 15.8% | N=267 | 15.3% | p=0.829 | N=362 | 14.2% | p=0.474 |

PS3/3

The ADVANCE clinical trial: changes from baseline to week 96 in DXA-assessed body composition in TAF/FTC + DTG compared to TDF/FTC+DTG, and TDF/FTC/EFV

K McCann1, M Moorhouse2, S Sokhela2, WDF Venter2, C Serenata2, A Qavi1, E Lindquist1, B Simmons1 and A Hill1

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Purpose: Following the increasing evidence-base to suggest integrase inhibitors lead to rises in body weight, there is a need to assess the impact on body composition among priority populations, such as black women. Dual-energy X-ray absorptiometry (DXA) can be used to assess body composition in patients to determine the type of weight gained. One aim of the ADVANCE study was to determine changes in body composition across treatment arms, using data from DXA scans.

Method: A sample of 1,053 treatment-naive patients in South Africa were recruited and followed over a 96-week period. Participants were randomized to TAF/FTC + DTG, and TDF/FTC/EFV. DXA scans measured fat and lean mass at baseline, week 48, and week 96. Change from baseline across all DXA measurements, recruited and followed over a 96-week period. Participants were randomized to TAF/FTC compared to men (4% TAF/FTC increase in fat was evenly distributed between trunk and limb mass. Lean mass

Results:

Changes in body composition are displayed in Table 1. The large increase in fat was evenly distributed between trunk and limb mass. Lean mass also increased to week 96. Treatment emergent obesity at week 96 was higher among women (30.5% TAF/FTC + DTG, 14% TDF/FTC + DTG, and 8% TDF/FTC/EFV) compared to men (4% TAF/FTC + DTG, 2% TDF/FTC + DTG, and 0% TDF/FTC/EFV), and statistically significant differences between TAF/FTC + DTG and the other groups (p<0.0001). There were statistically significant differences between men and women across all DXA measurements, with women showing higher rises in fat, and weight more generally. Concomitant medications, appetite and nausea, and insomnia had no impact on these increases in weight, and quality of life was similar across all arms.

Conclusion: Our study demonstrates DTG used in combination with TAF is associated with large increases in weight, predominately fat. This increase is statistically significant and higher in women compared to men. Our results suggest these findings are not a return to health effect, with no clear plateau before week 96.

PS3/4

Integrase inhibitors dolutegravir and raltegravir exert proadipogenic and profibrotic effects and induce insulin resistance in adipose tissue and adipocytes

J Gorwood1, C Bourgeois2, V Pourcher1, F Charlotte1, G Pourcher1, M Mantecon1, C Rose1, R Morichon1, R Le Grand2, C Katlama3,5, B Fève1,6, O Lambotte2,7, J Capeau1, V Bézéat1 and C Lagathu1

1Sorbonne Université INSERM UMR 938 Saint-Antoine research center, Paris, France 2CEA, Université Paris Sud, Inserm U1184, IMVA, IDMIT, Fontenay-aux-Roses, France 3AP-HP, Sorbonne Université, Hôpital Pitié-Salpêtrière, Service de maladies infectieuses et tropicales, INSERM U1136, Institut Pierre Louis d’épidémiologie et de Santé publique et d’Anatomato-Pathologie, Paris, France 4Institut Mutualiste Montrouzier, Service de Chirurgie Digestive, Paris, France 5Sorbonne Université, Inserm, Institut Pierre Louis d’épidémiologie et de Santé publique, Paris, France 6AP-HP, Hôpital Saint-Antoine, Service d’endocrinologie, Paris, France 7APHP, Hôpital Bicêtre, Service de Médecine Interne et Immunologie Clinique, Kremlin-Bicêtre, France

Purpose: There is growing evidence that integrase inhibitors (INSTI) dolutegravir and raltegravir promote peripheral and central adipose tissue/weight gain in HIV-infected individuals, but the mechanisms involved remain unknown. We aimed to assess the effect of these molecules on adipose tissue morphology, function and metabolism.

Method: Morphology and function of subcutaneous (SCAT) and visceral adipose tissue (VAT) were studied in: -HIV-infected patients from the ObéVIH study, at the time of bariatric surgery (BMI 41.8 kg/m²): 14 patients received INSTI (10 dolutegravir, 2 raltegravir, 2 elvitegravir) and 5 an INSTI-sparing regimen.

Human Adipose Stem Cells (ASCs) were chronically treated with dolutegravir or raltegravir before or during adipogenesis. Adipogenic capacities, insulin response and extracellular matrix component expression were analyzed.

Results: SCAT from the ObéVIH patients presented peri-lobular and peri-adipocyte fibrosis in most samples. Conversely, VAT of INSTI-treated patients presented a higher level of peri-adipocyte fibrosis than that of non-INSTI-treated patients. Dolutegravir-treated macaques presented a higher level of fibrosis and an increased adipocyte size in both SCAT and VAT, when compared to untreated macaques. Adipogenic marker expression was increased in SCAT and VAT, whereas adiponectin expression was decreased in SCAT, suggesting that, despite a pro-adipogenic effect, dolutegravir may favor insulin resistance.

In ASCs, INSTI-treatment increased collagen 1 and 6 and a-smooth-muscle-actin expression indicating a pro-fibrotic effect. In ASC differentiated adipocytes, dolutegravir, and to a lesser extent raltegravir, increased lipid

Table 1: Body composition change from baseline to week 96

<table>
<thead>
<tr>
<th>Women</th>
<th>TAF/FTC+DTG</th>
<th>TDF/FTC+DTG</th>
<th>TDF/FTC/EFV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total weight (kg): mean (±change)</td>
<td>+5.3 (±1.1)</td>
<td>+5.0 (±0.9)</td>
<td>+2.9 (±1.3)</td>
</tr>
<tr>
<td>Trunk fat, mean(SD)</td>
<td>+3.4 (±0.7)</td>
<td>+2.1 (±1.2)</td>
<td>+1.2 (±0.8)</td>
</tr>
<tr>
<td>Limb fat, mean(SD)</td>
<td>+3.1 (±0.5)</td>
<td>+1.9 (±2.3)</td>
<td>+1.2 (±0.6)</td>
</tr>
<tr>
<td>Trunk lean, mean(SD)</td>
<td>+0.7 (±0.3)</td>
<td>+0.3 (±0.1)</td>
<td>-0.02 (±0.4)</td>
</tr>
<tr>
<td>Limb lean, mean(SD)</td>
<td>+2.0 (±1.4)</td>
<td>+1.1 (±0.5)</td>
<td>+0.4 (±0.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Men</th>
<th>TAF/FTC+DTG</th>
<th>TDF/FTC+DTG</th>
<th>TDF/FTC/EFV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total weight (kg): mean (±change)</td>
<td>+5.0 (±1.4)</td>
<td>+5.0 (±0.8)</td>
<td>+2.9 (±0.6)</td>
</tr>
<tr>
<td>Trunk fat, mean(SD)</td>
<td>+1.7 (±0.3)</td>
<td>+1.5 (±0.4)</td>
<td>+0.2 (±0.3)</td>
</tr>
<tr>
<td>Limb fat, mean(SD)</td>
<td>+1.3 (±0.2)</td>
<td>+1.4 (±0.7)</td>
<td>+0.1 (±0.6)</td>
</tr>
<tr>
<td>Trunk lean, mean(SD)</td>
<td>+0.9 (±0.6)</td>
<td>+0.1 (±0.1)</td>
<td>+0.3 (±0.4)</td>
</tr>
<tr>
<td>Limb lean, mean(SD)</td>
<td>+1.5 (±1.0)</td>
<td>+1.2 (±1.8)</td>
<td>+0.1 (±1.3)</td>
</tr>
</tbody>
</table>

*Includes patients with paired weight and DXA data at week 96. Excludes pregnant women.
accumulation and adipogenic marker expression, decreased adiponectin expression and induced insulin resistance.

Conclusion: We demonstrate here for the first time, by using in vivo and in vitro complementary models, that INSTI exert a direct impact on adipose tissue adipogenesis, fibrosis and insulin resistance. These results, which reveal the adipose tissue toxicity of dolutegravir and raltegravir, are important to explain fat modifications reported in INSTI-treated HIV-infected patients.

PS3/5
Changes in weight after switching to dolutegravir containing antiretroviral therapy in the Swiss HIV cohort study

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1Bern University Hospital, University of Bern, Department of Infectious Diseases, Bern, Switzerland 2Geneva University Hospital, Division of Infectious Diseases, Geneva, Switzerland 3University Hospital Zurich, Division of Infectious Diseases and Hospital Epidemiology, Zürich, Switzerland 4Kantonsspital Basel, University of Basel, Department of Medicine and Infectious Diseases Service, Bruderalz, Switzerland 5University Hospital and University of Zurich, Division of Infectious Diseases and Hospital Epidemiology, Zürich, Switzerland 6Lausanne University Hospital and University of Lausanne, Service of Infectious Diseases, Lausanne, Switzerland 7University Hospital of Basel and University of Basel, Division of Infectious Diseases and Hospital Epidemiology, Departments of Medicine and Clinical Research, Basel, Switzerland 8Cantonal Hospital St. Gallen, Division of Infectious Diseases and Hospital Epidemiology, St. Gallen, Switzerland 9Regional Hospital Lugano, Division of Infectious Diseases, Lugano, Switzerland

Purpose: We assessed changes in weight and BMI after switching to Dolutegravir (DTG) containing antiretroviral therapy (ART) among patients with suppressed HIV viremia in the Swiss HIV Cohort Study (SHCS).

Methods: Weight, other demographic and clinical characteristics were prospectively collected at 6-monthly follow-up visits. Switching was defined as changing to a DTG containing regimen after being at least 18 months on a triple-drug ART regimen. We excluded pregnant women and patients not virally suppressed 6 months before switching. We assessed weight change within a window of 18 months of DTG start by comparing pre- and post-switch changes using t-tests and interrupted time series analysis. Risk factors for disproportionate weight gain were identified using logistic regression comparing the top quartile of weight gainers to the rest.

Results: 2,215 patients met the inclusion criteria. Patients were predominantly white males (66%). At time of switch, median age was 51 (interquartile range (IQR) 44 - 56), median BMI 24.0 (IQR 21.7 - 26.8), and median time on ART 11 years (IQR 6 - 17). The Figure shows weight change before and after switching to DTG. Mean weight change over 18 months was 0.5 kg (95% confidence interval (CI) 0.3 - 0.7) before switching, and 1.0 kg (95% CI 0.8 - 1.2) after switching (p<0.001). BMI changed + 0.2 units (95% CI 0.1 to 0.2) before and + 0.3 units (95% CI 0.3 to 0.4) after switching (p<0.001). Risk factors for disproportionate weight gain included males (adjusted odds ratio (aOR) 1.5 95% CI 1.1 to 2.0) and people of African origin (aOR 1.5 95% CI 1.1 to 2.1).

Conclusion: Among patients on stable ART, switching to DTG was associated with a modest increase in weight compared to the time-period before switch. Weight gain was more prominent among participants of African origin and males.

PS3/6
Switching to an integrase inhibitor containing antiretroviral regimen is not associated with above-average weight gain in middle-aged people living with HIV on long-term suppressive antiretroviral therapy, the AGEhIV cohort study

S Verboeket1,2, A Boyd3,4, F Wit2,5, E Verheij1,2, M Schim van der Loef2,4, N Kootstra3, M van der Valk2, P Reiss1,2,4 and AGEhIV Cohort Study

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Purpose: Recently, several cohorts reported above-average weight gain in people with suppressed HIV-viremia after switching to an integrase inhibitor (INSTI) containing antiretroviral regimen. We evaluated similar changes in standardized bodyweight measurements from HIV-positive and HIV-negative AGEhIV cohort participants.

Methods: In 598 HIV-positive and 550 HIV-negative AGEhIV participants bodyweight was measured biennially. Virally-suppressed HIV-positive participants switching to an INSTI-containing antiretroviral regimen were matched 1:2:2 with (1) HIV-positive participants not changing antiretroviral regimen and (2) HIV-negative participants, using time-dependent propensity score. We assessed changes in weight after switching (real or hypothetical switch) using time-dependent propensity score matching with covariates age, sex, viral load, bodyweight and CD4 count.

Mean yearly change in body weight within each group, before and after real or hypothetical moment of switch to INSTI

<table>
<thead>
<tr>
<th></th>
<th>Before switch</th>
<th>After switch</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>kg/year</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>kg/year</td>
<td>-0.00, 0.02</td>
<td>0.00, 0.06</td>
</tr>
</tbody>
</table>

Reported results were calculated from a linear mixed-effects model with bodyweight as the outcome, and the interaction-term study group*time*before/after switch as predictor variable.

Differences in mean yearly change in body weight

Difference in mean yearly change in body weight after vs. before real or hypothetical moment of switch to INSTI within each study group

<table>
<thead>
<tr>
<th></th>
<th>Δ kg/year</th>
<th>95% CI P</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSTI switchers</td>
<td>0.06</td>
<td>-0.37, 0.48 0.8</td>
</tr>
<tr>
<td>HIV-positive non-switchers</td>
<td>0.08</td>
<td>-0.18, 0.34 0.5</td>
</tr>
<tr>
<td>HIV-negative</td>
<td>0.09</td>
<td>-0.16, 0.35 0.5</td>
</tr>
</tbody>
</table>

Difference in mean yearly change in body weight between study groups before and after real or hypothetical switch to INSTI

<table>
<thead>
<tr>
<th></th>
<th>Before switch</th>
<th>After switch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Δ kg/year</td>
<td>-0.03</td>
<td>-0.05</td>
</tr>
<tr>
<td>95% CI</td>
<td>-0.32, 0.27</td>
<td>-0.49, 0.38 0.8</td>
</tr>
<tr>
<td>Δ kg/year</td>
<td>-0.02</td>
<td>-0.02</td>
</tr>
<tr>
<td>95% CI</td>
<td>-0.28, 0.33</td>
<td>-0.28, 0.33 0.8</td>
</tr>
</tbody>
</table>

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scores based on gender, ethnicity, age and BMI. In all matched controls a hypothetical moment of switch was determined, at which matched controls most resembled propensity scores of the index-participant at INSTI-switch. Average yearly bodyweight changes before and after (hypothetical) switch within and between study groups were compared using linear mixed-effects models. The frequencies of 5% and 10% weight gain were compared using logistic regression.

Results: 119 HIV-positive participants switched to an INSTI-containing regimen (53% dolutegravir; 35% elvitegravir; 13% raltegravir) and had a bodyweight measured 1 times before and after switch. In 49% the NRTI-backbone was simultaneously modified, the majority from tenofovir disoproxil/emtricitabine to tenofovir alafenamide/emtricitabine (18%) or abacavir/lamivudine (11%). There were no significant differences in yearly mean changes in bodyweight within and between the groups before and after (hypothetical) switch. A 5% increase in bodyweight occurred in 28 (23.5%) HIV-positive participants after INSTI initiation, and in 31 (13%, p = 0.013) non-switching HIV-positives, and in 28 (11.8%, p = 0.005) HIV-negative controls, after their hypothetical moment of switch. A 10% increase in bodyweight occurred in 6 (5.0%), 7 (2.9%, p = 0.3) and in 6 (2.5%, p = 0.2) respectively.

More than the sum of its parts? Multimorbidity in PLWH

PS4/1

AIDS defining and non-defining cancers in persons living with HIV in a single center cohort followed since 1986

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1Hospital Universitario La Paz - IDIPAZ, Madrid, Spain 2Instituto de Salud Carlos III, Madrid, Spain

Purpose: To review AIDS-defining cancer (ADCs) and non-AIDS-defining cancer (NADCs) and temporal changes in the ADCs/NADCs ratio, in a large single center cohort.

Patients and methods: 5411 HIV-infected participants followed-up between 1986–2018. Data were collected from our clinical database. ADCs and NADCs were defined according to the CDC classification.

Results: We diagnosed 643 patients with at least one malignancy. Patients with NADCs were older and mostly male. (Table 1) HIV infection and cancer were simultaneously diagnosed in 21.3%, more frequently in the ADCs group (34.7% vs. 8.07%; p<0.001). Cancers were diagnosed as clinically advanced in 86 participants (13.4%), similarly distributed between groups, 10.9% ADCs vs 15.7% NADCs. The most frequent cancers were: cervix cancer (134, 20.8%), Kaposi sarcoma (113, 20.53%), non–Hodgkin lymphoma (52, 8.09%), Hodgkin lymphoma (43, 6.7%), hepatocellular carcinoma (32, 4.9%), anal cancer (30, 4.67%), head and neck tumor (27, 4.2%) and lung cancer (25, 3.9%). NADCs increased over time resulting in a decrease in the ADCs/NADCs ratio with calendar year. (Figure 1) In the late ART period (>2006) NADCs were more frequent (65.6%) than ADCs, (p=0.001). (Table 2) In 2018, 25/30 (75%) were NADCs, being the most frequent hepatocellular carcinoma (5/25) and lung cancer (4/25). Overall, 430 (66.8%) cancers were related to oncogenic viruses: 166/430 human papillomavirus, 232/430 herpes virus 8 and EBV and 32/430 HBV and/or HCV.

Among 643 patients, 101 (15.9%) patients died due to cancer progression, 86 participants (13.4%), similarly distributed between groups, 10.9% ADCs vs 8.07% (p=0.2) respectively. Among 643 patients, 101 (15.9%) patients died due to cancer progression, 86 participants (13.4%), similarly distributed between groups, 10.9% ADCs vs 8.07% (p=0.2) respectively.

Conclusions: NADCs increased over the time, being more frequent during the late ART period and with higher mortality. A malignancy was, in an important number of cases, the first manifestation of HIV infection. A significant proportion of cancers were related with oncogenic virus coinfection.

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>ALL (n=643)</th>
<th>ADCs (n=320)</th>
<th>NADCs (n=323)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, male, n (%)</td>
<td>422 (65.6)</td>
<td>169 (52.9)</td>
<td>253 (78.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age at cancer diagnosis (years), median (IQR)</td>
<td>44.2 (35.9–51.9)</td>
<td>38.5 (32.5–45.6)</td>
<td>49.6 (42.5–56.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Caucasian Race, n (%)</td>
<td>&lt;585 (91.7)</td>
<td>281 (88.6)</td>
<td>304 (94.7)</td>
<td>0.006</td>
</tr>
<tr>
<td>Route of HIV transmission, n (%)</td>
<td>381 (59.2)</td>
<td>217 (67.8)</td>
<td>164 (50.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sexual</td>
<td>IDU</td>
<td>Other/Unknown</td>
<td>68 (10.6)</td>
<td>26 (8.1)</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>194 (30.2)</td>
<td>77 (24.1)</td>
<td>117 (36.2)</td>
<td></td>
</tr>
<tr>
<td>Chronic/previous Hepatitis coinfection, n (%)</td>
<td>130 (22.3)</td>
<td>48 (16.9)</td>
<td>81 (27.5)</td>
<td>0.001</td>
</tr>
<tr>
<td>HIV V* =583/643</td>
<td>248 (41.6)</td>
<td>110 (37.3)</td>
<td>139 (45.7)</td>
<td>0.053</td>
</tr>
<tr>
<td>AIDS, n (%)</td>
<td>545 (84.7)</td>
<td>320 (100)</td>
<td>225 (69.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nadir CD4 (cells/mm³), median (IQR)</td>
<td>135 (52–230)</td>
<td>133 (50–216)</td>
<td>140 (55–245)</td>
<td>0.48</td>
</tr>
<tr>
<td>*N=507/643</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time of HIV infection at cancer diagnosis (years), median (IQR)</td>
<td>8.9 (1.9–17.7)</td>
<td>4.1 (0.1–10.9)</td>
<td>15.1 (6.6–21.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Receiving ART at cancer diagnosis, n (%)</td>
<td>400 (62.1)</td>
<td>146 (45.7)</td>
<td>254 (78.4)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
**Table 1. Baseline Demographic and Clinical Characteristics**

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Age, median (IQR)</td>
<td>29 (25, 35)</td>
<td>49 (41, 53)</td>
<td>52 (47, 57)</td>
<td>31 (26, 38)</td>
<td>28 (23, 34)</td>
<td>41 (36, 46)</td>
<td>52 (46, 57)</td>
</tr>
<tr>
<td>eGFR, median (IQR)</td>
<td>117.8 (106.2, 128.2)</td>
<td>77.4 (68.9, 85.6)</td>
<td>115.7 (104.8, 125.9)</td>
<td>95.8 (85.1, 106.8)</td>
<td>105.2 (94.3, 116.1)</td>
<td>125.0 (113.2, 136.8)</td>
<td>95.8 (85.1, 106.8)</td>
</tr>
</tbody>
</table>
| Cancer distribution according to ART era at diagnosis

| TDF-containing regimens by D:A:D CKD risk and boosting. |

**Table 2. Initial ART and Other Medication Use at Baseline**

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Boosted regimen (PI or EVG), n (%)</td>
<td>1128 (39.9)</td>
<td>222 (46.2)</td>
<td>124 (45.6)</td>
<td>2231 (47.0)</td>
<td>457 (46.0)</td>
<td>207 (42.7)</td>
<td></td>
</tr>
<tr>
<td>Non-boosted INSTI, n (%)</td>
<td>1502 (53.1)</td>
<td>216 (44.9)</td>
<td>122 (44.9)</td>
<td>405 (8.5)</td>
<td>115 (11.6)</td>
<td>61 (12.6)</td>
<td></td>
</tr>
<tr>
<td>Concurrent nephrotoxic medication use, n (%)</td>
<td>197 (7.0)</td>
<td>43 (8.9)</td>
<td>26 (9.6)</td>
<td>2107 (44.4)</td>
<td>422 (42.5)</td>
<td>217 (44.7)</td>
<td></td>
</tr>
<tr>
<td>Concurrent use of medication affecting proteinuria, n (%)</td>
<td>292 (10.3)</td>
<td>78 (16.2)</td>
<td>46 (16.9)</td>
<td>798 (16.8)</td>
<td>233 (23.4)</td>
<td>123 (25.4)</td>
<td></td>
</tr>
<tr>
<td>Concurrent use of medication affecting proteinuria, n (%)</td>
<td>69 (2.4)</td>
<td>68 (14.1)</td>
<td>57 (21.0)</td>
<td>159 (3.4)</td>
<td>119 (12.0)</td>
<td>93 (19.2)</td>
<td></td>
</tr>
</tbody>
</table>
Changes in bone and renal markers

PS4/3
The ADVANCE trial: the impact of DXA-assessed bone mineral density of TDF/FTC/EFV and TDF/FTC+DTG versus TAF/FTC+DTG

A Qavi1, M Moorhouse*, S Sokhela2, WDF Venter2, C Serenata2, B Simmons1, K McCann1 and A Hill1

1Imperial College London, Faculty of Medicine, London, UK 2Wits Reproductive Health and HIV Institute, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa 3Liverpool University, Pharmacology, Liverpool, UK

Purpose: In previous clinical trials and cohort studies, tenofovir disoproxil fumarate (TDF) has been associated with decreased bone mineral density (BMD) and renal function. One of the aims of the ADVANCE study was to determine whether BMD and renal changes over 96 weeks differed in HIV-infected persons taking TDF-containing regimens versus those taking tenofovir alafenamide fumarate (TAF)-containing regimens.

Method: We conducted a 96-week, open-label randomised trial in South Africa, comparing TAF/FTC+DTG, TDF/FTC+DTG and TDF/FTC/EFV. Inclusion criteria included age ≥ 12 years, no prior ART >30 days, creatinine clearance≥60 mL/min (≥80 mL/min if <19 years), and HIV-1 RNA≤500 copies/mL. Investigators were blinded to renal tubular markers and DXA scans unless patient safety concerns were an issue.

Results: The TDF-containing arms had most impact on hip and spine DXA-assessed bone density and renal markers. Changes in DXA were: treatment emergent osteopenia for hip was lowest in the TAF/FTC+DTG arm (7%) versus 16% in the TDF/FTC+DTG and 18% in the TDF/FTC/EFV arms (p<0.001). Similarly, treatment emergent osteopenia for spine was lowest in the TAF/FTC+DTG arm (18%) versus 23% and 22% in the TDF/FTC+DTG and TDF/FTC/EFV arms respectively. However, there was no statistical difference seen between the arms. Grade 3-4 renal adverse events (AEs) and bone fractures were rare. None of the fractures were related to the study drugs. Tubular markers above the upper limit of normal (ULN) were higher in TDF-containing arms than in the TAF arm. (Table 1)

Conclusion: In the ADVANCE study, TAF/FTC+DTG had less impact on bone density and renal function than the TDF-containing regimens.

Figure 1. Unadjusted Incidence of CKD Over Follow-up

Figure 2. Adjusted Association Between TDF Use, D:A:D CKD Risk Group and Incidence of CKD*
The association between environmental exposures and respiratory symptoms for people living with HIV

Conclusion: We describe that indoor environmental exposures are common and associated with greater respiratory morbidity in a cohort of PLWH, with HIV increasing susceptibility to certain pollutants.

PS4/6

Comparing a risk score against physiological markers for predicting diabetes incidence in HIV+ individuals

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1Emory University, Atlanta, USA 2Johns Hopkins University, Baltimore, USA
2University of California, San Francisco, USA

Purpose: To compare the performance of a clinical diabetes risk score with physiological markers for predicting diabetes incidence in HIV+ and HIV- individuals.

Method: We determined 10-year diabetes incidence (defined as self-reported diabetes medication use) in HIV+ and HIV- participants from the Women’s Interagency HIV Study and the Multicenter AIDS Cohort Study. For each participant, we obtained baseline values for the Finnish Diabetes Risk Score (FINRISC), Homeostasis Model Assessment for Insulin Resistance (HOMA-IR), HOMA for β-cell function (HOMA-[β]), and Triglycerides/HDL Cholesterol Ratio (TG/HDL). Discrimination of each model was assessed using the Harrell C-statistic. Calibration was assessed by comparing the observed versus the predicted cumulative probabilities of developing diabetes (determined from 1-Kaplan-Meier) in each tertile of the distribution.

Results: We included 2489 men (1285 HIV+ and 1214 HIV-, median age=44 years, 60% non-Hispanic white, 25% non-Hispanic black) and 2408 women (1812 HIV+ and 596 HIV-, median age=41, 12% non-Hispanic white, 62% non-Hispanic black). Over 10 years of follow-up, 10% of HIV+ men, 9% of HIV- men, 11% of HIV+ women, and 12% of HIV- women developed diabetes. FINRISC had the best discrimination, though it performed better in HIV- participants (men c=0.74 [95% CI 0.70, 0.78], women c=0.75 [0.70, 0.80]) than in HIV+ participants (men c=0.68 [0.62, 0.73]), women c=0.70 [0.66, 0.74]). HOMA-IR discrimination was similar by HIV status but better in men (HIV+ c=0.70 [0.65, 0.75], HIV- c=0.72 [0.67, 0.77]) than in women (HIV+ c=0.65 [0.61, 0.69], HIV- c=0.67 [0.60, 0.74]). TG/HDL and HOMA-β had poor discrimination (<0.7 and <0.6, respectively). Regarding calibration, FINRISC underestimated risk among HIV+ men in the highest risk tertile, while HOMA-IR and TG/HDL underestimated risk among all participants in the highest risk tertiles. HOMA-β was well-calibrated.

Conclusion: In HIV+ men, FINRISC predicted incident diabetes similarly to physiological markers. In HIV+ women, FINRISC was superior.

PS4/5

Environmental exposures are associated with increased respiratory morbidity among persons living with HIV (PLWH)

S Raju1, H Ramamurthi2, T Brown3, G Kirk4 and M McCormack1

1Johns Hopkins School of Medicine, Medicine, Baltimore, USA 2Johns Hopkins School of Public Health, Epidemiology, Baltimore, USA

Purpose: Chronic respiratory disease has emerged as an important comorbidity among people living with HIV and its ability to predict frailty and mortality

Method: We analyzed cross-sectional data from the Study of HIV Infection in the Etiology of Lung Disease (SHIELD) in Baltimore, Maryland, USA, consisting of both PLWH and HIV-uninfected participants. Participants complete lung function testing and questionnaires about environmental exposures; including secondhand smoke (SHS), NO2 producing appliances (Gas Stoves), mold, and occupational exposures (dust, fumes). Respiratory symptoms included: chronic cough, wheeze, phlegm, and experiencing ≥2 wheezing attacks/year. We included 2499 men (1285 HIV+ and 1214 HIV-, median age=44 years, 60% non-Hispanic white, 25% non-Hispanic black) and 2408 women (1812 HIV+ and 596 HIV-, median age=41, 12% non-Hispanic white, 62% non-Hispanic black). Over 10 years of follow-up, 10% of HIV+ men, 9% of HIV- men, 11% of HIV+ women, and 12% of HIV- women developed diabetes. FINRISC had the best discrimination, though it performed better in HIV- participants (men c=0.74 [95% CI 0.70, 0.78], women c=0.75 [0.70, 0.80]) than in HIV+ participants (men c=0.68 [0.62, 0.73]), women c=0.70 [0.66, 0.74]). HOMA-IR discrimination was similar by HIV status but better in men (HIV+ c=0.70 [0.65, 0.75], HIV- c=0.72 [0.67, 0.77]) than in women (HIV+ c=0.65 [0.61, 0.69], HIV- c=0.67 [0.60, 0.74]). TG/HDL and HOMA-β had poor discrimination (<0.7 and <0.6, respectively). Regarding calibration, FINRISC underestimated risk among HIV+ men in the highest risk tertile, while HOMA-IR and TG/HDL underestimated risk among all participants in the highest risk tertiles. HOMA-β was well-calibrated.

Conclusion: In HIV+ men, FINRISC predicted incident diabetes similarly to physiological markers. In HIV+ women, FINRISC was superior.

PS4/7

Development and validation of a comorbidity index for people living with HIV and its ability to predict frailty and mortality

D De Francesco1, SO Verboeket2, E Verheij3, J Underwood4, E Bagkeris1, FW Wit5, A Winston6, P Reiss7, CA Sabin1 and POPPY Study and the AGHIV Cohort Study

1UCL, Institute for Global Health, London, UK 2Amsterdam University Medical Centers, Department of Global Health and Division of Infectious Diseases, Amsterdam, Netherlands 3Cardiff University, Division of Infection and Immunity, Cardiff, UK 4Imperial College London, London, UK

Purpose: Despite the increasing prevalence of multi-morbidity in people living with HIV (PLWH), there is no tool designed specifically for PLWH to assess...
Association of the CBI, comorbidity count and VACS index with patient-reported physical and mental health, frailty, frailty development and mortality

<table>
<thead>
<tr>
<th>Index</th>
<th>Physical health</th>
<th>Mental health</th>
<th>Frailty</th>
<th>Frailty development</th>
<th>Mortality</th>
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<tr>
<td></td>
<td>rho (95% CI)</td>
<td>rho (95% CI)</td>
<td>C-statistic (95% CI)</td>
<td>C-statistic (95% CI)</td>
<td>C-statistic (95% CI)</td>
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<tr>
<td>p vs. CBI</td>
<td>p vs. CBI</td>
<td>p vs. CBI</td>
<td>p vs. CBI</td>
<td>p vs. CBI</td>
<td>p vs. CBI</td>
</tr>
<tr>
<td>CBI</td>
<td>-0.34 (–0.41, –0.26)</td>
<td>-0.18 (–0.26, –0.10)</td>
<td>0.73 (0.66, 0.79)</td>
<td>0.62 (0.52, 0.72)</td>
<td>0.66 (0.56, 0.75)</td>
</tr>
<tr>
<td>Comorbidity count</td>
<td>-0.30 (–0.38, –0.22)</td>
<td>-0.15 (–0.23, –0.07)</td>
<td>0.71 (0.63, 0.78)</td>
<td>0.64 (0.54, 0.74)</td>
<td>0.71 (0.62, 0.79)</td>
</tr>
<tr>
<td>p=0.08</td>
<td>p=0.16</td>
<td>p=0.27</td>
<td>p=0.55</td>
<td>p=0.12</td>
<td>p=0.84</td>
</tr>
<tr>
<td>VACS index</td>
<td>-0.07 (–0.15, 0.02)</td>
<td>0.10 (0.02, 0.19)</td>
<td>0.63 (0.56, 0.70)</td>
<td>0.55 (0.44, 0.66)</td>
<td>0.67 (0.56, 0.77)</td>
</tr>
<tr>
<td>p=0.001</td>
<td>p=0.001</td>
<td>p=0.02</td>
<td>p=0.32</td>
<td>p=0.84</td>
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</table>

Overall comorbidity burden. We developed and externally validated a comorbidity burden index (CBI), specific to PLWH, assessing its cross-sectional association with health status and ability to predict mortality and frailty.

Method: We developed the CBI using information on 65 comorbidities collected in PLWH enrolled in the POPPY (development) cohort and compared its performance against the comorbidity count and the VACS index in the AGElIV (validation) cohort. Spearman’s correlation and the C-statistic assessed associations of indices with physical/mental health (SF-36), adapted Fried frailty phenotype prevalence and 4-year incidence, and 6-year all-cause mortality. These were compared across indices using the Steiger’s and DeLong tests, as appropriate.

Results: The development and validation cohorts included 1073 [85% males, 16% black-Africans, median age 52 years] and 598 [88% males, 14% black-Africans, 53 years] PLWH, respectively. Of the three indices, the CBI demonstrated the strongest associations with physical and mental health (Table); these associations were significantly stronger than those of the VACS index (both p’s < 0.001) but not of those of the comorbidity count (p = 0.08, p = 0.16). At baseline, 11.4% of PLWH were frail; frailty incidence and death rate were 19.5/1000 and 12.0/1000 person-years, respectively. Cross-sectionally, the CBI showed a stronger association with frailty than either the VACS index (p = 0.02) or the comorbidity count (p = 0.27). Whilst prospective associations with frailty development and mortality were strongest for the comorbidity count, the difference with associations of the CBI were not significant (p = 0.55 and p = 0.12, respectively).

Conclusion: The proposed CBI, specifically developed in PLWH showed strong associations with several health outcomes when externally validated. These findings justify the use of the CBI when adjustment for comorbidity is needed and when evaluating the effectiveness of interventions.

Basic and translational HIV biology

PS5/1

Stem-cell-like CD4+ memory T cells expand during the acute HIV-1 infection accelerating disease progression

J Puśnik1, MA Eller2, B Tassaneetrithep1, BT Schulz1, LA Eller1, S Nitayaphan4, J Kosgei1, L Maganga3, H Kubuaka2, G Alter3, NL Michael2, ML Robb3, H Strecker1 and RV217 Study Team

1Institute for HIV-1 Research, University Hospital, University Duisburg-Essen, Essen, Germany 2U.S. Military HIV-1 Research Program, Walter Reed Army Institute of Research, Silver Spring, USA 3Office for Research and Development, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand 4United States Army Medical Component, Armed Forces Research Institute of Medical Sciences (USAMC- writetoreims), Department of Retrovirology, Bangkok, Thailand 5Kenya Medical Research Institute/Walter Reed Project, Kericho, Kenya 6Walter Reed Program-Tanzania, Mbeya, Tanzania, United Republic of 7Makerere University Walter Reed Project, Kampala, Uganda 8Massachusetts General Hospital, Boston, USA

Purpose: During acute HIV-1 infection a reservoir of latently infected cells is established, that represents an important road block for HIV cure through antiretroviral therapy. Maturational CD4 + T cell subsets play different roles in reservoir maintenance and differ in their susceptibility to HIV-1 infection.

Longitudinal changes in CD4 + T cell subset frequencies during the acute phase of HIV-1 infection

However, the dynamics and infectibility of these subsets during acute HIV-1 infection have not been sufficiently investigated.

Method: Using flow cytometry, we analyzed longitudinal changes in the frequency of memory CD4 + T cell subsets in peripheral blood of subjects from acute HIV-1 infection cohort RV217 (ECHO) and in HIV-1 infected cell cultures. We also performed flow cytometry-based proliferation assay, measurement of cytoplasmic p24 levels and qPCR-based measurement of HIV-1 integration in the cell cultures.

Results: We observed a profound expansion of stem-cell-like memory (SCM) CD4 + T cells (2.7-fold; p = 0.0001) in parallel to viral load peak, which is believed to be a critical time for latent reservoir seeding. Since SCM were previously identified as an important long-lived latent reservoir, SCM expansion during acute HIV infection may be important contributor for HIV pathogenesis. Furthermore we found that the expansion of SCM is due to the upregulation of the Fas receptor on the surface of naive CD4 + T cells. Both, the extent of Fas upregulation and increase in SCM frequency were positively associated with the early set point viral load, a reliable predictor of the disease progression (rho = 0.47, p = 0.02, and rho = 0.42, p = 0.041 respectively). We also demonstrated that highly differentiated memory CD4 + T cell subsets show higher susceptibility to HIV-1 integration and replication, causing a decline in their frequencies towards the end of the acute phase.

Conclusion: Collectively, our findings revealed an expansion of SCM, known as the especially persistent reservoir component, during acute HIV-1 infection. The degree of this expansion was associated with rapid disease Progression.
PS5/2
Correlation between cerebrospinal fluid (CSF) and plasma concentrations of neurofilament light protein (NFL) in treated HIV infection in the COMorBidity in Relation to AIDS (COBRA) study
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2Imperial College London Healthcare NHS Trust, GU Medicine & HIV, London, UK
3University College London, Institute for Global Health, London, UK
4University College London, UK Dementia Research Institute, London, UK
5Sahlgrenska University Hospital, Clinical Neurochemistry Laboratory, Mölndal, Sweden
6UCL Queen Square Institute of Neurology, Department of Neurodegenerative Disease, London, UK
7University College London, UCL Dementia Research Institute and ION Department of Neurodegenerative Disease, London, UK
8Amsterdam UMC, University of Amsterdam, Department of Experimental Immunology, Amsterdam, Netherlands
9Cardiff and Vale University Health Board, Department of Infectious Diseases, Cardiff, UK
10Cardiff University, Division of Infection and Immunity, Cardiff, UK
11University of Gothenburg, Department of Infectious Diseases, Institute of Biomedicine, Sahlgrenska Academy, Gothenburg, Sweden
12Sahlgrenska University Hospital, Department of Infectious Diseases, Gothenburg, Sweden
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14Amsterdam Institute for Global Health, Amsterdam, Netherlands
15Stichting HIV Monitoring, Amsterdam, Netherlands

Purpose: CSF NFL is an established biomarker of central nervous system neuro-axonal injury. A novel ultra-sensitive assay can determine plasma NFL. In untreated people with HIV (PWH), plasma and CSF NFL are strongly correlated. We assessed this correlation in antiretroviral therapy (ART)-treated PWH and lifestyle-similar HIV-negative controls, and determined factors associated with plasma and CSF NFL in PWH.

Method: Differences in paired plasma (Simoa digital immunoassay, Quantix®) and CSF (sandwich ELISA, UmanDiagnostics) NFL between PWH and HIV-negative controls were tested for significance using Wilcoxon’s test; associations between the values (after log-transformation) were assessed using Pearson’s correlation. Log-transformed plasma and CSF NFL, standardised to Z-scores, were included as dependent variables in linear regression models to identify factors independently associated with values in PWH; factors significant (p<0.05) in univariable analyses for either outcome were included in the multivariable models.

Results: We included 132 PWH (median age 56 years, 94% male, 88% white, 100% HIV-1 RNA<50 copies/mL) and 79 HIV-negative controls (57 years, 92% male, 97% white). Neither CSF (570 vs 568 pg/mL, p=0.15) nor plasma (10.7 vs 9.9 pg/mL, p=0.15) NFL differed significantly between the two groups. Plasma and CSF NFL correlated moderately, with no significant difference by HIV status (PWH: r=0.52 (95% confidence interval 0.38-0.63); HIV-negative: r=0.47 (0.27–0.62), p(interaction)=0.63). In multivariable regression, older age and lower weight were each associated with higher plasma and CSF NFL Z-scores in PWH. Whereas lower plasma albumin and higher serum creatinine were associated with higher plasma NFL Z-scores, higher CSF protein was associated with higher CSF NFL Z-score.

Conclusion: In PWH on suppressive ART, the correlation between CSF and plasma NFL is weaker than previously described in untreated PWH but similar to that observed in lifestyle-similar controls. Consideration of renal function and body composition may be required when utilising plasma NFL.

Baseline Characteristics for Participants of the START and FIRST trials

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>Parameter estimate (The associated impact (measured in standard deviations) of each independent variable on the dependent variable)</th>
<th>p-value</th>
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</thead>
</table>

| Dependant variable | Independent variables included in the model were males, being on antihypertensive medication, duration diagnosed with HIV infection, duration on ART | Parameter estimate (The associated impact (measured in standard deviations) of each independent variable on the dependent variable) | p-value |
|-------------------|-------------------------------------------------|--------|
| Log10(plasma NFL) Z-score | Age ([10 years older]) | 0.60 (0.42, 0.79) | <0.001 |
|                   | Weight ([5 kg higher]) | -0.13 [-0.18, -0.08] | <0.001 |
|                   | Serum creatinine ([10 μmol/L higher]) | 0.12 (0.04, 0.19) | 0.002 |
|                   | Plasma albumin ([10 g/L higher]) | -0.39 [-0.69, -0.09] | 0.012 |
| Log10(CSF NFL) Z-score | Age ([10 years older]) | 0.69 (0.50, 0.89) | <0.001 |
|                   | Weight ([5 kg higher]) | -0.07 [-0.12, -0.01] | 0.021 |
|                   | CSF protein ([1 g/L higher]) | 1.33 (0.50, 2.16) | 0.002 |

PS5/3
TET2 genetic variation affects HIV viral load in ART-naïve persons
DD Murray1, CR Macpherson2, B Grund3, C Ekenberg4, A Zucco1, J Riekie1, D Fusco1, J Gras5, J Gerstof6, MN Polizotto6, JD Lundgren7 and INSIGHT START study group and the FIRST study group

1Centre of Excellence for Health Immunity and Infections, Department of Infectious Diseases, Rigshospitalet, Copenhagen, Denmark
2Division of Biostatistics, School of Public Health, University of Minnesota, Minneapolis, USA
3Tulane University School of Medicine, New Orleans, USA
4Saint Louis Hospital, Paris, France
5Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark
6Kirby Institute of Infection and Immunity in Society, Sydney, Australia

Purpose: Ten-eleven methylcytosine dioxygenase 2 (TET2) and related genes (IDH1 & IDH2) in the TET2 pathway regulate de-methylation of human DNA. There is also a developing literature connecting the molecular function of the TET2 pathway to regulation of HIV and other retroviruses. We explored if genetic variability in the TET2 pathway explains variability in HIV viral load (VL) using data from two clinical trials (START and FIRST) that enrolled ART-naïve people with HIV.

Method: Participants from the START and FIRST clinical trials were genotyped using a custom content Affymetrix Axiom SNP array. Associations between genetic variation in genes of the TET2 pathway and log10(VL) at study entry were estimated using SKAT-O (gene-level) and linear regression models (SNP-level). START and FIRST were treated as separate cohorts and associations were assessed independently in each cohort. The leading four eigenvectors and sex were included as co-variates. To control for multiple testing at the SNP-level, the Benjamini-Hochberg procedure was used to limit the false discovery rate to<5% (q-value<0.05).

Results: Table 1 shows entry characteristics. Gene level variation in TET2 was significantly associated with VL in both START and FIRST (SKAT-O p-value<0.001). SNP-level analyses revealed 15 SNPs associated with VL in both START and FIRST (q<0.05) (Figure 1). Additionally, 13 and 8 SNPs were associated with VL in one of either START or FIRST, respectively (Figure 1). These SNPs were predominantly found in TET2 (35/36) and clustered in two linkage disequilibrium groups (Figure 2). Each TET2 SNP that associated with higher or lower VL in START associated with the same effect size in FIRST (Figure 2).

Conclusion: Genetic variation in TET2 is associated with HIV viral load, providing further evidence that TET2 is an important regulator of HIV-replication in vivo.
Temporal evolution of a unique N332 supersite directed bnAb lineage in slow progressing HIV-1 infection

M Schanz1, H Ebner1,2, IA Abela1, P Rusert1, J Weber1, O Zagordi1, M Zaheri1, DL Braun1,3, H FGunthard1,3, M Huber1 and A Trkola1

1University of Zurich, Institute of Medical Virology, Zurich, Switzerland 2Tecan Austria GmbH, Graz, Austria 3University Hospital Zurich, Division of Infectious Diseases and Hospital Epidemiology, Zurich, Switzerland

Purpose: Elicitation of broadly neutralizing antibodies (bnAbs) is considered as a prerequisite for a preventive HIV-1 vaccine but induction of bnAbs by immunization has so far not been successful. Unravelling pathways of bnAb development in natural infection thus provides a crucial basis to guide bnAb vaccine strategies. Here, we report on the evolution of ZPHI-12, a unique N332 supersite directed bnAb, which we isolated approximately five years post infection (p.i.) from a slow progressor with Subtype B infection enrolled in the Zurich Primary HIV Infection Cohort (ZPHI).

Method: To investigate the evolution of ZPHI-12 longitudinally we utilized a series of NGS strategies, which yielded 279 heavy and 44 light chain variants. Germline-reverted, representative intermediate and mature Ab variants were probed for neutralization activity against a multi-clade virus panel and binding properties on a panel of 61 different HIV-1 antigens.

Results: ZPHI-12 belongs to the V3 glycan class of bnAbs and binds the “GDIR” motif. Sequence analysis revealed an unusual stretch of seven tyrosines in the ZPHI-12 CDRH3 that has not been observed in other bnAbs. ZPHI-12 clonal relatives already appeared at week (wk) 46 p.i. and showed superior breadth compared to the more mutated mature antibody. The most potent heavy chain variants were identified at wk89 and 115 p.i. Phenotypic analysis of ZPHI-12 lineage Ab producing cells revealed large numbers of plasmablasts at wk89 p.i., whereas the majority of ZPHI-12 lineage members at wk115p.i. was identified in memory B cells, suggesting that the peak of ZPHI-12 evolution had already passed.

Conclusion: Our study highlights the potential of differentiating plasmablast and memory B cell derived bnAb sequences longitudinally as this provides powerful means to improve time-based definition of bnAb evolution. The comprehensive knowledge of early ZPHI-12 lineage evolution we present elucidates the protracted development of bnAbs that are important for devising HIV-1 vaccination strategies.

Prevalence of InSTI resistance and effectiveness of InSTI-based regimens in HIV-infected patients: results from a European cohort study

B Rossetti1, M Fabbiani1, D Di Carlo2, F Incardona3, A Abecasis4, C Devaux5, F Garcia6, R Kaiser7, S Modica1, A Shallvari8, ASönnerborg9, M Zazzi10 and EuResist Network, INTEGRATE Study Group

1Infectious Diseases Unit, University Hospital of Siena, Siena, Italy 2University of Milan “La Statale”, Milano, Italy 3EuResist Network, Rome, Italy 4Instituto de Higiene e Medicina Tropical, Universidade NOVA de Lisboa, Lisboa, Portugal 5Luxembourg Institute of Health, Strassen, Luxembourg 6Hospital Universitario San Cecilio, Granada, Spain 7University of Cologne, Cologne, Germany 8IPRO, Rome, Italy 9Karolinska Institutet, Stockholm, Sweden 10University of Siena, Siena, Italy

Purpose: The global dynamics of InSTI resistance remains to be investigated. This study aimed at analyzing InSTI resistance and effectiveness of InSTI-based regimens.

Method: INTEGRATE is a large European collaboration enrolling patients who started InSTI-based regimens from 1/1/2012. We investigated time to InSTI discontinuation (intra-class switch = discontinuation) and to virological failure (VF, defined as 1 viral load (VL) > 1,000 copies/mL or 2 consecutive VL > 50 copies/mL or 1 VL > 50 copies/mL followed by treatment change).

Results: A total of 10,969 InSTI-based regimens were analysed of which 1,711 treatments from ART-naïve (group, G, 1), 2,975 from ART-experienced, InSTI-naïve, aviremic (G2a), 1,244 from ART-experienced, InSTI-naïve, aviremic (G2a), 1,244 from ART-experienced,
InSTI-naive, viremic (G2b), 3,502 from ART-experienced, InSTI-experienced, aviremic (G3a) and 1,537 from ART-experienced, InSTI-experienced, viremic (G3b) patients.

Transmitted InSTI major drug resistance mutations (DRMs) were detected in 1/520 (0.2%) patients from G1, 1/361 (0.3%) from G2a and 3/355 (0.8%) from G2b; however, InSTI-DRM were detected in 35/954 (3.6%) and 61/705 (8.6%) cases from G3a and G3b, respectively. The 1-year probability of InSTI discontinuation was 28% in G1, 18% in G2a, 26% in G2b, 17% in G3a and 29% in G3b and the 1-year estimated probabilities of VF were 2% in G1, 4% in G2a, 24% in G2b, 4% in G3a and 27% in G3b.

The Cox models showed that the use of first generation InSTIs was associated to a higher risk of InSTI discontinuation in all groups. A longer time of virosuppression predicted a lower risk of VF in G2a and G3a, while previous VF was associated to a higher risk of VF in all treatment-experienced patient groups (G2a–b, G3a–b).

Conclusions: InSTI resistance remains virtually non-existent without InSTI exposure and is detectable in a modest proportion of InSTI-experienced patients, making InSTI resistance testing mandatory after failure. Previous VF and duration of virosisuppression before switch were independent predictors of VF.

**In vitro analysis of doravirine activity on HIV-1 clones harboring multiple NNRTI resistance mutations**

F Saladini 1, F Giammarino 1, A Giannini 1, A Boccuto 1, F Dragoni 1, I Vicenti 1, RW Shafer 2 and M Zazzi 1

1University of Siena, Siena, Italy 2Stanford University, Stanford, USA

**Purpose:** Doravirine is a NNRTI recently approved for HIV-1 therapy with improved efficacy, pharmacokinetics and safety profile compared to efavirenz and limited cross-resistance with rilpivirine and etravirine. This study aimed to evaluate the in vitro activity of doravirine in a panel of HIV-1 clones harboring combinations of major NNRTI resistance associated mutations (RAMs).

**Method:** Infectious clones with intermediate to high-level resistance to rilpivirine, etravirine, efavirenz and nevirapine were obtained from the AIDS Reagent Program. In vitro susceptibility to doravirine was measured by a TZM-bl cell-based assay and fold-change (FC) values were calculated with respect to the wild-type NL4–3 strain. FC values were compared with predicted doravirine activity by HIVdb and ANRS algorithms.

**Results:** Viruses harboring both doravirine and major NNRTI RAMs showed FC > 100 in two cases (ID 12225 and 12237), while 12229, 12231, 12241 and 12243 showed a moderately decreased susceptibility (FC 4.0, 22.1, 3.1 and 6.2, respectively) (Figure 1). Two samples without doravirine RAMs but including 181C (12235 and 12239) showed a considerably reduced susceptibility to doravirine (FC 31.8 and 14.2, respectively), while the absence of doravirine RAMs in the clones was associated with a much lower susceptibility to doravirine (ID 12245 and 12246) with respect to the wild-type NL4–3 strain (Figure 1).

**Figure 1.** FC values and predicted susceptibility to DOR of viruses harboring NNRTI RAMs

**Table 1.** Baseline characteristics of population

<table>
<thead>
<tr>
<th>Variables</th>
<th>ART-naïve (n=1,711) Group 1</th>
<th>ART-experienced InSTI-naïve aviremic (n=2,975) Group 2a</th>
<th>ART-experienced InSTI-naïve viremic (n=1,244) Group 2b</th>
<th>ART-experienced InSTI-experienced aviremic (n=3,502) Group 3a</th>
<th>ART-experienced InSTI-experienced viremic (n=1,357) Group 3b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HIV-RNA Log10 (cps/mL), median (IQR)</td>
<td>4.9 (4.3–5.5)</td>
<td>1.4 (0–1.6)</td>
<td>3.4 (2.1–4.7)</td>
<td>1.4 (1.1–1.6)</td>
<td>2.6 (1.8–4.5)</td>
</tr>
<tr>
<td>Baseline CD4 cells count (cells/mm³), median (IQR)</td>
<td>329 (139–510)</td>
<td>620 (440–815)</td>
<td>336 (170–560)</td>
<td>578 (381–807)</td>
<td>316 (145–551)</td>
</tr>
<tr>
<td>Raltegravir use, n (%)</td>
<td>401 (23.4%)</td>
<td>643 (21.6%)</td>
<td>474 (38.1%)</td>
<td>1191 (34.0%)</td>
<td>455 (33.5%)</td>
</tr>
<tr>
<td>Elvitegravir use, n (%)</td>
<td>421 (24.6%)</td>
<td>468 (16.4%)</td>
<td>173 (13.9%)</td>
<td>614 (17.5%)</td>
<td>176 (13.0%)</td>
</tr>
<tr>
<td>Dolutegravir use, n (%)</td>
<td>889 (52.0%)</td>
<td>1,845 (62.0%)</td>
<td>598 (48.2%)</td>
<td>1,750 (50.0%)</td>
<td>744 (54.8%)</td>
</tr>
<tr>
<td>Cumulative PI RAMs pre-baseline, n (%)</td>
<td>16 (0.9%)</td>
<td>96 (3.2%)</td>
<td>58 (4.7%)</td>
<td>331 (9.5%)</td>
<td>161 (11.9%)</td>
</tr>
<tr>
<td>Cumulative NRTI RAMs pre-baseline, n (%)</td>
<td>26 (1.5%)</td>
<td>262 (8.8%)</td>
<td>175 (14.1%)</td>
<td>641 (18.3%)</td>
<td>327 (24.1%)</td>
</tr>
<tr>
<td>Cumulative NNRTI pre-baseline, n (%)</td>
<td>10 (0.6%)</td>
<td>237 (8.0%)</td>
<td>184 (14.8%)</td>
<td>476 (13.6%)</td>
<td>274 (20.2%)</td>
</tr>
<tr>
<td>Cumulative INI RAMs pre-baseline, n (%)</td>
<td>1/520 (0.1%)</td>
<td>1/361 (0.3%)</td>
<td>3/355 (0.8%)</td>
<td>35/954 (3.6%)</td>
<td>61/805 (8.6%)</td>
</tr>
</tbody>
</table>

Figure 2. Estimated probability of VF according to InSTI exposure and baseline VL

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Addressing the HIV and STI syndemics co-organised with the International AIDS Society (IAS)

PS6/1

The natural history of anal high grade squamous intraepithelial lesions in HIV positive and HIV negative gay and bisexual men

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Purpose: Gay and bisexual men (GBM), especially those living with HIV, are disproportionately affected by anal cancer. Prevention is hindered by incomplete understanding of the natural history of its precursor, anal high grade squamous intraepithelial lesions (HSIL). We aimed to describe the natural history of anal HSIL in GBM in Sydney, Australia, where anal HSIL is not routinely treated.

Method: The Study of the Prevention of Anal Cancer was a prospective, 3-year, cohort study conducted 2010–2018. HIV-positive and HIV-negative GBM aged ≥35 years were recruited from community-based settings. HSIL was diagnosed on cytology and/or high-resolution-anoscopy-guided-biopsy at baseline and at 3 annual visits. Predictors of HSIL incidence and clearance were calculated using Cox regression.

Results: Among 617 men, 220 (35.7%) were HIV-positive, median age 49 years. There were 124 incident HSIL cases over 1079.3 person-years of follow-up (PFYU) (11.3 [95% CI 9.5–13.5] per 100PYF). Univariate predictors of higher HSIL incidence included age≥45 years (HR 1.64, 95% CI 1.11–2.41), HIV-positivity (HR 1.43, 95% CI 0.99–2.06), prior SIL diagnosis (p-trend=0.001) and HPV16 DNA detection (HR 3.39, 2.38–4.84). Over 695.3 PFYU, 153 HSIL cleared (clearance 22.0 [95% CI 18.8–25.8] per 100PY). Predictors of HSIL clearance were age<45 years (HR 1.52, 1.08–2.16), anal intraepithelial neoplasia (AIN2) rather than AIN3 (HR 1.79, 1.29–2.49), smaller lesions (HR 1.62, 1.11–2.36) and lack of persistent HPV16 (HR 1.72, 1.23–2.41). There was one progression to cancer (incidence 0.224 [95% CI 0.006–1.25] per 100 PY).

Conclusion: Approximately one in ten men per year developed anal HSIL. Clearance was common, at about 20% per year after baseline HSIL. Progression to anal cancer was rare. These data strongly suggest that not all anal HSIL detected in screening requires treatment. Men with persistent HPV16 were less likely to clear HSIL and are more likely to benefit from effective HSIL treatments.
sensitivity and 56.1% specificity for biopsy-proven HSIL (AUC=0.68, p>0.05 compared with other biomarkers). Sensitivity and specificity of biomarkers are shown in the table.

Conclusion: E6/7-mRNA-test alone has high sensitivity and specificity, and could be considered for triage. LA has high sensitivity but low specificity due to the high HPV prevalence, not being useful for triage. First combined strategy increases sensitivity but decreases specificity and AUC are similar to aLBC alone, not providing triage advantages. Second combined strategy decreases sensitivity but increases specificity, with high AUC and the advantage of biomarker and HRA performance.

**PS6/3**  
Modelling the syphilis epidemic among HIV-positive and negative MSM in Switzerland

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2Institute of Medical Virology, University of Zurich, Zurich, Switzerland  
3Department of Infectious Diseases, Bern University Hospital, University of Bern, Bern, Switzerland  
4Division of Infectious Diseases and Hospital Epidemiology, University Hospital Basel, Basel, Switzerland  
5Division of Infectious Diseases, Geneva University Hospital, Geneva, Switzerland  
6Division of Infectious Diseases, Lausanne University Hospital, Lausanne, Switzerland  
7Division of Infectious Diseases, Hospital Epidemiology, Cantonal Hospital St. Gallen, St. Gallen, Switzerland  
8Division of Infectious Diseases, Regional Hospital Lugano, Lugano, Switzerland

**Background:** Over the last decade, syphilis incidence among HIV-positive and negative men who have sex with men (MSM) has strongly increased in Switzerland. Here we use a mathematical model that considers factors such as changing sexual behaviour to reproduce the syphilis epidemic.

**Methods:** We set up a transmission model consisting of 36 coupled ordinary differential equations to model the syphilis epidemic in MSM in Switzerland between 2006 and 2017. We stratified the model by syphilis stage, cascade of care and sexual risk behaviour (MSM reporting occasional partners) to account for infectiousness, disease progression and exposure to transmission. Additional model layers include the episode of syphilis (first or recurrent) and HIV status. The model was parameterized and calibrated by fitting to the observed diagnosed cases from the Swiss HIV Cohort Study (SHCS) and the published data from the Federal Office of Public Health (FOPH), Switzerland.

**Results:** We assessed the information of 5560 HIV-positive MSM registered in the SHCS between 2006 and 2017. 1272 (22.8%) HIV-positive MSM had at least one episode of syphilis and 521 (41.0%) of them had recurrent episode(s) of syphilis. The overall diagnosed cases of syphilis among MSM in Switzerland have increased from 113 in 2006 to 456 cases in 2017. Our mathematical model reproduced the strong increase in syphilis diagnoses from a mean of 208 episodes in 2006–2008 up to a mean of 438 episodes in 2015–2017, with an estimated additional 35 episodes every year. The model also reproduced about three-fold higher syphillis incidence in MSM reporting occasional partners compared to MSM reporting no occasional partners.

**Conclusions:** Our model accurately reconstructs the syphilis epidemic among MSM in Switzerland by capturing changes in sexual risk behaviour and interactions between HIV-positive and negative MSM. Syphilis incidence increased markedly in both HIV-positive and negative MSM and correlated with sexual risk behaviour.

**Antiretroviral therapy in special populations**

**PS7/1**  
RPV+DRV/cobi as 2DR option in HIV-infected subjects on virologic suppression

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2San Raffaele Scientific Institute, Infectious Diseases, Milano, Italy  
3Fondazione FROM, ASST Papa Giovanni XXIII, Infectious Diseases, Bergamo, Italy

**Purpose:** Rilpivirine plus cobi-boosted darunavir was compared to standard cART in virologically suppressed patients.

**Method:** Randomized, non-inferiority trial in chronically HIV-1 infected patients=18 years-old on a stable, effective (>6 months) three-drug CART. The primary endpoint was non-inferiority of the virological response at 6 months between treatment groups, according to the FDA snapshot design.

**Results:** 180 patients received RPV+DRV/cobi or continued their ongoing triple-regimen (see figure 1). Patients were 73% males with a median age of 50 years and more than 10 years of cART history. NNRIs were used in 70% of subjects, PIs in 38% and INIs in 22%. NRTIs included: TDF (49%); TAF (32%) and ABC (19%). Baseline median CD4 were 761 cells/mcL and median time below detection was 7.4 years.

RPV+DRV/cobi was non-inferior. At 6 months, 0% of patients with RPV+DRV/cobi presented a HIV-RNA level=50 copies/mL compared to 3.7% of controls (difference 3.75%, 95% CI –0.41 + 7.91). A HIV-RNA level <50 copies/mL was detected in 91.3% of patients on 2DR and in 93.8% of controls (difference –2.5%, 95% CI –10.65 + 8.65) (figure 2). CD4 medians slightly increased (20 cells/mcL) with RPV+DRV/cobi and decreased (77 cell/mcL) among controls. We observed a statistically significant increment of total cholesterol and LDL-cholesterol with RPV+DRV/cobi (17 and 12 mg/dl, respectively) and no change in HDL in either group. Bone mineral density was stable among switched patients and decreased among controls (+0.3 vs. –2.0 g/cm²; p=0.025 within

**Patients’ disposition**

![Figure 1. Patients’ disposition](image1.png)

Model predictions and observed syphilis cases in HIV-infected and uninfected MSM

![Figure 2. Snapshot analysis](image2.png)
PS7/2
Switching to DTG/3TC fixed dose combination (FDC) is non-inferior to continuing a TAF-based regimen (TBR) through 48 weeks: subgroup analyses from the TANGO study

M Ait-Khaled1, MC Nascimento1, KA Pappa2, R Wang2, J Wright2, AR Tenorio2, B Wyne3, MA Aboud3, MG Garland2 and J van Wyk4

1ViiV Healthcare, Brentford, UK 2ViiV Healthcare, Research Triangle Park, USA 3GlaxoSmithKline, Stockley Park, UK

Purpose: The 2-drug regimen (2DR) of DTG/3TC reduces cumulative drug exposure in people treated for HIV-1 infection, when compared to traditional 3DRs. DTG/3TC 2-drug regimen (2DR) is non-inferior to DTG+TDF/FTC 3DR in HIV-1 infected ART-naïve adults (GEMINI) and in ART-experienced virologically suppressed participants switching from a TAF-based 3DR (TANGO). Here we present a key secondary endpoint from the TANGO study: Snapshot virologic success by baseline regimen third agent class, disease and demographic characteristics.

Method: TANGO is a randomized, open-label, multicenter, non-inferiority Phase III study evaluating the efficacy and safety of switching to DTG/3TC once daily in HIV-1 infected adults on TBR, with HIV-1 RNA<50 c/mL for 6 months, without prior virologic failure or historical NRTI or INSTI major resistance mutations. Participants were randomized 1:1 [stratified by baseline 3rd agent class: PI, NRTI, INSTI] to switch to DTG/3TC or continue TBR through Week 148. The primary endpoint was the proportion of participants with plasma HIV-1 RNA<50 c/mL at Week 48 (FDA Snapshot algorithm, Intention To Treat-Exposed [ITT-E] population).

Results: 741 randomized/exposed participants (DTG/3TC: 369; TBR: 372) were included. Snapshot success rates across subgroups were generally consistent with the overall TANGO Week 48 study results and were similar between arms (Table 1). Zero participants on DTG/3TC and 1 participant (<1%) on TBR met confirmed virologic withdrawal with no resistance mutations observed at failure.

Conclusion: Switching to DTG/3TC FDC was non-inferior to continuing a TAF-based 3DR in maintaining virologic suppression in HIV-1 infected ART-experienced adults through Week 48. Efficacy by subgroups was consistent with overall Week 48 study results, demonstrating that switching from TBR to DTG/3TC is effective at maintaining virologic suppression regardless of baseline regimen, patient or disease characteristics.

Proportion of participants with plasma HIV-1 RNA<50 c/mL at Week 48: Snapshot Analysis by subgroup

<table>
<thead>
<tr>
<th>TANGO Study</th>
<th>DTG/3TC</th>
<th>TAF-Based Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Population</td>
<td>344/369 (99.2)</td>
<td>346/372 (98.0)</td>
</tr>
<tr>
<td>Adjusted difference and 95% CI</td>
<td>0.2 (–4.3, 9.9)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>&lt;35</th>
<th>35–&lt;50</th>
<th>≥50</th>
</tr>
</thead>
<tbody>
<tr>
<td>% index</td>
<td>138/139 (99.6)</td>
<td>209/210 (99.6)</td>
<td>351/361 (99.8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>% index</td>
<td>12/24 (42.0)</td>
<td>27/29 (94.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>White</th>
<th>African Heritage</th>
<th>Other</th>
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<tbody>
<tr>
<td>% index</td>
<td>276/292 (96.9)</td>
<td>52/58 (96.9)</td>
<td>9/10 (90.9)</td>
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</table>

<table>
<thead>
<tr>
<th>Baseline Third Agent Class</th>
<th>INSTI</th>
<th>NNRTI</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>% index</td>
<td>268/289 (92.7)</td>
<td>40/41 (96.1)</td>
<td>27/29 (93.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline CD4+ (cell/mm3)</th>
<th>&lt;200</th>
<th>200–&lt;350</th>
<th>≥350</th>
</tr>
</thead>
<tbody>
<tr>
<td>% index</td>
<td>32/35 (94.4)</td>
<td>29/30 (96.7)</td>
<td>1/2 (50.0)</td>
</tr>
</tbody>
</table>

* Adjusted difference for overall population (DTG/3TC–TBR) and 95% confidence intervals are based on stratified analysis (adjusting for baseline 3rd agent class) using Cochran-Mantel-Haenszel weights and an 8% non-inferiority margin.

PS7/3
Safety and efficacy of triple therapy with Dolutegravir plus 2 NRTIs, in treatment-naïve HIV-2 infected patients – 48 weeks results from a phase II study

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1Hospital Professor Doutor Fernando Fonseca, Amadora, Portugal 2Hospital Garcia de Orta, Almada, Portugal 3Hospital Beatriz Angelo, Loures, Portugal 4Hospital Egas Moniz, Lisboa, Portugal 5Hospital Curry Cabral, Lisboa, Portugal 6Hospital Santa Maria, Lisboa, Portugal 7BlueClinical, Ltd, Matosinhos, Portugal

Objectives: Evaluate the efficacy, safety and tolerability of triple therapy with Dolutegravir (DTG) plus 2 nucleoside reverse transcriptase inhibitors in treatment-naive HIV-2 infected patients.

Methods: A phase II open label study was conducted in Portugal (EudraCT: 2016–000346–61). DTG/abacavir/lamivudine or DTG+tenofovir (TDF) emtricitabine was administered for 48 weeks. Inclusion criteria were CD4<500 cells/µL or plasma viral load (pVL)<40 copies/µL. Treatment efficacy was evaluated by the proportion of subjects achieving a pVL<40 copies/µL and/or by the change from baseline in CD4 cell count and in CD4/CD8 ratio at week 48 (W48).

Results: Thirty individuals were enrolled, 73% female and mean age of 54 years. At baseline 17 (56.7%) were viremic (mean pVL 403.3 (min-max: 56–1959) copies/µL), with median CD4 count 438 cells/µL and median CD4/CD8 ratio 0.81. Ninety percent of participants completed the study. At W24, all viremic participants at baseline, had a pVL<40 copies/µL. At W48, 27/30 participants had pVL<40 copies/µL (1 subject withdrawn, 1 discontinued due to adverse event and 1 lost to follow-up). No virological failures were observed. Mean change from baseline of CD4 count and CD4/CD8 ratio at W48 were of +95.6 (95% CI: 28.0–163.1) cells/µL and +0.26 (95% CI: 0.17–0.43), respectively. The most common drug-related adverse events were headache (20.0%) and nausea (13.3%) and were grade 1–2. There were no serious adverse events. One subject discontinued due to drug-related insomnia, anxiety and memory disturbance. No AIDS associated clinical events were reported.

Conclusion: This is the first clinical trial assessing the use of DTG in HIV-2 infection. Our data suggest that DTG + 2 NRTIs is a safe and effective first-line treatment, with CD4 cell recovery comparable to other regimens already tested in HIV-2 infection. There were no virological failures and no resistance mutations emerged, suggesting a higher genetic barrier of DTG in HIV-2 as observed in HIV-1.
plasma (SP) and in blood plasma (BP) of men starting a dolutegravir-based regimen at the time of PHI.

Methods: Open, single-arm, prospective study enrolling men diagnosed at the time of PHI (<3 months) and starting dolutegravir (DTG) plus TDF/FTC. Paired samples of BP and SP were collected at Baseline (BL), Week (W) W2, W4, W12, W24, W36 and W48, for VL quantification and measurement of TDF/FTC and total and free DTG concentrations (UPLC-MS/MS). The primary outcome was the achievement of a first VL below the lower limit of quantification (LOQ) in BP (20 cp/mL) and in SP (60 cp/mL), assessed with the Kaplan–Meier method. Results: 19 men were enrolled, 4 at Fiebig stage II (F-II), 5 F-III, 1 F-IV, 4 F-V and 5 F-VI. Baseline characteristics and their distribution over time are shown in Table. At BL, median (IQR) VL was 6.5 (5.6–7.9) and 4.5 (3.5–5.0) log10 cp/mL in BP and SP, respectively. Treatment was started a median of 7 days (3–12) after diagnosis. Between BL and W48, a significantly higher proportion of participants achieved a first VL below LOQ in SP (93.0%) than in BP (84.2%; p = 0.008). Median time to reach a first VL below LOQ was 8 weeks in SP (95% CI: 5.6–10.4) and 24 weeks in BP (95% CI: 14.1–33.9). DTG concentrations in BP and SP were mainly expected, adequate and stable along the study period.

Conclusion: DTG-based regimen initiated at the time of PHI was able to rapidly achieve VL suppression in seminal plasma.

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>All participants (n = 41)</th>
<th>Historical resistance to 3TC (n = 21)</th>
<th>No historical resistance to 3TC (n = 20)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, n (%)</td>
<td>32 (78.0)</td>
<td>16 (76.2)</td>
<td>16 (80)</td>
<td>0.768</td>
</tr>
<tr>
<td>Age (years), median (IQR)</td>
<td>35.0 (25.0–45.0)</td>
<td>33.9 (23.5–43.5)</td>
<td>36.3 (25.0–46.5)</td>
<td>0.636</td>
</tr>
<tr>
<td>Time since HIV diagnosis (years),</td>
<td>20.5 (14.8–25.0)</td>
<td>21.4 (17.4–23.4)</td>
<td>18.6 (15.0–21.3)</td>
<td>0.342</td>
</tr>
<tr>
<td>median (IQR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 count (cells/mm³), median (IQR)</td>
<td>534 (305–1011)</td>
<td>547 (310–985)</td>
<td>527 (400–900)</td>
<td>0.815</td>
</tr>
<tr>
<td>Nadir</td>
<td>196 (93–290)</td>
<td>229 (98–329)</td>
<td>215 (85–294)</td>
<td>0.610</td>
</tr>
<tr>
<td>Baseline</td>
<td>636 (522–886)</td>
<td>612 (542–836)</td>
<td>669 (578–946)</td>
<td>0.272</td>
</tr>
<tr>
<td>ART duration (years), median (IQR)</td>
<td>17.9 (13.0–21.3)</td>
<td>18.7 (17.1–20.9)</td>
<td>13.0 (7.8–21.5)</td>
<td>0.085</td>
</tr>
<tr>
<td>Duration of suppressed plasma HIV RNA (years), median (IQR)</td>
<td>7.7 (3.9–12.2)</td>
<td>9.7 (4.3–12.5)</td>
<td>7.4 (3.5–11.6)</td>
<td>0.636</td>
</tr>
<tr>
<td>Number of previous ART regimens, median (IQR)</td>
<td>6 (4–10)</td>
<td>7 (5–12)</td>
<td>4 (2–10)</td>
<td>0.272</td>
</tr>
<tr>
<td>Type of ART regimen at baseline, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Including 3TC or FTC</td>
<td>28 (68.3)</td>
<td>25 (75.0)</td>
<td>3 (15.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2 NRTIs + NNRTIs or bPI</td>
<td>17 (41.4)</td>
<td>10 (30.0)</td>
<td>7 (35.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>bPI + NRTI</td>
<td>16 (42.6)</td>
<td>16 (48.6)</td>
<td>0 (0)</td>
<td>0.900</td>
</tr>
<tr>
<td>bPI monotherapy</td>
<td>1 (2.5)</td>
<td>0 (0)</td>
<td>1 (5.0)</td>
<td>0.296</td>
</tr>
<tr>
<td>M184V detected by NGS in seminal DNA, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&gt;20%</td>
<td>1 (7.1)</td>
<td>1 (5.0)</td>
<td>0 (0)</td>
<td>0.367</td>
</tr>
<tr>
<td>&gt;5%</td>
<td>2 (9.2)</td>
<td>1 (4.8)</td>
<td>1 (4.8)</td>
<td>0.226</td>
</tr>
<tr>
<td>&gt;1%</td>
<td>3 (7.3)</td>
<td>3 (14.3)</td>
<td>0 (0)</td>
<td>0.135</td>
</tr>
</tbody>
</table>

*1 patient not amplify

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Table 2. Snapshot at W48, Intention to treat–exposed (ITT-e) analysis population.

<table>
<thead>
<tr>
<th></th>
<th>All participants (n=41)</th>
<th>Historical resistance to 3TC (n=21)</th>
<th>No historical resistance to 3TC (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 RNA≤50 copies/mL</td>
<td>38 (92.7)</td>
<td>18 (85.7)</td>
<td>20 (100)</td>
</tr>
<tr>
<td>HIV-1 RNA≥50 copies/mL in W48 window</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Discontinuation Study Drug due to Lack of Efficacy</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Discontinuation Study Drug due to other reasons and Last available</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>HIV-1 RNA≥50 copies/mL</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>No virologic data at W48</td>
<td>3 (7.3)</td>
<td>3 (14.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Discontinuation Study Drug due to AE</td>
<td>1 (2.4)</td>
<td>1 (4.8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Discontinuation Study Drug due to other reasons and Last available HIV-1 RNA&lt;50 copies/mL</td>
<td>2 (4.9)</td>
<td>2 (9.5)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

PS7/6

Efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide vs comparators in cis–women and girls (living with HIV): an analysis of 5 clinical trials

C Orkin1, C Kityo2, E Koenig3, E Natukunda4, F Ajana5, B Gandhi-Patel1, Y Liu1, L Wei1, K White1, T Makadzange1, C Pikora1, D Brainard6 and S Chuck7

1Barts Health NHT Trust, The Royal London Hospital, Ambrose King Centre, London, UK 2Joint Clinical Research Centre, Kampala, Uganda 3Instituto Dominicano de Estudios Virologicos (IDEV), Santo Domingo, Dominican Republic 4Centre Hospitalier de Toucouleur, Toucouleur, France 5Gilead Sciences, Foster City, USA

Purpose: Globally, the majority of people living with HIV are cis–women. Cis–women bear the brunt of HIV epidemic but remain significantly under–represented in clinical trials. Coformulated bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a once-daily, single-tablet regimen with demonstrated efficacy and safety in clinical trials of treatment-naïve and virologically suppressed adults, adolescents and children living with HIV. Efficacy and safety of B/F/TAF versus comparators in cis–women and girls across five phase 2/3 B/F/TAF clinical trials through 48 weeks were assessed.

Method: Analysis included cis–women and girls from five clinical trials: virologically suppressed adults (studies 1961, 4449), and adolescents and children (study 1474), and treatment–naïve adults (studies 1489, 1490). Participants were grouped by age: children (6–11), adolescents (12–17), adults (18–49) and older adults (≥50). Comparators included dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) (1489), DTG+F/TAF (study 1490), elvitegravir/cobicistat/F/(TAF or tenofovir disoproxil fumarate[TDF]) (study 1961) or atazanavir-ritonavir+F/TDF (study 1961). We assessed efficacy using FDA Snapshot for HIV-1 RNA<50 c/mL, safety, and tolerability at Week 48.

Results: 679 cis–women and girls were analyzed (table); age range was 6–74 years; 44% Black, 28% White, 17% Asian and 12% other. High and similar rates of virologic suppression were observed across age groups (B/F/TAF 87%–100%; comparators 86%–95%). No treatment-emergent resistance was detected with B/F/TAF versus 1 participant on comparator regimen developed resistance. Drug-related adverse events (AEs) occurred in similar proportions of participants taking B/F/TAF versus comparators. Overall rates of grade 3/4 AEs were low. No women and 1 girl discontinued due to any AE in B/F/TAF group vs 2 women in comparators.

Conclusion: B/F/TAF is an effective, safe and well tolerated HIV treatment in this large analysis of cis–women and girls living with HIV spanning ages 6–74 years. High rates of virologic suppression and low incidence of AEs, observed among diverse participants, make B/F/TAF an important treatment option for cis–women and girls.
Antiretroviral therapy: today and in the future

PS8/1
Adherence and clinical outcomes in asymptomatic patients starting ART: the Swiss HIV Cohort Study
TR Glass1,2, H Günthard3, A Calmy3, E Bernasconi4, A Scherrer5, M Battegay4,6, A Steffen7, J Boni8, S Yerly9, T Klümkait10, M Perreau11, M Cavassini11, H Furrer14 and Swiss HIV Cohort Study
1Swiss Tropical & Public Health Institute, Department of Medicine, Basel, Switzerland 2University Basel, Basel, Switzerland 3University Hospital Zurich, Division of Infectious Diseases and Hospital Epidemiology, Zurich, Switzerland 4University of Zurich, Institute of Medical Virology, Zurich, Switzerland 5University Hospital Geneva, Division of Infectious Diseases, Geneva, Switzerland 6Ospedale Regionale di Lugano, Division of Infectious Diseases, Lugano, Switzerland 7Swiss HIV Cohort Data Center, Zurich, Switzerland 8University Hospital Basel, Division of Infectious Diseases, Basel, Switzerland 9Kantonsspital St. Gallen, Division of Infectious Diseases, St. Gallen, Switzerland 10Gemeinschaftliches Universitätsklinikum, Laboratory of Virology, Geneva, Switzerland 11University Hospital, Department of Internal Medicine, Basel, Switzerland 12University Hospital Lausanne, Division of Oncology, Lausanne, Switzerland 13University Hospital Lausanne, Infectious Disease Service, Lausanne, Switzerland 14Bern University Hospital, Department of Infectious Diseases, Bern, Switzerland

Purpose: Since the advent of universal test and treat approach, a higher share of individuals initiating ART are asymptomatic with a preserved immune system. We explored the association between adherence and clinical outcomes in asymptomatic patients starting ART.

Method: ART-naïve patients registered in the SHCS between 2003 and 2018. Asymptomatic was defined as CDC-stage A within 30 days of starting ART. Non-adherence was defined as any self-reported missed doses. Viral failure was defined as viral load ≥50 copies/ml on two consecutive measurements after >24 weeks on ART. Logistic regression models were used to measure the association between demographic variables and asymptomatic status. Cox proportional hazard models were used to assess the association between symptom status and viral rebound.

Results: Of 7131 individuals, 76% started ART when asymptomatic and this increased over time (62% in 2003 to 83% in 2017; p < 0.001). In multivariable logistic regression models, asymptomatic individuals were more likely to be younger, MSM, more educated, having unsafe sex, have a stable HIV-positive partner, lower viral load, and have started ART in later calendar years. Adherence to ART was significantly better in asymptomatic with non-adherence reported in 48% versus 55% in symptomatic individuals (p < 0.001). 1478 individuals (22%) experienced viral failure a median of 1.9 years (IQR: 1.1–4.2) after starting ART. In multivariable Cox models, asymptomatic individuals were at a decreased risk of viral rebound (HR 0.85, 95% CI: 0.74–0.98, p = 0.02). After starting ART, 1025 individuals were tested for acquired resistance of which 185 (18%) were detected. Asymptomatic individuals were less likely to develop resistance (14% versus 27%, p = 0.02) even in the subset starting ART after 2009 (12% versus 24%, p = 0.02).

Conclusion: Despite concerns regarding lack of readiness in those starting ART when asymptomatic or shortly after diagnosis, there is consistent evidence of improved clinical outcomes in these individuals.

PS8/2
Assessments of very low level HIV replication for dolutegravir+lamivudine (DTG + 3TC) vs dolutegravir+tenofovir disoproxil/emtricitabine (DTG+TDF/FTC) in the GEMINI 1&2 studies through week 96
M Underwood1, R Urbailyte2, R Wang3, A Tenorio1, B Wynne1, K Pappa1, J Koteff1, M Garrett2, J Van Wyk3, C Mar1 and J Sievers1
1ViiV Healthcare, Research Triangle Park, USA 2GlaxoSmithKline, Stockley Park, UK 3ViiV Healthcare, Brentford, UK

Purpose: The GEMINI-1&2 studies in treatment-naïve adults showed DTG + 3TC was non-inferior to DTG+TDF/FTC at Week 96 by FDA snapshot algorithm. 50 copies/ml. Abbott’s RealTime HIV-1 assay measures HIV-1 RNA viral load, VL) from 40 copies/ml to 10,000,000 copies/ml, and provides qualitative target detected (TD) or target not detected (TND) for VL ≤ 40 copies/ml. We assessed participants with TND over time and by baseline (BL) VL and CD4.

Method: The proportion of participants with VL ≤ 40 copies/ml and TND status at Week 96 was analysed using a Cochran–Mantel–Haenszel test stratified by VL (≤ 100,000 vs > 100,000 copies/ml) and CD4 + cell count (< 200 vs ≥ 200 cells/µl) at BL. Participant subgroups were assessed using three approaches: Snapshot, Observed Analysis (only participants with VL ≤ 50 copies/ml at Week 96 by Snapshot analysis), and Last Observation Carried Forward (LOCF). Times to TND Status were estimated using non-parametric Kaplan–Meier method.

Results: At Week 96 similar proportions of participants in each arm had TND overall, regardless of BL VL and for CD4+200 (Table 1). The % TND was lower in DTG + 3TC arm for CD4 < 200 (Table 2), however numbers in this subgroup were small limiting ability to make conclusions. Proportions with TND were similar between arms at all visits (Figure 1). Median time to TND (all participants or Observed Analysis populations) was 8 weeks in DTG + 3TC and DTG+TDF/FTC arms for overall population and in BL VL ≤ 100,000 copies/ml subgroup, and 16 vs 24 weeks in BL VL > 100,000 copies/ml subgroup.

Conclusion: Proportions of participants with TND were similar in the DTG + 3TC and DTG+TDF/FTC arms, regardless of BL VL. Median time to TND was similar overall and in BL VL ≤ 100,000 copies/ml subgroup, and shorter for DTG + 3TC vs DTG+TDF/FTC if VL > 100,000 copies/ml at BL. These data, utilizing a more stringent VL measure, continue to demonstrate the potency and a durable efficacy of DTG + 3TC in treatment-naïve subjects.

<p>| Table 1. Proportion of Participants with Plasma HIV-1 RNA &lt;40 copies/ml at Week 96 Overall and by Baseline Plasma HIV-1 RNA Levels |</p>
<table>
<thead>
<tr>
<th>Analysis</th>
<th>Subgroup</th>
<th>DTG + 3TC</th>
<th>DTG+TDF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snapshot</td>
<td>Overall</td>
<td>474/716 (66)</td>
<td>487/717 (66)</td>
</tr>
<tr>
<td></td>
<td>&lt; 200</td>
<td>320/400 (80)</td>
<td>304/369 (83)</td>
</tr>
<tr>
<td>Observed</td>
<td>Overall</td>
<td>475/516 (87)</td>
<td>489/514 (87)</td>
</tr>
<tr>
<td></td>
<td>&lt; 200</td>
<td>343/419 (82)</td>
<td>394/452 (87)</td>
</tr>
<tr>
<td>LOCF</td>
<td>Overall</td>
<td>500/573 (87)</td>
<td>547/571 (98)</td>
</tr>
<tr>
<td></td>
<td>&lt; 200</td>
<td>557/654 (85)</td>
<td>642/655 (98)</td>
</tr>
</tbody>
</table>

<p>| Table 2. Proportion of Participants with Plasma HIV-1 RNA ≤ 40 copies/ml and TND at Week 96 by Baseline CD4 + cell count |</p>
<table>
<thead>
<tr>
<th>Analysis</th>
<th>Subgroup</th>
<th>DTG + 3TC</th>
<th>DTG+TDF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snapshot</td>
<td>CD4 &lt; 200</td>
<td>27/63 (43)</td>
<td>32/55 (58)</td>
</tr>
<tr>
<td></td>
<td>CD4 &gt; 200</td>
<td>447/653 (68)</td>
<td>452/662 (68)</td>
</tr>
<tr>
<td>Observed</td>
<td>CD4 &lt; 200</td>
<td>27/43 (63)</td>
<td>32/48 (67)</td>
</tr>
<tr>
<td></td>
<td>CD4 &gt; 200</td>
<td>447/573 (78)</td>
<td>452/594 (76)</td>
</tr>
<tr>
<td>LOCF</td>
<td>CD4 &lt; 200</td>
<td>55/62 (89)</td>
<td>53/55 (96)</td>
</tr>
<tr>
<td></td>
<td>CD4 &gt; 200</td>
<td>636/650 (98)</td>
<td>642/655 (98)</td>
</tr>
</tbody>
</table>

a – Participants were included in assessment via: 1. FDA Snapshot algorithm; 2. Having HIV-1 RNA VL ≤ 50 copies/ml at Week 96 (Observed Analysis); 3. Using Last observation carried forward (LOCF). Subjects without any post baseline HIV-1 RNA are not included b – BL Subgroup in cells/µl; c - Number Responded/Number Assessed (%); d - Unadjusted (Adjusted for baseline, covariates and unthar3,4, A Calmy5, E Bernasconi6, A Scherrer7, M Battegay2,8, M Garrett9, J Van Wyk3, C Mar1 and J Sievers1

Figure 1. Proportion of Participants with TND by Visit: Snapshot analysis
Dolutegravir/efavirenz dual therapy is non-inferior to standard combination antiretroviral therapy in maintaining HIV suppression throughout 48 weeks (SIMPL’HIV study)


1Geneva University Hospital, Geneva, Switzerland 2Bern University Hospital, Bern, Switzerland 3University Hospital – HIV Center, Basel, Switzerland 4Lugano Regional Hospital, Lugano, Switzerland 5University Hospital Zurich, Zurich, Switzerland 6Kantonsspital St. Gallen, St Gallen, Switzerland 7Lausanne University Hospital, Lausanne, Switzerland 8University of Bern, Bern, Switzerland

Purpose: Dolutegravir (DTG)-based dual therapy is becoming a new paradigm for both the initiation and maintenance of HIV treatment. The SIMPL’HIV study investigated the outcomes of virologically suppressed patients on standard combination antiretroviral therapy (cART) switching to DTG plus emtricitabine (FTC) in Switzerland. We present the 48-week efficacy and safety data on DTG+FTC vs cART.

Method: SIMPL’HIV is a multicentre, factorial, open-label, non-inferiority randomized trial among HIV-1 infected adults on cART with HIV-RNA<50 copies/mL for at least 24 weeks (no CD4 or pre-treatment HIV-RNA restriction). Participants were randomized 1:1:1:1 to switching to DTG+FTC or to continuing cART, and to patient-centred surveillance defined as reduced biological monitoring and individualized follow-up vs continuation of 3-monthly monitoring. The primary endpoint was the proportion of patients maintaining HIV-RNA<100 copies/mL throughout 48 weeks. Secondary endpoints included the proportion of patients with HIV-RNA<50 copies/mL at week 48 (FDA Snapshot).

Results: Ninety-three participants were randomized to DTG+FTC and 94 to cART. Mean nadir CD4 count was 259 cells/mm3 (SD: 187); 17% were female. In the intention-to-treat analysis, the proportion of patients with HIV-RNA<100 copies/mL throughout 48 weeks was 93.5% (87/93) in the DTG+FTC group and 94.7% (89/94) in the cART group (difference: −1.2%, 95% CI: −7.8% to +5.6%; non-inferiority margin: −12.0%). In the week 48 window, FDA snapshot virological success was 90.3% vs 91.5% (difference: −1.1%, 95% CI: −9.3% to +7.1%) (Table 1). Protocol-defined virological failure (two consecutive HIV-RNA<100 copies/mL) was observed in one participant in the cART group and none in the DTG+FTC group, with no acquired drug resistance mutations. Overall rates of adverse events, including weight gain, were similar in both groups.

Conclusion: Switching to DTG+FTC was non-inferior to cART in maintaining HIV suppression throughout 48 weeks and appears to be a safe maintenance therapy strategy.

FDA Snapshot analysis

<table>
<thead>
<tr>
<th>Week 48 study outcome by FDA Snapshot analysis</th>
<th>DTG=FTC (N=93)</th>
<th>cART (N=94)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-RNA&lt;50 copies/mL*</td>
<td>84 (90.3%)</td>
<td>86 (91.5%)</td>
</tr>
<tr>
<td>HIV-RNA&lt;50 copies/mL or change of therapy or discontinuation of therapy due to lack of efficacy**</td>
<td>2 (2.1%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Discontinuation of therapy due to adverse events</td>
<td>1 (1.1%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Discontinuation of therapy due to consent withdrawal or loss to follow-up</td>
<td>3 (3.2%)</td>
<td>3 (3.2%)</td>
</tr>
<tr>
<td>Included patients with missed data in the Snapshot time window</td>
<td>3 (3.2%)</td>
<td>3 (3.2%)</td>
</tr>
</tbody>
</table>

*Risk difference (95% CI): −1.1% [−9.3%; +7.1%] **According to FDA snapshot, failure is defined by HIV-RNA>50 copies/mL or change of therapy or discontinuation of therapy due to lack of efficacy; by contrast, the protocol-defined virological failure refers to two consecutive HIV-RNA>100 copies/mL.

Figure 1. Treatment Failure at 48 weeks in study without Maraviroc

Figure 2. Virological failure at 48 weeks in study without Maraviroc
Table 1. Meta-analysis of study presenting data at 48 weeks

<table>
<thead>
<tr>
<th>Analysis</th>
<th>No. of studies</th>
<th>No. of patients in analysis</th>
<th>No. of events in analysis</th>
<th>RR Dual vs triple</th>
<th>95% CI</th>
<th>Heterogeneity test (I²%; p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment failure (TF)</td>
<td>12</td>
<td>2038/1865</td>
<td>285/223</td>
<td>1.10</td>
<td>0.84–1.44</td>
<td>51.7,0.019</td>
</tr>
<tr>
<td>TF in patients with less than 10 000 copies of HIV RNA</td>
<td>7</td>
<td>1200/1198</td>
<td>161/106</td>
<td>1.52</td>
<td>1.21–1.92</td>
<td>16.4,0.304</td>
</tr>
<tr>
<td>TF in patients with equal or more than 10 000 copies of HIV RNA</td>
<td>7</td>
<td>358/397</td>
<td>66/74</td>
<td>1.03</td>
<td>0.77–1.38</td>
<td>16.5,0.304</td>
</tr>
<tr>
<td>TF in patients with less than 10 000 copies of HIV RNA in study without Maraviroc</td>
<td>4</td>
<td>808/790</td>
<td>83/58</td>
<td>1.40</td>
<td>1.01–1.93</td>
<td>31.3,0.225</td>
</tr>
<tr>
<td>TF in patients with equal or more than 10 000 copies of HIV RNA in study without Maraviroc</td>
<td>4</td>
<td>263/277</td>
<td>35/46</td>
<td>0.82</td>
<td>0.56–1.21</td>
<td>18.2,0.299</td>
</tr>
<tr>
<td>Virological failure</td>
<td>8</td>
<td>1578/1612</td>
<td>86/52</td>
<td>1.63</td>
<td>0.93–2.85</td>
<td>49.1,0.056</td>
</tr>
<tr>
<td>Adverse drug reaction leading to discontinuation of regimen</td>
<td>9</td>
<td>1986/2023</td>
<td>72/88</td>
<td>0.83</td>
<td>0.62–1.12</td>
<td>5.1,0.391</td>
</tr>
<tr>
<td>Adverse drug reaction leading to discontinuation of regimen in study without Maraviroc</td>
<td>5</td>
<td>1472/1471</td>
<td>44/59</td>
<td>0.75</td>
<td>0.51–1.09</td>
<td>42.0,0.159</td>
</tr>
</tbody>
</table>

Table 2. Meta-analysis of study presenting data at 96 weeks and mutations

<table>
<thead>
<tr>
<th>Analysis</th>
<th>No. of studies</th>
<th>No. of patients in analysis</th>
<th>No. of events in analysis</th>
<th>RR Dual vs triple</th>
<th>95% CI</th>
<th>Heterogeneity test (I²%; p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment failure (TF)</td>
<td>4</td>
<td>941/1025</td>
<td>212/315</td>
<td>0.84</td>
<td>0.58–1.22</td>
<td>74.2,0.009</td>
</tr>
<tr>
<td>TF in patients with less than 10 000 copies of HIV RNA</td>
<td>4</td>
<td>941/1025</td>
<td>153/216</td>
<td>1.07</td>
<td>0.89–1.29</td>
<td>0.0,0.53</td>
</tr>
<tr>
<td>TF in patients with equal or more than 10 000 copies of HIV RNA</td>
<td>2</td>
<td>308/329</td>
<td>35/46</td>
<td>0.80</td>
<td>0.54–1.19</td>
<td>34.0,0.218</td>
</tr>
<tr>
<td>Virological failure</td>
<td>3</td>
<td>153/137</td>
<td>57/38</td>
<td>1.34</td>
<td>0.95–1.87</td>
<td>0.0,0.622</td>
</tr>
<tr>
<td>Adverse drug reaction leading to discontinuation of regimen</td>
<td>3</td>
<td>540/621</td>
<td>30/45</td>
<td>0.91</td>
<td>0.57–1.45</td>
<td>53.5,0.117</td>
</tr>
<tr>
<td>Mutation</td>
<td>9</td>
<td>149/120</td>
<td>54/41</td>
<td>1.13</td>
<td>0.85–1.52</td>
<td>0.0,0.450</td>
</tr>
</tbody>
</table>

PS8/5
Shorter time to treatment failure in PLHIV switched to dolutegravir plus either rilpivirine or lamivudine compared to integrate inhibitor-based triple therapy in a large Spanish cohort – VACH

R Teira¹, H Díaz-Cuervo², F Aragón³, M Castaño⁴, A Romero⁵, R Boca⁵, M Montero⁶, M Galindo⁷, M Muñoz-Sánchez⁸, N Espinosa⁹, J Peraire¹⁰, E Martínez¹¹, B de la Fuente¹² and P Domingo¹³

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Objective: Randomized controlled clinical trials have demonstrated non-inferiority of two-drug combinations (2DC) of dolutegravir (DTG) plus either rilpivirine (RPV) or lamivudine (3TC) compared to triple-therapy (TT). Data on real-world effectiveness of 2DC strategies are limited. This study compared time to discontinuation due to treatment failure (TF) and adverse events (AEs) of DTG-based 2DC versus integrase inhibitor (INSTI)-based TT in a real-world setting.

Methods: A retrospective analysis was performed using data from the VACH cohort (prospective, multicenter, Spanish cohort of adult HIV patients). All patients switching to INSTI-based TT or to a 2DC consisting of DTG+RPV or DTG+3TC between 02/05/2016–15/05/2019 were included. Unit of analysis was patient-regimen. Relevant endpoints were time to discontinuation due to TF (defined as clinician report of virological failure (VF), immunologic failure or disease progression), VF and AEs. Patients were censored at loss-to-follow-up, death or end of observation period (20/06/2019). Kaplan-Meier curves and Cox proportional hazard models (controlling for demographics, viral load, CD4, number of previous regimens/VFs, and years on antiretroviral therapy) were conducted.

Results: 5,047 TT and 617 2DC patient-regimens were analyzed. Baseline patient-regimen characteristics differed between groups (Table); 2DC were older and more experienced but a higher proportion was virologically suppressed at switch. Time to TF was significantly shorter for 2DC (Figure, p<0.0001). The hazard ratio (HR) for discontinuation due to TF on 2DC vs TT was 2.334 (p=0.003). No difference was observed for discontinuation due to AEs (HR=0.797, p=0.488). Results were maintained when looking at discontinuations due to VF (HR=2.236, p=0.024) and when restricting to patients with viral load<50 copies/mL at regimen initiation.

Conclusion: In a real-world setting, the risk of discontinuation due to TF and VF were more than two-times higher in patients switching to DTG-based 2DC compared to INSTI-based TT, with no difference in discontinuation due to AEs.

Baseline Characteristics by Group

<table>
<thead>
<tr>
<th></th>
<th>INSTI-based triple therapy</th>
<th>DTG+3TC or DTG+RPV</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), Mean (SD)</td>
<td>48.1 (10.7)</td>
<td>52.0 (10.3)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Gender, % Female</td>
<td>23.4</td>
<td>28.7</td>
<td>0.0020</td>
</tr>
<tr>
<td>AIDS diagnosis, % Yes</td>
<td>23.2</td>
<td>26.7</td>
<td>0.0264</td>
</tr>
<tr>
<td>CD4 count, % &gt;350 cells/μL</td>
<td>81.8</td>
<td>82.9</td>
<td>0.4527</td>
</tr>
<tr>
<td>Viral Load, % &lt;50 copies/mL</td>
<td>81.0</td>
<td>90.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Duration of ART regimens (years), Mean (SD)</td>
<td>12.0 (8.4)</td>
<td>14.9 (8.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Number of previous ART regimens, Mean (SD)</td>
<td>5.3 (3.6)</td>
<td>7.4 (4.6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Number of previous virologic failures, Mean (SD)</td>
<td>1.1 (2.4)</td>
<td>1.5 (2.9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>HCV, % Yes</td>
<td>32.6</td>
<td>35.4</td>
<td>0.1323</td>
</tr>
</tbody>
</table>

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PS8/6

Five-year follow-up of patients enrolled in NEAT001/ANRS 143 randomized clinical trial (NEAT001 LONG TERM (NLT) study)

F Raffi1, A Gaultier1, A Pozniak2, J-M Molina1, H Jessen1, A Antinori5, A Soria1, M Cavellée1, A Le Thuaut1, M Ningre1, S De Wit6 and Neat Long Term Study Group

1University Hospital, Nantes, France 2Chelsea and Westminster Hospital NHS Foundation Trust and LSHTM, London, UK 3Saint-Louis Hospital, Paris, France 4Gemeinschaftspraxis Jessen-Stein, Berlin, Germany 5National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy 6Saint Pierre University Hospital, Université Libre de Bruxelles, Brussels, Belgium

Background: Few long-term data are available on patients having initiated ART with a NRTI-sparing regimen. We assessed the 5-year outcome of patients taking part in NEAT001, NLT was conducted in 39 sites in 8 countries. Data were analyzed without imputation. Chi2 (or Fisher’s Exact) or Student’s tests were used for comparisons.

Methods: Retrospective data collection, through anonymized cCRF, of patient outcomes up to 5 years post-enrolment. Of the 78 sites from 15 countries participating in NEAT001, NLT was conducted in 39 sites in 8 countries. Data were analyzed without imputation. Chi2 (or Fisher’s Exact) or Student’s tests were used for comparisons.

Results: Last NEAT001 visit (W96) was conducted in 745/805 randomized patients (363/401 RAL vs TVD) at the end of 5 years follow-up. Median weight gain between baseline and last follow-up was 3.15 ± 7.79 vs 4.08 ± 6.49 kg in patients exposed >50% of follow-up to INI vs never exposed to INI (p=0.38). TDF exposure (>50% of follow-up vs never exposed) was associated with higher creatinine increase (p=0.036).

Conclusion: After a median of 5.7 years, patients initiating ART with DRV/r+RAL or DRV/r+TVD experienced few serious clinical events. A quarter of patients were still receiving their initial regimen, most discontinuations being for reasons unrelated to AE or virologic failure.

Table 1 NEAT001 LONG TERM (NLT) main outcomes according to initial randomization group

<table>
<thead>
<tr>
<th>W96-Year 4</th>
<th>Year 4-Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRV/r + RAL</td>
<td>DRV/r + TVD</td>
</tr>
<tr>
<td>Available data</td>
<td>182/201 (90.5%)</td>
</tr>
<tr>
<td>Median follow-up months</td>
<td>32.3</td>
</tr>
<tr>
<td>Unchanged ART since enrolment into NEAT001</td>
<td>27.5%</td>
</tr>
<tr>
<td>AIDS event</td>
<td>N=0</td>
</tr>
<tr>
<td>Non-AIDS event</td>
<td>3.9%</td>
</tr>
<tr>
<td>HIV RNA=50 c/mL</td>
<td>3.3%</td>
</tr>
<tr>
<td>Serious adverse event</td>
<td>4.5%</td>
</tr>
</tbody>
</table>

PS8/7

Uptake and discontinuation of Integrase Inhibitors (INSTIs) in a large cohort setting

L Greenberg1 and on behalf of RESPOND – The International Cohort Consortium of Infectious Diseases

1UCL, London, UK

Objectives: To compare characteristics of those initiating INSTIs in real-world settings across Europe and Australia, and describe reasons for and factors associated with discontinuation of first INSTI-based regimen.

Methods: RESPOND participants first starting dolutegravir (DTG), elvitegravir (EVG) or raltegravir (RAL) after 1/1/2012 were compared using multinomial logistic regression. Kaplan Meier and Cox proportional hazards models describe time to and factors associated with discontinuation.

Results: Overall, 9702 persons started INSTIs; 5051 (52.1%) DTG, 1933 (19.9%) EVG, 2718 (28.0%) RAL. The likelihood of starting RAL or EVG versus DTG decreased over time (adjusted risk ratio 0.25 per year increase [95% CI 0.23–0.26] RAL, 0.81 [0.77–0.85] EVG; p<0.001) but was higher in Eastern Europe (50% of follow-up vs never exposed) was associated with discontinuation. By 6 months (Figure), those on RAL or EVG were more likely to discontinue than DTG. Other factors associated with discontinuation included year of INSTI initiation, gender, hepatitis C coinfection, prior non-AIDS defining malignancies, and region. Similar results were seen for discontinuations after 6 months and for treatment-naive and experienced persons (p=0.79; interaction test).

Conclusion: Uptake of DTG versus EVG or RAL has increased over time. Discontinuation was highest on RAL, mainly due to treatment simplification. Albeit relatively low, the main reason for discontinuation within 6 months was toxicity; nervous system toxicity was highest on DTG.
Factors associated with INSTI discontinuation in the first 6 months after INSTI start

Emerging issues in public health and epidemiology of HIV in Europe

PS9/1

Current trends in HIV/AIDS epidemic in Russia

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1Central Research Institute of Epidemiology, Russian Federal AIDS Centre, Moscow, Russian Federation

Purpose: Early diagnostic plays a crucial role in reaching the 90–90–90 targets, along with the timely provision of patients with an efficient HIV treatment.

Method: Analysis of data coming from the personalised accounting system, along with the data collected in the federal statistic surveillance forms containing the findings of HIV antibody tests and the federal Rospotrebnadzor forms for monitoring HIV response.

Results: Annually a significant proportion of Russia’s population is tested for HIV. In 2016 more than 31 million of Russian citizens were tested (21 tests for each 100 Russian citizens), along with 2.1 million of foreign citizens. The number of tested Russians increased in 2016 by 57% from 1996, and by 24% from 2011. The number of newly diagnosed HIV cases by 2016 increased to 102,179 (69.7 HIV diagnoses per 100,000 population), which is 63.5% more than in 2011 and 65 times more than in 1996. Proportion of late diagnosis (CD4 cell count <350 per mm3) was low: among the newly diagnosed patients in 2016, 33.7% had immunodeficiency. The number of people receiving ART increased threefold by 2016 compared to 2011 and 18 times compared to 2006. However, until 2016, only a third of the number of registered patients received ART (32.8%), which was largely due to low adherence to medical care and treatment among drug users. The main reported modes of HIV transmission in 2016 became heterosexual contacts (50.0%).

Conclusion: There has been an increase in the number of new HIV cases associated with the continuation of the HIV epidemic among IDUs and the active transmission of infection among the heterosexual population in Russia. This trend can also be attributed to low ART coverage among PLHIV, along with the increasing increase in the number of people tested for HIV in the country.

PS9/2

A simple tool to evaluate the effectiveness of HIV care for settings with gaps in data availability

D Raben1 and for the International Cohort Consortium of Infectious Diseases RESPOND

1Rigshospitalet, University of Copenhagen, CHIP, Copenhagen, Denmark

Purpose: Many HIV clinics do not have the IT infrastructure or resources to routinely report information on people on treatment and virologically suppressed. We investigated the minimal data required to make it feasible for clinics to estimate the “right-side” of the HIV continuum of care with the purpose of developing a simple, accessible, online tool to aid estimation.

Method: Data were collected on all people living with HIV seen at least once during 2017 at seven RESPOND clinics. The percentage on antiretroviral therapy (ART) and virologically suppressed (VS; VL<200 copies/mL [<500 copies/mL in Belarus]) was calculated using the number in care as the denominator. Bootstrapping techniques using 1000 repetitions identified 2.5 and 97.5 percentiles for the percentage on ART/Vs.

Results: Data from 8,852 persons were included; Georgia (N=3,839), Albania (N=542), Macedonia (N=202), Montenegro (N=150), Serbia (N=521), Belarus (N=133) and Poland (N=3,465). Median age was 40 (IQR 34–48) and median CD4 count was 548 (IQR 360–753/mm3). Overall, 93.8% were on ART (95% CI 93.3–94.2) and 76.7% were VS (95% CI 75.8–77.6%), where persons without a viral load measurement were assumed not to be VS. There were considerable differences in ART and VS and in the percentage with missing data across HIV exposure groups and gender (Figure). Continuums based on a random sample of 100 individuals produced a reliable estimate, while increasing the random sample to 250 decreased uncertainty around the estimate (Figure).

Conclusion: We provide proof of concept that collecting data from a small random sample of a clinic produces a reliable estimate of the ‘right-side’ of the HIV continuum. This methodology will be further developed into an online tool enabling clinics to estimate these figures for reporting and for a self-applied auditing tool, strengthening monitoring of the effectiveness of care in different population subgroups.
Purpose: The established 90–90–90 target to end the HIV epidemic follows a cross-sectional continuum of care (CoC) analysis, without considering early diagnosis, rapid treatment initiation and durable suppression. We propose a new CoC analysis combining cross-sectional and longitudinal elements, i.e. time spent between and within stages of the CoC.

Method: Based on the cross-sectional CoC, we: a) divided the percentages of diagnosed by years since infection, estimating corresponding times by the cross-sectional continuum of care (CoC) analysis, without considering early diagnosis and late presenters as key population highlights the need for early diagnosis and late presenters as key population

missing, unsuppressed and suppressed); c) add the cumulative incidence of ART initiation and viral suppression treating LTFU as competing event. Viral suppression definition: VL<500 copies/mL. We applied the proposed method to people living with HIV (PLHIV) in Greece at the end of 2016, who participated in AMACS, the Greek multicenter HIV cohort study.

Results: According to Hellenic CDC, 81% of PLHIV were diagnosed in 2016. Among 7407 eligible AMACS participants, median time from infection to diagnosis was 3.3 years (IQR: 1.1–6.7). Among diagnosed, 86.6% were ever treated, of whom 86% remained on ART. Cumulative incidence of ART initiation and LTFU before ART initiation were 79.6% and 6.7% at 5 years, respectively (Figure 1). Among treated, 86.2% achieved viral suppression, of whom 85.2% were currently virally suppressed. LTFU was strongly dependent on CD4 at diagnosis; the probability of LTFU after ART initiation at 5/10 years was 12.1/19.5% and 8.1/12.3% for those with<200 and>350 CD4/µL, respectively.

Conclusion: The new proposed analysis highlights time gaps in CoC not evident by the standard cross-sectional approach. Analysis by CD4 count highlights the need for early diagnosis and late presenters as key population for interventions that could decrease cascade shortcomings.

Figure 1. Greek HIV Continuum of Care at the end of 2016 applying the proposed method

<table>
<thead>
<tr>
<th>CD4 counts/µL</th>
<th>&lt;200 (N=1864)</th>
<th>200–350 (N=1534)</th>
<th>&gt;350 (N=3643)</th>
<th>Total (N=7407)</th>
<th>CD4 counts/µL</th>
<th>&lt;200 (N=1864)</th>
<th>200–350 (N=1534)</th>
<th>&gt;350 (N=3643)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART status, among diagnosed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>p&lt;0.001</td>
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<tr>
<td>Never treated</td>
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<tr>
<td>Lost before ART initiation</td>
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<tr>
<td>Ever treated</td>
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<tr>
<td>ART current status, among treated</td>
<td>p&lt;0.001</td>
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<td>OFF ART</td>
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<tr>
<td>Lost after ART initiation</td>
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<tr>
<td>On ART</td>
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<td></td>
</tr>
<tr>
<td>VL status, among treated</td>
<td>p&lt;0.001</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Never VL suppressed</td>
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<td>Lost before VL suppression</td>
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<td>Ever VL suppressed</td>
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<td></td>
</tr>
<tr>
<td>VL current status, among ever VL suppressed</td>
<td>p&lt;0.001</td>
<td></td>
<td></td>
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<tr>
<td>VL unsuppressed</td>
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<td></td>
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<tr>
<td>Lost or missing VL status</td>
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<td>VL suppressed</td>
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</tbody>
</table>
PS9/4

Reaching the second and third UNAIDS 90–90–90 targets is accompanied by a dramatic reduction in primary HIV infection and in recent HIV infections in a large French nationwide HIV cohort

A Le Guillou1, P Pugliese2, F Raffi3, A Cabie4, L Cuzin5, C Katlama6, C Allavena7, M Drame7, L Cotte8, F Bani-Sadr9 and DatAIDS Study Group

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In late 2013, France was one of the first countries to recommend initiating combination antiretroviral therapy (cART) irrespective of CD4 count. To assess the impact on HIV incidence of achieving the second and third UNAIDS 90-90-90 targets (i.e. 90% of diagnosed people on sustained cART, and of those, 90% virologically controlled), we conducted a longitudinal study to describe the epidemiology of primary HIV infection (PHI) and/or recent HIV infection (patients with CD4 cell count 500/mm³ at HIV diagnosis) (PRHI) between 2007 and 2017 in a large French multicentre cohort. To identify changes in trends in PHI and PRHI, we used simple breakpoint linear segmented regression analysis.

Results: During the study period, a total of 61,822 patients were followed in the DatAIDS cohort; 20,263 of these were new patients. Among them, 2,027 (10.0%) had PHI and 7,314 (36.1%) had PRHI. The second and third targets were reached in 2014 and 2013, respectively. The median delay between HIV diagnosis and cART initiation decreased from 9.07 (IQR: 1.39–33.47) months in 2007 to 0.77 (IQR: 0.37–1.60) months in 2017. A decrease in PHI (~35.1%) and PRHI (~25.6%) was observed since 2013. The break-points for PHI and PRHI were 2012.6 (95% CI 2010.8–2014.4) and 2013.1 (95% CI 2011.3–2014.8), respectively.

Conclusion: Our findings show that the achievements of two public health targets in France and the early initiation of cART were accompanied by a reduction of about one third in PHI and PRHI between 2013 and 2017.

PS9/5

Similar but different: Using combined phylogenies of Austria and Switzerland reveals differences in transmission patterns of the local HIV-1 epidemics

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1Division of Infectious Diseases and Hospital Epidemiology, University Hospital Zurich, Zurich, Switzerland 2Institute of Medical Virology, University of Zurich, Zurich, Switzerland 3Division of Infectious Diseases and Hospital Epidemiology, University Hospital Basel, University of Basel, Basel, Switzerland 4Division of Infectious Diseases, Regional Hospital Lugano, Lugano, Switzerland 5Laboratory of Virology and Division of Infectious Diseases, Geneva University Hospital, University of Geneva, Geneva, Switzerland 6Division of Infectious Diseases, Lausanne University Hospital, Lausanne, Switzerland 7Paracelsus University of Salzburg, Salzburg, Austria 8Medical University Vienna, Vienna, Austria 9Landeskranenkranz Graz Süd-West, Graz, Austria 10Molecular Virology, Department of Biomedicine–Petersplatz, University of Basel, Basel, Switzerland 11Kepler University Hospital, Linz, Austria 12University of Lausanne, Lausanne, Switzerland 13Division of Infectious Diseases, Bern University Hospital, University of Bern, Bern, Switzerland 14Medical University of Innsbruck, Innsbruck, Austria

Objectives: Using combined phylogenies of two or more countries allows to detect differences in transmission dynamics of HIV-1 beyond differences in demographic characteristics. Austria and Switzerland, two neighboring countries of similar size and comparable numbers of new HIV-1 diagnoses per year, serve as an ideal show case for this type of analysis.

Methods: A maximum-likelihood phylogenetic tree was built using pol-sequences of the Swiss HIV Cohort Study (SHCS) and the Austrian HIV Cohort Study (AHIVCOS), with Los Alamos background sequences. Phylogenetic clusters of size 2 and cophenetic distance smaller than 0.03, with both patients being in the SHCS or AHIVCOS, called SHCS-cherries and AHIVCOS-cherries, respectively, were extracted from the tree. Demographic characteristics of SHCS and AHIVCOS patients were compared across the tree and cherries using Fisher exact tests. By varying the distance threshold for inclusion of the cherries (range: 0.015–0.045) and down-sampling SHCS sequences (range: 20%-100%), we assessed the robustness of the results.

Results: Overall, 554/2'219 (25.0%) AHIVCOS patients were in AHIVCOS-cherries and 4530/12'776 (35.5%) SHCS patients were in SHCS-cherries. The fraction of patients belonging to the group of intravenous drug users (IDU) was similar in both cohorts (p=0.29) (Figure 1A), but there were significantly (p<0.001) less AHIVCOS-cherries with one patient being IDU and the other patient non-IDU (20/277 (7.2%)) compared to SHCS-cherries (322/2265 (14.2%)) (green, Figure 1B). These differences were robust for varying cophenetic distances and down-sampling SHCS sequences with 6.8%-9.6% IDU-nonIDU-AHIVCOS-cherries and 10.4%-17.5% IDU-nonIDU-SHCS-cherries.

Conclusion: A combined phylogeny of Austrian and Swiss HIV-1 sequences revealed differences in transmission patterns in the respective local epidemics, which could not be detected by comparing cohort characteristics: Despite the same fraction of IDU, transmission events between IDU and other risk groups were more frequent in the SHCS as compared to the AHIVCOS.

Figure: A) The distribution of risk groups on the tree for patients in the Austrian HIV Cohort Study (AHIVCOS) and the Swiss HIV Cohort Study (SHCS). B) The distribution of risk groups in the cherries with both patients being participants of the AHIVCOS or the SHCS. MSM: men who have sex with men; IDU: intravenous drug users, HET: heterosexual.
Purpose: Our study aims to describe the rates of self-reported recreational drug use among MSM attending HIV services across centres in the UK, Spain, Greece and Italy, as well as rates of other sexual risk behaviours, STIs and ill-health.

Method: A cross-sectional multi-centre study, using a self-reported questionnaire was undertaken, focusing on chemsex drug use (sexualised use of methamphetamine, mephedrone, GHB/GBL, cocaine and ketamine), harms and whether support services were accessed.

Results: 1700 questionnaires were included in the primary analysis. The median age was 39 years (IQR 32–47). There were high rates of recreational drug use overall (51%) and chemsex use in the past 12 months was high (23%); ranging from 32% in UK to 12% in Italy, with Spain and Greece 22% and 19% respectively. Slamsex use (sexualised use of injecting the same group of drugs) was 13% UK, 2.8% Spain, 4.9% Greece and 0.6% Italy. (Table 1).

There were high rates of harms across the countries; unwanted side effects in 41%, 22% reporting symptoms of drug withdrawal and a concerning number reporting non-consensual sex (16%) and overdose (16%). Over 41%, 22% reporting symptoms of drug withdrawal and a concerning number reporting non-consensual sex (7.1%) and overdose (7.3%). Over 60% found these services met their needs. (Table 2).

Conclusion: This is a large study across 4 European countries which shows high rates of chemsex use amongst MSM attending for HIV care. There are high rates of harms overall, particularly unwanted side effects (41%) and symptoms of withdrawal (22%) and a concerning number reporting non-consensual sex (7.1%) and overdose (7.3%). Strikingly there are significant negative impacts on work, family/friends and relationships, but few accessing support services. 

Severe infections co-organised with the European Society of Clinical Microbiology and Infectious Diseases (ESCMID)

<table>
<thead>
<tr>
<th></th>
<th>UK</th>
<th>Spain</th>
<th>Greece</th>
<th>Italy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-consensual sex (n, %)</td>
<td>58 (33%)</td>
<td>31 (20%)</td>
<td>11 (13%)</td>
<td>5 (24%)</td>
<td>105 (27%)</td>
</tr>
<tr>
<td>Negative effect on work (n, %)</td>
<td>50 (29%)</td>
<td>34 (29%)</td>
<td>13 (15%)</td>
<td>4 (19%)</td>
<td>101 (26%)</td>
</tr>
<tr>
<td>Negative effect on friends/family (n, %)</td>
<td>53 (30%)</td>
<td>41 (35%)</td>
<td>16 (19%)</td>
<td>6 (29%)</td>
<td>116 (29%)</td>
</tr>
<tr>
<td>Access to professional services (n, %)</td>
<td>35 (20%)</td>
<td>19 (16%)</td>
<td>7 (8.3%)</td>
<td>1 (4.8%)</td>
<td>62 (16%)</td>
</tr>
</tbody>
</table>

Table Continued.

<table>
<thead>
<tr>
<th></th>
<th>UK</th>
<th>Spain</th>
<th>Greece</th>
<th>Italy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unwanted side effects (n, %)</td>
<td>70 (40%)</td>
<td>51 (44%)</td>
<td>35 (42%)</td>
<td>6 (29%)</td>
<td>162 (41%)</td>
</tr>
<tr>
<td>Drug withdrawal (n, %)</td>
<td>49 (28%)</td>
<td>31 (26%)</td>
<td>6 (7.1%)</td>
<td>0 (0%)</td>
<td>86 (22%)</td>
</tr>
<tr>
<td>Overdose (n, %)</td>
<td>11 (6.3%)</td>
<td>8 (6.9%)</td>
<td>9 (11%)</td>
<td>1 (4.8%)</td>
<td>30 (7.1%)</td>
</tr>
</tbody>
</table>
| Eosinophilia (eosinophil count >500 × 10^9/L) was observed in 19 (53%) participants. Median CD4 level was 386 µL (IQR 299–520) at diagnosis of coinfection. Of note, 8 (22%) patients with strongyloidiasis had no reported symptoms nor eosinophilia. None of the patients developed hyperinfection or died. Only eosinophilia was strongly correlated with the presence of Strongyloides infection in multivariate analysis (OR 10.74 [95% CI 5.19–22.25], p<0.001).

Conclusion: Strongyloidiasis was diagnosed in about 5% of HIV-infected patients and was only predicted by the presence of eosinophilia. However, a sizeable proportion (22%) of coinfected individuals were asymptomatic and had normal eosinophil count, supporting universal screening of all HIV-positive patients native from tropical countries.
**PS10/2**

Diagnosing tuberculosis in people living with HIV in a rural district of Mozambique: yield of TB-LAM, digital chest X-ray and Xpert Ultra

S Izco1, A Murias1, A Jordan2, G Greene3, N Catorze2, C Tom2 and E Letang1,5

1ISGlobal, Barcelona, Spain 2Centro de Investigación en Saúde de Maníchico, Maputo, Mozambique 3Centers for Disease Control and Prevention-USA, Mycotic Diseases Branch, Atlanta, USA 4PhD Program in Methodology of Biomedical Research, Faculty of Medicine, University of Barcelona, Barcelona, Spain 5Hospital del Mar Research Institute (IMIM), Department of Infectious Diseases, Barcelona, Spain

**Purpose:** The implementation of new tuberculosis (TB) diagnostic tools among people living with HIV (PLHIV) in sub-Saharan Africa should be tested in real-life conditions among ambulatory and hospitalized patients.

**Method:** During a TB active-case finding strategy in Maníchico District, Mozambique, sputum induction and Xpert Ultra were made available to officials of all district health centres and district hospital. All notified TB cases were HIV-tested. Those ART-naïve or poorly ART-adherent PLHIV were visited and offered counselling, clinical evaluation, digital chest-X-ray (CXR), CD4 cell counting, urine TB-LAM (if CD4 < 200 cells/mm3 or seriously-ill) and timely ART initiation.

**Results:** Between June-December 2018, the ART status of 373 TB/HIV cases and 315 of their contacts who were HIV+ was assessed. 124/373 (33%) TB cases and 31/315 (9.8%) contacts were ART-naïve or poorly ART-adherent. Of those, 5/31 (16%) contacts had TB, giving a TB study population of 128, including 64/128 (50%) outpatients and 64/128 (50%) inpatients; the median CD4 counts were 214 (interquartile range [IQR] 74.5–357.0) and 72 (IQR 24.7–122.5) cells/mm³ respectively; a sputum sample was obtained from 57/64 (89%) outpatients and 39/64 (61%) inpatients, and Xpert Ultra was positive in 34/57 (60%) and 16/39 (41%) respectively; a CXR was done in 57/64 (89%) and 56/64 (88%), being TB-suggestive in 47/57 (82%) and 41/56 (73%) respectively. TB-LAM was positive in 65% (22/34) outpatients and 74% (46/62) inpatients. Overall, 116/128 (91%) cases had ≥1 positive tests. Xpert Ultra and TB-LAM were the only positive TB test in 33% and 14% outpatients and in 8% and 55% inpatients, respectively. ART was initiated in 94% (77/82) of ART-naïve cases. Six-month mortality was 21% (27/128) overall and 25% (17/68) among TB-LAM positive patients.

**Conclusion:** TB-LAM increased TB diagnosis confirmation by 14% and 55% in ambulatory and hospitalized HIV patients respectively. The test should become standard of care in HIV/TB high-burden settings.

<table>
<thead>
<tr>
<th>Combined yield of TB tests</th>
<th>OUTPATIENTS (n: 64)</th>
<th>INPATIENTS (n: 64)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Xp ULTRA result</strong></td>
<td><strong>TB-LAM result</strong></td>
<td><strong>Yield of TB diagnosis</strong></td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>12 (19%)</td>
</tr>
<tr>
<td>Positive</td>
<td>Negative</td>
<td>21 (33%)</td>
</tr>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>22 (34%)</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>9 (14%)</td>
</tr>
</tbody>
</table>

**PS10/3**

A New Health Care Index independently predicts 12-month mortality among HIV positive individuals diagnosed with tuberculosis

A Roen1, D Podlekaresz2, R Miller3, A Mocroft3, A Panteleev3, AM Skrahina4, JM Miro5, S Tetrudov6, E Derisova7, H Furrer8, M Losso9, A Vassilenko10, E Girardi11, J Lundgren12, F Post12, O Kirk2 and TB:HIV Study Group

1University College London, London, UK 2University of Copenhagen, Copenhagen, Denmark 3TB Hospital, Department of HIV/TB, St. Petersburg, Russian Federation 4Republican Research and Practical Centre for Pulmonology and TB, Minsk, Belarus 5University of Barcelona, Barcelona, Spain 6Dr Victor Babes’ Hospital of Tropical and Infectious Diseases, Bucharest and ‘Carol Davila’ University of Medicine and Pharmacy, Bucharest, Romania 7Botkin Infectious Disease Hospital, St. Petersburg, Russian Federation 8Bern University Hospital, University of Bern, Bern, Switzerland 9Hospital J.M. Ramos Mejia, Buenos Aires, Argentina 10Belarusian State Medical University, Minsk, Belarus 11Ospedale L. Spallanzani, Rome, Italy 12Kings College Hospital NHS Foundation Trust, London, UK

**Purpose:** Based on data from 2004–7, we previously generated a health care index (HCI) for TB-HIV co-infected individuals which indicated that drug...
susceptibility testing (DST), initial TB regimens containing rifampicin, isoniazid and pyrazinamide (RHZ), and timely combination antiretroviral treatment (cART) predict 12-month mortality. To take account of improvements in diagnostic and management practices, we re-evaluated the HCI based on newer data.

Method: Using data from the TB-HIV Study (2011–4), we evaluated nine aspects of health care in Cox Proportional hazards models on time from TB diagnosis to death. We created a HCI using the significant covariates. Kaplan-Meier methods were used to estimate the probability of death within 12-months by HCI quartile. Harrel's C-statistic was used to assess model fit and improvement from the previous HCI.

Results: Of 1396 eligible individuals (72% male, 59% from Eastern Europe, 70% known HIV-positive<3 months before TB diagnosis and 64% cART naïve at TB diagnosis), 269 died within 12-months of commencing TB treatment. We found RHZ (adjusted HR=0.67; 95% CI (0.50,0.89) vs. no RHZ), DST and active TB drugs (DST E<3 known active TB drugs (1.09 (0.80,1.48)) DST ≥3 known active TB drugs (0.49 (0.35,0.70) compared with no DST), a recent HIV-RNA measurement (0.64 (0.50,0.82), vs. no recent HIV-RNA) and timely cART initiation (0.72 (0.53,0.97) vs. no cART) to be associated with 12-month mortality, and these factors were used to create the updated HCI. A lower HCI was associated with an increased probability of death at 12-months; 30% (26,35) vs, 9% (6,13) in the lowest vs. highest quartile, Figure.

Conclusion: We found five main potentially modifiable health care components that were associated with 12-month mortality among TB/HIV positive individuals and created an index using these components. Validation of our HCI in a modern TB cohort could enhance our findings.

PS10/4
Comparison of TB drug susceptibility, treatment regimens and outcome among TB/HIV-patients in a setting with high prevalence of resistant TB: results from a national and supranational reference laboratories

D Podlekareva 1, D Bek Folkvardsen 2, A Skrahina 3, A Vassilenko 4, A Skrahin 3, H Hurevich 3, D Klimuk 3, I Karpov 4, T Lillebaek 2, JD Lundgren 1 and O Kirk 1,5

Purpose: Treatment of MDR-TB should be based on detailed information on resistance patterns of Mycobacterium tuberculosis (Mtb), and is a special challenge in areas with high prevalence of multi-drug resistant TB (MDR-TB).

1CHIP, Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark
2International Reference Laboratory of Mycobacteriology, Statens Serum Institut, Copenhagen, Denmark
3Republican Scientific and Practical Center for Pulmonology and TB, Minsk, Belarus
4Belarusian State Medical University, Minsk, Belarus
5University of Southern Denmark, Department of Clinical Research, Odense, Denmark

We aimed to compare results of conventional drug susceptibility testing (DST) performed in Minsk, Belarus (high MDR-TB burden country) with extensive geno- and phenotypic analyses performed at the WHO TB Supranational Reference Laboratory (SRL) in Denmark, and relate DST results to treatment patterns and outcomes for TB/HIV patients.

Methods: 30 HIV-patients from Minsk with TB-diagnosis between 2011–2013, and with Mtb-culture samples were included. Descriptive statistics applied to compare DST results and analyze treatment regimens and outcome. Results: Twenty-two (73%) patients were males; median age 37.2 years (IQR 30.4–41.0); 19 (63.3%) had a history of injecting drug use. There was a good agreement in DSTs for Rifampicin (R) and Isoniazid (H) – 93%. For 2nd-line TB-drugs, discrepancies were more pronounced: 14 (46.7%) had disagreement for at least one 2nd-line TB-drug, and more patients were classified as having pre-XDR-TB according to SRL results (Table).

All patients started TB-treatment based on RH and pyrazinamide, which was an active regimen for 40% of patients only. Patients with at least MDR-TB changed to 2nd-line drugs after median of 1.5 months (IQR 1–2) to a median of 4 susceptible drugs (IQR 3–5). (Table) Median treatment duration after regimen change was 8 months (IQR 2–11). Only 4 (22%) patients received treatment for<18 months, and 53% patients died within 24 months of follow-up.

Conclusions: Despite good quality local DSTs, patients were treated insufficiently. A delay in initiating adequate regimens, suboptimal number of active drugs and too short treatment duration were observed. Better accessibility to rapid molecular DSTs and 2nd-line TB-drugs should potentially allow constructing potent regimens, and initiating timely targeted DST-tailored treatment, ultimately improving outcome.

PS10/5
Influence of vitamin D deficiency on development of opportunistic infection in people living with HIV/AIDS (PWHA)

S Lee 1, JE Lee 1, SO Lee 1, YK Sim 1 and SH Lee 1

1Pusan National University Hospital, Busan, Korea, Republic of

Purpose: The association between vitamin D deficiency and development of chronic infections such as tuberculosis has been reported. However, there is few studies concerning the association between vitamin D deficiency and opportunistic infection (OI) in people living with HIV/AIDS (PWHA).

Method: To identify the association between vitamin D deficiency and OI, a retrospective observational study was conducted in a tertiary care hospital. PWHAs who had vitamin D (25-OH vitamin D) test results from 2012 to 2017 were enrolled. All enrolled PWHAs were divided into vitamin D deficiency group and non-deficiency group according to the vitamin D cutoff set by ROC curve analysis. The rates of OIs were compared between two groups.

Results: Among 440 PWHAs with<1 vitamin D tests, 394 (89.5%) were male, 59 were more than 60 year old (13.4%), 237 (53.9%) were ART-naïve, 107 (24.3%) had CD4 + T cell<200/µL and 278 (63.2%) were vitamin D deficient according to general cutoffs (< 20 ng/mL).Seventy-five cases of OIs occurred in 63 PWHAs (14.3%); Most common OI was tuberculosis (27, 6.1%) following pneumonia (20, 4.5%) and CMV disease (10, 2.3%). In ROC curve analysis, AUC was 0.770 (95% CI 0.62–0.78, P<0.001) and vitamin D concentration of 15 ng/mL was proper cut-off to predict OIs.

Overall OI development significantly more prevalent in vitamin D deficiency group (aOR 3.603, 95% CI 1.740–7.461); tuberculosis (aOR 2.973, 95% CI 1.215–7.726) and CMV disease (aOR 9.218, 95% CI 1.103–77.026) significantly associated with vitamin D deficiency and pneumocystis pneumonia was not (aOR 1.459, 95% CI 0.551–3.864).

Conclusion: Vitamin D deficiency was associated with development of OIs, particularly with intracellular infections such as tuberculosis or CMV infections and stringent cutoffs of vitamin D deficiency (< 15 ng/mL) was well correlated with development of OIs in PWHAs.
Factors associated with PrEP discontinuation in the Prevenir study

### PS11/1
**PrEP persistence and associated factors: an analysis from the ANRS Prevenir study**

D Costagliola1, J Ghosn2, B Spire3, D Rojas Castro4, L Béniguel5, M Algarte-Gein1, G Pialoux6, C Pintado7, J-P Viard2, C Katlama3, C Séquing7, C Delaugerre4, K Lacombe1, J Lourenço8, M Olayo9, S Le Mestre10, V Dore11, S Morel12, L Sagan-Teyssié13, L Assoumou14, J-M Molina15 and Prevenir ANRS Study Group

**Purpose:**
Pre-exposure prophylaxis (PrEP) has become an important component of HIV prevention, but little is known on PrEP persistence. Our objective was to study both within the ANRS Prevenir study conducted since May 2017 in Paris area.

**Method:**
The analysis was restricted to MSM participants enrolled in the Prevenir study (99% of participants) with at least one follow-up visit, whether already on PrEP at enrolment or not. PrEP discontinuation was defined as stopping PrEP, or being lost to follow-up. The rate of PrEP discontinuation was estimated using Kaplan-Meier estimate from date of PrEP initiation and accounting for staggered entries in the study, using multiple imputation for missing characteristics.

**Results:**
Out of 3057 participants in Prevenir, 2699 fulfilled inclusion criteria with a median age of 36 years (IQR: 29–43), 84% born French, 73% with >2-year university degree, 50% already on PrEP at baseline (median: 9.1 months), 51% using on demand PrEP. Overall 358 participants discontinued PrEP, including 258 being lost of follow-up and 100 stopping PrEP, mainly for no change of PrEP regimen (53.8% and 46.2% opted respectively for a daily versus for non-daily regimen. Chemsex was reported by 22.9% of the users; in line with other countries, the uptake of PrEP in Belgium has been almost entirely limited to MSM, mainly Belgians. Heterosexuals from Sub-Saharan African origin - the other key-population affected by HIV in Belgium – are less represented among PrEP users. The variation of reported STIs may be partly explained by differences in testing practices across HRCs. STIs been almost entirely limited to MSM, mainly Belgians. Heterosexuals from Sub-Saharan African origin - the other key-population affected by HIV in Belgium – are less represented among PrEP users. The variation of reported STIs may be partly explained by differences in testing practices across HRCs. STIs diagnosed outside HRCs are not captured by this data collection. This highlights the need to gather robust data to develop a tailored STI screening and treatment strategy for PrEP users. The frequent reporting of chemsex calls for offering pathways to support for those in need.

**Conclusion:**
Young MSM starting PrEP without a high educational level are at higher risk of PrEP discontinuation. More research is needed to understand the reasons and to design targeted interventions aiming at increasing PrEP persistence.

### PS11/2
**Monitoring PrEP implementation in Belgium: national surveillance results, 2017–2018**

J Deblan1, D Van Beckhoven2, E Florence3, A Libois4, S Callens4, S Henrard4, M Moutchen5, S Allard5, P Messiaen6, P De Munter7, J Van Praet8, A Vincent9, R Demeester10, N Ausselet11, W Vanden Bergh1 and A Sasse1

**Purpose:**
Since 01/06/2017, PrEP was reimbursed in Belgium for individuals at increased risk of HIV acquisition. PrEP is delivered in the HIV Reference Centres (HRCs). An authorization for reimbursement is valid for 12 months. First surveillance data are presented.

**Method:**
Aggregated data on number and profile of the starters, regimen chosen at start, new STI diagnoses during follow-up, reported chemsex (GBL/GBH, Crystal Methamphetamine, Mephedrone or mixed use) and number of PrEP interruptions (>12 months without visit record) for the period 1/06/2017 until 31/12/2018 were collected from the 12 HRCs. Data were combined into a unique data set and analysed for distribution of those factors.

**Results:**
Of the 2845 starters (Table 1), 99.3% were male, 98.8% men having sex with men (MSM), 81.5% Belgians, 51.7% were 26–39 years. At initiation, 53.8% and 46.2% opted respectively for a daily versus for non-daily regimen. At least one new STI was diagnosed in 22.6% of the users with proportions by HRC ranging from 11.9% to 44.5%; gonorrhoea and Chlamydia diagnoses were the most common (Table 2). There was one HIV seroconversion due to inconsistent PrEP adherence. Chemsex was reported by 22.9% of the users; 5.3% interrupted PrEP care.

**Conclusion:**
In line with other countries, the uptake of PrEP in Belgium has been almost entirely limited to MSM, mainly Belgians. Heterosexuals from Sub-Saharan African origin – the other key-population affected by HIV in Belgium – are less represented among PrEP users. The variation of reported STIs may be partly explained by differences in testing practices across HRCs. STIs diagnosed outside HRCs are not captured by this data collection. This highlights the need to gather robust data to develop a tailored STI screening and treatment strategy for PrEP users. The frequent reporting of chemsex calls for offering pathways to support for those in need.

---

**Table 1:**

<table>
<thead>
<tr>
<th>Gender (N=2844)</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>2824</td>
<td>99.3</td>
</tr>
<tr>
<td>Women</td>
<td>11</td>
<td>0.4</td>
</tr>
<tr>
<td>Transgender</td>
<td>9</td>
<td>0.3</td>
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</table>

<table>
<thead>
<tr>
<th>Age group (N=2840)</th>
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<th>%</th>
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</thead>
<tbody>
<tr>
<td>18–39</td>
<td>1654</td>
<td>58.2</td>
</tr>
<tr>
<td>40+</td>
<td>1186</td>
<td>41.8</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Nationality (N=2232)</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgian</td>
<td>1820</td>
<td>81.5</td>
</tr>
<tr>
<td>Sub-Saharan African</td>
<td>26</td>
<td>1.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk group (N=2687)</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSM</td>
<td>2655</td>
<td>98.8</td>
</tr>
<tr>
<td>Hetero</td>
<td>26</td>
<td>1.0</td>
</tr>
</tbody>
</table>

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Policy and distribution of new STI diagnoses among PrEP users, June 2017–December 2018

<table>
<thead>
<tr>
<th>STI</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one STI</td>
<td>625</td>
<td>22.6</td>
</tr>
<tr>
<td>Gonorrhoea</td>
<td>309</td>
<td>11.2</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>260</td>
<td>9.4</td>
</tr>
<tr>
<td>Syphilis</td>
<td>128</td>
<td>6.4</td>
</tr>
<tr>
<td>HCV</td>
<td>10</td>
<td>0.4</td>
</tr>
<tr>
<td>HAV</td>
<td>4</td>
<td>0.2</td>
</tr>
<tr>
<td>HBV</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Conclusion: Awareness of PrEP is low among young adults who may need to empower young adults, especially women in the country. When PrEP is available, awareness campaigns are needed to increase awareness among young adults. Common factors associated with inadequate testing frequency were on-demand or intermittent PrEP use (HIV: OR=5.63, 95% CI 4.15–7.64; STI: OR=2.55, 95% CI 1.83–3.55), no tests prior to PrEP start (HIV: OR=14.4, 95% CI=4.62–46.41; STI: OR=7.89, 95% CI 2.83–22.04), and ≤10 anal sex partners within the last 6 months (HIV: OR=2.23, 95% CI 1.60–3.10; STI: OR=1.94, 95% CI 1.4–2.68). Use of PrEP from informal sources (OR=3.29, 95% CI=2.33–4.64) was associated only with inadequate HIV testing, while self-payment for tests was associated with inadequate STI testing (OR=1.55, 95% CI=1.11–2.17). Conclusion: Inadequate testing frequency was common in German PrEP users. Coverage of costs for PrEP and medical testing should reduce some barriers for inadequate testing and could improve safe PrEP use. Future changes in testing behavior will be monitored.

PS11/3

Awareness gaps on pre-exposure prophylaxis among late adolescents and young adults in the region characterised by high HIV prevalence and sexual violence

AI Ajayi1, OV Adeniyi2, N Rala1, DT Goon1 and EO Owolabi3

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Purpose: The vulnerability of young women in South Africa to HIV transmission is well documented. In South Africa, over 270 000 people were newly infected with HIV in 2017, and the vast majority of them were young adults. This study examines the level of awareness of PrEP among young adults in Eastern Cape, South Africa.

Method: This cross-sectional study was conducted between June and November 2018 among 834 young adults (aged 16–24 years) selected using stratified random sampling with probability proportional to the size of each stratum. An electronic self-administered questionnaire was used to elicit demographic information, HIV testing, disclosure of HIV status to partners, discussion of HIV with partners and awareness of PrEP. Adjusted and unadjusted logistic regression model analysis were used to examine the predictors of PrEP awareness.

Results: The mean age of study participants was 21.09 years (SD: 1.70). Only 19.0% of the participants were aware of PrEP with no sex disparity (male 16.5% vs female 20.5%). Ever fewer proportion of the respondents knew where to obtain the drugs (14.5%), how much it cost (4.7%), have seen it within the last 6 months. There was no significant difference in the level of awareness of PrEP by sociodemographic and lifestyle behavioural characteristics. In the adjusted regression analysis, only discussion of HIV/STI with sexual partners [AOR: 1.76; CI: 1.10–2.81] and ever tested for HIV [AOR: 1.68; CI: 1.02–2.76] were associated with a higher likelihood of awareness of PrEP.

Conclusion: Awareness of PrEP is low among young adults who may need to empower young adults, especially women in the country.

PS11/4

Risk factors for inadequate HIV and STI testing among German PrEP users

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Purpose: Safe use of HIV pre-exposure prophylaxis (PrEP) requires regular testing for HIV and sexually transmitted infections (STI). The objective was to identify risk factors for inadequate testing frequency among current PrEP users in Germany.

Method: From 24 July to 1st November 2018, we recruited PrEP users on geolocation dating apps for MSM, community-based HIV testing sites and a community website in Germany for an anonymous online survey. The outcome was inadequate testing interval, defined as >3 months for HIV and >6 months for STI. Risk factors were assessed with univariate logistic regression.

Results: We recruited 2118 current PrEP users; 52.3% used PrEP for >6 months. The median age was 38 years (IQR 31–45) and 80.83% identified as cisgender male and 0.76% as not cisgender-male (missing 18.41%). Testing frequencies were reported by 1821 participants for HIV and 1808 for STI. Of those, 27.07% and 40.93% reported inadequate testing frequencies for HIV and STI, respectively.

Conclusion: Inadequate testing frequency were common in German PrEP users. Coverage of costs for PrEP and medical testing should reduce some barriers for inadequate testing and could improve safe PrEP use. Future changes in testing behavior will be monitored.

PS11/5

Changes in bone mineral density over 2 years in men who have sex with men on tenofenovir disoproxil fumarate-based HIV pre-exposure prophylaxis: longitudinal cohort data

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Purpose: Tenofenovir disoproxil fumarate (TDF)-based HIV pre-exposure prophylaxis (PrEP) can reduce bone mineral density (BMD) by 1–2% or more over 12 months. Minimal longer-term data are available.

Method: Men who have sex with men (MSM) initiating daily TDF-emtricitabine (FTC) PrEP through a PrEP demonstration project were offered BMD assessment by dual-energy x-ray absorptiometry (DXA) using a single scanner at baseline and after completing 1 and 2 years of PrEP. Hip data are the mean of left and right hip results. We excluded participants who ceased PrEP or who received anti-erosive therapy. Mean changes were assessed using paired t-tests.

Results: Of 185 men with baseline scans, 118 (64%) and 51 (43%) men were assessed at a median (IQR) of 420 (391–449) and 824 (776–885) days on PrEP. The mean (SD) ages and body mass index (BMI) of those men that had baseline BMD assessment compared to the 282 that did not was 35 (10) and 32 (9) years (p<0.05) and 25 (4) and 25 (4) kg/m², respectively (p=0.05). Changes in BMD are shown in Table 1. No participant experienced a low trauma fracture during the study.

Table 1. BMD Changes

<table>
<thead>
<tr>
<th>BMD assessments</th>
<th>Baseline to Year 1 (n=118)</th>
<th>p value</th>
<th>Year 1 to Year 2 (n=51)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change (% median) IQR</td>
<td>g/cm²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L1–L4</td>
<td>−0.86% (−2.6–1.5)</td>
<td>0.045</td>
<td>−0.78% (−2.7–2.5)</td>
<td>0.499</td>
</tr>
<tr>
<td>Femoral neck</td>
<td>−1.1% (−3.3–0.54)</td>
<td>0.0001</td>
<td>−0.42% (−2.7–1.9)</td>
<td>0.502</td>
</tr>
<tr>
<td>Total (total)</td>
<td>−0.87% (−2.3–0.87)</td>
<td>0.004</td>
<td>0.49% (−0.82–1.5)</td>
<td>0.147</td>
</tr>
<tr>
<td>Total hip</td>
<td>16%</td>
<td></td>
<td>6%</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion: Over 12 months, a substantial proportion of MSM on daily HIV TDF–FTC PrEP lose ≥3% BMD at all measured sites over 24 months. There may be a plateau in loss after 12 months. Long-term studies of TDF-based PrEP in MSM are warranted.
Can HIV epidemics be eliminated using PrEP?  
S Jijon1, J-M Molina2, D Costagliola1, V Superville1 and R Breban2  
1INSERM U1138, Institut Pierre Louis d’Épidémiologie et de Santé Publique, Paris, France  
2Institut Pasteur, Paris, France

Purpose: Pre-exposure prophylaxis (PrEP) is highly effective in preventing HIV infection. Modeling studies concluded that PrEP could eliminate HIV epidemic, once certain PrEP coverage levels are achieved. However, whether and how such coverage levels can be reached remains unknown. Here we address this issue.

Method: We propose an innovative approach combining a compartmental model of HIV transmission at the population level, and a game-theoretic model for decision-making about PrEP at the individual level. Individuals at high-risk of HIV infection choose to use PrEP, or not to use PrEP, and undergo antiretroviral treatment (ART) if they acquire HIV, depending on the perceived risk of infection and relative cost of using PrEP, which includes price and access model of PrEP, consequences of being infected and lifelong ART, etc.

We determine the conditions under which the voluntary use of PrEP could eliminate HIV among men who have sex with men (MSM) in the Parisian region of France.

Results: We found that if PrEP offers high protection at low relative cost, HIV can be eliminated. For instance if PrEP effectiveness is 86%, as in the IPERGAY trial, PrEP coverage among high-risk MSM can reach 63% (OR: 57%-67%), the minimum required for elimination, if individuals have a fair risk perception and the relative cost of using PrEP versus ART is sufficiently low. Drop of condom use among PrEP users does not play a major role against elimination while the risk perception does. Moreover, we found that epidemic elimination is only temporary.

Conclusion: To reach PrEP coverage levels necessary to eliminate HIV, urgent efforts are needed to lower the cost of using PrEP. Furthermore, maintaining low cost for PrEP once the HIV epidemic is eliminated will be essential to sustain PrEP coverage levels and elimination in the long run.

Viral co-infection and liver disease

“Giving HepC a place and letting it go again”: response to a sexual risk reduction intervention in HIV/HCV co-infected men who have sex with men

P Künzler-Heule1,2, K Fierz2, M Rasi2, A Kocher2, J Bogdanovic1, S Engberg1,5, M Battegay1,2, C Nöstlinger8, A Lehner2, M Stöckle2, C Beguin1,10, J Delaloye11, P Schmid12, M Flepp13, M Rougemont14, DL Braun15,16, J Fehr15,17, D Nicca1,17, and
the Swiss HepC Cohort Study (SHCS)

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2Cantonal Hospital St Gallen, Department of Gastroenterology/Hepatology, St. Gallen, Switzerland  
3Zurich University of Applied Sciences, Winterthur, Switzerland  
4University of Zurich, Department of Public Health, Epidemiology, Biostatistics and Prevention Institute, Zurich, Switzerland  
5University of Pittsburgh, School of Nursing, Pittsburgh, USA  
6University Hospital Basel, Division of Infectious Diseases and Hospital Epidemiology, Basel, Switzerland  
7University Basel, Nursing Science, Basel, Switzerland  
8University Hospital Bern and University of Bern, Department of Infectious Diseases, Bern, Switzerland  
9University Hospital Lausanne and University of Lausanne, Intensive Care Unit, Department of Intensive Care Medicine, Lausanne, Switzerland  
10University Hospital St Gallen, Division of Infectious Diseases, St. Gallen, Switzerland  
11University Hospital of Geneva, Primary Care Medicine Unit, Geneva, Switzerland  
12University Hospital Zurich, Division of Infectious Diseases and Hospital Epidemiology, Zurich, Switzerland  
13University of Zurich, Institute of Medical Virology, Zurich, Switzerland  
14University Hospital Basel, Ressort MTT, Basel, Switzerland

Purpose: Within the Swiss HCVfree trial, HIV/HCV co-infected men who have sex with men received HCV treatment and a sexual risk reduction intervention to reduce HCV re-infection. This evaluation explored the response to intervention perceived by participants’ to better understand intervention mechanisms and acceptance.

Method: Qualitative thematic analysis with a constructivist orientation was used. With a purposive sampling approach, 21 of 51 intervention participants were asked to participate in single semi-structured interviews 6 to 12 months post-intervention. Seventeen respondents participated.

Results: The main theme “Giving HepC a place and letting it go again” describes how participants position themselves to the program and their sense-making work after having been exposed. The two sub-themes “Realizing it’s about me and not risks” and “Strengthening awareness of what I do” provide insights into the process of the intervention.

Three constructed typologies illustrate individual differences within themes. “Modifiers” (n=5) perceived HCV as a serious problem. The intervention empowered them to move on with life-style changes aiming to eliminate HCV for lifetime. “Keepers” (n=4) perceived HCV as unproblematic and treatable. Through the intervention, they perceived their chosen risk reduction strategy (fewer sexual encounters) as unsuccessful, while medical treatment seemed easy. They imagined living with HCV or repeating treatment when re-infected.

“Traders” (n=8) perceived HCV as a “disease of others” but manageable once
Changes of the T cell response to cognate antigen re-challenges in HIV-HCV co-infected individuals on suppressive antiretroviral therapy (cART) after successful direct acting antiviral (DAA) HCV-treatment.

**Method:** Peripheral Blood Mononuclear Cells (PBMCs) from HCV (genotype 1) co-infected patients of the Swiss HIV Cohort Study (n=11) were prospectively collected before and after successful DAA treatment. A comparator group that had spontaneously cleared HCV infection (n=6) was used to investigate T cell phenotype by fluorescent activated cell sorting (FACS) after ex vivo re-challenge for 10 days in comparison to direct ex vivo Stimulation (6 hours) with cognate HCV (NS3) and HIV (Gag) antigens.

**Results:** Ex vivo re-stimulation with NS3 for 10 days as proxy for HCV re-infection resulted in an increase of programmed cell death 1 (PD-1) positive effector memory (CD45RA-CCR7-) and decrease of terminal effector (TEMRA; CD45RA-CCR7-) CD8 T cells in persons after successful DAA treatment (p=0.07 and <0.05, respectively; Wilcoxon Rank Test). The same pattern was observed with Gag re-stimulation (both p<0.05). In contrast, no change in PD-1 expressing effector memory or TEMRA was observed in spontaneous HCV clearers after NS3 re-stimulation (p>ns). PD-1 expression changes were not limited to interferon-γ positive CD8 T cell populations.

**Conclusion:** HCV treated HIV positive individuals exhibit an impaired PD-1 positive CD8 T cell memory pool in contrast to spontaneous HCV clearers after antigen re-challenge. Our results offer a possible explanation for the lack of immune protection for HCV re-infections after a successful DAA treatment. Further analyses are needed to investigate the epigenetic imprinting of potentially dysfunctional memory T cells.

**PS12/2**

Impairment of CD8 T cell memory in DAA treated HCV/HIV co-infected patients

**M Hoffmann**, M-T Abdou, S Ring, DL Braun, M Flepp, M Stockle, A Conen, C Beguelin, P Schmidt, J Delaloye, A Nguyen, E Bernasconi, C Bannan, L Dorrell, E Barnes, A Rauch, J Boni, JS Fehr, L Flatz and Swiss HIV Cohort Study; PEACHi Consortium

**Objective:** To study the impact of sustained virologic response (SVR) on immunologic markers in HIV-HCV co-infected patients treated with DAA.

**Research Question:** Whether patients on cART after SVR will have a normalization of CD8 T cell memory.

**Methods:** A total of 1173 HIV+ HCV+ patients treated with DAA were included in the study. The dominant HCV genotype was 1a (87%) and 1b (11%). 281 patients achieved SVR (24% of all DAA treated patients), 88 of whom were enrolled in the present study. The median time to SVR was 14 weeks (95% CI 13.6-14.2) after the start of DAA treatment.

**Results:** The 1173 patients were compared to the 88 patients who had achieved SVR, and the remaining 1085 non-responders. The SVR group had a higher rate of spontaneous hepatitis C clearance before the first DAA treatment (p<0.05). Differences in the rate of spontaneous hepatitis C clearance before and after the first DAA was not significant between the two groups (p=0.16). The CD8 T cell memory pool was higher in the SVR group compared to the non-responders group (p=0.05). In the SVR group, the CD8 T cell memory pool was similar to the spontaneous hepatitis C clearance group (p=0.16). The CD8 T cell memory pool was lower in the non-responders group compared to the spontaneous hepatitis C clearance group (p=0.05). The CD8 T cell memory pool was similar in the SVR group and the spontaneous hepatitis C clearance group (p=0.16). The CD8 T cell memory pool was lower in the non-responders group compared to the spontaneous hepatitis C clearance group (p=0.05).

**Conclusion:** The CD8 T cell memory pool is impaired in HIV-HCV co-infected patients treated with DAA. The CD8 T cell memory pool is lower in the non-responders group compared to the spontaneous hepatitis C clearance group. The CD8 T cell memory pool is similar in the SVR group and the spontaneous hepatitis C clearance group. The CD8 T cell memory pool is lower in the non-responders group compared to the spontaneous hepatitis C clearance group.
In the DAA era, APRI increased (0.04 units/year; 95% CI, −0.09, 0.18) before, dropped dramatically during, and then declined minimally (−0.04 units/year; 95% CI, −0.10, 0.02) after treatment. Fibroscan values, however, increased (1.02 KPa/year; 95% CI, 0.27, 2.10) before treatment, changed little by the end of treatment, and then declined (−1.15 KPa/year; 95% CI, −2.28, −0.42) after SVR.

Conclusions: APRI drops immediately after treatment initiation, more slowly during, and then declined minimally (1.15 KPa/year; 95% CI, 0.27, 2.10) before treatment, changed little by the end of treatment, and then declined (−1.15 KPa/year; 95% CI, −2.28, −0.42) after SVR.

Trends in HIV/HBV coinfection in Spain

<table>
<thead>
<tr>
<th>Year</th>
<th>Centers</th>
<th>Reference population</th>
<th>Sample size</th>
<th>Tested for HBSAg</th>
<th>HBSAg (+) among those tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>39</td>
<td>31,800</td>
<td>1,260</td>
<td>4.9%</td>
<td>3.4%</td>
</tr>
<tr>
<td>2009</td>
<td>43</td>
<td>29,559</td>
<td>1,458</td>
<td>3.4%</td>
<td>3.0%</td>
</tr>
<tr>
<td>2015</td>
<td>41</td>
<td>35,791</td>
<td>1,867</td>
<td>3.0%</td>
<td>3.9%</td>
</tr>
<tr>
<td>2016</td>
<td>43</td>
<td>38,904</td>
<td>1,588</td>
<td>3.2%</td>
<td>3.0%</td>
</tr>
<tr>
<td>2017</td>
<td>43</td>
<td>40,322</td>
<td>1,690</td>
<td>3.0%</td>
<td>3.2%</td>
</tr>
<tr>
<td>2018</td>
<td>43</td>
<td>40,650</td>
<td>1,733</td>
<td>3.2%</td>
<td></td>
</tr>
</tbody>
</table>

PS12/5
Outcomes after switching from TDF to TAF in HIV/HBV–coinfected individuals with renal impairment: a nationwide cohort study

B Sural1, C Béguelin1, M Stöckle1, J-P Chave4, N Boillat-Blanco5, T Doco-Lecompte6, E Bernàscori1, J Fehr2, H Günthard4, P Schmid4, H Furrer3, A Rauch3, G Wanderer10 and the Swiss HIV Cohort Study

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Purpose: The impact of the use of tenofovir alafenamide (TAF) on clinical outcomes among HIV/hepatitis B virus (HBV)–coinfected individuals with renal impairment.
dysfunction is unclear. We explored HBV outcomes and renal function after switching from tenofovir disoproxil fumarate (TDF) to TAF in a prospective nested study within the Swiss HIV Cohort Study.

Method: We included all HBsAg-positive adults who had TDF replaced by TAF while having a suppressed HIV viral load and an eGFR $\geq 90$ mL/min. We assessed HIV and HBV suppression as well as HBsAg loss at 1 year after switch using descriptive statistics and evaluated changes in renal function and ALT levels with paired Wilcoxon rank-sum tests.

Results: Of 104 HIV/HBV co-infected patients, 22 (21.2%) were female, 53 (51%) men who have sex with men, and 31 (29.8%) were of African origin. At switch, median age was 51 years (IQR 46–56), median CD4 count 600 cells/µL (IQR 422–625) and median eGFR 73.0 mL/min (IQR 61.5–81.0), with 25 patients (24%) having an eGFR $< 60$ mL/min. At baseline, HBV was suppressed (< 50 IU/mL) in 88/92 (95.7%) with available HBV-DNA measurements, ALT was elevated ($\geq 40$ IU/L) in 20 (19.2%) individuals, and 23.8% had significant fibrosis (liver stiffness stage $\geq F2$). One year after switch, 74/76 (97.4%) of individuals with available HIV-RNA measurements were suppressed ($\leq 50$ cp/mL). Of 50 patients with HBV-DNA follow-up measurements, 48 (96.0%) were suppressed, and 5 (4.8%) lost their HBsAg. Median eGFR remained stable among individuals with a baseline eGFR 60–89 mL/min but improved among those with a baseline eGFR $< 60$ mL/min (Figure). Among patients with elevated baseline transaminases, ALT levels decreased over time.

Conclusion: In HIV/HBV co-infected patients with moderate renal impairment, replacing TDF by TAF was associated with improvements in renal function and ALT decline, with maintenance of HIV and HBV viral suppression.

Changes in eGFR (Panel A) and ALT (Panel B) 1 year after replacing TDF by TAF

PS12/6

Hepatic steatosis in HIV mono-infected individuals: which impact has baseline BMI and treatment with integrase inhibitors?

J Bischoff1, C Schwarze-Zander1,2, C Boesecke1,2, J-C Wasmuth3,4, R Mohr5, K van Bremen6, L Dold1, M Praktiknjo1, C Jansen1, JK Rockstroh1,2 and J Trebicka7

1Bonn University Hospital, Bonn, Germany 2German Center for Infection Research (DZIF), Partner Site Bonn–Cologne, Bonn, Germany 3University Hospital Frankfurt, Frankfurt, Germany

Purpose: The natural history of non-alcoholic fatty liver disease (NAFLD) in HIV-infected individuals is still not fully understood and risk factors remain to be determined. This cohort study analyses factors associated with progression of hepatic steatosis (HS) in HIV-positive patients.

Method: This single-center longitudinal observational study enrolled 432 HIV-positive patients between August 2013 to July 2017. Liver stiffness and HS were assessed yearly by transient elastography using an M-probe of FibroScan (Echosens, Paris, France). Primary endpoints were progression of HS or development of HS during the study period assessed by CAP values.

Results: Patients with underlying fibrosis ($\geq 7.1$ kPa) or steatosis ($\geq 238$ dB/m) at baseline were significantly older ($P = 0.04$) and had a higher baseline BMI ($P = 0.01$) than those without HS and fibrosis. AUIC of BMI was 0.753 ($95\% CI 0.694–0.813$, $P = 0.001$) revealing a cut-off value of 23.5 kg/m² associated with HS. Interestingly, those patients being treated with Integrase Inhibitors (INSTI) ($n = 88$) showed significantly higher CAP values at their last visit than those receiving alternate treatment regimens (HR $n = 50$; NNRTI $n = 84$) ($243$ dB/m vs. $268$ dB/m; $P = 0.01$). Moreover, gain of weight over the study period (mean study period 30.8 ± 8.8 and 30.1 ± 8.8 months; 2.4 ± 7.8 kg vs. 0.5 ± 12.0 kg, $P = 0.007$), BMI ($25.9 ± 4.8$ kg/m² vs. $24.6 ± 4.3$ kg/m²; $P = 0.009$) and weight ($81.5 ± 15.9$ kg vs. $75.8 ± 17.5$ kg; $P = 0.004$) at last visit were significantly higher in these patients, indicating an impact of INSTIs on body weight and hereby on development and progression of HS.

Conclusion: This is the first observational longitudinal study showing, that hepatic steatosis develops in HIV-positive individuals despite a non-obese BMI ($> 23.5$ kg/m²). Moreover, we detected a significant effect of INSTIs on body weight and HS.

Table 1. Patients’ characteristics according to the presence of evolutive NAFLD

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>No evolutive NAFLD</th>
<th>Evolutive NAFLD (n)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, male (%)</td>
<td>535 (76.2%)</td>
<td>479 (75.4%)</td>
<td>56 (8.1%)</td>
<td>0.18</td>
</tr>
<tr>
<td>Age, years, mean</td>
<td>52.5 (10.0)</td>
<td>50.8 (10.2)</td>
<td>53.2 (9.12)</td>
<td>0.350</td>
</tr>
<tr>
<td>BMI, kg/m² (xSD, [n])</td>
<td>25.6 (4.2) [770]</td>
<td>24.7 (3.95) [533]</td>
<td>27.7 (4.19) [72]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Waist circumference, cm (xSD, [n])</td>
<td>90.6 (43.7) [509]</td>
<td>90.6 (43.7) [509]</td>
<td>90.6 (43.7) [509]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>64 (9.08%)</td>
<td>58 (9.0%)</td>
<td>26 (38.1%)</td>
<td>0.011</td>
</tr>
<tr>
<td>Mild/moderate physical activity</td>
<td>310 (43.65%)</td>
<td>292 (43.5%)</td>
<td>18 (25.0%)</td>
<td>0.200</td>
</tr>
<tr>
<td>HIV duration, months, median (IQR, [n])</td>
<td>276 (165-330) [1150]</td>
<td>276 (165-330) [1150]</td>
<td>276 (165-330) [1150]</td>
<td>0.007</td>
</tr>
<tr>
<td>NADIR CD4, median (IQR, [n])</td>
<td>224 (100-328) [278]</td>
<td>224 (100-328) [278]</td>
<td>180 (87-247) [58]</td>
<td>0.027</td>
</tr>
<tr>
<td>Current CD4, median (IQR, [n])</td>
<td>700 (539-888) [691]</td>
<td>700 (539-888) [691]</td>
<td>680 (436-891) [69]</td>
<td>0.394</td>
</tr>
<tr>
<td>Undetectable viral load (%)</td>
<td>698 (98.73%)</td>
<td>627 (97.84%)</td>
<td>71 (98.51%)</td>
<td>0.990</td>
</tr>
<tr>
<td>Type 2 diabetes (%)</td>
<td>129 (16.25%)</td>
<td>69 (9.55%)</td>
<td>40 (51.75%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Current exposure to NNRTI (%)</td>
<td>169 (26.61%)</td>
<td>160 (26.12%)</td>
<td>9 (15.74%)</td>
<td>0.018</td>
</tr>
<tr>
<td>AST, U/L, median (IQR, [n])</td>
<td>24.8 (12.62) [870]</td>
<td>24.09 (12.44) [945]</td>
<td>30.22 (14.88) [951]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total cholesterol, mg/dL (xSD, [n])</td>
<td>179.37 (36.0) [906]</td>
<td>180.94 (36.54) [903]</td>
<td>166.88 (41.85) [903]</td>
<td>0.003</td>
</tr>
<tr>
<td>LDL cholesterol, mg/dL (xSD, [n])</td>
<td>116.7 (33.49) [964]</td>
<td>117.83 (32.77) [964]</td>
<td>110.61 (31.75) [964]</td>
<td>0.004</td>
</tr>
<tr>
<td>Triglycerides, mg/dL (xSD, [n])</td>
<td>136.98 (42.0) [867]</td>
<td>133.49 (96.50) [863]</td>
<td>160.78 (108.2) [832]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Frailty index, median (IQR, [n])</td>
<td>0.22 (0.09) [570]</td>
<td>0.22 (0.09) [512]</td>
<td>0.21 (0.09) [546]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CD4 fractile cut-off 0.25 (%)</td>
<td>387 (67.99%)</td>
<td>369 (72.07%)</td>
<td>18 (31.33%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CD4 fractile cut-off 0.5 (%)</td>
<td>165 (28.6%)</td>
<td>134 (26.17%)</td>
<td>29 (50.0%)</td>
<td>0.050</td>
</tr>
<tr>
<td>CD4 fractile cut-off 0.9 (%)</td>
<td>20 (3.51%)</td>
<td>9 (1.76%)</td>
<td>11 (18.57%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Objective: The objective of the study was to investigate the relationship between liver steatosis and significant fibrosis alone and in association with an outcome (evolutive NAFLD) and frailty in PLWH.

Methods: This was a cross-sectional study of consecutive patients attending Modena HIV Metabolic Clinic in 2016–2019. Patients with hazardous alcohol intake and HBV or HCV coinfection were excluded. Liver steatosis was defined as the contemporary presence of liver steatosis (CAP ≥2, 1–3, 3–6, >6). Evolutive NAFLD was defined as the contemporary presence of liver steatosis (CAP ≥28) and significant liver fibrosis or cirrhosis (stage ≥F2). Frailty was assessed using the 36-Item frailty index (Fl). Fl was categorized as fit (<0.25), frail (0.25–0.4), and most frail (>0.4). Logistic regression was used to explore frailty predictors using steatosis and evolutive NAFLD as covariates.

Results: We analysed 707 PLWH. Mean age was 53.5 (±8.2) years, 76.2% males, current median was CD4 700 μL (IQR=539–899). Evolutive NAFLD was present in 10.2%; frail and most-frail in 18.9% and 3.9%, respectively. Other patients’ characteristics and association of evolutive NAFLD with co-morbidities are provided in Table 1 and 2, respectively. Predictors for FI were age (OR=0.6, 0.4–0.9), steatosis (OR=2.1, 1.3–3.5) and fibrosis (OR=2, 1–3.7), evolutive NAFLD (OR=9.2, 5.2–16.8), diabetes (OR=1.7, 1–2.7), multimorbidity (OR=2.5, 1.5–4).

Table 2. Association of the evolutive NAFLD with co-morbidities

<table>
<thead>
<tr>
<th>HIV clinical variable</th>
<th>Median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>58 (35–88)</td>
</tr>
<tr>
<td>Time on cART (years)*</td>
<td>15 (1–130)</td>
</tr>
<tr>
<td>Time since HIV diagnosis (years)*</td>
<td>20 (1–34)</td>
</tr>
<tr>
<td>CD4 cell count*</td>
<td>607 (98–1868)</td>
</tr>
<tr>
<td>VL&lt;40 copies/mL</td>
<td>97.5%</td>
</tr>
</tbody>
</table>

*Median (range)

Table 1. H IV clinical variables

<table>
<thead>
<tr>
<th>Problem with administration</th>
<th>Baseline Control</th>
<th>Six-month follow-up (new MRPs) Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling or administration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unnecessarily complex regimen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potentials adverse drug reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential drug-drug interaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose adjustment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Problem with label use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inappropriate off label use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undertreatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Type and number of MRPs seen in each group at each time point

Liverpool/EACS pharmacology workshop – pharmacology today and tomorrow

PS13/1

Safety and PK of subcutaneous GS–6207, a novel HIV–1 capsid inhibitor

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1Gilead Sciences, Foster City, USA

Purpose: GS–6207, a selective, multi-stage inhibitor of HIV–1 capsid function, is in development for the treatment of HIV–1 infection. GS–6207 is characterized by potent antiviral activity, low predicted human clearance, and low aqueous solubility, making it well suited for a sustained-release parenteral formulation. This Phase 1 study evaluated the safety, tolerability and pharmacokinetics (PK) of a subcutaneous (SC) suspension of GS–6207 in healthy volunteers.

Method: This was a randomized, blinded, placebo-controlled study with staggered single dose escalation cohorts. Within each cohort, subjects were randomized (4:1) to receive single SC doses of 30, 100, 300 or 450 mg GS–6207 (n=8/cohort) or placebo (N=2/cohort). PK parameters were estimated and summarized by dose and dose proportionality was assessed. Safety, tolerability and PK were evaluated for 24–32 weeks post-dose.

Results: A single SC doses of 450 mg were administered across the dose range of 30–450 mg, dose-proportional increases in AU(0-t) were observed. The median t1/2 ranged from 32 to 45 days. At doses of 100 mg or greater, GS–6207 plasma concentrations exceeded the protein adjusted EC95 for wild type HIV–1 for at least 12 weeks.

There were no deaths, or Grade 3 or 4 adverse events (AEs). Other than injection site reactions (mild) experienced by 53% of patients, the most common AEs were headache (13%) and viral upper respiratory tract infection (8%). Most AEs were mild (Grade 1) and resolved. There were no clinically relevant laboratory findings.

Conclusion: GS–6207 was safe and well tolerated following single SC doses of up to 450 mg. Sustained exposure supports a dosing interval of at least 3 months. Safety and PK of GS–6207 supports its development as part of a long-acting antiretroviral regimen for people living with HIV.

PS13/2

A multicentred randomised controlled open study of the utility and acceptability of a medicines optimisation review (MOR) toolkit compared to standard pharmaceutical care in HIV outpatients

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Purpose: Polypharmacy seen in older people living with HIV (PLWH) increases risks of medicine related problems (MRP). Evidence that medicine reviews reduce MRPs in HIV outpatients is limited. We aimed to examine the utility and acceptability of a Medicines Management Optimisation Review (MOR) tool in HIV outpatients.

Method: A multicentred randomised controlled open study in 4 HIV outpatient services, randomly allocated PLWH to receive either a MOR (intervention) or standard pharmaceutical care (control). Inclusion criteria included cART use and aged ≥40 with another health condition.

Results: 93 with another health condition requiring medication. Intervention patients received MOR consultations at a median of 6 months post enrolment. The median number of interventions was 0.75 (IQR: 0.5–1.25) and 0.25 (IQR: 0.1–0.5) respectively.

Conclusion: The median number of interventions was 0.75 (IQR: 0.5–1.25) and 0.25 (IQR: 0.1–0.5) respectively. There were no deaths, or Grade 3 or 4 adverse events (AEs). Other than injection site reactions (mild) experienced by 53% of patients, the most common AEs were headache (13%) and viral upper respiratory tract infection (8%). Most AEs were mild (Grade 1) and resolved. There were no clinically relevant laboratory findings.

Conclusion: GS–6207 was safe and well tolerated following single SC doses of up to 450 mg. Sustained exposure supports a dosing interval of at least 3 months. Safety and PK of GS–6207 supports its development as part of a long-acting antiretroviral regimen for people living with HIV.
baseline, 6 and 12 months. MOR consultations consisted of patient-oriented questionnaire promoting self-review and adherence and a MOR form designed to aid a structured patient consultation. Changes in health-related quality of life (EQ-5D-5L), acceptability, healthcare utilisation and intervention cost will be examined at 12 months. Primary outcome measure was the difference in number of MRPs between intervention and control groups at each time interval. Mean comparisons were examined using t-tests.

Results: Baseline data was collected from 200 patients (see Table 1); mean number of non-ART medications 6.6 (3.4), with the most common being statins (31%), antidepressants (25%) and analgesics (21%). Significantly more MRPs were identified at baseline and 6 months in the MOR group (1.16 ± 1.32), (0.54 ± 0.87) compared to control (0.02 ± 0.15), (0.37 ± 0.19), p<0.001 and p<0.001, respectively. Two-way ANOVA revealed no main effect of time phase on quality of life, (p=0.51) and no interaction between experimental arm and time phase on quality of life (p=0.82). Pharmacists fully resolved 42 (35%) MRPs at baseline with 67 (52%) resolved within 6 months.

Conclusion: MOR identified a significant number of MRPs compared to standard pharmaceutical care in both time phases, suggesting HIV outpatients services should consider implementing MOR for targeted populations under their care.

PS13/3
Prevalence of potential drug–drug interactions in patients of the Swiss HIV cohort study in the era of HIV integrase inhibitors
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3EYE T Services, Freiburg, Germany
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11Ospedale Regionale di Bellinzona e Valli, Bellinzona, Switzerland
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Purpose: The analysis of the Swiss HIV Cohort Study (SHCS) in 2010 showed a high prevalence of potential drug–drug interactions (PDDIs) with antiretroviral drugs (ARVs) [1]. In recent years, ARVs with more favorable interaction profiles are used. We reassessed the prevalence of PDDIs with ARVs in the era of HIV integrase inhibitors (INI).

Method: The period prevalence of PDDIs in the SHCS between 01/2018 and 12/2018 in patients receiving at least one ARV was analyzed to determine PDDIs between ARVs and non-ARV drugs. PDDIs were identified by linkage of the Liverpool drug interactions and SHCS databases and categorized as harmful (red), of potential clinical relevance (amber) or of weak clinical significance (yellow).

Results: In total, 9,034 patients were included, median age 51 years (IQR 43,57), males (72%), Caucasians (77%). Overall, 14% (1'290/9'034) of patients received a protease inhibitor (PI), 28% (2'561/9'034) a non-nucleoside reverse transcriptase inhibitor (NNRTI)- and 65% (5'849/9'034) an INI–based regimen. Of those, 48% (4'368/9'034) were unboosted INI regimens. Overall, 77% (6'926/9'034) of patients received<1 comedication, and 24% (2'163/9'034) had≥1 PDDI. Among patients with comedication, 2% (159/6'926) had red, 24% (1'863/6'926) amber and 13% (920/6'926) yellow PDDIs. The most prevalent red PDDIs were between boosted ARVs and corticosteroids (25%) whereas most frequent amber PDDIs involved cardiovascular drugs (36%). Compared to 2010, more patients received≥1 comedication (88% vs 77%); but fewer received boosted PI (46% vs 14%) and NNRTI (38% vs 28%) based regimens leading to a 16% overall PDDI reduction, with red PDDIs remaining unchanged (2%).

Conclusion: The proportion of patients with comedications in the SHCS has increased in the past decade; however, the overall prevalence of PDDIs has decreased mainly due to the increasing use of unboosted INIs. Corticosteroids are a major component of the clinically relevant PDDIs.


Cure symposium co-organised with the National Agency for AIDS Research (ANRS)

PS14/1
HIV reservoir in gut from PHI treated individuals is stable over time and correlates with blood markers of HIV reservoir and inflammation– findings from the HEATHER gut study

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2University of Oxford, Oxford, UK
3Guy’s and St Thomas’ NHS Foundation Trust, London, UK

Purpose: Gut HIV reservoir is a key site of HIV persistence. Antiretroviral therapy (ART) in Primary HIV Infection (PHI) has been used as a strategy to limit HIV reservoir. However, tissue sampling is not routine in HIV cure studies. We present the HEATHER gut study, describing the impact of ART in PHI on gut HIV reservoir over time and identify blood correlates of the gut HIV reservoir.

Method: The HEATHER gut study is an observational cohort of individuals with PHI; commenced on ART within 3 months. Participants underwent colonoscopy with biopsies from terminal ileum (TI) and rectum. An optional second colonoscopy was performed approximately 1 year later. HIV DNA was measured using qPCR. Plasma inflammatory markers were measured using Luminex. Lasso regression models identified plasma markers associated with gut HIV DNA.

Results: 21 PHI individuals were enrolled (table 1). 10 had longitudinal sampling, with HIV DNA measured at two time points, approximately 1 year apart.
apart, for these the HIV DNA levels in TI \((p=0.77)\) and rectum \((p=0.32)\) remained stable. HIV DNA, in log_{10} copies/million CD4 cells, from TI was higher at 3.47 (3.32–3.95) compared to 3.43 (3.06–3.66) in rectum, \(p=0.049\). Both TI \((p<0.001)\) & rectum \((p=0.008)\) had higher HIV DNA compared to PBMC; 3.01 (2.88–3.21). PBMC measures of HIV DNA correlated with those in TI \((r=0.59\ p=0.001)\) and rectum \((r=0.48\ p=0.009)\), (figure 1). Lasso regression models (table 2) identified plasma markers most associated with gut HIV reservoir, including sCD40, sCD14, RANTES, MADCAM-1 for both rectal & TI HIV DNA (figure 2)

Conclusion: GUT HIV DNA is stable over time despite ART in PHI. HIV reservoir was higher in gut compared to blood. However, peripheral blood HIV DNA and markers of inflammation correlate with gut reservoir and therefore may be useful surrogate markers of gut reservoir in cure studies.

HEATHER Gut Study Patient Characteristics

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Age, years</th>
<th>Seroconversion CD4, cells/mm³</th>
<th>Seroconversion HIV viral load, log_{10}CPM</th>
<th>Time from PHI to ART start, days</th>
<th>Time on ART at 1st gut biopsy, months</th>
<th>CD4 count at 1st gut biopsy, cells/mm³</th>
<th>HIV viral load at 1st gut biopsy</th>
<th>Time on ART at 2nd gut biopsy, months</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUT 1</td>
<td>55</td>
<td>705</td>
<td>5.63</td>
<td>21</td>
<td>18</td>
<td>839</td>
<td>&lt;20</td>
<td>32</td>
</tr>
<tr>
<td>GUT 2</td>
<td>35</td>
<td>278</td>
<td>7.13</td>
<td>28</td>
<td>21</td>
<td>707</td>
<td>&lt;20</td>
<td>34</td>
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<tr>
<td>GUT 3</td>
<td>56</td>
<td>188</td>
<td>5.7</td>
<td>17</td>
<td>81</td>
<td>957</td>
<td>&lt;20</td>
<td>94</td>
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<tr>
<td>GUT 4</td>
<td>34</td>
<td>752</td>
<td>5.18</td>
<td>54</td>
<td>23</td>
<td>1208</td>
<td>&lt;20</td>
<td>35</td>
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<tr>
<td>GUT 5</td>
<td>37</td>
<td>968</td>
<td>4.2</td>
<td>26</td>
<td>33</td>
<td>1396</td>
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<td>46</td>
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<td>GUT 7</td>
<td>49</td>
<td>459</td>
<td>6.9</td>
<td>21</td>
<td>26</td>
<td>537</td>
<td>&lt;20</td>
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<td>GUT 9</td>
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<td>GUT 10</td>
<td>56</td>
<td>568</td>
<td>NA</td>
<td>20</td>
<td>3</td>
<td>703</td>
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<td>GUT 11</td>
<td>27</td>
<td>470</td>
<td>5.88</td>
<td>0</td>
<td>34</td>
<td>776</td>
<td>&lt;20</td>
<td>46</td>
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<tr>
<td>GUT 12</td>
<td>23</td>
<td>443</td>
<td>3.23</td>
<td>28</td>
<td>14</td>
<td>476</td>
<td>&lt;20</td>
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<tr>
<td>GUT 6</td>
<td>26</td>
<td>300</td>
<td>4.62</td>
<td>35</td>
<td>34</td>
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<td>10</td>
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<tr>
<td>GUT 14</td>
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<td>13</td>
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<td>6.3</td>
<td>18</td>
<td>17</td>
<td>760</td>
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<tr>
<td>GUT 18</td>
<td>36</td>
<td>789</td>
<td>5.59</td>
<td>46</td>
<td>33</td>
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</tr>
<tr>
<td>GUT 19</td>
<td>33</td>
<td>957</td>
<td>NA</td>
<td>27</td>
<td>24</td>
<td>1195</td>
<td>&lt;20</td>
<td>–</td>
</tr>
<tr>
<td>GUT 20</td>
<td>24</td>
<td>450</td>
<td>6.7</td>
<td>33</td>
<td>96</td>
<td>892</td>
<td>&lt;20</td>
<td>–</td>
</tr>
<tr>
<td>GUT 21</td>
<td>27</td>
<td>608</td>
<td>5.84</td>
<td>7</td>
<td>37</td>
<td>927</td>
<td>&lt;20</td>
<td>–</td>
</tr>
<tr>
<td>GUT 24</td>
<td>24</td>
<td>543</td>
<td>4.43</td>
<td>7</td>
<td>16</td>
<td>957</td>
<td>&lt;20</td>
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<tr>
<td>GUT 28</td>
<td>37</td>
<td>786</td>
<td>NA</td>
<td>0</td>
<td>22</td>
<td>1158</td>
<td>&lt;20</td>
<td>–</td>
</tr>
<tr>
<td>Overall</td>
<td>35 (27.38)</td>
<td>514 (443, 752)</td>
<td>5.56 (4.48, 5.91)</td>
<td>21 (13.28)</td>
<td>24 (17.24)</td>
<td>768 (645, 957)</td>
<td>&lt;20</td>
<td>35 (28.44)</td>
</tr>
</tbody>
</table>

Abbreviations: CPM, copies per million; PHI, primary HIV infection; ART, antiretroviral therapy; VL, viral load; NA, not available. All participants were male.

Lasso regression models of gut total HIV DNA and plasma inflammatory markers

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>1 Terminal Ileum HIV DNA (CPM gut cells)</th>
<th>2 Terminal Ileum HIV DNA (CPM CD4 cells)</th>
<th>3 Rectum HIV DNA (CPM gut cells)</th>
<th>4 Rectum HIV DNA (CPM CD4 cells)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-squared</td>
<td>0.54</td>
<td>0.53</td>
<td>0.53</td>
<td>0.59</td>
</tr>
<tr>
<td>Unstandardised β Coefficients*</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Variables</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>sCD14</td>
<td>0.2706</td>
<td>–</td>
<td>–</td>
<td>0.3941</td>
</tr>
<tr>
<td>sCD14</td>
<td>0.0079</td>
<td>0.0178</td>
<td>–</td>
<td>0.3941</td>
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<tr>
<td>IL-4</td>
<td>0.0019</td>
<td>–</td>
<td>–</td>
<td>0.0032</td>
</tr>
<tr>
<td>IL-6</td>
<td>0.0017</td>
<td>–</td>
<td>–</td>
<td>0.0021</td>
</tr>
<tr>
<td>MIP-1β</td>
<td>0.004</td>
<td>0.0004</td>
<td>–</td>
<td>0.0004</td>
</tr>
<tr>
<td>MCP-1</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>MCP-1</td>
<td>–</td>
<td>0.0005</td>
<td>–</td>
<td>0.0021</td>
</tr>
<tr>
<td>RANTES</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>MADCAM-1</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>sCD163</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>MIP-1α</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>L-Selectin</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>IP-10</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>IL17A</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>IL12 p70</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
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<tr>
<td>IFN-γ</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>CD40 Ligand</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

*Only variables with β coefficients > 0 were included in the final models are shown. The prefix “s” indicates soluble. Abbreviations; CPM, copies per million
PS14/2
Effects of long-term ART on integrated and intact HIV-DNA in acutely treated vs chronically infected patients: is there a real advantage of treating early?

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1Università degli Studi di Messina, Department of Clinical and Experimental Medicine, Messina, Italy 2University of Pennsylvania, Department of Pathology and Laboratory Medicine, Philadelphia, USA

Purpose: Integrated HIV-DNA declines significantly (~5-fold) in the first year of antiretroviral therapy (ART) if individuals are treated early (<6 months from the infection) but does not decline perceptibly if the individuals are treated with ART during chronic infection (Pinzone et al, 2016; Koelsch et al, 2011, 2008; Murray et al, 2012). Herein, we investigated if early treatment results in sustained accelerated decay of intact proviral DNA after many years of ART.

Method: We measured integrated HIV-DNA in samples that were collected after 2 and 7 years of ART in an HIV infected individual treated during acute and chronic infection. From the same samples, we amplified near full length HIV-DNA at limiting dilution and performed Illumina sequencing. We then bioinformatically categorized the proviruses as intact, deleted and hypermutated (Pinzone et al, 2019).

Results: In contrast to the rapid decline detected in the first year of ART (Pinzone et al, 2016), the integrated HIV-DNA did not decline between 2 and 7 years of ART in the acutely treated subject. However, sequence analysis revealed that the decline of the intact reservoir between years 2 and 7 was ~4-fold in the chronically treated individual and ~2-fold in the acutely infected individual, despite clonal expansion and the apparent stability of the HIV-DNA. Clonal expansion was more important in the acute patient than the chronic one, especially within deleted proviruses (Fig. 1).

Conclusion: Final outcome after 10 years of ART may be a more similar intact reservoir size whether an individual is treated acutely or after chronic infection. Nonetheless, our results also suggest that treating early is beneficial because the reservoir declines more rapidly and thus these individuals are exposed to less harmful inflammation (Fig. 2).

PS14/3
Increased frequency of cytotoxic CXCR5+ effector memory CD8+ T cells during natural control of HIV-1 infection

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1Luxembourg Institute of Health, Esch-sur-Alzette, Luxembourg 2Luxembourg Institute of Tropical Medicine, Antwerp, Belgium 3Ghent University Hospital, Gent, Belgium 4Saint Pierre University Hospital, Université Libre de Bruxelles, Brussels, Belgium 5Université Ziekenhuis Brussel, Brussels, Belgium 6Hasselt University, Hasselt, Belgium 7Jesuisziekenhuis, Hasselt, Belgium 8Liège University Hospital, Liège, Belgium 9Vrije Universiteit Brussel, Brussels, Belgium

Purpose: Potent HIV-specific immune responses and a small latent viral reservoir are likely required to control viral replication during HIV-1 infection. Here we investigated the antiviral CD8+ T cell response of elite and viremic
controllers (EC and VC) and antiretroviral therapy-(ART) suppressed patients at baseline and after peptide stimulation.

**Method:** Peripheral blood mononuclear cells of 58 patients were analyzed by 18 color flow cytometry and IFN-γ ELIspot at baseline and after 7 days of in vitro HIV peptide stimulation (PTE GAG pool, NIH). Plasmas were analyzed for IFN-γ, CXCL-10, IL1-β, IL6, TNF-α, IL-18 concentrations. Cytometry data was clustered using viSNE and analyzed by Boolean gating strategy to assess multifunctional characteristics. Statistical comparison was executed with Quicore and Prism nonparametric statistics (Kruskal-Wallis test correcting for multiple comparison).

**Results:** IL-18 in plasma and CD38 expression on CD4 + T cells were significantly lower in EC and ART patients with low reservoir than in VC (p<0.05). We observed a significant increase in IFN-γ production at baseline and after 7 days of peptide stimulation (p<0.0005) while CD107a and Ki67 expression were also significantly increased for ECs compared to ART patients (p<0.001).

Detailed phenotyping revealed that CD8 + effector memory T cells which are IFN-γ+, Ki67+, CD107a+, Perforin+, and GrzB significantly increased in EC (p<0.005) compared to VC and ART patients. Similarly, we observed central memory CD8 + T cells subsets with increased cytotoxic and polyfunctional features in EC (p<0.005). Interestingly, CD8 + T cells subsets expressing CXCR4, a homing receptor for lymph node follicles, and cytotoxic markers were significantly increased in EC as well (p<0.005).

**Conclusion:** Distinct functional subsets coexist during natural control of HIV-1 infection. Access to the B cell zone of lymph node follicles by cytotoxic CD8 + T cells might explain long-term control of the HIV reservoir.

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**PS14/4**

**HIV-1 reservoir formation, stability and dynamics during cART**

**F Otte¹, T Klimkait¹ and Swiss HIV Cohort Study (SHCS)**

¹University of Basel, DBM, Basel, Switzerland

**Purpose:** While the continuing global HIV-related health crisis requires new approaches for sustainable therapy and towards a cure, strategies of reversing viral latency remained disappointing.

Our research strategy instead follows the changing viral properties of HIV-1 over the course of infection during suppressive therapy. We recently demonstrated that envelope properties of HIV strongly correlate with immune-recovery and disease outcome. In particular, the CXCR4-tropism of virus but also in silently infected cells, correlating with poorer outcomes in therapy-naive individuals, appears to trigger superior HIV control during treatment. We thus aim at characterizing HIV inside the key T-cell populations during periods of suppressive therapy to identify cell populations driving such selective virus elimination and understand the preservation/re-establishment of crucial immune compartments.

**Method:** To study the properties of peripheral HIV-infected cells, we analyze T cell memory, the lymphoid homing potential and HIV protein expression by multi-parameter FACS, utilizing t-distributed stochastic neighborhood embedding (tsne) to identify specific target cell clusters.

**Results:** Although only venous blood is examined here, nave cell populations can be clearly separated from differentiated memory cells, allowing studies of cellular homing properties. Env-pos. staining (Fig. 1) reveals a phenotype of stimulated CD4 + T-cells with lymph node homing properties (CD3 + CD4 + CD28 + CCR7 + ). Env-expression with co-expression of HIV-Gag discretely localizes in the tsne map (Fig. 2), hinting particle production.

**Conclusion:** By applying a new multi-parameter FACS staining protocol, we can now precisely map infectious cells inside bulk PBMCs of HIV positive individuals down to single cell resolution. This will guide to cell subsets with elevated viral activity, allowing to address the dormant HIV pool by reactivation and expansion of viable cells in the peripheral blood of HIV patients. Linking viral properties to cell homing properties will help to explain tropism-dependent pressure on the virus and clearance of these cells by cART and the recovering immune system.

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**Best poster discussion I – Antiretroviral (ARV) BPD1/1**

**Causes of treatment failure in independent and industry-funded clinical trials of dolutegravir for HIV, and outcomes of unsuppressed patients continued on treatment in the ADVANCE study**

**T Pepperrell¹, S Sokhela², M Moorhouse², F Venter², A Qavi¹, B Simmons¹, V Pilkington¹, K McCann¹ and A Hill²**

¹Imperial College London, London, UK ²University of the Witwatersrand, Johannesburg, South Africa ³University of Liverpool, Liverpool, UK

**Purpose:** Over 20 million people living with HIV could be switched from efavirenz (EFV) to the integrase-inhibitor dolutegravir (DTG) in the coming years. ADVANCE is a randomised clinical trial (RCT) comparing tenofovir alafenamide(TAF)/emtricitabine(FTC) + DTG, tenofovir disoproxil fumarate (TDF)/FTC=DTG and TDF/FTC/EFV. This project investigated reasons for treatment failure in ADVANCE and other RCTs.
Method: In ADVANCE, treatment failure was HIV RNA≥50 copies/mL at week-48, discontinuation for adverse events (AEs) or discontinuation for other reasons. Multiple logistic regression was used to determine clinical and sociodemographic predictors of treatment success. Each participant with HIV RNA≥50 copies/mL was followed to determine sustained failure. A systematic review identified sixteen other RCTs (n=10738) for EFV and eight for DTG (n=5954).

Results: In ADVANCE, week-48 HIV RNA suppression rates were 84% for TAF/FTC+DTG, 85% for TDF/FTC+DTG and 79% for TDF/FTC/EFV. Efficacy of DTG in ADVANCE (84.3%; CI 81.7–87.0%) was lower than industry-funded RCTs (89.8%; CI 87.2–92.5%) (p<0.01).

Trials in low and middle-income countries show less AE discontinuation than trials in high-income countries for DTG (0.5% vs 1.9% [p<0.01]) and EFV (4.2% vs 10.5% [p<0.01]). In multivariate analysis of ADVANCE, employment (OR 2.11, CI 1.50–2.96, p<0.001), older age (OR 1.04, CI 1.02–1.07, p<0.01) and DTG use (OR 1.53, CI 1.09–2.15, p=0.05) were the most important predictors of suppression. Participants on both drugs re-suppressed HIV RNA after an initial high week-48 reading (36/54), with retesting and adherence counselling (Table 1). Significantly more participants were able to re-suppress at follow-up on DTG than EFV (p<0.05)(Table 1).

Conclusion: In ADVANCE, treatment failure was predicted by sociodemographic more than clinical factors. Employment and older age improved chances of suppression. Most people with HIV RNA≥50 copies/mL at week-48 re-suppressed after retesting and adherence counselling. This research promotes social protection, monitoring and adherence counselling during HIV treatment, especially for younger people.

Table 1. Follow-up outcomes of patients with HIV RNA≥50 copies/mL at week-48.

<table>
<thead>
<tr>
<th>Time</th>
<th>HIV RNA&lt;50 copies/mL</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>On sample read</td>
<td>15 (4.5)</td>
<td>7 (2.3)</td>
</tr>
<tr>
<td>Within week-48 window</td>
<td>4 (1.2)</td>
<td>4 (1.2)</td>
</tr>
<tr>
<td>Long-term follow-up (12-week window)</td>
<td>10 (2.9)</td>
<td>4 (1.2)</td>
</tr>
<tr>
<td>Treatment failure</td>
<td>2.1 (0.3)</td>
<td>2.1 (0.3)</td>
</tr>
<tr>
<td>HIV Risk at last visit of treatment-emergent drug resistant</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Last-to-follow-up/missing data</td>
<td>1 (0.0)</td>
<td>2 (0.0)</td>
</tr>
</tbody>
</table>

Evolution of the therapeutic classes involved in drug interactions from 2012 to 2016.
for the USA (2000) and UK (2000). Interaction profiles for complete antiretroviral regimens were calculated using the frequency of each interaction type (red, amber, yellow, green). Interactions were grouped according to those requiring an intervention (contraindicated/do not co-administer, dose modification, monitoring; red and amber) and those not requiring such a priori actions (green and yellow). The interaction potential with comediations used to treat three comorbidity clusters (mental health, cardiovascular and metabolic; De Francesco et al, 2018) were determined for the current first line regimens and the new FDCs.

Results: A total of 16 regimens were identified in at least one of the current guidelines and 28 regimens in the historic guidelines. The percentage of interventional interactions when assessed against the comedication list (n=689) are shown for the guidelines (Table 1) and the comorbidity clusters (Table 2). Both recently approved FDCs were unboosted regimens and had interventional interaction percentages within the ranges observed for unboosted regimens in the current guidelines and in each of the comorbidity clusters.

Table 1. Percentage of interventional interactions in current and historical treatment guidelines.

<table>
<thead>
<tr>
<th>% Intervventional Interactions in Guidelines</th>
<th>Current</th>
<th>Historic</th>
</tr>
</thead>
<tbody>
<tr>
<td>All regimens (range)</td>
<td>8–54%</td>
<td>37–57%</td>
</tr>
<tr>
<td>PI and/or boosted regimens (mean)</td>
<td>45%</td>
<td>52%</td>
</tr>
<tr>
<td>Unboosted regimens (mean)</td>
<td>12%</td>
<td>44%</td>
</tr>
</tbody>
</table>

Table 2. Percentage of interventional interactions in comorbidity clusters for currently recommended first-line regimens.

<table>
<thead>
<tr>
<th>% Intervential Interactions in Comorbidity Clusters</th>
<th>Mental Health</th>
<th>Cardiovascular</th>
<th>Metabolic</th>
</tr>
</thead>
<tbody>
<tr>
<td>All regimens (range)</td>
<td>0–61%</td>
<td>1–55%</td>
<td>0–53%</td>
</tr>
<tr>
<td>Boosted regimens (mean)</td>
<td>52%</td>
<td>44%</td>
<td>41%</td>
</tr>
<tr>
<td>Unboosted regimens (mean)</td>
<td>1%</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Conclusion: Although the interaction potential of first-line regimens has declined over the last 20 years, an awareness of possible drug-drug interactions, particularly when treating certain comorbidity clusters, remains critical for appropriate patient management.

BPD1/5

TDF/FTC is a cost-saving maintenance option in HIV-infected people with low reservoir

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9CHU de Rouen, Service des Maladies Infectieuses et Tropicales, Rouen, France
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12Centre Hospitalier de Chartres, Service des Maladies Infectieuses et Tropicales, Chartres, France
13Hopital Necker-Enfants Malades, APHP, Laboratoire de Microbiologie Clinique, Paris, France
14CHU de Caen, Unité de Biostatistique et de Recherche Clinique, Caen, France
15Universite Caen Normandie, EA2656 Groupe de Recherche sur l’Adaptation Microbienne, Caen, France

Purpose: We investigated whether tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) was able to maintain virological suppression in HIV-1-infected individuals with a low HIV reservoir on a successful TDF/FTC-based triple therapy.

Method: Academic, multicenter, open-label, non-inferiority randomized trial (margin 12%, 92% of success in both arms, power 90%; alpha 2.5%) comparing TDF/FTC once daily (experimental arm) versus triple regimen continuation (TDF/FTC with a third agent, control arm) in virologically suppressed adults with HIV DNA<2.7 log10 copies/10^6 PBMCs at screening (details at https://clinicaltrials.gov/ct2/show/NCT02302547). Primary endpoint was the percentage of patients with plasma viral load (pVL)<50 copies/mL in intention-to-treat (ITT, Non Completer = Failure, FDA Snapshot approach) at week 48 (W48). A per protocol (PP) analysis excluded patients with non-inclusion criteria and non-completers.

Results: 325 patients screened, 223 randomized to TDF/FTC (n=113) or control arm (n=110): 165 males (74%); age: 44.7 years (SD, 11.4); CD4 cells 739/µL (IQR, 578–912). At W48, TDF/FTC and triple regimen continuation maintained pVL<50 cp/mL in 100/113 (88.5%) and 100/110 (90.5%) of the patients, respectively. The primary outcome difference was 2.4% with a 95% confidence interval (CI) of [−5.9 to 10.7] in ITT and 3.4% with a CI of [−4.2 to 11.0] in PP. Six virological failures occurred in the TDF/ FTC arm (with mutation M184V in patient and K65R in another) versus two in
the control arm (p=0.16 by the log-rank test). All virological failures were rapidly re-suppressed after treatment intensification. Four patients in each arm switched their antiretroviral therapy while the pVL was<50 copies/mL. The average expected antiretroviral therapy cost per patient for 48 weeks was 7,407€ (SD, 1,373€) for triple regimen continuation compared to 3,820€ for branded Truvada® (French cost).

Conclusion: De-escalation to TDF/FTC is an acceptable and cost-saving strategy among virologically suppressed HIV+ patients with a low reservoir.

Best Poster discussion II – ageing: long-term complications

BPD2/1

DXA Scan vs. FRAX score for the evaluation of fracture risk in a cohort of elderly people living with HIV

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3Tokyo Medical University Hospital, Tokyo, Japan

Purpose: Osteoporosis and fractures increase morbidity and mortality in people living with HIV (PLWH). EACS guidelines recommend routine assessment of fracture risk using FRAX, and dual-energy X-ray absorptiometry (DXA) scan only for those with FRAX over 10%, even though it can underestimate fracture risk in PLWH. Objective of our study was to evaluate level of concordance of DXA results (T score of the spine and of the femur) and FRAX in a population of PLWH over 50 years of age.

Methods: DXA scan results of PLWH who attended specialist Over 50’s clinic in Chelsea and Westminster Hospital between January 2009 and December 2018 were collected as well as demographic and clinical characteristics. FRAX was calculated using Sheffield algorithm. Mean and standard deviation were calculated. For univariate analysis Wilcoxon test was used.

Results: 744 patients were included, 92.9% were male, mean age of 56 ± 5 years. Prevalence of osteoporosis (in the spine and/or in the femur) was 12.2% and osteopenia 63.7%. A statistically significant association was found between age and time of exposure to boosted protease inhibitors and osteoporosis in the femur (p=0.05). Two out of 744 cases FRAX major was>10% indicating need to perform DXA scan according to EACS guidelines (Table 1), while 90/91 (98.9%) patients with osteoporosis had a normal FRAX score. Even when FRAX score was calculated considering HIV as a risk factor of secondary osteoporosis and using BMD results, only 1.5% (11/744) patients had FRAX score>10%.

Discussion: Our results show that the FRAX score may not be a reliable screening tool for fracture risk in PLWH. Most patients with osteoporosis in our cohort had a normal FRAX score. These findings were maintained when BMD results and HIV infection were included in the FRAX calculation tool. Bone fracture screening in PLWH over 50 years of age requires optimisation.

BPD2/2

Prevalence of and risk factors for low bone mineral density assessed by central quantitative computed tomography in people living with HIV and uninfected controls

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2Department of Cardiology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark
3Department of Clinical Biochemistry, Herlev and Gentofte Hospital, University of Copenhagen, Copenhagen, Denmark
4Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark
5CHIP, Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark
6Department of Infectious Diseases, Hvidovre Hospital, University of Copenhagen, Copenhagen, Denmark
7Department of Endocrinology, Hvidovre Hospital, University of Copenhagen, Copenhagen, Denmark

Purpose: Low bone mineral density (BMD) has previously been described in people living with HIV (PLWH). We determined the prevalence of low BMD measured by central Quantitative Computed Tomography (cQCT), a method that allows three-dimensional volumetric density measures of trabecular BMD, in well-treated PLWH and uninfected controls and assessed if HIV status was an independent risk factor for low BMD.

Method: Cross-sectional study including 718 PLWH from the Copenhagen Co-Morbidity in HIV infection (COCOMO) study and 718 uninfected controls matched on age- and sex from the Copenhagen General Population Study (CGPS). Trabecular BMD was determined by cQCT.

Results: Median age was 52.2 (IQR: 47.1–60.9) and 54.1 (IQR: 48.2–61.0) years in PLWH and uninfected controls, respectively, and 86% of the participants were men. Median time since HIV diagnosis was 15.8 (IQR: 8.4–23.1) years, and 96.1% of PLWH had undetectable viral replication. Median BMD was 144.2 mg/cm³ in PLWH vs. 146.6 mg/cm³ in controls (p=0.580). HIV was not associated with BMD in unvariable- or multivariable linear analyses. However, higher prevalence of very low BMD (T-score<-2.5) was found in PLWH (17.2% vs. 11.0% in controls, p=0.003). In unadjusted analysis HIV was associated with very low BMD (OR 1.68 [95% CI: 1.24–2.27], p=0.001), but this association was not significant after adjusting for age, sex, pack-years, alcohol, body mass index (BMI), physical activity and ethnicity. Very low BMD was associated with age, BMI and pack-years. Previous AIDS-defining disease was associated with lower BMD.

Conclusion: Using cQCT, we found a higher prevalence of very low BMD in PLWH than in controls. However, HIV status was not independently associated with BMD indicating that traditional risk factors contribute to the difference in prevalence of very low BMD. Focus on lifestyle, especially in PLWH with previous AIDS-defining disease, may prevent very low BMD in PLWH.

BMD and T-scores in people living with HIV and controls

<table>
<thead>
<tr>
<th>People living with HIV</th>
<th>Uninfected controls</th>
<th>F-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMD (mg/cm³), median (IQR)</td>
<td>144.2 (110.7–183.8)</td>
<td>146.6 (119.2–177.4)</td>
</tr>
<tr>
<td>T-score, median (IQR)</td>
<td>–0.8 (–2.1 to 0.4)</td>
<td>–0.9 (–1.8 to 0.2)</td>
</tr>
<tr>
<td>T-score, categories, % (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal, T-score &gt;–1</td>
<td>50.6 (363)</td>
<td>52.8 (379)</td>
</tr>
<tr>
<td>Low, T-score &lt;–1 and &gt;–2.5</td>
<td>32.3 (231)</td>
<td>36.2 (260)</td>
</tr>
<tr>
<td>Very low, T-score &lt;–2.5</td>
<td>17.2 (123)</td>
<td>11.0 (79)</td>
</tr>
</tbody>
</table>

Unadjusted and adjusted linear regression estimates for BMD in people living with HIV

<table>
<thead>
<tr>
<th>Coefficient Estimate</th>
<th>SE</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>0.82</td>
<td>0.18 to 1.46</td>
<td>0.015</td>
</tr>
<tr>
<td>Adjusted</td>
<td>0.68</td>
<td>0.04 to 1.32</td>
<td>0.039</td>
</tr>
</tbody>
</table>

Unadjusted and adjusted logistic and linear regression in BMD to 316
Restless legs syndrome and health-related quality of life in HIV: results from the POPPY sleep substudy

K Kunisaki 1,3, D DeFrancesco 1, C Sabin 1, A Winston 1, P Mallon 1, J Vera 6, F Post 7, I Williams 8, E Bagkeris 2, N Doyle 1, W Khalil 2,2, S Redline 8,13,11, Pharmacokinetics and Clinical Observations in People Over Fifty (POPPY) Study

1Minneapolis VA Health Care System, Minneapolis, USA 2University of Minnesota, Minneapolis, USA 3University College London, London, UK 4Imperial College London, London, UK 5University College Dublin, Dublin, Ireland 6Brighton and Sussex University Hospitals, Brighton, UK 7King’s College Hospital, London, UK 8Mortimer Market Centre, London, UK 9Brigham and Women’s Hospital, Boston, USA 10Beth Israel Deaconess Medical Center, Boston, USA 11Harvard Medical School, Boston, USA

Purpose: Restless legs syndrome (RLS) is a sleep disorder characterized by leg dysesthesias, typically relieved by movement, with sequelae that may include daytime sleepiness, mood problems, functional impairments, and decreased work productivity. RLS often responds to dopaminergic drugs, suggesting a central nervous system (CNS) etiology. Given the high burden of sleep symptoms and CNS disorders in persons with HIV (PWH), we evaluated RLS prevalence and associations with health-related quality of life (QoL) in PWH and lifestyle-similar HIV-negative controls.

Methods: A subset of POPPY participants (PWH<50 y/o, PWH<50 y/o, HIV-negative controls<50 y/o) completed standardized RLS and QoL questionnaires. RLS was defined using international guideline criteria. Sleep-related QoL was assessed with PROMIS questionnaires. Physical and mental health QoL was evaluated with SF-36 scores. Logistic regression was used to compare RLS prevalence in PWH and controls. QoL in those with and without RLS were compared using Wilcoxon tests.

Results: Of 435 participants (220 older PWH (median age 60 y), 99 younger PWH (45 y) and 116 older HIV-negative (60 y)), RLS criteria were met by 77 (35%), 33 (33%) and 25 (22%) of the groups, respectively. In analyses adjusted for age, sex, and race, PWH were more than twice as likely to meet RLS criteria (35%), 33 (33%) and 25 (22%) of the groups, respectively. In analyses adjusted for age, sex, and race, PWH were more than twice as likely to meet RLS criteria than controls [aOR 2.4 (1.4 to 4.1), p=0.002].

Of 110 PWH with RLS (55% of whom reported symptoms at least 2 times/week), only 7 (6%) reported a diagnosis of RLS and 3 (3%) reported a history of RLS medication treatment. PWH with RLS reported worse sleep-related QoL than controls [aOR 2.4 (1.4 to 4.1), p=0.002].

Conclusion: Among PWH, RLS is common, associated with health-related QoL impairments, and rarely diagnosed or treated. Further research is needed to understand risk factors for RLS and the effects of RLS treatment.

Depression and kynurenine/tryptophan ratio in people living with HIV

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Purpose: Tryptophan is a precursor for serotonin and a higher kynurenine/tryptophan ratio (KTR) has been described in People living with HIV (PLWH) resulting in lower serotonin that may predispose to depression. We aimed to determine the prevalence of depression among PLWH and to identify if KTR as well as traditional and HIV-specific risk factors were associated with depression. We hypothesized that high KTR would be associated with higher risk of depression among PLWH.

Method: 828 PLWH were recruited from the Copenhagen Comorbidity in HIV infection (COCCOMO) Study. Demographic information was obtained from questionnaires. Depression was defined using Major Depression Inventory (MDI) and/or current use of antidepressant medication. Plasma kynurenine and tryptophan were analyzed by liquid chromatography-tandem mass spectrometry.

Regression models were adjusted for age, sex, origin, marital status, educational level and alcohol use.

Results: Population characteristics are presented in table 1. Depression was present in 113 (14%) of the participants with a majority having moderate depression (50%). The median KTR was 3.2 versus 3.2 (p=0.999) in PLWH without and with depression, respectively. In adjusted analyses, KTR was not associated with presence or severity of depression. Being unmarried was associated with higher risk of depression and current treatment with Efavirenz was associated with lower risk. No other associations were found between depression and traditional and HIV-specific risk factors.

Conclusion: The prevalence of depression was relatively low in this cohort predominantly well-treated PLWH compared to previous reports. Being unmarried was and current treatment with Efavirenz were independently associated with higher and lower risk of depression, respectively. KTR and other HIV-specific risk factors were not found to be associated with depression. Our hypothesis that increased KTR would be associated with increased risk of depression was not supported, albeit a low depression prevalence in this cohort may challenge the conduction of a biomarker study.

Table 1. Characteristics of PLWH

<table>
<thead>
<tr>
<th>Covariates</th>
<th>PLWH (n=792)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs, median (IQR)</td>
<td>50.2 (43.3–58.3)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Origin, n (%)</td>
<td>European: 695 (85%) Other: 119 (15%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td>Married, 399 (51%)</td>
<td>0.5</td>
</tr>
<tr>
<td>Smoking status (Current smoker vs ex-smoker/never smoker)</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td>HIV RNA copies/mL</td>
<td>792 (95.6%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Treatment with CART, n (yes) (%)</td>
<td>814 (98.7%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Treatment with Efavirenz (yes)</td>
<td>242 (29%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Prevalence of depression (%)</td>
<td>113 (13.7%)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Table 2. Traditional and HIV-specific risk factors associated with depression in PLWH

<table>
<thead>
<tr>
<th>Covariates</th>
<th>Crude OR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per decade)</td>
<td>0.99 (0.97–1.01)</td>
<td>0.357</td>
</tr>
<tr>
<td>Sex (male vs. female)</td>
<td>0.65 (0.38–1.12)</td>
<td>0.216</td>
</tr>
<tr>
<td>Marital status (Unmarried vs. married)</td>
<td>1.82 (1.15–2.88)</td>
<td>0.017</td>
</tr>
<tr>
<td>Heavy drinkers, units/week, &gt;7 (female), &gt;14 (male)</td>
<td>0.73 (0.42–1.28)</td>
<td>0.200</td>
</tr>
<tr>
<td>Smoking status (Current smoker vs ex-smoker/never smoker)</td>
<td>1.61 (1.03–2.51)</td>
<td>0.068</td>
</tr>
<tr>
<td>KTR (only adjusted for age)</td>
<td>1.01 (0.987–1.039)</td>
<td>0.122</td>
</tr>
<tr>
<td>Time since HIV diagnosis, years (IQR)</td>
<td>1.01 (0.99–1.04)</td>
<td>0.057</td>
</tr>
<tr>
<td>Efavirenz (yes vs. no)</td>
<td>0.14 (0.06–0.32)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

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BPD2/S
Antiretroviral therapy and clearance of oncogenic HPVs in HIV positive MSM

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Conclusions: The duration of ART appears to positively affect oncogenic genotype clearance in the anal mucosa of HIV does not affect the incidence of HSILs or ASCC.

P Vernazza 8, A Marzel 9, H Heinrich 10,11, M Egger 12, M Zwahlen 12, H FG
SK Rampini 13, R Kouyos 1, JS Fehr 1,2 and the Swiss HIV Cohort Study

Purpose: Our main objective was to establish high-risk human papillomavirus (HR-HPV) clearance and acquisition rates and related factors and their relationship with the incidence of HSILs and ASCC in an anal mucosa of HIV+ MSM.

Patients and methods: The study included consecutive HIV-infected MSM between May 2010 and December 2018. Data were gathered at baseline and annually on their sexual behavior, CD4 and CD8 levels, plasma HIV viral load, and results of anal cytology, HPV PCR, and high-resolution anoscopy.

Results: Out of the 405 patients studied, 34.9 % of patients cleared oncogenic genotypes (IQR: 37–69) within 49 months, and 42.9 % acquired new genotypes within 36 months (IQR: 12–60). In multivariate analysis, clearance was only significantly influenced by the duration of antiretroviral therapy (ART) (OR: 1.016, 95% CI 1.003–1.030). The incidence of HSILs was 30.86/1,000 patient-years and that of ASCC was 81.22/100,000 patient-years; these incidences were not influenced by the acquisition (acquired: 14.9% ± 0.662) rates of these viruses.

Conclusions: The duration of ART appears to positively affect oncogenic genotype clearance in the anal mucosa of HIV+ MSM, although this clearance does not affect the incidence of HSILs or ASCC.

Best poster discussion III – hot topics

BPD3/1
HIV infection in individuals seeking post-exposure prophylaxis (PEP): a retrospective data linkage study

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Objectives: Evidence on the long term outcome of individuals taking post-exposure prophylaxis (PEP) is lacking. Therefore, we conducted a data linkage study to estimate the number of “late” HIV diagnoses (=minimum 6 months following PEP intake) in individuals who sought PEP at the University Hospital of Zurich (USZ) between 2007 and 2013.

Methods:
Design: Retrospective analysis, anonymous linkage between 4 databases (PEP-USZ database, USZ electronic patient record system (KISIM), Zurich Primary HIV Infection (ZPHI) cohort and Swiss HIV Cohort Study (SHCS) – figure 1). The PEP-USZ database contains data from 975 individuals; HIV diagnoses are obtained from KISIM/ZPHI/SHCS.

Primary outcome: Number of HIV diagnoses, defined as: (1) HIV infection diagnosed at the USZ (internal linkage: PEP-USZ/KISIM/ZPHI) and/or (2) enrolment in the SHCS (external linkage: PEP-USZ/SHCS).

Data linkage: external linkage using a privacy-preserving probabilistic linkage method.

Ethical approval: obtained.

Results: Internal linkage retrieved 17 potential matches. Seven were further discarded (3 duplicates, 3 HIV diagnoses at PEP consultation, 1 compatible with a PEP failure (=HIV diagnosis within 6 months of PEP intake)). Thus, late HIV diagnoses were found in 10/975 (1.03%). All were men-having-sex-with-men. Compared to seronegative PEP-seekers, those who seroconverted were more likely to take PEP repeatedly (40% versus 10%) and to have a strong indication for PEP (90% versus 54%) – table 1. There was a median of 3.8 years (IQR: 2.3 – 6.4) between PEP consultation and HIV diagnosis. Of 3 potential PEP-failures (case number 1, 2 and 3 – figure 2), 2 had laboratory tests compatible with recent seroconversion (case 2 and 3). Case 1 refused PEP. Conclusion: Although HIV diagnoses were scarce, PEP-seekers who seroconverted seem to share a specific risk profile. Nearly half of these HIV cases could have been prevented by pre-exposure prophylaxis. External linkage with the SHCS will provide further insights (expected September 2019).

Table 1. Baseline characteristics, stratified by HIV diagnosis

<table>
<thead>
<tr>
<th></th>
<th>HIV negative (n=965)</th>
<th>HIV positive (n=10)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (IQR)</td>
<td>31 (26–38)</td>
<td>33 (23–40)</td>
<td>0.89</td>
</tr>
<tr>
<td>Sex, male, n (%)</td>
<td>791 (82%)</td>
<td>10 (100%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Swiss nationality, n (%)</td>
<td>680 (70%)</td>
<td>7 (70%)</td>
<td>1.0</td>
</tr>
<tr>
<td>MSM, n (%)</td>
<td>342 (35%)</td>
<td>10 (100%)</td>
<td>-0.0001</td>
</tr>
<tr>
<td>Repeated PEP, n (%)</td>
<td>93 (10%)</td>
<td>4 (40%)</td>
<td>0.012</td>
</tr>
<tr>
<td>PEP indicated, n (%)</td>
<td>523 (54%)</td>
<td>9 (90%)</td>
<td>0.026</td>
</tr>
</tbody>
</table>

*Repeated PEP: number of individuals who received PEP prior to PEP consultation (medical history) + those who sought PEP at the USZ >1.*

**PEP indicated: number of individuals for whom PEP was strongly indicated (risk assessment based on: exposure=<72 h, partner with unknown HIV status AND high risk group (MSM, sex worker, IDU, endemic region), HIV+ partner with viral load>50 copies/mL)
BPD3/2
Harnessing big data on Indonesian MSM and transgender individuals using temanTeman.org platforms to assess their vulnerabilities, HIV support seeking patterns and immediate HIV prevention needs
T Anand and C Nilpolprasert
1Adam’s Love Global Foundation for MSM and Transgender Health (ALGO), Bangkok, Thailand

Introduction: Indonesia is the world’s largest Islamic-majority nation. Homophobia is contributing to the concentrated explosion of HIV epidemic among men who have sex with men (MSM), who for their HIV support needs resort to accessing top Google suggested websites such as TemanTeman.org, processing significant critical insights on key populations with potential for developing novel service-delivery models.

Methods: Between September 2013-June 2019, datasets spread over TemanTeman.org web-logs and databases were mined to address the gaps in our understanding on Indonesian key populations through assessing their vulnerabilities, online search patterns and immediate prevention needs.

Results: Over 3 million Indonesians engaged in TemanTeman.org platforms. ‘How is HIV transmitted’, ‘HIV testing and treatment services’, ‘condoms and lubricants’, ‘HIV testing procedures (city-based)’ were search queries originating primarily from Jakarta, Surabaya, Bandung, Medan, Makassar, Denpasar and Yogyakarta. Age demographics included 13-17 years (3%) - male 7%, female 26%), 18-24 years (35% - male 71%, female 29%), 25-34 years (45% - male 74%, female 26%) and 35-39 years (18.7% - male 60%, female 40%). TemanTeman.org videos featuring medical doctors from Indonesia’s leading university hospitals garnered nearly 1.6 million views, watch-time 60,861 hours (equivalent to 6 years and 344 days), primarily via mobile phones (84% - Android 90%, iOS 7.3%), and computers (12% - Windows 95%, Macintosh 4.3%). Top video search trends included

1 HERPES - Skin/genital, causes, treatment, cure (63,903 + searches),
2 HIV/AIDS - early stage signs/symptoms/characteristics, vaccine, transmission, testing procedure and costs (59,850 + searches),
3 SYPHILIS - early symptoms, effective treatment (27,591 + searches),
4 HIV in men/women, symptoms and treatment (11,167 + searches),
5 GENITAL WARTS in male/female, treatment, surgical removal (11,090 + searches), and
6 GONORRHEA in men/women, treatment (10,848 + searches).

Conclusions: Our study shares evidence of high sexual-risk related web-searching behaviors among Indonesians. We propose intensive real-time interventions as a way to strengthen the cascade.

BPD3/3
Prescription of antimicrobials in primary health care as a marker to identify people living with undiagnosed HIV infection
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2University Hospital Germans Trias i Pujol, Badalona, Spain
3University of Southern Denmark, Department of Public Health, Research Unit of General Practice, Odense, Denmark
4Kolding Hospital, Department of Internal Medicine, Kolding, Denmark
5Copenhagen University Hospital, Rigshospitalet, Infectious Diseases Department, Copenhagen, Denmark

Purpose: Despite efforts in health care policies, approximately 50% of newly diagnosed HIV-infected individuals continue to present late for HIV care. Identifying factors associated with occult HIV infection is crucial in order to improve targeted HIV testing strategies and achieve earlier detection. We analysed antimicrobial prescriptions in the three years preceding the HIV diagnosis assessing whether there was a higher consumption in those diagnosed with HIV and whether the consumption was associated with increased risk of subsequent HIV diagnosis.

Method: We conducted a nested case-control study from national registers, identifying all individuals diagnosed with HIV in Denmark during 1998–2016 (N=2,784 cases) and 13 age- and gender-matched population controls per case (N=36,192 controls). Antimicrobial prescriptions were estimated as defined daily doses (DDD) per person-year (PYR). We used conditional logistic regression to compute odds ratios (OR) and 95% confidence intervals (CI).

Results: In the three years preceding the HIV diagnosis we observed a more frequent and higher consumption of some antimicrobials in cases compared to controls, with 72.4% vs. 46.3% respectively having had at least one prescription (p<0.001) (Table and Figs. 1–2). For all antimicrobial classes analysed, we found a statistically significant association between consumption and the risk of subsequent HIV diagnosis (p<0.001) (Fig. 3). The association was stronger with higher consumption, with some antimicrobials and with shorter time to HIV diagnosis. The correlation was more pronounced for males and among those presenting with late-stage HIV infection.

Conclusion: HIV-infected individuals have a significantly higher use of some antimicrobial drugs in the three years preceding HIV diagnosis than their age- and gender-matched controls. Prescription of antimicrobials in primary health care could be regarded as surrogate marker of occult HIV infection and an opportunity to consider proactive HIV testing. Further studies are needed to identify optimal prescription cut-offs, that could endorse its inclusion in public health policies.

Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>HIV N=2784</th>
<th>Controls N=36192</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, n (%)</td>
<td>2237 (80.4)</td>
<td>29081 (80.4)</td>
</tr>
<tr>
<td>Age at HIV diagnosis, median years (IQR)</td>
<td>39 (32–48)</td>
<td>39 (32–48)</td>
</tr>
<tr>
<td>CD4 + cell count at study median cells/µL (IQR)</td>
<td>330 (130–540)</td>
<td>–</td>
</tr>
<tr>
<td>VL at study inclusion, median log10 copies/mL (IQR)</td>
<td>4.8 (4.1–5.4)</td>
<td>–</td>
</tr>
<tr>
<td>Antimicrobial prescription in the study period (yes)</td>
<td>2015 (72.4)</td>
<td>16750 (46.3)</td>
</tr>
<tr>
<td>Antibiotics, n (%)</td>
<td>1895 (68.1)</td>
<td>15973 (44.1)</td>
</tr>
<tr>
<td>Antiviral, n (%)</td>
<td>353 (12.7)</td>
<td>736 (2.0)</td>
</tr>
<tr>
<td>Antifungals, n (%)</td>
<td>382 (13.7)</td>
<td>1563 (4.3)</td>
</tr>
</tbody>
</table>

Figure 1. Antimicrobial drug prescription in the three years prior to HIV diagnosis for cases and controls

Figure 2a,b,c. Prescription of antimicrobials for cases and controls in the 3 years prior to HIV dx.
However, bNAb monotherapy selects for antibody-resistant viral variants. Thus, we focused on the identification of new antibody combinations and/or novel bNAbs that restrict pathways of HIV-1 escape.

Methods: We screened HIV-1 positive patients for their neutralizing capacities. Following, we performed single cell sorting and PCR of HIV-1 Env-reactive mature B cells of identified elite neutralizers. Found antibodies were tested for neutralization and binding capacities in vitro. Further, their antiviral activity was tested in an HIV-1 infected humanized mouse model.

Results: Here we report the isolation of antibody 1-18, a VH1-46-encoded CD4 binding site (CD4bs) bNAb identified in an individual ranking among the top 1% neutralizers of 2,274 HIV-1-infected subjects. Tested on a 119-virus panel, 1-18 showed to be exceptionally broad and potent with a coverage of 97% and a mean IC50 of 0.048 μg/mL, exceeding the activity of most potent CD4bs bNAbs described to-date. A 2.4 Å cryo-EM structure of 1–18 bound to a native-like Env trimer revealed that it interacts with HIV-1 env similar to other CD4bs bNAbs, but includes additional contacts to the V3 loop of the adjacent protomer. Notably, in vitro, 1–18 maintained activity against viruses carrying mutations associated with escape from VRC01-class bNAbs. Further, its HIV-1 env wide escape profile differed critically from other CD4bs bNAbs. In humanized mice, monotherapy with 1–18 was sufficient to prevent the development of viral escape variants that rapidly emerged during treatment with other CD4bs bNAbs. Finally, 1–18 overcame classical HIV-1 mutations that are driven by VRC01-like bNAbs in vivo.

Conclusion: 1–18 is a highly potent and broad bNAb that restricts escape and overcomes frequent CD4bs escape pathways, providing new options for bNAb combinations to prevent and treat HIV-1 infection.

BPD3/4

Novel highly potent CD4bs bNAb with restricted pathway to HIV-1 escape

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Purpose: Broadly HIV-1 neutralizing antibodies (bNAbs) can suppress viremia in humans and represent a novel approach for effective immunotherapy.

However, bNAb monotherapy selects for antibody-resistant viral variants. Thus, we focused on the identification of new antibody combinations and/or novel bNAbs that restrict pathways of HIV-1 escape.

Methods: We screened HIV-1 positive patients for their neutralizing capacities. Following, we performed single cell sorting and PCR of HIV-1 Env-reactive mature B cells of identified elite neutralizers. Found antibodies were tested for neutralization and binding capacities in vitro. Further, their antiviral activity was tested in an HIV-1 infected humanized mouse model.

Results: Here we report the isolation of antibody 1-18, a VH1-46-encoded CD4 binding site (CD4bs) bNAb identified in an individual ranking among the top 1% neutralizers of 2,274 HIV-1-infected subjects. Tested on a 119-virus panel, 1-18 showed to be exceptionally broad and potent with a coverage of 97% and a mean IC50 of 0.048 μg/mL, exceeding the activity of most potent CD4bs bNAbs described to-date. A 2.4 Å cryo-EM structure of 1–18 bound to a native-like Env trimer revealed that it interacts with HIV-1 env similar to other CD4bs bNAbs, but includes additional contacts to the V3 loop of the adjacent protomer. Notably, in vitro, 1–18 maintained activity against viruses carrying mutations associated with escape from VRC01-class bNAbs. Further, its HIV-1 env wide escape profile differed critically from other CD4bs bNAbs. In humanized mice, monotherapy with 1–18 was sufficient to prevent the development of viral escape variants that rapidly emerged during treatment with other CD4bs bNAbs. Finally, 1–18 overcame classical HIV-1 mutations that are driven by VRC01-like bNAbs in vivo.

Conclusion: 1–18 is a highly potent and broad bNAb that restricts escape and overcomes frequent CD4bs escape pathways, providing new options for bNAb combinations to prevent and treat HIV-1 infection.

BPD3/5

Effect of norethisterone, combined contraceptive vaginal ring (CCVR) and COCPs on HIV cervical target cells in adolescent girls: a randomized crossover study

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Purpose: Majority of new HIV infections in Sub-Saharan Africa occur in adolescent girls and young women, who are also at risk for unintended pregnancies. While a variety of contraceptives are available, the use of progestin-only injectables particularly DMPA, have been associated with increased risk of HIV acquisition. Although the ECHO trial recently revealed that women on DMPA are no more likely to acquire HIV than those using other long-acting methods. We aimed to investigate the effects of NET-EN, combined contraceptive vaginal ring (CCVR) and combined oral contraceptive pills (COCPs) on the frequencies of endocervical T cells, and their expression of CCR5, HLA-DR and CD38.

Methods: Adolescent females (n=130; 15–19 years) were randomized 1:1:1 to receive either NET-EN, CCVR, or COCPs, and followed for a total of 32-weeks, crossing over to another HC at 16-weeks. Cervical cytobrush-derived T cells were analyzed by flow cytometry for the expression of CCR5 (HIV co-receptor) and activation markers (HLA-DR and CD38). Paired data was performed using the Wilcoxon signed-rank non-parametric test.

Results: Between baseline and crossover, initiation of CCVR was associated with increased proportions of cervical CD4+ T cells that expressed CD38 singly (p=0.01), and HLA-DR together with CD38 (p=0.03), despite decreased overall frequencies of CD4 + T cells compared to NET-EN and COCPs use. In addition, both CCVR and NET-EN users had increased proportions of CD8 + CD38 + T cells (p=0.01). Interestingly, expression of HLA-DR on CD8 + T cells was reduced at week 16 compared to baseline in all the HC arms.

Conclusion: Although all HC altered the phenotype of cervical CD8 + T cells, the use of the CCVR increased the activation (CD38+) of both cervical CD4+ and CD8+ T cells in adolescent girls. The use of the CCVR in adolescents at high risk of HIV warrants further investigation.
Access to and models of care

PE1/1
Barriers in TB services for people living with HIV and overcoming them according to the health care workers opinion in the TB facilities in Russia (sociological study)
Z Zagyda and A Kulizhka
Saint Petersburg Research Institute of Phthisiopulmonology, St. Petersburg, Russia

Introduction: The increase in HIV/TB with background of the HIV epidemic progression requires improvement in tuberculosis (TB) care for people living with HIV (PLWH). Sociological studies among specialists of TB facilities related to HIV/TB in Russia are limited. We found only one publication where, according to a questionnaire survey the activity and structure of most TB facilities in several Russian regions did not meet the required standards in TB services for PLWH.

Purpose: To identify barriers in TB services to PLWH and ways to overcome them, the opinions of specialists in TB facilities was surveyed using a questionnaire in 4 territories of Russia – St. Petersburg, Leningrad, Kaliningrad and Arkhangelsk oblasts.

Method: The total number of participants in the study was 284 people. Each respondent have signed the informed consent. The survey toolkit was a questionnaire online survey using a Google form, followed by automatic statistical processing of information. The questionnaire consisted of 19 structured questions, divided into blocks, of which 5 questions were open with the possibility of free expression of the respondent’s opinion and 11 questions – closed with alternative answer for respondent choice.

Results: According to the specialists’ opinion in TB facilities, the main barriers to provide TB services for PLWH are: low level of stakeholders interaction, especially with nargoclastic dispensaries (49.0%), prison system (35.2%) and Nongovernmental Organizations (32.7%), migration (48.6% – in Kaliningrad oblast), increase in the number of injecting drug users (76.0% - in Leningrad oblast), lack of regional government support (34.9% – in total), legal acts inconsistency with reality (51.1% – in total).

Conclusion: Currently the TB services providing for PLWH are imperfect. TB system enhancing is associated with the strengthening of stakeholders collaboration, providing a full ART and TB chemoprophylaxis and effective and affordable TB treatment in patients with HIV, including establishment of low-threshold centers.

PE1/2
Investigating the impact of peer counseling intervention on access and use of sexual and reproductive health services in women Living with HIV in Nepal: a prospective cohort study
K Pokhrel1, K Gaule Pokhrel2 and VD Sharma3
1Integrated Development Foundation Nepal, Kathmandu, Nepal
2Integrated development Foundation, HIV and Mental Health, Kathmandu, Nepal
3Institute of Medicine, Tribhuvan University, Psychiatry and Mental Health, Kathmandu, Nepal

Purpose: Women living with HIV experience inadequate access and treatment to sexual and reproductive health in resource-limited settings. Evidence is limited about the effects of peer counseling on access and use of contraceptive services, treatment of sexually transmitted infections, and unintended pregnancies in women with HIV. Therefore, this study aimed to examine the effect of HIV women led counseling to their peers on access and use of the sexual and reproductive health services in Nepal.

Method: A prospective cohort study was performed among 630 HIV-positive women (Intervention: 315; Control: 315) of major six cities of Nepal between June and November 2018. Women were provided counseling on sexual and reproductive health problems and facility-based services. Women were interviewed using semi-structure questionnaires about access, barrier, stigma, and utilization of services. Generalized estimating equation examined the effects of intervention comparing with control groups after adjusting sociodemographics.

Results: Of 630 women living with HIV, 22.2% (n=140) reported to have Sexually Transmitted Infections, 46% (n=290) had felt stigma and 52% (n=328) women did not seek sexual and reproductive health services prior to the intervention. Women in the intervention had significantly lower level of stigma in accessing health facility compared to the control (Adjusted odds ratio (AOR): 2.8; 95% confidence interval (CI): 1.6–3.9). Condom use during last sexual intercourse also significantly increased from baseline to the end among women in intervention compared to control (AOR: 3.4; 95% CI: 2.1–5.3).

Conclusion: Counseling and support from HIV women peer was effective to reduce self-stigma and improve use of services for sexual transmitted infections and condom use. Access and utilization of services can be improved by providing tailor made training to peers. Existing health system services can be improved through the community-based peer counseling approaches integrating in existing health system.

PE1/3
Health care delivery for HIV-positive people with tuberculosis in Europe
A Bentzon1, A Panteleva2, V Mitsura3, E Borodulina4, A Skrahina5, E Derisova6, S Tetradow7, R Podlasin8, V Rieks11, Z Kanczukiew11, D Paduta11, A Mocroft12, T Trofimova11, R Miller14, F Post15, A Grezescuz16, J Lundgren1, M Inglot17, D Podlekaeva11, N Bolokadze18, O Kirk1 and TS Group

1Saint Petersburg Research Institute of Phthisiopulmonology, St. Petersburg, Russian Federation
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5Gomel State Medical University, Gomel, Belarus
6Samara State Medical University of Minzrat of Russia, Department of Phthisiology and Pulmonology, Samara, Russian Federation
7Republican Research and Practical Centre for Pulmonology, Minsk, Belarus
8Botkin Hospital of Infectious Disease, St. Petersburg, Russian Federation
9Dr. Victor Babes Hospital, Bucharest, Romania
10Centre for Communicable Diseases and AIDS, Vilnius, Lithuania
11Gomel Region Centre for Hygiene, Svetlogorsk, Belarus
12University College London, Department of Infection and Population Health, London, UK
13Centre for Prevention and Control of AIDS, Novgorod, Russian Federation
14Mortimer Market Centre, London, UK
15King’s College Hospital, London, UK
16Medical University Teaching Hospital, Bialystok, Poland
17Wroclaw University School of Medicine, Wroclaw, Poland
18Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia

Purpose: To analyze differences in tuberculosis (TB) and HIV services in Eastern Europe (EE) vs. Western Europe (WE).

Method: Twenty-three clinics completed a survey on management of HIV/TB coinfected patients in 2018 (EE: 14, WE: 9; 88% response rate). Results of the survey were compared to data from a similar survey in 2013.

Results: Delivery of health care was significantly less integrated in EE: provision of TB and HIV services in the same clinic (35.7% in EE vs. 88.9% in WE; p=0.034), treatment of both diseases by the same doctor (28.6% vs. 100%; p=0.002), and continued TB follow-up in one location (42% vs. 100%; p=0.007). Although access to TB diagnostics and standard TB drugs was good in both regions, fewer clinics in EE reported unlimited access to rifabutin and drugs to treat MDR-TB. Opioid substitution therapy (OST) was less commonly available for all in need in EE (42.9% vs. 100%; p=0.037). Integrase inhibitors based HIV treatment regimens were indicated as a possibility in 50% in EE and 100% in WE, p=0.02.

In EE, routine usage of GeneXpert improved from 2013 to 2018 (53.8% vs. 92.3%; p=0.073), as did access to moxifloxacin (46% vs. 91%, p=0.033), linezolid (31% vs. 64%, p=0.217), and bedaquiline (0% vs. 25%, p=0.217), while integration of TB and HIV services (46.2% vs. 38.5%; p=1.000) and provision of OST to all in need (54% vs. 46%; p=0.693) did not improve.

Conclusion: Delivery of TB and HIV health care still differ between WE and EE, although availability of rapid TB diagnostics and availability of standard TB therapy improved in EE. By contrast, little progress was made towards integration of TB and HIV care, and access to drugs to treat MDR-TB remains highly variable.
PE1/4

A survey of physicians on circumstances and factors influencing testing for HIV in Lithuania

I Kubiliute 1, E Matutlyte 2, K Zagminas 3, A Rackauskaiene 4, G Kubiliunaite 5 and R Matulionyte 1,2

1 Vilnius University, Faculty of Medicine, Institute of Clinical Medicine, Department of Infectious Diseases and Dermatovenerology, Vilnius, Lithuania
2 Vilnius University Hospital Santaros Klinikos, Infectious Diseases Centre, Vilnius, Lithuania
3 Vilnius University, Faculty of Medicine, Institute of Health Sciences, Department of Public Health, Vilnius, Lithuania
4 Central Policlinic, Vilnius, Lithuania
5 University of Ghana, Department of Psychiatry, Accra, Ghana

Abstract Book 2019 – Abstract Book

Results: Phenomenological Analysis.

One-to-one, in-depth interviews were conducted with 15 PLWHA living with HIV/AIDS.

Purpose: To explore lived experiences of forgiveness/unforgiveness of HIV-specific offenses among people living with HIV/AIDS in Ghana.

Methods: Anonymous questionnaire-based survey was conducted among physicians and residents in nine clinics in four cities: Accra, Kumasi, Tema and Takoradi.

Results: 620 questionnaires were distributed, 599 returned, 594 suitable for analysis. Respondents were divided into the groups by city (Accra 67.7%, Kumasi 14.2%, Tema 12.5%, Takoradi 5.6%).

Conclusion: Physicians apply IC-guided testing insufficiently, but are open for integrated care models.

Purpose: Assess the circumstances and factors influencing testing for HIV among Ukrainian physicians.

Methods: Anonymous questionnaire-based survey was conducted among physicians and residents in nine clinics in four cities: June—September, 2018. The test-retest of the questionnaire was conducted before the investigation to determine questionnaire reliability. Correlation coefficient was from very good (25.4%) to moderate (14.1%) in all question categories. Chi-square and Fisher’s tests were used to compare categorical variables.

Results: 491 questionnaires were distributed, 384 returned, 371 suitable for analysis. Respondents were divided into the groups by city (Vilnius 47.5%, others 32.3%), position (position 74.1%, resident 25.9%), specialty: work experience (0–20 years 56.1%, >20 years 43.9%), workplace (in-patient 38.8%, out-patient 36.7%, both 23.5%). Forty-one percent of respondents prescribe 0 test/month, 48% - 1–5 tests/month. HIV risk factors are the main reason for testing (84.9%), followed by indicator conditions (ICS) (63.1%). The most common 22 given HIV ICs for which respondents would test for HIV was unexplained persistent lymphadenopathy (69.3%), unexplained leukocytopenia/thrombocytopenia (66.8%), hepatitis C (HCV) (66.3%), sexually transmitted infection (STI) (65.0%); the most uncommon - seborrhoeic dermatitis (5.7%), community acquired pneumonia (8.9%), severe or atypical psoriasis (10.8%). On average a physician would test for HIV in 8.4 (38%) ICs, would never test in 6.0 (27%) ICs. ICs are a more frequent testing motive for internal medicine specialists compared to other specialties (71.7% vs. 56.6%, p<0.003), for residents compared to physicians (75.0% vs. 61.5%, p=0.017). Among respondents, 49.9% indicated no barriers for testing, 20.8% - lack of knowledge, 20.2% – testing price.

Conclusion: The main reason for testing in Ghana remains HIV risk factors.

Physicians apply IC-guided testing insufficiently, but are open for integrated HIV testing in HCV infection and STIs. The lack of knowledge is the major barrier demonstrating a need for broader dissemination of information on HIV.

PE1/5

Experiences of forgiveness and unforgiveness of HIV-specific offenses among people living with HIV/AIDS in Ghana

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5 University of Ghana, Psychiatry, Accra, Ghana
6 University of Ghana, Psychology, Accra, Ghana
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Purpose: To explore lived experiences of forgiveness/unforgiveness of HIV-specific offenses and meaning of these experiences among people living with HIV/AIDS.

Method: One-to-one, in-depth interviews were conducted with 15 PLWHA receiving antiretroviral therapy across the Korle-Bu, Komfo Anokye, and Tamale Teaching Hospitals in Ghana. Data were analysed using Interpretative Phenomenological Analysis.

Results: Four main themes emerged: (1) Behavioural, Spiritual, and Situational offenses; (2) Positive Personal and Interpersonal changes; (3) Restoration; and (4) Motivation for Positive and Purposeful living. Regarding theme (1), participants’ most perceived HIV-related offense concerned the sexual behaviours of their partners (which led to their HIV+ status). Past risky lifestyles and discrimination by significant others were other behavioural offenses experienced. The belief that God allowed one’s HIV+ status, and the financial, laboratory, and adherence demands of ART, respectively, constituted spiritual and situational offenses experienced. These often led to unforgiveness. Unforgiveness was characterized by reports of prolonged hurt, painful rumination, fear, and unhappiness, which were associated with poor concentration, social relationships, body image, and life-goal achievements. Regarding theme (2), participants described forgiveness of their perceived HIV-related offenses as personal changes in their thoughts (e.g., deciding to let go of retaliation and remove hatred/pain from their heart) and emotions (e.g., feeling free in mind, at peace, happy, and as if a burden has been lifted off); and offender-oriented, positive-behaviour changes (e.g., greeting, talking to, and laughing with offender). Regarding theme (3), to forgive meant to have one’s physical/mental health, body-image, social relationships, family structure, and self-value/efficacy restored. Regarding theme (4), forgiving also meant increased motivation to live life, engage in ART-adherence and HIV-protective behaviours, and pursue significant career and family aspirations.

Conclusion: Forgiveness is one stress-relieving strategy for coping with offenses that holds implications for the health/wellbeing of PLWHA. The results hold significant implications for HIV/AIDS counselling models, collectivistic forgiveness coping, and stress-positive emotions-health research.

PE1/6

Time to antiretroviral therapy: service model adaptation during an outbreak of HIV in people who inject drugs (PWIDs)

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Purpose: There is currently an ongoing and extensive outbreak of HIV amongst people who inject drugs (PWIDs) in Glasgow City, Scotland, comprising over 150 cases. Viral sequencing revealed the majority of cases were Clade C virus with similar drug resistant mutations. Early initiation of antiretroviral therapy (ART) has both individual health benefits and population benefits as ‘treatment as prevention’. This vulnerable cohort have difficulty accessing to optimal HIV care, and the national model for ART does not offer the level of support and services required. The aim was to investigate the current service model for ART in Glasgow and make recommendations for improvement.

Method: A mixed methods approach was used. Qualitative data were collected through semistructured interviews with 16 healthcare professionals from two clinics in Glasgow, and a series of focus groups with PWIDs in the area. A focus group with key stakeholders was also conducted. Quantitative data were collected through electronic patient records and analysed. Time to serological HIV diagnosis to ART initiation was recorded and compared across the two time periods.

Results: 155 patients were diagnosed between April 2014 and June 2019. 53/155 (34%) were female. Mean age was 42. 10 were removed from analysis due to death or moved HIV care. The median time from HIV diagnosis to ART initiation has reduced from 324 days in 2015 to 24 days in 2019.

Figure 1. Time from HIV diagnosis to ART initiation by year of diagnosis.
Conclusion: In the midst of an HIV epidemic, we have shown that adaptation of service delivery can reduce time to ART initiation, with the aims of viral suppression, reduction in morbidity and prevention of onward transmission of HIV. This complex patient group require novel approaches to delivery of HIV care.

PE1/7

HIV infection hospital-based active case finding in Sardinia, Italy: results from the SHOT project

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Purpose: Many evidences suggest that some diseases occur more frequently in HIV-infected individuals and could represent target conditions to increase diagnosis in unaware patients. The aim of our study was to increase HIV-diagnosis by indicator condition based HIV-testing in Hospital settings.

Method: The SHOT project is a prospective, observational study, started in 2017. Patients were enrolled based on the presence of target conditions from the Units of Infectious Diseases (ID), Hematology, Respiratory Diseases (RD), Dermatology, Internal Medicine (IM) and Oncology (ON) of the University of Sassari. HIV positive individuals were evaluated by an ID nurse and specialist during hospitalization and linked to care.

Results: We enrolled 300 individuals during the first 27 months of study, 202 males and 98 females. The main reasons for screening were fever, non-Hodgkin lymphoma, lymphadenopathy, acute or chronic HCV/HIV infection, sexually transmitted diseases and pneumonia. We diagnosed 11/300 (3.68%) new cases of HIV infection, 4 were females and 7 were males. Five had a CD4 count <100/mm³, one <200/mm³, one >300/mm³, two >500/mm³ and two >800/mm³. Eight out of 11 had a viral load >100,000 cp/mL. Data about CD4 count of a 41-years-old woman who has been diagnosed few days ago are pending. Among AIDS presenters, CDC stage was C3 in 4 and C2 in one patient. 90% referred a sexual exposure, 55% of them were heterosexuals.

Conclusion: We recorded an unexpectedly high number of new HIV diagnoses when considering the small number of individuals tested. Although most patients were diagnosed with advanced stage infection, at least 4 cases, including an acute HIV infection, would have been undiagnosed if not included in the study. Proactive testing may increase the diagnosis among unaware HIV-infected patients in hospital settings.

PE1/8

Retention activities based on home visits as a tool of return and keeping in care of low adhered patients. Results of work 2016–2019 Krasnoyarsk AIDS clinic

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Purpose: Retention in care of low adherent clients is one of the main challenges in HIV care. Services that address social needs of PLWH and retention activities are recommended by WHO to be included into comprehensive integrated HIV care

Method: We analyzed efficiency of social support model developed in Krasnoyarsk AIDS center in collaboration with AHF Russia in 2016–2018 years and analyzed the number of clients who returned to HIV care, started ART and their retention. Interventions implemented in the framework of the program included: home visits, phone calls, reminder phone calls, home visits with social worker, psychologist and HIV physician follow up

Results: 4,621 clients who stopped visiting AIDS clinic more than 6 months earlier or missed ART within 3 months between 2016 and 2019, were included into this analysis. 8,430 home visits were done, 2,918 home consultation were provided, 4,370 phone consultations were provided for clients, their relatives, close friends, and partners. 2,701 (61.8%) clients returned to regular HIV clinic visits, 1,373 (51%) re-started ART within 30 days. 351 patient were provided with social support services. Out of all clients 207 deceased, 70 were found out as imprisoned, 401 (8.7%) clients refused social support. 170 clients moved to another region.

Conclusion: Social services with home visits and follow up for clients who are lost to follow up from HIV care show to be an effective way to return clients to HIV care and re-start ART. Retention in care of that group plays an essential role in the epidemic control as well as OIs and TB prevention. Social support should be adapted as integral part of an HIV care program
treatment on sexual risk behavior. Few studies have examined the effect of ART on sexual risk behavior in sub-Saharan Africa.

Method: We conducted a prospective cohort analysis to test the hypothesis that ART use would be associated with increased sexual risk behavior among female sex workers in Uvira, Congo, in the cohort were invited to return for monthly follow-up including a standardized interview about sexual risk behavior. They received basic HIV care, sexual risk reduction counseling, and free condoms. Data from 1993–2008 were included in this analysis. Since 2006, ART has been offered to women in the cohort who qualify for treatment according to the Congolese National Guidelines. We compared sexual risk behavior during ART-naive versus ART-exposed follow-up using generalized estimating equations.

Results: Of the 899 HIV-seropositive women included in this analysis, 147 (16.4%) initiated ART. The women accrued 2,380 person-years of follow-up. The median number of visits was 10 (IQR 3–27) and the median interval between visits was 33 days (IQR 29–49). In analyses adjusted for calendar year, there was no increase in reported unprotected sex (aOR 0.74, 95% CI 0.53–1.02). Women on ART were significantly more likely to report 100% condom use (aOR 1.69, 95% CI 1.17–2.44) and less likely to report multiple partners (aOR 0.77, 95% CI 0.60–0.98). Sex frequency was similar during ART-naive and ART-treated periods of follow-up.

Conclusion: In the setting of ongoing sexual risk reduction counseling and provision of free condoms, the introduction of ART did not increase sexual risk behaviour. On the contrary, while the overall level of sexual activity remained stable, condom use increased and there was a reduction in the number of sexual partners.

PE2/3

Effectiveness, persistence and safety of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/FTAF), F/TAF + 3rd agent or rilpivirine/FTAF (R/FTAF) in treatment-naive HIV-1 infected patients – 24-month results from the German TAFNES cohort study

R Pauli1, H Jessen2, N Postel3, T Heuchel1, A Rieke1, H Hillenbrand2, T Kuenemerte4, S Schreiber5, K Goerner6, M HeinzkiI7, R Haubrich8 and H-J Stellbrink9

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Purpose: The prospective TAFNES cohort study was initiated to evaluate the effectiveness and safety of FTAF-based single-tablet (STR) or multi-tablet regimens (MTR) in people living with HIV (PLHIV) in a real-life setting.

Methods: The analysis population consisted of treatment-naive (TN) PLHIV receiving E/C/FTAF, F/TAF + 3rd agent or R/FTAF ≥21 months prior to data cut (03/31/2019). 24-month outcome measures included ART persistence (Kaplan–Meier estimate), virologic effectiveness (HIV-RNA < 50 cp/mL), discontinuation=failure, loss-to-follow-up/withdrawal consent missing=excluded, (non-)serious adverse drug reactions (ADRs)/SADRs and health-related quality of life (HRQL).

Results: Of 247 TN patients (95% men, median age 36 years) eligible for analysis, 150 patients received E/C/FTAF, 69 patients F/TAF + 3rd agent (86% dolutegravir, 7% darunavir/ritonavir, 4% raltegravir, 3% other), 28 patients R/FTAF. Late presentation was common in the E/C/FTAF and F/TAF + 3rd agent groups (Table 1).

Overall persistence was 83% (E/C/FTAF 85%, F/TAF + 3rd agent 79%, R/FTAF 84%); 32% of patients (n=78/247) discontinued before month 24 [including discontinuation of FTAF-based regimens due to ADRs [3.6%], drug-drug interactions [2.4%], therapy simplification [2.0%] or virologic failure [1.6%], and loss-to-follow-up [14.2%] (Table 2)]. At month 24, 80% of patients (n=161/202) had HIV-RNA < 50 cp/mL (83% of patients treated with E/C/FTAF (n=103/124), 72% of patients treated with F/TAF + 3rd agent (n=39/54), 79% of patients treated with R/FTAF (n=19/24)). By month 24, 26 ADRs [including one virologic failure classified as SADR] were documented in 19 patients (7.7%).

Overall HRQL outcomes indicated improvements in HIV Symptom Index (HIV-SI) and in the mental and physical components of the SF-36 questionnaire (Table 3).

Conclusion: Persistence was high with FTAF-based in treatment-naive PLHIV in the TAFNES cohort. Overall virologic effectiveness was ≥80% two years after treatment initiation with only 2% virologic failure and low discontinuation rates (< 4%) due to ADRs. Improvements in self-reported HRQL and symptoms after 24 months of treatment illustrate the safety and effectiveness of FTAF-based regimens in clinical routine care.

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Overall</th>
<th>E/C/FTAF</th>
<th>F/TAF + 3rd agent</th>
<th>R/FTAF**</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-RNA, log cp/mL, median (IQR)</td>
<td>4.4 [4.0–5.1]</td>
<td>4.3 [3.9–4.9]</td>
<td>5.1 [4.3–5.6]</td>
</tr>
</tbody>
</table>

*defined as ≤350 CD4/μL and/or AIDS; **groups not comparable due to different inclusion criteria.
Table 2. Reasons for discontinuation

<table>
<thead>
<tr>
<th>Discontinuations by month 24, n/N (%)</th>
<th>Overall</th>
<th>EC/FTAF</th>
<th>F/TAF + 3rd agent</th>
<th>R/TAF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>78/247</td>
<td>43/150</td>
<td>27/69</td>
<td>8/28</td>
</tr>
<tr>
<td>Reason for ADR and drug-drug-interaction</td>
<td>(32)</td>
<td>(29)</td>
<td>(29)</td>
<td>(29)</td>
</tr>
<tr>
<td>virologic failure</td>
<td>9 (3.6)</td>
<td>5 (3.3)</td>
<td>3 (4.3)</td>
<td>1 (3.6)</td>
</tr>
<tr>
<td>therapy</td>
<td>6 (2.4)</td>
<td>5 (3.3)</td>
<td>0 (0.0)</td>
<td>1 (3.6)</td>
</tr>
<tr>
<td>simplification</td>
<td>5 (2.0)</td>
<td>2 (1.3)</td>
<td>2 (2.9)</td>
<td>1 (3.6)</td>
</tr>
<tr>
<td>investigator decision</td>
<td>9 (3.6)</td>
<td>5 (3.3)</td>
<td>3 (4.3)</td>
<td>1 (3.6)</td>
</tr>
<tr>
<td>other/unknown</td>
<td>5 (2.0)</td>
<td>2 (1.3)</td>
<td>2 (2.9)</td>
<td>1 (3.6)</td>
</tr>
<tr>
<td>withdrew consent</td>
<td>35 (14.2)</td>
<td>20 (13.3)</td>
<td>11 (15.9)</td>
<td>4 (14.3)</td>
</tr>
</tbody>
</table>

Table 3. SF-36/HIV-SI outcomes in patients with completed questionnaires at baseline (BL) & month 24

PE2/4

"Attracting men" - extended clinic hours as differentiated model of care in an urban Malawian cohort

S Phiri1, H Tweya1 and C Trapence1

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Purpose: Male HIV patients initiate antiretroviral therapy (ART) later and are less adherent to ART than females. One known explanation is that males are the primary providers who often work during regular clinic hours. Several studies have shown that busy schedules are associated with high rates of ART treatment interruption. As a model of HIV care, Lighthouse Trust started providing extended hours as a differentiated service model targeting those who may fail to receive medications due to work.

Method: Bwaila is a large ART clinic in Lilongwe, with 21917 patients alive in 2017. The clinic started offering extended service hours till 19:00. All patients data at this facility is managed in real-time using the electronic medical record system (EMR). From the EMR, we extracted HIV patients visit data for 2017. The visits were categorized into "regular hours" (06:00 to 16:30) and "extended hours" (16:31 till 19:00) and "weekend". The proportion of visits attended by males in the regular hours were compared to the extended and weekend services using a two-proportion z-test.

Results: The proportion of men attending "extended hours" was 49% (6,862/14,023), significantly higher compared to the proportion of men during regular hours [36%(8242/21917), p<0.001]. By age, the increase was most pronounced in the ages 25–34 years (38% vs. 24%, p<0.001) and 35–50 years (58% vs. 44%). In addition, during the weekend services, a significantly higher proportion of men were seen in the ages 35–50 (49% vs. 44%, p<0.001) and above 50 years (67% vs. 56%, p<0.001). Conclusion: Extending clinic hours in the public ART program provide opportunity for patients on ART to have access to treatment and care beside their busy work. This seems to be particularly attractive to men.

PE2/5

HIV care in India: a systematic review of barriers to anti-retroviral therapy adherence

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Purpose: To determine the barriers to adherence to ART among HIV/AIDS patients in New Delhi, India.

Method: 21 observational studies published in India from January 2014 to March 2019 were selected which were fulfilling inclusion criteria. Searches were conducted in MEDLINE, EMBASE and PsycINFO. Searches were limited to English-language articles, using combinations of the terms: HIV, ART, adherence and barriers. Study characteristics were tabulated by summing the number of studies region wise and then stratifying by study outcome. Factors that might influence adherence like health status, beliefs and perceptions, and health risks were also studied. Ethical clearance was obtained from Institutional Ethics Committee.

Results: All studies used quantitative research methods (mainly cross-sectional study design). ART adherence outcomes were assessed using pharmacy records (pill count method, self-reported adherence and viral load). Non-adherence to ART was significantly associated with younger age, female gender, lower socio economic status, homelessness and duration of ART. Among young males, substance use were associated with poor adherence across studies, including heroin and alcohol use.

Conclusion: HIV treatment adherence is key issue of good outcome. This review suggests that urgent interventions are needed to improve treatment adherence especially among vulnerable groups.
there were no deaths, two virologic failures and eight treatment changes due to toxicity. Conclusion: Estimates of relative effectiveness suggest that both dolutegravir regimens are not inferior to the alternative regimens used previously. Updated analyses show the stability of the earliest estimates with a slight gain in precision with each update.

Table 1. Analyses of an emulated trial comparing two partly NRTI-sparing regimens.

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Initial analysis</th>
<th>One year later</th>
<th>Two years later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events among cases</td>
<td>3/58</td>
<td>13/86</td>
<td>20/112</td>
</tr>
<tr>
<td>Event rate among cases, per 100PY</td>
<td>7.9</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Events among controls</td>
<td>9/17</td>
<td>11/22</td>
<td>17/27</td>
</tr>
<tr>
<td>Event rate among controls, per 100PY</td>
<td>53</td>
<td>53</td>
<td>53</td>
</tr>
<tr>
<td>Hazard ratio (95% CrI)</td>
<td>0.34 (0.13, 0.83)</td>
<td>0.48 (0.24, 1.0)</td>
<td>0.43 (0.24, 0.78)</td>
</tr>
<tr>
<td>On treatment and undetectable: difference at 48 weeks (95% CI),%</td>
<td>15 (2, 33)</td>
<td>12 (0, 26)</td>
<td>15 (4, 28)</td>
</tr>
</tbody>
</table>

Abbreviations: NRTI, nucleoside (or nucleotide) reverse transcriptase inhibitor; DTG, dolutegravir; DRV/r, darunavir boosted with ritonavir; 3TC/FTC, lamivudine or emtricitabine; PY, patient years.

Table 2. Analyses of an emulated trial comparing two fully NRTI-sparing regimens.

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Initial analysis</th>
<th>One year later</th>
<th>Two years later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events among cases</td>
<td>6/54</td>
<td>13/71</td>
<td>17/77</td>
</tr>
<tr>
<td>Event rate among cases, per 100PY</td>
<td>9.5</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>Events among controls</td>
<td>12/22</td>
<td>14/38</td>
<td>15/39</td>
</tr>
<tr>
<td>Event rate among controls, per 100PY</td>
<td>55</td>
<td>55</td>
<td>55</td>
</tr>
<tr>
<td>Hazard ratio (95% CrI)</td>
<td>0.51 (0.23, 1.1)</td>
<td>0.69 (0.35, 1.3)</td>
<td>0.74 (0.39, 1.4)</td>
</tr>
<tr>
<td>On treatment and undetectable: difference at 48 weeks (95% CI),%</td>
<td>9 (−1, 21)</td>
<td>5 (−4, 15)</td>
<td>4 (−4, 13)</td>
</tr>
</tbody>
</table>

Abbreviations: NRTI, nucleoside (or nucleotide) reverse transcriptase inhibitor; DTG, dolutegravir; DRV/r, darunavir boosted with ritonavir; RAL, raltegravir; PY, patient years.

PE2/8

Simplifying salvage regimens with darunavir-based dual therapy in HIV-infected individuals harboring multidrug-resistance

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Purpose: We assessed the efficacy of simplifying salvage regimens with boosted darunavir plus raltegravir (DRV/b-RAL) in virologically suppressed patients with protease inhibitors (Pis) resistance-associated mutations (RAMs). Method: Retrospective, multicenter cohort study (NCT03348449) on HIV-infected individuals switched to DRV/b-RAL who met the following criteria: plasma HIV-RNA levels≤50 copies/mL for≥12 months, no previous integrase inhibitors failure or resistance, previous PIs failure, and at least one genotypic resistance test (GRT) performed. The primary endpoint was the proportion of patients maintaining HIV-RNA<50 copies/mL at week 96. Efficacy was analyzed according darunavir genotypic sensitivity score (GSS).

Results: Overall, 228 individuals were included (mean age 50 years, men 75%) with a median time of virologic suppression before simplification of 49 months (interquartile range, IQR 39.8–63.5). Patients had a median (range) of 2 (1–3), 4 (3–6), and 5 (2–9) major mutations to non-nucleoside reverse transfer inhibitors, nucleoside reverse transfer inhibitors, and PIs, respectively. One hundred and seventy-seven individuals were darunavir full-susceptible (GSS=2), whereas 51 had reduced susceptibility (GSS=2). Individuals with reduced susceptibility to darunavir had a higher number of PIs-rams (9.3 vs 4.5, p<0.01), and had been suppressed for longer time (median of 61 months, IQR 29–59). At week 96, only 2 individuals (0.9%; 95% confidence interval, CI, 0.4–2.7%) failed to maintain HIV-RNA<50 copies/mL. The efficacy excluding non-virologic reasons was 94.3% (95% CI, 90.2–98.4%), without differences according to GSS (p=0.60). No individual with virologic failure had darunavir-ram at baseline. The median CD4/CD8 ratio increased significantly at week 96 (9.5%); p=0.01), without differences between groups (p=0.57).

Conclusion: The simplification to a dual regimen with boosted darunavir plus raltegravir after a long period of virologic suppression was not associated with higher rates of treatment failure, even in patients with multidrug-resistant HIV infection harboring PIs-RAMS.

PE2/7

Physicians’ opinions on generic antiretroviral drugs and single tablet regimen (STR) de-simplification for the treatment of HIV infection: a multicentre survey in Spain

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Objective: The aim of our study was to assess the attitudes and opinions about generic antiretroviral drugs (ARV) and single-tablet regimen (STR) de-simplification among physicians prescribing HIV treatment in the cohort of the Spanish HIV/AIDS Research Network (CoRIS).
Clinical outcomes among HIV-infected Africans with advanced disease in Spain

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Objectives: To characterize advanced HIV disease (AHD) among African people living with HIV (PLHIV), and to compare its prevalence, clinical-epidemiological characteristics, and outcomes between Africans and individuals from other regions (OtR) living in Spain.

Methods: Prospective cohort study among all adult PLHIV enrolled in Spanish AIDS Research Network Cohort, a multicenter cohort of antiretroviral therapy-naïve PLHIV enrolled in 45 Spanish centers between 2004 and 2017. AHD was defined as having CD4 cell count <200 cells/mm³ at diagnosis; loss to follow-up (LTFU) as not having a visit >12 months after enrollment; and attrition, as death / LTFU. This study is part of an international multi-cohort collaboration to characterize AHD among African PLHIV.

Results: Overall, 13,851 subjects were analysed, including 635 (4.6%) African individuals. Compared with PLHIV from Western Europe (WE), Africans were predominantly women (55% vs. 12.1%, p < 0.0001), had lower median CD4 count (299 [155–477] vs 408 [223–609], p < 0.0001) and higher proportion of AIDS-defining illnesses (19.4% vs. 10.9%, p < 0.0001) at HIV diagnosis. 31% of Africans presented with AHD vs. 22.4% WE and 24.5% OtR (p < 0.0001). Median follow-up was 42 [15–88], 60 [22–105] and 47 [14–91] months among Africans, WE and OtR respectively. Of those with AHD, 12.2% Africans vs 33.2% WE developed non-AIDS comorbidities during follow-up. Among Africans, 42% were kidney-related (8/10, acute renal failure). 44.2% of Africans were LTFU compared with 17.3%, 30.1% WE and OtR respectively. Mortality was documented in 6.6% Africans vs 12.2% WE. Causes of death were more similar by region of origin and mainly HIV/AIDS-related.

Conclusion: AHD is a major concern among African PLHIV in Spain. The high proportion of attrition and the occurrence of renal comorbidities during follow-up are of particular relevance. The lower mortality observed among Africans is likely biased by the higher rates of LTFU in this group.

References:
**PE2/11**

No decrease in CD4/CD8 ratio after 36 months therapy in patients who were switched to two dual regimens containing rilpivirine

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**Purpose**: The CD4/CD8 ratio has been associated with the risk of AIDS and non-AIDS events. Dual therapy is a new option for some patients but information on some aspects like immune activation control is still scarce. We evaluated the impact of two rilpivirine containing dual therapies (DT) on CD4/CD8 in the medium term.

**Method**: Observational, retrospective study including all the patients from an HIV Clinic at the Arnau de Vilanova Hospital in Valencia, Spain, who were switched to DTG+rilpivirine or DRTNc+rilpivirine between January 2014 to December 2016. Patients should have VL<50 for at least 6 months before switch. CD4, CD8 and CD4/CD8 pre switch and after 12, 24, 36 months were recorded. Mean with IC 95%, were calculated for quantitative variables and frequencies for qualitative variables. The two tailed t-test for repeated measures was applied.

**Results**: From a total of 61 patients on DT, 7 were excluded because VL was not undetectable before switch. 54 patients enter in the analysis, 31 of them were on DTG+rilpivirine and 23 were on DRTNc+rilpivirine. The mean (IC95%) age was 51 (49–54) and 50% were men. Patients were undetectable for a mean of 6.61 (IC95% 5.54–7.67) years before switch and the mean of CD4 at switch was 740 (646–834) cell/mm3. Mean time on DT was 33 months. During the follow up one patient had VL>50 in 2 consecutive determinations and it was due to poor adherence. No significant variations for CD4, CD8 and CD4/CD8 after 12, 24 and 36 months were found. The results did not change after stratify analysis by type of therapy (DTG+RLP or DRN+RLP).

**Conclusion**: In patients with suppressed viral load and sustained immune response before switching to a rilpivirine containing DT regimen we did not find any significant change in the CD4/CD8 ratio after 36 months of therapy.

**PE2/12**

Clinical experience of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) in real life practice: data from the Turkish HIV-TR cohort

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1Marmara University Hospital, Istanbul, Turkey 2Haydarpasa Numune Training and Research Hospital, Istanbul, Turkey 3Istanbul University Hospital, Bursa, Turkey 4Ege University Hospital, Izmir, Turkey 5Kartal Lütfi Kirdar Training and Research Hospital, Istanbul, Turkey 6Akdeniz University Hospital, Antalya, Turkey 7Başkent Training and Research Hospital, Izmir, Turkey 8Kocaeli University Hospital, Izmit, Turkey 9Beykoz State Hospital, Istanbul, Turkey 10Ankara Numune Training and Research Hospital, Ankara, Turkey 11Okmeydani Training and Research Hospital, Istanbul, Turkey 12Tepecik Training and Research Hospital, İzmir, Turkey 13Gaziantep University Hospital, Gaziantep, Turkey

**Objectives**: Since its availability in October 2017, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) has been widely used in Turkey. We aimed to describe the effectiveness and tolerability of E/C/F/TAF in a real-life setting.

**Methods**: Observational, retrospective, multicenter cohort study with treatment-naive (TN) and treatment-experienced (TE) HIV patients starting E/C/F/TAF. Clinical, immuno-virological variables, switch reasons and changes in lipids and glomerular filtration rate (eGFR by CKD-EPI formula) were analyzed at month-6 (M6) and –12 (M12). Virologic outcomes were assessed in patients with at least 6 months follow-up by a modified intention-to-treat approach (death or discontinuation of E/C/F/TAF failure, missing data and lost to follow-up-excluded).

**Results**: Baseline characteristics of 1743 persons (34% TN) from 32 HIV clinics are shown in Table 1. Of the 1146 TE patients, 994 (86.7%) were virologically suppressed before switch [viral load (VL)<50 copies/mL]. Main reasons for E/C/F/TAF switch were to prevent future toxicities (46.9%), intolerance/tolerance (17.3%), treatment simplification (15.4%), provider's preference (5.7%), patient's willingness (2.9%), poor compliance (1.5%), virological failure (0.8%), and others (9.5%). At M12, 92.4% (315/341) of TN and 94.8% (674/711) of TE patients had a VL<50 copies/mL. One adverse drug reaction leading to discontinuation (bruisng) and 4 deaths (3 TN and 1 TE patients) not related to E/C/F/TAF were documented during the study period. At M12, median CD4 lymphocyte count increased by 229 and 38 cells/mm³ in TN and TE patients, respectively. In TE patients who switched from tenofovir disoproxil fumarate (TDF) to TAF, fasting lipid values increased compared to baseline while total/HDL cholesterol ratio did not change significantly. Median non-HDL cholesterol increase was 14 mg/dL at M12. Mean change in eGFR at 12 m mean, IC95% (n=53) was 0.42 (−1.15) 0.98 (0.81–1.16). No decrease in CD4/CD8 ratio after 36 months therapy in patients who were switched to two dual regimens containing rilpivirine.

**Conclusion**: E/C/F/TAF had a high virological efficacy in both TN and TE patients and was tolerated very well.

**Table 1. Variations and their statistical significance for CD4, CD8 and CD4/CD8 at switch 12, 24 and 36 months are shown in the table below**

<table>
<thead>
<tr>
<th></th>
<th>At switch mean, IC95% (n=53)</th>
<th>12 months after switch mean, IC95% (n=53)</th>
<th>24 months after switch mean, IC95% (n=53)</th>
<th>36 months after switch mean, IC95% (n=46)</th>
<th>Difference from switch to 12 m mean, IC95% (n=53) p-value</th>
<th>Difference from switch to 24 m mean, IC95% (n=53) p-value</th>
<th>Difference from switch to 36 m mean, IC95% (n=46) p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 Cell count</td>
<td>740 (646–834)</td>
<td>720 (633–806)</td>
<td>755 (647–863)</td>
<td>723 (616–831)</td>
<td>−21 (−87, +46) p=0.53</td>
<td>15 (−75, +105) p=0.73</td>
<td>−2 (−97, +93) p=0.96</td>
</tr>
<tr>
<td>CD4 Cell count</td>
<td>907 (786–1028)</td>
<td>875 (756–958)</td>
<td>898 (775–1021)</td>
<td>851 (742–960)</td>
<td>−50 (−130, +30) p=0.21</td>
<td>−9 (−98, +80) p=0.83</td>
<td>−65 (−166, +35) p=0.19</td>
</tr>
<tr>
<td>CD4/CD8</td>
<td>0.95 (0.79–1.12)</td>
<td>0.94 (0.79–1.09)</td>
<td>0.99 (0.83–1.16)</td>
<td>0.98 (0.81–1.15)</td>
<td>−0.01 (−0.07, +0.05) p=0.66</td>
<td>0.04 (0.1, +0.9) p=0.14</td>
<td>0.04 (−0.05,+0.13) p=0.42</td>
</tr>
</tbody>
</table>

**Table 1. Baseline characteristics of the study population**

<table>
<thead>
<tr>
<th></th>
<th>Overall n (%)</th>
<th>Treatment-naive n (%)</th>
<th>Treatment-experienced n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>1743 (100)</td>
<td>597 (100)</td>
<td>1146 (100)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>1525 (87.5)</td>
<td>536 (89.8)</td>
<td>989 (86.3)</td>
</tr>
<tr>
<td>Age, years, median (IQR)</td>
<td>35 (28–44)</td>
<td>33 (27–43)</td>
<td>35 (29–45)</td>
</tr>
<tr>
<td>Pre-treatment CD4 cells/μL, median (IQR)</td>
<td>568 (369–794)</td>
<td>401.5 (263.5–554)</td>
<td>673 (486–870)</td>
</tr>
<tr>
<td>Pre-treatment HIV-RNA=100,000 copies/mL, n (%)</td>
<td>278 (15.9)</td>
<td>253 (42.4)</td>
<td>25 (2.2)</td>
</tr>
<tr>
<td>Pre-treatment CD4 count&lt;350 cells/μL, n (%)</td>
<td>378 (21.7)</td>
<td>245 (41.0)</td>
<td>133 (11.6)</td>
</tr>
<tr>
<td>Transmission Mode, n (%)</td>
<td>837 (48.0), 617</td>
<td>287 (48.1), 204</td>
<td>550 (48.0), 413</td>
</tr>
<tr>
<td>Heterosexual, MSM/Bisexual, IDU, Unknown/Other</td>
<td>(35.4, 4.0, 2.2), (34.2, 4.0, 0.7)</td>
<td>(36.0, -), (183, 16.0)</td>
<td></td>
</tr>
<tr>
<td>Overall n (%)</td>
<td>285 (16.4)</td>
<td>102 (17.1)</td>
<td>285 (16.4)</td>
</tr>
</tbody>
</table>
PE2/13
Real world utilisation of raltegravir 1200 mg once daily (The RETRO Study)
M Boetto1,2, A Ustianowski3, A Milinkovic4, G Lindergard2, A Moore5, G Taylor-Stokes3, Y Patell1, C Prat1 and C Mackay6
1Chelsea and Westminster Hospital NHS Foundation Trust, London, UK 2Imperial College London, London, UK 3North Manchester General Hospital, Manchester, UK 4Adelphi Real World, Bollington, UK 5MSD, Hoddesdon, UK

Purpose: Raltegravir 1200 mg once daily (RAL OD) became available in England in September 2017. This study is the first to describe the population in which it is prescribed in clinical practice. Primary objectives include description of subject demographics and their baseline clinical and treatment characteristics. Antiretroviral therapy (ART) initiated with RAL OD will also be described.

Method: Retrospective data collection using standardised case report forms from 300 adult records taking≥1 dose of RAL OD from first availability and who returned for their six-month (–1/+3 months) follow-up appointment in London or Manchester.

Results: Of 300 subjects included, 255 (85%) were male, 182/255 (71%) men who have sex with men, 56% were of white ethnicity. Median age at diagnosis and RAL OD initiation was 34 (18–86) and 45 (21–96), respectively. 56 (19%) were recreational substance users, five (9%) reporting chemsex use. 286 were ART experienced (ART-E) and 14 treatment naive (TN). Baseline (BL) viral load (VL) and CD4+ count was available for 254 and 249 ART-E subjects respectively. 94% had BL VL of<50 c/mL, and 96%<200 c/mL. 5% of ART-E subjects had BL CD4+ < 200 vs 21% TN. At baseline, 60% took non-ART comedications and 68% experienced comorbidities, most commonly hyperlipidaemia, depression, and hypertension in 68 (23%), 56 (19%) and 51 (17%), respectively. 205 (68%) initiated TDF/FTC and 46 (15%) ABC/3TC. 5/200 (2%) with BL VL of<50c/mL, and 10/300 (3%) RAL OD initiated reported VL>50c/mL at follow-up. 21 (7%) discontinued RAL OD by six months.

Conclusion: In this real world setting of individuals initiating RAL OD, subjects are predominantly white MSMs, consistent with clinical trial populations. They are however initiated at an older age, and experience significant comorbidities, with associated burden of comedications. Discontinuations and VL measures are within UNAIDS 90:90:90 targets.

Baseline Demographics

| Male | 255 (85%) |
| Female | 45 (15%) |
| Transgender Female | 3 (1%) |
| Age | 45 (21–96) |
| White ethnicity | 169 (56%) |
| Black (African) | 50 (17%) |
| Black (Caribbean) | 8 (3%) |
| Mixed/Other ethnicity | 73 (24%) |
| Recreational substance use within 6 months | 56 (19%) |
| Chemsex use | 5/56 (9%) |

Baseline Clinical Characteristics

| ARV Treatment Experienced (ART-E) | 286 (95%) |
| Viral Load: ART-E<50 copies/mL | 239 (84%) |
| Viral Load: ART-E ≥50 copies/mL | 15 (5%) |
| Viral Load: ART-E Unknown | 32 (11%) |
| Viral Load: TN<100,000 copies/mL | 10 (71%) |
| Viral Load: TN≥100,000 copies/mL | 4 (29%) |
| CD4 + T-cells: ART-E -<200 cells/mm3 | 234 (82%) |
| CD4 + T-cells: ART-E ≥200 cells/mm3 | 15 (5%) |
| CD4 + T-cells: ART-E Unknown | 37 (13%) |
| CD4 + T-cells: TN<200 cells/mm3 | 3/14 (21%) |

PE2/14
Effectiveness, persistence and safety in treatment-naïve and treatment-experienced HIV-1 infected patients receiving elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) – 12-month evaluation of the French TARANIS cohort
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1Hôpital Saint Antoine, Paris, France 2Hôpital Necker, Paris, France 3Hôpital Saint Louis, Paris, France 4CH Tourcoing, Tourcoing, France 5CH Avignon, Avignon, France 6Hôpital Saint André, Bordeaux, France 7Hôpital Pontoise, Rennes, France 8Hôpital Sainte Marguerite, Marseille, France 9CH Orleãns, Orlãns, France 10CH Annecy Gennevois, Metz Tessy, France 11Hôpital d’Argenteuil, Argenteuil, France 12Hôpital de la Pitie Salpetriãére, Paris, France 13Hôpital Albert Michallon, La Tronche, France 14Gilead Sciences, Foster City, USA 15Gilead Sciences, Ltd, UK 16Gilead Sciences, Boulogne Billancourt, France

Purpose: Long-term tolerability of ART coupled with sustained virologic efficacy are essential for healthy ageing in HIV-infected patients. The prospective TARANIS cohort was initiated to provide evidence concerning the effectiveness and safety of using F/TAF-based regimens in routine clinical care.

Methods: Treatment-naïve (TN) and treatment-experienced (TE) patients having initiated E/C/F/TAF 9–12 months prior to data-cut (04/09/2019; corresponding to the 12-month visit window) were eligible for evaluation. Month-12 (M12) outcomes comprised treatment persistence (Kaplan-Meier analysis), virologic effectiveness (HIV-1-RNA<50c/mL; discontinuation= failure, loss-to-follow-up/withdraw consent/missing= excluded; D=F, missing ignored), (non-)serious adverse drug reactions (ADRs)/SADRs) and self-reported health-related quality of life (HRQL).

Results: The analysis population consisted of 270 patients (TN: n=57; TE: n=213) (Table 1). Of TN patients, 16% presented with<200 CD4+/µL, 29% with>100,000 HIV-1-RNA cp/mL. Of TE patients, 90% had<50 HIV-1-RNA cp/mL, 87% switched from TDF-based ART (42% from E/C/F/TDF). Main reasons for switch were ART simplification (42%) and side effects of previous ART (36%) (multiple-responses permitted).

By M12, overall estimated persistence on E/C/F/TAF was 86% (TN: 87%, TE: 86%) (Figure 1). Overall, 17% of patients (n=46/270) discontinued before M12 (including discontinuations due to ADRs [7%] [not kidney/bone related] or virologic failure [0.4%] [Table 2]).

At M12, virologic effectiveness was 80% (D=F, missing ignored; on-treatment: 94%) (TN: 84% [95%], TE: 79% [93%]). Overall, 58 ADRs and 4 SADRs were documented in 12% and 0.7% of patients, respectively. Improvements in HRQL were seen in SF-36 mental component for TN and in treatment satisfaction for TE patients (Table 3).

Conclusion: In the prospective French TARANIS cohort, persistence to E/C/F/TAF was high in TN and TE patients during the first year. Virologic effectiveness and safety of using E/C/F/TAF were confirmed in a real world setting with 7.4% discontinuations due to ADRs (not related to kidney or bone) and<1% due to virologic failure.

Table 1. Baseline characteristics of the analysis population; IQR: inter quartile range

<table>
<thead>
<tr>
<th>Overall</th>
<th>N=270</th>
<th>TN (n=57)</th>
<th>TE (n=213)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender, n (%)</td>
<td>212 (78.5)</td>
<td>53 (93.0)</td>
<td>159 (74.7)</td>
</tr>
<tr>
<td>Age, years, median (IQR)</td>
<td>46 (36–54)</td>
<td>43 (37–47)</td>
<td>49 (40–55)</td>
</tr>
<tr>
<td>CDC stage C, n (%)</td>
<td>47 (17.7)</td>
<td>3 (5.6)</td>
<td>44 (20.8)</td>
</tr>
<tr>
<td>CD4 count, cells/µL, median (IQR)</td>
<td>642 (414–840)</td>
<td>428 (287–606)</td>
<td>697 (459–872)</td>
</tr>
<tr>
<td>HIV-1-RNA, cp/mL, median (IQR)</td>
<td>34 (19–159)</td>
<td>40,148 (8,960–137,850)</td>
<td>20 (19–39)</td>
</tr>
<tr>
<td>HIV-1-RNA&lt;50 cp/mL, n (%)</td>
<td>N/A</td>
<td>N/A</td>
<td>188/209 (90.0)</td>
</tr>
<tr>
<td>Most common previous antiretroviral regimen, n (%)</td>
<td>N/A</td>
<td>N/A</td>
<td>120 (57.4)</td>
</tr>
<tr>
<td>NNRTI-based</td>
<td>N/A</td>
<td>N/A</td>
<td>35 (16.7)</td>
</tr>
<tr>
<td>PI-based</td>
<td>N/A</td>
<td>N/A</td>
<td>44 (21.1)</td>
</tr>
</tbody>
</table>
Table 2. Documented reasons for discontinuation of E/C/F/TAF and/or study.

<table>
<thead>
<tr>
<th>Reason</th>
<th>Overall (N=270)</th>
<th>TN (n=57)</th>
<th>TE (n=213)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinuations by month 12, n/N</td>
<td>46/270 (17.0)</td>
<td>11/57 (19.3)</td>
<td>35/213 (16.4)</td>
</tr>
<tr>
<td>(%) due to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADRs</td>
<td>20 (7.4)</td>
<td>2 (3.5)</td>
<td>18 (8.5)</td>
</tr>
<tr>
<td>Drug-drug-interaction</td>
<td>2 (0.7)</td>
<td>0 (0.0)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Virologic failure</td>
<td>1 (0.4)</td>
<td>0 (0.0)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Patient decision/withdrawal of consent</td>
<td>8 (3.0)</td>
<td>6 (10.5)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>11 (4.1)</td>
<td>3 (5.2)</td>
<td>8 (3.8)</td>
</tr>
<tr>
<td>Death</td>
<td>1 (0.4)</td>
<td>0 (0.0)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Loss to follow-up</td>
<td>3 (1.1)</td>
<td>0 (0.0)</td>
<td>3 (1.4)</td>
</tr>
</tbody>
</table>

Overall (N=270, 100%)

Bl SF-36 score, mental component\(^1\), mean (+/- SD) [n]

- +1.5 (11.1) [172]
- +5.9 (12.4) [37]
- +0.3 (10.4) [31]

Bl SF-36 score, physical component\(^1\), mean (+/- SD) [n]

- +1.0 (7.4) [172]
- +1.0 (8.8) [37]
- +1.0 (7.4) [31]

Bl HIV SF\(^2\), mean (+/- SD) [n]

- 14.5 (12.0) [173]
- 14.5 (12.3) [38]
- 14.5 (11.5) [135]

Change in HIV SF\(^2\), mean (+/- SD) [n]

- -1.0 (10.2) [172]
- -3.3 (12.7) [37]
- -0.3 (9.3) [31]

Bl TS (treatment satisfaction)\(^2\), mean (+/- SD) [n]

- 51.0 (8.9) [131]
- 21.3 (10.9) [31]

PE2/15

24-month evaluation of the German TAFNES cohort – Effectiveness, persistence and safety of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF), F/TAF + 3\(^{rd}\) agent or rilpivirine/F/TAF (R/F/TAF) in treatment-experienced HIV-1 infected patients

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1P2B, Aachen, Germany 2Praxis Hohenstaufenring, Cologne, Germany 3Infektiologisches Centrum Klinikum, Osnabrueck, Germany 4MVZ Praxis City Ost, Berlin, Germany 5Praxis am Ebertplatz, Cologne, Germany 6Gilead Sciences, Munich, Germany 7Gilead Sciences, Foster City, USA 8ICH Study Center, Hamburg, Germany

Purpose: Minimizing side effects and optimizing long-term tolerability of ART are essential requirements for achieving healthy ageing in people living with HIV (PLHIV). The prospective TAFNES cohort was initiated to provide evidence concerning effectiveness and safety of using F/TAF-based regimes in routine clinical care.

Methods: Treatment-experienced adults of the TAFNES cohort receiving either E/C/F/TAF, F/TAF + 3\(^{rd}\) agent or R/F/TAF at least 21 months prior to data-cut (03/31/2019) were included. 24-month outcomes included ART persistence (Kaplan-Meier analysis), virologic effectiveness (HIV-RNA<50 cp/mL, discontinuation=failure, loss-to-follow-up=withdrawal consent=missing=excluded), and (non-)serious adverse drug reactions (ADRs/SADRs).

Results: A total of 434 PLHIV were eligible for analysis (E/C/F/TAF: n=151; F/TAF and/or rilpivirine based: n=146; 32% dolutegravir, 17% nevirapine, 12% darunavir/ritonavir, 11% raltegravir; R/F/TAF: n=137). Baseline characteristics are shown in Table 1: 95% of participants had HIV-RNA<50 cp/mL prior to switch, 93% switched from TDF-based ART.

By month 24, overall persistence on F/TAF-based ART was 81%. The corresponding persistence in the subgroups using E/C/F/TAF, F/TAF + 3\(^{rd}\) agent or R/F/TAF was 89%, 72% and 82%, respectively (Figure 1). In total, 25% of participants (n=109/434) discontinued before month-24 visit (including discontinuations due to ADRs [4.4%], therapy simplification [3.7%], virologic failure [VF] [1.2%], death [0.9%], or loss-to-follow-up [6.0%]) (Table 2).

Conclusion: Overall persistence on F/TAF-based regimens was high in treatment-experienced PLHIV. >80% during 24 months of observation. Virologic effectiveness and safety were illustrated in a real world setting with 5%-discontinuations due to ADRs and 2%-due to virologic failure.

Table 1. Baseline characteristics; IQR: inter quartile range; *inclusion criteria; age≥50y

<table>
<thead>
<tr>
<th>Overall (N=434, 100%)</th>
<th>E/C/F/TAF (n=151, 35%)</th>
<th>F/TAF + 3(^{rd}) agent* (n=146, 34%)</th>
<th>R/F/TAF (n=137, 32%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender, n (%)</td>
<td>394 (91)</td>
<td>134 (89)</td>
<td>130 (95)</td>
</tr>
<tr>
<td>Age, years, median (IQR)</td>
<td>51 (40-65)</td>
<td>51 (40-65)</td>
<td>51 (40-65)</td>
</tr>
<tr>
<td>CD4 count, cells/μl, median (IQR)</td>
<td>624 (467-830)</td>
<td>608 (423-800)</td>
<td>660 (500-800)</td>
</tr>
<tr>
<td>HIV-RNA&lt;50 cp/mL, n (%)</td>
<td>403 (95)</td>
<td>137 (93)</td>
<td>139 (97)</td>
</tr>
<tr>
<td>Most common previous antiretroviral regimen, n (%)</td>
<td>158 (36)</td>
<td>97 (64)</td>
<td>55 (38)</td>
</tr>
</tbody>
</table>

Figure 1. Persistence on E/C/F/TAF in TN and TE patients (Kaplan-Meier estimates)
HIV Medicine © 2019 The Authors HIV Medicine, 20 (Suppl. 9), 3–316

Table 2. Documented reasons for discontinuation: *including switches to (other) F/TAF-based single tablet regimens (see table 3)

<table>
<thead>
<tr>
<th>Reason for Discontinuation</th>
<th>ADR</th>
<th>Drug-drug-interaction</th>
<th>Virological Failure</th>
<th>Therapy Simplification</th>
<th>Patient Decision/Withdrawal of Consent</th>
<th>Investigator Decision</th>
<th>Other/Unknown</th>
<th>Death</th>
<th>Loss to Follow-up</th>
<th>Overall</th>
<th>ADR/F/TAF</th>
<th>F/TAF</th>
<th>R/F/TAF + F/TAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>19</td>
<td>6</td>
<td>5</td>
<td>16</td>
<td>12</td>
<td>5</td>
<td>16</td>
<td>4</td>
<td>26</td>
<td>109</td>
<td>52</td>
<td>47</td>
<td>137</td>
</tr>
</tbody>
</table>

Table 3. Post-study regimens in F/TAF study drug discontinuers

<table>
<thead>
<tr>
<th>Substitutions</th>
<th>Throughout</th>
<th>E/C/F-TAF</th>
<th>F/TAF</th>
<th>R/F/TAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most common</td>
<td>20 (26)</td>
<td>19 (50)</td>
<td>1 (4)</td>
<td></td>
</tr>
<tr>
<td>Post-Study</td>
<td>20 (26)</td>
<td>19 (50)</td>
<td>1 (4)</td>
<td></td>
</tr>
<tr>
<td>Drug-drug</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. Drug persistence (CAVE: groups not comparable due to different inclusion criteria)

Effectiveness, safety and tolerability of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in HIV-1-infected adult patients in routine clinical practice – 6 months results of the BICSTaR cohort


1 University Hospital Essen, Clinic of Dermatology, Department of Venerology, Essen, Germany 2 Praxis Jessen + Kollegen, Berlin, Germany 3 Technical University of Munich, School of Medicine, University Hospital rechts der Isar, Department of Medicine II, Munich, Germany 4 Novopraaxis Berlin GbR, Berlin, Germany 5 ICH Study Center, Hamburg, Germany 6 Praxis Waizmann, Leipzig, Germany 7 MVZ Praxis City Ost, Berlin, Germany 8 Gilead Sciences Europe Ltd, Uxbridge, UK 9 Gilead Sciences GmbH, Munich, Germany 10 Gilead Sciences Inc., Foster City, USA

Purpose: In clinical studies, B/F/TAF is highly efficacious and well tolerated in both antiretroviral treatment (ART)-naïve (TN) and ART-experienced (TE) HIV-1-infected participants, with zero resistance. BICSTaR is the first cohort to evaluate the effectiveness, safety and tolerability of B/F/TAF in clinical practice.

Method: BICSTaR is an ongoing, non-interventional, prospective, multinational, cohort study planned to enroll at least 1400 adult participants. In this analysis, data from 20 German sites are presented. Outcomes included HIV-1 RNA (loss-to-follow-up/excluding-excluded), drug-related (DR) adverse events (AEs) and persistence of the B/F/TAF regimen.

Results: A total of 223 HIV-1 infected patients (32 TN, 191 TE) initiated B/F/TAF and were followed-up for at least 6 months at time of data cut-off. Main reasons for starting B/F/TAF were "patient's wish" (53%, TN) and "simplification" (63%, TE). Comorbidities at baseline included neuropsychiatric disorders (23%), arterial hypertension (21%), hyperlipidemia (15.3%) and cardiovascular disorders (10%). Of those participants with available HIV-1 RNA data at month 6 (n=180), HIV-1 RNA was <50 copies/mL in 21/25 (84%) TN participants (24/25 [96%] < 200 copies/mL and in 143/155 [92%] of TE participants (153/155 [99%] < 200 copies/mL). Median CD4 cell counts increased from 479 to 731 and from 695 to 752 cells/μL, respectively. Persistence with B/F/TAF was high (96% still on treatment) with 8 (4%: 1 TN and 7 TE) participants discontinuing B/F/TAF prior to month 6 (3 due to DRAEs). No discontinuations were due to renal or bone AEs. Overall, DRAEs and DR serious AEs were reported in 21 (10%) and 1 (0.4%) participants, respectively. Most common DRAEs were psychiatric, 7 (3%) and gastrointestinal disorders, 5 (2%).

Baseline characteristics by antiretroviral treatment status

Table 3. Post-study regimens in F/TAF study drug discontinuers

Conclusion: Consistent with randomized controlled trials, preliminary data from this observational cohort support the effectiveness, safety and tolerability of B/F/TAF in routine clinical practice, including in participants with comorbidities, and demonstrate high persistence through 6 months.

PE2/16

Short-term increase in Body Mass Index and systolic blood pressure elevation in treatment naïve persons starting INSTI-based antiretroviral therapy

R. Galdamez1, J. García2, M. Fernández2, C. Robledano3, V. Aguillo1, J. García-Abellán1, G. Telenti1, S. Padilla1, F. Gutiérrez2 and M. Masía3

1 Hospital General Universitario de Elche, Elche, Spain

Purpose: Integrate strand transfer inhibitors (INSTI)-based ART has been associated to weight gain, but it remains unknown if this effect leads to higher overweight incidence or increases the risk of metabolic and cardiovascular disturbances. We aimed to explore the frequency of excessive weight gain in HIV+ treatment naïve patients starting INSTI-based regimens and to determine whether they are associated with changes in metabolic markers and blood pressure (BP).

Method: Medical records of treatment naïve persons starting ART at the HIV-clinic of University Hospital of Elche (Spain) between July-1991 and March-2018 were retrospectively reviewed. Standard procedures included measurements of weight, BP and comprehensive metabolic assessments at each visit. Data at baseline and post 48, 72, and 96 weeks of ART initiation were analyzed. We used Cox mixed-effects model to generate overweight predictions over time, adjusting for baseline characteristics. Generalized additive mixed models (GAMM) were used to relax the linearity assumptions and generate 95% confidence intervals (95% CI) in the multivariable adjust

Results: Among 457 participants (median age 44.0 years, IQR 30–55, 108 females), 55 (12.0%) and 402 (88.0%) started ART with INSTI-based and non-INSTI-based regimens respectively. The baseline weight mean was 70.4 kg. 50% were enrolled with a BMI ≥ 25 kg/m². The incidence of overweight after initiating ART was significantly greater in INSTI-based regimens: 14(35.9%) of 39 patients treated with INSTI vs 36(17.8%) of 192 treated with other ART regimens (HR 1.96; 95% CI, 1.06–3.62; p=0.032).
We did not find differences among ART regimens in fasting blood glucose, lipid panel, and hepatic steatosis indexes.

Conclusion: INSTI-based ART was associated in the short-term with a greater risk of overweight and a modest elevation of SBP linked to weight gain.

### PE2/18

Baseline characteristics in JUNGLE, a German observational cohort study of Juluca as 2-drug Regimen in virologically suppressed patients, compared to the phase–3 SWORD 1 & 2 study populations

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1MVZ Karlsplatz, München, Germany 2Praxis Ebertplatz, Cologne, Germany 3prinemed, Munich, Germany 4isopraxis, Munich, Germany 5Medcenter, Weimar, Germany 6Infektiologisches Zentrum Steglitz, Berlin, Germany 7Praxis Hohenstaufenfingen, Cologne, Germany 8ViV Healthcare, Munich, Germany 9GlaxoSmithKline, Munich, Germany

Purpose: Juluca, the combination of Dolutegravir (DTG) and Rilpivirine (RPV) was approved by the EMA in 2018 as the first single-tablet 2-drug regimen (2DR) for maintenance therapy in HIV-1 infected patients. The JUNGLE cohort will provide prospective real-world data regarding effectiveness and tolerability of using Juluca.

Methods: JUNGLE is an ongoing non-interventional, prospective, multicenter, German cohort study in virologically suppressed patients switched to DTG/RPV in accordance with the summary of product characteristics. Here we describe the characteristics of the study population and reasons for switch to DTG/RPV.

Results: By June 2019, 185 patients have been enrolled (90.3% men; median age 49 years; baseline characteristics see table 1). Patients had been on ART for a median time of 8 years prior to DTG/RPV (9.9% still on first-line ART, 42.9% with ≥3 ART–changes); 96.1% of patients were switched from triple ART and 48.9% had been on a multi-tablet regimen. Comorbidities were common, among them hypertension (28.4%), depression (15.8%), lipid disorders (15.8%), chronic kidney disease (12.0%). Primary reasons for switch to DTG/RPV were side effects of previous ART (25.4%), switch to a single-tablet regimen (22.7%) and reduction in number of drugs (19.9%; table 2).

Conclusions: In the JUNGLE cohort, 86.1% of patients were on triple ART prior to switching to the 2DR Juluca. Main reasons for switch were side effects of previous ART, simplification to a single-tablet regimen and reduction in

### Table 1. HIV related characteristics and ART history

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male, n (%)</th>
<th>n=185</th>
<th>167 (90.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (median, IQR)</td>
<td>n=185</td>
<td>49 (IQR 40–57)</td>
<td></td>
</tr>
<tr>
<td>Age≥50 years, n (%)</td>
<td>n=185</td>
<td>48 (47.8)</td>
<td></td>
</tr>
<tr>
<td>Time since HIV diagnosis, years (median, IQR)</td>
<td>n=179</td>
<td>11 [5–16]</td>
<td></td>
</tr>
<tr>
<td>Time since start of first ART, years (median, IQR)</td>
<td>n=162</td>
<td>8 [4–14]</td>
<td></td>
</tr>
<tr>
<td>Time on previous ART, years (median, IQR)</td>
<td>n=166</td>
<td>2.6 [1.5–4.7]</td>
<td></td>
</tr>
<tr>
<td>CD4 T-cell count, cells/µL (median, IQR)</td>
<td>n=175</td>
<td>714 [577–933]</td>
<td></td>
</tr>
<tr>
<td>History of AIDS (CDC C), n (%)</td>
<td>n=180</td>
<td>32 (17.8)</td>
<td></td>
</tr>
</tbody>
</table>

*IQR: inter quartile range; calculations based on observed data

### Table 2. Primary reasons for switch to DTG/RPV

<table>
<thead>
<tr>
<th>Reason</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side effects of previous ART</td>
<td>46 (25.4)</td>
</tr>
<tr>
<td>Simplification to a single-tablet regimen</td>
<td>41 (22.7)</td>
</tr>
<tr>
<td>Reduction in number of drugs</td>
<td>36 (19.9)</td>
</tr>
<tr>
<td>Patient's preference</td>
<td>22 (12.2)</td>
</tr>
<tr>
<td>NNRTI-free regimen</td>
<td>9 (5.0)</td>
</tr>
<tr>
<td>Potential/actual interactions</td>
<td>8 (4.4)</td>
</tr>
<tr>
<td>Pill size</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Other</td>
<td>18 (9.9)</td>
</tr>
<tr>
<td>Calculations based on observed data</td>
<td></td>
</tr>
</tbody>
</table>
Examining the efficacy in clinical practice of the dual antiretroviral therapy regimen of boosted protease inhibitors with maraviroc

A Katiyar1, F Burns1,2, L Swaden1, M Youle1 and TJ Barber1

Purpose: A focus on reducing long-term drug exposure while maintaining viral suppression has led to new strategies for treatment-experienced patients involving dual therapy. Maraviroc (MVC), a chemokine receptor 5 co-receptor antagonist, is licensed for use in treatment experienced HIV-1 positive patients. Boosted protease inhibitor (bPI) with MVC is not a recommended combination in guidelines. In the past, this option was chosen for selected patients with some declining to switch despite evidence. We set out to assess the outcomes of patients who have or are currently receiving this combination in our clinic.

Method: All patients prescribed a bPI with MVC until December 2018 were identified through our HIV database. Age, sex, and time on ART before/after switch were collected. A review of medical records determined reasons for switch off bPI/MVC where relevant.

Results: In total 114 patients (mean age 53 years (range 33–76), 80% male) had been prescribed a bPI/MVC. The median time on ART prior to bPI/MVC switch was 13 years. Patients stayed a median of 4 years on bPI/MVC; 63 (55%) patients were on MVC 300 mg dosing while 51(45%) were dosed at MVC 150 mg. At censure 69 (61%) remained on bPI/MVC, 30 (26%) had switched ART, 7 (6%) died, 7 transferred their care, and 1 was lost to follow up. Reasons for switching included hyperlipidaemia (n=6), lipodystrophy (n=2), rationalisation (n=6), drug interactions (n=5), potential toxicity (n=5), side effects (n=1), no documentation (n=1) and viral failure (n=5). Four of the five patients who failed therapy reported issues around adherence. Of patients who remained on bPI/MVC 97% (67/69) were virally suppressed (median duration 4.5 years).

Conclusion: We continue to proactively review patients on bPI/MVC and suggest contemporary alternatives but our data suggest that, if adherence is good, established patients may be reassured about the safety and efficacy of this approach.

Good efficacy but side effects including hypercholesterolemia and body weight gain after switching to dolutegravir plus booster protease inhibitor regimen among treatment experienced HIV-positive patients

Y-L Lee1, C-E Liu1, C-C Hung1, K-Y Lin2, S-H Cheng3, C-J Yang4, Y-T Lee5, S-P Lin6, N-C Wang7 and Taiwan HIV Study Group (THSG)
1Changhua Christian Hospital, Infectious Diseases, Changhua, Taiwan, Province of China 2National Taiwan University Hospital, Taipei, Taiwan, Province of China 3Taoyuan General Hospital, Ministry of Health and Welfare, Taoyuan, Taiwan, Province of China 4Far Eastern Memorial Hospital, New Taipei City, Taiwan, Province of China 5Chung Shan Medical University Hospital, Taichung, Taiwan, Province of China 6Taichung Veterans General Hospital, Taichung, Taiwan, Province of China 7Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan, Province of China

Purpose: In Taiwan, the regimen of antiretroviral (ARV) therapy was strictly regulated by CDC. The two-drug regimen (2-DR) with dolutegravir (DTG) and boosted protease inhibitor (bPI) was most used as a salvage therapy for treatment experienced HIV-positive patients. The efficacy and long-term adverse effects was unknown.
Rates of DTG/ABC/3TC discontinuation in a real-life setting: no surprises found in reported adverse events

A Gorgulho1, I Vaz Pinto2, C Santos2, T Vilari2, M Guimarães2 and V Castro2
1Hospital de Cascais, Internal Medicine Department, Alcabideche, Portugal
2Hospital de Cascais, HIV Unit, Alcabideche, Portugal

Purpose: Dolutegravir (DTG) is the most frequently used integrase inhibitor (INSTI) at our clinic. Since its widespread use, concerns grew about safety issues not clearly identified in randomized controlled trials (RCTs), namely neuropsychiatric adverse events (AE), neural tube defects in pregnancy and significant weight gain (WG).

We assessed the rates of discontinuation of the single tablet regimen (STR) of DTG + Abacavir + Lamivudine (DTG/ABC/3TC), the reasons for discontinuation and the factors associated with discontinuation.

Methods: A retrospective analysis was done of a cohort of patients starting DTG/ABC/3TC between September 2016 and June 2018. All patients had at least 52 weeks of follow-up. Primary endpoints were discontinuation and reasons for discontinuation of the STR. Treatment naïve and treatment experienced (TE) patients were included; in TE patients the reasons for switching to DTG/ABC/3TC were noted.

Results: 295 patients were identified, of which 25 were excluded from the analysis due to death, unrelated to therapy (n=10), HIV 2 infection (n=7) and transfer of care to another institution (n=8). 270 patients were included in the analysis: 33 (12.2%) were naïve and 237 (87.8%) were treatment experienced. The main reasons for TE patients to switch to DTG/ABC/3TC were simplification in 75%, virologic failure in 10.5% and AE from the previous regimen in 5%.

Overall 40 patients discontinued DTG/ABC/3TC (14.8%). Of these, only 15 patients (5.5%) from the total discontinued due to AE; the second most common reason for discontinuation was being lost to follow-up (4.0%); other reasons were HBV infection and drug–drug interactions.

Conclusions: In our cohort of patients treated with DTG/ABC/3TC we observed 5.5% of discontinuations due to AE, which is higher than found in RCTs but similar to discontinuation rates described in real-life settings. The most commonly observed AE were neuropsychiatric (n=4) and WG (n=3). Some AE were unrelated to DTG.

Low baseline HIV viral loads with a history of PrEP use – how should these patients be managed?

V Tittle1, N Girometti1, D Nugent1, T Suchak1, E Bird1, A McOwan1 and G Whitlock1
1Chelsea and Westminster Hospital, London, UK

Purpose: Low baseline viral loads (VL) in newly diagnosed HIV patients, with a history of recent pre-exposure prophylaxis (PrEP) use, may present difficulties for rapid initiation of anti-retrovirals therapy (ART) due to concerns of viral drug resistance or failure of viral amplification at baseline. There is a lack of data on the optimal management for these patients and their outcomes. We have identified these cases from a single sexual health clinic in London and present the management of these cases.

Method: This is retrospective case review of newly diagnosed HIV patients with low baseline HIV VL (<2000 copies/mL) and documented PrEP-use (within ~6 months) between January 2017 – April 2019. VL threshold of <2000 copies/mL was selected due to the commonly used definition of ‘viremic controllers’.

Demographics, baseline investigations and initial management were recorded.

Results: Seven patients met the inclusion criteria; all were men-who-have-sex-with-men. Initial investigations and management are listed in Table 1.

Prior to starting PrEP, two patients did not have a baseline HIV test, four patients did not have a baseline HIV test documented and one patient reported a baseline test elsewhere. Three patients, who initially started a protease inhibitor as the third ART agent, were switched to a integrase inhibitor. At three months post-ART initiation, five patients had an undetectable VL, one was lost-to-follow-up and one result was pending.

Conclusion: Newly diagnosed patients should have a careful PrEP history. This data shows successful VL suppression with integrase and protease inhibitors, alongside a dual nucleoside/nucleotide backbone, for six out of seven patients who started ART within 14 days of diagnosis.

Lamivudine-based maintenance 2-drugs regimens: an algorithm for the estimation of 2-years risk of virological failure in clinical practice

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1Fondazione Policlinico Universitario Agostino Gemelli IRCCS, UOC Malattie Infettive, Roma, Capitale, Italy
2Università Cattolica del Sacro Cuore, Roma, Italia
3Università Cattolica del Sacro Cuore, Roma, Italia
4Mater Olbia Hospital, Olbia, Italia
5Clinica delle Malattie Infettive e Tropicali dell’Università di Modena e Reggio Emilia, Modena, Italy
6Siena University Hospital, Infectious Diseases Unit, Siena, Italy
7Infectious Dermatology, IFO S. Gallicano, Roma, Capitale, Italy
8Clinica delle Malattie Infettive e Tropicali dell’Università di Modena e Reggio Emilia, Roma, Capitale, Italy
9University of Siena, Department of Medical Biotechnology, Siena, Italy
10Fondazione IRCCS Policlinico ‘San Matteo’, Infectious Diseases Unit, Pavia, Italia
11Fondazione Policlinico Universitario Agostino Gemelli IRCCS, UOC Malattie Infettive, Rome, Italy

Purpose: We developed a tool for estimating the 2-years risk of virological failure (VF) in patients switching to a maintenance regimen with lamivudine plus a boosted-protease inhibitor (bPI) or dolutegravir.

Method: From a multicentre Italian cohort of patients with undetectable HIV-RNA (according to the centre-specific threshold) and negative HBVAg status, starting lamivudine plus a bPI (darunavir, atazanavir or lopinavir) or dolutegravir, predictors of VF (i.e., a single HIV-RNA<1000 cp/mL or 2 consecutive HIV-RNA<50 cp/mL) at 2 years were analysed by Cox regression. The Cox-regression-based prediction scores were calculated based on variables independently associated with the outcome (as described by Sullivan et al., Statist. Med. 2004; 23:1631–1660). The discriminatory power of the point total was expressed as the area under the receiver-operator characteristic curve (ROC-AUC).

Results: The cohort included 703 patients starting lamivudine plus boosted-atazanavir (17.3%), boosted-darunavir (37.5%), boosted-lopinavir (4.1%).
dolutegravir (41.2%). Characteristics of study population are summarized in table 1. Over 2 years of median follow-up, 58 VF(s) occurred. Prediction scores were based on the following variables (reported with hazard ratios for VF): non-B viral subtype (vs B, aHR 3.06, p=0.002), CD4 count nadir (per 100 cells/mm³ more, aHR 0.83, p=0.063), residual HIV-RNA (per 1 cp/mL more, aHR 1.03, p=0.002), years since HIV diagnosis (per 1 year more, aHR 1.08, p=0.001) and duration of viral suppression before switch (per 1 month more, aHR 0.99, p=0.011). A point total of 0 and ≤5 reflected a risk of VF of ≤5% and >20%, respectively. The model showed moderate discrimination power: ROC-AUC was 0.69 (95% CI 0.62–0.76; p<0.001).

Conclusion: Some viro-immunological characteristics of patients switching to a lamivudine-based maintenance dual-therapy can be incorporated in a useful algorithm to identify subjects at higher risk of VF.

Characteristics of study population at baseline (N=703)

<table>
<thead>
<tr>
<th>Variables</th>
<th>N (% or IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>50 (42–56)</td>
</tr>
<tr>
<td>Male sex</td>
<td>493 (70.1)</td>
</tr>
<tr>
<td>Risk factor for HIV: - Heterosexual</td>
<td>287 (40.8) 271 (38.5) 120 (17.1) 25 (3.6)</td>
</tr>
<tr>
<td>MSM - IDU - Other</td>
<td></td>
</tr>
<tr>
<td>Years since HIV diagnosis: - 0.5 - 5</td>
<td>180 (25.6) 158 (22.5) 91 (12.9) 90 (12.8) 184 (26.2)</td>
</tr>
<tr>
<td>&gt;5.10 - &gt;10.15 - &gt;15.20 - &gt;20.24</td>
<td></td>
</tr>
<tr>
<td>Zenith HIV-RNA (log10 cp/mL)</td>
<td>5.15 (4.68–5.56)</td>
</tr>
<tr>
<td>Nadir CD4 count (cells/mm³): - ≤ 100 - 101–200 - 201–350 - &gt;350</td>
<td>167 (23.8) 134 (19.1) 267 (38.0) 135 (19.1)</td>
</tr>
<tr>
<td>Residual HIV-RNA at baseline (copies/mL): - ≤ 0–10 - 11–20 - 21–30 - 31–40</td>
<td>515 (73.3) 62 (8.8) 36 (5) 90 (12.8)</td>
</tr>
<tr>
<td>Months of viral suppression: - 0–48</td>
<td>531 (75.6) 104 (14.8) 55 (7.8) 13 (1.8)</td>
</tr>
<tr>
<td>- &gt;48–96 - &gt;96–144 - &gt;144</td>
<td></td>
</tr>
<tr>
<td>Non-B viral subtype</td>
<td>115 (16.4)</td>
</tr>
</tbody>
</table>

PE2/24

Adding raltegravir to a bPI failing regimen was not associated with higher virologic suppression

MM Gomes-da-Silva1,2, MC Araipé Sucupira1, RR Petterle3 and RS Diaz4

1Universidade Federal de São Paulo, Doenças Infecciosas e Parasitárias, São Paulo, Brazil 2Universidade Federal do Paraná, Saude Comunitaria, Curitiba, Brazil 3Universidade Federal do Paraná, Departamento de Ciencias da Saúde, Curitiba, Brazil

Purpose: After a failure with a NNRTI based regimen, it was previously suggested that boosted protease inhibitor (bPI) combined with recycling NRTI is comparable to bPI associated with INSTI in their ability to attain virologic suppression. However, adding the INSTI after a short period of N(t)RTI and bPI combination might evidence those patients harder to treat and direct this strategy only for them.

Method: This is a prospective, single center, single arm trial, enrolling HIV-1 infected patients who presented virologic failure to a NNRTI based regimen. Eligible patients presented at least 1 major resistance associated mutation (RAM) (IAS 2019). Visits were scheduled at 12, 24, 36 and 48 weeks after baseline. On week 24, patients with virologic failure had a resistance test. If no new RAM was detected, raltegravir was added to patient’s regimen and response was analyzed at 48 weeks of follow up. VL, CD4 + , safety analysis and “detuned” HIV-1 EIA were performed in all visits.

Results: We studied 31 patients. From them, 24 (77.4%) patients presented virologic failure to a NNRTI based regimen and “detuned” HIV-1 EIA were performed in all visits. Of 10 virologic failures, only one case had a new RAM (10i, 64V, 82F). Patients who previously failed on AZT had aHR 0.029 and were on ARV for longer period (p=0.01) had higher virologic control on 24 weeks. On the other side, the presence of 70E on baseline resistance test (p=0.045) and use of raltegravir were associated with lower virologic response (p=0.036) on 24 and 48 weeks, respectively.

Conclusion: Adding raltegravir to a second line failing regimen, even in the absence of RAM, was not associated with a better virologic outcome.

PE2/25

Neuropsychiatric tolerability of bictegravir combined with FTC/TAF in clinical practice

C Hoffmann1,2, K Schewe1, S Fenske1, T Buhk1, M Sabranski1, A Adam1, S Hansen1 and H-J Stellbrink1

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Purpose: Neuropsychiatric AEs (NPAEs) leading to dolutegravir (DTG) discontinuation were seen more frequently in real-world use than in randomized clinical trials (RCTs). The recently approved fixed dose combination bictegravir plus FTC and TAF (BIC/FTAF) has shown comparable NPAE rates but some favourable patient-reported outcomes in RCTs. We were interested in its neuropsychiatric tolerability in routine clinical practice.

Methods: All patients starting BIC/FTAF from June 2018 in a single center (two subcenters) were followed retrospectively. Discontinuation rates due to any AEs and NPAEs were compared with those of patients initiating DTG-based regimens.

Results: As of May 2019, a total of 943 patients (852 males, 76 females, 15 TGID) initiated BIC/FTAF outside RCTs. After a median follow-up of 6.2 months, 50 (5.3%) and 31 (3.3%) patients had discontinued BIC/FTAF due to any AEs or to NPAEs, respectively. In multivariate analysis, a pre-existing depression and subcenter remained predictive for NPAEs, but not age, gender, ethnicity, or prior DTG-related AEs. Compared to 1,043 patients treated with DTG-based regimens, the estimated NPAE-related discontinuation rate with BIC/FTAF was comparable during the first 6 months (p=0.31). Cross-intolerance was low, and only 5/35 patients with prior DTG intolerance had to discontinue BIC/FTAF due to NPAEs.

Conclusion: Short-term tolerability of BIC/FTAF was comparable to DTG-containing regimens. As seen with DTG, discontinuation rates were higher than in RCT. A pre-existing depression but also physician’s awareness may have an impact on tolerability and continuation of BIC/FTAF. In contrast, prior intolerance of DTG was of limited predictive value.
PE2/26
Real-world clinical outcomes of patients switched from complex multi-tablet regimens to TAF-based single-tablet regimens plus a boosted protease inhibitor

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Purpose: Multi-tablet regimens (MTRs) used in treatment-experienced patients are associated with increased adverse events (AEs) and non-adherence. Single tablet regimens (STRs) plus boosted protease inhibitors (PIs) are a promising treatment option for MTR-treated patients seeking simplification; however, real-world data is needed to validate this therapeutic strategy.

Method: This retrospective analysis evaluated all records from HIV-infected patients seen at the Orlando Immunology Center from 8/2012 to 12/2017 who were switched from BID regimens or regimens containing ≥3 pills daily to elvitegravir/cobicistat/tenofovir-alafenamide (E/C/F/TAF) plus darunavir (DRV) or ritonavir/tenofovir-alafenamide (RPV/TF) plus DRV boosted with Norvir or cobicistat. Eligible patients had baseline HIV-1 RNA<50 copies/mL and at least two HIV-1 RNA measurements after switch. The primary endpoint was virologic rebound (HIV-1 RNA≥50 copies/mL) at week 48. Adherence, AEs and laboratory parameters were analyzed throughout the study.

Results: Fifty-nine patients met inclusion criteria, 54 (92%) were switched to E/C/F/TAF+DRV and 5 (8%) were switched to RPV/TF plus boosted DRV. The median age (range) was 53 (27–99) years, median baseline CD4 count (range) was 510 (87–1798) cells/mm³, and the median number of pills taken daily (range) was 5 (3–9). At Week 48, of 41 subjects with virologic data within window, 2 (5%) had HIV-1 RNA≥50 copies/mL (Figure 1). Two patients treated with E/C/F/TAF plus DRV experienced confirmed virologic rebound during the study period however there was no evidence of treatment-emergent resistance. Median LDL cholesterol significantly increased from baseline to Week 48 (+20 mg/dL, 95% confidence interval [9, 31.8]). Treatment-related AEs occurred in 3/59 (5%) patients (all Grade 2) leading to 3/59 (5%) discontinuations.

Conclusion: In this “real-world” cohort of MTR-treated patients, switching to a TAF-based STR plus boosted PI maintained virologic control in 97% of patients and was well-tolerated, supporting potential use of this strategy for regimen simplification.

Figure 1. Virologic Outcomes through Week 60

Overall Group, N=59

PE2/27
Detectability of HIV residual viremia despite therapy is highly associated with treatment with protease inhibitor

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Purpose: To better understand the complex link between clinical and treatment features and HIV persistence despite therapy.

Method: 11045 samples (from June 2009 to July 2018) from 1160 patients under combination antiretroviral therapy (cART) with unquantifiable viral load (VL), level of quantification: 20 copies/mL were categorized as detectable or undetectable, depending on the detection of a PCR signal using a commercially-available assay. Generalized estimating equations regression was used to model viral load detectability and to assess determinants of residual viremia (RV: VL detected below 20 copies/mL). Low CD4+ T cell nadir and high VL zenith were associated with a higher probability to have a detectable viremia under cART. Conversely, the probability to have a detectable viral load below 20 copies/mL decreased with time under therapy. Regarding therapy, protease inhibitor (PI)-based treatment was also associated with a statistically higher probability of detectable RV compared to non-nucleoside transcriptase inhibitor and integrase inhibitor.

Conclusion: PI-based treatment regimen is highly associated with an increased frequency of RV, supporting the previous evidence suggesting that PI-based cART regimens could favor an ongoing viral replication in some patients. This phenomenon could support the chronic activation of the immune system involved in the excess of aging-associated events.

Table 1. Impact of patients' characteristics on the probability to detect HIV RNA below 20 copies/mL (N=10227 samples)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Coef. ± SE</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low CD4+ T cell nadir and high VL zenith</td>
<td>0.12 ± 0.075</td>
<td>0.32</td>
</tr>
<tr>
<td>Low CD4+ T cell nadir</td>
<td>0.13 ± 0.077</td>
<td>0.053</td>
</tr>
<tr>
<td>Others</td>
<td>0.32 ± 0.18</td>
<td>0.51</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>1.40 ± 0.24</td>
<td>0.29</td>
</tr>
<tr>
<td>NNRTI backbone</td>
<td>0.12 ± 0.075</td>
<td>0.32</td>
</tr>
<tr>
<td>ART naive or experienced</td>
<td>-0.029 ± 0.028</td>
<td>0.29</td>
</tr>
<tr>
<td>Age at sampling (10 years)</td>
<td>0.0023 ± 0.0003</td>
<td>0.36</td>
</tr>
<tr>
<td>Treatment duration (10 days)</td>
<td>-0.002 ± 0.0002</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>VL, virology at sampling (log2copies/mL)</td>
<td>-0.0002 ± 0.0002</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

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PE2/29
Prediction of virological failure in patients with low level HIV-1 viremia using a joint latent class model
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1Hospital General Universitario Reina Sofia, Murcia, Spain 2Hospital Universitario Virgen del Rocio, Sevilla, Spain 3Hospital Universitario de la Princesa, Madrid, Spain 4Hospital Universitario Basurto, Bilbao, Spain 5Nuestra Senora de Valme, Sevilla, Spain 6Hospital Universitario de Valencia, Valencia, Spain 7Hospital General Universitario de Elche, Elche, Spain

Purpose: To identify HIV infected patients at risk of virological failure (VF) by generating a dynamic predictive model that take into account their viral loads (VL) trajectories.

Method: A joint latent class and competing risk model investigating the impact of plasma VL time-trajectories after viral suppression on VF was developed. We analyzed data from the cohort of the Spanish AIDS Research Network (CoRIS) from January 2004 to 2017. Eligible patients were those who achieved plasma VL<50 copies/mL within 3–9 months after ART initiation. The capacity of the model to calculate individual predicted probabilities of VF over time was evaluated in 6,441 independent patients. The model classified patients in latent classes with significantly different VL time profiles and different VF trajectories and cumulative incidence of VF were identified. Class 1 (4.65% of the sample) and class 2 (86.58% of the sample) were strongly associated with a very low risk of VF (1% and 2.8%, resp.), whereas class 3 (50 copies/mL were achieved plasma VL=50 copies/mL within 3–9 months after ART initiation. The model had excellent dynamic predictive accuracy.

Conclusions: We provide an excellent dynamic prognostic tool for individual predictions in the short term, which allows us to anticipate viral failure in patients with low level HIV-1 viremia.

Table 2. Effect of treatment regimens on the probability to detect HIV RNA below 20 copies/ml (N=10438)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Conf. Int.</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDF</td>
<td>0.009 (0.003</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TAF</td>
<td>0.038 (0.003</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Baseline Characteristics by Treatment (1)

<table>
<thead>
<tr>
<th>Variable</th>
<th>F/TDF</th>
<th>F/TAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs), Median (IQR)</td>
<td>38 (30–44)</td>
<td>41 (34–48)</td>
</tr>
<tr>
<td>Age&gt;50 yrs, n (%)</td>
<td>24 (8.6)</td>
<td>103 (18.9)</td>
</tr>
<tr>
<td>HIV-1 RNA log10 cp/mL, Median (IQR)</td>
<td>4.5 (4.1–4.9)</td>
<td>4.5 (3.9–5.1)</td>
</tr>
<tr>
<td>HIV-1 RNA&lt;50 cp/mL, n (%)</td>
<td>1 (0.4)</td>
<td>422 (77.3)</td>
</tr>
</tbody>
</table>

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Results: A total of 826 HIV-infected patients received F/TDF- and 1,259 patients received F/TAF-based regimens for up to 12 months (or discontinued before) at the time of data cut-off. Persistence was high at M12 (F/TDF: 84%, for both TN and TE, F/TAF: 88%, TN 85% and TE 89%), with a significantly lower likelihood of discontinuing F/TAF-based regimens (MLRA: odds ratio [OR] of 0.37, 95% confidence interval [CI] 0.59–0.99, p-value 0.046). No difference was observed in the likelihood of being virologically suppressed at M12 (MLRA: p-value 0.3). Significantly fewer F/TAF patients (8%) experienced at least one drug-related AE than F/TDF patients (14%) (MPRA: incidence rate ratio [IRR] 0.68 [95% CI 0.55–0.83, p-value 0.0002]).

Baseline Characteristics by Treatment (2)

<table>
<thead>
<tr>
<th>F/TDF TN=280</th>
<th>F/TDF TE=546</th>
<th>F/TAF TN=357</th>
<th>F/TAF TE=902</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 count, cells/µL</td>
<td>Median (IQR)</td>
<td>CD4 count, cells/µL</td>
<td>Median (IQR)</td>
</tr>
</tbody>
</table>
| CD4+ was 99 cells/µL after initial virologic suppression) was 7%, and mean increase in loss of virologic suppression (2 consecutive HIV-1 VL measurements of virologically suppressed (Table 2), survival probability estimate of experiencing are shown on Table 1; of note 33% were female and 69% had an undetectable VL <50 copies/mL) using on-treatment analysis. Secondary endpoints included (i) durability of treatment (Kaplan–Meier survival analysis), (ii) immunological response, (iii) reasons and reasons for DTG discontinuation; and (iv) change in weight. Results: 4,101 patients were included from 6 centers. Baseline characteristics are shown on Table 1; of note 33% were female and 69% had an undetectable HIV-1 VL at DTG initiation. Through 96 weeks, 96% of study participants were virologically suppressed (Table 2), survival probability estimate of experiencing loss of virologic suppression (2 consecutive HIV-1 VL measurements of <200 copies/mL after initial virologic suppression) was 7%, and mean increase in CD4 was 99 cells/µL. 785 patients (19.1%) discontinued DTG (Figure 1). The most frequent reason for discontinuation (Table 3) was an adverse drug reaction (ADR; 9.6%) with neuropsychiatric (NP) toxicity being the most prevalent (5.2%). Overall, the mean on-treatment weight gain was 2.01 kg at week 96, with larger weight gains observed in women (2.55 kg; p=0.006), cART-naïve patients (3.83 kg; p=0.0003), and patients with CD4 < 200 cells/µL at DTG initiation (6.3 kg; p=0.0001).

Conclusion: This large ‘real-world’ study confirms the high efficacy and tolerability of DTG. ADR-induced and NP toxicity-induced discontinuations were rare, albeit slightly higher than in clinical trials. Some sub-groups experienced statistically significant weight gains, however the clinical relevance of this finding remains to be evaluated.

Table 1. Baseline characteristics of the study population.

<table>
<thead>
<tr>
<th>Number of participants (%)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Median (IQR)</td>
<td>46.7</td>
<td>44.8</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>(n (%))</td>
<td>Caucasian</td>
<td>2,069 (50.3)</td>
</tr>
<tr>
<td>Sub-Saharan African</td>
<td></td>
<td>446 (10.9)</td>
<td>94 (2.3)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>171 (4.1)</td>
<td>76 (1.9)</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td>76 (1.9)</td>
<td>21 (0.5)</td>
</tr>
<tr>
<td>Weight</td>
<td>Median (IQR)</td>
<td>75 (66–84)</td>
<td>72 (63–81)</td>
</tr>
<tr>
<td>Mode of HIV acquisition, (n (%))</td>
<td>Heterosexual</td>
<td>1,727 (41.4)</td>
<td>20 (0.5)</td>
</tr>
<tr>
<td>Homosexual/ Bisexual</td>
<td></td>
<td>47 (1.1)</td>
<td>16 (0.4)</td>
</tr>
<tr>
<td>NVDU</td>
<td></td>
<td>516 (12.4)</td>
<td>18 (0.4)</td>
</tr>
<tr>
<td>Transfusion related</td>
<td></td>
<td>13 (3.1)</td>
<td>11 (0.3)</td>
</tr>
<tr>
<td>Vertical</td>
<td></td>
<td>11 (3.9)</td>
<td>11 (0.3)</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td></td>
<td>27 (0.6)</td>
<td>8 (0.2)</td>
</tr>
<tr>
<td>HIV treatment status, n (%</td>
<td>Treatment-naive &amp; Treatment-experienced</td>
<td>1,907 (46.5)</td>
<td>1,031 (25.1)</td>
</tr>
<tr>
<td>902</td>
<td></td>
<td>131 (3.2)</td>
<td>144 (3.5)</td>
</tr>
<tr>
<td>HIV-1 viral load (copies/mL)</td>
<td>&lt;50</td>
<td>67.8</td>
<td>70.2</td>
</tr>
<tr>
<td>Mean CD4 T-cell count</td>
<td>(n (%))</td>
<td>350–499</td>
<td>1,369 (32.9)</td>
</tr>
<tr>
<td>≥500</td>
<td>487 (14.8)</td>
<td>209 (5.3)</td>
<td>696 (18.2)</td>
</tr>
<tr>
<td>200–499</td>
<td>397 (11.9)</td>
<td>224 (5.5)</td>
<td>621 (17.1)</td>
</tr>
<tr>
<td>&lt;200</td>
<td>122 (4.6)</td>
<td>47 (1.1)</td>
<td>169 (4.6)</td>
</tr>
<tr>
<td>Prior AIDS defining illness, n (%)</td>
<td>Yes</td>
<td>535 (12.7)</td>
<td>328 (8.6)</td>
</tr>
<tr>
<td>No</td>
<td>1,362 (33.6)</td>
<td>1,074 (26.8)</td>
<td>2,436 (65.4)</td>
</tr>
<tr>
<td>Concomitant backbone, n (%)</td>
<td>ABC/3TC</td>
<td>1627 (39.7)</td>
<td>794 (19.3)</td>
</tr>
<tr>
<td>TDF/FTC</td>
<td>496 (12.4)</td>
<td>104 (2.6)</td>
<td>600 (16.7)</td>
</tr>
<tr>
<td>TAF/FTC</td>
<td>107 (2.6)</td>
<td>55 (1.4)</td>
<td>162 (4.5)</td>
</tr>
<tr>
<td>Other NRTI</td>
<td>322 (7.9)</td>
<td>171 (4.2)</td>
<td>493 (13.2)</td>
</tr>
<tr>
<td>No NRTI</td>
<td>206 (5.0)</td>
<td>119 (2.9)</td>
<td>325 (9.1)</td>
</tr>
</tbody>
</table>

Table 2. Proportion of participants (%) with virologic suppression (HIV-1 VL<50 copies/mL). MSM, men who have sex with men; SSA, sub-Saharan African

<table>
<thead>
<tr>
<th>Week 24</th>
<th>Week 48</th>
<th>Week 96</th>
</tr>
</thead>
<tbody>
<tr>
<td>All study participants</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td>Men</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td>Women</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td>MSM</td>
<td>94</td>
<td>95</td>
</tr>
<tr>
<td>SSA patients</td>
<td>94</td>
<td>95</td>
</tr>
<tr>
<td>Treatment-naïve</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td>Treatment-experienced</td>
<td>94</td>
<td>95</td>
</tr>
<tr>
<td>CD4 + T-cell count &lt;350 cells/µL</td>
<td>94</td>
<td>96</td>
</tr>
<tr>
<td>CD4 + T-cell count ≥350 cells/µL</td>
<td>85</td>
<td>90</td>
</tr>
</tbody>
</table>

Figure 1. Rates and reasons for Dolutegravir discontinuation. ADR, adverse drug reaction.
Characterizations of weight gain following antiretroviral regimen initiation in treatment-naive individuals living with HIV

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Purpose: Antiretroviral therapy (ART) regimens may be associated with weight gain. We described weight gain continuously or at various thresholds (≥3 kg, ≥5 kg, or ≥5% increase from baseline) in ART-naive people living with HIV (PLWH) initiating common core agents.

Method: ART-naive adults initiating dolutegravir (DTG), elvitegravir/cobicistat (EVG/c), raltegravir (RAL), rilpivirine (RPV), or boosted darunavir (bDRV) for the first time between 01AUG2013 and 31DEC2017 were identified in the OPERA® cohort. Changes in weight were assessed at 6, 12, and 24 months following regimen initiation by mean change in weight, mean change in BMI, or an increase in BMI category (underweight: BMI<18.5, normal: 18.5–24.9, overweight: 25.0–29.9, obese: ≥30). Weight gain was categorized as weight increase ≥3 kg, ≥5 kg, or ≥5% from baseline.

Results: Among 6246 ART-naive PLWH, demographics and weight by group varied significantly at baseline (Table 1). At 6, 12, and 24 months, mean increases in weight showed more variability than mean increases in BMI, patterns were similar (Table 2). Of PLWH with normal or overweight BMI at baseline, 15% to 33% increased by at least one BMI category at 12 months after regimen initiation. Of underweight PLWH at baseline, the majority increased to a normal BMI at 12 months (Figure 1). Obese PLWH at baseline could not increase category, by definition. Weight gain varied across thresholds: ≥3 kg (37% to 53%), ≥5 kg (23% to 41%), ≥5% (30% to 49%; Figure 2).

Conclusion: While the proportion of PLWH experiencing weight gain across groups and definitions was substantial, mean increases were relatively small across regimens over up to 24 months of follow-up; not taking into consideration baseline differences or restoration of healthy body weight in sicker patients. More research is needed to identify clinically relevant weight gain thresholds and improve the interpretability of weight gain studies.

Table 1: Baseline demographic and clinical characteristics (N=6246)

<table>
<thead>
<tr>
<th></th>
<th>DTG (N=2118)</th>
<th>EVG/c (N=2665)</th>
<th>RAL (N=116)</th>
<th>RPV (N=757)</th>
<th>bDRV (N=590)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥50 years</td>
<td>237 (11.2)</td>
<td>287 (10.8)</td>
<td>40 (3.45)*</td>
<td>57 (7.5)*</td>
<td>81 (13.7)*</td>
</tr>
<tr>
<td>Female</td>
<td>245 (11.6)</td>
<td>285 (10.7)</td>
<td>36 (3.10)*</td>
<td>131 (17.3)*</td>
<td>99 (16.8)*</td>
</tr>
<tr>
<td>Black non-Hispanic</td>
<td>881 (41.6)</td>
<td>1225 (46.0)*</td>
<td>60 (5.17)*</td>
<td>406 (53.6)*</td>
<td>321 (54.4)*</td>
</tr>
<tr>
<td>Hypertension</td>
<td>240 (11.3)</td>
<td>300 (11.3)</td>
<td>28 (2.41)*</td>
<td>115 (15.2)*</td>
<td>82 (13.9)</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>239 (11.3)</td>
<td>258 (9.7)</td>
<td>22 (1.90)*</td>
<td>44 (7.5)*</td>
<td>92 (12.2)*</td>
</tr>
<tr>
<td>Meds associated w/ weight gain</td>
<td>228 (10.8)</td>
<td>245 (9.2)</td>
<td>26 (2.24)*</td>
<td>90 (11.9)</td>
<td>87 (14.7)*</td>
</tr>
<tr>
<td>Overweight (BMI 25–29.9)</td>
<td>640 (30.2)</td>
<td>789 (29.6)</td>
<td>40 (3.45)</td>
<td>219 (28.9)</td>
<td>168 (28.5)</td>
</tr>
<tr>
<td>Obese (BMI≥30)</td>
<td>387 (18.3)</td>
<td>428 (16.1)</td>
<td>27 (2.33)</td>
<td>196 (26.9)*</td>
<td>103 (17.5)*</td>
</tr>
</tbody>
</table>

Table 3. Adverse drug reactions leading to Dolutegravir discontinuation.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuropsychiatric toxicity</td>
<td>215</td>
<td>5.2</td>
</tr>
<tr>
<td>Gastrointestinal side effects</td>
<td>56</td>
<td>1.4</td>
</tr>
<tr>
<td>Hypersensitivity reaction</td>
<td>22</td>
<td>0.5</td>
</tr>
<tr>
<td>Abnormal fat redistribution</td>
<td>10</td>
<td>0.2</td>
</tr>
<tr>
<td>Liver toxicity</td>
<td>10</td>
<td>0.2</td>
</tr>
<tr>
<td>Renal toxicity</td>
<td>7</td>
<td>0.2</td>
</tr>
<tr>
<td>Pancreas/Endocrine toxicity</td>
<td>4</td>
<td>0.1</td>
</tr>
<tr>
<td>Hematological toxicity</td>
<td>1</td>
<td>0.02</td>
</tr>
<tr>
<td>Other</td>
<td>68</td>
<td>1.7</td>
</tr>
</tbody>
</table>

Figure 1. Proportion of PLWH with a BMI category increase at 12 months after core agent initiation

Figure 2. Comparison of weight gain definitions at 12 months after initiation, by core agent
How to RESPOND to modern challenges for people living with HIV: a new cohort collaboration

B Neesgaard1 and for the International Cohort Consortium of Infectious Diseases: RESPOND
1Rigshospitalet, University of Copenhagen, CHIP, Department of Infectious Diseases, Section 2100, Copenhagen, Denmark

Objectives: The RESPOND cohort consortium was formed as a platform for collaborative HIV research, investigating comorbidities and outcomes of contemporary antiretroviral therapy (ART), impact of hepatitis coinfection, and public-health focused questions for people living with HIV (PLWHIV).

Methods: RESPOND uses a modular electronic data collection structure, allowing for project specific data capture, in addition to routine data collection, including: demographics, risk of HIV acquisition, viral load (VL), CD4 count and detailed information on ART. Incident cardiovascular disease, malignancies, fractures, end-stage liver- and renal diseases are reported by clinical event forms and centrally validated. Prospective enrolment of consecutive PLWHIV aged≥18 years started 1/10/17, collecting data from established cohorts back to 1/1/12. Follow-up data is collected annually.

Results: Overall, 17 cohorts from Europe and Australia joined RESPOND in 2017, supplying data from more than 26,000 individuals. At study enrolment, median age was 48 years [IQR 40–56]; 44.6% were aged≥50 years. The majority was white (72.4%), males (74.3%), with the most common risk group for HIV acquisition being males-who-have-sex-with-males (43.3%); Intravenous drug use accounted for 14.9%. Coinfection with hepatitis B- and C was prevalent in 5.2% and 25.5%, respectively. At enrolment the majority had a VL≤200 copies/mL (91.3%), and median CD4 count was 262 cells/μL [439–833]; 59.7% had a CD4 count<500 and 4.8%≤200 cells/μL. CD4 nadir was<350 cells/μL for 78.1%; ≤50 cells/μL for 16.4%. Study participants had significant exposure to contemporary ART (figure) while 5.3% were ART-naive. Malignancies were the predominant reported clinical event, followed by cardiovascular disease and fractures (figure).

Conclusion: The RESPOND cohort study is a large, innovative and modern collaboration, using validated clinical events and detailed treatment information to assess outcomes of contemporary ART, the impact of hepatitis coinfection and to examine the continuum of care for PLWHIV, in a heterogeneous real-life setting.

Method: We analyzed electronic data of patients under follow-up in CRT DST/AIDS and selected whose last ARV prescription until April 30th, 2019 was 3TC+DTG or 3TC+DRV/r regimens. We collected data from their charts using REDCap platform.

Results: From 6445 HIV patients, we selected 62 patients under dual therapy. Profile, mean age, mean time of ART use and mean time of infection (from HIV diagnosis until the beginning of dual therapy) was 57.9 (37–87), 13.9 and 16 years, respectively. None of them was ART naive and the mean number of previous schemes were 3.7 (1–12). Therapy was simplified to 3TC+DTG for 47 patients (75.8%) and to 3TC+DRV/r for 15 (24.2%). Reasons for ART simplification are described in the graphic. There were no switches due to failure or drug interactions. The main reason was bone disease (osteopenia or osteoporosis) in 30.6%. Prior to dual therapy, HIV viral load was not detected in 87.1% patients and under the detection limit (40 copies) in 12.9%, CD4 was above 500 cells/mm³ in 61 patients and only one had CD4<200. After 6 months, viral load was available for 35 patients: 34 not detected and one had a blip of 60 copies. Viral load after 12 months were available for 10 patients, all not detected or under limit.

Conclusion: Simplification of ART regimens might be a secure option when we need to reduce toxicity considering ageing of HIV patients, multi-morbidity and polypharmacy, especially in a country where TAF is not available in the public health system. This is an early analysis and we need a longer follow-up to evaluate maintenance of virological suppression.

PE2/33

Simplification of ART regimens might be a secure option when we need to reduce toxicity considering ageing of HIV patients, multi-morbidity and polypharmacy, especially in a country where TAF is not available in the public health system. This is an early analysis and we need a longer follow-up to evaluate maintenance of virological suppression.

Reasons for ART simplification

PE2/34

ART simplification: use of dual therapy for HIV in a public health reference center (CRT–DST/Aids) in Sao Paulo, Brazil

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1Centro de Referencia e Treinamento DST/Aids, Sao Paulo, Brazil

Purpose: Evaluate the reasons for ART simplification and virological response with 2 drug regimens.

PE2/35

Simplification to dual (2D) antiretroviral therapy (ART) with lamivudine and dolutegravir in HIV-infected patients with solid organ transplantation (SOT): a preliminary single-center experience

A Castelli1, C Manzardo2, J Ambrosioni3, P Ruiz1, G Crespo1, A Forner1, M Tuset1, F Cofan1, MA Castel1, A Rimon2, M Brunet1, A Moreno1, JM Miro1 and SIH-IPWG Investigators
1Hospital Clinic – IDIBAPS, University of Barcelona, Barcelona, Spain 2HIV Unit, Arnu de Vilanova & Santa Maria University Hospitals –IRB, Lleida, Spain

Purpose: Dolutegravir is a non-boosted integrase inhibitor that theoretically has no pharmacokinetic interactions (DDI) with immunosuppressant drugs. In addition, dual ART treatment (2D) with lamivudine and dolutegravir is as effective and safe as triple ART in naive patients (Cahn P. Lancet, 2019) and in simplifying studies (Joly V. JAC, 2018). Therefore, this strategy could be useful in HIV-infected solid organ transplant (SOT) recipients, since it would avoid DDI and the potential bone and kidney toxicity of tenofovir and the cardiovascular risk associated with abacavir. The aim was to analyze the efficacy and safety of the simplification of triple-to-dual ART with lamivudine and dolutegravir in HIV-infected patients with SOT at the Hospital Clinic, Barcelona.

Method: A retrospective single-center study of SOT recipients who had to stop tenofovir or abacavir from triple ART due to toxicity and simplified to lamivudine and dolutegravir in HIV-infected patients with SOT at the Hospital Clinic, Barcelona

Results: The clinical characteristics of the six included patients are described in the table. Five patients were receiving effective ART with two NRTI and raltegravir (4 cases) or rilpivirine (1 case) and switched to dolutegravir plus...
lamivudine (2L). One patient (case 6) was on dual therapy pre-transplant. Renal function [creatinine, glomerular filtration] stabilized or improved in all cases. There were no significant changes in the dose of calcineurin inhibitors (either cyclosporin or tacrolimus) or mycophenolic acid. All remained suppressed and none had an episode of acute rejection. One patient (case 4) with positive anti-core HBV antibodies and negative HBsAg, HBeAg and plasma DNA–HBV, developed acute HBV two years after simplification

Demographic and clinical characteristics

Table 1. Therapeutic outcomes at week 48

Conclusion: Simplification to lamivudine and dolutegravir was effective and safe in the short/medium term in HIV-infected SOT recipients who had no history of active/past infection with HBV

PE2/36

Comparable effectiveness of Raltegravir-based dual therapy versus other regimens in patients switched for maintenance K Martin1, B Funke1, T Wünsche2, T Lutz3, H läger4 and V Witte1

In clinical practice Raltegravir is used in nuke-free dual therapy. Here, we compared profiles and 48-week treatment outcomes of patients on RAL-based dual versus other RAL-based ART in a historical German real-life cohort. The WIP study was a real-life, prospective, observational cohort study with data collection from 2010–2014. Safety and efficacy outcomes of RAL-based ART were compared with other ART, patients initiated on RAL-based dual therapy were on average 3.9 years older and suffered more likely from hypertension (26% vs. 18%), coronary artery disease (12% vs. 4%) and renal insufficiencies (10% vs. 4%) at baseline. They were less frequently therapy-naïve (17% vs. 22%) or pretreated with suppressed viral load (VL) (45% vs. 51%) but more often failing (35% vs. 24%). Dual therapies mainly included a PI (94%, 7277); most other regimens combinations included NRTI (77%, 2873). Treatment outcomes of dual vs. other ART differed slightly: 48-week virologic response (VL<50 c/mL; early DC (discontinuation)=failure) was numerically lower in therapy-naïve patients (69% vs. 76%). However, in virologically suppressed patients switched for maintenance efficacy of RAL-based dual therapy was high and comparable to other RAL-based regimens (63% vs. 81%; Table 1).

Table 1. Baseline Characteristics

Patients on RAL-based dual vs. other ART showed differing comorbidity profiles and RAL utilization patterns. While outcomes in therapy-naïve and pretreated failing patients were less favorable, response rates in virologically suppressed patients were high and comparable supporting the concept of maintenance switch to RAL-based dual therapy to avoid drug toxicities or intolerances.

PE2/37

Comparison of a two-drug regimen (dolutegravir/ritonavir) to standard three-drug regimens in virologically suppressed, treatment experienced individuals in the real world G Pierone1, K Schulman2, J Fusc3, V Vanmappagar3, M Aboud4, L Ragone1 and G Fusc5

1Whole Family Health Center, Vero Beach, USA 2Epidian, Inc., Durham, USA 3ViiV Healthcare, Research Triangle Park, USA 4ViiV Healthcare, London, UK

Purpose: Dolutegravir/ritonavir (DTG/RPV) was the first single tablet, once daily regimen containing only two antiretrovirals to be approved. The objective of this study was to compare the effectiveness and durability of DTG/RPV to standard three-drug regimens (3-DR) in a real-world population.

Method: People living with HIV-1 (PLWH) who initiated DTG/RPV or 3-DR, defined as one core agent and two NRTIs, were identified in the OPERA Database. Those who initiated therapy between 1/1/2018–6/30/2018 were ART experienced, age≥13 years, and suppressed (<50 copies/mL) at start were analyzed. Discontinuation (d/f) was defined as cessation of DTG/RPV or 3-DR.

Table 1. Baseline Characteristics

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Sustained suppression was defined as last viral load (VL) ≤50 copies/mL or 200 copies/mL OR 1 VL ≤200 copies/mL + d/c. The population was observed through 12/31/2018. Baseline characteristics were described using Pearson’s chi-square, Fisher exact, or Wilcoxon rank-sum tests. Kaplan–Meier methods were used to describe d/c and VF. Cox Hazards models compared time to VF. Results: Among 259 PLWH who initiated DTG/RPV and 2,792 PLWH who initiated 3-DR, DTG/RPV users were older, more likely to be Hispanic, to live in the southern US, and have comorbidities (Table 1). DTG/RPV users were followed for less time and experienced fewer discontinuations and did not differ in sustained suppression compared to 3-DR users (Table 2, Figure 1). VF rates per 100 patient-years (95% CI) did not differ either (DTG/RPV: 1.7 [0.6, 5.4] vs. 3-DR: 2.3 [1.7, 3.1]) (Table 2, Figure 2). Differences in the risk of virologic failure between 3-DR, DTG/RPV initiators in adjusted Cox models were not significant (p = 0.0885).

Conclusion: Among ART-experienced, virologically suppressed PLWH initiating DTG/RPV or standard 3-DR, there was no observed difference in their ability to remain suppressed or risk of virological failure in a real-world setting.

**PE238**

Effectiveness of the combination elvitegravir/cobicistat/tenofovir/emtricitabine (EVG/COB/TFV/FTC) plus darunavir in treatment-experienced patients: a multicentre cohort study

J. Suárez-García1,2, C. Moreno1, B. Alejos1, M. Ruiz-Algueró3, M.J. Pérez Elias4, M. Navarro5, M. Díez Martínez6, P. Viciana7, C. Amador Prous8, I. Jarrin1 and Cohort of the Spanish HIV/AIDS Research Network (CoRIS)

1Hospital Universitario Infantia Sofia, Madrid, Spain 2Universidad Europea, Madrid, Spain 3Instituto de Salud Carlos III, Centro Nacional de Epidemiología, Madrid, Spain 4Hospital Universitario Ramón y Cajal, Madrid, Spain 5Corporación Sanitaria Parc Taulí, Sabadell, Spain 6Hospital General Universitario de Alicante, Alicante, Spain 7Hospital Virgen del Rocío, Sevilla, Spain 8Hospital de la Marina Baixa, Alicante, Spain

Objective: The aim of this study was to investigate the effectiveness of the combination elvitegravir/cobicistat/tenofovir/emtricitabine plus darunavir (EVG/COB/TFV/FTC+DRV) in treatment-experienced patients from the cohort of the Spanish HIV/AIDS Research Network (CoRIS).

Methods: Treatment-experienced patients starting treatment with EVG/COB/TFV/FTC+DRV during the years 2014–2018 and with more than 24 weeks of follow-up were included. TFV could be administered either as tenofovir disoproxil fumarate or tenofovir alafenamide. We evaluated virological response (defined as viral load ≤50 copies/mL) and change in CD4 count at 24 and 48 weeks after starting this regimen.

Results: We included 39 patients (12.8% women). Median CD4 count at the start of the regimen was 437 (IQR: 108–740) cells/μl. Patients had been receiving ARV for a median of 5.3 (IQR: 2.5–7.5) years, had received a median of 3 (IQR: 2–6) previous antiretroviral regimens and were receiving a median of 2 (IQR: 1–5) pills per day. Ten (25.6%) patients had viral load ≤50 copies/mL at the start of EVG/COB/TFV/FTC+DRV, and the most frequent reasons for changing to this regimen were treatment failure in 14 (35.6%) and simplification in 10 (25.6%) patients.

The patients received EVG/COB/TFV/FTC+DRV for a median of 391 (IQR: 205 to 514) days. At their last follow-up visit, 18 patients continued receiving the regimen and 21 had changed to another regimen (nine [23.1%] changed due to simplification, 6 [15.4%] due to treatment failure, 1 [2.6%] due to toxicity, and 5 [12.8%] due to nonadherence, interactions or other reasons). Treatment outcomes are shown in the table.

Conclusions: EVG/COB/TFV/FTC+DRV was well tolerated and effective in treatment–experienced patients with undetectable viral load as a simplification strategy, allowing once-daily, two-pill regimen with three antiretroviral drug classes. Effectiveness was low in patients with detectable viral loads. This is the largest cohort published to date showing results from "real-life" clinical practice with this treatment regimen.

**Outcome**

<table>
<thead>
<tr>
<th></th>
<th>24 weeks</th>
<th>48 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load ≤50 copies/mL</td>
<td>6/7 (85.7%)</td>
<td>4/5 (80%)</td>
</tr>
<tr>
<td>Viral load &gt;50 copies/mL</td>
<td>11/23 (47.8%)</td>
<td>9/27 (40.8%)</td>
</tr>
<tr>
<td>CD4 change, cells/μl</td>
<td>50 median (IQR)</td>
<td></td>
</tr>
<tr>
<td>Viral load ≤50 copies/mL</td>
<td>29 (14–48)</td>
<td>8 (-85 to 50)</td>
</tr>
<tr>
<td>Viral load &gt;50 copies/mL</td>
<td>-6 (-134 to 107)</td>
<td>-16 (-116 to 77)</td>
</tr>
</tbody>
</table>

Outcomes of patients at 24 and 48 weeks after starting EVG/COB/TFV/FTC+DRV, stratified by viral load at the start of the regimen.
High persistence of dolutegravir-containing 2-drug regimens in routine clinical care

S Noe1, C Jonsson-Oldenburg1, S Heldwein1, C Wiese1, A von Krogh1, F Schabas2, H Jaeger1, E Wolf2 and ArchiV

Purpose: To describe the persistence of DTG-containing 2DR and three-drug regimens (3DR) in people living with HIV from real-life cohort data.

Method: Monocentric time-on-treatment analysis. The 2DR-group consisted of patients initiated on DTG+rilpivirine (RPV) or lamivudine (3TC) between 2014-2018 with or without history of DTG-containing 3DR. Of all others, patients initiated on DTG with abacavir (ABC)/3TC or tenofovir (aafenamide (TAF) or disoproxil fumarate (TDF))entricitabine (TDF) were included into the 3DR-group. In Kaplan-Meier analysis, discontinuation of 2DR or 3DR was defined as event (exluding switches from DTG-containing 2DR or 3DR to another 2DR or 3DR in the absence of virologic failure. Associations of covariates with time-on-treatment were analyzed using Cox regression analysis.

Results: Of 617 patients, 134 (21.7%) received a 2DR. 79.1% and 76.3% of patients on 2DR and 3DR were male (p=0.473), median age was 52 and 46 years (y.) (p=0.001), median time since HIV-diagnosis was 16 and 7y. (p=0.001), respectively; 4 (3.0%) and 163 (33.8%) of patients had been treatment-naive. Persistence on 2DR and 3DR was not significantly different (p=0.245) with 94.9% (93.0%) and 91.1% (88.8%) after 46 weeks (96 weeks). After adjusting for age<=50y., time since HIV-diagnosis<=10y., HIV-RNA<50 cp/mL, treatment-naivety, CD4 cells<200/xL, 2DR wasn’t associated with a higher risk of discontinuation (HR 0.7 (95% CI: 0.3-1.6); p=0.427), while only CD4<200/xL (HR 2.2 (95% CI: 1.2-4.0; p=0.009) was.

Conclusion: Persistence of 2DR was comparable to 3DR up to>200 weeks. Experienced HIV-centers seem to identify potential candidates for 2DR well, with 2DR being as effective as 3DR in routine clinical practice.

Table 1. Kaplan-Meier graph of persistence on DTG-containing 2DR or 3DR

<table>
<thead>
<tr>
<th>Time (weeks)</th>
<th>2DR</th>
<th>3DR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-50</td>
<td>134</td>
<td>483</td>
</tr>
<tr>
<td>51-100</td>
<td>67</td>
<td>394</td>
</tr>
<tr>
<td>101-150</td>
<td>54</td>
<td>320</td>
</tr>
<tr>
<td>151-200</td>
<td>35</td>
<td>238</td>
</tr>
<tr>
<td>201-250</td>
<td>17</td>
<td>136</td>
</tr>
<tr>
<td>251-300</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

AIDS or death. On-treatment analysis (success: VL<200 cp/mL) excluded individuals with unknown VL/any regimen change. Immunologic success was defined as a CD4=750 cells/mm² or 33% increase where baseline CD4=500 cells/mm². Poisson regression compared clinical outcomes (failure: AIDS/death occurring>14 days after starting ART). Interactions between ARV class and subpopulations (defined by age, CD4 count, VL) were determined for each endpoint.

Results: Of 4249 ART-naive persons in RESPOND, 42.4% started INSTIs, 28.0% PI/b and 29.6% NNRTIs. After adjustment, compared to those starting INSTI, those treated with a PI/b had lower odds of cTO success. In contrast, those treated with an NNRTI had lower odds of immunologic success than those on INSTI (Figure). During 10568 persons-years-of-follow-up the rates of new AIDS/death were similar across all drug classes (Figure). Virologic or immunologic success and clinical failure were completely consistent across age groups (<40, 40-50 and >50y.), CD4 count at starting ART (<350 cells/mm²) or VL at starting ART (<100,000 versus>100,000 cp/mL) with all interactions non-significant (p=0.1).

Conclusion: Virologic, immunologic and clinical outcomes ART naive participants were similar across subpopulations defined by age, immune suppression or VL at ART initiation suggesting that these subpopulations will equally benefit from ART, regardless of ART class. Confounding by indication cannot be excluded.
including >100,000 genotypes, >170,000 treatments, >1 million viral load and >1 million CD4 values.

Patients were selected into either the dual therapy or triple therapy treatment group. Both groups need to have a VL (viral load) measurement short before switch with VL under 50 cp/mL and multiple viral load measurements while on therapy. Viral failure was defined as two consecutive VL measurements with VL over 200 or one measurement above 1000.

The triple therapy cases were then selected via propensity score matching to contain similar covariates gender, age, route of transmission, CD4 at start, time on ART and time before switch with VL below 50.

Those data were used to generate Kaplan Meier curves for the dual and triple therapy groups. Afterwards, a TOST (two-one-sided-t-test) was performed comparing the Kaplan Meier estimator at 48 weeks, the endpoint for most prospective studies in this area.

Results: In contrast to older dual therapies, we found no significant difference between INI containing dual and triple therapies in the Kaplan Meier curve. The two-one-sided-t-test at week 48 showed that dual-therapy was significantly non-inferior compared to triple-therapy.

Conclusion: Our results showed that in a real-life clinical setting, INI containing dual therapies have a similar success rate compared to INI containing triple therapies. Therefore, we consider dual therapy as a valuable addition in HIV management.

Table 1. Differences in baseline eGFR, and changes in outcomes stratified by ARVs

<table>
<thead>
<tr>
<th>Group 1: Remain on TDF</th>
<th>Group 2: TDF to TAF</th>
<th>Group 3: Non-TDF to TAF</th>
<th>Group 4: Neither on TDF or TAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=56</td>
<td>n=135</td>
<td>n=29</td>
<td>n=59</td>
</tr>
<tr>
<td>Mean baseline eGFR (SD)</td>
<td>77.4 (13.7)</td>
<td>71.5 (20.0)</td>
<td>58.8 (15.0)</td>
</tr>
<tr>
<td>ml/min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean change in eGFR (SD)</td>
<td>4.47 (9.22)</td>
<td>5.75 (11.39)</td>
<td>5.31 (15.15)</td>
</tr>
<tr>
<td>Mean change in total cholesterol (TC) (SD)</td>
<td>-0.0963 (0.640)</td>
<td>0.1754 (0.802)</td>
<td>-0.6545 (1.084)</td>
</tr>
<tr>
<td>Mean change in TCHDL ratio (SD)</td>
<td>-0.0299 (0.721)</td>
<td>-0.0335 (0.7342)</td>
<td>-0.111 (0.814)</td>
</tr>
<tr>
<td>Mean change in body weight (SD)</td>
<td>1.306 (5.247)</td>
<td>1.571 (4.642)</td>
<td>0.82 (6.27)</td>
</tr>
</tbody>
</table>

PE2/43

Effect of simplification to INSTI-based dual therapy on residual immunological and viral reservoir

E Merlini1, A Cozzi-Lepri2, C Altri3, R Scutari4, A Cingolani5, F Bai6, F Petroni7, F Ceccherini-Silberstein7, S Lo Caputo8, A Antinori9, C-F Perno10, A d’Arminio Monforte11, G Marchetti12, and Icona Foundation Study Group

1University of Milan Clinic of Infect Dis, Milan, Italy 2Centre for Clinical Research, Epidemiology, Modelling and Evaluation (CREME) Institute for Global Health UCL, London, UK 3University of Milan, Department of Oncology and Hemato-Oncology, Milan, Italy 4University of Rome Tor Vergata, Rome, Italy 5Institute of Clinical Infectious Diseases, Catholic University of Sacred Heart, Rome, Italy 6National Institute for Infectious Diseases ‘L. Spallanzani’ IRCCS, Rome, Rome, Italy 7Department of Experimental Medicine, University of Rome “Tor Vergata”, Rome, Italy 8Department of Infectious Diseases, University of Bari ‘Aldo Moro’, Bari, Italy 9HIV/AIDS Unit, National Institute for Infectious Diseases ‘L. Spallanzani’ IRCCS, Rome, Rome, Italy 10Department of Oncology and Hemato-Oncology University of Milan, Milan, Italy 11University of Milan, Italy 12University of Milan, Dept of Health Sciences, Milano, Italy

Purpose: Whether dual regimens (2DR) might reduce the control over immune activation/inflammation has not been fully addressed. We aimed to describe the trend in pro-inflammatory markers and monocyte activation over 1 year of observation after a switch to INSTI-based dual therapy with VL<500 copies/mL.

Method: Inclusion criteria: (i) cART-treated HIV+ patients (HIV-RNA<50cp/ mL) in Icona cohort, (ii) switched from triple combinations to INSTI-containing 2DR for any cause, (iii) on a stable triple cART for >= 12 months prior to the switch and iv) availability of plasma samples at switch (T0) and 12 ± 6 months post-switch (T1). Laboratory: circulating sCD14, C Reactive Protein (CRP), IL-6 (Luminex); HIV-DNA (ddPCR).

Statistics: paired T-test, non-parametric Spearman correlation.

Results: We included 50 patients, with median (IQR) CD4, HIV-RNA and CART duration of 732 cell/mmc (568–920), 15 cp/mL (1–37), 4 years (2–10) respectively. 18 switched from INSTI triple, 13 from boosted-PI, 19 from NRTI (Table 1). 17 (34%) patients simplified to RAL-based dual, 33 (66%) to DTG-based dual therapy. Median follow-up between 10 and 11: 15 months (IQR: 12–18). Simplifying to 2DR resulted in a slight CD4 increase (p=0.038) coupled with a parallel decrease in sCD14 (p<0.001), the latter being more relevant in patients switching to DTG- vs RAL-containing regimens (p interaction=0.014), and evident only in patients switching from other than INSTI-containing regimens. Upon switch to 2DR, no changes in CD8, CD4/CD8 ratio, HIV-RNA and HIV-DNA, as well as other pro-inflammatory markers were shown (Table 2). No correlations between inflammatory markers and viro-immunologic parameters were found.

Conclusion: In our cohort of long-treated HIV+ patients, simplification to INSTI-based 2DR appeared to reduce sCD14 – slightly increasing CD4 – notwithstanding stable HIV reservoirs, suggesting no disturbance to immune balance, rather an amelioration of the immune and inflammatory profile, during the first year of dual INSTI-based regimens.
Changes in LDL after switch from TDF to TAF in the U.S.

P. Mallon1, L Brunet2, J Fusco3, G Prajapati2, A Beyer3, G Fusco2 and M Wohlfeiler4

1University College Dublin, School of Medicine, Dublin, Ireland 2Epividian, Inc., Durham, USA 3Merck & Co., Inc., Kenilworth, USA 4AIDS Healthcare Foundation, Miami, USA

Purpose: Increases in lipids have been observed in people living with HIV (PLWH) switching from tenofovir disoproxil fumarate (TDF) to tenofovir alafenamide (TAF). We assessed changes in LDL over time following a switch from TDF to TAF.

Method: Adults switching from TDF to TAF, including those who maintained all other components of their antiretroviral regimen, with ≥1 lipid measure on TDF taken ≤6 months prior to switch and ≥1 lipid measure ≥7 days after switch to TAF were identified in the OPERA cohort (84 clinics in 18 U.S. states/territories). Predicted changes in lipids over time on TAF were assessed with multivariable linear regression using generalized estimating equations to account for repeated measures.

Results: 6,451 PLWH switched from TDF to TAF (main population), of whom 4,328 maintained all other ARVs (sensitivity population, Table 1). Over 80% had normal or borderline abnormal LDL values at their last lipid panel on TDF (Figure 1). Among switchers, LDL values increased significantly by 1.40 mg/dL per month over the first 3 months of TAF exposure, continued to increase significantly, though less rapidly, by 0.33 mg/dL per month between 3 and 9 months, and plateaued beyond 9 months (Table 2). Similar patterns were observed in the sensitivity population (Table 3). The overall LDL response appears to be well predicted by regression models (Figure 2).

Table 1. Demographic and Clinical Characteristics at the Time of Switch from TDF to TAF in the Main and Sensitivity Populations

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Main population: All switches (N=6,451)</th>
<th>Sensitivity population: Maintained other ARVs (N=4,328)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months on TDF pre-switch</td>
<td>29.2 (13.8, 51.5)</td>
<td>27.7 (14.0, 46.4)</td>
</tr>
<tr>
<td>Age</td>
<td>48 (38, 55)</td>
<td>47 (37, 54)</td>
</tr>
<tr>
<td>Female</td>
<td>1,010 (15.7)</td>
<td>674 (15.6)</td>
</tr>
<tr>
<td>HIV viral load ≥50 copies/mL</td>
<td>1,103 (17.2)</td>
<td>620 (14.0)</td>
</tr>
<tr>
<td>PI Use</td>
<td>1,272 (19.7)</td>
<td>815 (18.8)</td>
</tr>
<tr>
<td>Boosting agent use</td>
<td>4,019 (62.3)</td>
<td>2,520 (58.2)</td>
</tr>
<tr>
<td>Concomitant hormone use</td>
<td>554 (8.4)</td>
<td>372 (8.6)</td>
</tr>
<tr>
<td>Concomitant statin use</td>
<td>1,112 (17.2)</td>
<td>732 (16.9)</td>
</tr>
<tr>
<td>Concomitant non-statin lipid lowering agent use (omega-3, fibrate, etc.)</td>
<td>425 (6.6)</td>
<td>267 (6.2)</td>
</tr>
</tbody>
</table>

Table 2. Rates of Change in LDL Over Time After Switch to TAF, Estimated from a Multivariable Linear Regression* in the Main and Sensitivity Population

<table>
<thead>
<tr>
<th>Months on TAF</th>
<th>Changes in LDL over time, mg/dL per month (95% CI)</th>
<th>Changes in LDL over time, mg/dL per month (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–3 months</td>
<td>+1.40 (1.19, 1.60)</td>
<td>+1.72 (1.47, 1.96)</td>
</tr>
<tr>
<td>3–9 months</td>
<td>+0.33 (0.20, 0.46)</td>
<td>+0.27 (0.11, 0.42)</td>
</tr>
<tr>
<td>9–16 months</td>
<td>+0.06 (–0.05, 0.16)</td>
<td>+0.10 (–0.03, 0.23)</td>
</tr>
<tr>
<td>16 + months</td>
<td>+0.03 (–0.07, 0.12)</td>
<td>–0.00 (–0.11, 0.11)</td>
</tr>
</tbody>
</table>

* Adjusted for baseline LDL (cubic splines, knots at 79, 96, 117 mg/dL), age (cubic splines, knots at 40, 50, 55 years), months on TDF (cubic splines, knots at 15, 28, 49 months) and sex; time-updated HIV viral load ≥50 copies/mL and concomitant hormone, statin, non-statin lipid lowering agent, PI and boosting agent use.
observed among PLWH who maintained all other ARVs (Table 2). Average predicted LDL values remained borderline abnormal throughout follow-up (Figure 2).

Conclusion: In this large, diverse cohort of PLWH in care in the U.S., switching from TDF to TAF was associated with an increase in LDL over the first 9 months on TAF, followed by a plateau at higher LDL levels. The observed LDL increases cannot be attributed to changes in other ARVs as indicated by a sensitivity analysis restricted to PLWH who maintained all other ARVs.

Figure 2. Adjusted\* Predicted LDL Over Time After Switch from TDF to TAF in the Main Population (All)

PE2/45

A retrospective analysis of the EuResist data set assessing if NRTI resistance impairs INSTI based treatment with NRTI backbone

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Purpose: Antiretroviral combination therapy (cART) normally contain two nucleotide reverse transcriptase inhibitors (NRTIs) and an integrase inhibitor (INSTI). But there is still a lack of studies showing how baseline resistance to NRTIs affects the risk of virologic failure in this constellation. We assess whether NRTI resistance can impair INSTI based treatment with NRTI backbone.

Method: This retrospective study uses the EuResist Integrated Database. EuResist is a meta database containing data from>81.000 HIV patients, including>100.000 genotypes, >170,000 treatments, >1 million viral load and>1 million CD4 values. Selected patients had a recorded first-line therapy and a baseline sequence within 1 month of the therapy start. Only therapies after 2009 were selected, the onset of dual therapies in the data set. NRTI resistance mutations where obtained by the Stanford HIVdb program. The cases were then classified as either no NRTI mutation or=1 NRTI mutation. Virologic failure was defined as after 6 months or after first virologic suppression a VL viral load measurement of over 1000 cp/mL. This resulted in 497 INSTI therapies without NRTI resistance and 38 INSTI therapies with NRTI resistance.

Kaplan Meier plots were generated both for the overall risk of viral failure stratified by NRTI mutation and specifically for INSTI based ARTs.

Results: The Log-rank test for the Kaplan Meier curve depicting overall viral failure shows a significant difference between no NRTI mutation and =1 NRTI mutation p=0.048. The log-rank test for INSTI-based ARTs was p=0.003. For INSTI based ARTs the risk of viral failure was 13% in the resistant group and 4% in the non-resistant group.

Conclusion: Our results point in the direction that NRTI resistance in first-line integrase therapies does indeed increase the risk of viral failure.

PE2/46

Impact of archived M184V/I mutations on the effectiveness of switching to coformulated elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide among virologically suppressed HIV-positive patients


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Purpose: Real-world experience with the effectiveness of coformulated, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) as a switch regimen among patients with HIV-1 harboring M184V/I mutations with or without other thymidine analogue-associated mutations (TAMs) are lacking.

Method: In this multicenter, retrospective matched cohort study, patients who were switched to E/C/F/TAF after having achieved viral suppression (plasma HIV RNA load [PVL] )< 200 copies/mL for 6 months or longer were included. Patients with archived M184V/I mutations (case patients) were matched to controls without previous M184V/I mutations by a 1:4 ratio. Those who had a previous history of virological failure or resistance to integrase inhibitor were excluded. The primary end point was PVL<50 copies/mL at week 24 of switch using FDA snapshot analysis.

Results: In total, 101 case patients with known M184V/I mutations were identified, including 6 (5.9%) with K65R and 19 (18.9%) with at least 1 TAM, gender (male, 98.0% vs 98.0%) and cumulative exposure duration to tenofovir disoproxil fumarate (median, 138 vs 140 weeks). At week 24, the rate of virological non-success (PVL<50 copies/mL) among case and control patients was 5.1% (5/101) and 2.7% (11/404), respectively (difference, 2.3%; 95% CI, 1.2–8.7%). The rate of virological success (PVL<50 copies/mL) was 84.8% vs 84.1% among the case and control patients, respectively. Discontinuations of E/C/F/TAF occurred in 4.0% (n=4) of the case patients due to adverse effects and missing scheduled blood testing occurred in 7.9% (n=8) at week 24, who continued to receive E/C/F/TAF, while the respective rate of discontinuations and missing blood testing was 4.0% (n=16) and 9.4% (n=38) among the control patients.

Conclusion: Among virally suppressed HIV-positive patients, E/C/F/TAF is effective in maintaining viral suppression at week 24 despite archived M184V/I mutations with or without TAMs.
Central nervous system (CNS) side effects and viral blips post cART switch from atazanavir boosted with ritonavir (ATZ/r) to atazanavir boosted with cobicistat (ATZ/c)

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Purpose: Cobicistat is a weaker inhibitor of the P-gp and BCRP efflux pumps expressed at the blood-brain barrier limiting the entry of protease inhibitors (Ronaldson et al., 2008). Atazanavir penetration is low in CSF (Best et al., 2009). Clinic experience of cases of CNS symptoms post switch to ATZ/c triggered a review.

Method: PLWH who had their PI switched from ATZ/r to ATZ /c were randomly selected from pharmacy audit data retrospectively and followed up to a maximum of 6 months to analyse data on CNS side effects and viral loads post switch. A comparative arm for DRV/r to DRV/c switch was selected.

Results: ATZ/r to ATZ/c switch group: A total of 41 patients [M23, F18; Mean CD4 count at switch 667 cells/μl; HIV viral load at switch <= 50 (n=37), < 100 (n=3), >100 copies/mL (n=1)] were included. 5 (12%) experienced CNS side effects reported at 1 month follow up (Headache, numbness of fingers, excessive sweating, anxiety, transient headache) which resolved only on discontinuation of cobicistat (n=5). All 5 maintained viral load<50 copies/mL. 4 (9%) out of 41 experienced viral blips during follow up period with previous undetectable viral load (<50 copies/mL).

DRV/r to DRV-c switch group: 50 patients [M32, F18; Mean CD4 count at switch 567 cells/μl; HIV viral load at switch: <50 (n=36), <100 (n=3), >100 copies/mL (n=1)] were included. 1 person developed low level viremia post switch. 2 developed CNS side effects (vivid dreams, increased appetite) reported at one month follow up and resolved without discontinuation of cobicistat.

Conclusion: Higher CNS side effects and viral blips are observed on ATZ/r to ATZ/c shift. This could be due to variable compartmental concentration of boosted atazanavir within CNS and other viral reservoir sites. Further studies are required to explore this association.

Quantitation of cellular HIV-1 DNA levels by droplet digital PCR in virologically-suppressed patients switching to dolutegravir plus lamivudine: a prospective study

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Purpose: The aim of this study was to assess HIV-1 cellular reservoir size in virologically-suppressed patients switching to dolutegravir (DTG) plus lamivudine (3TC).

Method: This was a single-arm, prospective study that enrolled 40 patients without previous virological failure, with HIV-1 RNA<50 copies/mL for≥48 weeks and CD4>200 cells/μl switching from 3-drug cART to DTG 50 mg +3TC 300 mg once daily. We assessed total blood-associated HIV-1 DNA levels at baseline (BL) and 48 weeks (T48) after switch by droplet digital PCR using a 5’ nuclease assay targeting the HIV-1 LTR region. Results were expressed as log10 HIV-1 DNA copies/10^6 leukocytes. Paired T-test was used to compare the means between the two time-points. Regression analyses were applied to assess the correlations.

Results: A subset of 31 subjects with a complete follow-up was analyzed: 81% males, mean age 53 years, mean CD4 count 688 cells/μl, previous regimen NNRTI-(42%), INSTI-(39%) and PI-based(19%). The mean BL HIV-1 DNA was 2.16 (95% CI 1.97; 2.35). At T48 the mean HIV-1 DNA was 2.04 (95% CI 1.85; 2.23), with a significant mean decrease from BL of ~0.13 (95% CI −0.008;0.25) (p=0.041). BL and T48 HIV-1 DNA levels were highly correlated (p<0.001). No demographic, clinical and viro-immunological variable was associated with HIV-1 DNA changes. Zenith log10 HIV-1 RNA, mean change +0.350 per +1log10 95% CI 0.157; 0.542 (p=0.001) and BL CD4, mean change −0.132 per +100 cells/μl 95% CI −0.178;-0.087 (p<0.001) were independently associated with BL HIV-1 DNA. No significant change in CD4 count and HIV-1 RNA levels was observed during the study, albeit one patient experienced a virological failure at T48.

Conclusion: Our data suggest that in virologically suppressed patients switching to DTG + 3TC may have a favorable impact on the cellular HIV-1 DNA reservoir. These results need to be confirmed by larger controlled studies.

Evaluation of weight gain in incarcerated individuals living with HIV/AIDS after switching to a raltegravir-based regimen

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1University of Illinois at Chicago College of Pharmacy, Pharmacy Practice, Chicago, USA 2University of Illinois at Chicago College of Pharmacy, Chicago, USA 3University of Illinois at Chicago College of Medicine, Chicago, USA

Purpose: Integrate Strand Transfer Inhibitors (INSTIs) are a class of antiretrovirals (ARVs), commonly used with other ARV classes, to achieve virologic suppression. However, recent data have demonstrated the potential for weight gain with the addition of an INSTI. The primary objective was to assess average weight change, in kilograms, before/after raltegravir (RAL) initiation. Secondary outcomes included change in body mass index (BMI) and BMI categorization.

Method: A retrospective cohort study was performed in incarcerated adults living with HIV in Illinois, USA, from January 1, 2011, through June 30, 2014. Included subjects were≥18 years old, on a non-INSTITI regimen prior to switching to RAL-based therapy, and received routine CD4, HIV-RNA, and weight monitoring at least 6 months prior and post switch to RAL. Subjects were excluded if previously receiving an INSTI, ARV-naive, or released prior to obtaining appropriate follow-up. Statistical analysis included paired t-tests and descriptive statistics.

Results: Among 29 patients placed on RAL, the majority were male (97%) with an average age of 41.9 years (range 20–57). Mean time on a pre-INSTITI regimen was similar to time on RAL (13.4 and 13.7 months, respectively). Twenty-six patients (90%) experienced weight gain with an average increase of 4.1 kg (p=0.0006) regardless of previous regimen (NNRTI or PI-based) or virologic suppression (p=0.9593). Twenty-three subjects (79.3%) received concomitant tenofovir while 20.7% (n=6) received Raltegravir—sparing regimens. Patients with CD4<200 cells/mm3 were more likely to experience an increase in their weight from baseline (p=0.0012). BMI data were available for 25 patients. BMI increased by an average of 0.932 (pre-RAL 25.344 vs. post-RAL 26.276) (p=0.0031) with 6 subjects re-categorized into an increased BMI classification.

Conclusion: Switching to RAL-based therapy may be associated with significant weight gain. Further studies should assess clinical consequences of increased weight with INSTI-regimens.

Determinants of viral non-suppression among people living with HIV (PLHIV) in rural setting, Neno: a retrospective cohort study

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1Partners In Health, Clinical, Neno, Malawi

Purpose: Early establishment of viral suppression status among patients on ART, is key for early detection of treatment failure and identification of patients in need of intensive adherence counseling. Viral suppression is defined as viral load (VL)<1000 ribonucleic acid (RNA) copies/mL. There is limited data on determinants of viral non-suppression among ART clients. This study investigated factors associated with viral non-suppression among PLHIV in Neno, Malawi.

Method: We conducted a retrospective cohort study using routinely collected HIV program data from 2007 to 2018. We extracted VL, defined as having VL in past four years, along with demographic variables in Electronic Medical Records (e.g., gender, age, presence of at least one NCD, BMI, ART duration, and default outcome). Viral non-suppression served as outcome variable in
analysis. Multivariate logistic model was used to identify determinants of viral non-suppression.

Results: We reviewed 14680 clients, of these, 53% (7847/14680) had VL, and 6% were not virally suppressed. After adjusting for covariates; age, default outcome, ART duration and BMI, likelihood of having non-suppressed VL decreases with increase in age, with 5 times higher among those below 20 years (AOR=5.00, 95% CI 2.36–10.57), 2 times higher (AOR=2.35, 95% CI 1.61–3.37) among those aged 20–25 compared to 25+ years. Defaulting outcome was associated with 4 times increase in non-suppressed VL (AOR=4.61, 95% CI 3.35–6.35) compared to non-defaulting. The odds of having non-suppressed VL was 62% higher among those on treatment for below 1 year compared to 7 + years. Viral non-suppression was 46% higher among underweight (< 18.5) compared to normal weight (18.5–24.9).

Conclusion: Specific and specialized programs targeting clients who are young, having history of defaulting, underweight, and in first year of ART treatment with comprehensive range of interventions including psycho-social support and treatment literacy are needed to further improve viral suppression outcomes.

PE2/51
Risk of developing HIV resistance in patients with low level viraemia in a large London cohort
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Purpose: Management of low-level viraemia (LLV) in patients on combined antiretroviral therapy (cART) remains a challenge. LLV is an independent risk factor for virological failure. We examined resistance patterns and management of patients with LLV in our clinic cohort.

Method: All individuals attending our HIV clinic who experienced LLV between 2015–2019 were included. LLV was defined as <2 consecutive detectable viral loads of 21–200 c/mL. Characteristics at the time of first detectable VL were summarised. Development of new mutations were summarised among those with repeat resistance tests whilst experiencing LLV.

Results: 84 experienced LLV during follow-up, representing 2% of the total clinic population. Characteristics are shown in table 1, with most (59%) receiving PI-based ART. 67 (79.8%) had at least one resistance test performed, of which 6 (9.0%) were unable to be amplified. Of those with a result, 15/61 (24.6%; 95% CI 14.5%-37.3%) had resistance to at least one class [4 [6.6%; 1.8-15.9%] PI-associated, 11 [18.0%; 9.4%-30.0%] NNRTI-associated, 7 [11.5%; 4.7%-22.2%] NRTI-associated, 0 [0.0%] triple-class]. 24 patients went on to have a second resistance test whilst experiencing LLV, a median (IQR) of 5 (3, 7) months later; 8 (33.3%; 95% CI 15.6%-55.3%) had a major mutation detected (Figure). There were 5 new M184V/I mutations detected, 2 new K103N and one each of K219E, D67E, P225H, Y188H/Y and low-level resistance to INSTI.

Conclusion: Low level viraemia in our cohort was rare. A high level of baseline resistance was seen in our LLV group. Repeat resistance testing during LLV was not done routinely. Of those with repeat resistance tests during LLV, a third developed a new major mutation. LLV at this level may represent assay variation, but suggests that in the cART era LLV remains a risk factor for resistance and possible virological failure. The optimum management strategy of LLV needs clarifying.

Table 1. Characteristics of PLWH experiencing low level viraemia, 2015–2019

<table>
<thead>
<tr>
<th>N (%) or Median (IQR; range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Subtype (n=69)</td>
</tr>
<tr>
<td>Comitant</td>
</tr>
<tr>
<td>Ever hepatitis B/C recombiant</td>
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<td>Gender Male Female</td>
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</tbody>
</table>

PE2/52
Virological outcomes of first line regimens in women living with HIV from Icona cohort: comparison with clinical trial data
C Mussini1, P Lorenzinii, A Cingolani3, M Lichtner5, S Di Giambenedetto5, AM Cattelan1, P Lorenzini2, A Cingolani3, M Lichtner4, S Di Giambenedetto3, 1University of Modena and Reggio Emilia, Modena, Italy 2INMI L. Spallanzani IRCCS, Rome, Italy 3Università Cattolica del Sacro Cuore, Rome, Italy 4University La Sapienza, Rome, Italy 5Policlinico of Padua, Padua, Italy 6Verona HIV Center, Verona, Italy 7University of Milan, Infectious Diseases, San Paolo Hospital, Milan, Italy

Purpose: Aim of this analysis was to verify in a real-life setting the efficacy of newer cART regimens and to compare results with those obtained by WLWH-specific RCTs.

Methods: Naïve WLWH enrolled in Icona from 2006 starting an ATV/r-, DTG-, ETV/c-, DRV/r or DRV/c-, RAL-, RPV-based regimens regardless of backbone and with at least 1 follow-up HIV-RNA were included. Primary endpoint was treatment failure (TF) [confirmed HIV-RNA>200 c/mL after 24 weeks or discontinuation for any reason but simplification]. Secondary endpoints: 1) first line discontinuation for any reason; 2) first line discontinuation for toxicity; 3) virological failure; 4) virological success at week 48 [Modified FDA Snapshot Algorithm] for regimens mimicking WLWH-RCT. Cox regression model was used to estimate the hazard risk (HR) of various outcome according to different cART regimens, after adjusting for main confounders.

Results: 1084 WLWH were included (median FU: 1.9 yrs [IQR 0.9-3.2]). 258 WLWH (26%) started ATV/r, 166 (16%) DTG, 115 (11%) ETV/c, 219 (21%) DRV/r or DRV/c, 71 (7%) RAL, 219 (21%) RPV. Study population's
characteristics are reported in table 1. At multivariable regression, women on ATV/r showed higher risk of TF; the other factor associated to higher risk of TF was AIDS (HR 1.58, 95% CI 1.13–2.20, p=0.007). HRs of different outcomes for each third of the regimen are reported in figure 1. 404 WLWH started regimens included in WLWH-RCT, the proportions of virological success were 50.7% in ATV/r (81% Waves and 71% ARIA), 79.2% in EVG/c (87.2% Waves) and 74.7% in DTG (vs 82% ARIA).

Conclusions: In a real-world cohort of WLWH, treatment failure is still an issue, particularly in case of PI/r based regimens. Results from clinical practice are far from those obtained in trials and suggest the need for focused intervention on adherence and vulnerability support in this population.

PE2/53

Well-being in people living with HIV/AIDS (PLWHA) according to cART exposure: data from ICONA cohort

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6National Institute for Infectious Diseases ‘L. Spallanzani’, HIV Unit, Roma, Italy
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Purpose: Patient-reported outcome measures (PROMs) are now being collected within a subset of the ICONA cohort. To evaluate one of a selection of PROMs suitable for PLWHA regardless of time since diagnosis, to examine differences associated with exposure to cART.

Methods: PROMs were administered to PLWHA not on cART (no-cART) or on cART (>6 months, without previous virological failure). PROMs included the W-BQ16, a measure of 4 aspects of well-being plus overall general well-being. Independent samples t-tests and Pearson’s r correlations were used with alpha set at 0.05.

Results: Participants included 318 PLWHA(72/246 no-cART/cART). Median CD4 cell count: 453/mmc and 678/mmc; median HIV-RNA: 39202 and 29 copies/mmc in no-cART or on cART PLWHA (median time on cART: 0.8 γ
Body composition changes in HIV: do INSTI matter?

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Objectives: The aim was to assess weight gain (WG) and body composition changes in people living with HIV (PLWH) switching to INSTI-based regimens in comparison to INSTI-naive patients. We assessed WG impact on incidence of co-morbidities.

Methods: In a prospective observational study, we included ART-experienced INSTI-naive PLWH from 2007 to 2019. Patients were divided in two groups: patients who remained INSTI-naive and patients who switched to an INSTI regimen either in 3-drugs regimens (3DR) or in 2-drug regimens (2DR). The groups were matched for sex, age, baseline BMI and time on regimen. We evaluated weight change among PLWH initiating ART in the current treatment era.

Results: Across 8 CNICS sites we identified ART-naive PLWH initiating ART between 2012–2018, including efavirenz (EFV, n=404), rilpivirine (RPV, n=347), atazanavir (ATV, n=90), darunavir (DRV, n=245), raltegravir (RAL, n=49), elvitegravir (EVG, n=981), and dolutegravir (DTG, n=295)-based regimens with a tenofovir (TDF)/emtricitabine (or lamivudine) backbone. We also examined dolutegravir-based regimens with abacavir/lamivudine (ABC, n=338). Weight change was estimated using linear mixed models adjusted for time on regimen, time on regimen x regimen interaction, age, sex, race, hepatitis C, hepatitis B, nadir CD4, smoking, diabetes, anti-psychotic medication use, and site.

PE2/55

Dolutegravir–based regimens are associated with weight gain over two years following ART-initiation in ART-naive people living with HIV (PLWH)

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1University of Washington, Seattle, USA 2Harvard Medical School, Fenway Institute, Boston, USA 3John Hopkins University, Baltimore, USA 4University of North Carolina, Chapel Hill, USA 5University of California San Francisco, San Francisco, USA 6University of California San Diego, San Diego, USA 7Case Western University, Cleveland, USA 8University of Alabama at Birmingham, Birmingham, USA 9VivIT Healthcare, Rtp, USA 10VivIT Healthcare, Brentford, UK 11GlasoSmithKline, Uxbridge, UK

Purpose: Previous studies have suggested that PLWH who initiate integrase inhibitor-based regimens may gain more weight than those who initiate other antiretroviral therapy (ART). These studies have often examined classes not individual agents, been small, combined ART-experienced and naïve PLWH, and did not address key potential confounders such as regimen backbone. We evaluated weight change among PLWH initiating ART in the current treatment era.

Method: Among 1158 PLWH (68.7% males) were analyzed at baseline and at 4 years (±2.23) follow-up. Patients who switched to INSTI showed significant changes in changes in age, BMI, waist circumference (WC), fat-free mass index (FFMI), appendicular skeletal muscle index (ASMI) and leg fat % (p=0.001). Mixed lipodystrophy, visceral adipose tissue (VAT) and subcutaneous adipose tissue (SAT) did not change over time. INSTI naïve showed significant changes in age, BMI, WC, FFMI, ASMI, leg fat %, sarcopenia, VAT and SAT. Higher prevalence of WG was observed in patients who switched to INSTI (68.9% vs. 31.2%, p<0.001). Figure describes independent predictor of WG. PLWH who experienced WG had higher incidence of T2DM (1.97 vs 1.22), CVD (1.67 vs 0.53), HTN (13.2 vs 7.07), CKD (6.82 vs 3.49), COPD (3.4 vs 1.06) cases per 100 patient-year, with the latter being the only statically significant.

Conclusions: We observed WG both in 3DR and 2DR in INSTI-based switch. Clinical relevance of this phenomenon needs to be explored in larger cohorts.
greater than EFV, RPV, ATV, and EVG, but not DRV (1.8 kg per year, 95% CI: 0.9–2.7). Generalized additive model plots suggested that weight gain on DTG occurred in the first two years following regimen initiation (Figure 1).

Conclusion: DTG users had the greatest two-year weight gain, regardless of backbone, although weight gain was not significantly higher than in DRV users. For ART-naive PLWH, potential weight gain should be considered in conjunction with the benefits of viral suppression when comparing DTG to other ART regimens.

Figure 1. Generalized additive model plots of weight gain over time for each regimen

Table 1. Demographics of study population (n=41)

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age (range)</td>
<td>54 (31–67)</td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Male, Female, Transgender</td>
</tr>
<tr>
<td></td>
<td>33 (80.5), 6 (14.6), 2 (4.9)</td>
</tr>
<tr>
<td>Race (%)</td>
<td>White, Black, Asian, Other</td>
</tr>
<tr>
<td></td>
<td>26 (63.4), 4 (9.8), 1 (2.4), 10 (24.4)</td>
</tr>
<tr>
<td>Ethnicity (%)</td>
<td>Hispanic, Non-Hispanic</td>
</tr>
<tr>
<td></td>
<td>26 (63.4), 26 (63.4)</td>
</tr>
</tbody>
</table>

Table 2. Virologic and treatment/resistance history for study population (n=41)

<table>
<thead>
<tr>
<th>Pharmacokinetic enhancer (%)</th>
<th>Cobicistat, Ritonavir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40 (97.6), 1 (2.4)</td>
</tr>
<tr>
<td>VL&lt;50 copies/mL at time of switch (%)</td>
<td>24 (58.5)</td>
</tr>
<tr>
<td>CD4 + T-cell count (cells/mm3) (median, range)</td>
<td>449 [13–1099]</td>
</tr>
<tr>
<td>Number of previous ARVs (mean, 95% CI)</td>
<td>10.8 [8.6–12.0]</td>
</tr>
<tr>
<td>Number of previous ARV classes (mean, 95% CI)</td>
<td>3.9 [3.7–4.0]</td>
</tr>
<tr>
<td>Years on ARV (mean, 95% CI)</td>
<td>18.2 [15.9–20.1]</td>
</tr>
<tr>
<td>Number of ARV class resistance (%)</td>
<td>Unknown, 1, 2, 3, 4</td>
</tr>
<tr>
<td></td>
<td>4 (9.8), 4 (9.8), 7 (17.1), 14 (34.1), 11 (26.8), 1 (2.4)</td>
</tr>
<tr>
<td>Documented integrase inhibitor resistance (%)</td>
<td>3 (7.3)</td>
</tr>
<tr>
<td>Reason for regimen change (%)</td>
<td>Side effects, Poor adherence/resistance, Low level/ongoing viremia, Regimen simplification, Drug interaction</td>
</tr>
<tr>
<td></td>
<td>4 (9.8), 14 (34.1), 5 (12.2), 16 (39.0), 2 (4.9)</td>
</tr>
<tr>
<td>Follow up time (days) (mean, 95% CI)</td>
<td>315 (285–348)</td>
</tr>
</tbody>
</table>

PE2/56

Efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in combination with boosted darunavir (DRV) in treatment experienced patients with HIV

L Hill1, J Momper2, K Abulhousn1, C Ballard1 and M Young3

1 UC San Diego Owen Clinic, San Diego, USA 2 UC San Diego Skaggs School of Pharmacy, San Diego, USA 3 UC San Diego Health, Department of Medicine, San Diego, USA

Purpose: We report the safety and efficacy of B/F/TAF with boosted DRV in antiretroviral (ARV) experienced patients with HIV.

Method: Retrospective chart review at a single academic center. Inclusion criteria were having started on B/F/TAF in combination with boosted DRV (cobicistat or ritonavir) between 2/2018 and 6/2019. Excluded were patients taking this combination with additional ARVs, those with less than 24 weeks of follow up who did not discontinue the regimen, and those without viral load (VL) data at or beyond 24 weeks. Patients who discontinued the regimen prior to completing a week 24 VL were excluded from the efficacy analysis only.

Results: Forty-one patients were included in the analysis, of whom five discontinued the regimen prior to completing a week 24 VL. Table 1 and 2 show demographics, baseline virologic data, and treatment/resistance history. The cohort was highly treatment experienced, with 63.4% resistant to at least two classes of ARVs and 7.3% with documented integrase resistance. Of the 21 patients with a VL of ≥50 copies/mL, 85.7% remained<50 copies/mL. Fifteen patients had a VL>50 copies/mL at time of switch [mean 416,578 copies/mL], of whom 66.7% achieved a VL of <200 copies/mL and 20% achieved<50 copies/mL at week 24. Mean change in CD4 count was +22 cells/mm3 at week 24. Ten patients discontinued the regimen, two due to adverse events (rash, diarrhea). The mean baseline serum creatinine (Scr) was 1.08 mg/dL and the mean change in Scr after 24 weeks was 0.01 mg/dL.

Conclusion: The combination of B/F/TAF with boosted DRV was effective in maintaining viral suppression in those with VL<50 copies/mL and in achieving VL<200 copies/mL in those with detectable viremia. There were few discontinuations due to adverse effects with no safety concerns after 24 weeks of treatment.

Table 2. Virologic and treatment/resistance history for study population (n=41)

<table>
<thead>
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<td>315 (285–348)</td>
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</tbody>
</table>

PE2/57

Real world data of using Triumeq (dolutegravir/abacavir/lamivudine; DTG/ABC/3TC): final outcomes of the 3-year German TRIUMPH cohort show good virologic effectiveness and safety in clinical routine

N Postel1, T Heucher2, F Malfertheiner3, J Brust4, S Scholten5, C Stephan6, U Bohr7, H Hill1, J Momper2, K Abulhousn1, C Ballard1 and M Young3

1 UC San Diego Owen Clinic, San Diego, USA 2 UC San Diego Skaggs School of Pharmacy, San Diego, USA 3 UC San Diego Health, Department of Medicine, San Diego, USA

Background: TRIUMPH was a prospective, 3-year observational German cohort study in ART-naive and pre-treated adult HIV-infected patients receiving Triumeq, an one-pill regimen consisting of DTG/ABC/3TC.

Methods: Primary and secondary outcomes included the rate of monitoring measures per patient year (PPY), virologic effectiveness using a modified ITT snapshot approach (HIV-RNA<50 copies/mL [visit-window ≥3 month]), discontinuation/failure, missing/lost-to-follow-up [excluded] and on-treatment (OT) analysis, persistence of DTG/ABC/3TC, and incidence of non-serious adverse drug reactions (ADRs/SADRs).

Results: The analysis population consisted of N=387 patients (40.1% ART-naive). Of ART-naive patients, 12.9% had<200 CD4/µL, 18.1% had≥100,000 HIV-RNA copies/mL. Of pre-treated, 84.9% had<50 HIV-RNA copies/mL, 19.4% had≥3 prior regimens and 47.8% switched from PI-based regimens. Comorbidities were documented in 44.2% of patients (Table 1). At last follow-up [≥3 month], in 36.2% of patients premature study discontinuation was reported, including 13.4% lost to follow-up, 5.7% patient decision/withdrawal of consent and 18.3% discontinuing DTG. ADRs and virologic failure were the reasons for DTG discontinuation in 9.6% and 0.8% of patients, respectively (Table 2).

After 3-year follow-up, virologic effectiveness was 73.1% (mITT; 244/334) [ART-naive 72.8 (99/136), pre-treated 73.2% (145/198)]. In OT analysis, persistence of DTG/ABC/3TC and incidence of non-serious adverse drug reactions were similar across ART-naive and pre-treated groups. In ART-naive patients, monitored ADRs were 19.0% and 10.4% in ART-naive and pre-treated groups, respectively.

Conclusion: During the course of the 3-year TRIUMPH cohort, the good safety profile and high virological effectiveness of DTG/ABC/3TC in clinical trials was confirmed in real-life with discontinuation rates for intolerance or virologic failure of 9.6% and 0.8%, respectively. Moreover, ADR rates decreased over time. Monitoring measures were mainly related to
PE2/58

The effectiveness of E/C/F/TAF in treatment-naïve (TN) or treatment-experienced (TE) adult HIV-infected patients in a real-world setting, results from southern Turkey

D Inan1, A Candevir Uluc1, F Sangül Yildirim1, G Erož1, S Kömür1, ÜUSER1, O Kandemir1, F Kuscu2, N Oztoprak Cuvaci3, AS Inal2, MK Celen4, R Saba5, B Kurtaran6 and Y Tabova7

1Akdeniz Universitesi, Tip Fakultesi, Infeksiyon Hastaliklari AD, H Blok, Antalya, Turkey
2Cukurova University, Infectious Diseases, Adana, Turkey
3Mersin University, Infectious Diseases, Mersin, Turkey
4Dicle University, Infectious Diseases, Diyarbakir, Turkey
5Medstar Hospital, Infectious Diseases, Antalya, Turkey

Purpose: In Turkey, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) is a recommended regimen for first-line treatment of HIV infection and for some TE patients, but limited data are available from real-world experience. This retrospective cohort study was done in southern Turkey to evaluate the effectiveness of E/C/F/TAF when used in TN or TE adult HIV-infected patients in a real world setting.

Method: All patients who received E/C/F/TAF for at least 6 months were included in this multicenter, retrospective study. Patient characteristics, reasons for selection of E/C/F/TAF, virological efficacy and reasons for discontinuations/modifications were evaluated.

Results: A total of 562 patients were included in the analysis population; 167 patients were TN, 395 patients were TE. In the TN group 24 (14.5%) patients were late presenters (Table 1). Patients were switched to E/C/F/TAF; 73.7% of them had previously used INSTI (Table 1). Overall 2.1% (12/562) of patients discontinued/modified study medication before M12 visit. Reasons are shown in Table 1.

At M6 visit 89.2% (n=501/562) had HIV RNA levels<50 cp/mL. At M12: 105 TN patients had treatment results, follow-up of 58 patients was not completed yet. 4 patients were lost to follow-up. 90.5% of patients (95/105) achieved HIV RNA<50 cp/mL at 12 months. In the TE group, virological suppression was 95.8% in 263 patients with M12 data (see Figure 1).

The most common reason for switch to E/C/F/TAF was to minimize long-term toxicity (n=140/562) and the most common reason for discontinuation was virological failure (n=291/737) (Figure 2). In TN patients at M12 there was no difference in viral suppression after stratification by baseline variables (p: 0.3). (Figure 2)

Conclusion: In TN and TE patients, 6 and 12 month data from this real world cohort confirmed the effectiveness E/C/F/TAF in routine practice. This virological effectiveness was unaffected by baseline HIV RNA and CD4 levels.
Comparison of efficacy and safety of a switch to fixed-dose combination FTC/TDF-TAF/RPV versus fixed-dose combination 3TC/ABC/DTG in HIV-1-infected, treatment experienced and virologically suppressed (VS), antiretroviral therapy (ART) experienced HIV-positive patients.

**Method:** This is a retrospective-monocentric cohort-study analyzing all ART-experienced HIV-infected patients with HIV-RNA level <50 copies/mL, switching to RPV-STR or to DTG-STR since 2013 and 2015, respectively. Study entry was drug-intaking date, study exit was virologic failure (VF) date or the discontinuation date due to any cause or loss to follow-up (FU)/death. VF was defined as consecutive detection of two HIV-RNA levels >50 copies/mL.

**Results:** We included 396 patients (244 with RPV-STR, 152 with DTG-STR). A significative more risk of discontinuation due to toxicity within 3 months from switch was observed in DTG-STR compared to RPV-STR.

**Table 1.** Clinical/demographic characteristics of the study population grouped by the different single tablet regimen

<table>
<thead>
<tr>
<th></th>
<th>FTC/TDF-TAF/RPV group (N=244)</th>
<th>3TC/ABC/DTG group (N=152)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italians, n (%)</td>
<td>221</td>
<td>126</td>
<td>82.9</td>
</tr>
<tr>
<td>Sex Female, n (%)</td>
<td>54</td>
<td>29</td>
<td>19.1</td>
</tr>
<tr>
<td>Age at entry, median [IQR]</td>
<td>49 [43–56]</td>
<td>51 [42–58]</td>
<td>0.136</td>
</tr>
<tr>
<td>Years of undetectable viremia, median [IQR]</td>
<td>5 [2–7]</td>
<td>4 [1–8]</td>
<td>0.594</td>
</tr>
<tr>
<td>AIDS diagnosis, n (%)</td>
<td>41</td>
<td>35</td>
<td>23.0</td>
</tr>
<tr>
<td>HCV Ab positivity, n (%)</td>
<td>53</td>
<td>29</td>
<td>19.1</td>
</tr>
<tr>
<td>HIV RNA Zenit, Log10 copies/mL, median [IQR]</td>
<td>5.09 [4.67–5.49]</td>
<td>5.12 [4.74–5.54]</td>
<td>0.585</td>
</tr>
<tr>
<td>Nadir CD4 (cells/mL), median [IQR]</td>
<td>265 [127–370]</td>
<td>281 [125–405]</td>
<td>0.488</td>
</tr>
<tr>
<td>Years of HIV, median [IQR]</td>
<td>13 [7–19]</td>
<td>10 [4–18]</td>
<td>0.063</td>
</tr>
</tbody>
</table>

**Table 2.** Outcome of the study population grouped by the different single tablet regimen

<table>
<thead>
<tr>
<th></th>
<th>FTC/TDF-TAF/RPV group (N=244)</th>
<th>3TC/ABC/DTG group (N=152)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>End-of-follow-up therapy outcome, n (%)</td>
<td>167 68.4 123 80.9</td>
<td>0.011</td>
<td></td>
</tr>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change for toxicity</td>
<td>23</td>
<td>19</td>
<td>12.5</td>
</tr>
<tr>
<td>Change for other causes</td>
<td>18</td>
<td>5</td>
<td>3.3</td>
</tr>
<tr>
<td>Virologic failure</td>
<td>16</td>
<td>2</td>
<td>1.3</td>
</tr>
<tr>
<td>Self-suspension of therapy</td>
<td>6 2.5 2 1.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>11</td>
<td>1</td>
<td>0.7</td>
</tr>
<tr>
<td>Dead</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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COPEDOL: a 2-year French multicentric, observational, longitudinal retro-prospective study, in pretreated HIV-1-infected patients starting dolutegravir based regimen due to treatment failure

R Landman1, A-G Marcelli1, M Bennani2, C Philippe3, P Kousignian4, L Finkielsztejn5, L Roustand6, G Nachbau7 and V Pourcher8

1Bichat Hospital, AP-HP, Department of Infectious Diseases, Paris, France
2Pitié Salpêtrière Hospital, AP-HP, Department of Virology, Paris, France
3Qualès, Paris, France 4ViVi Healthcare, Rueil Malmaison, France
5GlaxoSmithKline, Rueil Malmaison, France 6Pitié-Salpêtrière University Hospital, AP-HP, Department of Infectious Diseases, Paris, France

Purpose: The main objective of this study was to assess the virological response in patients switched to dolutegravir based regimen (DBR) at the time of their treatment failure. The main secondary objectives were to assess the Virological sustained response in addition to the safety.

Method: COPEDOL is a 2-year, French multicentric, observational, longitudinal, retro-prospective study in which patients were stratified in two groups according to the reason of their failure. Patients in EV group had failed due to virological reason and patients in TOX group had failed due to toxicity of previous treatment regimen. TOX patients were studied according to their virological status (detectable or not at the time they started DBR). To be included HIV patients were to have started DBR between February 2014 and September 2016.

Results: 50 centers included 459 patients (EV N=222 and TOX N=237). The mean age was 50 years (11-111 years; range 16-82) with 64.1% of men and 21.8% presented 3 or more comorbidities. The median time since HIV diagnosis was 18 years and the median duration of treatment was 14 years. The mean CD4 nadir was 198 cells/mm3 (±182). At DTG introduction, 30.7% and 27.2% had OSS≤1 (genotypic sensitivity score) in the EV and TOX groups respectively.

Virological response (VL≤50 copies/mL) through 24 months

<table>
<thead>
<tr>
<th>Time</th>
<th>EV group</th>
<th>TOX group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>117</td>
<td>6</td>
</tr>
<tr>
<td>3 months</td>
<td>138</td>
<td>6 (66.67%)</td>
</tr>
<tr>
<td>6 months</td>
<td>172</td>
<td>4 (66.67%)</td>
</tr>
<tr>
<td>12 months</td>
<td>173</td>
<td>11 (64.52%)</td>
</tr>
<tr>
<td>24 months</td>
<td>148</td>
<td>6 (100.00%)</td>
</tr>
</tbody>
</table>

EV group:

- 30.7% presented OSS≤1 at DTG introduction.
- 27.2% presented OSS≤1 at DTG introduction.

TOX group:

- 64.5% presented OSS≤1 at DTG introduction.
- 100.0% presented OSS≤1 at DTG introduction.

Conclusion: The results obtained in real life conditions are aligned with those observed in clinical trials in pretreated patients in terms of efficacy and safety and few patients experienced virological failures with emergent resistance mutation to DTG.

Drug-drug interactions with recommended first-line antiretroviral therapy in real-world settings

W-H Shih1, C-C Wang2 and H-J Li3

1National Taiwan University Hospital, Department of Internal Medicine, Taipei, Taiwan, Province of China 2National Taiwan University, School of Pharmacy, Taipei, Taiwan, Province of China

Purpose: Extended life expectancy of patients with human immunodeficiency virus (HIV) necessitates treatments for their comorbidities. Given the complex metabolic pathway of antiretroviral therapies (ARTs), polypharmacy may increase the risk of drug-drug interactions (DDIs), leading to detrimental clinical outcomes. Therefore, we investigated the DDIs with recommended first-line ARTs using claims data from National Health Insurance.

Methods: This was a nationwide cross-sectional study with HIV patients receiving ART in 2016. Potential or contraindicated DDIs with recommended first-line ARTs were identified from University of Liverpool drug interaction database. The DDIs were defined as having at least one day overlap of comediations within an ART exposure period. Fisher exact or chi-square test was used to determine a significant association between categorical variables.

Results: A total of 25,863 HIV-infected individuals were identified, including 5,877 TDF/FTC/EFV users, 3,519 TDF/FTC/RPV users and 2,517 ABC/3TC/DTG users. Highest percentage of potential DDIs was observed among patients receiving TDF/FTC/EFV (50%), followed by TDF/FTC/RPV (32%) and ABC/3TC/DTG (15%). Most frequently co-prescribed medications related to potential DDIs were diclofenac and polyanionic cation-containing antacids. The percentage of patients with more than one contraindicated DDI was low, with the highest percentage of DDIs observed for TDF/FTC/EFV (4%), followed by TDF/FTC/RPV (4%), followed by TDF/FTC/EFV (2%) and ABC/3TC/DTG (1%). The most commonly co-administered medications for contraindicated DDIs were midazolam and dexamethasone. Compared to patients without DDIs, those with potential or contraindicated DDIs were more likely to be elder, and had more comorbidities and comediations.

Conclusion: Our study showed low prevalence of contraindicated DDIs in the HIV population, suggesting that most physicians in Taiwan aware of the severe DDI issue. However, strategies used to avoid potential DDIs and maintain the effectiveness and safety of medications should be implemented. Future research that focuses on long-term clinical impact of the potential DDIs is warranted.

Abbreviations: TDF-tenofovir; FTC-emtricitabine; EFV-efavirenz; RPV-riprovirine; ABC-abacavir; 3TC-lamivudine; DTG-dolutegravir

Determinants of switching to TAF-based cART or dual combinations (DC) from TDF-based regimens in a cohort of HIV-infected individuals with controlled viral load≤50 copies/mL

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1National Institute for Infectious Diseases “L Spallanzani” IRCCS, HIV/AIDS Unit, Rome, Italy 2San Raffaele Scientific Institute, IRCCS, Infectious Diseases Department, Milan, Italy 3Fondazione IRCCS Ca’ Granda, Ospedale Maggiore Policlinico, Department of Internal Medicine, Milan, Italy 4Sapienza University of Rome, Polo Pontino, Department of Public Health and Infectious Diseases, Latina, Italy 5University of Bari, Clinic of Infectious Diseases, Bari, Italy 6University of Sassari, Department of Clinical and Experimental Medicine, Unit of Infectious Diseases, Sassari, Italy 7AOU Policlinico “P.Giaccone”, University of Palermo, Department of Infectious Diseases, Palermo, Italy 8Policlinico Hospital San Martino, Infectious Diseases Clinic, Genova, Italy 9ASST Sant’ Anna, Department of Clinical and Experimental Medicine, Unit of Infectious Diseases, Genoa, Italy 10Sant’ Anna, Department of Clinical and Experimental Medicine, Unit of Infectious Diseases, Genoa, Italy 11Institute for Global Health, UCL, Centre for Clinical Research, Epidemiology, Modelling and Evaluation (CREME), London, UK

Emergence of mutations associated with resistance to DTG
Purpose: The main aim of this analysis was to evaluate the impact of recent results of randomised studies on the shift between TDF to TAF-based regimens or dual combinations (DC) therapy in real-life.

Method: HIV+ (HBsAg-negative) patients in the Icona Cohort, who achieved a VL≤50 copies/mL for the first time on a TDF-based regimen after January 2016 are included. Kaplan-Meier (KM) curves and (unweighted and weighted) Cox regression models were used to separately estimate the time to switch from TDF to either TAF or DC. A competing KM risk analysis was conducted to jointly model both switches. The main association of interest was between eGFR and the probability of switching after controlling for confounding factors (Tables 1 and 2). An alternative analysis was performed excluding switches to TAF/F/EVG/c as they could be triggered by reasons not strictly related to renal toxicity.

Results: A total of 1,412 participants were included, 20% female, median (IQR) age of 36(30–42) years, CKD-EPI eGFR 99.1(85.8–111.1) mL/min/1.73 m², 86% acquired HIV through sex. At baseline, the most commonly used anchor drugs were RPV(27%), EVG/c(26%), DTG(20%) and DRV/r(13%). By 2 years from baseline, the probability of switching was 4% (95% CI 2.3–6.4) to DC and 21% (95% CI 18.8–23.7) to TAF-based cART (Figure 1). A significant higher probability of switching to TAF-based regimen was found for those receiving INSTI at baseline (KM estimates: 48.8%;95% CI 45.2%,54.5% by 2 years, log-rank p=0.0001; figure 2),not confirmed in the alternative analysis. A eGFR>60 mL/min/1.73 m² both as time-fixed at baseline or as current value, was associated with a higher probability of switching to DC but not to TAF-based cART (Table 1).

Conclusion: A consistent proportion of people with a VL≤50 copies/mL have switched from TDF to alternative strategies (20% to TAF-based and 4% to DC by 2 years). eGFR does not seem to change the probability of switching to TAF-based regimens.

Table 1. HR of TAF-based therapy initiation after excluding switches to EVG/c from fitting a Cox-regression model-association with time-dependent eGFR

<table>
<thead>
<tr>
<th>eGFR (mL/min/1.73 m²)</th>
<th>Unadjusted</th>
<th>Adjusted1</th>
<th>Adjusted2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60+</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>0–59</td>
<td>2.46 (1.12, 5.37); 1.88 (0.76, 4.66);</td>
<td>0.024</td>
<td>0.173</td>
</tr>
<tr>
<td>Most recent value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60+</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>0–59</td>
<td>2.07 (0.98, 4.34);</td>
<td>1.34 (0.59, 3.04);</td>
<td>0.055</td>
</tr>
</tbody>
</table>

**(1) Adjusted for gender, age, mode of HIV transmission, nationality, AIDS diagnosis, hep C-coinfection status, calendar year of VL≤50 copies, number of drugs failed prior to baseline, type of anchor drug of TDF-based regimen, number of concomitant co-morbidities and current CD4 count, HIV-RNA as time dependent variables **(2) Adjusted for gender, age, mode of HIV transmission, nationality, AIDS diagnosis, hep C-coinfection status, calendar year of VL≤50 copies, number of drugs failed prior to baseline, type of anchor drug of TDF-based regimen, number of concomitant co-morbidities and current CD4 count, HIV-RNA using inverse probability weighting

Table 2. HR of DC from fitting a Cox regression model- association with time-dependent eGFR

<table>
<thead>
<tr>
<th>eGFR (mL/min/1.73 m²)</th>
<th>Unadjusted</th>
<th>Adjusted1</th>
<th>Adjusted2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60+</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>0–59</td>
<td>6.91 (2.65, 18.03); 6.01 (2.10, 17.24);</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Most recent value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60+</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>0–59</td>
<td>7.78 (3.38, 17.9);</td>
<td>6.28 (2.30, 17.15);</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**(1) Adjusted for gender, age, mode of HIV transmission, nationality, AIDS diagnosis, hep C-coinfection status, calendar year of VL≤50 copies, number of drugs failed prior to baseline, type of anchor drug of TDF-based regimen, number of concomitant co-morbidities and current CD4 count, HIV-RNA as time dependent variables **(2) Adjusted for gender, age, mode of HIV transmission, nationality, AIDS diagnosis, hep C-coinfection status, calendar year of VL≤50 copies, number of drugs failed prior to baseline, type of anchor drug of TDF-based regimen, number of concomitant co-morbidities and current CD4 count, HIV-RNA using inverse probability weighting
PE2/63
An early proactive switch to elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/T/TAF) is effective in maintaining virologic control and improving quality of life (QoL) in patients with a primary HIV-1 infection (PHI).

An interim analysis of a phase IV clinical trial (ESTER study)
M Camici,1 A Mondi,1 A Amendola,1 S Abbate,2 P Lorenzini,1 S Ottou,1 A Vergori,1 MM Plazzi,1 R Bellagamba1, S Cicalini1, MR Capobianchi2, A Antinori1 and C Pinnetti1

1HIV/AIDS Clinical Unit, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy 2Laboratory of Virology, National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS, Rome, Italy

Purpose: The aim of this study was to evaluate virologic and immunologic efficacy, adherence, and QoL of an early simplification strategy in HIV+ patients starting ART during PHI.

Method: ESTER is a pilot 96-week (w) single-arm trial enrolling HIV+ patients who achieved virologic suppression on a 4-drug ART regimen of darunavir 800 mg boosted with ritonavir or cobicistat or raltegravir 400 mg + tenofovir disoproxil fumarate/emtricitabine started during PHI. Included pts were switched to E/C/T/TAF. Virologic failure (VF) was defined as two consecutive HIV-1 RNA test<40 copies/mL. Evolution of residual viremia from baseline was assessed by ultrasensitive HIV-RNA<5 cp/mL and HIV-DNA evaluated at w24 and w48. QoL was assessed through both a visual analogue scale and the 30-item version Medical Outcome Study-HIV Health Survey (MOS-HIV) score.

Results: 30 participants were enrolled, of whom 18 have completed 48 weeks: 97% male, 87% MSM, median age 34 yrs, baseline CD4 count 667 cells/mm³. At 48w both CD4 count and CD4/CD8 ratio significantly improved compared to baseline (Table 1). At 48w 55% patients achieved undetectable ultrasensitive HIV-RNA compared to 15% at baseline (p<0.011). Median HIV RNA decreased from 3.3 at baseline to 3.0 log10 copies/10⁶ PBMC at 48w (p=0.035) (Table 1). 2/30 (6.6%) pts experienced VF, of whom none developed drug resistance mutations and all achieved resuppression without ART changes. There was a non-significant trend toward improved health perception and adherence over time (Tables 2). Pain and physical functioning scores significantly improved from baseline to w24 (p=0.046; p=0.049).

Table 1. Viro-immunological outcomes at W24 and W48. *n (%) ; ** median (interquartile range); *** mean (SD)

<table>
<thead>
<tr>
<th></th>
<th>N=23</th>
<th>W24</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4***</td>
<td>655 (520–750)</td>
<td>701 (582–839)</td>
<td>0.026</td>
</tr>
<tr>
<td>CD4/CD8***</td>
<td>0.87 (0.80–1.34)</td>
<td>1.07 (0.78–1.34)</td>
<td>0.176</td>
</tr>
<tr>
<td>log HIV DNA cp/mL***</td>
<td>3.2 (0.69)</td>
<td>3.0 (0.49)</td>
<td>0.265</td>
</tr>
<tr>
<td>US HIV RNA&lt;5cp/mL</td>
<td>4 (16.7%)</td>
<td>10 (41.7%)</td>
<td>0.009</td>
</tr>
<tr>
<td></td>
<td>N=18</td>
<td>W48</td>
<td>p value</td>
</tr>
<tr>
<td>CD4***</td>
<td>650 (586–773)</td>
<td>766 (616–884)</td>
<td>0.024</td>
</tr>
<tr>
<td>CD4/CD8***</td>
<td>1.00 (0.81–1.34)</td>
<td>1.11 (0.73–1.55)</td>
<td>0.035</td>
</tr>
<tr>
<td>log HIV DNA cp/mL***</td>
<td>3.3 (0.7)</td>
<td>3.0 (0.61)</td>
<td>0.135</td>
</tr>
<tr>
<td>US HIV RNA&lt;5cp/mL</td>
<td>3 (15%)</td>
<td>11 (55%)</td>
<td>0.011</td>
</tr>
</tbody>
</table>

Conclusion: Although not recommended from guidelines, starting ART with an intensified quadruple regimen in patients with PHI has represented a clinical practice in recent years. In those patients an early switch to E/C/T/TAF showed to be effective in maintaining virologic control, reducing low level viral replication and in continuing immunological recovery.

PE2/64
Prevalence of neuropsychiatric conditions in patients living with HIV-1 treated with antiretroviral therapies — a perspective from US Medicaid
W Chow1, H Hardy1, J Song1, N Connolly1 and B Wu2
1Janssen Scientific Affairs, LLC, Titusville, NJ, USA

Objective: Neuropsychiatric events have been reported in patients living with HIV, treated with antiretroviral therapy (ART). Such events may lead to poor adherence, treatment interruptions, or change of therapy regimens; yet, the prevalence of such events is not well-understood. This study aimed to describe the demographics and clinical characteristics of patients living with HIV-1 who were newly initiated on ART and to estimate the prevalence of neuropsychiatric conditions (NPCs) of interest in this population.

Methods: A retrospective cohort study was conducted using administrative claims data from the IBM MarketScan® Multi-State Medicaid Database (MCDDB, 1/1/2014–12/31/2017). The database includes hospital and outpatient diagnoses, procedures and pharmacy claims for Medicaid enrollees. Adults (≥18 years) with a diagnosis of HIV-1, were newly initiated on ART (no pharmacy claims 12 months prior) and had continuous health plan enrollment for 12 months prior to (baseline period) and at least 6 months following the start of ART (post-period) were included. Demographics and clinical characteristics were described, and period prevalence of NPCs 6- and 12-months post ART initiation was calculated.

Results: Among 1,971 included patients (mean age (SD) 38.5 (12.7) years, 41.4% female; 59.7% Black, 16.8% White and 1.6% Hispanic), the mean (SD) Quan-Charlson Comorbidity Index (QCI), a measure of comorbidity burden to which presence of HIV/AIDS contributes 4 points, was 4.2 (2.2). NPC period prevalence at 6- and 12-months post treatment initiation are presented in Table 1.

Table 1: Period Prevalence of NPCs in ART-treated Patients with HIV at 6- and 12-months post treatment initiation

<table>
<thead>
<tr>
<th></th>
<th>6 months (N=1,971)</th>
<th>12 months (N=1,835)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥2 NPC</td>
<td>51.4%</td>
<td>63.9%</td>
</tr>
<tr>
<td>≥3 NPC</td>
<td>35.1%</td>
<td>36.6%</td>
</tr>
<tr>
<td>≥4 NPC</td>
<td>19.3%</td>
<td>19.5%</td>
</tr>
</tbody>
</table>

NPC = neuropsychiatric condition (pectoritis, major depressive disorder, other depression, bipolar disorder, diziness, fatigue, headache, insomnia/sleep disorder, trauma and stressor related disorders, cognitive impairment/poor concentration) (combined diagnosis codes for specific memory loss, mild cognitive impairment, and other specified cognitive deficit, suicidal ideation, suicide attempt).

Conclusion: In this study of Medicaid patients living with HIV-1 who were newly initiated on ART, NPCs during follow up were common, with 1 in 2 patients having evidence of at least 1 condition during the 6-month follow up; over the longer follow up period (12 months), NPCs were more common. Further studies are needed to investigate potential factors influencing the frequency of neuropsychiatric events, including the effects of ART.

PE2/65
Switch to dolutegravir dual regimens and inflammation mediated by annexin
C Uciferri1,2, K Falasca1, A Aurichio1, F Vignale1, M Reale1, C D’angelo3, F Lombardi1, S Belmonti1, A Ciccillo1, G Baldini1, S Giambenedetto4 & 5 and J Vecchiet1
1University “G. d’Annunzio” Chieti-Pescara, Clinic of Infectious Diseases, Department of Medicine and Science of Aging, Chieti, Italy 2University of Molise, Department of Medicine and Health Sciences ‘Vincenzo Tiberio’, Campobasso, Italy 3University “G. d’Annunzio”, Chieti- Pescara, Unit of Immunodiagnostic and Molecular Pathology, Department of Medical, Oral and Biotechnological Sciences, Chieti, Italy 4Catholic University of Sacred Heart, Clinic of Infectious Diseases, Rome, Italy 5Fondazione Pollicinico Agostino Gemelli IRCCS, Infectious Diseases Unit, Rome, Italy

Background: The toxicities associated with long-term use of NRTIs have led to the assessment of dual therapy approaches that reduce an NRTI component. The toxicities associated with long-term use of NRTIs have led to the assessment of dual therapy approaches that reduce an NRTI component.

Conclusion: In this study of Medicaid patients living with HIV-1 who were newly initiated on ART, NPCs during follow up were common, with 1 in 2 patients having evidence of at least 1 condition during the 6-month follow up; over the longer follow up period (12 months), NPCs were more common. Further studies are needed to investigate potential factors influencing the frequency of neuropsychiatric events, including the effects of ART.
Several strategies of treatment optimization and simplification gained interest, with the objectives of improving quality of life, minimizing ART-related toxicity and drug-drug interactions. The ART de-escalation from 3 to 2 drugs (dual-) therapies has mainly been evaluated in virologically suppressed patients. Due to its interesting pharmacokinetic profile, good tolerability and high genetic barrier to resistance, dolutegravir (DTG) is often used in simplified treatment regimens. Several studies evaluating DTG-based dual therapy showed a high virological efficacy, but no data are currently available on circulating Annexins, such as Annexin A1(AnxA1) and Annexin V(AnxV) that play an anti-inflammatory role. In addition low AnxV levels are related to a greater atherosclerotic and thrombotic risk in systemic diseases. The aim of this study is to evaluate the levels of plasmatic AnxA1 and AnxV before and after 48 weeks in a population which switched from triple standard therapy without DTG to a dual therapy DTG-based (plus lamivudine or rilpivirine).

**Methods:** A total of 16 HIV-positive male outpatients on cART attending the Infectious Diseases Clinics of Chieti and Roma were enrolled. Demographic and anamnestic data were collected, blood and immunological parameters were measured and AnxA1 and V were analyzed. Framingham risk score was calculated.

**Results:** The data were summarized in table 1. All patients were virologically suppressed at time of the enrolment(0) and after 48 weeks(1). At T0 AnxA1 was 16.9 ± -12.2 ng/mL and AnxV was 1.56 ± 0.55 ng/mL and at T1 AnxA1 was 16.2 ± 14.7 ng/mL and AnxV was 1.44 ± -0.71 ng/mL, no significant different were found.

**Conclusions:** Annexins levels were not altered after 48 weeks DTG-based dual therapy switch, indicating that there are no inflammatory and endothelial changes after switch. These data will be confirmed in a larger population.

| Age (years) | 52.7 ± 11.5 | 53.7 ± 11.8 | ns |
| CD4 + (CD8 + ratio) | 0.83 ± 0.38 | 0.85 ± 0.36 | ns |
| eGFR (mL/min/1.73 m²) | 93.6 ± 22.9 | 93.1 ± 16.7 | ns |
| GGT (UI/mL) | 30.6 ± 15.8 | 23.6 ± 6.7 | 0.06 |
| Total cholesterol (mg/dL) | 168.1 ± 50.8 | 197.4 ± 56.6 | ns |
| HDL (mg/dL) | 64.7 ± 15.0 | 49.3 ± 15.4 | ns |
| LDL (mg/dL) | 92.1 ± 45.9 | 117.1 ± 50.0 | 0.07 |
| Triglycerides (mg/dL) | 146.3 ± 88.0 | 154.7 ± 124.9 | ns |
| Framingham risk score | 13.1 ± 10.3 | 14.2 ± 10.7 | ns |

**Table 1**

**PE2/66**

**Efficacy of dual antiretroviral therapy (ART) as intermitent short cycle regimen in virologically suppressed HIV-infected patients: an observational cohort**

R Palich1, G Lourida1, B Abdī2, R Agher2, Q Beytou1, A Fayssal1, S Pereira3, P Palma1, R Serrao1, A Sarmento4 and C Moreno5

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2Institute of Public Health of the University of Porto, EPI Unit, Porto, Portugal

3University of Porto Medical School, Porto, Portugal

4CMAT - School of Sciences, University of Minho, Braga, Portugal

**Purpose:** This study aims to evaluate the dynamics of HIV viral load and CD4 cell count over time in response to different antiretroviral therapy (ART) regimens in a cohort of HIV naive patients and to investigate the factors associated to the inability to achieve viral load suppression.

**Method:** A cohort of 1044 HIV infected patients who started a first ART regimen based on INSTI, NNRTI or PI classes was evaluated with a mean of 5.6 (range: 1–16) measurements of CD4 counts and viral load over 2 years follow-up. Longitudinal linear mixed-effect models were used to evaluate changes in viral load and CD4 cell count over time according ART classes, among other predictors. To investigate the determinants associated to non-virologic suppression (evaluated after 6 months of treatment) propensity score-based weighted method, calculated with the generalized boosted method, was used.

**Results:** Mean CD4 cell count was found for NNRTI and PI treated patients compared with INSTI based ART (−130/mm3 and −194/mm3, respectively), after adjusting for other determinants of CD4 count variation as age, MSM related transmission and presence of opportunistic infection at ART initiation. HIV Viral load variation over follow-up time was significantly and independently associated with the presence of an opportunistic infection and MSM related transmission. Mean viral load was higher in NNRTI and PI treated patients compared with those treated with INSTI based ART, without statistical significance. Compared with INSTI, PI based ART was significantly associated with risk of non-virologic suppression (OR=2.9; 95% CI: 2.1–3.9) after accounting for the effect of treatment compliance, basal viral load and CD4 cell count, age, mode of transmission and presence of opportunistic infections.

**Conclusion:** This real-world study evidenced higher effectiveness of INSTI based ART when virologic and immune response was evaluated using multiple measurements over time, with significant better CD4 cell count trajectory.

**PE2/68**

**Impact of switching to E/C/FTAF on lipid profile and renal function in HIV-infected patients**

B Mete1, A Gunduz2, E Zerdili3, S Senoglu4, S Bolukcu5, I Yilmaz Nakir3, H Kumbasar1, A Valantin1, L Schneider1, A Simon1, A-G Marcelin2 and C Katlama1

1Istanbul University-Cerrahpasa, Istanbul, Turkey

2Hamidiye Sisli Etfal Research and Training Hospital, Istanbul, Turkey

3Haseki Research and Training Hospital, Istanbul, Turkey

4Bakırköy Dr. Sadi Konuk Research and Training Hospital, Istanbul, Turkey

5Bakırköy Dr. Sadi Konuk Research and Training, Istanbul, Turkey

**Purpose:** Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/FTAF) is a recommended and widely used regimen for HIV infection. In this...
study we aimed to determine the impact of switching to E/C/F/TAF on the lipid profile and renal function in HIV-infected patients.

**Method:** ACTIV-HIV-IST Study Group produced a database and 5 dedicated HIV centers in Istanbul entered data on HIV patients who switched from any tenofovir disoproxil fumarate-containing regimen to E/C/F/TAF. Viral parameters, lipid studies, renal function tests, adverse events, and adherence to the treatment were recorded.

**Results:** The study included 171 patients; 93% (159/171) were male and mean age was 41 years (SD: 11 years). Among them, 48% (83/171) described themselves as men who have sex with men. Median duration of HIV infection was 40 months (interquartile range=IQR 53–31). Median duration of E/C/F/TAF use was 18 months (IQR 20–15). HIV-RNA was undetectable at months 6 and 12 in 88% (151) and 87% (149), respectively. Median CD4 counts were 729 cells/μL (IQR: 931–595) and 789 cells/μL (IQR: 970–580).

Renal functions tests and lipid profile at month 12 were available in 84% and 60% of the patients, respectively. Patients with abnormal lipid parameters and kidney functions with treatment were given in Table 1. There were trends toward a decrease in serum creatinine and an increase in eGFR at month 12.

Median total cholesterol levels at baseline and month 12 were 162 and 204 mg/dL; LDL-cholesterol 103 and 135 mg/dL; HDL-cholesterol 38 and 45 mg/dL; and triglycerides 99 and 129 mg/dL, respectively. The total cholesterol/HDL ratio at baseline and month 12 were 4.4 at both time points.

**Conclusion:** Switching to E/C/F/TAF was associated with stable renal functions. Its use was associated with increases in LDL-cholesterol, triglycerides and also in HDL cholesterol levels at month 6; these effects were diminished at month 12.

**Patients with abnormal lipid parameters and kidney functions with treatment**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline</th>
<th>Month 6</th>
<th>Month 12</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine level, median (IQR)</td>
<td>0.87 (0.98–0.75)</td>
<td>0.86 (0.97–0.79)</td>
<td>0.85 (0.96–0.77)</td>
<td>NS</td>
</tr>
<tr>
<td>High creatinine*</td>
<td>0.6% (1/167)</td>
<td>2.1% (3/145)</td>
<td>1.4% (2/143)</td>
<td>NS</td>
</tr>
<tr>
<td>eGFR, median (IQR)</td>
<td>105.97 (115.9–94.2)</td>
<td>105.4 (113.2–95.0)</td>
<td>107.2 (116.2–96.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Low eGFR** Stage 2</td>
<td>18.7% (31/166)</td>
<td>15.9% (23/144)</td>
<td>14.8% (21/142)</td>
<td>NS -</td>
</tr>
<tr>
<td>(60–89) Stage 3</td>
<td>1.2% (2/166)</td>
<td>14.8% (21/142)</td>
<td>14.8% (21/142)</td>
<td>O</td>
</tr>
<tr>
<td>(30–59) Stage 4.5</td>
<td>166</td>
<td>144</td>
<td>142</td>
<td></td>
</tr>
<tr>
<td>TC&gt;200 mg/dL</td>
<td>16.7% (25/150)</td>
<td>58.1% (88/147)</td>
<td>53.4% (55/103)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>LDL&gt;130 mg/dL</td>
<td>15.9% (22/142)</td>
<td>51.9% (59/114)</td>
<td>56.3% (54/96)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Low HDL***</td>
<td>74.6% (106/142)</td>
<td>50.4% (57/113)</td>
<td>43.0% (43/100)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>TG&gt;200 mg/dL</td>
<td>14.9% (22/148)</td>
<td>27.4% (31/113)</td>
<td>19.0% (19/100)</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

**Antiretroviral randomized clinical trials**

**PE3/1**

Genital HIV-1 RNA and DNA shedding in virologically suppressed individuals switching from triple- to dual- or monotherapy: pooled results from two randomized controlled trials

L Hocqueloux1, C Guibavu1, T Prazuck1, B De Dieuleveult1, J Guinar2, A Sève1, E Gardiennet3, P Lopez2, C Rouzioux3,4, S Lefeuvre3, V Avettand-Fenelon1,4, MONCAY and TRULIGHT Study Groups

1Centre Hospitalier Régional d’Orléans, Infectious Diseases, Orléans, France
2Centre Hospitalier Régional d’Orléans, Pôle de Biopathologies, Orléans, France
3Université Paris Descartes, Sorbonne Paris Cité, EA 7327, Paris, France
4Hôpital Necker-Enfants Malades, APHP, Laboratoire de Microbiologie Clinique, Paris, France

**Purpose:** Increasing HIV-infected individuals benefit from less-drug regimens (LDRs). Exploring viral genital shedding during LDRs is crucial to ensure their safety.

**Method:** We pooled genital sub-studies from two clinical trials in this area. Patients were randomized 1:1 to continue abacavir / lamivudine / dolutegravir or switch to dolutegravir (MONCAY trial), or to continue tenofovir / emtricitabine + 3rd agent or to switch to tenofovir / emtricitabine (TRULIGHT trial). Participants whose plasma HIV-RNA remained<50 copies/mL had sperm or cervicovaginal lavage collected between weeks 24 and 48. RNA- and HIV-DNA were amplified by ultrasensitive PCR. The main objective was the proportion of participants who had no detectable HIV in genital fluids according to each strategy, then in an aggregated analysis (LDR versus triple therapies).

**Results:** Sixty-four participants (35 males, 29 females) were included: 16 dual therapies and 16 triple therapies in TRULIGHT; 16 monotherapies, 16 triple therapies in MONCAY. In TRULIGHT, 13/15 (87%) of evaluable participants on dual therapy had no detectable HIV in their genital fluid, versus 14/15 (93%) under triple therapy (p=1.0). In MONCAY, this figure was 12/15 (80%) on monotherapy versus 13/16 (81%) on triple therapy (p=1.0). In the pooled analysis, a similar proportion of participants in LDR and triple therapy groups had no detectable HIV: 25/30 (83%) and 27/31 (87%), respectively (p=0.73).

**Conclusion:** In our experience, LDRs did not increase the risk of detecting RNA- or HIV-DNA in genital fluids of people who maintained undetectable plasma HIV-RNA.

**PE3/2**

Comparison of the Ease of Swallowability of B/F/TAF placebo compared to DTG/ABC/3TC placebo

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**Purpose:** People living with HIV require daily adherence to lifelong antiretroviral therapy (ART) regimens to achieve long term treatment success. However, patient medication preferences for ART pill size have not been well studied. The study aims to assess the factors associated with the ease of swallowability and tolerability of two placebo pills representing BIC/ FTC/TAF (BPP) and DTG/ABC/3TC (DPP).

**Method:** Fifty ART naïve patients (1 seropositive/49 negative) were recruited from the Infectious Diseases Clinic at Henry Ford Hospital in Detroit, MI, and randomized into 2 groups, and then administered the 2 placebo pills in different order by group assignment. Questionnaires using Likert scale (1–5) were administered regarding factors influencing the ease of swallowability, adherence, home medications, pill preferences and their perceptions of the placebo tablets. Comparisons were done using Student t-tests and ordinal regression.

**Results:** Participants were 64% female, 61% white, mean (+/-) age 43(14.6) years, mean of 1.7 comorbidities and taking a mean(median) of 4(1) pills/day. BPP was reported to be easier to swallow than DPP 1.76 vs. 2.42 (p<0.001). Pill size for DPP was correctly perceived as larger than BPP (p<0.005); with both pills perceived as smaller than actual size (p<0.005); BPP ease of swallowability was associated with the size of the largest home pill and how easy to swallow that pill was reported (p=0.021, p<0.05, respectively). DPP swallowability was only correlated with ease of swallowing of the largest home pill (p=0.003). No differences were found by gender, race, age, number/ size of home medications or order of administration for ease of swallowability for either placebo pill.

**Conclusion:** A BIC/FTC/TAF placebo pill was perceived as easier to swallow and better tolerated than the larger DTG/ABC/3TC placebo pill. Patient's perceptions of swallowability can affect medication adherence, especially in HIV, a chronic medical condition that requires lifelong daily adherence.
Evaluation of total HIV-DNA changes in HIV-1 infected patients who continue a 2-drug regimen with dolutegravir plus one reverse transcriptase inhibitor or switch to elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide enrolled in the Be-One Study

Methods:
This is a randomized, single-center, open-label, 96-week superiority study (NCT03493568; Be-One Study). Total HIV-DNA was measured with a standardized in-house ddPCR-assay and normalized for CD4+ T-cells. Spearman correlation coefficients were calculated to assess linear relationship between HIV-DNA and several immunological parameters (including D-Dimer, CRP, %CD8+, %CD4+CD8+ HLA-DR+, CD4 + CD8 T-cells, respectively) both at baseline and at W48. Results were described by median (IQR) and n (%). Differences in HIV-DNA levels were evaluated by using Wilcoxon signed-rank test among patients within the same arm or Mann-Whitney test between the two arms.

Results:
HIV-DNA measurements at baseline and at W48 were available for 40/50 patients (Figure). Overall, HIV-DNA was 2247 (767–4268) and 1587 (556–3543) copies/10^6 CD4+ T-cells at baseline and at W48, respectively, without any significant difference between arms (Table 1). No significant correlations were found between HIV-DNA levels and the immunological parameters, neither at baseline nor at W48. At W48, a modest decrease in HIV-DNA from baseline was observed in both arms: −225 (−99 to −315) copies/10^6 CD4+ T-cells (p=0.465) in the DTG + 1RTI-arm and −137 (−983; 133) copies/10^6 CD4+ T-cells (p=0.334) in the E/C/F/TAF-arm, without significant differences between the two arms (p=0.968).

HIV-DNA slightly increased from baseline to W48 in some patients of both arms (DTG + 1RTI: 8/19; E/C/F/TAF: 7/21, p=0.745). Interestingly, in the DTG + 1RTI-arm ≥4-fold increase in HIV-DNA (15 to 429 and 320 to 1210 copies/10^6 CD4+ T-cells, respectively) was observed in two individuals.

Conclusion:
Changes in HIV-DNA from baseline to W48 in virologically suppressed individuals who switch from a 2DR with DTG + 1RTI to E/C/F/TAF did not significantly differ from changes in those who continue with the ongoing 2DR.

Phase-3 trials of new antiretrovirals are not representative of the global HIV epidemic

Purpose:
People living with HIV (PLWH) are mainly African or Asian, the majority female. In contrast, pharmaceutical companies typically conduct phase-III regulatory clinical trials in high income countries (HICs), where PLWH are mainly white males. Regulatory authorities can be conservative about including pregnant people in trials, discouraging female participation. Some adverse events are more common in females. Most drugs have insufficient safety data in pregnancy and non-white people even after regulatory approval. This analysis compared race and sex demographics of phase-III clinical trials of dolutegravir (DTG), bictegravir (BIC) and tenofovir alafenamide (TAF) with global HIV epidemic demographics.

Method:
National epidemic sizes by sex were extracted from UNAIDS 2018 data. National demographics were used to estimate prevalence by race. PLWH by national socioeconomic status were calculated from World Bank data. Race and sex demographics for 11 trials of DTG (n=6483) were extracted from clinicaltrials.gov. Some adverse events are more common in females. Most drugs have insufficient safety data in pregnancy and non-white people even after regulatory approval.

Results:
Black females (42%) and black males (30%) have highest prevalence globally. Caucasian males comprise 6% of PLWH. Over 60% PLWH live in low or low-middle income countries, 68% of whom are black and 23% Asian. 76% of DTG trial centres were in high income countries (HICs) [5% global burden] and 23% in upper-middle income countries (UMICs). DTG trials were unrepresentative of PLWH even within the UMIC/HIC setting [49% white males versus 31% income band]. Caucasian males were over-represented by +48% to DTG, BIC and TAF trials in comparison to prevalence. Black females were underrepresented by –38%.

Conclusion:
Phase-III clinical trial populations for new antiretrovirals comprised 54% white males, vastly disproportionate to the global HIV epidemic (6%). Females and non-white people are underrepresented. Female safety data are insufficient despite drug approval in Europe and USA. HIV trials must be located in regions representing the global epidemic with no gender-based selection.
PE3/5
Impact of susceptibility scoring on virologic response in heavily treatment-experienced participants with HIV-1 receiving a fostemsavir-based antiretroviral regimen: results through week 96 from the randomized cohort of the Phase 3 BRIGHTE study

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1ViV Health care, Branford, USA 2ViV Health care, Research Triangle Park, USA 3GlaxoSmithKline, Upper Providence, USA

Purpose: Fostemsavir (FTR) is an investigational, first-in-class, attachment inhibitor produg of the active moiety tamsavir (TMR).[1] BRIGHTE is a Phase 3 study evaluating FTR in heavily treatment-experienced (HTE) participants with multidrug resistant HIV-1 who cannot form a viable regimen from remaining fully active ARVs (FAAs; based on historical/screening resistance activity). Virologic response by subgroups was previously reported.[2]

Methods: HTE participants failing their current antiretroviral (ARV) regimen (>400c/mL) were assigned to the Randomized Cohort if they had 1 or 2 FAAs to pair with FTR. Following 8-days of functional monotherapy (FTR + failing ARV regimen), participants commenced open-label FTR plus optimized background therapy (OBT). Virologic response (<40 c/mL, Snapshot) was analyzed by baseline susceptibility including: OSS (genotypic susceptibility score), PSS (phenotypic susceptibility score), OSS-new (net assessment of genotypic + phenotypic susceptibility) and OSS-new (net assessment of genotypic + phenotypic susceptibility fully active=1, Partially active=0.5, and Resistant=0) and previous exposure to an ARV.

Results: Participants had 1 (52%) or 2 (42%) available FAAs in the initial OBT per historical/screening resistance. Participants with baseline OSS-new>2 had higher rates of virologic response compared to participants with lower baseline OSS-new. At Week 96, 88% of participants with OSS-new>2 achieved <40 c/mL; rates decreased with decreasing scores [1–2=68%, 0–1=58%, 0–31%]. This trend was less pronounced for OSS and inconsistent for GSS, PSS, and number of FAAs. Among most common ARVs in initial OBT, inclusion (vs. non-inclusion) of fully active dolutegravir yielded the greatest difference in virologic response by OSS and OSS-new (Table 2).

PE3/6
Reversibility of dolutegravir/lamivudine/abacavir neuropsychiatric toxicity after 24 weeks of switching to elvitegravir/cobicistat/emtricitabine/tenofovir-alafenamide (EVG/c/FTC/TAF). The DREAM Clinical Trial

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1Hospital Universitario La Paz, Madrid, Spain 2Hospital Fundación Jimenez Diaz, Madrid, Spain 3Hospital Infantil de la Princesa, Madrid, Spain 4Hospital Puerta de Hierro, Madrid, Spain 5Hospital de la Princesa, Madrid, Spain 6Hospital Universitario Ramón y Cajal, Madrid, Spain 7Fundación SEIMC/GeSIDA, Madrid, Spain

Objective: To assess whether neuropsychiatric symptoms observed in some patients treated with dolutegravir/lamivudine/abacavir (DTG/3TC/ABC) are true drug-related adverse events (AEs) that improve after DTG/3TC/ABC discontinuation or AEs related to other concomitant conditions.

Methods: Open-label, randomized (1:1), multicenter clinical trial designed to assess, in participants with suppressed HIV viral-load (≥6 months) on DTG/3TC/ABC and either developed a new treatment-emergent neuropsychiatric AE or had worsening of an existing neuropsychiatric AE, improvement of these AEs after switching DTG/3TC/ABC to elvitegravir/cobicistat/emtricitabine/tenofovir-alafenamide (EVG/c/FTC/TAF). Participants were randomized to either immediately switch to EVG/c/FTC/TAF for 24 weeks or defer the switch for 4 weeks followed by EVG/c/FTC/TAF for 24 weeks. At each visit, a grading of neuropsychiatric AEs score (DREAM) was obtained and each participant completed the Hospital Anxiety & Depression Scale (HADS) and the Pittsburgh Sleep Quality Index (PSQI) questionnaires. Raw results on DREAM, HADS and PSQI scores were normalized (0–100) and changes from baseline were compared at each visit using t-test, McNemar test or generalized estimating equations (for longitudinal linear models). We analyzed differences at week 4 between study arms (primary objective) and changes in the DREAM, HADS and PSQI scores after 4, 12 and 24 weeks of switching to EVG/c/FTC/TAF (secondary objectives).

Results: 19 participants with similar baseline characteristics were included in each arm (Table 1). At week 4, compared to the deferred arm, participants in the immediate-switch arm had significant improvements in DREAM, HADS and PSQI scores (Table 2). After switching to EVG/c/FTC/TAF, we observed a consistent and continuous improvement in neuropsychiatric symptomatology up to week 24 (figure).

Conclusions: Our study supports existing evidence that DTG/3TC/ABC is associated with neuropsychiatric AEs that improve after switching to EVG/c/
FTC/TAF and confirms the improvement observed in neuropsychiatric symptomatology in some cohorts after DTG/3TC/ABC discontinuation and in the GS-US-380–1844 clinical trial after switching to bictegravir/FTC/TAF.

Table 1. Baseline characteristics

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<th>Deferred switch to EVG/c/FTC/TAF n=19</th>
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<tr>
<td>Gender (male), n (%)</td>
<td>19 (100)</td>
<td>18 (94.7)</td>
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<td>Age (years), mean (SD)</td>
<td>40.2 (10.1)</td>
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<td>Years since HIV diagnosis, mean (SD)</td>
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<td>Weeks of HIV RNA &lt;50 cop/mL, mean (SD)</td>
<td>235.9 (216.3)</td>
<td>292.5 (257.1)</td>
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<td>Weeks on DTG/3TC/ABC, mean (SD)</td>
<td>67.1 (38.3)</td>
<td>83.7 (35.3)</td>
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<td>CD4 Nadir, mean (SD)</td>
<td>416 (218)</td>
<td>413 (225.5)</td>
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<td>History of illicit drug consumption, n (%)</td>
<td>6 (31.6)</td>
<td>5 (26.3)</td>
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<tr>
<td>History of psychiatric conditions, n (%)</td>
<td>4 (21.1)</td>
<td>5 (26.3)</td>
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<tr>
<td>Neurocognitive impairment, n (%)</td>
<td>5 (26.3)</td>
<td>5 (26.3)</td>
</tr>
</tbody>
</table>

Table 2. Changes at week 4 in neuropsychiatric symptomatology by study arms

<table>
<thead>
<tr>
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<th>Immediate switch to EVG/c/FTC/TAF arm n=19</th>
<th>Deferred switch to EVG/c/FTC/TAF arm n=19</th>
<th>P value</th>
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</thead>
<tbody>
<tr>
<td>Neuropsychiatric AEs (DREAM) Score, mean change (SD)</td>
<td>−14 (9.8)</td>
<td>−1 (9.1)</td>
<td>&lt;0.001</td>
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<td>HADS Anxiety subscale, mean change (SD)</td>
<td>−11.9 (16.4)</td>
<td>−1 (9.6)</td>
<td>0.021</td>
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<tr>
<td>HADS Depression subscale, mean change (SD)</td>
<td>−5.8 (11.1)</td>
<td>1.8 (10.8)</td>
<td>0.041</td>
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<td>Pittsburg sleeping questionnaire, mean change (SD)</td>
<td>−14 (13.4)</td>
<td>−1 (12.0)</td>
<td>0.008</td>
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</table>

Changes in neuropsychiatric scores after switching to E/C/F/TAF

PE3/7

A switch to dolutegravir in combination with boosted darunavir is safe and effective in suppressed patients with HIV – a predefined psychosocial subanalysis of the DUALIS study

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Purpose: The DUALIS study assessed a combination of Dolutegravir (DTG) and boosted Darunavir (bDRV) (2DR) for maintaining HIV-suppression and demonstrated non-inferiority as compared to 2NRTI+bDRV(3DR). A predefined psychosocial sub-analysis focused on psychopathology and health related quality of life (HRQoL).

Methods: The study sample of the exposed intention to treat (ITT)e population consisted of n=263 predominantly male Caucasian persons with a mean age of 46.7 years. All patients completed a sociodemographic questionnaire together with two validated outcome instruments: the Hospital Anxiety and Depression Scale (HADS) with two scales and the Medical Outcomes Study HIV Health Survey (MOS-HIV) with 11 scales characterizing HRQoL. Multiple logistic regressions were carried out for each outcome criterion at the last visit (48 months after enrollment) with treatment arms as group factor and baseline value of the outcome, age, sex, population size of the patients’ area of residence, current occupation and current or earlier treatment for mental disorder as predictors. Odds ratios (OR) and their 95% confidence intervals for the 2DR group as compared to the 3DR group were computed.

Results: The study population did not differ in regards to sociodemographic factors. Odds ratio (OR; 95% confidence interval) of the two HADS subscales, anxiety (0.76; 0.42–1.38) and depression (0.73; 0.41–1.30), as well as the OR of the 11 HRQoL scales of the MOS-HIV scale, including physical functioning (0.64; 0.34–1.21), role functioning (0.55; 0.21–1.38), mental health (0.75; 0.41–1.37), energy (1.02; 0.52–1.90), health distress (0.78; 0.40–1.53), cognitive functioning (0.80; 0.42–1.44), overall health (1.30; 0.70–2.42),
pain (0.75; 0.43–1.31), social functioning (0.81; 0.44–1.46), quality of life (0.60; 0.31–1.12) and health transition (1.01; 0.51–1.99), until 48 weeks of treatment did not show significant differences (Forest plot of...). Conclusion: Switching to a 2 DR regimen consisting of DTG+bDRV does not lead to any significant differences, neither in anxiety nor depression, nor in HRQoL outcome measures.

PE3/8

Tenofovir alafenamide versus tenofovir disoproxil fumarate – is there a true difference in safety?

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Purpose: Plasma tenofovir is associated with renal and bone adverse events (AEs) in treatment of HIV and HBV. Lower plasma and higher intracellular tenofovir concentrations are achieved with tenofovir alafenamide (TAF) than tenofovir disoproxil fumarate (TDF). Pharmacokinetic boosters ritonavir and cobicistat increase plasma tenofovir concentration, compounding existing safety concerns for tenofovir formulations. We assess TAF versus TDF safety with and without booster co-formulation.

Method: A systematic review identified eight phase-3 and two phase-2 clinical trials which recruited HIV patients, and two which recruited hepatitis B patients. TAF and TDF safety were compared in predefined boosted and unboosted subgroups. Safety endpoints included all AEAs, serious AEAs and AE discontinuation. Individual AEs investigated included bone mineral density (BMD) change, fractures, all gastrointestinal AEs, serious gastrointestinal AEs, nausea, and discontinuation for bone or renal AEs. Pooled risk differences were calculated using random-effects models with Mantel-Haenszel’s methods.

Results: There were no significant differences in boosted or unboosted subgroups between TAF and TDF for all AEs, serious AEs, AE discontinuation, nausea, or serious gastrointestinal AEs. Boosted TDF caused more fractures (p<0.05), larger BMD decreases (p<0.001), and more bone (p<0.001) and renal (p=0.01) discontinuations than boosted TAF. Unboosted TDF caused more gastrointestinal AEs than unboosted TAF (p<0.05), however, this reversed with booster co-formulation (p<0.05); boosted TAF caused more gastrointestinal AEs than boosted TDF (p<0.11).

Conclusion: Ritonavir–cobicistat–boosted TDF was associated with higher bone and renal AE risk than boosted TAF. However, unboosted TAF and TDF risk differences were marginal. Boosted TAF caused higher gastrointestinal AE risk than boosted TDF. Both formulations have booster-dependent AEs. The broadened health economic benefits of TAF versus generic TDF may be reduced without boosters. Systematic bias from boosted and unboosted trial result grouping needs to be dispelled.

PE3/9

Biologic sex is not the only difference between men and women: data from the Doravirine phase 2/3 clinical trials

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Purpose: Doravirine (DOR) is a recently approved NNRTI for the treatment of HIV-1, available as a single entity and a fixed-dose combination with lamivudine and tenofovir disoproxil fumarate (DOR/3TC/TDF). Differences in baseline characteristics between men and women, beyond biological sex, in DOR phase 2/3 clinical trials (Protocol 007, DRIVE-FORWARD, and DRIVE-AHEAD) were examined.

Method: Antiretroviral-naïve adults with pre-treatment HIV-1 RNA ≤10,000 copies/mL received once-daily DOR 100 mg or efavirenz 600 mg (EFV) with FTC/TDF in PO07; DOR 100 mg or darunavir/ritonavir 800 mg/100 mg with FTC/TDF or ABC/3TC in DRIVE-FORWARD; and DOR/3TC/TDF or EFV/FTC/TDF in DRIVE-AHEAD. All treatment groups were combined for this analysis, which included all randomized participants who received ≥1 dose of study therapy. Differences in proportions were analyzed using the Miettinen-Nurminen method. Association between sex and race was investigated using Pearson’s chi-square test. For continuous variables, linear regression models were used to investigate treatment difference for age (with no adjustment); for baseline body weight, body mass index (BMI), CD4 + T-cell count, CD4/CD8 ratio, and HIV-1 RNA (adjusted for age); and for treatment compliance (adjusted for age and study group).

Results: Racial distribution was significantly different between men and women, with Black or African Americans representing 40.6% of women vs. 16.6% of men. Statistically significant differences were also found for age, weight, BMI, CD4 + T-cell count, HIV-1 RNA, and medication use (table). Despite these differences, DOR demonstrated similar efficacy and safety in men and women in the phase 2/3 clinical trials.

Conclusion: Women in the phase 2/3 clinical trials of DOR were statistically significantly different from their male counterparts in certain baseline characteristics beyond biological sex. Although women had similar efficacy and safety results, women represented 15% of participants. Increased enrollment of women in clinical trials or women-only trials should be considered to further understand antiretroviral efficacy and safety in this important population.

PE3/10

No metabolic or renal benefits when switching to an NRTI-free dolutegravir-containing 2 drug regimen (2DR) – a subanalysis of the DUALIS study

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Purpose: The DUALIS study assessed efficacy and safety of switching to Dolutegravir (DTG) and boosted darunavir (bDRV) (2DR) and has demonstrated non-inferiority as compared to 2 NRTI+bDRV (3DR). Here we present a post-hoc subanalysis on changes in metabolic and renal parameters.

Method: In DUALIS PLWH with HIV-RNA<50cps/mL on 2 NRTI+bDRV (3DR) for 24 weeks (one accepted blip<200cps/mL) were randomized to switch to...
DTG 50 mg=DRV 800 mg (with 100 mg Ritonavir or 150 mg Cobicistat) or remain on 3DR.

Results: Overall, 266 subjects were randomized and treated (2DR: n=133, 3DR: n=133). Over 48 weeks, patients in the 2DR arm gained median +2.0 kg in body weight (IQR: −0.2 to −4.0) vs. +0.2 kg (−1.9 to −2.1) in the 3DR arm (p=0.0006; comparing 2DR and 3DR); median increase in BMI was +0.05 kg/m² (−0.1 to +1.2) for 2DR and +0.1 kg/m² (−0.5 to +0.7) for 3DR (p=0.0006). After 48 weeks, total cholesterol had increased by a median of +2.0 mg/dL (+3.0 to +35.5) in 2DR vs. no increase, i.e. 0.0 mg/dL (−18.5 to +15.5), in 3DR (p=0.0001). LDL increased by +13.3 mg/dL (−3.0 to +31.3) in 2DR vs. 0.0 mg/dL (−14.0 to +18.0) in 3DR (p=0.0003). HDL increased by +4.9 mg/dL (−1.0 to +10.4) in 2DR vs. a decrease of −1.0 mg/dL (−5.0 to −4.0) in 3DR (p=0.001).

Changes in MDRD-eGFR over 48 weeks were −7.8 mL/min/1.73 m² (−17.4 to −0.3) in 2DR vs. −0.4 mL/min/1.73 m² (−8.8 to +5.7) in 3DR (p=0.0002); changes in Creatinine-CKD-EPI-eGFR were −8.0 mL/min/1.73 m² (−17.0 to −0.6) in 2DR vs. −0.7 mL/min/1.73 m² (−9.4 to +4.5) in 3DR (p=0.0002). CKD-EPI Creatinine-Cystatin eGFR decreased by −6.7 mL/min/1.73 m² (−14.4 to −5.3) in 2DR vs. −2.7 mL/min/1.73 m² (−10.0 to +4.3) in 3DR (p=0.0157).

Conclusion: While being non-inferior with regard to virologic suppression, a switch to a 2DR consisting of DTG+DRV does not yield significant metabolic or renal advantages by substituting the NRTI components of a comparative 3DR antiretroviral therapy.

PE3/11 Sustained viral suppression with dolutegravir monotherapy during 9,899 patient weeks of follow-up in individuals starting combination antiretroviral therapy during primary HIV infection (EARLY SIMPLIFIED): a randomized, controlled, multi-site, non-inferiority trial

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1University Hospital Zurich, University of Zurich, Division of Infectious Diseases and Hospital Epidemiology, Zurich, Switzerland 2Institute of Medical Virology, University of Zurich, Zurich, Switzerland 3Checkpoint Zurich, Zurich, Switzerland 4Kalkbreite Praxis, Zurich, Switzerland 5Center of Infectious Diseases Zurich, Zurich, Switzerland

Purpose: Dolutegravir (DTG) monotherapy has been criticized because of the risk of long-term failure. Our EARLY-SIMPLIFIED trial showed that at week 48 DTG monotherapy was non-inferior to combination antiretroviral therapy (cART) and the long-term data shows the patients on DTG monotherapy. The dotted lines indicate cumulative number of patients who have been excluded from the study or are lost to follow-up, whereas the vertical bars (−) indicate the last study visit (at with HIV-1 RNA<50 cp/mL) of active participants at the time of abstract submission. a) DTG monotherapy group. The single patient who experienced a viral rebound violated the inclusion criteria as he was chronically infected at the start of cART. One patient switched to cART after 75 weeks due to side effects and was lost to follow-up with last HIV-1 RNA<50 cp/mL before week 120. 63 of 48 patients have reached week 120. b) cART group. Sixteen patients switched to DTG monotherapy, four patients were lost to follow-up with last HIV-1 RNA<50 cp/mL and there was no virological failure. 28 of 33 participants have reached week 120.

Follow-up times of the Early Simplified Study (intention-to-treat population)

PE3/12 Rapid initiation of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) in patients with human immunodeficiency virus (HIV)-1 infection: age, race/ethnicity, and gender subgroup analyses from the DIAMOND study

D Anderson1, R Bolan2, E De Jesus3, JG Castro4, RB Simonson1, P Cosler1, S SeyediKazemi1, D Luo2 and K Dunn3

1Janssen Scientific Affairs, LLC, Titusville, NJ, USA 2Los Angeles LGBT Center, Los Angeles, CA, USA 3Orlando Immunology Center, Orlando, FL, USA 4University of Miami, Miami, FL, USA 5Janssen Research & Development, LLC, Titusville, NJ, USA

Objective: To evaluate Week 48 efficacy and safety results from the DIAMOND study across age, race/ethnicity, and gender subgroups.

Methods: DIAMOND (NCT03227861), a phase 3, single-arm, prospective study, assessed efficacy/safety of rapidly initiating D/C/F/TAF 800/150/200/10 mg. Adults enrolled within 14 days of HIV-1 diagnosis and started D/C/F/TAF without baseline laboratory results. Patients not meeting predefined stopping rules continued treatment, as per study protocol. Efficacy/safety were assessed across subgroups based on age (18–25/26–50/<50 years), race/ethnicity (white-black or African American/other; Hispanic/non-Hispanic), and gender (women/men). Virologic response rates (HIV-1 RNA<50 copies/mL) were assessed by intent-to-treat FDA snapshot and an observed analysis (excluding patients with missing samples).

Results: Overall, 109 patients enrolled (median [range] age: 28 [19–66] years; 32% black/African American; 44% Hispanic/Latino; 13% women); 97 (89%) patients completed the study with no discontinuations due to virologic failure or developed resistance. Demographic characteristics, virologic response, and D/C/F/TAF-related adverse events (AEs) by subgroup are shown (Tables 1–3). Across age subgroups, Week 48 virologic response rates were high and similar. No D/C/F/TAF-related renal or bone AEs were reported, including among patients aged>50 years. Virologic response rates were also similar across race/
ethnicity subgroups, while virologic response rates by FDA snapshot (but not observed) analysis were lower among women versus men. The latter should be interpreted with caution given the small sample size of women (see Table 2 footnote). Patients ≥50 years, black/African Americans, and women had numerically lower rates of related AEs versus other subgroups.

Conclusion: In the first phase 3 study of a single-tablet regimen in a rapid initiation model, DIAMOND enrolled patients synonymous with the population most affected by HIV-1 infection today. D/C/F/TAF resulted in high virologic response rates across a variety of baseline demographics. Treatment was safe and well tolerated, indicating D/C/F/TAF as a preferred antiretroviral therapy option for rapid initiation.

Results: Among the 14 of the 17 included studies; results are shown in the tables conducted on 14 of the 17 included studies; results are shown in the tables.

### Table 1. Baseline Demographic Characteristics by Subgroups*

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<th>Parameter</th>
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<th>Non-White</th>
<th>Male</th>
<th>Female</th>
<th>Non-switch Studies</th>
<th>Switch Studies</th>
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### Table 2. Virologic Response at Week 48

<table>
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<th>Subgroup</th>
<th>Comparison Arm</th>
<th>Number of Participants</th>
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<td>5.18</td>
<td>92/2337</td>
<td>3.95</td>
</tr>
</tbody>
</table>

### Table 3. Related Adverse Events Through Week 48

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Comparison Arm</th>
<th>Number of Participants</th>
<th>Total Events/Percentage</th>
<th>Total Events/Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switch Studies</td>
<td>20/2689</td>
<td>0.74</td>
<td>21/2688</td>
<td>0.78</td>
</tr>
<tr>
<td>Non-switch Studies</td>
<td>121/2335</td>
<td>5.18</td>
<td>92/2337</td>
<td>3.95</td>
</tr>
</tbody>
</table>

### Table 4. Comparison of Related Adverse Events Through Week 48

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Comparison Arm</th>
<th>Number of Participants</th>
<th>Total Events/Percentage</th>
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Conclusion: Overall, this analysis shows an increased risk of insomnia for dolutegravir. Although cases of suicide related adverse events have been seen in patients taking dolutegravir, this was not significant when compared to other antiretrovirals. With the anticipated roll out of dolutegravir based regimens in LMICs, it is essential to closely monitor patients for adverse events.

### PE3/13

A systematic review and meta-analysis evaluating the risk of central nervous system adverse events in randomised controlled trials of dolutegravir

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1Imperial College London, Faculty of Medicine, London, UK 2University of Liverpool, Department of Translational Medicine, Liverpool, UK

**Purpose:** Dolutegravir was recently added as the recommended first-line treatment for HIV-1 infection by the World Health Organisation. With the changes in guidelines and the generic manufacturing of dolutegravir, it is anticipated that there will be a mass roll out of the drug in low- and middle-income countries (LMIC). Results from observational studies have demonstrated safety issues relating to the drug. The purpose of this review was to evaluate the risk of central nervous system (CNS) adverse events observed in randomised controlled trials of dolutegravir in patients with HIV-1 infection.

**Method:** Embase, Medline and Global Health databases were searched using word variants of “dolutegravir” and “randomised controlled trial” from the earliest possible start date until 11th March 2019. Phase 3 clinical trials with at least one treatment arm containing dolutegravir were included. CNS adverse events were extracted and analysed, then stratified for switch studies versus non-switch studies and efavirenz versus other antiretrovirals. Relative risk for the comparisons were calculated and a Mantel-Haenszel random-effects model was applied to the meta-analysis.

**Results:** 17 studies of unique randomised controlled trials were included in the review, with a combined total of 11,138 participants. A meta-analysis was conducted on 14 of the 17 included studies; results are shown in the tables below. There was a higher risk of insomnia for dolutegravir compared to other antiretrovirals (RR=1.32, p=0.008). The results for suicide related adverse events showed no significant differences between dolutegravir and either efavirenz or other antiretrovirals, across each analysis.

**Table 1:** Virologic Response at Week 48

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Comparison Arm</th>
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<th>Total Events/Percentage</th>
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**Table 2:** Comparison of Related Adverse Events Through Week 48

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**Conclusion:** Overall, this analysis shows an increased risk of insomnia for dolutegravir. Although cases of suicide related adverse events have been seen in patients taking dolutegravir, this was not significant when compared to other antiretrovirals. With the anticipated roll out of dolutegravir based regimens in LMICs, it is essential to closely monitor patients for adverse events.

### PE3/14

Long-term efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in ART-naïve adults

C Orkin1, PE Sax1, J Arribas1, S Gupta1, C Martorell2, JL Stephens3, H-J Stellbrink4, E DeJesus8, F Maggioni9, H Huang10, R Acosta10, DM Brainard10, SE Collins10 and H Martin10

1Barts Health NHS Trust, Royal London Hospital, Ambrose King Centre, London, UK 2Brigham and Women’s Hospital, Boston, USA 3Hospital Universitario La Paz, Madrid, Spain 4Indiana University, Indianapolis, USA 5The Research Institute, Springfield, USA 6Mercer University School of Medicine, Macon, USA 7ICH Study Center, Hamburg, Germany 8Orlando Immunology Center, Orlando, USA 9Azienda Ospedaliera Papa Giovanni XXIII, Bergamo, Italy 10Gilead Sciences, Inc., Foster City, USA

**Purpose:** To evaluate comparative efficacy and safety of B/F/TAF and dolutegravir (DTG)-containing regimens through 144 weeks (W).

**Method:** We conducted two randomized, double-blind, active-controlled phase 3 studies of B/F/TAF in ART-naïve adults living with HIV. Study 1489 randomized HLA-B*5701-negative adults without HBV to receive B/F/TAF, abacavir, and lamivudine (DTG/ABC/3TC). Study 1490 randomized adults to B/F/TAF or DTG/F/TAF. Participants were pooled into three groups: B/F/TAF (Studies 1489, 1490), DTG/ABC/3TC (Study 1489), and DTG/F/TAF (Study 1490). A pre-specified pooled analysis at W144 assessed efficacy as the proportion with HIV-1 RNA<50 c/mL (FDA Snapshot) and safety; proteinuria and bone mineral density (BMD) were measured in 1489 only.

**Results:** 1274 adults were randomized/treated (634 B/F/TAF, 315 DTG/ABC/3TC, 325 DTG+F/TAF), 89% male, 33% Black. Baseline characteristics were similar across groups. At W144, 82% on B/F/TAF, 84% on DTG/ABC/3TC, and 84% on DTG+F/TAF achieved HIV-1 RNA<50 c/mL (table 1). No participant
developed resistance. The proportion with drug-related adverse events of any grade was 26% (B/F/TAF), 42% (DTG/ABC/3TC), and 29% (DTG+F/TAF). Adverse events led to discontinuation for 1% (B/F/TAF), 2% (DTG/ABC/3TC), and 2% (DTG+F/TAF). Changes in eGFR at W144 were similar across groups. In Study 1489, comparing B/F/TAF to DTG/ABC/3TC, changes in proteinuria and renal biomarkers were similar and mean percentage change from baseline in hip and spine BMD by DXA at W144 were similar. Small treatment differences in changes from baseline in fasting LDL, HDL, and TC:HDL ratio were observed with B/F/TAF vs DTG/ABC/3TC but not vs DTG+F/TAF.

Conclusion: Through 3 years of follow-up in ART-naïve adults, use of B/F/TAF resulted in high rates of virologic suppression through W144. B/F/TAF was well tolerated, had fewer drug-related adverse events compared with DTG/ABC/3TC, and no clinically relevant effect on bone and renal safety or fasting lipids.

Table 1. Key efficacy and safety results at week 144

PE3/15

Switching from a 3-drug tenofovir alafenamide (TAF)-based regimen (TBR) to a 2-drug dolutegravir/lamivudine (2DR, DTG/3TC FDC) was not associated with a higher frequency of intermittent viremia in suppressed patients in the TANGO study. R Wang1, J Horton2, J Wright3, R Razeek3, MC Nascimento4, AR Tenorio5 and M Underwood1

1ViiV Healthcare, Research Triangle Park, USA 2Paraxel International, Durham, USA 3GlaxoSmithKline, Stockley Park, UK 4ViiV Healthcare, Brentford, UK

Purpose: TANGO is a 200-week, Phase III, randomized, open-label trial to evaluate efficacy and safety of replacing TBR with a 2DR of DTG/3TC in HIV-1-infected adults, with HIV-1 RNA<50 c/mL and without prior virologic failure or historical NRTI or INSTI major resistance mutations. Switching to DTG/3TC was non-inferior to continued TBR through Week 48 using a 4% non-inferiority margin for Snapshot virologic failure.

Method: Frequency of elevated viral loads (VL, HIV-1 RNA<50 c/mL) was assessed after 48 weeks of therapy overall and in a subset of participants with archived M184V/I or K65R genotypes. Proviral DNA genotyping was conducted retrospectively on baseline samples using GenoSure Archive assay by Monogram Bioscience. Participants with 1 post-baseline VL (Intent-to-Treat population) were categorized as described in Table 1. Results are generated using all available on-treatment VL through Week 48 for participants with available baseline samples.

Results: 741 participants were randomized and exposed [DTG/ABC/3TC; TBR, 372]. At baseline, M184V/I was detected in 1% (7/626) participants by proviral genotype, and K65R was present in <1% (1/626). One participant (<1%) on TBR met confirmed virologic withdrawal criteria with no resistance mutations observed at failure. Through Week 48, the occurrence of elevated VL (see Table 1) was low and comparable across arms; most frequently observed VL rebounds are in category 1a. Elevated VLs (regardless of category) were not observed in the low number of participants with archived M184V/I or K65R (see Table 1).

Conclusion: Incidence of intermittent viremia through 48 weeks was low and similar between the two treatment arms. Frequency of archived M184V/I or K65R at baseline was very low and did not increase the risk of elevated VL in either treatment arm with no participants exhibiting intermittent viremia through Week 48. Switching from a 3-drug TBR to a DTG/3TC 2DR was not associated with higher frequency of intermittent viremia.
Conclusion: These preliminary data demonstrate proof-of-concept for in vivo antiviral activity via capsid inhibition. Following a single SC dose, potent antiviral activity was observed in all participants who received GS-6207 at 50, 150, or 450 mg through D10. GS-6207 was generally safe and well tolerated. These results support further evaluation of GS-6207 as a long-acting antiretroviral agent in people living with HIV.

PE3/18

Long-term safety and efficacy of rilpivirine plus nucleoside/nucleotide reverse transcriptase inhibitors in HIV–1 infected patients: 7-year roll-over study from phase 2 and 3 clinical studies

J-M Molina1, G Fäkkenheuer2, E Van Wijngaarden3, P Cahn4, L Ene5, J Lombard6, N Zakharaova7, V Van Eygen8, S Vanveggel9 and R Van Solingen-Ristlea

1University of Paris Diderot, Department of Infectious Diseases, Paris, France
2University of Cologne, Department of Internal Medicine, Cologne, Germany
3University Hospitals Leuven, Department of General Internal Medicine, Leuven, Belgium 4Fundacion Huesped, Buenos Aires, Argentina 5Spitalul de Boli Infectioase si Tropicale ‘Dr. Victor Babes’ Bucharest, Bucharest, Romania 6Joshua Research, Bloemfontein, South Africa 7Centre for Prophylaxis and Control of AIDS and Infectious Diseases, St. Petersburg, Russian Federation 8Janssen Research & Development, Beerse, Belgium

Purpose: Evaluate long-term safety, tolerability and efficacy of rilpivirine (RPV) plus background regimen of two nucleos(t)ide reverse transcriptase inhibitors (N(t)RTIs) in human immunodeficiency virus type-1 (HIV–1) infected patients.

Methods: In this open-label study, RPV-treated HIV–1 infected adults rolled-over from phase 2–3 studies and received continued access to RPV 25-mg once-daily with two N(t)RTIs. Adverse events (AEs), viral load, and genotypic data were assessed. Time to virologic failure (rebound, viral load <50 copies/mL) was analyzed using Kaplan–Meier estimates.

Results: Of 482 enrolled patients, majority were men (74.1%), aged =50 years (85.5%), and white (59.5%). At 7 years data cut-off (RPV exposure: 1374.8 ± 1319.7 weeks), 347 (70.7%) patients had already discontinued, of which 371 (77%) switched to commercially available RPV, 14 (2.9%) discontinued due to AE, and 6 (1.2%) had virologic failure. Overall, 102 (21.2%) reported any AE, most were grade 1–2 AE (87 [18%]); most common: pregnancy (7 [1.5%]) and syphilis (5 [1%]). Grade 3–4 AEs: n=17 (3.5%), no grade 3–4 rash observed. AEs at least possibly related to RPV: n=23 (4.8%), most frequent: increased blood triglycerides, n=3. There were 23 AEs and 2 deaths, none considered RPV-related. AEs of special interest: n=39 (8.1%), most frequently neuropsychiatric events (14 [2.9%]). Majority (80%; 95% CI: 75%, 84%) maintained virologic suppression (< 50 copies/mL) through 288 weeks of treatment, beyond which data considered insufficient for meaningful conclusions. Throughout the study, rebound rate per 100 patient-years (95% CI) was 5.5 (4.4, 6.9) corresponding to 68/482 (14.1%) patients (mostly during first 24 weeks, n=59); 46/68 patients with virologic rebound had genotypic data available with RPV-associated mutations in 3 patients (E138K, Y181C, M230L).

Conclusion: Long-term treatment with once-daily RPV and two N(t)RTIs was well-tolerated with no new safety findings and with sustained virologic suppression in HIV–1 infected patients.
Prevalence of archived HIV-1 DNA resistance-associated mutations (RAMs) and their lack of effect on virologic outcome at week 96 in antiretroviral treatment (ART)-experienced, virologically-suppressed patients receiving the once-daily, single-tablet regimen (STR) darunavir/cobicistat/ emtricitabine/tenofovir alafenamide (D/C/F/TAF) in the EMERALD phase III trial

E Lathouwers1, S Murrow2, B Baugh2, A Ghys3, J Jezorwski3, EG Mohsine1, M Opsomer4 and S De Meyere1

1Janssen Pharmaceuticals NV, Beerse, Belgium 2Janssen Research & Development, LLC, Raritan, USA 3Janssen Research & Development, Pennington, USA

Purpose: Through 96 weeks in EMERALD (ART-experienced, virologically-suppressed adults; NCT02269917), D/C/F/TAF 800/150/200/10 mg showed high virologic response (91% [692/763] viral load [VL] < 50 copies/mL) and low virologic failure (VF; 1% VL ≥ 50 copies/mL) rates, with no emergence of darunavir, primary protease inhibitor (PI), tenofovir or emtricitabine RAMs. We examined baseline archived RAMs and their effect on virologic outcome through week 96 in the D/C/F/TAF arm.

Method: HIV-1 proviral DNA from baseline samples (VL < 50 copies/mL) was analysed post-hoc (GenoSure Archive®) to assess prevalence of archived RAMs in the D/C/F/TAF subgroup with prior VF (n = 116) or protocol-defined virologic rebound (PDVR; cumulative confirmed VL ≥ 50 copies/mL) at week 96. Patients most likely to have baseline resistance. If historical genotypes were available, patients with darunavir RAMs were excluded; Patients with archived resistance maintained virologic response at week 96 or longer.

Results: In EMERALD, 59% of D/C/F/TAF patients had multiple prior antiretroviral experience; 15% had VF prior to screening. Of those VFs, 7% had previously failed ≥ 1 PI, 12% ≥ 1 N(t)RTI, 7% ≥ 1 NNRTI and 1% ≥ 1 integrase inhibitor. Predicted phenotype showed that 100% were susceptible to darunavir, 63% to emtricitabine and 78% to tenofovir. At baseline, in 98 D/C/F/TAF patients with prior VF and genoarchive data, 4 (4%) had archived darunavir RAMs, 4 (4%) tenofovir RAMs, 19 (19%) ≥ 3 TAMs and 35 (36%) emtricitabine RAMs, mainly at position M184, 31 (32%) (Table 1). All these patients with archived resistance maintained virologic response at week 96 or last on-treatment VL and no VF was observed. None of the 22 D/C/F/TAF patients with PDVR and baseline geno-archive data had archived RAMs to darunavir, emtricitabine or tenofovir.

Conclusion: In EMERALD, in ART-experienced, virologically-suppressed patients, baseline archived darunavir, emtricitabine and tenofovir RAMs had no effect on virologic response/failure rates through 96 weeks, confirming the efficacy and high genetic barrier of D/C/F/TAF.

Table 1: EMERALD: Prevalence of baseline RAMs in HIV-1 proviral DNA for patients with previous virologic failure

<table>
<thead>
<tr>
<th>RAMs</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>All PI</td>
<td>80 (82)</td>
<td></td>
</tr>
<tr>
<td>Darunavir</td>
<td>53 (54)</td>
<td></td>
</tr>
<tr>
<td>Emebricitabine</td>
<td>62 (65)</td>
<td></td>
</tr>
<tr>
<td>Tenofovir</td>
<td>56 (57)</td>
<td></td>
</tr>
<tr>
<td>All NNRTI</td>
<td>86 (88)</td>
<td></td>
</tr>
<tr>
<td>3 primary N RTIs, n (%)</td>
<td>20 (20)</td>
<td></td>
</tr>
<tr>
<td>2 darunavir RAMs, n (%)</td>
<td>4 (4)</td>
<td></td>
</tr>
<tr>
<td>L2V</td>
<td>1 (1)</td>
<td></td>
</tr>
<tr>
<td>1 NNRTI</td>
<td>46 (47)</td>
<td></td>
</tr>
<tr>
<td>1 tenofovir RAMs</td>
<td>19 (19)</td>
<td></td>
</tr>
<tr>
<td>1 TAMs</td>
<td>35 (36)</td>
<td></td>
</tr>
<tr>
<td>1 L2V</td>
<td>20 (20)</td>
<td></td>
</tr>
<tr>
<td>Emebricitabine</td>
<td>33 (33)</td>
<td></td>
</tr>
<tr>
<td>MISM/1VA</td>
<td>5 (5)</td>
<td></td>
</tr>
<tr>
<td>1 NNRTI, n (%)</td>
<td>3 (3)</td>
<td></td>
</tr>
<tr>
<td>3 TAMs, n (%)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>3 primary integrase inhibitor RAMs, n (%)</td>
<td>0 (0)</td>
<td></td>
</tr>
</tbody>
</table>

 Islatravir efficacy and safety for selected demographic and baseline subgroups from a Phase 2 trial in treatment naive adults with HIV-1 infection

J-M Molina1, Y Yazdanpanah2, A Afani Saud3, C Bettacchi4, Chahin Anania6, E DeJesus5, S Kloper7, A Grandhi5, K Eves5, M Robertson7, T Correll7, C Hwang4 and P Sklar8

1University of Paris, Hôpital Saint-Louis, Paris, France 2Bichat Hospital, AP-HP, Paris, France 3University of Chile, Santiago, Chile 4North Texas Infectious Diseases Consultants, Dallas, USA 5Hospital Herman Henriquez Aravena de Temuco, Temuco, Chile 6Orlando Immunology Center, Orlando, USA 7Merck & Co., Inc., Kenilworth, USA

Purpose: Islatravir (ISL, MK-8591) is the first nucleoside reverse transcriptase translocation inhibitor (NRTTI) in development for treatment of HIV-1 infection. We analyzed the week 48 results of a Phase 2 ISL trial in treatment naïve adults with HIV-1 infection by pre-specified subgroups for efficacy and safety.

Method: In this randomized, double-blind, dose-ranging trial, participants were initially assigned to receive ISL (0.25 mg, 0.75 mg, or 2.25 mg) with darunavir (DDR, 100 mg) and lamivudine (3TC, 300 mg) or a fixed-dose combination of DOR, 3TC, and tenofovir disoproxil fumarate (DDR/3TC/TDF) once daily. Participants receiving ISL who achieved HIV-1 RNA < 50 copies/mL at Week 20 or later stopped taking 3TC at their next visit and continued DDR+ISL at initial dosage; most participants stopped 3TC at Week 24. Efficacy endpoints included the overall proportion of participants at week 48 with HIV-1 RNA < 50 copies/mL. For the current analysis, efficacy results were summarized within pre-specified subgroups (age, sex, race, region, baseline HIV-1 RNA, baseline CD4+ T-cell count) using the Observed Failure Approach (excludes participants with data missing for reasons other than lack of efficacy).

Results: 121 participants received study drug and were included in analyses (mean age 31 yr, 92.6% male, 76.0% white, 49.6% Hispanic or Latino, 22% HIV-1 RNA > 100,000 copies/mL, median CD4+ T-Cell Count 456 cells/mm³). At week 48, 92.9% (26/28), 93.1% (27/29), 85.7% (24/28), of participants achieved HIV-1 RNA < 50 copies/mL in the 0.25 mg, 0.75 mg, and 2.25 mg dose of ISL respectively, compared to 92.9% (26/28) with DOR/3TC/TDF. Across the pre-specified and selected demographic and baseline subgroups, proportions of participants with HIV-1 RNA < 50 copies/mL at week 48 were comparable between all treatment arms (Figure 1). In the safety analysis, similar adverse event rates between treatment groups were observed across subgroups.

Conclusions: At week 48, across all baseline subgroups, the ISL regimens demonstrated similar efficacy and safety comparable to DOR/3TC/TDF.
Antiretroviral therapy preclinical

**PE4/1**

**Discovery of novel pyrazole based dual inhibitor of HIV and HCV together with attenuation of oxidative stress**

*UP Singh1 and HR Bhat1*

1Sam Higginbottom Institute of Agriculture, Technology & Sciences, Department of Pharmaceutical Sciences, Allahabad, India 2Dibrugarh University, Department of Pharmaceutical Sciences, Dibrugarh, India

**Purpose:** HIV-infected people are on average six times more prone to HCV infection than HIV-uninfected people, which warrants need to improve integrated HIV/HCV services together with affordable newer medications. HCV infection has been associated with a high oxidative stress via depletion of protective system, activation of immune signalling molecules (cytokines and chemokines) and an increased production of free radicals leading to activation of lymphocytes and phagocytising cells, chronic inflammation. Therefore, the present study was intended to discover novel pyrazole based dual inhibitor of HIV and HCV infection.

**Method:** The compounds were developed via facile synthetic route and subsequently tested for anti-HIV activity using TZM-bl cell lines along with Luciferase expression profile of the TZM-bl cells after infection with NL43 virus and MTT assay for the cytotoxicity determination. The anti-HCV activity was also determined by capability to obstruct the HCV replicase (HCV NS5B) activity in vitro and HCV replication in a cell culture system carrying replicating HCV subgenomic RNA replicon. The DPPH assay was conducted to determine the antioxidant activity of the molecules.

**Results:** It has been found that compound 8a showed utmost 97% inhibition of HIV with K = 523.45 μM against HIV-RT. Rest of the molecules showed also significant inhibition pattern. The target molecules also found to exhibit potent inhibition of RNA dependent RNA polymerase (RdRp) activity of HCV replicase in vitro with IC50 15.21 μg/mL. Compound 8c, significantly inhibited HCV replication in culture system which leads to reduction in HCV RNA level and translation level of viral proteins in concentration-dependent manner. In DPPH assay, molecules showed significant reduction of oxidative stress.

**Conclusion:** As a concluding remark, we have developed novel pyrazole based dual inhibitor of HIV and HCV infection, while presenting no considerable toxicity at the test dosages.

**PE4/3**

**In vivo dissection of the effects of HIV and antivirals on mitochondrial function in chronic treated HIV**

*H Vasilopoulos1, R Heymans1, W Mu1, P Hamid2, A Kossyvakis3, S Sen Roy1 and T Kelesidis4*

1University of California, Los Angeles, Medicine, Los Angeles, USA

**Purpose:** The mechanisms that drive comorbidities in chronic treated HIV remain unclear. Mitochondria are responsible for creating the energy needed for function of organs. Mitochondrial dysfunction likely plays a role in aging in chronic treated HIV. Given that observational human studies cannot dissect the differential effects of HIV versus antivirals (ART) on mitochondria, we used a physiologically relevant humanized mouse model of chronic treated HIV to determine HIV-1 and/or ART-driven mitochondrial dysfunction in vivo.

**Method:** The C57BL/6 Rag2−/−; LysMcre−/−; CD47−/−; Bone Marrow/Liver/Thymus mice do not develop early graft versus host disease. After 4 weeks of infection with the dual-tropic 89.6 HIV-1 virus, mice (n=20) were treated with daily emtricitabine (200 mg/kg), tenofovir (208 mg/kg), raltegravir (80 mg/kg) for up to 12 weeks. The groups were: A (n=5): uninfected (HIV-); B (n=10): HIV-; C (n=15): HIV+; ART. Reduction in mitochondrial DNA (mtDNA) levels compromises cellular function and the mtDNA:ntDNA ratio was determined by real-time PCR (Figure). Results are described as mean and SEM and t-test was used for statistical analysis.

**Results:** HIV-1 induced a mean 26% reduction in human mtDNA:ntDNA ratio in the liver of infected compared to uninfected mice (p<0.05) but did not affect the human and murine mtDNA:ntDNA ratio in the brain (data not shown). Potent ART for 12 weeks suppressed viremia within 4 weeks and induced a mean >20% reduction in human and mouse (not shown) mtDNA:ntDNA ratio in the liver and human mtDNA:ntDNA ratio in the brain of infected compared to uninfected mice (p<0.05).

**Conclusion:** HIV-1 and/or potent ART had a differential impact on mitochondria at the tissue level in vivo. Potent ART consistently induced mitochondrial dysfunction in both liver and brain and in both human and murine cells and may be a more important (than HIV-1) instigator of mitochondrial dysfunction in chronic treated HIV.

**Figure**

**PE4/4**

The main barriers to “Test and Start” in Central Asia from the service providers’ and patients’ point of view

*Y Kudussova1, Y Yanchenko1, A Deryabina1 and E Morrison2*

1ICAP at Columbia University, Almaty, Kazakhstan 2ICAP at Columbia University, New York, USA

**Purpose:** Under the Test and Start (T&S) guidelines being introduced in Central Asian countries (Kazakhstan, Kyrgyzstan and Tajikistan), all people living with HIV (PLHIV) are eligible for antiretroviral therapy (ART), regardless of CD4 cell count. T&S strategy has been approved by the MOH in three countries, but only about 70% actually start ART within 30 days after HIV diagnosis. To assess the readiness of local HIV service providers and patients to move towards T&S, ICAP conducted an assessment of HIV service providers’ capacity and a patient flow analysis in the three largest AIDS centers.

**Method:** During May–June 2018 ICAP conducted individual semi-structured interviews with clinical staff and PLHIV, carried out mapping of PLHIV visits and patient-flow observations, and reviewed government documents in three AIDS centers in Kazakhstan, Kyrgyzstan and Tajikistan.

**Results:** We interviewed 20 clinical staff and 161 PLHIV, including 152 on ART. The results of interviews showed that clinical staff and most patients are supportive and understand the benefits of early ART initiation. However, assessment identified several key challenges to effective roll-out of T&S, including lack of appropriate space for confidential examination and counseling of patients, limited number of nurses and insufficient information about ART provided to the patients. PLHIV still have fears about potential side-effects of ART, treatment complexity, privacy violation and, therefore, are not fully supportive of the prompt ART initiation.

**Conclusion:** There are several barriers to the effective roll-out of T&S in Central Asia. Key opportunities to overcome these barriers are to improve the management of patient flow by scheduling of clinical visits, implementation of “fast tracking” of stable patients on ART, and improving patients’ understanding of ART. Facility staff should invest more time in explaining the benefits of ART and the way ART is provided and should actively involve community organizations and peers in these information sessions.
**PE4/5**

Preclinical aspects of an anti-HIV molecule targeting vimentin


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**Purpose:** Host proteins are essentials for HIV replicative cycle. We have identified vimentin, an intermediate filaments forming protein, as a potential target for inhibiting HIV-1. The present work exposes a preclinical characterization of a vimentin targeting peptide.

**Method:** The HIV replication in presence of a synthetic peptide capable of modifying vimentin intermediate filaments was evaluated. Flow cytometry, fluorescence and electron microscopy and circular dichroism spectroscopy analysis were applied to study the effect of the peptide on the supramolecular structure of vimentin and its cell penetration capacity. The peptide safety was assessed through the macroscopic and microscopic analysis of the organs and the evaluation of immune system functionalities in mice. The pharmacokinetic profile and the bio-distribution were investigated in rodents.

**Results:** A synthetic peptide, derived from human keratin 10, was capable to change the structure of vimentin intermediate filaments. The peptide exhibited a high anti-HIV activity with a half maximal inhibitory dose at the nanomolar range and a low cytotoxicity. The capacity of the peptide to penetrate in human cell lines of different origins was demonstrated. A mostly disordered structure in aqueous solution, with an estimated alpha helical content of less than 5% was determined. The peptide safety was evidenced in repeated doses schemes, in mice. The half-life of elimination from blood was 4 hours. The peptide was found in HIV relevant tissues like lymph nodes.

**Conclusion:** The results show a synthetic peptide with a dose-dependent HIV inhibitory activity, a low cytotoxicity and a good cell uptake. Since this peptide targets a genetically conserved host factor there is low probability of selecting drug-resistant viruses. The preclinical data suggests a favorable pharmacokinetic and biodistribution profile for this potential drug candidate against HIV-1 infection.

**PE4/6**

PK/PD modelling of bnAbs for HIV treatments identifying knowledge gaps

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**Purpose:** Broadly neutralizing antibodies (bnAbs) are a potential HIV monoclonal antibody (mAb) therapy whose clinically effective dose often exceeds its in vitro potency by more than 10-fold. Pharmacokinetic and pharmacodynamic (PK/PD) modelling is critical for drug development and is used for:

1) Candidate progression into clinical trials.
2) Characterizing processes critical to treatment success, and
3) Drug combination trials.

Application of relevant antibody models to bnAbs, incorporating pre-existing HIV and mAb knowledge, has the potential to identify knowledge gaps and solutions.

**Method:** A review of infectious disease models identified a unified PK/PD scaffold, adapted to model published in vivo bnAb (BNC117) PK and PD data. A non-linear mixed effects model predicted bnAb data obtained from patients with detectable viral load. Sensitivity analyses evaluated the impact of tissue biodistribution, accelerated antibody clearance and resistance on parameter and dose estimation.

Results: The model predicted bnAb PK/PD data estimating dose-dependent effects on viral depletion and expansion. The influence of tissue biodistribution, enhanced clearance, and the presence of resistant viral quasispecies could not be estimated due to data paucity and model specification issues. The model identified a clinically ‘effective’ IC50 that was approximately 10-fold higher than the in vitro assessment. Viral suppression was maintained when plasma concentrations exceeded the 90th percentile of the ‘effective’ IC95 (determined from the ‘effective’ IC50). Sensitivity analyses indicate: tissue biodistribution could have a significant impact on estimating IC50, some emerging resistance and antibody clearance can be mitigated with increased doses.

**Conclusion:** The bnAb model had a structure similar to other infectious disease models including resistance development and the maintenance of effective drug concentrations. A difference in in vitro and in vivo potency was quantified that was dependent on biodistribution. Future characterisation of influential processes like biodistribution, presence of virus and effectors of PK will improve forecasting of bnAb effectiveness.

**PE4/7**

A new inhibitor of HIV-1 infection exploiting host intracellular signaling to alter viral RNA processing

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**Purpose:** The ability of HIV-1 to evolve resistance to current antiretroviral drugs has stimulated research into alternative means of modulating infection. We assayed ~60 modulators of RNA splicing to identify novel inhibitors of HIV-1 RNA processing—a segment of the viral lifecycle that is not targeted by current drugs.

**Method:** Cell-based inhibitor screening and protein/RNA quantification assays, SNUSET, RNA-Seq, and LC-MS/MS.

**Results:** We identified compound 191 as a potent inhibitor of both wild-type (IIIB/LAI–3NS4) and drug-resistant strains of HIV-1 in CD4 + T cells (IC50: ~700 nM), and in HeLa cells (IC50: 750 nM), and Bal in CD4 + primary T cells (IC50: 1.8 μM) with insignificant effects on cell viability at concentrations tested. 191 dramatically reduces expression of four essential HIV-1 structural/regulatory proteins (Gag/Env/Tat/Rev) without affecting total protein synthesis. These results are associated with altered viral RNA accumulation and transport: reduced unspliced and singly-spliced HIV-1 RNAs by 60% and loss of Rev. Consistent with perturbing HIV-1 RNA processing, 191 affects the abundance (and modification) of serine/arginine-rich splicing factors 1, 3, and 4. Decreased expression of Tat, but not Gag/Env, by 191 treatment was reversed by a proteasome inhibitor, suggesting that this compound also promotes degradation of this key viral factor. In contrast, 191 causes only 0.25% and 0.01% perturbation (resp.) in alternative splicing and expression of host RNAs and 0.02% alteration in abundance of host proteins. Inhibition of HIV-1 expression by 191 requires G protein-coupled receptor and Raf-MEK1/2-ERK1/2 signaling. Supporting this hypothesis, pre-treatment with G-protein blockers reversed 191’s inhibition of HIV-1 Gag and reduces spliced/singly-spliced RNA expression. Conversely, exogenous expression of variants of the small G protein, N-Ras, inhibited expression of these viral products.

**Conclusion:** These findings reveal the potential of modulating host intracellular signaling, with minimal consequences observed to cells, as an alternative approach for controlling HIV-1 infection.
Behavioural interventions

PE5/1
Close group social media network and social gatherings for comprehensive HIV services among adolescent MSM in Lagos Nigeria
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Purpose: Men who have sex with men (MSM) in Nigeria contribute significantly to the national HIV epidemic. In Lagos, Nigeria, the prevalence of HIV among MSM is as high as 41%. Adolescent MSM are more at risk. As effort to achieve UNAIDS 90:90:90 target, this project focused on adolescent MSM, to facilitate their access to comprehensive HIV testing services (HTS) and educate them on how to access biomedical HIV prevention tools.

Method: Target group were adolescent MSM aged 15–19 years. The targets were reached through close group social media networks using the snowball approach. Focus group discussions were conducted once a week during strategic social gathering for sixteen weeks to facilitate HTS. Ten main topics on HIV, AIDS, sexual and reproductive health, biomedical HIV prevention tools, PrEP, PEP, and common misconceptions were covered over sixteen weeks. Skills building were included in the training activities.

Results: Close group social media network complemented with targeted face to face meetings during social gatherings/parties using snowball approach can facilitate comprehensive HIV services for adolescent MSM. Face-to-face meetings is important to facilitate access to HTS. Of the 52 adolescent MSM reached, 45 (86%) completed the educational sessions and learnt about new HIV prevention tools. Ninety-two percent (92%) had access to HTS for their first time. Forty-seven HIV positive and were all (100%) linked to HIV treatment.

Conclusion: Close group social media network with targeted social gatherings and social media network can improve comprehensive HIV services for adolescent MSM. There is need for more targeted interventions tailored to the specific needs of adolescent MSM in the State.

PE5/2
Good hygiene practices post circumcision: a case for low adverse events in VMMC
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Purpose: Kenya continues to implement Voluntary Male Circumcision (VMMC) for HIV prevention due to its cost effectiveness and projected long term benefits. However, provision of VMMC in resource limited settings raises safety concerns of VMMC services. This study sought to determine the rates and correlates of adverse events among men at Migori County hospital, Kenya.

Method: This was a quantitative cross sectional study of men attending VMMC follow up visits between November 15 2015 and December 20 December 2015. Participants were examined by a clinician for adverse events and interviewed by the Investigator for data on hygiene.

Results: A total of 138 men, with an average age of 22 years were enrolled into the study. A total of 4 participants (2.9%) had moderate adverse events. A total 52 (43%) showed daily after circumcision while 25 (18%) showed once every two days, and an additional 47 (34%) showed at least once in three days and only 4 (3%) showed after more than 3 days. A total of 122 (89%) participants wore underpants after circumcision while 15 (11%) participants did not. A total of 55 (45%) reported a daily change of underpants, 44 (36%) changed the underpants after two days. 17 (14%) changed underpants after three days while 6 (5%) did not change or wash their underpants post-circumcision. Infrequent bathing (p=0.001) and not wearing of underpants (p=0.005) was associated with infection and swelling. Additionally men who never changed their underpants were more likely to experience infection and delayed healing (p=0.001).

Conclusion: Despite the standard practice of counseling and provision of information on post circumcision practices, there is a need for further evaluation on what messages are provided and how they are understood by clients. There may be a need for specific instructions on the frequency of bathing and the wearing, changing and washing of underpants.

PE5/3
Challenges of implementing HIV counselling and testing (HCT) campaigns for higher education distance learning students at University of South Africa
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Purpose: Higher education distance learning institutions do not usually have students who are physically present on campus as is the case with residential higher education institutions. Therefore, the purpose of this study was to investigate the challenges faced by implementers of HIV Counselling and Testing (HCT) campaigns for higher education distance learning students at University of South Africa.

Method: This study used a qualitative approach supported by exploratory and case study techniques to collect and analyse data. In-depth interviews and observations at research sites uncovered rich data elucidated by Health Belief Model approach

Results: It has been concluded that the administrative planning procedures of HCT campaigns were not properly followed, which resulted in the following difficulties: defining the roles and responsibilities of stakeholders, using limited resources, and the inability to reach all the students, in order to get them to actively participate in the campaigns. Lack of coordination of HIV and AIDS activities and the absence of monitoring and evaluation also impacted negatively on the success of HCT campaigns.

Conclusion: This study recommended that HCT campaigns at University of South Africa should have a proper task team constituting of experts in HCT campaign operations, in order to strategically plan and coordinate all the campaigns activities. The implementers should also monitor and evaluate these activities on a regular basis.

PE5/4
Enhancing effective HIV prevention among girls by fighting child marriage and sexual and gender based violence in Karonga district, Malawi
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Purpose: In Malawi, early sexual debut and marriages, initiation and marriage systems, intergenerational and transactional sex, multiple partners, and sexual coercion expose youth especially girls to HIV. More than half of Malawian youth marry while still in their teens and 69% of sexually-active young people have multiple partners. Example, 30% of young women aged 15–19 years have first sexual intercourse before they were 15 years old making themselves more vulnerable to HIV and AIDS, STIs and maternal death. Similarly, in TA Kilupula, Karonga district, youth especially girls were affected by the situation. Cases of Sexual and Gender Based Violence (SGBV), early child marriages (CM) among girl children exposed girls to HIV infections while denying their education rights. The situation was influenced by culture, poverty and ignorance.

Therefore, FOHOP implemented a project supposed to enhance protection of 3500 girls from Early child Marriages and SGBV situations which were increasing the rate of new infections of HIV.

Method: Baseline data from 10 health facilities and 4 schools was collected. Trained 50 girls in HIV infection, early childbearing, marriages prevention; Established 10 girls’ clubs of 10 members each, Trained 11 young women as paralegals, Conducted 12 awareness campaigns, Trained community leaders, teachers, in child marriages, SGBV and HIV prevention.
Facilitated linkages to care and treatment for HIV infected and/or victims of child marriage/SGBV.

Results: 8 child marriages were divorced and girls were retained at school. 143 girls went for HIV testing. Reduced cases of SGBV by 90%.

Improved communication between parents and children on HIV. 47,300 people were sensitized on HIV infection in connection to Child marriage and SGBV.

Increased support from religious and local leaders.

Conclusion: Enhancing effective HIV prevention among girls by fighting child marriage and sexual and gender based violence is possible and improves girls’ health.

PE5/5

Effectiveness of rapid HIV and HCV testing programmes based on mobile units
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Purpose: Increasing coverage of HIV and hepatitis testing by increasing the availability of services.

Method: In the “Humanitarian action” fund’s programs rapid testing is carried out in mobile units. The team of each unit includes health workers, peer consultants and case managers. Testing is free and anonymous, accompanied with before and after test counseling. All clients who have received a positive result of the rapid HIV or HCV test are accompanied to the specialized medical services. Testing and consultations take no more than 15 minutes. Mobile units park in the places with large gatherings of people: shopping centers, subway, etc.

Results: According to the professional community, in Russia 50% more people live with HIV than indicated in the official statistics. Thus, in 2015–2018, 38 thousand people were examined for HIV infection, 1,900 new cases of HIV infection were detected and more than 1,500 people were treated at mobile units of the Fund “Humanitarian action”. According to official data, detectability during testing in medical institutions does not exceed 3%, in our projects it is 6% of the total number of tested. We also tested 600 people for HCV, of which 347 new cases were identified, which is more than 50% of the total number tested.

Conclusion: Based on these figures, we can conclude that the mobile service is more effective than in-patient testing for HIV and HCV, in identifying these infections among the population.

PE5/6

It can’t happen to me – tackling cognitive mistakes and HIV using a national campaign
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Purpose: National campaign It can’t happen to me was conducted from October to December 2018 by CAHIV, pointing out a general assumption that bad situations happen more likely to others than to yourself. Rather, it is important to assess the risk reflecting on the past sexual behaviors. To do that, citizens were invited to assess their risk by an expert at CheckPoint Zagreb (CPZ). The idea was promoted using various sources – from educative videos and talk shows to engagement of influencers and promoting mobile application Spolno zdravlje (Sexual health), inspired by the experiences in CPZ. It was also possible to assess the risk through a calculator inside the application.

Method: Data was collected individually for each CPZ user in order to assess risk. In case of high-risk, person was tested for HIV. To measure effects better, frequency data was drawn from the named mobile application’s Risk calculator.

Results: Excerpt of the data in table 1. shows risky behavior increase in CPZ during the time of a campaign – namely, high-risk users who have never been tested for HIV, other STDs and who have been practising anal and vaginal sex. A number of HIV+ results remained steady at 1 or 2 per month, but with increasing success.

![Figure 1. Risk calculator users May-Dec 2018](image)

Further analysis was conducted on various other key populations in order to track success of a campaign.

Conclusion: A campaign was organised to emphasize high risk of getting infected by an STD due to risky behavior. Data shows the importance of understanding why risky behaviors happen, as focusing on cognitive mistakes may contribute to better perception of personal risk and motivate people to seek help, hence prevent getting infected or further spreading the STD infections.

PE5/7

Is mobility still a HIV/STI associated vulnerable factor in the changing sex work dynamics among female sex workers in India? - Emerging evidence
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Background: Mobility for sex work poses increased vulnerability for HIV/STI among Female Sex workers (FSWs) in India. In addition, there is limited evidences on the FSWs who are reported to be travelling for sex work, not associated with HIV prevention program and in context of changing solicitation practices.

Objective: This analysis attempts to explore association between mobility and various factors including new mode of solicitation, association with HIV prevention programs, sexual risk behavior and violence among FSWs.

Method: A cross sectional study, mixed method study at 14 districts spread over seven states of India. This analysis focused on quantitative part, 1,750 FSWs, recruited between January–March 2019. Study broadly, observed FSWs soliciting through NACO identified approaches, defined as traditional and all other solicitation approaches defined as non-traditional approaches.

Table 1. Characteristics of high-risk CPZ users May-Dec 2018

<table>
<thead>
<tr>
<th></th>
<th>May</th>
<th>Jun</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-risk users</td>
<td>86</td>
<td>72</td>
<td>40</td>
<td>109</td>
<td>127</td>
<td>119</td>
<td>61</td>
</tr>
<tr>
<td>MSM</td>
<td>46.5%</td>
<td>45.8%</td>
<td>50.0%</td>
<td>47.7%</td>
<td>43.3%</td>
<td>48.7%</td>
<td>39.3%</td>
</tr>
<tr>
<td>Chemsex</td>
<td>22.1%</td>
<td>37.5%</td>
<td>37.5%</td>
<td>21.1%</td>
<td>22.8%</td>
<td>35.3%</td>
<td>27.9%</td>
</tr>
<tr>
<td>HIV never tested</td>
<td>43.0%</td>
<td>58.3%</td>
<td>47.5%</td>
<td>23.3%</td>
<td>55.9%</td>
<td>52.9%</td>
<td>50.8%</td>
</tr>
<tr>
<td>Other STDs never tested</td>
<td>64.0%</td>
<td>63.9%</td>
<td>60.0%</td>
<td>31.2%</td>
<td>74.8%</td>
<td>65.5%</td>
<td>83.6%</td>
</tr>
<tr>
<td>Practising anal sex</td>
<td>57.0%</td>
<td>52.8%</td>
<td>62.5%</td>
<td>56.0%</td>
<td>59.1%</td>
<td>67.2%</td>
<td>55.7%</td>
</tr>
<tr>
<td>Practising vaginal sex</td>
<td>55.8%</td>
<td>62.5%</td>
<td>50.0%</td>
<td>61.0%</td>
<td>65.4%</td>
<td>59.3%</td>
<td>68.9%</td>
</tr>
<tr>
<td>Practising oral sex</td>
<td>91.9%</td>
<td>97.2%</td>
<td>100%</td>
<td>95.4%</td>
<td>96.1%</td>
<td>100%</td>
<td>96.7%</td>
</tr>
<tr>
<td>HIV+ results</td>
<td>2.3%</td>
<td>1.4%</td>
<td>0.0%</td>
<td>1.3%</td>
<td>1.2%</td>
<td>1.7%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

Also, risk calculator use skyrocketed during the time of a campaign, as seen in figure 1.

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Univariate, bivariate and binary logistic regression has been applied to address objectives.

Results: Among 1750, 33% (578) reported of practicing non-traditional, including 20% (350) exclusively through social network applications and 13% (228) through new physical spaces. 21% (368) via traditional approaches, while remaining 46% (804) has reported more than one approach of solicitation. 23% (394) FSWs has travelled outside district for sex work and they were more likely (OR=3.62, 95% CI 2.4–5.3) to solicit through non-traditional mode. Further, these FSWs were found to be significantly associated with not using condom with clients (OR=1.58, 95% CI, 1.23–2.03), engages in anal sex in last one month (OR=2.24, 95% CI, 1.72–2.88), reported violence (OR=1.84, 95% CI, 1.46–2.32) whereas it is not significant with consumption of alcohol before and during sex (OR=1.38, 95% CI, 0.94–2.03).

Conclusions: National HIV program should consider new approaches such technology and new physical spaces, for reaching out FSWs not associated with HIV programs. Adapting these newly identified solicitation approaches would facilitate for sharing information on importance of safe-sex and educating them on HIV/STI risk reduction strategies.

**PE5/8**

"Amare con Sapienza": an Italian digital ambient media prevention campaign in one of the largest European University to increase U, PreP, TasP knowledge

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Purpose: Purpose of the study is the evaluation of the effectiveness of digital ambient media in promoting the prevention of HIV infection.

Methods: The project included 3 phases:

- the pre-evaluative: a questionnaire was sent to Sapienza employees and students by email. It included 20 items focused on transmission and preventive measures including PreP, TASP and U=U concept and HIV test.

- the informative campaign via social networks and digital ambient media installed in the campus, both routing target people to the project website where they could get information about the infection and actively contribute to the campaign playing quiz-games that, when correctly solved, animated a digital opera in the campus heart (Fig. 1).

- the post-evaluative: the same questionnaire of the 1st phase was sent, the number of visits to the website, of post impressions were counted.

Non-parametric tests were used for statistical analysis.

Results: A total of 7263 persons replied to the questionnaires. We compare the answers before and after the campaign that was set up for 2 months in the campus (Table 1). Overall after the informative campaign an increase in all new HIV knowledge was observed. Through the website and the social campaign were reached about 16.000 persons.

Interestingly in the 2 months period of the campaign, an increase of 31% of the HIV tests and 22% of the new HIV diagnosis was registered in the nearby hospital comparing the same period of the previous years (Fig. 2).

Conclusion: The university population have poor knowledge of recent objectives. The baseline analysis reported here is performed by uni- and multivariable regression analysis in order to plan intervention.

Methods: Cohort pilot, intervention study on VW (aged 18–49 y) in the municipality of Gulu actively recruited by community outreach. HIV-Ab (4th generation Alere® HIV Combo) and electronic comprehensive questionnaire on SRB and HIV awareness (by ODK system, 110 questions) performed at baseline and every 6 months up to 3 y, educational interventions planned every 6 m. The baseline analysis reported here is performed by univariate and multivariable regression models.

Results: 488 VW were enrolled (mean age: 29 (SD 7.7)). 40/468 (8.5%) were found to be HIV-Ab +. 231 (49%) had a primary level of education; 242 (51%) did not use condom in the last 12 m; 13 (2.7%) have a HIV- stable sexual partner, median sexual partners in the last 12 m were 1.05 (SD 1.2); 30 (6%) did transactional sex at least once; Factors associated to a recent HIV diagnosis are reported in table 1. After controlling for several sociodemographic, behavioral and knowledge variables, the likelihood of engaging in SHRB (defined as not having used condom in the last 12 m or...
having done transactional sex at least once) was significantly higher among those not knowing the protective role of a monogamous union (AOR 11.3, 95% CI 2.2–58.3, p = 0.003), and not thinking that a healthy-looking person may have HIV infection (AOR 18.3, 95% CI 1.84–183.5, p = 0.01).

Conclusions: In this cohort of VW HIV prevalence is considerably high and sexual risky behaviors are multifaced; HIV prevention should be tailored through educational approaches focused on health information and avoiding stigma.

Sociodemographic, behavioral and knowledge factors associated to recent HIV diagnosis in uni- or mul

PE5/10 HIV/AIDS educational program for secondary school female students in Iran: a school-based randomized controlled trial
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Purpose: Adolescents form a particularly important target group for primary prevention against HIV/AIDS. The aim this study was to assess the effectiveness of TBP training based program on attitude, norms, parental control, behavioral control and intention among high school female students in Tehran.

Method: A randomized controlled trial was conducted in Tehran, among female high school students aged 12–16 years in 2015–16. They were selected using multistage random cluster sampling and then were randomly assigned to the experimental (n = 289) and control (n = 289) groups. The Theory of Planned Behavior (TPB) is the basis of both education and evaluation. During the study, the experimental group received an HIV training program based on a modified TPB. Respondents in the two groups completed a questionnaire both at baseline and 6 months follow up.

Results: In the experimental group, significant improvement was shown in attitude (16.6%, 95% CI = 14.4 to 18.8), subjective norm (16.8%, 95% CI = 12.9 to 20.6), perceived behavioral control (19.1%, 95% CI = 16.2 to 22.1), perceived parental control (17%, 95% CI = 13.8 to 20.2), behavioral intention (19%, 95% CI = 16.3 to 21.6) and behavior (17.3%, 95% CI = 13.9 to 20.6) compared to the control group (p < 0.001 for all dimensions).

Conclusion: Theory-based HIV/AIDS intervention may be effective in reducing high risk behaviors related to HIV/AIDS among adolescent girls. Routine educational programs need to be replaced by these active educations about HIV/AIDS in school systems.

Cascade of care

PE6/1 Self-reported non-receipt of HIV test Results a silent barrier to HIV epidemic control in Mozambique
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3Vanderbilt University Medical Center, Department of Pediatrics, Division of Pediatric Infectious Disease, Nashville, USA
4Eduardo Mondlane University, Faculty of Medicine, Maputo, Mozambique

Purpose: People living with HIV (PLHIV) and who are aware of their HIV status can access and benefit from antiretroviral therapy (ART) with subsequent individual and public health benefits; however, many PLHIV are unaware of their HIV status. We assessed the magnitude and determinants of self-reported non-receipt of HIV test results in adults aged 15–59 years old in Mozambique.

Method: We performed a secondary analysis of data from the 2015 Mozambique Immunization indicators, Malaria and HIV/AIDS Survey (IMASIDA 2015). Adults (aged 15–59 years) were interviewed and data on sociodemographic characteristics, HIV knowledge, attitudes and behaviors, and HIV testing history were collected. Multivariable logistic regression assessed factors associated with self-reported non-receipt of HIV test results. Population representative estimates were calculated.

Results: A total of 6,654 (51.1%) respondents had previously been tested for HIV and were included in the analysis. Of these, 308 (4.6%; 95% CI: 3.70–5.77) self-reported not having received HIV test results. In the multivariable analysis, previous sexually transmitted infection (aOR: 2.76; 95% CI: 1.44–5.31), HIV stigmatizing attitudes (aOR: 1.96; 95% CI: 1.14–3.37), and lack of decision-making power towards health care seeking (aOR: 2.51; 95% CI: 1.39–4.52) were associated with non-receipt of HIV test results. Whereas, secondary or higher education (aOR: 0.25; 95% CI: 0.12–0.54), higher HIV knowledge (aOR: 0.47; 95% CI: 0.26–0.86), and age between 30–34 and 35–39 years old (aOR: 0.47; 95% CI: 0.28–0.80; and aOR: 0.40; 95% CI: 0.27–0.90, respectively), were associated with receipt of HIV test results.

Conclusion: In this nationally representative survey, self-reported non-receipt of HIV test results was high and of public health relevance. These findings suggest adaptation of HIV counseling and testing programs emphasizing individualized approaches that target the youngest, least educated and the poorest individuals, especially those living in rural areas.

PE6/2 Improvement in ART initiation in different regions of Ukraine from 2010 to 2014
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2Independent Consultant, Kiev, Ukraine

Purpose: Ukraine is affected by one of the most severe HIV epidemics in Europe with HIV prevalence around 0.67% of adult population and AIDS death rate 25 per 100,000. ART therapy massively came in Ukraine in 2009 covering 25% of the need. ART Protocol has been changing in order to prioritize treatment initiation based on CD4 cell counts from 250 to 350 cells till 2015. HIV case reporting in Ukraine is paper based thus limited data available for analysis. The study describes the major changes in ART uptake between 2010 and 2014.

Methods: We analyzed clinical data routinely collected at regional AIDS centers, HTS points, and ART sites. The study dataset contains only depersonalized clinical information on patients receiving HIV care between 2010 and 2014. We used Kaplan–Meier estimator to determine the time between HIV diagnosis and treatment initiation and log-rank test to assess the difference between years and regions.

Results: Annual ART coverage has increased moderately from 54% in 2010 to 60% in 2014, while average and median time decreased significantly: average time from 45.4 months (95% CI: 44.7–46.2) to 28 month (95% CI: 27.1–28.9); median from 58 (95% CI: 55–61) to 10 (95% CI: 9–11). Improvement in some regions even more prominent (see Tables 1 and 2).
Seven years of European Testing Week: impact of a regional awareness campaign on increase in awareness and testing activities in Europe

L Combs1, B Collins2, V Delpech1, D Simões4,5, JK Rockstroh6, D Raben1 and on behalf of the EuroTEST Steering Committee and European Testing Week Working Group

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2ReShape/International HIV Partnerships, London, UK
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Purpose: European Testing Week (ETW) started in 2013 to unite organisations across Europe to increase testing efforts and awareness of earlier testing for HIV and in 2015, also viral hepatitis. We present the effectiveness and impact of ETW over the past 7 years.

Method: To participate, interested organisations sign up on the ETW website. At the completion of ETW, all participants are asked to complete an online evaluation recording types of activities, targeted key groups, details on testing activities, promotion activities, satisfaction with ETW and challenges. Organisations who conducted testing are invited to submit aggregated data on people tested, reactive results and linkage to care. Results from all surveys (2013 – 2019) were included.

Results: With the exception of 2015, where there was miscommunication regarding sign-up renewal, the number of organisations signed-up to participate increased on average 29% per year (Figure 1). Participating organisations on average overall are NGOs/CSOs (63%), 19% health care, 11% government and 7% other organisations. Over the years, the most common ETW activity have been testing activities followed by awareness raising and promotion activities, satisfaction with ETW and challenges. Organisations who conducted testing are invited to submit aggregated data on people tested, reactive results and linkage to care. Results from all surveys (2013 – 2019) were included.

Conclusions: Now in its seventh year, ETW has established itself as a well-known European campaign which now occurs biannually and has proven impact on increasing awareness and testing rates.
PE6/5
Impact of integrated family planning and HIV services on early postpartum contraceptive use among women with HIV in the Eastern Cape, South Africa
Owen Nkomo, MDC, Pukoroko Mabaso, BSc, Lrinah Mtshali, MSc, and Luleke Tsoga, B.Sc.

Purpose: To determine the prevalence of early contraceptive use and determinants of uptake in women living with HIV in the Eastern Cape, South Africa.

Method: A cross-sectional study was conducted among women attending antenatal clinics in the Eastern Cape. Data was collected using a pre-tested questionnaire.

Results: Nearly all the women (93%) received one form of contraception. Age, educational level, and pre-conception awareness of HIV serostatus were significantly associated with a higher likelihood of using contraception. Factors significantly associated with a higher likelihood of using contraception were younger age (<30 years), higher educational level, and pre-conception awareness of HIV serostatus.

Conclusion: The implementation of integrated family planning and HIV services in antenatal clinics appears to be effective in promoting early contraceptive use among women living with HIV in the Eastern Cape, South Africa.
be in-depth analyzed and reduced to guarantee a better health assistance. Madrid patients, maybe due to an efficacious network with lab, were treated more quickly with cART obtaining a better virological response at the first month. At the same time, Catania outpatient unit should reduce laboratory timing to achieve more rapidly cART administration with optimal regimens.

PE6/8
The HIV- and HCV-cascade in Swiss opioid agonist treatment (OAT) patients - the SAMMSU-cohort
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1Cantonal Hospital Aarau, Division of Infectious Diseases and Hospital Epidemiology, Aarau, Switzerland 2Ard, Centre for Addiction Medicine, Zurich, Switzerland 3Private Practice, Lausanne, Switzerland 4Epatocentro Ticino SA, Lugano, Switzerland 5Ingrado Servizi per Le Dipendenze, Lugano, Switzerland 6Private Practice, Basel, Switzerland 7Cantonal Hospital St. Gallen, Division of Infectious Diseases and Hospital Epidemiology, St. Gallen, Switzerland 8Bern University Hospital, Department of Infectious Diseases, Bern, Switzerland

Background: To end the HIV/AIDS-epidemic by 2030, until 2020, 90% of all HIV-infected people should be diagnosed, 90% of those diagnosed should receive antiretroviral treatment (ART) and 90% of those treated should achieve viral suppression (90–90–90 targets of UNAIDS). To reach HIV-elimination by 2030, the WHO considers 80% treatment-uptake to be necessary. However, a 90–90–90 target is also discussed for viral hepatitis.

Objectives: To describe the HIV- and HCV-cascade in Swiss opioid agonist treatment (OAT) patients and compare the HCV-cascades in HIV-negative and HIV-positive people.

Methods: The Swiss Association for the Medical Management in Substance Users (SAMMSU)-Cohort is an open cohort with yearly follow-up enrolling OAT patients in eight different centres throughout Switzerland.

Results: Between 2014 and 05/2019, 906 patients have been enrolled (78% male, median age: 48 years, 81% ever intravenous drug use). For 904 (99.8%) patients the HIV/HCV-serostatus was known. HIV- and HCV-seroprevalence were 12.8% and 68.5%, respectively. Of the 116 HIV-positive patients, 114 (98.3%) received treatment (interferon-based or interferon-free). In 327 (82.4%) of them SVR was documented. The overall HCV-RNA-prevalence was 13.8% (66/95) versus 81.7% (331/405). In Swiss OAT patients of the SAMMSU-cohort, the 90% HCV-treatment-uptake lower: 69.5% (66/95) versus 81.7% (331/405).

Accordingly, one out of four HIV-positive patients is still HCV-RNA-positive (i.e. infectious) compared to only one out of eight HIV-negative patients.

Conclusion: HIV testing rates increased significantly after the introduction of ICHT and test acceptance rates were high (fig 1). Overall HIV testing rate baseline in Lithuania (12 months before) was 10.6%; the highest (37%) for STIs, the lowest [0%] for Herpes infection. HIV testing rate during the pilot study (10 months) increased to 67%; the highest (96%) for STIs, the lowest (38%) for H. simplex. HIV/HCV combined testing was effectively introduced with test acceptance rates of 100% and overall testing rate of 99%, although baseline HCV testing for STIs was 0.8%. Three new cases of HIV and 2 of HCV positivity were identified. All patients were linked to care. For tuberculosis the introduction of a PIL improved the testing rates from 67.4% before the INTEGRATE project to 87% after the introduction of the PIL.

Conclusion: ICHT and HIV/HCV combined testing are feasible and acceptable methods to increase HIV and HCV testing rates in health care settings and methods to implement ICHT has proven transferable to implement combined HIV/HCV testing. Introduction of a PIL can ease work for consent and increase the number of HIV tests among TB patients.

PE6/10
AIDS and late presentation follows testing gaps in Poland - data from Test and Keep in care (TAK) Polska project
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Method: A baseline audit was conducted in both clinics on HIV testing performance and questionnaires on staff attitudes towards HIV testing were completed by clinic staff. Data on testing was collected monthly to monitor progress. Training of staff and PDSA (Plan-do-study-act) cycles were frequently performed and a patient information leaflet (PIL) on reasons for HIV testing was introduced to ease consent process in Romania. After 7 months of HIV testing HCV testing was added routinely for all STI patients in Lithuania.

Results: HIV testing rates increased significantly after the introduction of ICHT and test acceptance rates were high (fig 1). Overall HIV testing rate baseline in Lithuania (12 months before) was 10.6%; the highest (37%) for STIs, the lowest [0%] for Herpes infection. HIV testing rate during the pilot study (10 months) increased to 67%; the highest (96%) for STIs, the lowest (38%) for H. simplex. HIV/HCV combined testing was effectively introduced with test acceptance rates of 100% and overall testing rate of 99%, although baseline HCV testing for STIs was 0.8%. Three new cases of HIV and 2 of HCV positivity were identified. All patients were linked to care. For tuberculosis the introduction of a PIL improved the testing rates from 67.4% before the INTEGRATE project to 87% after the introduction of the PIL.

Conclusion: ICHT and HIV/HCV combined testing are feasible and acceptable methods to increase HIV and HCV testing rates in health care settings and methods to implement ICHT has proven transferable to implement combined HIV/HCV testing. Introduction of a PIL can ease work for consent and increase the number of HIV tests among TB patients.
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15UImba-Mazurski w Olsztynie, Kliniczny Oddział Chorób Zakaźnych, Olsztyn, Poland
16Fundacja Edukacji Społecznej, Warsaw, Poland
17Pomorski Uniwersytet Medyczny, Katedra i Klinika Chorób Zakaźnych, Tropikalnych i Nabytych Niedoborów Immunologicznych, Szczecin, Poland

Background: Data on late presentation (LP) in Poland are not available from surveillance authorities, while to date it is the most effective measure of HIV testing access and linkage to care. To address this gap clinical centres initiated TAK Polska project to assess the prevalence and characteristics of AIDS and LP in the country.

Methods: Clinical and demographic data were collected retrospectively on predefined questionnaires for all patients newly registered in 13 HIV centres in 2016 and 2017. Data were cleaned and queried centrally. LP was defined as AIDS and/or CD4 count<350 cells/mm3 at first visit. Information on number of HIV tests performed in 2016 in voluntary counselling and testing centres (VCTs) in the region represented by each clinical centre were acquired from national VCTs system. In statistical analyses logistic regression models were used to identify factors associated with AIDS and LP.

Results: Data on 1751 patients were received (89.6% men, 64% infected through MSM contacts). The median age was 33.1 (IQR:27.5–39.8) years, CD4 count 383 (210–552) cells/mm3. Information about AIDS at baseline was available for 1535 (87.7%) of patients: 693 (45.1%) patients were LP and 184 (11.7%) presented with AIDS. The prevalence of AIDS was highest in cities from regions with lowest number of HIV tests in VCTs (Figure).

The relation between HIV test coverage and AIDS at diagnosis in Poland stratified by cities

The most common AIDS conditions: pneumocystis pneumonia (25.2%), candidiasis (22.4%), tuberculosis (14.7%) and wasting syndrome (14.0%). The odds of AIDS/LP were higher for each 10 years older (aOR 1.65[1.41–1.92] / 1.15[0.7–1.74]), persons infected through heterosexual contacts (2.07 [1.31–3.22] / 2.18 [1.00–4.94]) and initiating drug use [4.11 [1.29–7.88] / 3.13 [1.29–7.88]).

Conclusions: LP/AIDS at first clinical visit is still common in Poland with large variation between the centres. This indicates suboptimal testing for HIV in certain regions of the country and for some groups, especially injecting drug users.

PE6/11
Loss to follow-up and re-linkage to care in a single cohort study: who do we re-link to care?

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3University of Genoa, Department of Health’s Sciences, Genoa, Italy
4Policlinico San Martino, Infectious Diseases Unit, Genoa, Italy

Purpose: Describe the HIV-infected patients lost to follow-up (LTFU) at our Centre and identify variables that might predict a subsequent re-linkage to care (RLTC).

Method: We conducted a single center, retrospective study including patients followed at the Infectious Diseases Clinic of San Martino Policlinic Hospital, Genoa. LTFU was defined as missing appointments for both visits and exams for≥12 months. All patients LTFU during the year 2015, who were already in care at the beginning of the previous year, were included. All RLTC up to December 2018 were registered. Data were retrieved through medical records and the electronic Medinfo database. The possible association of different variables with RLTC was assessed through univariable logistic regression model.

Results: Sixty-three patients were enrolled, of whom 32 (50.8%) re-entered care. Median time between LTFU and RLTC was 1 year (range 1–3 years). Median viral load at RLTC was 46.5 copies/mL (IQR 0–1500 copies/mL). Seventeen patients (53.1%) had undetectable viral load (HIV RNA<50 copies/mL) at RLTC. Other characteristics of the two populations are illustrated in Table 1. At univariable logistic regression, only age showed a statistically significant association with RLTC (OR 0.9; 95% CI 0.9–1.0; p=0.033). No multivariable analysis was performed due to the small sample size.

Conclusion: To maintain linkage to care is crucial in the cascade of care of HIV-infected patients.

Half of the patients we LTFU in 2015 re-entered care after a median time of 1 year, half of them had an undetectable viral load upon re-linkage, testifying that they carried on antiretroviral treatment despite the apparent LTFU. Younger age was the only factor we found could predict the re-entrance in care.

Limitations to the interpretability of our data stem from the small sample size and the retrospective design of the study, with a consistent amount of missing data.

Table 1. Characteristics of LTFU and RLTC populations with unadjusted odds ratio and corresponding 95% confidence intervals.

<table>
<thead>
<tr>
<th></th>
<th>LTFU, n=63 (100%)</th>
<th>RLTC, n=32 (50.8%)</th>
<th>Unadjusted OR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male 41 (65.0)</td>
<td>Male 18 (56.3)</td>
<td>0.5 (0.2–1.3)</td>
<td>0.139</td>
</tr>
<tr>
<td></td>
<td>Female 22 (35.0)</td>
<td>Female 14 (43.7)</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Median Age</td>
<td>53 years (IQR 45–60)</td>
<td>49 years (range 43–58)</td>
<td>0.9 (0.9–1.0)</td>
<td>0.033</td>
</tr>
<tr>
<td>Origin</td>
<td>European 55 (87.3)</td>
<td>European 29 (80.6)</td>
<td>Reference</td>
<td>0.568</td>
</tr>
<tr>
<td></td>
<td>Other 8 (12.7)</td>
<td>Other 3 (9.4)</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Type of transmission</td>
<td>Other 20 (40.8)</td>
<td>Other 12 (44.4)</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Missing 14</td>
<td>Missing 5</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>CDC stage</td>
<td>A 26 (45.6) B 16</td>
<td>A 17 (56.7) B 6</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(28.1) C 15 (26.3)</td>
<td>(20.0) C 7 (23.3)</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Psychoactive treatment</td>
<td>Yes 11 (21.2) No 41</td>
<td>Yes 6 (21.4) No 22</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Missing 6</td>
<td>Missing 2</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Heroin replacement therapy</td>
<td>Yes 7 (13.2) No 46</td>
<td>Yes 4 (14.3) No 24</td>
<td>1.0 (0.3–3.9)</td>
<td>0.958</td>
</tr>
<tr>
<td></td>
<td>Missing 10</td>
<td>Missing 0</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Median time since HIV diagnosis</td>
<td>12 years (IQR 6–22)</td>
<td>12 years (IQR 8–23)</td>
<td>1.0 (1.0–1.1)</td>
<td>0.565</td>
</tr>
<tr>
<td>Median nadir of CD4+</td>
<td>158 cell/mL (IQR 61–315)</td>
<td>202 cell/mL (IQR 80–378)</td>
<td>1.0 (1.0–1.0)</td>
<td>0.372</td>
</tr>
</tbody>
</table>

PE6/12
Expanding access to HIV tests in 13 cities in Indonesia: an interrupted time series investigating effect of HIV policy intervention using six years population data

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2University of Padjajaran, Research centre of infectious diseases, Bandung, Indonesia

Purpose: To control the growing HIV epidemic in Indonesia, the Strategic Use of Antiretroviral (SUFA) was launched in 2013. Since an evaluation of SUFA’s impact on the rate HIV testing and detection has not been performed, we performed a study to assess the impact on these outcomes.

Method: Monthly data were collected from persons 15 years of age or older from 13 cities. The pre-SUFA data collection period was defined as 26 Dec
2010–25 Dec 2013 and post-SUFA as 26 Dec 2013–25 Dec 2016. An interrupted time-series analysis was performed using a multilevel negative binomial regression model to assess the number and rate of HIV tests and detected cases. Rates of HIV cases were assessed with and without adjustment for the number of HIV tests performed.

Results: Pre-SUFA there was a median (IQR) of 44 (22–70) HIV cases detected/month from 448 (200–910) HIV tests performed. Post-SUFA there were 50 (27–79.5) HIV cases detected/month from 1546 (676.5–2394.5) HIV tests performed. Post-SUFA there was an immediate increase in the rate of HIV tests performed (41%; 95% CI 1.25–1.59; p<0.001) and an immediate reduction in the rate of HIV cases detected (23%; 95% CI 0.69–0.86; p<0.001) even after adjusting for the number of tests performed. The time trends for rates of HIV tests performed and detected cases also differed significantly between periods.

Conclusion: SUFA effectively increased the rate of HIV testing which likely contributed to the reduced rate of detected HIV cases. Future evaluation is important to explore strategies to find additional areas of the population containing PLHIV.

PE6/13
Link HIV-infected injection drug users after the imprisonment to continuum of HIV care program in Taiwan
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Purpose: Injection drug users (IDUs) is criminalized in Taiwan. In 2019, 28,680 people were found guilty of drug crime, and there are 1899 people (6.6%) living with HIV (PLHIV) in detention centers. However, the key challenge is 2nd 90% which is the worst among IDU (58% vs. 92% in men who have sex with men) in Taiwan. Once HIV-infected inmates are released from prison, there is a breaking point in the treatment cascade as the patients are less likely to return to HIV designated hospital. The aim of the program is to improve continuum of HIV care among IDUs.

Method: Taoyuan General Hospital staff is taking care of 550 HIV IDU patients in 3 prisons, and the program was implemented from August 2017 till December 2018. We provided comprehensive awareness and educational programme before release from prison aiming at providing (1) Social and psychological support with planning life after imprisonment (stable job search, housing); (2) Peer-education about importance of continued HIV treatment (3) Methadone replacement therapy (4) Removal of possible barriers to return to outpatient clinic (pre-arranged return visit date, reminding card with location, incentive (transportation/meal coupon)). (figure 1)

Results: From August 2017 till December 2018, forty-three inmates were enrolled (32 males and 11 females), and 36 patients (83.7%) remain on stable linkage to the continuum of HIV care program in Taoyuan General Hospital, and 36 patients (83.7%) are taking anti-retroviral regimens (ARV) with full suppressed HIV viral loads (<50 copies/mL) by December 2018. Two patients died and 5 patients were lost to follow-up by end of observation period.

Conclusion: After the implementation of linkage to continuum of HIV care among this most challenging population, more HIV-infected IDU patients increased adherence to their treatment and also achieved suppressed HIV viral loads.

PE6/14
HIV continuum of care by sex and mode of transmission in Spain, 2016: use of different sources of information
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Purpose: Our aim was to calculate the HIV Continuum of Care (CoC) by sex and mode of transmission in Spain, 2016.

Method: Stage 1: People living with VIH (PLHIV) and stage 2: PLHIV diagnosed were estimated using mathematical models based on surveillance data (New HIV diagnoses and AIDS cases Information Systems). Stage 3: Diagnosed PLHIV on ART and stage 4: PLHIV on ART with viral load suppressed (VLSUP) were calculated using both cohort data – multicenter cohort of HIV-infected adults of the Spanish HIV/AIDS Research Network (CoRIS) and cross-sectional data – one-day cross-sectional hospitals survey.

The four stages were estimated stratifying by sex and mode of transmission.

Results: The overall HIV prevalence was 0.37%, 0.62% in men and 0.13% in women. Table 1 summarizes the estimates for the four stages of the HIV Continuum of Care by sex and mode of transmission. The global percentage of PLHIV with viral load suppressed varied from 69.0% using cohort data to 72.8% using cross-sectional data in Spain. These percentages varied from 69.6% to 71.3% for men and from 65.7% to 76.4% for women using cohort or cross-sectional data, respectively. Likewise, these figures ranged between 68.7% and 70.7% for men who had sex with men (MSM); 66.8% and 84.9% for persons who inject drugs (PWID) and between 64.9% and 69.9% for heterosexuals using cohort or cross-sectional data, respectively.

Conclusion: Spain is very close to achieve the global UNAIDS goal (73% of PLHIV virally suppressed). In our complex epidemic, there is a need to assess gaps in the different subpopulations for guiding specific prevention strategies. The use of different data sources lets us a better approach to the current situation of HIV infection in Spain.

<table>
<thead>
<tr>
<th></th>
<th>On ART</th>
<th>VLSUP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PLHIV (number)</td>
<td>Diagnosed PLHIV</td>
</tr>
<tr>
<td></td>
<td>Global</td>
<td>Sex</td>
</tr>
<tr>
<td></td>
<td>146,500</td>
<td>119,937</td>
</tr>
<tr>
<td></td>
<td>86.2%</td>
<td>86.2%</td>
</tr>
<tr>
<td></td>
<td>93.4%</td>
<td>92.4%</td>
</tr>
<tr>
<td></td>
<td>92.5%</td>
<td>92.5%</td>
</tr>
<tr>
<td></td>
<td>90.4%</td>
<td>89.6%</td>
</tr>
<tr>
<td></td>
<td>86.5%</td>
<td>87.3%</td>
</tr>
</tbody>
</table>

Estimates for the four stages of the HIV Continuum of Care by sex and mode of transmission in Spain, 2016
PE6/15
Temporal trends in time from HIV diagnosis to viral load suppression in CoRIS
B Alejos1, C Diez2, MJ Galindo1, L Garcia-Fraile4, F Gutierrez5, G Samperiz6, V Estrada1, M Gomez-Vidal1, J Jarin1, J Berenguer and CCS Group
1Institute of Health Carlos III, Madrid, Spain 2Hospital Gregorio Maranon, Madrid, Spain 3Hospital Clinico de Valencia, Valencia, Spain 4Hospital Universitario La Princesa, Madrid, Spain 5Hospital de Eiche, Eiche, Spain 6Hospital Miguel Servet, Zaragoza, Spain 7Hospital Clinico San Carlos, Madrid, Spain 8Hospital de Jaen, Jaen, Spain

Purpose: Our aim was to analyze trends in time from HIV diagnosis to Viral Load Suppression (VS) in the Cohort of the AIDS Research Network (CoRIS).

Method: We analyzed treatment-naive adults with HIV infection recruited in CoRIS from 2004 to 2017 who achieved VS (two consecutive Viral Load measurements <50 cop/mL) during follow-up. We categorized the year of HIV diagnosis in periods corresponding to ART initiation guidelines recommendations (< 2004;2004–08;2009–12;2013–14;2015–17). We calculated medians and interquartile ranges (IQR) to describe the time intervals from HIV diagnosis to VS and subintervals of interest (table).

Results: From 2004 to 2017, 14,458 persons were enrolled in CoRIS. We excluded 2,438 who never initiated ART and 2,050 who had not achieved VS (992 had no or just one Viral Load measurement after ART initiation, 496 were lost to follow-up before achieving VS, 95 died and 467 never achieved VS). The final analysis included 9,970 (69%) persons who achieved VS during follow-up. They were predominantly male (84%), and 61% were from Spain. Median age at HIV diagnosis was 36 (IQR: 30–43). Transmission mechanism was heterosexual in 30% and sex between men in 59%. Median time from HIV diagnosis to VS (and subintervals) decreased over time (table 1). From 2004–08 to 2015–17, time (median days [IQR]) from enrolment in CoRIS to ART initiation decreased from 108(20–741) to 23(6–53), respectively. Likewise, considering the same periods, time from HIV diagnosis to VS decreased from 62(261–1363) to 161(99–249), respectively.

Conclusion: Time from HIV diagnosis to VS in CoRIS declined sharply from 2004 to 2017, mainly due to a decrease in time from enrollment in CoRIS to ART initiation. Efforts to speed up the linkage to care and rapid initiation of ART after HIV diagnosis should be made to furtherly decrease the time from HIV diagnosis to VS.

Table 1. Median (IQR) time (days) from HIV diagnosis to VS and subintervals of interest

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>HIV diagnosis to enrolment</td>
<td>3318</td>
<td>36</td>
<td>29</td>
<td>22</td>
</tr>
<tr>
<td>Enrolment to ART initiation</td>
<td>(1271–5439)</td>
<td>(12–100)</td>
<td>(10–73)</td>
<td>(7–48)</td>
</tr>
<tr>
<td>Enrolment to ART initiation</td>
<td>62</td>
<td>106</td>
<td>91</td>
<td>38</td>
</tr>
<tr>
<td>ART initiation to VS</td>
<td>(14–580)</td>
<td>(20–741)</td>
<td>(17–476)</td>
<td>(12–144)</td>
</tr>
<tr>
<td>ART initiation to VS</td>
<td>143</td>
<td>149</td>
<td>147</td>
<td>127</td>
</tr>
<tr>
<td>HIV diagnosis to seroconversion to VS</td>
<td>3871</td>
<td>621</td>
<td>456</td>
<td>272</td>
</tr>
<tr>
<td>HIV</td>
<td>3996</td>
<td>966</td>
<td>702</td>
<td>476</td>
</tr>
</tbody>
</table>

PE6/16
Navigation of HIV positive clients. Reasons of gaps in HIV cascade among PWID
O Pashchuk1
1Alliance for Public Health, M&E, Kyiv, Ukraine

Purpose: To reach an ambitious treatment target 90–90–90 to help end the AIDS epidemic.

Method: Directly assisted self-testing is a combination of self-testing and testing performed by outreach worker. The last one describes in detail the testing procedure, monitor compliance with the key requirements for the test (temperature regime, correct volume of blood and buffer, time to wait for the test result etc.) and helps the clients to conduct tests correctly. In the end of procedure, the social worker fixes the test result in the form of testing records, thus the Alliance gather the information about the number of testing and detection rate. In case of the positive result, social worker accompanies such clients to the health care facilities to get the confirmation test, link them to care and start the ART. For this purpose in 2018 Alliance started the component of Navigation of HIV positive clients. Main features of Navigation: Easy cases – client is encouraged to start treatment; Duration – up to 3 weeks for the first stage of cascade; One-time rewards for social workers for linkage to care and start of ART.

Results: Among all PWID involved in Navigation in 2018: 48% have initiated ART, 24% were in progress, 12% connection with client was lost, 5% refused to receive support, 11% – other reasons of lost to follow up. The results are to be compared with the 1 half of 2019.

Conclusion: Due to Navigation 72% of PWID initiated ART, in 19% of cases we still can affect, in 8% of cases we can’t affect.

PE6/17
Tracing the patterns of HIV-1 transmission among individuals with different time to diagnosis in Greece
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1Medical School, National and Kapodistrian University of Athens, Department of Hygiene, Epidemiology and Medical Statistics, Athens, Greece 2G. Genimatas GH, 1st Department of Internal Medicine, Athens, Greece 3Korgialeneio-Benakeio’ Red Cross General Hospital, 3rd Department of Internal Medicine–Infectious Diseases Unit, Athens, Greece 4Hellenic Center for Diseases Control and Prevention, Maroussi, Greece 5AHEPA University Hospital, Aristotle University Medical School, 1st Department of Internal Medicine, Thessaloniki, Greece 6Evaggelismos GH, 5th Department of Medicine and Infectious Diseases, Athens, Greece 7Aristotle University Medical School, National AIDS Reference Centre of Northern Greece, Department of Microbiology, Thessaloniki, Greece 8Atikion University GH, National and Kapodistrian University of Athens, 4th Department of Medicine, Athens, Greece 9Laikon GH, National and Kapodistrian University of Athens, 1st Department of Medicine, Athens, Greece 10School of Medicine, Aristotle University of Thessaloniki, Thessaloniki, Greece 11Tzanio GH, Department of Internal Medicine, Piraeus, Greece 12Syngros Hospital of Dermatology and Venereology, HIV/AIDS Unit, Athens, Greece 13Hippokration GH, Medical School, National and Kapodistrian University of Athens, HIV Unit, 2nd Department of Internal Medicine, Athens, Greece 14Laikon GH, National and
Kapodistrian University of Athens, Department of Pathophysiology, Athens, Greece 15Sismanogleio GH, 2nd Department of Internal Medicine, Athens, Greece 16University Hospital of Heraklion ‘PAGNI’, School of Medicine, University of Crete, Department of Internal Medicine, Heraklion, Greece 17University GH, Democritus University of Thrace, Department of Internal Medicine, Alexandroupolis, Greece

Purpose: To investigate the contribution of late and recent diagnosis to subsequent HIV transmission in Greece.

Method: Our analysis included 3,127 sequences of subtypes A1 and B, collected from people living with HIV (PLHIV) between 1999 and 2015 in Greece. HIV acquisition dates were estimated by molecular clock analysis. Individuals were categorized into four quartiles according to the time interval between HIV acquisition and diagnosis (median, IQR, in years): recent (0.49, 0.32–0.72), intermediate (1.40, 1.16–1.65), late (2.64, 2.25–3.16) and very late (5.97, 4.68–7.98); the four categories in this analysis were not based on CD4 count at diagnosis. The HIV dispersal patterns between PLHIV with different diagnosis status were estimated by a modified statistical phylogeography method.

Results: For the recently diagnosed group, 55.4% and 51.9% of subtypes A1 and B transmissions, respectively, originated from individuals of the same group. Late diagnosed individuals were infected at 39.1% and 36.9% within each group and at 23.3% and 16% from those with very late status, for subtypes A1 and B, respectively. For both subtypes, PLHIV were a significant source of transmission mostly to the neighboring groups (i.e. intermediate to recent, recent and late to intermediate). The recently diagnosed PLHIV were a major source of HIV transmissions only to the intermediate category. The largest number of transmissions were found to originate from the very late presenters.

Conclusions: We provide evidence that a large proportion of infections took place among PLHIV with a recent diagnosis, suggesting that for this group most transmissions occur close to their HIV acquisition dates. Very late diagnosed individuals are sources of HIV transmissions across different categories. Given the contribution of all groups to subsequent transmission, additional effort is needed to improve diagnosis rates across different categories and to initiate treatment rapidly.

Late diagnosis and delayed presentation in Korean HIV/AIDS cohort

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Purpose: Late diagnosis and delayed presentation are problems in the control of HIV epidemics. We aimed to quantify the degree of late diagnosis and delayed presentation in Korean HIV/AIDS Cohort.

Method: The Korea HIV/AIDS cohort is a multi-center, prospective study consisting of 15 university hospitals nationwide with ongoing enrollment of HIV-infected adult patients older than 18 years. We analyzed 1,369 HIV individuals enrolled in Korea HIV/AIDS cohort between December 2006 and December 2016. Late diagnosis (CD4 count <350 cells/mm3 or AIDS-defining condition (ADC) within 3 months of diagnosis), very late diagnosis (CD4 count <250 cells/mm3 or ADC within 3 months of diagnosis), delayed presentation (≥3 months from diagnosis to treatment) and late treatment (CD4 count <350 cells/mm3 or ADC within 3 months of treatment) were measured.

Results: Mean age of patients was 38.3 (SD 12.4). Male was 79.8%. Mean CD4+ count at diagnosis and at anti-retroviral therapy (ART) were 272.0 (SD 205.9) and 193.2 (SD 159.3), respectively. Proportion of late and very late diagnosis were peak in 2008–2010 (79% and 43%, respectively) (Figure). And, decreasing linear trend of late diagnosis was observed after 2010 (Figure). Trend of late treatment is very similar to late diagnosis. Decreasing linear trend of delayed presentation from 2001 to 2016 (80% to 23%) was observed (Figure).

Conclusion: Late and very late diagnosis is very common in Korea. Recent improvement of late diagnosis and continuous improvement of rapid linkage to ART is present. Still we have to give an effort to increasing early HIV diagnosis and rapid linkage to ART.
Interruption of HIV care: understanding the predictors and outcomes in the Belgian national HIV cohort
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1Sciansano, Brussels, Belgium 2Institute of Tropical Medicine, Antwerp, Belgium 3CHU Saint Pierre, Brussels, Belgium 4University of Ghent, Ghent, Belgium 5Université Catholique de Louvain, Brussels, Belgium

Purpose: We aimed to study HIV care interruption (HCI) in Belgium and its predictors and outcomes.

Method: We analyzed data of adult patients with at least 2 HIV care records in the Belgian HIV cohort between 01/01/2007 and 31/12/2016. HCI was defined as one year without HIV care record. HCI rate was analyzed using Poisson regression, return to HIV care with a cumulative incidence function with death as competing risk, and factors associated with gap in care during HCI by cause-specific hazard models.

Results: We included 16066 patients accounting for 78625 person-years of follow-up. Rate of HCI was 5.3/100 person-years (95% CI: 5.1–5.4/100). The incidence of return to HIV care after HCI was estimated at 77.5% (95% CI: 75.7–79.2%) (Figure 1). Of those returned, 43.7% had a VL<200 copies/mL suggesting care abroad or suboptimal care in Belgium without HIV follow-up record during HCI. The 56.3% returned without controlled VL were considered as having experienced a gap in HIV care.

After adjustment, HCI was strongly associated with never on ART and moderately with lower age, IDU, non-Belgian nationalities and shorter time since HIV diagnosis. Lower rate of HCI was moderately associated with female gender, being a man having sex with men, high blood pressure, low nadir CD4. Return after a gap in HIV care was associated with younger age, female gender, Belgian nationality and longer time since HIV diagnosis (Tables).

Conclusion: Maintenance in care for HIV as a chronic condition will increasingly be necessary in the context of a growing HIV population. This study highlights the need to examine return to care and viral status at return, to better understand HCI. The rate of real gap during HCI was estimated at 2.3/100 person-years. Identified predictors could help healthcare workers to target patients at higher risk of HCI for awareness and support.

Figure 1. Cumulative incidence for return to HIV care and death after the initial one-year HCI

Rate ratios for HCI and for return after a gap in HIV care by demographic characteristic, adjusted for variables significant at univariate analysis

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
<th>Adjusted RR for HCI</th>
<th>Adjusted HR for return after gap among patients with a HCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (ref: Men)</td>
<td>Women</td>
<td>0.8 (0.7–0.8)</td>
<td>1.2 (1.1–1.4)</td>
</tr>
<tr>
<td>Age (ref: ≥ 50 years)</td>
<td>18–24 years</td>
<td>1.9 (1.6–2.2)</td>
<td>2.3 (1.8–2.9)</td>
</tr>
<tr>
<td></td>
<td>25–39 years</td>
<td>1.4 (1.1–1.7)</td>
<td>1.9 (1.6–2.2)</td>
</tr>
<tr>
<td></td>
<td>40–49 years</td>
<td>1.2 (1.1–1.3)</td>
<td>1.5 (1.2–1.8)</td>
</tr>
<tr>
<td>Mode of HIV acquisition (ref: Heterosexual)</td>
<td>MSM</td>
<td>0.7 (0.6–0.8)</td>
<td>1.0 (0.8–1.1)</td>
</tr>
<tr>
<td></td>
<td>IDU</td>
<td>1.6 (1.3–1.9)</td>
<td>1.1 (0.8–1.5)</td>
</tr>
<tr>
<td></td>
<td>MTCT</td>
<td>0.9 (0.7–1.3)</td>
<td>1.2 (0.7–1.8)</td>
</tr>
<tr>
<td>Nationality (ref: Belgian)</td>
<td>Sub-Saharan</td>
<td>1.5 (1.4–1.6)</td>
<td>0.7 (0.6–0.8)</td>
</tr>
<tr>
<td></td>
<td>Africa</td>
<td>1.7 (1.6–1.9)</td>
<td>0.4 (0.4–0.5)</td>
</tr>
</tbody>
</table>

Rate ratios for HCI and for return after a gap in HIV care by clinical characteristic, adjusted for variables significant at univariate analysis

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
<th>Adjusted RR for HCI</th>
<th>Adjusted HR for return after gap among patients with a HCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART (ref: Ever)</td>
<td>Never</td>
<td>6.6 (6.0–7.2)</td>
<td>1.1 (0.9–1.2)</td>
</tr>
<tr>
<td>Time since HIV diagnosis (ref: &lt;1 year)</td>
<td>1 to 3 years</td>
<td>1.9 (1.7–2.1)</td>
<td>0.7 (0.6–0.9)</td>
</tr>
<tr>
<td></td>
<td>&gt;3 to 10 years</td>
<td>1.2 (1.1–1.4)</td>
<td>0.9 (0.8–1.1)</td>
</tr>
<tr>
<td></td>
<td>&gt;10 years</td>
<td>1.1 (1.0–1.2)</td>
<td>1.0 (0.8–1.1)</td>
</tr>
<tr>
<td>Nadir CD4 (ref: &lt;350)</td>
<td>&gt;350</td>
<td>0.8 (0.8–0.9)</td>
<td>0.9 (0.8–1.0)</td>
</tr>
<tr>
<td>Systolic BP (ref: Normal)</td>
<td>High</td>
<td>0.8 (0.8–0.9)</td>
<td>1.0 (0.8–1.1)</td>
</tr>
<tr>
<td>Obesity (ref: BMI&lt;30)</td>
<td>Obese</td>
<td>1.1 (1–1.2)</td>
<td>1.1 (0.9–1.3)</td>
</tr>
<tr>
<td></td>
<td>(BMI≥30)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PE6/20**

The HIV continuum of care: current situation and advances. A systematic review

G Youl1, I Katsarolis2, N Pantazis1 and G Touloumi1

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Purpose: The continuum of care (CoC) model has been used to illustrate the progress of HIV care with a view to end the epidemic. However, modelling studies predict that reaching the 4-stage cross-sectional UNAIDS targets does not guarantee HIV elimination. This study aims to review the used CoC methods and illuminate gaps in the CoC analyses not captured so far, especially in terms of time analysis which stand as critical factors for an effective response to the epidemic.

Method: A PubMed and EMBASE databases search resulted in 1,667 papers, of which 382 were considered relevant. Abstract reading led to the rejecting of 200, mainly because CoC definitions were not provided.

Results: Included studies (182) reported results on 1–6 CoC stages, i.e. people living with HIV, diagnosed, linked, retained, treated and virally suppressed. Sixty-five studies estimated the undiagnosed fraction, either nationwide (35) or in subgroups/cohorts (30). Only 52 provided the number of diagnosed individuals from surveillance/national data, whereas 34 and 63 used data from cohorts or HIV (+) surveys, respectively. In 91 studies, linkage was determined by a medical test/consultation, while in 28 studies it was based on self-report. In 48 studies retention was determined from medical records, in 8 was self-reported, and in 2 was based on other information. In half of the studies, viral suppression was defined as a viral load<200 copies/mL. Thirty-three studies provided time-based information on the CoC (e.g. time spent at specific stages) or attrition rates (Table 1).

Conclusion: This study summarizes methods applied in HIV CoC studies worldwide. Our results indicate that only a few studies provide additional information on the CoC stages and gaps.
information beyond the standard, cross-sectional CoC. To accurately evaluate progress towards HIV elimination, an updated CoC model that will include longitudinal components is warranted in order to highlight gaps in the time-response to the HIV epidemic.

Table 1. Details of the 33 studies which included additional time-based information or attrition rates*.

<table>
<thead>
<tr>
<th>Type of information</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time between diagnosis, linkage, ART or suppression</td>
<td>15 (45.5)</td>
</tr>
<tr>
<td>Time between infection and diagnosis**</td>
<td>1 (3.0)</td>
</tr>
<tr>
<td>Time between infection and VL suppression**</td>
<td>1 (3.0)</td>
</tr>
<tr>
<td>Observed*** time from diagnosis to linkage</td>
<td>2 (6.1)</td>
</tr>
<tr>
<td>Cumulative time spent in each stage</td>
<td>4 (12.1)</td>
</tr>
<tr>
<td>Mortality/LTFU rates</td>
<td>4 (12.1)</td>
</tr>
<tr>
<td>% loss from previous stage</td>
<td>1 (3.0)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (15.2)</td>
</tr>
</tbody>
</table>

* Four studies also use graphs to visualize the additional information ** Infection date has been estimated in these studies *** These studies did not use time-to-event analysis techniques

PE6/21

The contribution of a partnership with a civil society organization (SCO) to early HIV diagnosis and UNAIDS goals

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Purpose: Portugal has just reached the 90–90–90 UNAIDS goals but still shows a high proportion of late diagnosis, higher than similar EU countries. The MSM had the fastest growing relative to the new HIV diagnoses in the last years. So, it’s important to evaluate the contribution of particular approaches of early diagnosis and linkage to care in this population, namely those established in partnership with SCO, looking at their benefits and potential for replication in other settings. The aim of this study is to compare the MSM new diagnosed cases admitted through a SCO referral with the total of new diagnosed cases in MSM and with all new diagnosed cases in Portugal, according to demographics and stage of infection and evaluate the potential benefits of this referral system.

Method: We study the MSM population admitted to our center by Checkpoint LX referral (MSM LX) with a new HIV diagnosis between 2014–2018 (n=192). We analyze some demographics and stage of HIV infection (CD4 cell count, late diagnosis/advanced disease) comparing these results with those obtained in a) the new HIV MSM diagnosed cases (MSM PT) and b) all new diagnosed cases (ALL PT). The statistical analysis was done using χ2 and t-test.

Results:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>30 (28.5)</td>
<td>33 (28.3)</td>
<td>&lt;0.0001</td>
<td>40</td>
</tr>
<tr>
<td>Migrant (n/%)</td>
<td>74 (38.5)</td>
<td>416 (28.3)</td>
<td>&lt;0.0001</td>
<td>1484 (36.2)</td>
</tr>
<tr>
<td>CD4/mm3 (mean)</td>
<td>486</td>
<td>447</td>
<td>0.036</td>
<td>386</td>
</tr>
<tr>
<td>CD4&lt;350/mm3 (n/%)</td>
<td>60 (31.2)</td>
<td>559 (38.0)</td>
<td>0.035</td>
<td>2043 (49.8)</td>
</tr>
<tr>
<td>CD4&lt;200/mm3 (n/%)</td>
<td>18 (9.3)</td>
<td>297 (20.2)</td>
<td>0.0002</td>
<td>1254 (30.6)</td>
</tr>
</tbody>
</table>

Results: demographics and stage of infection

Conclusion: 1) The HIV (+) MSM admitted through Checkpoint LX referral were significantly younger, had a higher proportion of migrants and significantly less late diagnosis and advanced disease; 2) These data reinforce that, at least in the MSM population, this methodology is a useful tool, should be applied in other regions and by other SCO in Portugal and can be useful in other key populations. 3) This methodology not only contributed to reach the 2020 but also can help to reach 2030 UNAIDS goals.
Results: The HIV-TR cohort includes 3242 registered cases between 2011 and 2016, and the total number of reported cases for the same time range in the MoH dataset is 10227. The predicted numbers of diagnosed and undiagnosed for both datasets are shown in Figure 1. The predicted rate of undiagnosed infection was 59% and 52% according to the HIV-TR cohort and the MoH data, respectively. The annual and overall cascade of care for the HIV-TR cohort is shown in Figure 2. ART initiation and virologic suppression increased during this period, exceeding the 90–90–90 goals in 2015 and 2016. HIV-TR cohort data and the MoH data seemed to be concordant in all calculations. Conclusion: The largest gap in the HIV cascade of care for Turkey is in the diagnosis step of the cascade. Once diagnosed, ART initiation and virologic suppression are high and above the targeted rates.

PE6/23
Cascade analysis of anonymous voluntary HIV counseling and testing among HIV-infected patients in Taiwan
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Purpose: To evaluate the implication and performance of anonymous voluntary HIV counseling and testing (VCT) cascade among HIV(+) Taiwanese. Method: We conducted a questionnaire among 430 participants diagnosed from 2015 to 2018 at three HIV/AIDS referrals in Taiwan. We designed a continuum of 5 stages targeting at regular access to VCT, called anonymous VCT cascade, from at high risk population (stage 1), through hearing of diagnosis of HIV, further strategies to lessen the fear of negative relationship and social consequences of HIV is needed to update the VCT in Taiwan.

Results: In multivariable analysis, regularly receive VCT (vs. never receive VCT) remains a protective factor of LP on diagnosis (p<0.05). The overall frequency of participants in each stage of cascade was 100%, 90%, 73.9%, 57.1%, and 28.7%, respectively, with the greatest loss from stage 4 to stage 5 (unable to receive VCT, unable to receive VCT regularly, and unable to receive VCT). 4 domains of reasons using the 5-point scale: perceived risk for HIV, fear of testing positive due to discrimination and stigma, and structural barriers to VCT, were used to measure the causes of unwilling to receive VCT, unable to receive VCT, and unable to receive VCT regularly. Finally, each participant was grouped based on the status of HIV stage on diagnosis: non-late presentation (LP) and LP.

Conclusion: Although the study prove the role of regular VCT on the early diagnosis of HIV, further strategies to lessen the fear of negative relationship and social consequences of HIV is needed to update the VCT in Taiwan.

PE6/24
Late presentation of HIV in Armenia
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Purpose: Early diagnosis of HIV infection has become critical for medical and public health purposes. The aim of this study was to investigate the issue of late presentation in Armenia. Method: Study includes adult Armenian citizens (aged ≥15 years) newly diagnosed with HIV from 2013–2017 case surveillance national database. Late presenter (LP) is defined as a person diagnosed with HIV with a CD4 cell count in the six months after HIV diagnosis. All analyses were performed using IBM SPSS software.

Results: Of the 1502 newly diagnosed HIV-infected individuals, 1352 (90%) had either a CD4 cell count <350 cells/mm3 or an AIDS defining illness regardless of the CD4 cell count in the six months after HIV diagnosis. All analyses were performed using IBM SPSS software. Results: Of the 1502 newly diagnosed HIV-infected individuals, 1352 (90%) had either a CD4 cell count <350 cells/mm3 or an AIDS defining illness regardless of the CD4 cell count in the six months after HIV diagnosis. All analyses were performed using IBM SPSS software. Results: Of the 1502 newly diagnosed HIV-infected individuals, 1352 (90%) had either a CD4 cell count <350 cells/mm3 or an AIDS defining illness regardless of the CD4 cell count in the six months after HIV diagnosis. All analyses were performed using IBM SPSS software. Results: Of the 1502 newly diagnosed HIV-infected individuals, 1352 (90%) had either a CD4 cell count <350 cells/mm3 or an AIDS defining illness regardless of the CD4 cell count in the six months after HIV diagnosis. All analyses were performed using IBM SPSS software. Results: Of the 1502 newly diagnosed HIV-infected individuals, 1352 (90%) had either a CD4 cell count <350 cells/mm3 or an AIDS defining illness regardless of the CD4 cell count in the six months after HIV diagnosis. All analyses were performed using IBM SPSS software.

Conclusion: The largest gap in the HIV cascade of care for Turkey is in the diagnosis step of the cascade. Once diagnosed, ART initiation and virologic suppression are high and above the targeted rates. Scaling-up HIV testing services coverage at community level, targeted to outbound labour migrants could mitigate this problem.

PE6/25
Oral self-testing for individuals absent or refusing testing during home-based HIV testing – a cluster-randomized trial in Lesotho (HOSENG trial)
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1Swiss Tropical & Public Health Institute, Department of Medicine, Basel, Switzerland 2University Basel, Basel, Switzerland 3University Hospital Basel, Division of Infectious Diseases, Basel, Switzerland 4SolidairMed Lesotho, Moseru, Lesotho 5University Basel, Department of Biomedicine, Basel, Switzerland

Purpose: In sub-Saharan Africa, home-based HIV testing is validated and accepted, but coverage remains low due to absent household members (HM). This cluster-randomized trial measured the effect of secondary distribution of oral HIV self-tests (HVST) on coverage during home-based testing. Method: Clusters were defined as villages in catchment area of 20 health facilities in Lesotho. In intervention clusters, HVST were left for HM who were absent or declined testing. The primary outcome was HIV testing coverage among HM (age ≥12) within 120 days after home-based testing, defined as a confirmed HIV test result, known HIV+, or recent HIV- result. Secondary outcomes included effect modification by sex and age (≤24, >24). Analyses were by intention-to-treat. Intervention effects were estimated with random effects logistic regression models. Trial registration: NCT03598686.

Results: 3106 consenting households with 7,846 HM aged ≥12 were enrolled (intervention: 57 clusters, 1628 households, 4192 HM; control: 49, 1478, 3654). 2413 (58%) intervention and 2070 (57%) control HM were present. Of those with unconfirmed status, 1278/1382 (92%) intervention HM and 1128/1224 (91%) control accepted testing. In intervention arm, 1899 HM were absent/refused testing, 1447 (77%) were left HVST of which 826 (57%) were returned. In control arm, 1695 HM were absent/refused testing of which 12 (0.7%) tested at the facility. HIV testing coverage was 3372/4188 (81%) in the intervention versus 2187/3654 (60%) in control arm (odds ratio 2.9 [95% confidence interval 2.5–3.5]).
Acceptability of rapid tests for migrants during the medical consultation at the migration point

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1INSERM UMR1123, Paris, France 2Kremlin Bicetre Hospital, Infectiology, Le Kremlin Bicetre, France 3Hôpital Henri Mondor, Hepatology, Créteil, France 4Hôpital Foch, Hepatology, Suresne, France 5ANRS, Paris, France 6OFII, Paris, France 7Universite Paris Osterre, Paris, France

Purpose: High prevalence of HIV and hepatitis B and C among migrants from certain countries justifies existing targeted screening recommendations from health authorities. Therefore, the STRADA study implemented the use of rapid tests, offered to migrants during the medical consultation at the OFII. A study of acceptability aimed at measuring the obstacles impeding screening so as to identify levers on which to act for a better acceptance rate.

Method: The acceptability study is performed in the 20 centers of the OFII in France. A 3-minutes online form is filled by the health practitioners at the end of every service period. The reasons for not offering or refusing the screening tests are analyzed and sorted into different categories, and the acceptability rate is calculated by comparing the number of patients who accepted screening to the number of screening propositions.

Results: The results over two months show the proposition and acceptability rates are respectively 83.3% and 48.7% of the patients who attended the consultation. Impeded communication is reported in 59.2% of the cases, of which 93.6% are related to language barriers. Organizational issues and lack of time are mentioned in 26.6% of the cases. Among the reasons for refusing screening, a previous screening is cited in 41.7% of the cases. 16% of the patients do not want screening, or do not see any relevance, and 12.7% feel either not at risk or not concerned.

Conclusion: To resort language and organization-related barriers, several solutions have been proposed: telephone interpreting services, adapting the conducting of medical consultations, calling less patients and hiring medical personnel specifically to offer screening.

PE6/27

Evaluation of the “test and treat” strategy in an high-income setting: data from a multicenter Italian cohort

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Purpose: We aim to evaluate Test and treat (T&t) strategies in a multicenter cohort of HIV-1 positive patients in Italy.

Method: We recognized 3 groups among patients diagnosed in 2018: the “one-day treatment” (1DT) group, in which patients started ARV on the same day of the first blood sample; the “fast treatment” (FT) group, including patients that started ARV within 7 days, and “standard of care” (SOC) group in which therapy was started after 7 days. We followed the patients evaluating retention in care and virological outcome.

Results: We enrolled 196 patients from 9 Italian clinical centers: 120 patients started a triple therapy with tenofovir/emtricitabine plus an integrase inhibitor (83 with dolutegravir, 21 with elvitegravir and 16 with raltegravir), 32 with abacavir/ lamivudine/dolutegravir, 17 with tenofovir/emtricitabine plus boosted darunavir, 11 with tenofovir/emtricitabine plus rilpivirine. Other patients’ characteristics at baseline are in Table 1. Median times from HIV diagnosis to the first visit and ARV initiation were 6 days (IQR 1–12) and 14 (IQR 8–29), respectively. Median time between the first visit and ARV initiation was 7 days (IQR 1–15). At ARV initiation, genotypic resistance test was available in 35.6% of patients. Regarding the above described classification, 44 (22.4%) pts belonged in the 1DT group, 53 (27.0%) in the FT group and 99 (50.5%) in the SOC group. At 12 months the overall rate of retention in care was 81.1%, with no significant differences between groups (p=0.103). We found a significantly lower rate of virological suppression in FT group compared with the other groups, both at 6 (p=0.033) and 12 months (p=0.017). Finally, we observed a higher rate of discontinuation of the first-line ARV in 1DT group (log-Rank p=0.023).

Table 1. Patients’ characteristics at baseline (N 196)

<table>
<thead>
<tr>
<th>Variables</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), Median (IQR)</td>
<td>39.3</td>
<td>32.2–49.1</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>32</td>
<td>16.5</td>
</tr>
<tr>
<td>Risk factor for HIV infection, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterosexual</td>
<td>71</td>
<td>36.2</td>
</tr>
<tr>
<td>MSM</td>
<td>79</td>
<td>40.3</td>
</tr>
<tr>
<td>Others/Unknown</td>
<td>46</td>
<td>23.5</td>
</tr>
<tr>
<td>Anti-HIV antibodies positive, n (%)</td>
<td>12</td>
<td>6.3</td>
</tr>
<tr>
<td>AIDS event at HIV infection diagnosis, n (%)</td>
<td>38</td>
<td>19.4</td>
</tr>
<tr>
<td>CD4 + cell count (cell/µL), Median (IQR)</td>
<td>270</td>
<td>108–496</td>
</tr>
<tr>
<td>Zenith HIV-RNA=500.000 copies/mL, n (%)</td>
<td>48</td>
<td>24.7</td>
</tr>
</tbody>
</table>

Conclusion: In our cohort, we did not observe an advantage in using a one-day treatment approach compared to other strategies of ARV initiation.

PE6/28

Pill box return as a predictor of adherence to antiretroviral therapy in PLHIV: a prospective cohort study

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Purpose: Adherence to antiretroviral therapy (ART) remains a challenge in developed and developing countries. Perceived and experienced stigma are associated with concealment of medication and disposal of the pillbox to avoid disclosure of status. We aimed to determine the association between pillbox return and treatment outcome among HIV-infected adults.

Method: We included consenting HIV-infected adults ≥18 years enrolled in the Kilombero and Ulanga Antiretroviral Cohort (KIULARCO) between 01/2013 to 11/2018 with ≥3 months on ART and ≥6 months of follow-up. Failed pillbox return was defined as failure to bring the pillbox in <95% of visits. Lost to Follow-up (LTU) was defined as not seen in the clinic >60 days from the last scheduled visit. Virological failure was defined as a viral load >1000 c/mL 6 months after starting ART and immunological failure as 50% drop in CD4 count from peak value or return to Pre-ART baseline CD4 count. Logistic regression was used to assess the association of failed pillbox return with LTU, immunological and virologic failure.

Results: Of 4,507 patients enrolled in KIULARCO, 2,414 adults were included (Figure 1). Median age at enrolment was 38.4 years (IQR 31.7–46.0), 1,643 (68.1%) were female and median CD4 cell count was 249/mm³ (IQR 115–438) (Table 1). During a median follow-up of 28.2 months (IQR 13.3–47.2) and
28,950 visits with pillbox return assessed, 78% (1883/2414) had a failed pill box return. In the multivariate regression, failed pill box return was associated with LTFU (OR=1.42 [95% CI 1.10, 1.84] and immunological failure (OR=1.78 [95% CI 1.37–2.31]). Association with virologic failure (OR=1.02 [95% CI 0.68, 1.54]) was insignificant (Table 2).

Conclusion: Failed pillbox return was associated with LTFU and immunological failure. Pillbox return might be used as a predictor of treatment outcome. Specific adherence interventions could be designed based on this prediction.

**Table 1.** Baseline characteristics of study participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Univariate OR (95% CI), P-value</th>
<th>Multivariate OR (95% CI), P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median (IQR)</td>
<td>38.4 (31.7–46.0)</td>
<td>38.4 (31.7–46.0)</td>
</tr>
<tr>
<td>Gender, Female (%)</td>
<td>1843 (68.1%)</td>
<td>1843 (68.1%)</td>
</tr>
<tr>
<td>Marital Status, Married (%)</td>
<td>1472 (61.0%)</td>
<td>1472 (61.0%)</td>
</tr>
<tr>
<td>Disclosed HIV Status, Yes (%)</td>
<td>1846 (79.0%)</td>
<td>1846 (79.0%)</td>
</tr>
<tr>
<td>Baseline CD4 count (cells/µl), median (IQR)</td>
<td>249 (115–438)</td>
<td>249 (115–438)</td>
</tr>
</tbody>
</table>

**Table 2.** Association between Failed Pill Box return and lost to follow up, Virological and Immunological failure

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Univariate OR (95% CI), P-value</th>
<th>Multivariate OR (95% CI), P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lost to follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Reference</td>
<td>1.44 (1.12 - 1.84) <strong>0.004</strong></td>
<td>1.42 (1.10 - 1.84) <strong>0.007</strong></td>
</tr>
<tr>
<td>Yes Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virological failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Reference</td>
<td>1.10 (0.74 - 1.63) 0.63</td>
<td>1.02 (0.68 - 1.54) 0.92</td>
</tr>
<tr>
<td>Yes Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunological failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes Reference</td>
<td>1.71 (1.31 - 2.12) &lt;0.001</td>
<td>1.78 (1.37 - 2.13) &lt;0.001</td>
</tr>
</tbody>
</table>

**PE6/30**

HIV Continuum of Care Cascade in Cluj County, Romania. Comparative situation of the years 2016, 2017, 2018

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²Hospital of Infectious Diseases, Cluj Napoca, Romania

Purpose: To evaluate the continuum of care for people living with HIV in Cluj county between 2016–2018. This was a retrospective study of the electronic database. Inclusion criteria: people diagnosed with HIV from Cluj County, on ART for at least 6 months. We included demographic data – e.g. age, sex, route of transmission, viral load. We compared the data from the years 2016, 2017 and 2018. P value less than 0.05 was considered statistically significant.

Results: At the end of 2018, 322 patients were linked to care. 88% (283) were on ART and 252 (89%) were viral suppressed. 214 were male, M/F ratio was 1.98. The median age was 32 years. Route of transmission: heterosexual 46.29%, MSM 37.80%, national cohort 8.93% and unknown 3.53%. In 2016, 264 patients were linked to care; of those 222 (87%) were on ART and 185 (83%) were viral suppressed. In 2017, 288 were linked to care, 264 (91%) were on ART and 208 (78%) were viral suppressed. There was a significant increase in the viral suppressed people, from 78% in 2017 to 89% in 2018. (p=0.001).

No significant difference for cascade of care in women with heterosexual transmission route was noticed (p=0.20). In MSM people, there was a significant increase in viral suppressed people in 2018 compared to 2016 (p=0.02).
Conclusion: The significant increase of virally suppressed peoples suggests that enhancement linkage to care and universal initiation of ART regardless CD4 cells count, are effective measures to fulfill UNAIDS targets.

PE6/31
People living with HIV who lost to follow up in the Paris region area and actions carried out by HIV care centers

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Purpose: Several studies have identified individual factors of PLWHIV loss to follow up (LTFU) but few studies investigated factors related to HIV care centers.

Method: A regional study has been set up in the Paris region in France. The rate of LTFU and actions carried out were collected by clinical study technicians and referring physicians.

Results: Out of 45 centers, 43 responded to the survey, representing 45,612 PLWHIV in care in 2016. In median the rate of LTFU was of 7.1%, IQR [1.3%–23.8%]. This rate was not correlated with the size of the center. The median number of physicians and nurses in therapeutic education involved in HIV care was 2.0, IQR [1–6] and 0.8, IQR [0–3] respectively. A therapeutic education consultation was absent in 35% of the centers, more often in small centers (<550 PLWHIV). While 65% of centers have an emergency consultation, only 15% have a consultation on Saturday morning. Only 51% of centers offered a day hospitalization for all patients annually, most often in large centers (≥1000 PLWHIV). In 16% of the centers, appointments could only be made via an appointment booking platform and not via the service secretariat and 79% send a systematic SMS before appointment. A systematic phone call of patients not come was carried out in 37.2% of the centers. Free access to antiretrovirals for patients without health insurance coverage was possible in 98% of centers. Access to a health mediator was not possible in 57% of centers. Physicians and nurses in therapeutic education involved in HIV care. The significant increase of virally suppressed peoples suggests that enhancement linkage to care and universal initiation of ART regardless CD4 cells count, are effective measures to fulfill UNAIDS targets.

Method: We collected data from 34 HIV centers on charge of 62,375 out of 499,020 patients under control in 8 LA countries. Patients admitted to care in 2016 were followed up and one-year outcomes were registered in grouped sex and age stratified sheets. The continuum of care was built starting from UNAIDS PLWH estimations, the number of patients under control following an elicitation procedure (1st 90 includes diagnosed and linked) and the results of follow up for retention and suppression. Sensitivity analysis was carried out according to the expected PLWH under control in each country.

Results: From 7,820 patients admitted to care in 2016, 252 died in the first year (3.2%) and 224 transferred out were censored for analysis. 85.4% of patients were retained in ART at one year (77.3% to 93.2%) and 90.0% of them achieved VS below 1,000 copies/mL (61.0% to 96.3%). The final 90–90–90 rate ranged from below 40% in Venezuela, Guatemala and Peru to 57.9% in Argentina with an average of 46.9% for the 8 countries.

Figure 1

Conclusion: Our independent data collection shows that rates of retention in ART and VS in LA are close to the goals. Nevertheless, we are far to achieve the final 90–90–90 in LA being the main gap insufficient testing and linkage to care. Our results are valuable to focus and intensify the treatment as prevention efforts.

PE6/32
Far from 90–90–90 goals in Latin America

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Purpose: Estimated number of people living with HIV in Ukraine is 244 000 persons. About 100 000 patients in Ukraine received ART now. National targets for 2020 year are to include 196,000 patients in ART. maximum engagement in treatment is an urgent challenge. For the last 14 years.

Method: An analysis of the data of the electronic health information system, which includes data on over 144000 HIV patients.

Results: Over the decade, patient enrollment for treatment has increased significantly over the year, from 245 per year in 2004, to about 5,000 in 2009–2012, and to about 15,000 in recent years. For the period from 2004 to 2018 years, more than 34 thousand PLHIV were registered but did not start ART by the end of 2018. The proportion of people who do not start treatment remains almost the same throughout all years, regardless of the number of patients who started ART.

Conclusion: To influence the HIV epidemic in Ukraine, the urgent need is to include the maximum number of patients in ART and reduce the proportion of patients, who did not start ART. Social and psychological support to the PLHIV prior to the start of ART is an important issue. Clarifying the causes of barriers to involving patients in ART and development of SOP and action plan are the next major steps for the national health system.

PE6/33
Barriers to involving patients in ART as a challenge to the national health system in Ukraine

S Rjabokon1

1State Institution “Public Health Center of the Ministry of Health of Ukraine”, HIV, HCV and OST Treatment Programs Coordination Department, Kyiv, Ukraine

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Dynamics of ART and the proportion of people who have not started ART

**PE8/2**
Could we recommend the current herpes zoster vaccine for patients living with HIV (PLHIV)?

**Purpose:** Most live attenuated vaccines (LAV) are recommended in PLHIV with undetectable HIV- RNA and CD4>200/mm3. The incidence of herpes zoster (HZ) with severe postherpetic neuralgia remains higher in PLHIV. As they are getting older and better with a similar quality of life to the general population, we should offer them all the vaccinations like prevention against the risk of zoster and its morbidity. The LAV against zoster virus is safe and efficient to reduce incidence and morbidity of HZ. But it is still not recommended for PLHIV while LAV against varicella virus is recommended in case of negative serology.

**Method:** Indications and injections of HZ vaccine were explained to the requesting PLHIV, aged 65 to 74 years (as recommended for the French general population), with CD4>200/mm3 and HIV- RNA<20 copies/mL in our center. Here we report clinical data collected from NADIS medical records since February 2017.

**Results:** Fourteen PLHIV received the HZ vaccine. The median age was 69 years (66–74), HIV- RNA was<20 copies/mL and the median CD4 was 517 /mm3 (306–990). Nine PLHIV received the vaccine between 65 and 69 years old, and 5 between 70 and 74 years old. Four had an history of HZ disease a median time before HZ vaccine of 19.5 years (15–22). During a median follow-up of 13 months (3–21), no side effect related to the vaccine was reported and no HZ event happened.

**Conclusion:** PLHIV are aging better with a safe immuno-virological status but they are at higher risk of HZ. Before to obtain the recombinant adjuvanted subunit vaccine, we could vaccinate them against HZ disease with the LAV in light of our data and a recent study by Benson et al. about 395 younger PLHIV.

**Clinical trials of vaccines**

**PE8/1**
Seroprevalence of vaccine preventable viral diseases and vaccine response among HIV positive patients

**Purpose:** Vaccination is very important to limit the increased risk of severe infectious diseases in HIV-infected patients . On the other hand, vaccine response may be diminished due to impaired immune functions. The purpose of the study was determination of serostatus against the common viral infections and vaccine needs of the newly diagnosed HIV-positive adult patients.

**Method:** All the newly diagnosed HIV-positive patients were included in the study. The vaccination history was obtained from each patient. All patients underwent serological testing by ELISA and immune status of them against hepatitis B, hepatitis A, measles, mumps, rubella, varicella were determined initially.

**Results:** Seventy four male and 18 female patients with a mean age of 43.4 years (20–78 yrs) old were evaluated. Almost all of them could not remember the vaccination history. Nearly Seronegativity rates were 52% for hepatitis B, 16.3% for hepatitis A, 1.1 % for measles, 3.30% for mumps, 1.1% for rubella, 1.1 for varicella. Hepatitis B co-infection was detected in 8.7 of the patients. All the seronegative patients responded to hepatitis B (standard doses) and hepatitis A vaccines independently from CD4 + T cells count.

**Conclusion:** More than half number of HIV positive adults lacked immunity against common vaccine preventable infections. Initial evaluation and personalized vaccination plans might be helpful to improve the vaccination among HIV positive patients.
Co-morbidities, ageing

**PE9/1**

Detectable subclinical myocardial abnormalities in people living with HIV: insights from cardiac magnetic resonance imaging (MRI)

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1Royal Free Hospital, Cardiology, London, UK 2University College London, Institute of Cardiovascular Sciences, London, UK 3ICDC Royal Free Hospital, Infection and Immunity, London, UK 4UCL Medical School, London, UK

**Introduction:** People living with HIV (PLWH) experience significant comorbidities as they age, with increased rates of cardiovascular disease (CVD), including acute myocardial infarction (MI), heart failure (HF) and sudden cardiac death (SCD).

Cardiac MRI is used for investigating young patients as there is no radiation exposure, good reproducibility of results and accurate comparative data during follow-up testing. It can be used to assess ischaemia, left (LV) and right ventricular function, structural heart disease and fibrosis/scar such as in MI, HF and SCD.

**Methods:** The study analysed 42 PLWH from cardiology clinic (37 men, mean age 55.7 ± 11.07 year (y) and HIV duration of 16.2 ± 9.27 years) and 39 healthy volunteers (39 men, mean age 46.1 ± 7.8) were recruited. All subjects underwent cardiac MRI with T1, T2 mapping, fourteen PLWH also underwent adenosine stress with myocardial perfusion mapping.

**Results:** Compared to healthy volunteers, PLWH had significantly decreased ejection fraction, increased LV mass, but no difference in native T1, a marker of diffuse fibrosis. T2, a more specific marker of myocardial oedema, was elevated in PLWH (Table 1). Sixteen PLWH (41%) showed late gadolinium enhancement (LGE) (8 ischaemic and 8 non-ischaemic pattern). Only 7 (18%) PLWH were classified as having normal test results.

**Table 1. Comparison of cardiac MRI parameters in PLWH and healthy controls**

<table>
<thead>
<tr>
<th></th>
<th>PLWH</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LVEF (%)</td>
<td>T1</td>
</tr>
<tr>
<td>Mean</td>
<td>60.0</td>
<td>1019.9</td>
</tr>
<tr>
<td>SD +/-</td>
<td>15.4</td>
<td>56.9</td>
</tr>
<tr>
<td>Control</td>
<td>n</td>
<td>31</td>
</tr>
<tr>
<td>Mean</td>
<td>64.7</td>
<td>1001.1</td>
</tr>
<tr>
<td>SD +/-</td>
<td>5.3</td>
<td>40.9</td>
</tr>
<tr>
<td>t Test</td>
<td>-2.36</td>
<td>1.96</td>
</tr>
<tr>
<td>P Value</td>
<td>&lt;0.05</td>
<td>0.053</td>
</tr>
</tbody>
</table>

LVEF: left ventricular ejection fraction; ECV: myocardial extracellular volume; LVM Idx: left ventricular mass index

**Conclusion:** In PLWH, the elevated LV mass may be associated with long-standing hypertension, common within this patient population. The high myocardial T2 may be due to chronic low grade cardiac inflammation. Focal areas of non-ischaemic scarring were present and may relate to previous myocarditis and provide a link to the increased SCD seen in PLWH. This study identifies a number of cardiac abnormalities associated with chronic HIV infection and prolonged ART. It illustrates the benefit of cardiac MRI in providing additional structural information which may require early medical intervention.

**Hypertension and ECG alterations in HIV positive patients in DREAM centres in Mozambique**

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1University of Rome Tor Vergata, Biomedicine and Prevention, Rome, Italy 2DREAM Program, Community of Sant’Egidio, Maputo, Mozambique 3Global Health Telemedicine, Rome, Italy 4DREAM Program, Community of Sant’Egidio, Beja, Mozambique 5ASL RM 1, Rome, Italy 6DREAM Program, Community of Sant’Egidio, Quelimane, Mozambique 7San Camillo Hospital, Department of Cardioscience, Rome, Italy 8Lumsa University, Rome, Italy

**Purpose:** Prevalence of hypertension in Mozambique raised from 33.1% in 2005 to 38.9% in 2015. Cardiology services in Mozambique are still scarce. HIV patients are known to have higher risk of hypertension and subsequent cardiac impairment.

DREAM program, run by Community of Sant’Egidio, is a program for HIV treatment established in Mozambique in 2002. Global Health Telemedicine (GHT) is an ONG supporting DREAM health centres with specialist teleconsultation. Purpose of the analysis is to evaluate blood pressure and basic ECG features in a cohort of African HIV+ patients.

**Methods:** Both routine or on demand ECG of HIV+ patients in ART attending 7 DREAM facilities in Mozambique in 2018 were enrolled. ECG were analysed by European cardiologist affiliated to GHT. Age, sex, blood pressure (BP) and heart rate (HR) were recorded.

**Results:** 711 ECG were executed in 2018. 395/711 (55.6%) were in female patients. Mean age, BP mix, BP max and HR were respectively: 48±12 years, 96±18 mmHg (n=621), 158±27 mmHg (n=621) and 75±14 bpm (n=601). 507/621 (81.6%) patients had elevated BP measurements (one systolic or diastolic BP measurement >140 mmHg or BP>90 mmHg) and had tachycardia (HR>100 bpm). 296/711 (41.6%) ECG were reported to have any alteration, 176/711 (24.6%) reported ventricular hypertrophy. 26258 (10.1%) patients with abnormal ECG had no sign (no hypertension nor tachycardia). Male patients had higher rates of elevated BP (86.3% vs 77.9%, OR 1.7 [1.16–2.73]), of abnormal ECG (47.2% vs 37.2%, OR 1.5 [1.11–2.03]) and ventricular hypertrophy (30.4% vs 20.0%, OR 1.7 [1.23–2.46]).

Elevated BP measurements (systolic BP>140 mmHg or diastolic BP>90 mmHg) were associated with older age (41 vs 50 years, p<0.00), abnormal ECG (OR 2.3 [1.47–3.65]) and ventricular hypertrophy (OR 5.0 [2.51–10.31]).

**Conclusion:** Special attention should be paid to cardiologic aspects in HIV patients in Mozambique. Despite not wide spread, ECG could represent a useful tool to early detect cardiologic diseases needing appropriate therapy.

**PE9/3**

Cardiovascular events are declining in men with HIV aged 50 years or older in Austria

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**Purpose:** To evaluate whether the rate of cardiovascular events changed in recent years in men with HIV in Austria.

**Methods:** We calculated the incidence rate of a first cardiovascular event per 1000 person-years (PY) for men in the Austrian HIV Cohort study. A first cardiovascular event was defined either as acute myocardial infarction (AMI) or invasive cardiovascular procedures (ICP) (stenting, bypass grafting or endarterectomy) or stroke. In absence of a cardiovascular event, patients were censored at date of last visit plus 6 months or death. Observation period lasted from 1st January 2003 until end of 2017. Use of antiretroviral, co-medications and viral load were also collected.

**Results:** Overall 6026 men accumulated 49857 years of follow-up. The median age increased from 40 to 46 years between 2003 and 2017, 1947 (55%) passed the age of 50 during the observation period, so that median age...
remained stable in men below 50 years of age and in those 50 years or older (39 and 57 years, respectively). We observed 597 cardiovascular events in 257 men (244 AMI, 192 ICP and 161 strokes). The incidence rate of their first cardiovascular events declined from 7.0 (95% CI 3.9–11.6) events per 1000 PY to 4.6 (95% CI 2.7–7.4) in 2017. In men aged 50 years or older declined from 18.6 (95% CI 7.5–38.4) in 2003 to 8.1 (95% CI 4.2–14.2) in 2017 (p-value for trend <0.004), respectively (Figure), whereas all factors, regarding risk of cardiovascular events, improved substantially (Table).

Limitations: Smoking was not included due to incomplete data.

Conclusion: The decline in cardiovascular events in men aged 50 or older is associated with factors, generally seen as beneficial. However, the observational design of our study precludes conclusions on causality of any particular effect.

Drugs and a viral load above 200 copies in men aged≥50 years (P-value for trend across all years from 2003–2017)

<table>
<thead>
<tr>
<th>2003</th>
<th>2008</th>
<th>2013</th>
<th>2017</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylsalicylic acid</td>
<td>14.6%</td>
<td>18.6%</td>
<td>20.6%</td>
<td>19.4%</td>
</tr>
<tr>
<td>ACE inhibitors/AT antagonists</td>
<td>17.9%</td>
<td>24.3%</td>
<td>34.9%</td>
<td>34.9%</td>
</tr>
<tr>
<td>Beta blocker</td>
<td>8.3%</td>
<td>13.1%</td>
<td>18.9%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Statin</td>
<td>12.6%</td>
<td>27.0%</td>
<td>36.0%</td>
<td>36.4%</td>
</tr>
<tr>
<td>Insulin</td>
<td>2.7%</td>
<td>3.2%</td>
<td>3.7%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Oral antidiabetics</td>
<td>6.0%</td>
<td>6.7%</td>
<td>6.5%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Abacavir use</td>
<td>28.2%</td>
<td>37.1%</td>
<td>24.2%</td>
<td>27.5%</td>
</tr>
<tr>
<td>PI use</td>
<td>36.5%</td>
<td>47.9%</td>
<td>43.1%</td>
<td>16.4%</td>
</tr>
<tr>
<td>≥1 viral load&gt;200 copies/mL</td>
<td>45.8%</td>
<td>22.5%</td>
<td>11.4%</td>
<td>8.0%</td>
</tr>
</tbody>
</table>

First cardiovascular events in men with HIV

PE9/4
Prevalence of HIV-associated neurocognitive disorder (HAND) in Turkey and assessment of Addenbrooke's Cognitive Examination Revised (ACE-R) test as a screening tool

V Korten1, E Harış2, U Ay3, E Tükenmez4, S Gence5, S Kalem6, A Demirtaş7, Tadhede8 and İH Gürvit8

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Purpose: We aimed to determine the prevalence and associated factors for HAND among HIV-infected patients in Turkey. In addition, ACE-R and three questions (3Qs, EACS Guidelines) were also assessed as potential screening tools for HAND.

Method: HIV-infected patients were enrolled consecutively from two different teaching hospitals between March 2018 and September 2018. Patients underwent the 2 screening tools, a neuropsychological (NP) test battery covering 7 cognitive domains and an assessment of activities of daily living. HAND was diagnosed according to the Frascati’s criteria and applying Global Deficit Score (GDS) approach. A ROC curve analysis was performed to compare the predictive accuracy of ACE-R to the NP test battery. Several factors were evaluated for association with HAND using a multivariate logistic regression analysis.

Results: The study population included 162 participants (median age: 43.5 years, 94% male, median education: 13 years, median nadir CD4: 295 cells/mL). Plasma HIV-RNA was≤200 copies/mL in 158 subjects (97.5%). The median time on ART was 3 years (IQR 1.5–6.6). HAND prevalence was 45.7% (asymptomatic neurocognitive impairment (ANI)=77.7%; mild neurocognitive disorder (MND)=7.4%; HIV-associated dementia (HAD)=6.6%) according to the Frascati criteria, and 31.5% (ANI=25.9%; MND=4.9%; HAD=0.6%) using the GDS. Memory (learning, recall) (27.2%), attention/working memory (24.7%) and planning/executive (20.4%) were the most frequently impaired domains. In ROC analysis, the ACE-R showed an area under the curve of 0.74 at a cut off score of 89 (Figure 1). Sensitivity, specificity and correct classification rate of screening tests for HAND diagnosis were as follows: ACE-R (62.2%, 67%, 64.8%) and 3Qs (10.6%, 88.6%, 53%). In multivariate analysis, only education level (aDR: 0.84; 95% CI: 0.76–0.92; p=0.001) was an independent risk factor for HAND.

Conclusion: Despite a very well controlled population, HAND is a prevalent comorbidity in HIV-infected persons in Turkey. The sensitivity of ACE-R and 3Qs as screening tools are lower than desired.

Figure 1. Receiver Operator Curves for Addenbrooke’s Cognitive Examination Revised (ACE-R) test

PE9/5
Pilot study assessing the Rotterdam Healthy Aging Score in a cohort of HIV-positive adults

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Purpose: A standard measure of healthy aging would enable identification of factors predictive of health and facilitate evaluation of interventions. The Rotterdam Healthy Aging Score (HAS) is a validated multidimensional index constructed from five health domains (mental health, cognitive function, physical function, social support and quality of life). We describe the HAS distribution among a cohort of HIV-positive adults.

Methods: A prospective pilot study of 100 adults attending a tertiary HIV clinic, aged≥40 on cART with suppressed HIV RNA. Participants completed
questionnaires to calculate the HAS (range 0–14). Demographics, HAS and domain scores were compared by age and sex using the Kruskal–Wallis Rank-Sum or Fisher’s Exact test.

Results: Median [IQR] age was 56 (50, 62), 81 (81%) male, and 50 (51.5%) born in Canada. Participants aged ≥61 were more often Caucasian (75%) compared to those 40–50 (47%) and 51–60 (59%), p < 0.056. Women were more often black (53%) compared to men (9%), p < 0.001. Participants ≥61 had longer HIV duration (25y, p = 0.001) and lower CD4 nadir (152 cells/mm³, p = 0.05) compared to 40–50 (16y, 267 cells/mm³) or 51–60 (22y, 190 cells/mm³). Median [IQR] CD4 was 574 (417, 790) cells/mm³. Median [IQR] HAS was 12 (10.13) and 38 (38.4%) achieved a score ≥12 (considered healthy aging). HAS did not vary by age group (p = 0.72) or sex (p = 0.49). Younger participants were more likely to have low mental health scores (27% for age 40–50 and 27% for age 51–60) compared to those ≥61 (6%), p = 0.04. Women were more likely to have low pain scores (i.e. experience greater pain, 16%) compared to men (1%, p = 0.02).

Conclusions: HAS scores ranged from 4–14 in this cohort of older treated HIV adults with 38% attaining the “healthy” range. The HAS requires further study for its ability to discriminate health outcomes and determine health domains that dominate poor scores.

PE9/6
Obesity and HIV – the overlapping epidemics
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2Chair of Infectious Diseases, Medical University of Warsaw, Warsaw, Poland

Background: Obesity is a leading cause of death among preventable diseases worldwide. The rates among adults are increasing. Here we investigate the prevalence of obesity among newly diagnosed HIV-positive patients.

Methods: We retrospectively analyzed ARV naive patients newly registered at the HIV Out-Patient Clinic in Warsaw between 1st Jan 2015 and 31st Dec 2018. The inclusion criteria were: BMI measured at first visit in the clinic, having at least one CD4 and VL measurement and starting ARV during follow-up. Data were exported from prospectively designed electronic database.

Results: 676 patients fulfilled the inclusion criteria: 637 (94.2%) were men, 544 (80.7%) MSM, median: age 32.4 [IQR: 27.1–37.8], BMI 22.5 (20.4–24.7), CD4 count 368 (232–506) cells/µl, HIV RNA 4.6 (4.0–5.1) log copies/mL. 280 (41.7%) patients started PI based and 302 (44.9%)-based regimen. As for RNTTs, 363 (70.1%) patients started TDF based and 302 (44.9%) InSTI based regimen. Hence, BMI classification in this group was as follows: Normal weight 367 (54.3%), overweight 130 (19.1%) and obesity 66 (9.8%) (Figure).

Obesity, but not overweight was associated with longer time to HIV<50 copies/ml (p = 0.027) OOB were associated with higher levels of triglycerides (p < 0.001), LDL (p < 0.003) and total cholesterol (p < 0.001). We did not find OOB to be associated with other baseline characteristics, choice of ARV regimen, time to starting ARV or switching ARV.

Conclusions: In a single center experience the proportion of OOB among newly registered patients increased over time. This was also reflected in lipid abnormalities, but did not affect ARV choice. The finding on association between OOB and time to HIV RNA<50 needs to be further investigated in a prospectively planned study including pharmacokinetic assessment of ARV.

PE9/7
Exhaled nitric oxide levels are higher in people living with HIV compared to uninfected controls suggesting increased eosinophilic pulmonary inflammation
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Objective: HIV infection is associated with an excess risk of chronic pulmonary diseases, including asthma and COPD. Exhaled nitric oxide (eNO) is a marker of eosinophilic pulmonary inflammation and is often increased in people with asthma. We assessed eNO levels in people living with HIV (PLWH) and matched uninfected controls and studied whether HIV status is independently associated with eNO.

Methods: eNO was quantified in breath by NIOX Vero® and pulmonary function was assessed by spirometry in 432 PLWH from the Copenhagen Comorbidity in HIV infection (COCOMO) Study and in 1623 age- and sex-matched uninfected controls from the Copenhagen General Population Study. Elevated eNO was defined as ≥25 parts per billion (ppb). Linear and logistic regression analyses were used to study associations between eNO and HIV status adjusting for potential confounders.

Results: Mean (SD) age of PLWH was 50.7 (11.3) and 97.4% received cART. PLWH had higher absolute eNO than uninfected controls (mean±SD) 21.0±16.0 versus 15.7±12.4 ppb, p<0.001 (Fig 1). Also, PLWH had a higher prevalence of elevated eNO than uninfected controls (25.2% versus 11.0%, p<0.001), (odds ratio (OR): 2.74 [95% CI: 2.10–3.58], p<0.001). This association was stronger after adjusting for age, sex, height, smoking status, blood eosinophils and S-IgE (adjusted OR [aOR]: 3.86 [95% CI: 2.72–5.47], p<0.001) (Table 1). Self-reported asthma and wheezing were also associated with elevated eNO [aOR: 2.55 [95% CI: 1.56–4.17], p<0.001 and aOR: 1.46 [95% CI: 1.03–2.08], p=0.034, respectively] whereas airflow limitation (FEV₁/FVC< lower limit of normal) was not [aOR: 0.95 [95% CI: 0.61–1.42], p=0.836]. Current smoking was negatively associated with elevated eNO [aOR: 0.18 [95% CI: 0.10–0.32], p<0.001].

Conclusion: HIV status was an independent predictor of elevated eNO suggesting increased eosinophilic pulmonary inflammation. Elevated eNO was associated with wheezing but not with airflow limitation and may contribute to the greater burden of respiratory symptoms in PLWH.
**Table 1.** Uni- and multivariate logistic regression analysis for factors associated with elevated eNO

<table>
<thead>
<tr>
<th>OR [95% CI]</th>
<th>p-value</th>
<th>aOR [95% CI]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV yes vs no</td>
<td>2.74 [2.10–3.58]</td>
<td>&lt;0.001</td>
<td>3.86 [2.72–5.47]</td>
</tr>
<tr>
<td>Smoking status (Ref: Never)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>0.25 [0.15–0.42]</td>
<td>&lt;0.001</td>
<td>0.18 [0.10–0.32]</td>
</tr>
<tr>
<td>Former smoker</td>
<td>0.96 [0.74–1.25]</td>
<td>0.786</td>
<td>0.82 [0.60–1.12]</td>
</tr>
<tr>
<td>Self-reported outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma yes vs no</td>
<td>2.31 [1.51–3.54]</td>
<td>&lt;0.001</td>
<td>2.55 [1.56–4.17]</td>
</tr>
<tr>
<td>Wheezing yes vs no</td>
<td>1.18 [0.87–1.59]</td>
<td>0.287</td>
<td>1.46 [1.03–2.08]</td>
</tr>
<tr>
<td>Airflow limitation FEV1/FVC &lt; LLN yes vs no</td>
<td>0.79 [0.52–1.18]</td>
<td>0.241</td>
<td>0.95 [0.61–1.42]</td>
</tr>
</tbody>
</table>

**PE9/8**

Comparison of changes in bone microarchitecture with abacavir-lamivudine versus tenofovir disopropyl fumarate-emtricitabine in adults living with HIV

R Bedino1,2, B Huet1, V Nguyen1, D Moore-Mathews1, J Poindexter2 and NM Maalouf2

1VA North Texas Health Care System, Dallas, USA 2University of Texas Southwestern Medical Center, Medicine, Dallas, USA tates

**Background:** Antiretroviral therapy with tenofovir disopropyl fumarate-emtricitabine (TDF/FTC) is associated with greater decreases in bone mineral density (BMD) than abacavir-lamivudine (ABC/3TC). Trabecular bone score (TBS) is a novel measurement of bone microarchitecture from Dual-energy X-ray Absorptiometry (DXA) scan images that improves fracture prediction independent of BMD. We hereby compared changes in TBS with initiation of ABC/3TC or TDF/FTC in first-line regimens, and analyzed predictors of TBS change.

**Methods:** We utilized BMD data collected in a multi-center randomized trial (ASSERT) of ABC/3TC vs. TDF/FTC. TBS scores were calculated from weeks 0, 24 and 48 lumbar spine (LS) DXA images captured with Hologic® densitometer. Mixed effects repeated measures models were used to compare changes in TBS from baseline to week 48, controlling for baseline values, age, BMI, race and sex.

**Results:** A total of 158 subjects were enrolled in the study (75 TDF, 83 ABC). Baseline mean TBS scores were 1.32 vs. 1.33. Age and BMI were predictors of BMD (p<0.05) but not TBS. In adjusted analyses, there was a greater BMD decline in the TDF than ABC group at weeks 24 (−2.6% vs. −1.7%) and week 48 (−2.2% vs. −1.4%). TBS declined significantly over 48 weeks in both groups. However, decline in TBS was not significantly greater in the TDF group at week 24 (−1.4% vs. −1.8%), week 48 (−2.3% vs. −1.5%; model p=0.3) (figure 1). Higher baseline TBS was predictive of greater TBS decline in the TDF group but not the ABC group (p=0.01). In the combined arms, changes in TBS were correlated with changes in BMD at weeks 24 (r=0.18; p=0.03) and 48 (r=0.41; p=0.01).

**Conclusions:** First-line ART containing either TDF/FTC or ABC/3TC led to significant decline in TBS. TBS use could potentially increase the accuracy of fracture risk assessment with newer antiretrovirals.

**PE9/9**

Limitations of FRAX equation for predicting low bone mineral density or bone loss progression among people living with HIV: the role of secondary causes of osteoporosis

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**Purpose:** We assessed the usefulness of the Fracture Risk Assessment (FRAX) tool to identify HIV-infected patients with low bone mineral density (BMD) and bone loss progression. We further evaluated the effect of secondary causes of osteoporosis and HIV-related factors on FRAX results.

**Method:** Longitudinal study of 217 consecutive patients (mean, 45.8 years, women 24%) included after dual X-ray absorptiometry (DXA) scan. Low BMD and osteoporosis were defined as a femoral neck or spine T-score <−2.5, respectively. The risk of major osteoporotic and hip fracture was calculated by FRAX equation, considering HIV as a secondary cause of osteoporosis, without/with femoral neck BMD data. The threshold for high-risk of fracture was defined as >3% for hip and >10% for lumbar spine.

**Results:** A low femoral neck and spine BMD was observed in 56% and 64% of patients, respectively. FRAX without BMD data did not identify any patient aged <75 at high risk of fracture. The inclusion of BMD data increased the estimated fracture risk (up to +221%) in individuals with osteoporosis, though only two patients reached the current high-risk threshold for fracture. Moreover, the estimated fracture risk decreased in the oldest patients (<33%) and in individuals with normal BMD (<93%) after including BMD data. Conversely, FRAX results increased significantly with the inclusion of BMD data among individuals with classical and HIV-related secondary causes of osteoporosis (Figure 1). Notably, patients with lower BMD and higher FRAX score at baseline had less bone decline in a consecutive DXA scan (r=−0.21, p<0.008).

**Conclusion:** FRAX equation without BMD data does not identify HIV-infected patients with low BMD, delaying DXA assessment. After including femoral neck BMD, patients most remain below the current high-risk threshold for fracture. Different secondary factors, classical and HIV-related, affect fracture risk estimation by FRAX in this population.

**Figure 1.** Estimated fracture risk by FRAX computed without and with bone mineral density (BMD)

**PE9/10**

Elevated body mass index during pregnancy and gestational weight gain in HIV-infected women in Cape Town, South Africa: association with adverse birth outcomes

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**Background:** In pregnancy, HIV infection has been shown to be associated with adverse birth outcomes, in part, via weight-loss related mechanisms. However, with the majority of HIV-infected people using ART, obesity in these women is becoming more prevalent. There is limited data regarding the impact of co-morbid HIV infection and obesity on birth outcomes in this population.

**Aim:** To examine whether adverse birth outcomes are associated with maternal body mass index (BMI) and gestational weight gain (GWG) among HIV-infected women.

**Methods:** In an urban South African community, 1058 consecutive HIV-infected pregnant women attending primary health care services were assessed at their first antenatal visit, with a subset enrolled in a longitudinal study.
study assessed three times during pregnancy. All women had birth outcome data from medical records and study questionnaires. In analysis, the associations between BMI, GWG, maternal factors and adverse birth outcomes were assessed with logistic regression models.

Results: Overall, HIV-infected women had a median BMI of 30 kg/m\(^2\) (IQR, 26–34) at their first antenatal visit. Increased BMI was positively associated with age, haemoglobin, parity and gestational age at first antenatal visit. In adjusted models, increased BMI was associated with a range of adverse outcomes, including 8% increase in high birthweight (aOR 1.08, 95% CI 1.02–1.15), 5% increase in large size for gestational age (aOR 1.05, 95% CI 1.02–1.08), 5% decrease in low birthweight (aOR 0.95, 95% CI 0.91–0.99) and 5% decrease in small size for gestational age (aOR 0.95, 95% CI 0.98–0.99). Associations involving GWG were in similar directions but did not achieve statistical significance consistently.

Conclusion: High BMI during pregnancy is prevalent in this setting and appears associated with increased risk of adverse birth outcomes in HIV-infected women. Weight management interventions targeting women of child-bearing age are needed to promote healthy pregnancies and reduce adverse birth outcomes.

PE9/11

Facilitating primary care non-antiretroviral drug prescribing in people living with HIV: the Think ARV project

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Purpose: Comorbidities affecting people with HIV (PWH) often result in general practitioners (GPs) prescribing non-ART drugs to PWH on cART. Partial knowledge on interactions between cART and non-ART drugs, and limited pharmacy support for prescribers in the community results in an increased risk of medication-related problems (MRPs). To address this, we developed an evaluated a pharmacy intervention to support self-prescribing of non-ART drugs by GPs.

Method: The "Think ARV" intervention was co-designed by HIV physicians, pharmacists and GPs. It was developed to facilitate local GPs’ access to real-time specialist prescribing advice, reflecting preferences for enhanced telephone and email access identified in a previous project. The intervention consisted of a bespoke sticker containing details of a new dedicated mobile phone staffed by pharmacists during working hours, and an email address for non-urgent advice. Data on cART, non-ART drugs, nature of query, intervention and method of communication were collected 6 months before implementation and 6 months thereafter. Severity of the DDIs were categorised according to www.hiv-druginteractions.orgragonising system.

Results: Over 12 months, 122 queries were recorded, with a significant increase from 26 pre-intervention to 96(p<0.001; CI 1.6–1.8). Table 1 summarises the types of queries received; most common was potential DDIs. More contraindicated DDIs were identified post-intervention compared to pre-intervention (7 vs 3), and a higher number of DDIs required dose adjustments and/or additional monitoring during the second period (18 vs 5). Although only 6 out of 15 service evaluations were returned, all reported a high level of satisfaction with the accessibility, timeliness and quality of the advice received.

Conclusion: The Think ARV intervention provided a simple and effective way of improving communication and support between GPs and pharmacists to prevent MRPs in PWH. Plans to implement this intervention in secondary care services and community pharmacies are ongoing.

PE9/12

Characterization of moderate and severe anemia by peripheral blood smear in HIV infected patients in the Kilombero and Ulanga antiretroviral cohort

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\(^1\)King’s College Hospital, London, London, UK, \(^2\)Ifakara Health Institute, Ifakara, Tanzania, United Republic of, \(^3\)Hospital Universitario Son Espases, Palma de Mallorca, Spain, \(^4\)St. Francis Referral Hospital, Ifakara, Tanzania, United Republic of, \(^5\)Hospital Son Espasses, Palma de Mallorca, Spain, \(^6\)Swiss Tropical & Public Health Institute, Basel, Switzerland, \(^7\)University of Basel, Basel, Switzerland

Purpose: Anaemia is the most common hematological complication among people living with HIV (PLHIV) and is associated with mortality and disease progression. In resource-limited settings, identification of the etiology of anaemia has been inadequately studied due to the lack of diagnostic tools and financial constraints.

Method: In this cross-sectional study of PLHIV ≥18 years of age enrolled in the Kilombero and Ulanga Antiretroviral cohort (KIUARCO) in Ifakara, rural Tanzania we analyze the prevalence of different anaemia etiologies by peripheral blood smear and blood analyzer in patients with moderate (Hb 7–9.9 g/dl) and severe (Hb<7 g/dl) anaemia at baseline or follow-up visits since 01/2019. Here we report on preliminary findings of the first 105 enrolled patients. Aetiologies of anaemia based on blood smear and interpretation by blood analyzer results were compared.

Preliminary results: During the first 6 months, moderate and severe anaemia was present in 76/105 (74%) and 29/105 (28%) PLHIV, respectively. Median age was 41 years (IQR 18–74); 96/105 (91.5%) were female, and 102/105 (97%) were on antiretroviral therapy. Of these, 62/79 (80%) were virally suppressed (HIV RNA<40 c/ml); 18/105 (17%) had a CD4 cell count>200 mm\(^3\). Multiple concurrent anaemia etiologies were more prevalent than single etiologies (62/105.59% vs 43/105.41%). Single etiologies were predominantly iron deficiency (16/43.37%) and chronic disease (16/37.33%), followed by malaria (6/43.14%) and possible non-megaloblastic macrocytic anaemia (5/43.12%). Peripheral blood smear results indicated multiple anaemia etiologies in 30/49 (61%) of patients with microcytosis and hypochromia by blood analyzer results and suggested an iron deficiency component in 5/15 (33%) of patients.

Aetiologies of anaemia based on blood smear results compared with blood analyzer.

<table>
<thead>
<tr>
<th>Aetiologies of anaemia based on blood smear results compared with blood analyzer.</th>
<th>Micro/N</th>
<th>Normo/N</th>
<th>Macro/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood smear + Blood analyser (by haematology)</td>
<td>Hypo N</td>
<td>Normo N</td>
<td>Hypo N</td>
</tr>
<tr>
<td>Single aetiology</td>
<td>19 (39%)</td>
<td>9 (60%)</td>
<td>10 (38%)</td>
</tr>
<tr>
<td>Multiple aetiology</td>
<td>30 (61%)</td>
<td>6 (40%)</td>
<td>16 (62%)</td>
</tr>
<tr>
<td>Iron deficiency component</td>
<td>42 (80%)</td>
<td>5 (33%)</td>
<td>18 (69%)</td>
</tr>
<tr>
<td>Chronic disease component</td>
<td>6 (12%)</td>
<td>8 (53%)</td>
<td>5 (19%)</td>
</tr>
</tbody>
</table>
cases with normocytosis and normochromia (Figure 1). Comparison of interpretation of etiologies by hematologist compared to clinician is shown in Table 1. Conclusion: Multifactorial causes of anaemia were more common than single disorders. The most prevalent reason in this rural sub-Saharan African setting was deficiency alone or in combination with hemoglobinopathy, vitamin B12/ folate deficiency and chronic disease anaemia.

PE9/13
HIV infection and smoking: PET imaging reveals early pulmonary perfusion abnormalities
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1Massachusetts General Hospital, Pulmonary and Critical Care Medicine, Boston, USA 2Ragon Institute, Boston, USA 3Massachusetts General Hospital, Anesthesiology, Boston, USA

Rationale: Studies suggest that the development of COPD is accelerated amongst people living with HIV. Although prior investigation has established an association between chronic HIV infection and the development of COPD independent of smoking, the cause for this enhanced susceptibility remains unclear. Multimodal functional imaging may detect early physiological abnormalities in the distribution of pulmonary perfusion in these susceptible individuals.

Methods: We used low dose computed tomography (LDCT) and positron emission tomography (PET) in 46 subjects. We collected anthropometrics, lung function and smoking history for all subjects. Global and regional perfusion in each subject were analyzed using nitrogen-13 (13NN) PET scans. We tested for a difference in the total spatial heterogeneity of perfusion (CV2_dglobal) and the heterogeneity caused by its components (CV2_Qtotal = CV2_Qgrad (vertical gradient) + CV2_Qr (residual heterogeneity)) between clinical groups, based on HIV infection and smoking.

Results: Of the 23 subjects with documented HIV infection, 12 were current smokers. There were no significant differences in demographic parameters between subjects living with and without HIV. Compared to controls, nonsmokers living with HIV had a significantly greater CV2_dglobal (0.36 vs 0.48, p=0.05) and reduced CV2_Qgrad/CV2_Qtotal (0.46 vs 0.65, p=0.038). Current smokers, independent of HIV status, had a significantly reduced CV2_Qgrad/CV2_Qtotal compared to nonsmokers (0.36 vs 0.8, p=0.002). Amongst smokers, there was a trend towards an attenuated slope of vertical perfusion gradient in smokers living with HIV.

Conclusions: In subjects living with well-controlled HIV and minimal radiographic emphysema, both HIV infection and smoking are associated with an increased perfusion heterogeneity and a reduction in the vertical gradient of perfusion. These data indicate the onset of subclinical pulmonary perfusion abnormalities prior to the development of significant lung disease in these susceptible individuals.

PE9/14
Bariatric surgery in HIV obese patients: first results of the French ObeVIH ongoing study
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Purpose: Bariatric surgery (BS) is the key treatment for morbid obesity and associated comorbidities. Few data exist in HIV obese patients particularly for sleeve gastrectomy.

Method: ObeVIH is a prospective cohort study of HIV obese patients with BMI>35 kg/m2 with comorbidity or>40 kg/m2 and plasma HIV viral load<50 copies/mL (pVL) who underwent single port sleeve gastrectomy. They were matched 1:1 with obese non HIV-infected subjects. The primary objective is to study subcutaneous and visceral adipose tissue. We reported here preliminary outcomes on clinical safety, evolution of body weight, comorbidities and HIV status.

Results: ObeVIH enrolled 20 patients: 15 women, median age of 49.5 years (range: 30–57), Sub-Saharan Africa origin (n=13), median ART duration: 13 years (3–21), duration of viral suppression: 3 years (1–10). ART included INI (13), NNRTI (8) and PI (2). All except one had comorbidities: sleep apnea (16), osteoarticular disorders (17), diabetes (2), dyslipidemia (6) and hypertension (6). At baseline, median weight was 113 kg (88–160), BMI of 39.9 kg/m2 (36–52) and CD4 count of 835/mm3 (326–1522). Surgery was performed within an ambulatory setting for 5 patients. Seven patients experienced grade 1 adverse effects (fatigue, nausea). The median weight loss was 10 kg (6–13.5) at M1, 18.4 (12–26) at M3 and 27 (13–37) at M6. Median BMI was 38 kg/m2 (32–49) at M1, 32.3 (25–45) at M3 and 29.3 (24.5–42) at M6. No change in ARV was performed. The pVL remain undetectable at M1 for all, one had 83 copies/mL at M3 and 3 patients had a detectable VL (only one>200 copies/mL) at M6, without resistance. No change in CD4 count occurred during the follow-up. All comorbidities have been improved or cured in the first 6 months.

Conclusion: BS had good results in weight loss, no impact on HIV infection and improved comorbidities.
PE9/16
Plasma cotinine cut-off for distinguishing smokers from non-smokers among people living with HIV (PLWH)
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Purpose: Cotinine is the main specific metabolite of nicotine and a biomarker of tobacco smoking. Plasma cotinine (P-cotinine) cut-off for distinguishing smokers from non-smokers has been defined to be 14 ng/mL (80 nmol/L) in the general population. Despite different metabolism rate, there is no standard cut-off among PLWH. We aimed to determine the best P-cotinine cut-off for smoking status in a large population of PLWH.

Method: We included 988 PLWH aged 30–70 years from the Copenhagen Co-morbidity in HIV infection (COCOMO) Study. Information about smoking habits was collected using a detailed and structured questionnaire. P-cotinine was measured using liquid chromatography/tandem mass spectrometry (LC-MS/MS). We used area under the receiver operating characteristic curve (AUROC) and Youden Index (J) to define the best P-cotinine cut-off.

Results: Median (IQR) age was 50 (43–58) years, 971 (98%) received cART, 926 (94%) had undetectable viral replication. The number of current, former and never smokers were 300 (30%), 350 (35%) and 338 (34%), respectively, and 87 (9.4%) used nicotine-substitution or E-cigarette. P-cotinine level was highest among current smokers and among former-smokers with nicotine substitution (Figure 1). Highest value for J (0.896) was at P-cotinine cut-off 19 ng/mL (108 nmol/L; AUROC=0.978, P<0.001, 95% CI: 0.968–0.989) (Figure 2). The sensitivity, specificity, PPV and NPV for cotinine cut-off 19 ng/mL among PLWH without nicotine-substitution or E-cigarette were 95%, 94%, 87% and 98%, respectively.

Conclusion: In a large population of well-treated PLWH, we found the best P-cotinine cut-off to differentiate current-smokers from non-smokers to be 19 ng/mL. This cut-off is marginally higher than that used in the general population possibly due to different smoking behavior or nicotine metabolism rate among PLWH. Cotinine level cannot separate former-smokers with nicotine-substitution or E-cigarette from current-smokers. This cut-off can be helpful in future studies, especially when there is no data on self-reported smoking.

Figure 1. Median P-cotinine level among people living with HIV

PE9/17
An analysis of HIV and co-morbidity profiles for adults accessing health care at Khayelitsha, South Africa
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Purpose: To explore the HIV co-morbidities profile of patients accessing public health care at Khayelitsha.

Method: A longitudinal dataset for all individuals who accessed public health facilities at Khayelitsha from January 2016-December 2017 was obtained from the Western Cape Provincial Health Data Centre. Descriptive and inferential statistics explored demographics, HIV cases, and co-morbidities, and pairwise associations between co-morbidities using Pearson’s product-moment correlation.

Results: Of 181 620 individuals (median age 37 years, IQR:30–48) seeking health, 131 933(72.6%) were females and 49 521(27.4%) were males. Of 88 316 people living with HIV (PLHIV), 63 016 (71.4%) were female and 25 219 (28.6%) male. Males seeking health care were 1.15 (CI:1.11–1.16) times more likely to have HIV than females. Median age (IQR) of HIV ascertainment differed in females 35 (30–43) and males 40 (34–47), p<0.001. Tuberculosis (31.4%), Hypertension (14%), Mental health conditions (5.3%), Diabetes (4.1%), Cancers (1.81%), and Chronic kidney disease (CKD) (1.7%) were the top 6 co-morbidities identified, with correlations between hypertension and diabetes (r=0.24), hypertension and CKD (r=0.13), and diabetes and CKD (r=0.13); all p<0.001 in PLHIV. Whilst co-morbidity clustering varied with age, median ages of ascertainment of co-morbidities were younger in PLHIV than HIV negative individuals except for tuberculosis

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Table 1. Median age [Interquartile range] of ascertainment of each co-morbidity in HIV- and HIV+ individuals

<table>
<thead>
<tr>
<th>Co-morbidity</th>
<th>HIV- Median Age (IQR)</th>
<th>HIV+ Median Age (IQR)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>38(28–55)</td>
<td>37(31–44)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>57(48–65)</td>
<td>48(40–56)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>55(46–64)</td>
<td>46(39–54)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>37(28–53)</td>
<td>39(33–48)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Chronic Kidney Disease</td>
<td>66(58–74)</td>
<td>50(42–58)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cervical Cancer</td>
<td>57(45–65)</td>
<td>42(36–48)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Chronic Obstructive Pulmonary Disease</td>
<td>53(36–64)</td>
<td>43(35–51)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mental Health Condition</td>
<td>42(29–57)</td>
<td>39(32–48)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Significant differences were also found between median ages of ascertainment for co-morbidities in females and males with HIV.

Conclusion: As HIV-related mortalities decline and life expectancy increases, PLHIV face increasing burden of chronic co-morbidities. This burden, in addition to existing tuberculosis, in PLHIV seeking care in South Africa is rising. Differences between female and male demographics also reflect to some extent contraceptive and maternal care access by women in good health. The emerging burden of chronic HIV co-morbidities requires in-depth studies to inform adequate planning for all-encompassing health care delivery.

PE9/18
Femoral arteries better indicator than carotid arteries of cardiovascular risk in HIV/AIDS patients
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Purpose: The aim of this study was to compare the prevalence of atherosclerotic plaques and subclinical atherosclerosis in the carotid and femoral arteries in HIV/AIDS patients on cART.

Method: In this cross-sectional study were included 135 HIV/AIDS patients on cART for at least 24 months. Measurements of intima media thickness (IMT) and assessment of the plaque presence was performed by a single radiologist using a linear array probe (10 MHz and 42 mm) in the supine position. The mean carotid-IMT (cIMT) and femoral-IMT (fIMT) were defined as the mean of IMT in both right and left sides of the common carotid artery and common femoral artery, respectively. Atherosclerotic plaque was defined as a focal structure with IMT ≥1.5 mm. Subclinical atherosclerosis was defined by IMT ≥0.9 mm or ≥1 plaque. All p-values less than 0.05 were considered significant.

Results: Subclinical atherosclerosis was present in the carotid and femoral arteries in 73 (54.1%) and 92 (68.2%) patients, respectively. The cIMT and fIMT were 1.09 mm (0.75–1.26 mm) and 1.46 mm (0.80–1.60 mm), respectively. The mean fIMT was significantly higher than mean cIMT (p=0.001). The prevalence of subclinical atherosclerosis in femoral arteries was statistically higher in femoral than in carotid artery (p=0.001). Atherosclerotic plaques were present in the carotid and femoral arteries in 35 (22.2%) and 44 (32.6%) patients, respectively. The prevalence of atherosclerotic plaques was statistically significantly higher in femoral arteries than in carotid arteries (p=0.004).

Conclusion: In accordance to our knowledge, we showed for the first time, that neither intima media thickness nor plaque formations located in the carotid arteries can reflect generalized atherosclerosis in HIV/AIDS patients. Thus femoral arteries should be also examined in order to estimate subclinical atherosclerosis in this patient population.

PE9/19
Cardiovascular risk assessment in PLWH over 50: agreement between cardiovascular risk predictors and Coronary Artery Calcium CT Scoring (CACS)
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Purpose: Conventional algorithms validated in the general population to predict the 10-year risk of developing cardiovascular disease (CVD) may underestimate risk in PLWH. We assessed the agreement between CVD risk predictors (QRISK2–2017, Framingham and D:A:D) with Coronary Artery Calcium CT Scores (CACS) in a cohort of PLWH seen in the “Over50 clinic” at Chelsea and Westminster Hospital.

Method: Cross-sectional study of PLWH over the age of 50 without prior CVD that performed a CACS between 2009–2018. CACS was calculated using the Agaston method and reported as a centile by comparing with age and gender-matched controls. QRISK2–2017, Framingham and full D:A:D scores were stratified into low (≤10%), intermediate (10–20%) and high (>20%) risk categories. Agreement between risk scores and CACS was assessed using weighted Cohen’s Kappa test.

Results: A total of 744 patients performed CACS during the study period (92.9% male, mean age 56 ± 5 years); 5 patients were excluded due to missing data. Level of agreement amongst CVR predictors was moderate to fair whereas CACS showed poor agreement with all CVR scores (Kappa values reported in Table 1). Overall, CACS allowed re-stratification of risk in 54.6–58.8% of patients. Within patients with significant coronary calcification (CACS≥50th centile), 15.6% were identified as low risk with QRISK2, 12.6% with Framingham and 16.1% with D:A:D and therefore would not have been eligible for CVD prevention. Age, polypharmacy and years of exposure to D-Drugs were significantly associated with raised CACS.

Conclusion: Our results indicate that CV risk predictors alone may fail to identify PLWH at high-risk of developing CVD and who would benefit from more aggressive prevention strategies. Incorporation of CACS can re-stratify CVD risk predictions and inform clinicians, allowing for more appropriately tailored preventative strategies.

Table 1. Agreement between CACS and CV risk scores

<table>
<thead>
<tr>
<th>Cardiovascular Risk</th>
<th>QRISK-2017</th>
<th>Framingham</th>
<th>D:A:D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agreement</td>
<td>44.5%</td>
<td>41.1%</td>
<td>45.3%</td>
</tr>
<tr>
<td>CACS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kappa (95% CI)</td>
<td>0.05 (poor)</td>
<td>0.07 (poor)</td>
<td>0.06 (poor)</td>
</tr>
<tr>
<td></td>
<td>0.0–0.67</td>
<td>0.0–0.08</td>
<td>0.0–0.08</td>
</tr>
</tbody>
</table>

PE9/20
Safety and tolerance of denosumab in HIV patients
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Purpose: Osteoporosis (OP) is about three times more frequent in HIV patients than the general population. Denosumab is a human monoclonal antibody that acts selectively against the activating receptor ligand of Nuclear Factor Kappa B (RANK-L). Among the side effects described are infections. Our objective is to analyse the safety and tolerance data of denosumab in HIV patients.

Method: Retrospective longitudinal observational study. We included all HIV patients with OP diagnosed by bone densitometry and treated with denosumab from August 2014 to the present. We recorded sociodemographic data, and variables related to HIV Infection and OP.
Results: We included 14 patients (8 women and 6 men) with a mean of 57.71 (54–64) years old, a mean of 20.96 (SD 9.45) years of HIV infection and 15.52 (SD 9.91) years of ART. The immunological situation at the onset of denosumab was heterogeneous with a median of CD4 549 cell/ml (240–1091) and a median viral load of 19 (19–52) copies/mL.

Reviewing the ART: 10 patients (71.42%) have been on protease inhibitors for a mean of 50.9 (SD 42.58) months. A mean time of 166.7 (SD 30.38) months and 11 (78.57%) were treated with TDF for a mean of 52.9 (SD 42.58) months. The mean of follow-up with denosumab was 24.07 (± 13.56) months. Three types of adverse events were reported: two upper respiratory tract infections, one rash and one death in a patient with lung carcinoma who died of pneumonia. There were neither new fractures nor mandibular osteonecrosis after the onset of denosumab. The treatment was withdrawn in two patients: the first one due to a rash and the second one temporarily after performing the dental procedure.

Conclusion: Treatment with denosumab is safe and well tolerated in HIV patients in our sample. We need more studies to confirm the safety of denosumab in our patients.

PE9/21
Lower incidence of liver steatosis in patients treated with lamivudine plus duloxetine dual therapy
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Purpose: We aimed to assess the prevalence of liver steatosis and its possible correlation with the therapeutic history of this population.

Method: A screening program with abdomen ultrasound (US) on HIV-positive patients at our clinical center by the same operator. Detection and grading of hepatic steatosis were based on the assessment of liver echogenicity; those with a history of chronic hepatitis (viral or alcoholic) were excluded. We compared parameters through non-parametric tests and linear regression, as appropriate.

Results: A total of 60 patients were analyzed 60 pts: 45 (75%) were males, with a median age of 50.5 years, a median of 13.1 years from HIV diagnosis and a median time from ARV initiation of 10.8 years. Full patients’ characteristics are shown in table 1. Median hepatic right lobe length was 15 cm while median spleen diameter was 10.5 cm; 14 pts (23.9%) had mild steatosis, 12 (20%) a moderate one while 3 pts (5%) presented severe steatosis. Being on a 2-drug regimen with TDF was inversely associated with any grade of hepatic steatosis vs other regimens (p=0.042). In patients with low-grade steatosis, a higher fib-4 value was predicted by years of suboptimal therapy (per 1 year more, +0.6, 95% CI 0.1–1.2, p=0.032), while it was negatively predicted by time of exposure to TDF (per one month more, −0.02, 95% CI −0.03 to −0.01, p=0.038); in patients with more severe steatosis, a higher fib-4 was exclusively predicted by a longer time of suboptimal therapy (+0.3, 95% CI 0.1–0.6, p=0.039).

Conclusion: Although NAFLD remains a common finding in HIV-infected patients receiving ART, those on DTG + 3TC seemed less likely to develop this condition, thus suggesting a safer metabolic profile of the 2-drug regimen when compared to standard cART.

PE9/22
Correlations between computerised and standard cognitive testing in persons with HIV and controls
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Purpose: Whilst computerised cognitive batteries offer shorter and potentially more accurate assessments of cognitive function, few studies have compared results of computerised and standard/traditional ‘pen-and-paper’ cognitive assessments. We investigated the correlation between cognitive function and agreement between classifications of cognitive impairment (CI) when measured via computerised and standard testing in people with HIV (PWH) and lifestyle-similar HIV-negative controls.

Method: PWH (≥10 years) and matched HIV-negative controls (≥50 years) enrolled in the POPPY study underwent both computerised (CogState, 6 domains) and standard (5 domains) cognitive batteries. Raw scores from both were converted into demographically-adjusted T-scores and used to define CI according to Frascati, global deficit score (GDS) and multivariate normative comparison (MNC) criteria. The correlation between the global T-scores in PWH and controls, separately, was assessed using the Spearman’s rank correlation and their difference using the z-test after Fisher’s transformation.

The agreement between classifications of CI obtained from different batteries was assessed using the Cohen’s k.

Results: In 316 PWH (median age: 61 years, 89% male, 97% white, 97% with HIV-RNA≤50 copies/mL) and 110 controls (median age: 57 years, 68% male, 95% white), global T-scores were poorer in PWH than controls when measured with both the computerised (difference =−2.2, p=0.001) and the standard battery (difference =−2.9, p=0.004). The correlation between global T-scores was 0.53 (0.45 – 0.60) in PWH and 0.47 (0.31 – 0.60) in controls (p=0.48). The prevalence of CI in PWH was higher when assessed with the computerised battery and the agreement between the same classification of CI obtained from different batteries was fair in PWH and slight in HIV-negative controls, regardless of the criteria considered (Table).

Conclusion: We observed a moderate correlation in overall cognitive function assessed via computerised and standard batteries, which was similar in PWH and lifestyle-similar controls. Classifications of CI only showed fair agreement, indicating substantial intra-individual variation.

Prevalence and agreement (Cohen’s k) between classifications of CI obtained from computerised and standard cognitive batteries

<table>
<thead>
<tr>
<th></th>
<th>PWH (n=316)</th>
<th>HIV-negative (n=110)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Computerised</td>
<td>Standard</td>
</tr>
<tr>
<td>Frascati</td>
<td>93 (29.5%)</td>
<td>72 (22.8%)</td>
</tr>
<tr>
<td>GDS</td>
<td>102 (32.3%)</td>
<td>94 (29.7%)</td>
</tr>
<tr>
<td>MNC</td>
<td>38 (12.9%)</td>
<td>14 (4.4%)</td>
</tr>
</tbody>
</table>
**PE9/23**

Whole body MRI detects high prevalence of incidental findings in older HIV-1-infected patients participating in a randomised, controlled trial of maraviroc and/or metformin for non-alcoholic fatty liver disease

M Chouhan1, A Latifotola1, F Post2, J Fox4,5, M Johnson6, L Garvey7, Y Collaco-Morales6, C Murphy6, L McCabe6, H Webb6, A Gregory6, S Purnwani6, S Pett8,9,10 and MTR Group

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**Purpose:** MAVMET is a randomised controlled 48-week trial of maraviroc and/or metformin for non-alcoholic fatty liver disease in HIV-1-infected participants aged ≥35 years. The primary endpoint is the change over 48 weeks in the percentage of liver fat assessed by the magnetic resonance proton density imaging fat fraction. The change in visceral and organ adiposity are exploratory endpoints requiring whole body MRI(WB-MRI). All research WB-MRI scans undergo clinical review and are formally reported for incidental or unexpected adverse findings as per trial protocol.

**Method:**

All scans were performed on a 3.0T Philips Ingenia system (Best, Netherlands). mDixon FatQuant sequences were used at 5 anatomical stations for coverage from the maxillary sinuses to the mid-thigh. Additional anatomical axial and coronal single-shot T2-weighted images were also obtained of the abdomen and pelvis.

**Results:** Baseline WB-MRI from 76/77 participants were included. Of these, 70(92%) were male; the median[IQR] (range) age was 53 years[48, 57] [35, 70] and median[IQR] (range) time on antiretroviral therapy was 12 years[7, 18] [1, 27]. All WB-MRI were reported within 2 weeks. Thirty-nine percent had ≥1 incidental finding (Table 1); in 87% there was a single incidental finding. The most common incidental finding was of gallstones or gallbladder polyps in 7 participants; in 1 of these participants, atazanavir was changed to darunavir, after discussion with the referring clinician and participant. Three participants were fast tracked for further radiological and/or specialist review to exclude malignancy; no malignancies were diagnosed at baseline.

**Conclusions:** The prevalence of incidental findings on WB-MRI was much higher than expected. This emphasises, first, the importance of ensuring a randomising system for trials with imaging endpoints, in particular where whole body scans are performed. Second, that there may be a role for WB-MRI screening in an ageing population of HIV-infected patients especially as the sensitivity/specificity of WB-MRI continues to improve.

<table>
<thead>
<tr>
<th>Organ System</th>
<th>Findings</th>
<th>Fast track to exclude malignancy, and subsequent diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory tract</td>
<td>Sinus abnormality (n=5); left upper paratracheal fatty tissue (n=1)</td>
<td></td>
</tr>
<tr>
<td>Skin and soft tissues</td>
<td>Sebaceous cyst (n=1); inguinal lymph nodes (n=1)</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>Lipoma (n=2)</td>
<td></td>
</tr>
<tr>
<td>Bone and joint</td>
<td>Traumatic injury right humeral head (n=1)</td>
<td></td>
</tr>
<tr>
<td>Upper GI tract</td>
<td>Distal esophagus nodularity (n=1)*; splenomegaly (n=3); irregular hepatic contour (n=1); atrophic left lobe of liver (n=1)**</td>
<td>*hiatus hernia diagnosed at endoscopy **Atypical hepatic configuration, likely congenital</td>
</tr>
<tr>
<td>Gallbladder</td>
<td>Gallstones or gallbladder polyps (n=7); pancreas cyst (n=2); epigastric hernia (n=1); hepatic haemangiommas (n=1)</td>
<td></td>
</tr>
<tr>
<td>Renal tract</td>
<td>Bladder diverticulum (n=1); renal cysts (n=2); dilated left renal collecting system (n=1)</td>
<td></td>
</tr>
<tr>
<td>Gynaecological</td>
<td>Bulky uterus (n=2); Bartholin’s cyst (n=1); discrete breast mass (n=1)**</td>
<td>**Biopsy confirmed benign fibroadenoma</td>
</tr>
</tbody>
</table>

**PE9/24**

An analysis of potential drug-drug interactions in an aging HIV cohort

P Gardiner1, G Rizzo2 and M O’Donovan3

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**Purpose:** The advent of antiretroviral drugs has transformed the treatment of HIV and has led to an increase in life expectancy of patients with HIV. Patients are therefore more likely to acquire comorbidities which require pharmacological management. This increased pill burden is likely to lead to an increase in potential drug-drug interactions (PDDIs) between medicines.

**Method:**

The files of HIV patients aged over 50 (n=128) at Cork University Hospital (CUH) were examined to obtain demographic data, ART regimens and co-medications. Interactions were then screened for using the University of Liverpool interaction database and stratified according to severity and statistical analysis conducted using SPSS.

**Results:** 72.3% (94/128) of patients took at least one co-medication with 49.2% (63/128) of patients having at least one PDDI. A total of 23 category yellow, 81 category orange and 6 category red interactions were detected. Statins and Colecalciferol were found to contribute the most to PDDIs, leading to 19.1% and 17.3% of all PDDIs respectively. Cobicistat (29.4%) and integrate inhibitors (32.2%) were found to be the ART agents which lead to the highest numbers of PDDIs. A correlation was found to exist between the total number of PDDIs and the number of co-medications which they took (R=0.621, p<0.0001) and between an increasing number of PDDIs and a decreased CD4 count (R=−0.207 p=0.019) while age and gender were found not influence on the number of PDDIs to a statistically significant degree.

**Conclusion:** Owing to the complexity of the pharmacological interactions taking place and the necessity to prescribe for co-morbid conditions, it is almost inevitable that some of these medications will interact. It is therefore advisable to utilise an interaction checker database as well as careful, consistent clinical monitoring to optimise patient outcome.

**PE9/25**

A standardized comparison of cardiovascular risk factor prevalence between people living with HIV and general population in Spain

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**Purpose:** The prevalence of traditional cardiovascular (CV) risk factors has been found higher in people living with HIV (PLWH), as compared to general population. However the role of age and sex distribution of HIV patients is rarely taken into account. We aim to compare the general Spanish population prevalence of CV risk factors with that of Spanish PLWH, after standardizing for referent age and sex population distributions.

**Method:** We used 5,680 PLWH with complete data from the VACH Spanish cohort and the general population DARIOS cohort, a pooled analysis of 11 population surveys from 10 Spanish communities (n=28,342) (http://darios.org).
The prevalence of diabetes, blood pressure, body mass index (BMI), total and high-density lipoprotein (HDL) cholesterol, and smoking was compared in the age group 35 to 74 years. Prevalence rates were standardized by the direct method by sex and 10-year age groups with the European standard populations. All participants signed their informed consent.

Results: In Darios and VACH, the proportion of males was 46.5% and 80.4% (p-value<0.001), respectively and mean age 53.5 (11.1) and 42.5 (7.4) (p-value<0.001), respectively. Standardized BMI and lipid profile are significantly better in PLWH except low HDL and triglycerides which are significantly higher in PLWH. Blood pressure profile is better in male PLWH males but similar between HIV and general female populations. Only female PLWH are heavier smokers than their general population counterparts (Table).

Conclusion: After appropriate standardization to correct the effect of age and sex differences between PLWH and the general population, we found that the prevalence of traditional CV risk factors are similar. However, PLWH have a higher frequency of diabetes, lower HDL levels and higher levels of triglycerides in both sexes, more female smokers, and higher total cholesterol/HDL cholesterol ratio in females.

Comparison of cardiovascular risk factor standardized prevalence between MALE PLWH and general population

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male PLWH</th>
<th>General population</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>50.3 (40.8, 55.7)</td>
<td>53.3 (41.6, 55.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male gender</td>
<td>83.5%</td>
<td>80.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time since HIV diagnosis, median years (Q1, Q3)</td>
<td>125.5 (61.6, 229.4)</td>
<td>123.9 (60.3, 206.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time on ARV treatment, median years (Q1, Q3)</td>
<td>8.8 (4.2, 11.0)</td>
<td>8.4 (4.0, 11.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stage 3 CDC</td>
<td>24.2%</td>
<td>28.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Current CD4 count (cells/µL)</td>
<td>124.5 (91.3, 177.3)</td>
<td>142.7 (108.4, 172.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Current CD4/CD8 ratio, mean (SD)</td>
<td>0.488</td>
<td>0.474 (0.28, 0.68)</td>
<td>&lt;0.001</td>
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Comparison of cardiovascular risk factor standardized prevalence between FEMALE PLWH and general population

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<td>Time since HIV diagnosis, median years (Q1, Q3)</td>
<td>127.5 (67.1, 229.1)</td>
<td>123.9 (60.3, 206.4)</td>
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</tr>
<tr>
<td>Time on ARV treatment, median years (Q1, Q3)</td>
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<td>8.4 (4.0, 11.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stage 3 CDC</td>
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</tbody>
</table>

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (388)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>1.128 (1.097–1.161)</td>
<td>1.009</td>
</tr>
<tr>
<td>Time from HIV diagnosis (months)</td>
<td>1.009 (1.000–1.010)</td>
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<tr>
<td>Current CD8 count (cells/µL)</td>
<td>1.001 (1.000–1.001)</td>
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<tr>
<td>Current CD4 count (cells/µL)</td>
<td>1.023 (1.004–1.043)</td>
<td>1.004</td>
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<tr>
<td>Stage 3 CDC (vs. stage 1)</td>
<td>2.522 (1.430–4.450)</td>
<td>1.430</td>
</tr>
<tr>
<td>Time on ARV treatment (years)</td>
<td>1.177 (1.133–1.244)</td>
<td>1.133</td>
</tr>
<tr>
<td>REGICOR CVR score</td>
<td>1.628 (1.410–1.879)</td>
<td>1.410</td>
</tr>
<tr>
<td>DAD equation: High CVR (vs. Low)</td>
<td>8.230 (6.32–41.497)</td>
<td>6.32</td>
</tr>
</tbody>
</table>

Table 2. Factors correlated with the presence of atherosclerotic plaques

PE9/27

Subcutaneous adipose tissue modifications induced by a switch to dual raltegravir-maraviroc therapy in controlled HIV-infected patients: a sub-study of the ANRS-ROCnRAL157 clinical trial


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Objectives: Integrase inhibitors including raltegravir have been associated with weight/fat gain. The mechanisms involved remain unknown. The ROCnRAL study enrolled suppressed HIV-infected patients with central fat accumulation switched to maraviroc/raltegravir. Herein, we analyzed the

PE9/26

Subcutaneous atherosclerosis burden by ultrasound in carotid and femoral territories in HIV subjects: relationships with HIV and non-HIV related factors

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Purpose: The study aims to describe the prevalence of subclinical atherosclerosis in different vascular territories and analyze the (HIV and non-HIV) factors associated with an increased risk of presenting the disease in a cohort of HIV-1 infected subjects

Method: Cross-sectional (with partial retrospective data collection) analysis of the prevalence of atherosclerotic plaques in four vascular territories. Bilateral carotid and femoral regions were examined by US to determine the number of plaques and areas affected. Patients must be chronically infected with HIV-1 with no history of cardiovascular disease (CVD) at the time of presentation. In this interim analysis, we seek for correlation (univariate analysis) of HIV and non-HIV related factors with the presence of atheromatous plaques

Results: 388 patients were included at the time of this analysis. Baseline characteristics are shown in table 1. A total of 166 subjects (47.2%) had atherosclerotic plaques in at least one vascular site. Subclinical disease was more frequent in the femoral vascular site (38.1%) than in the carotid arteries (18.3%).

In the univariate analysis presence of atherosclerotic plaques correlated positively with age, time with HIV, current CD8 (count and percentage), Stage 3 CDC (versus stage 1), Time on ARV treatment and CVR score (Regicor and D: A/D equations). Odds ratios (95% CI) are shown in table 2.

Conclusion: We have seen a high prevalence of subclinical atherosclerosis in our cohort of HIV-1 infected patients. Among HIV related factors, time with HIV, time on ART, advanced HIV disease, and immune activation have been correlated with the presence of atherosclerotic plaques. Vascular ultrasound may be a promising method to improve the early detection of cardiovascular disease risk in HIV patients.

Table 1. Baseline characteristics

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effects of this switch on metabolic modifications and subcutaneous abdominal adipose tissue (scAT) transcriptome.

Material and methods: In 8 patients, paired scAT samples, withdrawn by needle aspiration at inclusion and the end of the study, were available. We extracted total mRNA and examined the transcriptomic profile using Illumina microarrays, as well as scAT adipocyte size.

Results: All patients were male, aged 55 ± 3y (mean ± SD), BMI = 26.1 kg/m², Waist circumference = 94.6 cm, HOMA-IR = 2.4. After a mean follow-up of 25 weeks, BMI increased to 26.4 kg/m² (p = 0.01), HOMA-IR to 6.7 (p = 0.05) and adipocyte size to 113 microns (p = 0.09). In the 16 paired samples, we identified 16094 variants: 458 genes were up-regulated with an FDR of 10.6 – 1.1 while 244 genes were down-regulated with an FDR of 0.66 – 0.9. We further examined the functional changes that characterized this transcriptomic profile using KEGG data base. The most enriched function (19.4%) was ubiquitin-mediated proteolysis. Functions related to apoptosis were also enriched. Moreover, the main impoverished functions (29.7%) were related to ribosomes, followed by functions related to cell adhesion, grouping genes involved into immune cell recognition (27%), and functions involved into immune-related diseases (10.8%) suggesting a major reduction of scAT immune function/activity. While IL2S, IL7R, CD247, CD3D and CD58 gene expression was decreased, that of IL10 and IL18 was increased.

Conclusion: In eight controlled HIV-infected patients with central fat accumulation switching to raltegravir/maraviroc resulted in major modification of adipocyte size and transcriptomic pattern. Overall, function related to protein degradation and apoptosis were increased and to protein synthesis decreased. Immune-related genes were mainly decreased. Further investigation is required to examine the link between these modifications and raltegravir-associated weight/fat gain.

PE9/29
Discordance in diagnosis of osteoporosis in HIV-infected patients: prevalence, characteristics, and impact on FRAX equation

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Purpose: We examined the prevalence and characteristics of people living with HIV (PLHIV) with spine–hip bone mineral density (BMD) measurement discordance.

Method: Cross-sectional study of consecutive PLHIV included after whole-body dual X-ray absorptiometry (DXA) scan. BMD categories of osteoporosis, osteopenia, and normal bone mass were defined as T-scores ≤ −2.5, −2.5 to 1.0, and > −1.0, respectively. Discordance was defined as different BMD categories at lumbar spine (LS) and femoral neck (FN): major discordance in the case of osteoporosis versus normal BMD, and minor discordance in the case of osteoporosis versus osteopenia, or osteopenia versus normal BMD. Results: Of a total of 208 PLHIV (mean 46 years, women 23%), 91 (44%) presented BMD discordance (major discordance, 2%; minor discordance, 42%); similar values were observed in individuals aged under and over 50. Discordance due to lower LS-BMD was more frequent, and 81% (30/37) of individuals with LS osteoporosis had discordance. Conversely, of 10 cases of FN osteoporosis, 43% were missed from measurements at the LS. Individuals with BMD discordance had distinctive characteristics: PLHIV with lower FN-BMD had a significantly higher prevalence of smoking (p = 0.01), lipodystrophy (p = 0.03) and HCV coinfection (p = 0.04), and longer duration of HIV infection (p = 0.04) and antiretroviral therapy (p = 0.01) than individuals with lower LS-BMD. Moreover, the risk of major osteoporotic and hip fracture was significantly higher in PLHIV with lower FN-BMD versus lower LS-BMD (+36%, p = 0.04, and +135%, p < 0.01, respectively) (Figure 1).

Conclusion: BMD measurement discordance was observed in 44% of PLHIV, largely due to lower LS-BMD. BMD measurement at a single site underestimates the prevalence of osteoporosis, as over 80% of cases of LS osteoporosis were not reflected by FN-BMD. HIV-related factors contribute to lower FN-BMD and in part, to discordance. Fracture risk estimation by FRAX was higher for PLHIV with discordant results.

Figure 1. Fracture risk in discordant individuals according to the site of lower bone mineral density.
PE9/30
CD4/CD8 ratio is a better indicator of acute phase inflammation than absolute CD4 count during virally-suppressed HIV infection
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2University Health Network, Biostatistical Research Unit, Toronto, Canada
3University of Toronto, Leslie Dan Faculty of Pharmacy, Toronto, Canada
4University of Toronto, Department of Medicine, Toronto, Canada
5University Health Network, Toronto General Hospital, Immunodeficiency Clinic, Toronto, Canada
6Toronto General Hospital Research Institute, Toronto, Canada

Purpose: Life expectancy of treated HIV infection approaches that of the general population. Persistent increased mortality and non-AIDS comorbidity is driven by residual immune activation/inflammation. Absolute CD4 count (CD4 count) and CD4/CD8 ratio (CD4/CD8) both correlate with poorer clinical outcomes in prospective cohorts. We sought to identify which parameter best correlates with biomarkers of acute phase immune activation.

Method: We enrolled 83 consenting ART-treated HIV-positive participants with viral load suppression and diverse CD4 count and CD4/CD8 responses from a tertiary care HIV site in Toronto, Canada. In a cross-sectional study, blood plasma and peripheral blood mononuclear cells were isolated and stored for batched measurement of soluble immune activation markers by ELISA (CRP, TNF, IFNγ, sCD14, D-Dimer, I-FABP, MCP-1, VCAM, ICAM), and co-expression of HLA-DR and CD38 on CD8 T cells (CD8 activation). Multiple log-linear regression models adjusted for age, sex, duration of ART, and recent infection/vaccination were used to estimate the association of each outcome with: (1) CD4 count, and (2) CD4/CD8.

Results: CD4 count and CD4/CD8 were strongly correlated (0.76, p<0.0001). A 0.1 increase in CD4/CD8 was associated with a 3% decrease in plasma TNF (p=0.01) and a 5% decrease in plasma CRP (p=0.05). Higher CD4 count (per 100 cells/mm²) was associated with a 2% decrease in sCD14 (p=0.02) while no association was observed with plasma TNF or CRP levels. Neither CD4 count nor CD4/CD8 were associated with CD8 activation.

Conclusion: CD4/CD8 and CD4 count are strongly linked, but CD4/CD8 correlates more strongly with two soluble markers of acute phase immune activation (TNF, CRP). CD4 count was more strongly associated with a marker of a distinct immune activation pathway (sCD14; TLR4 activation by LPS). Novel therapies to reduce non-AIDS comorbidity by targeting residual immune activation pathways warrant exploration in the context of persistently low CD4/CD8.

PE9/31
Immune activation and chronic inflammation: is there an additional effect of HIV in a geriatric population?
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2Assistance Publique-Hôpitaux de Paris, Sorbonne université, Pitié-Salpêtrière Hospital, Infectious Diseases, Paris, France
3Sorbonne Université, INSERM, UMR-S 1136, Paris, France
4Hospices Civils de Lyon, Croix-Rousse Hospital, Infectious Diseases, Lyon, France
5Centre international de recherche en Infectiologie, OIRI, INSERM U1111, CNRS UMR5308, ENS de Lyon, UCB1, Lyon, France

Purpose: It is known that aging is intrinsically associated with hyper-inflammation and immune system deterioration, the relative impact of chronic HIV infection on such inflammatory and immune activation has not yet been studied on an aging HIV-infected population. The objectives were to assess blood markers of immune activation and inflammation, using ultrasensitive techniques (Luminex & Simoa), in HIV-infected patients≥75 years with no or 1 comorbidity, in comparison with age adjusted HIV-uninfected individuals aged≥75 years (control group), to identify whether biomarkers were associated with comorbidities.

Method: 28 inflammatory and immune biomarkers were performed in a centralized laboratory. Wilcoxon nonparametric tests were used to compare the levels of each biomarkers between control and HIV+ groups; logistic regression to identify biomarkers associated to comorbidity in the HIV+ group and principal component analysis (PCA) to determine clusters associated with a group or a comorbidity.

Results: 111 HIV+ subjects of whom 39 without comorbidity (median age 81 years (IQR 78–84), median HIV duration and ART of 18.2 (12–23) and 15.9 (9–19) years, respectively, were included from the Dat’AIDS cohort and compared to a control group of 63 HIV-negative subjects (median age of 83.4 years (IQR 78–89)). In the HIV+ group, 4 biomarkers were associated with comorbidity: MCP-1 OR(CI95%) 0.78(0.68–0.91), NFL 1.42(1.08–1.87), Neopterin 1.96(1.33–2.87) and sCD14 1.01(1.00–1.02). Six biomarkers (IL-1β, IL-7, IL-18, Neopterin, sCD14 and FABP) were significantly higher in the HIV+ group compared to the control group, 11 biomarkers (MPD, IL-1RA, TNFR1, IFN gamma, MCP-1, TNF-R2, IL-22, usCRP, fibrinogen IL-6 and NFL) were lower. Despite those differences, PCA analysis did reveal no clustering. Conclusion: No specific inflammatory or immune profile has been identified in HIV+ group according to comorbidity status. In this selected geriatric HIV population, HIV infection does not seem to have an additional impact on age-related inflammation and immune disorder.

PE9/32
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2Institut d’Investigació Sanitària Illes Balears, Palma de Mallorca, Spain

Purpose: The aim of this study was to describe cardiovascular risks factors changes during the years 2010–2018 in a cohort of PLWH

Method: Since 2010, adult HIV-infected patients attended in our hospital (Hospital Universitario Son Espases, Palma de Mallorca, Spain) have underwent cardiovascular risk estimation using the Regico and Framingham risk scores at least annually. Additional cardiovascular risk factors including creatinine clearance, urine proteins, weight, body mass index, and smoking were also prospectively collected using proprietary software (eViHa).

Results: At the end of 2018, 2030 patients were actively followed up in our centre. Mean age was 48 years and 76.6% were males. Almost all were receiving antiretroviral treatment, being over 90% with HIV viral load<50 copies/ul.

Cardiovascular Risk Score (FHS)

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<th>Year</th>
<th>High Risk</th>
<th>Intermediate Risk</th>
<th>Low Risk</th>
</tr>
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<tr>
<td>2018</td>
<td>42</td>
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</table>

Figure 1
Despite a modest reduction in smoking prevalence, 10-Year Cardiovascular risk estimated in our cohort tended to worsen over the years with 15% of the patients being classified as high risk and 25% as intermediate. Prevalence of
obesity, decreased creatinine clearance and comorbidities presented all a steady increase.

Conclusion: Estimated cardiovascular risk increased during follow up despite lower smoking prevalence. Moreover, the prevalence of additional risk factors such as obesity increased and should be also considered.

Table 1. Socio-demographic characteristics of HIV positive patients who screened positive for depression. (n=66).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CATEGORY</th>
<th>FREQUENCY</th>
<th>PERCENTAGE</th>
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<td>50–54</td>
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Table Continued.

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<th>FREQUENCY</th>
<th>PERCENTAGE</th>
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</tr>
<tr>
<td></td>
<td>Peasant</td>
<td>24</td>
<td>36.4</td>
</tr>
<tr>
<td></td>
<td>Farmer/student/pupil</td>
<td>5</td>
<td>7.6</td>
</tr>
<tr>
<td></td>
<td>Teacher</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td>Religion</td>
<td>Catholic</td>
<td>16</td>
<td>24.2</td>
</tr>
<tr>
<td></td>
<td>Protestant</td>
<td>4</td>
<td>6.1</td>
</tr>
<tr>
<td></td>
<td>Muslim</td>
<td>5</td>
<td>7.6</td>
</tr>
<tr>
<td></td>
<td>Born again</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td>Education level</td>
<td>Primary</td>
<td>29</td>
<td>43.9</td>
</tr>
<tr>
<td></td>
<td>Secondary</td>
<td>4</td>
<td>6.1</td>
</tr>
<tr>
<td></td>
<td>Tertiary</td>
<td>8</td>
<td>12.1</td>
</tr>
<tr>
<td>Number of Children</td>
<td>0–5</td>
<td>54</td>
<td>81.8</td>
</tr>
<tr>
<td></td>
<td>6–10</td>
<td>12</td>
<td>18.2</td>
</tr>
<tr>
<td>Tribe</td>
<td>Acholi</td>
<td>55</td>
<td>83.3</td>
</tr>
<tr>
<td></td>
<td>Langi</td>
<td>6</td>
<td>9.1</td>
</tr>
<tr>
<td></td>
<td>Muganda</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Lugbara</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Samya</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>Munyankole</td>
<td>1</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Table 2. Profile of symptoms and psychosocial factors amongst HIV positive patients (n=385).

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency</th>
<th>Percentage</th>
<th>p-value</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience Pessimism</td>
<td>85</td>
<td>22.1%</td>
<td>0.023</td>
<td>5.297</td>
</tr>
<tr>
<td>Loss of pleasure</td>
<td>121</td>
<td>31.4%</td>
<td>0.032</td>
<td>4.397</td>
</tr>
<tr>
<td>Self-criticalness</td>
<td>121</td>
<td>31.4%</td>
<td>0.003</td>
<td>7.776</td>
</tr>
<tr>
<td>Suicidal thoughts</td>
<td>57</td>
<td>14.8%</td>
<td>0.025</td>
<td>6.287</td>
</tr>
<tr>
<td>Irritability</td>
<td>108</td>
<td>28.1%</td>
<td>0.011</td>
<td>5.817</td>
</tr>
<tr>
<td>Concentration difficulty</td>
<td>69</td>
<td>17.9%</td>
<td>0.022</td>
<td>5.110</td>
</tr>
<tr>
<td>Loss of interest in sex</td>
<td>203</td>
<td>52.7%</td>
<td>0.019</td>
<td>10.427</td>
</tr>
<tr>
<td>Changes in sleep pattern</td>
<td>115</td>
<td>29.9%</td>
<td>0.025</td>
<td>4.191</td>
</tr>
<tr>
<td>Changes in appetite</td>
<td>116</td>
<td>30.1%</td>
<td>0.002</td>
<td>8.037</td>
</tr>
</tbody>
</table>

Purpose: Mental health is a major problem in Uganda contributing 13% to the national disease burden. Depression is one of the commonest psychiatric complications of HIV/AIDS and is associated with poor HIV-related outcomes including poor ART adherence, treatment failure, HIV progression and death. Despite how common depression is among HIV positive patients; it is commonly missed. Prompt diagnosis and treatment of this comorbidity is critically important in HIV/AIDS management.

Aim: To determine the prevalence of depression and associated psychosocial factors among HIV positive patients attending ART clinic at Gulu Regional Referral Hospital.

Methods: In this cross sectional study, 385 HIV positive patients attending ART clinic at Gulu Regional Referral Hospital were enrolled between February and May 2016. Data was collected using the Beck Depression Inventory (BDI) questionnaire. Descriptive and analytical statistics were performed using data base software computer package SPSS 16.0.

Results: The prevalence of depression was 17.1% (66/385). Of the total enrolled, 3.6% (14/385) had been diagnosed and started on treatment for depression. Without the depression screening questionnaire, 13.5% (52/385) of patients with depression would have been missed. For those who screened positive for depression, demographics are summarized in (Table 1) Symptoms associated with depression included; experience pessimism, loss of pleasure, guilty feeling, self-criticalness, suicidal thoughts, irritability, concentration difficulty, loss of interest in sex, changes in sleep pattern, changes in appetite (p<0.05) (Table 2)

Conclusions: We demonstrated that depression is common amongst HIV positive patients, but is commonly missed. Associated symptoms included; experience pessimism, loss of pleasure, guilty feeling, self-criticalness, suicidal thoughts, irritability, concentration difficulty, loss of interest in sex, changes in sleep pattern, changes in appetite. HIV positive patients should routinely be screened for depression using validated depression screening tools for prompt referral.

PE9/33

Prevalence of depression and associated psychosocial factors among HIV positive patients attending ART clinic at Gulu Regional Referral Hospital

R.Kiyemba

1Uganda-CWRU Research Collaboration, Kampala, Uganda
PE9/34

Potentially inappropriate medications in older adults with HIV in the region of Madrid, Spain
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Objective: Age-related comorbidities, physiological changes, and care by multiple providers predispose older (≥ 65 years) people living with HIV (O-PLWH) to inappropriate prescribing. We assessed the prevalence of potentially inappropriate medication (PIM) among O-PLWH in the region of Madrid.

Methods: We analyzed the dispensation registry of community and hospital pharmacies from the Madrid Regional Health Service (SERMAS) between January 1 and June 30, 2017, looking specifically at PIMs according to the 2019 Beers Criteria (J Am Geriatr Soc 2019; 67: 674-694). The SERMAS registry commits to demographics and all prescription drugs (antiretrovirals [ARVs] and non-antiretroviral medications [co-medications]). Co-medications were classified according to the Anatomical Therapeutic Chemical (ATC) Classification System.

Results: During the study period, 6,636,451 different individuals received medications. Among them, 22,945 were receiving ARVs, of those 1,292 were O-PLWH. Overall, 1,135 (87.8%) O-PLWH were taking at least one co-medication. Factors independently associated with PIM were polypharmacy (aOR 7.08 [95% CI: 5.16–9.72]) and female sex (aOR 1.75 [95% CI: 1.30–2.35]). The distribution of PIMs according to ATC drug classes were nervous system drugs (N=369 [28.6%]), musculoskeletal system drugs (N=140 [10.8%]), gastrointestinal and metabolism drugs (N=72 [5.6%]), cardiovascular drugs (N=61 [4.7%]), respiratory system drugs (N=13 [1.0%]), antineoplastic and immunomodulating drugs (N=10 [0.8%]), and systemic anti-infectives (N=2 [0.2%]). Five drugs accounted for 84.8% of the 482 O-PLWH with PIMs: lorazepam (38.2%), ibuprofen (18.0%), diazepam (10.2%), metoclopramide (9.9%), and zolpidem (8.5%).

Conclusions: The results of this population-based study show that prescription of PIMs is highly prevalent in O-PLWH. Consistent with data in uninfected elderly, the most frequently observed PIMs were benzodiazepines and NSAIDs (Eur J Clin Pharmacol 2018; 74:679–700). Targeted interventions are warranted to reduce inappropriate prescribing and polypharmacy in this vulnerable population.

PE9/35

Impact of the reproductive/hormonal status on weight, fat and insulin resistance in HIV-infected women switching from a PI regimen to dual raltegravir-etravirine therapy: results from the ANRS163-ETRAL trial at 48 and 96 weeks
L Assoumou1, N di Clemente2, S Fellahi2, L Beniguèl1, J-P Bastard2, B Feve2, H Fromentin2, C Kallama3, D Costagliola4 and J Capeau5
1Sorbonne Université, INSERM, Institut Pierre Louis d’Épidémiologie et de Santé Publique (IPLESP), AP-HP, Pitié Salpêtrière Hospital, Paris, France 2Sorbonne Université, CRSA Inserm UMR 939, Paris, France 3ANRS, Paris, France 4Sorbonne Université, INSERM, Institut Pierre Louis d’Épidémiologie et de Santé Publique (IPLESP), AP-HP, Pitié Salpêtrière Hospital, Paris, France
5Université de Cape Town, School of Public Health and Family Medicine, Cape Town, South Africa

Objectives: The ANRS-163 ETRL trial has previously shown the viral efficacy of dual raltegravir/etravirine therapy in 165 PI-controlled ageing individuals virally suppressed (Kallama et al. 2019). While lipid and bone parameters improved, patients gained weight, trunk and limb fat and increased insulin resistance (HOMA-IR). We evaluated whether these modifications were dependent upon sex and the reproductive/ menopausal status.

Methods: We recorded the menopausal status of the 48 women. Fat mass and bone mineral density were evaluated by DXA at D0/W48/W96. In 40 women, the anti–Müllerian hormone (AMH Gen II ELISA) level evaluated ovarian reserve. Baseline values and percent changes from baseline were compared between groups using Mann-Whitney and Kruskal-Wallis tests.

Results: BMI, total, trunk and limb fat mass similarly increased in men (n=117) and women (n=48) and lipid parameters improved similarly (increased HDL, decreased triglycerides) at W48/W96. HOMA-IR, similar at baseline, increased in men at W48 and W96 and in women only at W48. Twelve women (30%, 46y) had reproductive activity with ovarian reserve (group 1, AMH>0.06 ng/mL, 6% [15], 47y) were premenopausal (group 2, no ovarian reserve, AMH<0.02 ng/mL and 22 (55%, 54y) post-menopausal (group 3). ART inclusion, BMI and fat repartition were similar in the 3 groups. At W48 and W96, BMI, total and trunk fat increased in groups 2/3 but not in group 1. Moreover, HOMA-IR tended to improve in group 1 but worsened in groups 2/3. The evolution of limb fat and bone parameters were not different between the three groups.

Conclusion: Women with reproductive activity and ovarian reserve were protected from raltegravir/etravirine-induced weight gain and associated insulin resistance while pre/post-menopausal women increased weight, fat and insulin resistance as did men. A role for the estrogen/androgen status should be considered in the impact of antiretroviral drugs on weight gain.

This study was granted by ANRS/MSD:

Comparison of BMI, total fat and HOMA-IR according to sex and to reproductive/menopausal status

PE9/36

Non-communicable disease screening and prevention in adolescents and youth living with HIV in the context of rapid urbanization in South Africa
M Kamkuemah1 and T Oni2
1University of Cape Town, School of Public Health and Family Medicine, Cape Town, South Africa 2University of Cambridge, MRC Epidemiology Unit, Institute of Metabolic Science, Cambridge, UK

Purpose: Non-communicable diseases (NCDs) are projected to become the leading cause of death in sub-Saharan Africa by 2030. HIV-positive individuals face elevated risk of NCDs, due to HIV-infection and complications of long-term anti-retroviral therapy (ART). Most risk factors for adult disease start during adolescence. We set out to investigate the integration of NCD risk screening and prevention in management of adolescents and youth living with HIV (AYLHIV) receiving ART.

Method: We reviewed medical records of 491 AYLHIV across nine primary care facilities in Cape Town from November 2018- March 2019. We collected information on HIV management and care, existent NCDs, NCD risk and any documented NCD-related health promotion.

Results: The median participant age was 20 years (IQR: 14–23) and the median duration on ART was three years (IQR: 1.1–5.0). The majority were virally suppressed (52%) and on first line ART regimens (78%). For those with a reported co-morbidity, there was documented history of substance use (3%), mental disorders (4%) and chronic respiratory diseases (4%). At least 13% had a documented and treated HIV opportunistic infection or ART-related condition. Of those with documented anthropometrics (62%), 48% were overweight or obese. Of those with documented blood pressure measurement. For 6% with documented family history: it was either tuberculosis (71%), diabetes (14%), alcoholism or high blood pressure (7%). Nineteen percent had a documented health promoting intervention, ranging
Cross-sectional characteristics of 491 Adolescents and Youth living with HIV receiving ART in primary care

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Data collected (N=491)</th>
<th>Median (IQR) or Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current ART regimen: Age at ART initiation</td>
<td>473 (96%)</td>
<td>18 (6 - 21)</td>
</tr>
<tr>
<td>CD4 count in cells/mm$^3$</td>
<td>395 (80%)</td>
<td>489 (355–690)</td>
</tr>
<tr>
<td>Viral suppression: VL&lt;20 copies/mL</td>
<td>369 (75%)</td>
<td>256 (52%)</td>
</tr>
<tr>
<td>First line: Abacavir+ Lamivudine+</td>
<td>84 (17%)</td>
<td></td>
</tr>
<tr>
<td>Efavirenz (ABC, 3TC, EFV)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenovir+ Entecavir+ Efavirenz (TDF, FTC, EFV)</td>
<td>298 (61%)</td>
<td></td>
</tr>
<tr>
<td>Second line: Abacavir+ Lamivudine+</td>
<td>39 (8%)</td>
<td></td>
</tr>
<tr>
<td>Zidovudine+ Lamivudine+</td>
<td>29 (6%)</td>
<td></td>
</tr>
<tr>
<td>Lamivudine+ 298 (61%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other regimens</td>
<td>303 (62%)</td>
<td></td>
</tr>
<tr>
<td>N=305 (62%)</td>
<td>30 (10%)</td>
<td></td>
</tr>
<tr>
<td>Normal weight (BMI 18.5–25 kg/m$^2$)</td>
<td>129 (42%)</td>
<td></td>
</tr>
<tr>
<td>Overweight (BMI 25–30 kg/m$^2$)</td>
<td>80 (26%)</td>
<td></td>
</tr>
<tr>
<td>Obese (BMI&gt;30 kg/m$^2$)</td>
<td>66 (22%)</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure in mmHg: Normal: SBP=130 &amp; DBP=85</td>
<td>210 (73%)</td>
<td></td>
</tr>
<tr>
<td>Systolic and Diastolic</td>
<td>41 (14%)</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure (SBP, DBP)</td>
<td>35 (12%)</td>
<td></td>
</tr>
<tr>
<td>n=289 (59%)</td>
<td>80–99</td>
<td></td>
</tr>
<tr>
<td>Moderate hypertension: SBP 160–179 or DBP 100–109</td>
<td>3 (1%)</td>
<td></td>
</tr>
<tr>
<td>Heart rate in beats per minute: n=224 (46%)</td>
<td>82 (74–94)</td>
<td></td>
</tr>
</tbody>
</table>

from alcohol or substance abuse (17%); healthy weight or diet (13%) and mental health counselling (14%).

Conclusion: Our results highlight NCD risk in AYLHIV among those measured and recorded. The true prevalence of these risk factors is uncertain and would be important focus for further investigation. Poor documentation of NCD risk-factors for the majority of participants demonstrates a missed opportunity for detecting comorbidity and NCD risk in primary care; and for early intervention in AYLHIV.

Physical Assessments Measured and Recorded for 491 Adolescents and Youth living with HIV on ART in Primary Health Care

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Median (IQR) or Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Mass Index in kg/m$^2$: Underweight (BMI&lt;18.5 kg/m$^2$)</td>
<td>30 (10%)</td>
</tr>
<tr>
<td>Normal weight (BMI 18.5–25 kg/m$^2$)</td>
<td>129 (42%)</td>
</tr>
<tr>
<td>Overweight (BMI 25–30 kg/m$^2$)</td>
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</tr>
</tbody>
</table>

BESIDE was a cross-sectional study evaluating the prevalence of concomitant diseases and co-medication including OTC in PLWH on ART from 2016–2017. Regional distribution of study sites (n=20), consecutive recruitment and age-stratified sampling ensured a representative sample of the PLWH population in Germany. 453 PLWH were enrolled: female 22%; median age 46 years (y), median time living with HIV 9y, CDC C 15%; median CD4 count 650 cells/µL. Among the top comorbidities, Vitamin D deficiency (29% overall) and depressive episodes (28% overall) were reported across age groups. The third differed: In younger PLWH, acute respiratory infections (<30y, 11%) and gastro-esophageal reflux disease (30–39y, 8%) were most prevalent, while older PLWH increasingly reported hypertension (40–49y, 12%; >60y, 41%). Women more often (f/m, Δ=5%) suffered from nutritional anemias (11%/4%), other nutritional deficiencies (39%/28%), bone density/structure disorders (9%/1%) and thyroid gland disorders (10%/4%). Conversely, metabolic disorders (10%/21%), sexually transmissible infections (2%/9%), polyneuropathies/peripheral nervous system disorders (1%/7%) and dorsopteses (2%/8%) were more common in men.

Most common drugs used across all ages were vitamin supplements (32% overall). Followed by anti-inflammatory/antiinflammatory agents (16%), except>60y where antithrombotic agents were more frequent (30%). Additionally, younger patients received vaccines (<30y, 9%) and used psychoactive drugs (30–39y; 10%; 40–49y, 12%), whereas in older patients renin-angiotensin system agents (50–59y, 21%; >60y, 30%) ranked highest. Women more commonly used (f/m, Δ=5%) antianemia preparations (14%/ 6%), vitamins (38%/30%) and mineral supplements (10%/5%); men used antithrombotic agents (4%/11%), renin-angiotensin system agents (7%/14%) and lipid modifiers (6%/12%).

Although prevalence of concomitant diseases and use of co-medication among PLWH in Germany are high across gender and all ages, the disease and drug patterns change in an age- and sex-related manner.

PE9/38
Kinetic transplantation in HIV-positive patients in Israel including the first case of HIV-positive living donor to HIV-positive recipient with a 7-year follow-up

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Purpose: Since the introduction of effective cART, the comparable patient and graft outcomes between HIV-negative and HIV-positive kidney recipients were demonstrated in several studies and the use of HIV-positive donors for HIV-infected recipients is increasing worldwide. However, there is a concern regarding the safety of kidney donation from an HIV-infected person, given the risk of renal disease associated with HIV infection. We report our experience in kidney transplantation to the HIV-infected patients, including the first case of a kidney transplantation from HIV-positive living donor to HIV-positive recipient with a 7 years follow-up.

Method: Tel Aviv Sourasky Medical Center is the Israeli national referral hospital for HIV-positive patients considered for organ transplant. We reviewed the data from our kidney transplant program and collected the cases of HIV-positive recipients, including the long-term follow-up.

Results: Since 2012, five kidney transplantations in the HIV-positive individuals were performed in our center (4 cases of living donor kidneys and 1 deceased donor kidney). A long-term post-transplant follow-up of 12 to 88 months showed good results with stable graft function, as well as satisfactory immune status and well controlled HIV viral load in all kidney recipients. In one of these cases, living donor kidney transplant was performed in July 2012 between a couple, both HIV-positive, infected with the same viral strain. Both donor and recipient were on effective ART with efficiently suppressed viral replication and satisfactory pre-transplantation immune status. The 7-years follow-up shows stable renal function and immune status in both donor and recipient.

Conclusion: To the best of our knowledge, this is the earliest case of HIV-positive-to-HIV-positive living donor kidney transplantation reported. The present successful case confirms our belief that an HIV-infected person meeting the
living-donor criteria may be safely considered for kidney donation when properly selected and adequately treated by a multidisciplinary team.

PE9/39
Vitamin D deficiency and frailty phenotype in HIV-infected men
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2University of Michigan, School of Dentistry, Ann Arbor, USA
3Northwestern University Feinberg School of Medicine, Division of Infectious Diseases, Chicago, USA
4Johns Hopkins University School of Medicine, Division of Endocrinology, Diabetes and Metabolism, Baltimore, USA
5Harbor-UCLA Medical Center, Los Angeles Biomedical Research Institute, Torrance, USA
6University of Washington, Department of Laboratory Medicine, Seattle, USA
7University of Washington, Department Medicine, Seattle, USA
8Johns Hopkins School of Medicine, Department of Ophthalmology, Baltimore, USA

Purpose: Frailty is a geriatric syndrome that increases vulnerability to stressors due to dysregulation in multiple physiological systems. More HIV-infected experience frailty with the introduction of highly active antiretroviral therapy (HAART). Vitamin D deficiency may interfere with immune restoration following HAART and accelerate onset of frailty in HIV-infected populations. We examined the association between vitamin D and frailty among HIV-infected men from the Multicenter AIDS Cohort Study.

Method: Levels of 25-hydroxyvitamin D (25[OH]D) and 1,25-dihydroxyvitamin D (1,25[OH]2D) were measured in serum from 625 HIV-infected men, collected 2 years post-HAART between 1999–2008. Vitamin D deficiency was defined as 25[OH]D<20 ng/mL, 1,25[OH]2D was analyzed as tertiles. Frailty was assessed at 6-month intervals between 1994–2018 using the Fried frailty phenotype criteria with those meeting≥3 of 5 criteria considered frail and 1–2 criteria prefrail. Discrete-time multistate models examined factors associated with transitioning from non-frail to prefrail or frail, adjusting for baseline and time-updated covariates.

Results: HIV-infected men had a median of 24 frailty measures (IQR: 18–32) and median follow-up of 14.9 years (11.8–18.6). At baseline, vitamin D deficiency prevalence was 41%, 60% of men were non-frail, 27% prefrail, and 5% frail. Vitamin D deficiency had no effect on the probability of becoming prefrail/frail. However, non-frail men with 1,25[OH]2D values in the smallest tertile had 2.74 (95% CI: 1.10–6.84) times the risk of becoming frail compared to the highest tertile. There was an elevated risk of becoming prefrail/frail with time, although adjusted ORs showed a significant effect of vitamin D among non-frail men only. Results were robust to additional adjustment for socio-demographic factors (age, stressors due to dysregulation in multiple physiological systems. More HIV-infected men had a median of 24 frailty measures (IQR: 18–32) and median follow-up of 14.9 years (11.8–18.6). At baseline, vitamin D deficiency prevalence was 41%, 60% of men were non-frail, 27% prefrail, and 5% frail.

Conclusion: Vitamin D deficiency was associated with higher risk of frailty among non-frail men. Risk factors contributed to varying degrees to increase or decrease the risk of becoming frail, consistent with prior work.

PE9/40
The UCSD performance-based skills assessment is associated to cognitive performance in HIV positive population with very good immunological condition
V Delle Donne1, N Ciccarelli2, A Borghetti1, F Lombardi3, A Dusina1, D Farinacci1, A Emilizzoi4, E Visconti5, E Tamburrini4, M Fabbiani3 and D Di Giambenedetto1,6
1Università Cattolica del Sacro Cuore, Istituto di Clinica delle Malattie Infettive, Roma, Italy
2Università Cattolica del Sacro Cuore, Istituto di Clinica delle Malattie Infettive, Roma, Italy
3Fondazione Policlinico Universitario Agostino Gemelli IRCCS, UOC Malattie Infettive, Roma, Italy
4Fondazione IRCAS Policlinico 'San Matteo', U.O. Malattie Infettive e Tropicali, Pavia, Italy

Purpose: Explore everyday functioning (EF) and its association with cognition in HIV+ subjects.

Method: Cross-sectional single cohort study enrolling 85 HIV+ outpatients and 23 age-and-education matched healthy controls (HC). Each patient underwent a comprehensive neuropsychological assessment (NPA). Global performance was measured by transforming raw scores at each task into standardized Z-scores and averaging to calculate a composite total score. IADL scale and the UCSD Performance-Based Skills Assessment-Brief Version (UPSA-B; assessing financial and communication skills) were administered.

Results: HIV+ patients were 77.6% male with a median age of 54 yrs (IQR 48–60). Median time from HIV diagnosis and first ART was 13 (IQR 4–23) and 12 (IQR 4–20) yrs, respectively. Overall 6% of patients were HCV co-infected, 28% with past AIDS-defining events and 93% showed HIV-RNA<50 copies/mL. Median adherence to ART was 95% (IQR 85–100) on a 0–100 VAS scale. All patients were cognitive asymptomatic and, on NPA, the total mean Z-score was 0.36 (SD 0.63). While IADL score was at ceiling, the mean UPSA-B total score was significantly worse in HIV+ group when compared to HC (mean 82.1 (SD 9.3) vs 89.2 (SD 6.2); p<0.001). At communication subtest HIV+ group and HC were significantly different (p=0.002), while no difference emerged at financial score (p=0.096).

In HIV+ patients, a better performance at UPSA-B total score was independently associated to higher total cognitive z-score (β 1.76; 95% CI 4.93/4.23, after adjusting for education (p=0.438) and adherence (p=0.106); in the same regression model, also the performance at UPSA-B communication (β 0.54; 95% CI 2.71/7.38 p=0.001) and financial (β 2.77; 95% CI 1.31/4.23 p=0.001) skills were associated to higher total cognitive z-score.

Conclusion: UPSA-B seemed to better discriminate EF impairment than IADL in HIV+ patients and it was associated with cognitive functions, also in the absence of symptomatic cognitive impairment.

PE9/41
Alcohol, smoking and the association with HIV virological non-suppression among people living with HIV on ART
TPW Jones1, F Lampe2, R Alison3 and AS Team
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2University College London, Research Department of Infection & Population Health, London, UK

Purpose: Evidence on the association between increased alcohol intake and viral non-suppression in people living with HIV (PLWH) is mixed, with limited data from large European studies. We investigated this association in an unselected outpatient population in the UK.

Method: Antiretroviral Sexual Transmission Risk and Attitudes (ASTRA) was a multi-centre cross-sectional self-completed questionnaire study in PLWH attending eight HIV clinics in the UK between February 2011 and December 2012. Evidence of hazardous drinking was based upon a self-reported CAGE score (≥2) or estimated weekly consumption (>20 units of alcohol). Current smoking status was also collected. HIV viral load at recruitment was obtained from the clinics. Logistic regression was used to assess the association of alcohol use and smoking, with virological non-suppression (VL≥50/mL), adjusted for socio-demographic factors (age, gender/sexual orientation, ethnicity, education), in those who were currently on ART and started ≥6 months previously.

Results: 3258 HIV-diagnosed individuals (2248 MSM; 373 heterosexual men; 637 women) completed a questionnaire (response rate 64%). Alcohol consumption was available for 2564 (81.3%), of which 566 (17.7%) had a CAGE score ≥2 and 325 (10.1%) drank ≥20 units per week. 31.5% (n=1213) were current smokers.

On multivariable analysis, among 2459 individuals on ART who started≥6 months previously, the adjusted ORs (95% CI) of virological non-suppression were: 1.52 [1.09, 2.13] for CAGE score ≥2, 1.23 [0.77, 1.96] for≥20 units per week and 1.67 [1.22, 2.27] for current smoking.

Conclusion: Elevated alcohol intake and currently smoking were both found in this study to be associated with having a detectable HIV viral load in PLWH currently on ART. Active screening, advice and referral to smoking cessation and alcohol services should be integrated into HIV outpatient clinics, while clinicians should be alert to the potential for increased risk of non-adherence and viral rebound.
**EACS 2019 – Abstract Book 135**

Odds Ratio of Alcohol Use and Cigarette Smoking in Astra Cohort separated by Demographic, Lifestyle Factors and Treatment

<table>
<thead>
<tr>
<th>Patient Cohort</th>
<th>High Risk Alcohol Use (CAGE score&gt;2 or ≥20 units/week)</th>
<th>Current Smoker</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSM</td>
<td>2248/2528 (89.0%) 554/706 (78.1%) 1.00 –</td>
<td>829/1011 (82.0%) 1.00 –</td>
</tr>
<tr>
<td>Heterosexual Male</td>
<td>373/3258 (11.5%) 87/706 (12.3%) 0.96 [0.74, 1.24] (0.702)</td>
<td>115/1011 (11.4%) 0.79 [0.62, 1.00] (0.046)</td>
</tr>
<tr>
<td>Female</td>
<td>637/2528 (19.6%) 68/706 (9.6%) 0.37 [0.28, 0.49] (&lt;0.001)</td>
<td>67/1011 (6.4%) 0.21 [0.16, 0.27] (&lt;0.001)</td>
</tr>
<tr>
<td>On ART</td>
<td>277/3202 (86.5%) 583/699 (83.0%) 0.70 [0.55, 0.87] (0.002)</td>
<td>837/1005 (83.3%) 0.68 [0.55, 0.84] (&lt;0.001)</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>101/3213 (31.5%) 283/704 (40.0%) 1.63 [1.37, 1.94] (0.001)</td>
<td>1011/1011 (100.0%)</td>
</tr>
<tr>
<td>Recreational Drugs (Past 3 months)</td>
<td>1242/3158 (38.1%) 346/706 (49.0%) 1.76 [1.47, 2.06] (&lt;0.001)</td>
<td>601/1011 (59.4%) 3.59 [3.05, 4.21] (&lt;0.001)</td>
</tr>
<tr>
<td>University or Higher Qualifications</td>
<td>1317/3172 (41.5%) 307/700 (43.9%) 1.12 [0.64, 1.92] (0.392)</td>
<td>332/985 (33.7%) 0.61 [0.52, 0.72] (&lt;0.001)</td>
</tr>
</tbody>
</table>

Odds Ratio of having an undetectable Viral Load separated by lifestyle factors in patients treated with ART for 6 months

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>N (%)</th>
<th>Unadjusted Odds ratio of Detectable Viral Load</th>
<th>Adjusted Odds ratio of Detectable Viral Load (Age, Gender, Ethnicity)</th>
<th>Adjusted Odds ratio of Detectable Viral Load (Age, Gender, Ethnicity, Hardship and Education)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 × Units/ wk</td>
<td>229/2450 (9.35%) 1.12 [0.72, 1.75] (0.615)</td>
<td>1.32 [0.83, 2.08] (0.234)</td>
<td>1.23 [0.77, 1.96] (0.386)</td>
<td></td>
</tr>
<tr>
<td>CAGE Score&lt;2</td>
<td>426/2454 (17.36%) 1.52 [1.10, 2.08] (0.011)</td>
<td>1.54 [1.11, 2.13] (0.009)</td>
<td>1.52 [1.09, 2.13] (0.015)</td>
<td></td>
</tr>
<tr>
<td>High Risk Alcohol Use (&gt;20 units or CAGE&gt;2)</td>
<td>518/2454 (21.11%) 1.43 [1.04, 1.92] (0.025)</td>
<td>1.52 [1.10, 2.08] (0.010)</td>
<td>1.45 [1.05, 2.00] (0.023)</td>
<td></td>
</tr>
<tr>
<td>Recreational Drugs (Past 3 months)</td>
<td>912/2459 (37.09%) 0.96 [0.72, 1.27] (0.759)</td>
<td>1.04 [0.76, 1.45] (0.794)</td>
<td>1.01 [0.72, 1.38] (0.963)</td>
<td></td>
</tr>
<tr>
<td>Injected Drugs (Past 3 months)</td>
<td>53/2459 (2.16%) 2.27 [1.12, 4.55] (0.023)</td>
<td>2.27 [1.11, 4.55] (0.025)</td>
<td>2.17 [1.04, 4.55] (0.038)</td>
<td></td>
</tr>
<tr>
<td>Current Smoker</td>
<td>733/2568 (29.97%) 1.69 [1.28, 2.22] (&lt;0.001)</td>
<td>1.82 [1.33, 2.44] (&lt;0.001)</td>
<td>1.67 [1.22, 2.27] (0.001)</td>
<td></td>
</tr>
</tbody>
</table>

**PE9/42**

Decreasing incidence of diabetes mellitus in HIV-positive Taiwanese patients on combination antiretroviral therapy from 2004 to 2011

P.Y. Wu1, Y-Z. Lou1, J-Y. Zhang1, H-Y. Chuang1, W-C. Liu1, H-Y. Su2 and C-C. Hung2

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**Purpose:** Increasing trends of metabolic complications, including type 2 DM, have threatened the long-term successful management of HIV infection. We aimed to examine the trend of DM in HIV-positive Taiwanese adults who initiated ART in 2004–2011.

**Method:** Between 2004 and 2011, 1,416 antiretroviral-naive patients without DM initiated ART at a university hospital. The trends of DM were compared between patients initiating cART in 2004–2007 (n=582) who were followed until 31 May, 2015 and those initiating cART in 2008–2011 (n=834) who were followed until 31 May, 2019. Incident DM was defined as fasting glucose≥126 mg/dl or HbA1C≥6.5%. Cox proportional hazards models were used to assess the relationship between DM and exposure to cART after adjustment for age, gender, and CD4 count and plasma HIV viral load at baseline.

**Results:** DM was diagnosed in 56 patients, resulting in an incidence rate of 4.43 per 1,000 PYFU, which has decreased from 5.05 per 1,000 PYFU in the 2004–2007 cohort to 3.35 per 1,000 PYFU in the 2008–2011 cohort (p=0.05). Incident DM was associated with older age (aHR, 1.089; 95% CI, 1.045–1.135) and exposure to protease inhibitor (aHR, 3.859; 95% CI, 1.007–14.793). The incident rate of DM increased with cumulative exposure duration to protease inhibitor-containing regimens: < 12 months, 1.7×; 12–24 months, 2.2×; 24–36 months, 8×; and ≥36 months, 12×; and that increased with exposure duration to zidovudine/lamivudine: < 12 months, 2.7×; 12–24 months, 3.6×; 24–36 months, 4.8×; ≥36 months, 4.8×. In contrast, the rate of DM remained stable with cumulative exposure to tenofovir-containing regimens.

**Conclusion:** We found that the incidence of DM has decreased from 5.05 per 1000 PYFU in the 2004–2007 cohort to 3.35 per 1000 PYFU in the 2008–2011 cohort. The risk of DM increased with older age and cumulative exposure to protease inhibitor-containing regimens in Taiwan.

**PE9/43**

Incidental findings in PLWH over 50 undergoing coronary artery calcium scoring (CACS) for cardiovascular risk assessment

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**Background:** Cardiovascular risk assessment of people living with HIV (PLWH)>50 years using coronary artery calcium scores (CACS) has added benefits and costs of detecting extra-cardiac abnormalities. Data is limited on the prevalence or progression of incidental lung findings detected on Cardiac CT in PLWH. The objective of this study was to analyse the prevalence and progression of non-coronary incidental findings in patients undergoing CACS.

**Methods:** Longitudinal observational study of PLWH>50 years undergoing Cardiac CT for CACS determination between 2009 and 2018. We report incidental extra-cardiac findings and follow-up required. A univariate logistic regression analysis was used to identify factors associated with incidental findings.

**Results:** 744 patients were included (92% male, mean age 56 ± 5 years, 84% white British, 87% MSM). The mean CD4 was 660 ± 258 cells/μL; 97% were on antiretroviral therapy (ART) with a suppressed viral load (VL) in 94%. Median years living with HIV was 16 years (IQR 12), median CD4:CD8 was 0.8 (IQR 0.6) and median CACS centile was 25–50%. 42% were active smokers.
30% of patients had an incidental finding and 85% were newly diagnosed. 94% were incidental lung findings, most commonly pulmonary nodules, followed by atelectasis, and emphysema. 27.8% required follow-up or onward referral; 58% were stable or resolved at follow-up. 2 lung malignancies were detected. CD4/CD8 ratio ≥0.5 was found to be associated with the presence of an incidental finding (p = 0.007).

Conclusions: Our study indicates PLWH on ART with a suppressed VL have a similar prevalence of incidental findings as HIV-negative populations on Cardiac CT. Having an impaired immune function despite a suppressed VL in this study was associated with incidental lung findings. CACS in risk stratification for cardiovascular disease has added value of identifying clinically significant lung abnormalities.

PE9/44
Aging biomarkers, inflammatory cytokines and development of cardiovascular ischemic events or diabetes in HIV-infected persons

JI Bernadino1, B Alejos2, J Rodríguez-Centeno1, A Esteban1, B Mora1, R Montejano1, R de Miguel1, N Stella-Ascari1, P Viciana1, I de los Santos1, I Suarez-García1, J García-García1, J Sanz1, JR Arribas1, B Rodes1 and CoRIS
1Hospital Universitario La Paz. IdiPAZ, Madrid, Spain 2Instituto de Salud Carlos III, Madrid, Spain 3Hospital Universitätsklinikum, Mannheim, Germany 4Hospital La Princesa, Madrid, Spain 5Hospital Infanta Sofía, Madrid, Spain 6Hospital General Universitario Santa Lucia, Cartagena, Spain 7Hospital Príncipe de Asturias, Madrid, Spain

Purpose: Novel biomarkers of aging could help identify persons at risk for Non-AIDS co-morbidities. To investigate if leukocyte telomere length (LTL), age acceleration, and soluble inflammatory cytokines related to occurrence of cardiovascular events or diabetes in treated HIV-infected persons.

Method: Cross-sectional study nested in the Spanish cohort of HIV-infected patients (CoRIS). Cases were participants with cardio-metabolic events (myocardial infarction (MI), stroke, sudden death, or diabetes (DM)) after starting ART and with available samples at inclusion. Controls without cardio-metabolic events were included with available samples at inclusion. Controls without cardio-metabolic event were matched 1:1 for sex, age, tobacco use, pre-ART CD4 cell count and viral load, and sample time-point. LTL was analysed in whole blood by qPCR (T/S ratio). Age acceleration (biological age minus chronological age) was analyzed with DNA methylation changes by next generation sequencing using the Weidner aging formula. Cytokines (CCL2, sCD14, sCD163, RANTES, GROα) were measured using specific ELISA kits. Conditional logistic regression explored the association between cytokines, telomere length and age acceleration with cardio-metabolic events.

Results: 188 participants (94 cases (44 MI/sudden death, 24 stroke and 120 diabetes (DM)) after starting ART and with available samples at inclusion. Controls without cardio-metabolic event were matched 1:1 for sex, age, tobacco use, pre-ART CD4 cell count and viral load, and sample time-point. LTL was analysed in whole blood by qPCR (T/S ratio). Age acceleration (biological age minus chronological age) was analyzed with DNA methylation changes by next generation sequencing using the Weidner aging formula. Cytokines (CCL2, sCD14, sCD163, RANTES, GROα) were measured using specific ELISA kits. Conditional logistic regression explored the association between cytokines, telomere length and age acceleration with cardio-metabolic events. LTL was significantly correlated with sCD14 (r = -0.2235; p = 0.01), chronological age (r = -0.3849; p = 0.001), and biological age (r = -0.1916; p = 0.0249). Monocyte activation markers were correlated with chronological age (sCD14 0.2095; p = 0.007 and sCD163 0.1709; p = 0.02).

Conclusion: In this cohort we found no associations between telomere length, age acceleration and inflammatory cytokines and myocardial infarction, stroke or diabetes after ART initiation.

PE9/45
Falls but not frailty are common in people living with HIV using an mHealth platform: issues of ageing within the EmERGE cohort

T Levet1, J Vera1, C Jones1, S Bremer1, A Leon2, J Begovac3, L Apers4, M Borges5, Z Žekan2, E Teofilo5, F García, J Whetham6 and on behalf of the EmERGE Consortium
1Brighton and Sussex Medical School, Brighton, UK 2Fundacio Clinic per la Recerca Biomedica, Barcelona, Spain 3Klinika za Infektivne Bolesti, Zagreb, Croatia 4Institute of Tropical Medicine, Antwerp, Belgium 5Centro Hospitalario de Lisboa Central, Lisbon, Portugal 6Brighton and Sussex University Hospitals NHS Trust, Brighton, UK

Mobile technology platforms represent a method of streamlining long-term HIV care, yet they may fail to address broader health issues such as age-related conditions. Purpose: To estimate the prevalence of frailty and falls among stable individuals with HIV engaged with remote healthcare, delivered via a novel smartphone application.

Method: Cross-sectional, questionnaire-based sub-study of EmERGE participants. Frailty was assessed using the FRAIL scale, a five-item self-report screening tool. Present criteria were summed (range 0–5) and categorized: 0:robust, 1–2:pre-frail, ≥3 frail. Falls and their frequency were assessed and dichotomised to faller/non-faller and single/recurrent falls.

Results: 944 individuals participated across five European study sites. Mean age was 44.6 years (SD 9.9), with 33% aged ≥50. 92% were male, 79% were of Caucasian ethnicity. Full frailty data were available for 891/944 (94%). Three quarters were robust (74%, 663/891); 25% (219/891) pre-frail; and 9 frail (1%). Of the frailty criteria, fatigue was most frequently reported (13%) followed by unintentional weight loss (12%), problems with walking (6%) and stairs (5%). Only 2 participants reported ≥4 comorbidities. Demographic data were available for 6/9 frail individuals: 83.3% were aged ≥50; all were male. 120/940 (13%) participants had fallen in the last year. Fallers experienced a median of 2 falls (IQR 1–3), with 59% (68/116) falling recurrently (≥2 falls). Fallers were on average 3.1 years older than non-fallers (pre-frail, ≥3 frail). Falls and their frequency were assessed and dichotomised to faller/non-faller and single/recurrent falls.

Conclusion: Ageing issues were relatively uncommon in this cohort. Frailty was rare, with pre-fraility seen in 25%. Falls occurred and often recurred, and were related to frailty status and older age. Opportunities to explore ageing concerns with patients should be retained within mHealth delivered care and comprehensive geriatric assessment considered if identified.
Purpose: Cardiovascular (CV) risk factor prevalence is often found different in people living with HIV (PLWH) as compared to general population. However, the treatment rates of risk factors is rarely addressed taking into account the age and sex distribution of PLWH. In this project we compare the general Spanish population treatment rates of main non-life style CV risk factors with that of Spanish PLWH, after standardizing for referent age and sex population distributions.

Method: We used 5,680 PLWH with complete data from the VACH Spanish cohort and the general population DARIOS cohort, a pooled analysis of 11 population surveys from 10 Spanish communities (n=28,342) (http://darios.imim.es/). The treatment of diabetes, hypertension and dyslipidemia was compared in the age group 35 to 74 years. Prevalence and treatment rates were standardized by the direct method by sex and 10-year age groups with the European standard populations. All participants signed their informed consent.

Results: In DARIOS and VACH, the proportion of males was 46.5% and 80.4% (p-value<0.001), respectively and mean age 53.5 (11.1) and 42.5 (7.4) (p-value=0.001), respectively. Standardized diabetes, hypertension and dyslipidemia treatments were significantly poorer among HIV patients than in general population (Table).

Conclusion: After the appropriate standardization to correct the effect of age and sex, we found striking differences in the control of risk factors between the general population and PLWH. The proportion of PLWH on pharmacological treatment for diabetes, hypertension, and dyslipidemia are significantly lower than in the general population. It is very important to improve the pharmacological control of CV risk factors in PLWH that matches at least that of the general population.

Comparison of cardiovascular risk factor treatment in FEMALE PLWH and general population

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>General population (DARIOS cohort, N=15,149)</th>
<th>Female PLWH (VACH cohort, N=1,114)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>10.6% (10.1%–11.1%)</td>
<td>19.5% (16.4%–22.7%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Treated</td>
<td>34.4 (31.5–37.2)</td>
<td>13.1 (8.4–17.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>27.4% (26.7%–28.0%)</td>
<td>25.9% (22.6%–29.2%)</td>
<td>0.392</td>
</tr>
<tr>
<td>Treated</td>
<td>62.7% (60.7%–64.7%)</td>
<td>22.9% (17.2%–28.6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>135.8 (135.2–136.3)</td>
<td>120.4 (116.3–124.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>mg/dL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treated</td>
<td>14.0% (13.5%–14.6%)</td>
<td>8.1% (5.9%–10.3%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Comparison of cardiovascular risk factor treatment in MALE PLWH and general population

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>General population (DARIOS cohort, N=13,193)</th>
<th>Male PLWH (VACH cohort, N=4,566)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>15.4% (14.8%–16.0%)</td>
<td>21.1% (19.6%–22.6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Treated</td>
<td>40% (37.1%–42.9%)</td>
<td>17.0% (14.3%–19.7%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>29.0% (28.2%–29.7%)</td>
<td>23.7% (22.2%–25.2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Treated</td>
<td>59.3% (57.5%–61.1%)</td>
<td>26.2% (23.2%–29.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>139 (138.4–139.6)</td>
<td>114 (112.2–115.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Treated</td>
<td>15.1% (14.5%–15.7%)</td>
<td>8.5% (7.4%–9.5%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 1. Perceptions of ageing and desire for within 'app' ageing information in EmERGE participants

<table>
<thead>
<tr>
<th>Ageing variable</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfied with ageing (n=937)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>63</td>
<td>6.7</td>
</tr>
<tr>
<td>Somewhat disagree</td>
<td>75</td>
<td>8.0</td>
</tr>
<tr>
<td>Slightly disagree</td>
<td>76</td>
<td>8.1</td>
</tr>
<tr>
<td>Slightly agree</td>
<td>78</td>
<td>8.3</td>
</tr>
<tr>
<td>Somewhat agree</td>
<td>331</td>
<td>35.3</td>
</tr>
<tr>
<td>Strongly agree</td>
<td>314</td>
<td>33.5</td>
</tr>
<tr>
<td>Inclusion of ageing information in 'app' (n=930)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>58</td>
<td>6.2</td>
</tr>
<tr>
<td>Somewhat disagree</td>
<td>38</td>
<td>4.1</td>
</tr>
<tr>
<td>Slightly disagree</td>
<td>41</td>
<td>4.4</td>
</tr>
<tr>
<td>Slightly agree</td>
<td>164</td>
<td>17.6</td>
</tr>
<tr>
<td>Somewhat agree</td>
<td>237</td>
<td>25.5</td>
</tr>
<tr>
<td>Strongly agree</td>
<td>392</td>
<td>42.2</td>
</tr>
</tbody>
</table>

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PE9/49
Switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in adults aged≥65 or older: week 48 results from a phase 3b, open-label trial

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3Saint Louis Hospital, Paris, France
4Unidad VHI, Hospital Universitario 12 de Octubre, Madrid, Spain
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9University of Paris Diderot, Paris, France
10University of Men, Hamburg, Germany

Purpose: As the age of people living with HIV increases, studies are needed to assess the safety and efficacy of antiretroviral therapy in this population. B/F/TAF is a small single-tablet regimen with few drug-drug interactions and a high barrier to resistance. In this ongoing 96-week study, we evaluated the efficacy and safety of switching participants aged≥65 years to B/F/TAF.

Method: Virologically suppressed (HIV-1 RNA<50 copies/mL) participants aged≥65 years old currently receiving either E/C/F/TAF or a TDF-based regimen were switched to B/F/TAF. The primary endpoint was HIV-1 RNA<50 copies/mL at Week W24 as defined by Food and Drug Administration Snapshot algorithm. Here we report efficacy and safety outcomes at W48.

Results: 86 participants were enrolled at sites across 5 European countries, median age was 68 years (IQR 66, 71), 13% were female, and 99% were ≥50 years. Through Week 48, high rates of virologic suppression were maintained in participants taking B/F/TAF. No Grade 3 or 4 laboratory abnormalities were observed. Three AEs led to premature study drug discontinuation; one (abdominal discomfort, grade 2) was considered study drug-related. Using the missing-excluded analysis, B/F/TAF reported 4 study drug-related adverse events (AEs) were observed. Three AEs were considered to be premature study drug discontinuation; one (abdominal discomfort, grade 2) was considered study drug-related (Table 1). Median changes from baseline in lipid parameters were: total fasting cholesterol (−0.26 mg/dL), LDL (−0.52 mg/dL), HDL (−0.02 mg/dL), triglycerides (−0.02 mg/dL) and total cholesterol:HDL (−0.52 mg/dL).

Conclusion: Through W48, high rates of virologic suppression were maintained in older participants who switched to B/F/TAF. The safety and efficacy data support the switch to B/F/TAF in virologically suppressed HIV-infected individuals aged≥65 years.

Table 1. Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>B/F/TAF (N=86), % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Grade 3–4 Study Drug-Related AEs</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Grade 3 or 4 Laboratory Abnormalities</td>
<td>6% (5)</td>
</tr>
<tr>
<td>Any Study Drug-Related Serious AE</td>
<td>0% (0)</td>
</tr>
<tr>
<td>AEs Leading to Study Drug Discontinuation</td>
<td>3.5% (3)*</td>
</tr>
</tbody>
</table>

* 1) abdominal discomfort (grade2, drug-related), 2) alcohol withdrawal, 3) benzodiazepine withdrawal

Adverse Events

PE9/50
Safety and efficacy of switching from tenofovir disoproxil fumarate to tenofovir alafenamide (TAF) in people with HIV (PW) aged≥50 years

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4Hospital Universitari La Paz, Madrid, Spain
5Hôpital de l’Archet, Nice, France
6University of Paris Diderot, Paris, France
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8University of Bonn, Bonn, Germany
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10Mortimer Market Centre, London, UK

Purpose: To compare safety and efficacy of switching from tenofovir disoproxil fumarate (TDF) to tenofovir alafenamide (TAF) in people with HIV (PW) aged≥50 years.

Method: We pooled data from five phase 3 randomized controlled trials evaluating switching from TDF to TAF-containing antiretroviral regimens. Virologic suppression was defined as proportion of participants with HIV RNA<50 copies/mL at 48 weeks (W) using the Snapshot algorithm. Renal and bone impact were assessed at W96 by eGFR (Cockcroft-Gault), β2M:Cr and RBP:Cr ratio, and bone mineral density (BMD) by DXA.

Results: Pooled analyses included 1,408 PW aged≥50y (768 TAF, 640 TDF). Median age was 54y; 86% male, 20.6% black, 14.9% Hispanic or Latino/Latina. Baseline medical conditions included hyperlipidemia (48.8%), hypertension (38.7%), diabetes (8.4%), and cardiovascular disease (5.9%). Virologic suppression was maintained in 94.1% of participants taking TAF and 93.5% taking TDF (p=0.086). Study drug-related adverse events occurred in 16.2% of participants taking TAF and 12.3% of participants taking TDF, leading to discontinuation in 0.5% and 2.2% respectively. Median eGFR increased in participants on TAF and decreased in those on TDF (Table 1). The frequency of osteoporosis decreased in participants taking TAF and increased in those taking TDF (Table 2). There were 2 cases of Fanconi syndrome in participants taking TDF and none in those taking TAF. Participants taking TAF had improvements in hip and spine BMD, while those taking TDF remained stable or worsened (Table 2). The frequency of osteoporosis decreased in participants taking TAF and increased in those taking TDF (Table 2).

Conclusion: In PW aged≥50, switching to TAF from TDF maintained virologic suppression and was associated with improved markers of renal function and improved BMD compared to TDF. These findings suggest that TAF is a safe and effective option for aging PW.

Table 1. Virologic Outcomes

<table>
<thead>
<tr>
<th>Week</th>
<th>TDF</th>
<th>TAF</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virologic suppression (HIV-1 RNA&lt;50 copies/mL)</td>
<td>87% (67/768)</td>
<td>100% (75/75)</td>
<td>0.001</td>
</tr>
<tr>
<td>Rate of virologic failure</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Grade 3 or 4 laboratory abnormalities</td>
<td>6% (52)</td>
<td>6% (52)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

* p-value is from the Wilcoxon rank sum test

Figure 1. Time to virologic failure in patients with HIV/PE9/50

[Tables]
**PE9/51**

**HIV testing in patients diagnosed with community acquired pneumonia or primary lung cancer from 2014 to 2018 in a tertiary reference hospital in Northern Spain**

J Modesto dos Santos1, M Eransus Garzaron1, T Rubio Obanos2, M Adelantado Lacasa1, A Aguinaera Perez2, C Martin Salas1, S Clemos Matamoros3 and J Sanchez Alvarez1

1Complejo Hospitalario de Navarra, Pamplona, Spain 2Hospital Reina Sofia de Tudela, Tudela, Spain

**Purpose:** HIV testing is reinforced in patients diagnosed with community acquired pneumonia (CAP) or primary lung cancer (PLC). The aim of this study is to evaluate the frequency for HIV testing on patients admitted with CAP or PLC to a tertiary hospital.

**Method:** The authors present a retrospective observational study from January 2014 to December 2018, evaluating HIV testing in patients diagnosed with CAP or PLC. Patients were included by CI-E-10 diagnostic codes in clinical records, and HIV testing was assessed by crosschecking databases.

**Results:** A total of 7745 patients were diagnosed with CAP and 3524 with PLC, with a total of 11269 opportunities for HIV testing. Patients were mostly males (62.9%) and with similar ages in both groups: 68.69 and 66.0 years-old in CAP and PLC. HIV was tested in 1197 patients (10.62%), detecting a higher request rate in patients with CAP (11.26%) than PLC (9.22%) (difference of 2.04%, p<0.01). HIV was also more often tested in male patients (OR 1.21, 95%CI 1.06–1.37), independently from diagnosis. In the CAP subgroup, HIV was more frequently tested when patients were admitted to the ICU (21.13%) or to an Infectious Diseases unit (ID) (34.29%), rather than Internal Medicine (IM) (12.16%) or Pneumology (8.38%).

Bone loss was more rapid in the early than late menopausal period, captured through BMD and TBS changes. From the 1175 samples processed for HIV test, 39 (3.32%) presented a positive result. Positive HIV tests proportion was similar in both diagnosis (CAP 3.75% vs PLC 2.17%, p=0.40). Only 13 positive tests were new diagnosis of HIV, representing 1.09% of the total HIV tests requested in this study.

**Conclusion:** HIV testing in patients with CAP or PLC in this cohort is very low, with some HIV diagnostic opportunities lost. Nevertheless, studies are needed to evaluate the reactivity of specific HIV diagnostic protocols in CAP or PLC patients.

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**PE9/52**

**Menopause in aging women living with HIV: changes in bone mineral density and trabecular bone score**

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1University of Modena and Reggio Emilia, Modena, Italy 2Modena HIV Metabolic Clinic, University of Modena and Reggio Emilia, Modena, Italy 3Clinical and Experimental Medicine PhD Program, University of Modena and Reggio Emilia, Modena, Italy

**Objective:** HIV infection and tenofovir-disoproxil fumarate (TDF)-containing antiretroviral regimens alone or in association with boosted protease inhibitors are associated with impaired bone quality and quantity and high fracture risk. The aim of the study was to describe pattern of bone quantity (lumbar bone mineral density (BMD)) and bone quality (trabecular bone score (TBS)) changes across menopause in WLWH undergoing ART with or without TDF.

**Methods:** We conducted a longitudinal retrospective study including WLWH attending Modena HIV Metabolic Clinic from 2012 to 2019. The observation period was divided into reproductive, transitional, early and late menopause according to STRAW criteria. Lumbar BMD and TBS derived from DEXA evaluation. GEE models were built to predict changes in BMD and TBS across menopause and TDF or TDF−Pi/irf containing ART regimens.

**Results:** We included 185 (mean age=49.3 years) ART-experienced women observed for a median of 6.08 years. 134 observations were assessed in the “Reproductive Period”, 180 in the “Menopause Transition”, 185 in the “Early Menopause” and 20 in the “Late Menopause”, for a total of 519 DEXA observations. At baseline, median duration of HIV infection was 244 months, median CD4 cell count was 635 cells/μl. Across menopause, LDL, CRP, vitamin D and PTH significantly increased, while ASMI, FFMI, lumbar BMD, TBS score and FRAX® score worsened (p<0.001). In GEE models, independent predictors of BMD and TBS changes were time from menopause and calcium concentration; waist circumference was positively correlated with BMD and negatively correlated with TBS. TDF and Pi/irf were not predictors of BMD and TBS changes.

**Conclusions:** BMD and TBS remained stable in the pre-menopause period. Bone loss was more rapid in the early than late menopausal period, captured both with BMD and TBS. Current TDF or Pi/irf exposure was not independently associated with neither BMD nor TBS lowering in menopause.

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**PE9/53**

**Higher anti–CMV IgG concentrations are not associated with longitudinal brain injury in virally suppressed people with HIV**

J Underwood1,2,3, D De Francescos4,5, N Koostaj5, MWA Caan1, JH Cole2,3, M Caan6,7,8,9,10,11,12, A Winston1,12, and on behalf of the ComorBidity in Relation to AIDS (COBRA) Collaboration

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**Introduction:** People with HIV (PWH) have a higher CMV seroprevalence than HIV-negative individuals. Higher CMV IgG concentrations have been associated with poorer cognitive function in cross-sectional studies of PWH. We compared the longitudinal relationships between CMV, cognitive function and neuroimaging biomarkers in PWH and demographically-matched HIV-negative controls.

**Methods:** CMV-seropositive, virally-suppressed PWH and HIV-negative controls from the COBRA study were included. The relationship between anti-CMV IgG and high avidity anti-CMV IgG titres with cognitive function (standardised T-scores measured with a six-domain battery) and MRI biomarkers (volumetric, diffusion and a machine-learning derived prediction of apparent ‘brain age’), measured at baseline and after two years, were determined using rank regression adjusted for potential confounders.

**Results:** 130 PWH and 61 HIV-negative controls were included. Across the whole cohort cross-sectionally, higher anti-CMV IgG titres were associated with poorer global cognitive function and in the domains of processing speed, executive and motor function. This was only observed in PWH (largest effect size motor function: rhoadj = −0.25, p<0.01) although there were no statistically significant interactions between HIV-status and anti-CMV IgG titres.

**Conclusions:** Higher anti-CMV IgG titres were not associated with short-term progressive brain injury in virally suppressed PWH. These findings and the lack of associations in HIV-negative controls suggest that the cross-sectional associations in PWH may represent type 1 errors or that CMV-associated brain injury is a static phenomenon in virally suppressed PWH.
Table 1. Rank regression of total anti-CMV IgG with neuroimaging biomarkers across the whole cohort (n=191)

<table>
<thead>
<tr>
<th>Neuroimaging biomarker</th>
<th>Cross-sectional</th>
<th>HIV-</th>
<th>Longitudinal</th>
<th>HIV-</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>rho adj (95% CI)</td>
<td>p</td>
<td>rho adj (95% CI)</td>
<td>p</td>
</tr>
<tr>
<td>Grey matter thickness - Left</td>
<td>-0.02 (-0.11, 0.08)</td>
<td>0.70</td>
<td>0.88</td>
<td>0.09 (-0.03, 0.22)</td>
</tr>
<tr>
<td>White matter thickness - Right</td>
<td>-0.01 (-0.10, 0.08)</td>
<td>0.84</td>
<td>0.14</td>
<td>0.00 (-0.12, 0.11)</td>
</tr>
<tr>
<td>Cortical thickness</td>
<td>-0.08 (-0.22, 0.05)</td>
<td>0.20</td>
<td>0.35</td>
<td>0.03 (-0.08, 0.15)</td>
</tr>
<tr>
<td>Whole brain FA</td>
<td>-0.07 (-0.19, 0.05)</td>
<td>0.25</td>
<td>0.14</td>
<td>0.00 (-0.12, 0.13)</td>
</tr>
<tr>
<td>Whole brain MD</td>
<td>0.10 (-0.01, 0.22)</td>
<td>0.08</td>
<td>0.28</td>
<td>0.03 (-0.09, 0.14)</td>
</tr>
<tr>
<td>Brain-PAD score</td>
<td>0.16 (0.03, 0.30)</td>
<td>0.02</td>
<td>0.03</td>
<td>-0.11 (-0.23, 0.02)</td>
</tr>
</tbody>
</table>

PE9/56
Effect of CMV viremia on endothelial dysfunction over 42 weeks in Malawian adults initiating ART with advanced immune suppression

C Kelly1,2, J. W Tinago1, P Hunter1, D Alber1, N Luckhurst1, J Connolly1, F Arrigo2, R Kamngona3, I Sheha3, M Chammudzi3, K Jambo3, A Mallewa4, R Heyderman1, PW Mallon1, H Mwandumba1, S Khoob1 and N Klein1

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Purpose: Advanced immune suppression in HIV is still common in low-income Sub-Saharan Africa. We characterised the effect of CMV viremia on endothelial dysfunction over 42 weeks of ART in late presenters.

Method: We recruited Malawian adults with CD4<100 cells/µL two weeks after starting ART (enrolment) in the REALITY trial (NCT01825031). CMV PCR and 22 inflammatory biomarkers were assessed at enrolment and 42 weeks later, along with carotid femoral pulse wave velocity (cfPWV). Logistic regression assessed predictors for CMV viremia and cfPWV.

Results: 61(32%) of 193 participants were CMV PCR+ at enrolment; 28(15%) had viral load<1000 copies/mL. Despite not receiving CMV specific treatment, 60(38%) participants became undetectable after 42 weeks’ ART. Advanced immune suppression remained significantly associated when adjusted for cfPWV, loge10 cfPWV and age (P<0.001).

Baseline characteristics among 1482 participants from the HIV and the HNR study

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HNR male N=874 (88.46%)</th>
<th>HIVH male N=437 (88.46%)</th>
<th>P-value</th>
<th>HNR female N=114 (11.54%)</th>
<th>HIVH female N=57 (11.54%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CKD2 (GFR&lt;60)</td>
<td>30 (3.43%)</td>
<td>45 (10.3%)</td>
<td>&lt;0.001</td>
<td>8 (7.02%)</td>
<td>15 (26.32%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age [years]</td>
<td>54.58 ± 6.55</td>
<td>51.33 ± 6.26</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline eGFR [mL/min/1.73 m²]</td>
<td>85.48 ± 19.25</td>
<td>78.03 ± 16.5</td>
<td>&lt;0.001</td>
<td>80.42 ± 18.66</td>
<td>69.5 ± 16.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Active smoker</td>
<td>255 (28.18 %)</td>
<td>214 (48.97 %)</td>
<td>&lt;0.001</td>
<td>35 (30.7 %)</td>
<td>27 (47.37 %)</td>
<td>0.064</td>
</tr>
<tr>
<td>Diabetes at baseline</td>
<td>65 (7.44 %)</td>
<td>37 (8.47 %)</td>
<td>0.512</td>
<td>8 (7.02 %)</td>
<td>6 (10.53 %)</td>
<td>0.430</td>
</tr>
<tr>
<td>Systolic blood pressure [mmHg]</td>
<td>134.39 ± 18.73</td>
<td>137.6 ± 21.68</td>
<td>0.006</td>
<td>123.66 ± 24.79</td>
<td>142.84 ± 29.31</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diastolic blood pressure [mmHg]</td>
<td>84.32 ± 10.65</td>
<td>85.11 ± 12.37</td>
<td>0.226</td>
<td>79.43 ± 12.88</td>
<td>88.37 ± 13.32</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Use of antihypertensive medication at baseline</td>
<td>253 (28.95 %)</td>
<td>103 (23.57 %)</td>
<td>0.039</td>
<td>22 (19.3 %)</td>
<td>15 (26.32 %)</td>
<td>0.294</td>
</tr>
<tr>
<td>BMI [kg/m²]</td>
<td>27.92 ± 3.93</td>
<td>24.61 ± 3.8</td>
<td>&lt;0.001</td>
<td>26.36 ± 5.14</td>
<td>24.55 ± 4.44</td>
<td>0.024</td>
</tr>
</tbody>
</table>
There was no difference in cfPWV between those CMV PCR+ and PCR− at enrolment [median cfPWV 7.3 m/s and 7.2, p=0.15 respectively]. There was a trend towards higher cfPWV for those with enrolment CMV viral load below compared to above 1000 copies/mL at both enrolment [median 7.7 m/s and 7.2, p=0.06] and 42 weeks [7.5 m/s and 6.6 m/s, p=0.05]. However, this association did not persist when adjusted for age, blood pressure and haemoglobin (enrolment p=0.34 and week 42 p=0.13 respectively).

Conclusion: CMV vireamia was common but did not explain endothelial dysfunction at ART initiation. However, CMV vireamia at presentation was associated with persistent inflammation at 42 weeks. Whether treating CMV vireamia at presentation reduces long-term endothelial dysfunction on ART in this cohort remains unknown.

PE9/57
High prevalence of neurocognitive impairment in adults with perinatally acquired HIV infection
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1University of Alicante, Psychology Health, Alicante, Spain. 2Institute for Health and Biomedical Research (ISABIAL-FISABIO Foundation). 3General University Hospital of Alicante, HIV and Infectious Diseases Researching Group. 4Department of Infectious Disease, Alicante, Spain. 5Spanish AIDS Research Network, Madrid, Spain. 6General University Hospital of Alicante, Alicante, Spain. 7Institute for Health and Biomedical Research (ISABIAL-FISABIO Foundation). 8HIV and Infectious Diseases Researching Group, Alicante, Spain. 9AIDS Spanish Research Network, Madrid, Spain. 10Inscanner S.L., Magnetic Resonance Department, Alicante, Spain. 11General University Hospital of Alicante, Radiodiagnosis Department, Alicante, Spain.

Purpose: To analyze the prevalence of neurocognitive impairment (NCI), affected neurocognitive domains and damaged brain areas in HIV-adults with perinatally acquired HIV (PHIV).

Method: Observational, cross-sectional study. Inclusion criteria: >18 years; perinatally acquired HIV; informed consent. NCI was diagnosed using Frascati criteria. 7 neurocognitive domains were analyzed: attention and working memory, processing speed, long-term memory, learning, executive functions, verbal fluency and motor functioning. Damaged brain areas were studied with Magnetic Resonance Imaging (MRI). We used a 3T clinical Magnet (Philips Achieva) employing a predefined protocol that included standard brain images (T2, FLAIR, SWI) as well as diffusion tensor imaging (DTI) and isotropic T1 images (Achieva) employing a predefined protocol that included standard brain images (T2, FLAIR, SWI).

Results: We included 2123 patients (74% men, mean age 53.5 years). Mean LDL-C and 10-year risk of CV events were 114 ± 33 mg/dL and 8.1 ± 0.9%.

Conclusion: The recent AHA scientific statement on prevention and management of CVD in people living with HIV failed in identifying recommendations that may clarify statin prescription needing in PLWH. The recommended LDL target was reached most often in patients with diabetes mellitus type 2. AHA-PLWH statement failed in identifying recommendations that may clarify statin prescription needing in PLWH.

PE9/58
Modeling 2018 AHA cholesterol guidelines in HIV
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1Università degli Studi di Modena e Reggio Emilia, Modena, Italy. 2Division of Cardiology and Mazankowski Alberta Heart Institute, University of Alberta, Edmonton, Canada.

Purpose: The objective was to assess statin use in people living with HIV (PLWH) in relation to the 2018 AHA Cholesterol Clinical Practice Guideline (CCPG) recommendations and related LDL targets. Data were analyzed vis-à-vis the recent AHA scientific statement on prevention and management of CVD in people living with HIV.

Method: Cross sectional study of PLWH followed at the Modena HIV Metabolic Clinic (MHMC) in 2017–2018. Mutually exclusive groups were built according to CCPG treatment algorithms recommending high and moderate intensity hypolipemic therapy (HIH or MIH).

Results: In 114 secondary prevention PLWH aged ~75 years (6% of our cohort), HIH was prescribed in 34 patients (29%) and MIH in 25 patients (21.9%). Among these patients, only 26.5% reached the LDL-C target <70 mg/dL.

Conclusion: In real life statins are largely under-prescribed. The recommended LDL target was reached most often in patients with diabetes mellitus type 2. AHA-PLWH statement failed in identifying recommendations that may clarify statin prescription needing in PLWH. The recent AHA statement on CV disease in PLWH is ambiguous with regards to treatment indications and LDL goals leaving a therapeutic gap that needs to be filled to improve patients’ outcome.
A multi-disciplinary Neuro-HIV Platform in managing patients with neurocognitive impairment

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1Lausanne University Hospital, Department of Infectious Diseases, Lausanne, Switzerland 2Lausanne University Hospital, Department of Clinical Neurosciences, Laboratory of Neuroimmunology, Lausanne, Switzerland 3Lausanne University Hospital, Department of Clinical Neurosciences, Service of Neuropsychology and Neurorehabilitation, Lausanne, Switzerland 4Lausanne University Hospital, Department of Psychiatry, Lausanne, Switzerland 5Lausanne University Hospital, Department of Medical Radiology, Lausanne, Switzerland

Purpose: Neurocognitive impairment (NCI) represents a potential health burden for people with HIV (PWH). A multidisciplinary platform was developed to optimise the care of PWH.

Method: The Platform was developed at Lausanne University Hospital and accepts referrals from practitioners throughout Switzerland. Once a month, patients are seen by a neurologist, neuropsychologist, psychiatrist and an infectious diseases physician and undergo cerebral MRI and lumbar puncture. NCI is graded according to Frascati criteria and by neuropsychological test z-scores. Following this multidisciplinary assessment, treatment recommendations are made to the referring practitioner and follow-up visits at the Platform are planned as required.

Results: Between 2011 and 2019, 185 patients were seen at the Platform over 218 visits. 158 patients were seen once, 27 more than once. The median age of the 185 patients was 48 (IQR: 42,55), 59% men, mean nadir CD4 count 214 cells/mL (SD: 14). NCI was identified in 135 patients (73%). 35 (19%) with HIV-associated NCI. Non-HIV NCI were identified among 100 (54%) patients, including psychiatric and structural neurological sequelae. Among these, 18 patients (18%) were identified as having previously undiagnosed depression. Among the 27 patients who have been seen at the Platform several times, the neuropsychological diagnosis was stable for 17 patients, improved for two patients, worsened for one patient and fluctuated for 7 patients.

Conclusion: The Neuro-HIV Platform provides a unique multidisciplinary single day clinic to PWH suspected of having NCI. By reviewing neurological, neuropsychological, psychiatric and HIV-related components in each patient, it has been possible to identify reversible causes of NCI which might otherwise be missed in patients followed up in a single-specialty setting.

Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex Male, n (%)</td>
<td>77 (78.6)</td>
</tr>
<tr>
<td>Age, median [IQR]</td>
<td>57 [51–64]</td>
</tr>
<tr>
<td>Years of HIV positivity, median [IQR]</td>
<td>20 [13–25]</td>
</tr>
<tr>
<td>Years of ART, median [IQR]</td>
<td>17.5 [10–22]</td>
</tr>
<tr>
<td>Nadir CD4 +, median [IQR]</td>
<td>262.5 [12–563]</td>
</tr>
<tr>
<td>Zenith HIV-RNA, median [IQR]</td>
<td>55000 [7000–225000]</td>
</tr>
<tr>
<td>Ethnicity Caucasian, n (%)</td>
<td>83 (84.69)</td>
</tr>
<tr>
<td>Risk, n (%)</td>
<td>47 (47.3)</td>
</tr>
<tr>
<td>• Heterosexual</td>
<td>47 (47.3)</td>
</tr>
<tr>
<td>• MSM</td>
<td>37 (37.7)</td>
</tr>
<tr>
<td>• VDU</td>
<td>9 (9.18)</td>
</tr>
<tr>
<td>• NNRTI</td>
<td>22 (22.45)</td>
</tr>
<tr>
<td>Charlson comorbidity score=4, n (%)</td>
<td>19 (20.21)</td>
</tr>
<tr>
<td>Cardiovascular event, n (%)</td>
<td>53 (54.08)</td>
</tr>
<tr>
<td>Type of cardiovascular event n (%)</td>
<td>16 (16.35%)</td>
</tr>
<tr>
<td>Framingham level (available for 85 patients), n (%)</td>
<td>31 (36.47)</td>
</tr>
<tr>
<td>IL-6&gt;10 pg/mL, n (%)</td>
<td>13 (13.98)</td>
</tr>
<tr>
<td>Lpa&gt;300 mg/mL, n (%)</td>
<td>37 (37.76)</td>
</tr>
<tr>
<td>NT-proBNP&gt;100 pg/mL, n (%)</td>
<td>13 (13.27)</td>
</tr>
<tr>
<td>hPCR&gt;0.9 mg/mL, n (%)</td>
<td>14 (14.28)</td>
</tr>
</tbody>
</table>

Archir-Prevaleat project. A national register of color-Doppler ultrasonography of the epi-aortic vessels in patients living with HIV

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Background: The introduction of effective antiretroviral (ARV) regimens has reduced mortality in patients with HIV, but has determined higher incidence of comorbidities like cardiovascular disease (CVD). Measurement of carotid Intima Media Thickness (IMT) with color-Doppler ultrasonography is a non-invasive, sensitive technique for identifying and quantifying atherosclerotic lesions. IMT measurement is especially important because it is predictive of future CV events.

Aim: PREVALEAT (PREmature VAascular Lesions and Antiretroviral Therapy) is a multicenter, longitudinal cohort study involving several Italian centers, aimed to the evaluation of CV risk in HIV-infected patients since 1998. Our aim is to generate a National Register of color-Doppler ultrasonography (Archir-Prevaleat) to evaluate the characteristics of vascular lesions in HIV patients.

Material and methods: The project involves, at present, 9 Italian centers in which the ultrasonographic examination is performed by specifically trained physicians during a Continuing Medical Education stage. The Register is made by an on-line platform aimed at collecting data regarding patients routinely submitted to the examination. We have enrolled until now 159 patients who performed color-Doppler ultrasonography whose data are summarized in Table 1. IMT of common and internal carotid for both left and right sides is registered. IMT of>1 mm is considered pathological. Atherosclerotic plaques, if present, are described.

Results: The tendency is to perform the investigation in older patients, in males and subjects with an history of AIDS. The prevalence of IMT>1 has been 22.6% at left carotid bulb, 13.6% at right carotid bulb, 12.6% at left common carotid and 11.7% at right common carotid (Fig.A).

Conclusions: The preliminary data of our Register show an unexpectedly high prevalence of pathological IMT even if the investigation is performed in patients at higher risk. This will prompt extend the investigation to all patients and will help to prevent CVD, that may have a negative impact on long-term prognosis.
Clinical and demographics characteristics are summarized in Table 1. CVD was diagnosed in 45 patients out of 98 (overall prevalence 45.2%; 29 (29.5%) had a non-ischemic heart disease, whereas 16 (16.3%) presented a coronary artery disease (CAD). All patients with CVD were treated with medical therapy. Four out of 16 patients with CAD were diagnosed with critical CAD and underwent coronary revascularization (3 percutaneous, 1 surgical). 1 had a silent myocardial infarction with no evidence of myocardial viability. At multivariate analysis only FS ≥ 20 was associated with higher risk of CVD (p = 0.06). Nevertheless, 8 (21.5%) patients with FS < 10 had a CVD. Levels of hCRP, Lp(a), IL-6 and NT-pro BNP were not significantly associated with CVD. Conclusion: CVD is increasingly common in HIV positive patients. According to our experience FS may underestimate the real cardiovascular risk burden in HIV asymptomatic positive patients. A diagnostic-therapeutic work-up may be useful to unmask CVD in patients with no prior history of cardiovascular accident.

Figure 1. Diagnostic work-up

**PE9/62**

Bone mineral density changes in young African women on tenofovir disoproxil fumarate antiretroviral therapy and non-hormonal contraception

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Purpose: There are limited prospective data on bone mineral density (BMD) changes in HIV infected young women in low income countries initiating tenofovir disoproxil fumarate (TDF) containing antiretroviral therapy (ART). The NIH funded BONE: CARE study (R01AI118332) enrolled HIV infected depot medroxyprogesterone acetate (DMPA), or non-hormonal contraceptive users initiating TDF based ART, as well as an HIV, DMPA unexposed control group. We compare longitudinal data on BMD changes 2 years post TDF initiation among infected non-hormonal users compared to un-infected controls.

**Method:** Women were recruited from HIV care centers and general health facilities in and around Kampala, Uganda and classified into 4 groups: A) HIV+/DMPA-/TDF; B) HIV+/DMPA+/TDF; C) HIV-/DMPA-/TDF; and D) HIV-/DMPA+/TDF. All HIV-infected women were ART-naive at baseline. We compare longitudinal data on BMD changes 2 years post TDF initiation among infected non-hormonal users compared to un-infected controls.

**Results:** Between March 2015 and October 2017, we screened 549 women. Of the 529 women enrolled, 176 were non-hormonal contraceptive users; 109 HIV-infected and 69 uninfected. The median age was 25. There was greater adjusted BMD percent decline among HIV-infected women than controls at the LS and NF compared to HIV-uninfected women (p=0.01, and 0.004 respectively) but not at the TH (p=0.718), figure. Prior use of DMPA≥2 years

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pre-ART initiation was not significantly associated with greater BMD loss among infected women.

Differences in bone mineral density among 2 years post TDF initiation among infected non-hormonal users compared to un-infected controls

<table>
<thead>
<tr>
<th>Body site</th>
<th>Crude % difference in mean BMD change (95% CI)</th>
<th>P-value</th>
<th>Adjusted % difference in mean BMD change (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar spine</td>
<td>-0.75 [-1.25 to -0.27]</td>
<td>0.002</td>
<td>-0.90 [-1.46 to -0.36]</td>
<td>0.001</td>
</tr>
<tr>
<td>Total</td>
<td>0.086 [-0.35 to 0.53]</td>
<td>0.703</td>
<td>-0.09 [-0.58 to 0.40]</td>
<td>0.716</td>
</tr>
<tr>
<td>Femur neck</td>
<td>-0.73 [-1.38 to -0.09]</td>
<td>0.026</td>
<td>-1.04 [-1.75 to -0.33]</td>
<td>0.004</td>
</tr>
</tbody>
</table>

Adjusted for age, BMI, education and baseline BMI

Conclusion: HIV-infected non-hormonal users experienced significantly greater BMD loss at the LS and TH. Data from DMPA users in this cohort will establish the additional effect of DMPA use on BMD among women on TDF.

PE9/63

Examination of HIV-infected patients regarding weight gain while using integrase inhibitors in Japan

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Purpose: The purpose of this study was to confirm the change in weight of HIV-infected patients using integrase inhibitors (doltegravir, raltegravir) over time, and to examine the change in weight.

Method: We targeted HIV-infected patients going to hospital from January 2014 to January 2018 in our university hospital. A triple drug regimen using one integrase inhibitor as the key drug and two reverse transcriptase inhibitors as the backbone was targeted for HIV patients who continued to take medication for 2 years. HIV-infected patients using integrase inhibitors were 25 doltegravir and 22 raltegravir. These patients aren’t naive. All have been treated as switch regimen cases. We analyzed using Wilcoxon’s rank sum test.

Results: All genders were male, with a median overall age of 46 (32 to 74). BMI was 24.11 (17.69–33.34), the average number of CD4 positive cells was 549 (326–1223), and HIV-RNA level was less than 20 copies/mL or undetected. In the doltegravir-treated group, body weight at one year after the previous value increased by an average of 1.9 kg, and after two years, body weight increased by an average of 3.02 kg (p<0.001). In the raltegravir group, the body weight one year after the previous value decreased by an average of 0.004 kg, and after two years, the body weight increased by an average of 0.03 kg and did not change significantly throughout the two years (p=0.566).

Conclusion: After two years of follow-up and comparison of the body weight of the two integrase inhibitors, it was found that the weight gain of doltegravir tends to be higher than that of raltegravir. Further accumulation of cases is considered necessary and will be studied.

PE9/64

The relationship between diabetes and depressive symptoms in men with or at risk for HIV

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Purpose: To compare the prevalence of comorbid diabetes and depressive symptoms between men with and at risk for HIV and to determine the associations between glycemic control and depressive symptoms.

Method: We conducted a cross-sectional analysis in HIV+ and HIV− men in the Multicenter AIDS Cohort Study (MACS). The exposure of interest was glycemic status, categorized as normal for fasting blood glucose (FBG) <100 mg/dL, prediabetes for FBG 100–125 mg/dL, and type 2 diabetes (T2D) (defined by self-report, diabetes medication use, or FBG ≥126 mg/dL for ≥2 consecutive visits). T2D was further categorized as controlled (HbA1C <7.5%) or uncontrolled (HbA1C ≥7.5%). The primary outcome, elevated depressive symptoms, was defined as a Center for Epidemiologic Studies Depression Score ≥16. A modified Poisson regression model with robust variance was used and adjusted for covariates including HIV-serostatus, body mass index, and depression treatment.

Results: The study included 920 HIV+ men and 840 HIV− men. HIV+ men had greater prevalence of depressive symptoms (28.5% vs 20.1% among HIV− men, p=0.001) but a similar prevalence of diabetes (12.83% vs.11.31%, p=0.330). The concomitant prevalence of diabetes and elevated depressive symptoms did not differ by HIV-serostatus (p=0.516). Compared to normal glycemic status, the adjusted prevalence ratios of elevated depressive symptoms were 1.06 (95% CI 0.82, 1.37) in men with prediabetes, 1.21 (95% CI 0.89, 1.65) in men with controlled T2D, and 1.55 (95% CI 1.06, 2.28) in men with uncontrolled T2D (Table 1). The associations between glycemic status and elevated depressive symptoms did not differ by HIV-serostatus (p=0.32).

Conclusion: Uncontrolled T2D was independently associated with depressive symptoms, regardless of HIV-serostatus. Longitudinal studies are needed to examine whether the relationship between glycemic status and incident elevated depressive symptoms differs by HIV-serostatus.

PE9/65

Predictors of sarcopenia and its impact on components of the frailty phenotype in an Asian population living with HIV

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1The Chinese University of Hong Kong, Hong Kong, Hong Kong 2Princess Margaret Hospital, Hong Kong, Hong Kong, China

Purpose: We aim to study the prevalence and predictors of sarcopenia in people living with HIV (PLWH) in Asia. The impact of sarcopenia on the components of frailty phenotype is explored.

Method: We performed a prospective observational cohort study in Hong Kong involving PLWH aged≥18 years (N=251). Sarcopenia was defined by appendicular skeletal muscle index (ASM-index: lean mass of extremities/height$^2$) <7.0 kg/m$^2$ in men and≤4.9 kg/m$^2$ in women according to the Asian Working Group for Sarcopenia, as measured by DXA. The Fried frailty phenotype (unintentional weight loss, exhaustion, low physical activity, and diminished gait speed and grip strength) was assessed in a subgroup of this cohort (N=142). Comparisons between groups were performed with Chi square test, Mann Whitney U tests and one-way ANOVA as appropriate. Multivariable binary logistic regression model was performed to determine predictors of sarcopenia.

Results: Mean±SD age was 52 ± 13 years, 209 (83.3%) were male, and 233 (92.8%) were Chinese. The duration of HIV diagnosis was 7 (IQR 1–13) years, 27 (10.8%) had hepatitis B. In this cohort, 105 (41.8%) had sarcopenia. Sarcopenia was independently associated with Chinese ethnicity (adjusted odds ratio [aOR 6.2 [95% CI 1.0–39.1]), hepatitis B (aOR 4.9 [1.6–15.7]), body weight (aOR 0.87 [0.84–0.91]), and exposure to stavudine (aOR 2.4 [1.1–5.4]), adjusted for confounders (Table).

Among the five components of frailty phenotype, sarcopenia was associated with weak hand grip (39.4% vs. 13.7%, p=0.001), low physical activity (24.2% vs. 10.7%, p=0.032), and weight loss (21.9% vs. 8.2%, p=0.024). A significant reduction of ASMI was observed with increasing number of deficits in the frailty phenotype (p=0.001) (Figure).

Conclusion: In an Asian cohort of PLWH, sarcopenia was present in 42%, and was associated with Chinese ethnicity, hepatitis B, low body weight and exposure to stavudine. Sarcopenia was associated with several components of the frailty phenotype.
Variables associated with sarcopenia in univariate analysis

<table>
<thead>
<tr>
<th>Variables</th>
<th>Sarcopenia N=105</th>
<th>No sarcopenia N=146</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chinese</td>
<td>103 (98.1%)</td>
<td>130 (89.0%)</td>
<td>0.006</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>17 (16.2%)</td>
<td>10 (6.8%)</td>
<td>0.018</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>10 (9.5%)</td>
<td>3 (2.1%)</td>
<td>0.008</td>
</tr>
<tr>
<td>History of AIDS</td>
<td>42 (40.0%)</td>
<td>41 (28.1%)</td>
<td>0.048</td>
</tr>
<tr>
<td>Body weight, kg</td>
<td>58.1 ± 8.0</td>
<td>71.4 ± 13.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Exposure to stavudine</td>
<td>26 (24.8%)</td>
<td>20 (13.7%)</td>
<td>0.025</td>
</tr>
</tbody>
</table>

![Appendicular skeletal muscle mass according to number of deficits in the Fried frailty phenotype](image)

PE9/67

High prevalence of left ventricular systolic dysfunction assessed by speckle tracking in asymptomatic HIV patients

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2Laikon Athens General Hospital and Medical School, National and Kapodistrian University of Athens, Department of Cardiology, Athens, Greece

Purpose: Advancements in the care of people living with HIV (PLWHIV), have shifted care from a cohort of young otherwise healthy individuals to an aging population with comorbidities. Immune dysregulation, inflammation and exposure to HAART have been associated with cardiomyopathy and peripheral vascular disease, aside from traditional risk factors. Diagnosis at preclinical stages could enable prompt and effective therapeutic interventions.

Method: We investigated the association between global longitudinal strain (GLS), assessed by 2–D speckle tracking and

a) patient history,
b) demographic and clinical baseline characteristics,
c) carotid intima-media thickness (IMT) and presence of carotid atheromatous plaque(s), measured by ultrasonography,
d) temperature difference along each carotid artery (ΔT), measured by microwave radiometry and
e) basic blood panel measurements, including high-sensitivity troponin-T (hsTnT) and NT-proBNP in virally suppressed HIV monoinfected individuals without history of cardiovascular disease.

Results: We prospectively enrolled forty PLWHIV. Baseline characteristics appear in table. Subclinical left ventricular systolic dysfunction, defined as a value of GLS>−18.7%, was prevalent in 14/40 (35%) patients. GLS was associated with age (Pearson co-efficient, r=0.410, p=0.013), history of hyperlipidemia (r=−0.370, p=0.026), BMI (r=−0.462, p=0.005), waist circumference (r=−0.471, p=0.007) and right bulb IMT (r=−0.390, p=0.036). hs-TnT levels were associated with age (r=0.513, p=0.001), current CD4 count (r=−0.357, p=0.025), serum creatinine (r=−0.338, p=0.035) and the presence of carotid plaque (r=−0.374, p=0.038). NT-proBNP levels were associated with history of diabetes (r=0.336, p=0.048) and serum creatinine (r=−0.548, p=0.001). ΔT was associated with length of TAF exposure (r=−0.402, p=0.014), but not with TDF or tenofovir, ABC exposure (r=−0.39, p=0.017), 3TC exposure (r=−0.481, p=0.003), d4T exposure (r=−0.360, p=0.029), NNRTI exposure (r=−0.374, p=0.023) and NVP exposure (r=−0.342, p=0.038).

Conclusion: Our results indicate that apart from age, a dysmetabolic component, may be implicated in the pathogenesis of premature systolic myocardial dysfunction. It appears that TAF might have a protective effect on the stability of carotid plaque.

PE9/66

Failure to restore CD4 cell count with combination antiretroviral therapy is associated with increased systemic inflammation

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2University Health Network, Biostatistical Research Unit, Toronto, Canada
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7University Health Network, NIH Allergy Institute, Toronto, Canada
8Toronto General Hospital, Immunodeficiency Clinic, Toronto, Canada

Purpose: Systemic immune activation is thought to drive non-AIDS comorbidity despite suppressive antiretroviral therapy (ART). Immunologic non-responders (INR) do not restore blood CD4 T cells to>350/mm<sup>3</sup>. We sought to characterize the inflammatory profile of INRs, including the level of T cell activation and inflammation-associated soluble markers linked to non-AIDS comorbidity. We hypothesized that co-expression of HLA-DR and CD38 and soluble immune activation-related markers by ELISA (CRP, TNF, IFNg, sCD14, D-Dimer, I-FABP, MCP-1, VCAM, ICAM) were elevated amongst INRs and require exploration as prognostic indicators.

Results: HIV-positive individuals had median (IQR) infection 16 [9, 26] years, and ART duration 12 [6, 21] years, with no difference between groups. In adjusted log-linear regression models, INRs had 35% higher CD8 activation (p=0.02), 54% higher CD4 presentation of HLA-DR (p=0.001), and 20% higher plasma VCAM (p=0.01) compared to CRs. HIV-positive individuals had higher median (IQR) CD8 (2.96 [1.88, 4.46]) compared to HIV-negatives (1.82 [1.17, 2.81], p=0.01). INR phenotype was not associated with CRP, TNF, IFNg, sCD14, D-Dimer, I-FABP, MCP-1, ICAM or CD8%DR. INRs had 35% higher CD8 activation and ART duration 12 [6, 21] years, with no difference between groups. In adjusted log-linear regression models, INRs had 35% higher CD8 activation (p=0.02), 54% higher CD4 presentation of HLA-DR (p=0.001), and 20% higher plasma VCAM (p=0.01) compared to CRs. HIV-positive individuals had higher median (IQR) CD8 (2.96 [1.88, 4.46]) compared to HIV-negatives (1.82 [1.17, 2.81], p=0.01). INR phenotype was not associated with CRP, TNF, IFNg, sCD14, D-Dimer, I-FABP, MCP-1, ICAM or CD8%DR. Conclusion: INRs, compared to CRs (and controls), had higher disease-associated CD8 activation that could be assessed as a target of intervention to improve outcomes. VCAM (marking endothelial activation) and CD4 activation were elevated amongst INRs and require exploration as prognostic indicators.

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Baseline characteristics of study cohort

<table>
<thead>
<tr>
<th>Variable</th>
<th>% or Value ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>51.6 ± 12.6</td>
</tr>
<tr>
<td>Male gender, %</td>
<td>92.5</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>30.0</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>15.0</td>
</tr>
<tr>
<td>Dyslipidemia, %</td>
<td>42.5</td>
</tr>
<tr>
<td>Chronic kidney disease, %</td>
<td>7.5</td>
</tr>
<tr>
<td>Body mass index (BMI), kg/m²</td>
<td>26.3 ± 4.9</td>
</tr>
<tr>
<td>Troponin-I, pg/mL</td>
<td>7.2 ± 6.2</td>
</tr>
<tr>
<td>NT-proBNP, pg/mL</td>
<td>51 ± 76</td>
</tr>
</tbody>
</table>

PE9/68

Polypharmacy and drug-drug interactions – prevalence in a Portuguese HIV Metabolic Clinic

J Fragoso¹, D Guerra¹, I Furtado¹, F Santos¹, C Silva¹, I Gonçalves¹, MJ Gonçalves¹, MA Abreu¹, J Méndez¹ and R Sarmento-Castro¹

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Introduction: With the advent of more effective and tolerable antiretroviral drugs, HIV patients are living longer. Ageing translates in an increasing rate of comorbidities, requiring chronic treatment. Therefore, polypharmacy has become a challenge in the mainstream treatment of this population.

Objective: Evaluate the frequency of polypharmacy and potential drug-drug interactions (DDI) in patients attending our HIV metabolic clinic.

Methods: Retrospective study with review of clinical records of patients that attended the HIV metabolic clinic between June 2018 and June 2019. Polypharmacy was defined by use of ≥5 medications not including antiretrovirals (ARV). Interactions were assessed using according to University of Liverpool database. Statistical analysis was performed using IBM SPSS 25.

Results: Two hundred and ten patients attended the consultation. Seventy-eight percent (n=164) were male. Mean age was 53 yo (min. 23 max 82) and 45.2% (n=95) were 55 yo or older. The main concomitant medications were statins in 45.4% of the patients, anti-hypertensive in 36.4% and colecalciferol in 38.6%.

Polypharmacy was found in 24.9% and was more prevalent in patients>55 yo (p=0.00), with lower CD4 + nadir (p=0.05) and with longer TARV exposure (p=0.05).

DDI were present in 34.3% of the patients. The antiretroviral classes implied in DDI were protease inhibitors (39.5%), non-nucleoside analogues (31.5%), integrase inhibitors (23.7%) and nucleoside analogues (5.3%). Two patients had concomitant medications that were contraindicated and in one patient the medication could potentially decrease ARV exposure.

Associating antiretroviral drugs, the pill burden in the polypharmacy group was 7.7 pills versus 3.5 pills in non-polypharmacy group (p=0.00).

Conclusion: We found a polypharmacy prevalence of 24.9% mainly in older with lower CD4 + and longer TARV exposure. The DDI frequency was 34.3%. Facing these results, we emphasize the importance of previous checking of potential interactions whenever a new drug is added.

PE9/69

Bone density alterations in the HIV-infected patient – epidemiologic characterization of a Portuguese cohort

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Background: Over 36 million people are infected with HIV making it one of the world’s most serious public health problems. Today, the average life expectancy of HIV-infected patients is on the rise thanks to combined antiretroviral therapy. Therefore, long-term comorbidities, such as decreasing bone density, became a major concern.

PE9/70

Cigarette smoking disproportionately impacts nitric oxide signaling in pulmonary artery endothelial cells in HIV: role of viral and host factors

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Purpose: The objective of this study is to determine whether cigarette smoking (CS) disproportionately impacts the pulmonary artery endothelial cell (PAEC) function and increases the risk of HIV-PAH. Studies have shown that the circulating HIV-1 viral accessory protein, Negative factor (Nef), binds to the host C-X-C motif chemokine receptor 4 (CXC4) on endothelial and other cells. We hypothesized that CS increases CXCR4–Nef interaction, which results in the downstream impairment of endothelial nitric oxide synthase (NOS3) dependent vasodilation and the development of HIV-PAH.

Methods: Smokers and non-smokers with and without HIV-1 infection were recruited at the University of Alabama at Birmingham HIV 1917 clinic. All HIV positive patients were on ART and had low blood viral load. Plasma levels of endothelial cell function markers were measured. To determine the role of CS in Nef-CXCR4 interaction and NOS3 dysfunction, human PAECs (HPAECs) were treated with recombinant Nef protein in the presence or absence of cigarette smoke extract (CSE), and CXCR4 binding to Nef, NOS3 expression and function was assessed. It was also determined whether the pharmacological inhibition of CXCR4 by AMD3100 attenuated Nef signaling.

Results: HIV positive smokers had significantly lower plasma levels of endothelial markers, nitrite/nitrate (stable metabolic products of nitric oxide), eGMP, and prostacyclin compared to HIV positive non-smokers or HIV negative smokers. Exposure to 2% of CSE increased CXCR4 protein levels in HPAEC and increased CXCR4–Nef interaction when these cells were treated with recombinant Nef. CSE and Nef also reduced plasma membrane expression of NOS3, cellular nitrite/nitrate and eGMP levels. Treatment of cells with AMD3100 abrogated effect of Nef on cells.

Conclusion: The data suggests that CS dependent Nef/CXCR4 signaling is an important driver of endothelial dysfunction in HIV and CXCR4 inhibition can be a potential therapeutic target for HIV-PAH.
PE9/71
Frailty phenotype in older virologically suppressed PLWHIV is strongly correlated with specific comorbidities and tobacco use
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Purpose: People living with HIV (PLWHIV) are mostly virologically suppressed. Frailty phenotype in older virologically suppressed PLWHIV. This state precedes polypathology or disabilities and undermines one's health. It is strongly correlated with specific comorbidities and tobacco use. Our study strongly suggests that comorbidities are the main factors that convey the embrittlement state of older virologically suppressed PLWHIV. This state precedes polyopathology or disabilities and undermines one's capacity to fight against mental or physical maladies. Efficient medical follow-up focusing on preventing comorbidities especially in individuals with cancer history, could delay frailty as well as its associated adverse outcomes.

PE9/72
HIV-FUNCRAIL study: differences between women and men aging with HIV
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Purpose: To evaluate differences between women and men aging with HIV.
Methods: Prospective cohort study. Patients from the "HIV-FUNCRAIL: Multicenter spanish cohort to study frailty and physical function in 50 years or older HIV-infected patients" were included and stratified by sex. We recorded sociodemographic data, comorbidities, variables related to HIV infection, frailty, physical function, VACS index and pain as a quality of life measurement.
Results: We evaluated 563 PLWH who were 50 years old or over, of which 146 (25.8%) were women. Median age was 56.2 (IQR:69) years. Median current CD4 + T-cell count was 711 (IQR:461) in women and 655 (IQR:421) in men (p=0.0002). Median CD4/CD8 ratio was 0.9 in women to 0.7 men (p=0.0001). There were differences in comorbidity between women and men regarding ischaemic heart disease, non-AIDS malignancy in the past, depression and osteoarticular pathology. Mean number of comorbidities was 2.9 (SD 1.9) in women and 2.6 (SD 1.8) in men (p=0.025) in men. Polypathy was significantly higher among women (28.7% vs 19.4% p=0.026) and particularly the use of neuroleptics, painkillers and opioids. Pain was more prevalent in women than in men [54.9% vs 34.7% (p=0.013)]. No differences were found regarding frailty, physical function (SPPB, grip speed), falls, while revealing associations with cancer history, tobacco use and CD4 T cell nadir count less than 200/mm3.
Conclusion: Our study strongly shows that comorbidities are the main factors that convey the embrittlement state of older virologically suppressed PLWHIV. This state precedes polyopathology or disabilities and undermines one's capacity to fight against mental or physical maladies. Efficient medical follow-up focusing on preventing comorbidities especially in individuals with cancer history, could delay frailty as well as its associated adverse outcomes.

PE9/73
Prevalence, risk factors and outcomes of cardiovascular, metabolic and chronic kidney diseases in HIV-infected vs. uninfected adults in sub-Saharan Africa: a systematic review and meta-analysis
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Purpose: To evaluate differences between women and men aging with HIV. Methods: Prospective cohort study. Patients from the "HIV-FUNCRAIL: Multicenter spanish cohort to study frailty and physical function in 50 years or older HIV-infected patients" were included and stratified by sex. We recorded sociodemographic data, comorbidities, variables related to HIV infection, frailty, physical function, VACS index and pain as a quality of life measurement.
Results: We evaluated 563 PLWH who were 50 years old or over, of which 146 (25.8%) were women. Median age was 56.2 (IQR:69) years. Median current CD4 + T-cell count was 711 (IQR:461) in women and 655 (IQR:421) in men (p=0.0002). Median CD4/CD8 ratio was 0.9 in women to 0.7 men (p=0.0001). There were differences in comorbidity between women and men regarding ischaemic heart disease, non-AIDS malignancy in the past, depression and osteoarticular pathology. Mean number of comorbidities was 2.9 (SD 1.9) in women and 2.6 (SD 1.8) in men (p=0.025) in men. Polypathy was significantly higher among women (28.7% vs 19.4% p=0.026) and particularly the use of neuroleptics, painkillers and opioids. Pain was more prevalent in women than in men [54.9% vs 34.7% (p=0.013)]. No differences were found regarding frailty, physical function (SPPB, grip speed), falls, while revealing associations with cancer history, tobacco use and CD4 T cell nadir count less than 200/mm3.
Conclusion: Our study strongly shows that comorbidities are the main factors that convey the embrittlement state of older virologically suppressed PLWHIV. This state precedes polyopathology or disabilities and undermines one's capacity to fight against mental or physical maladies. Efficient medical follow-up focusing on preventing comorbidities especially in individuals with cancer history, could delay frailty as well as its associated adverse outcomes.

Background: Sub-Saharan Africa (SSA) has the highest burden of HIV in the world; more than 25.5 million Africans are living with HIV in the region, including nearly 15 million on antiretroviral therapy (ART). Expanding use of ART has led to a notable decline in HIV-associated morbidity and death in SSA. Nonetheless, people living with HIV (PWH) in SSA are at substantially increased risk for both cardiovascular and metabolic disease (CVD) and chronic kidney diseases (CKD).
Methods: We searched electronic databases (Ovid MEDLINE and EMBASE) from 1985 to July 2018. We included studies that reported prevalence estimates for any CVD and CKD in SSA and information on HIV status and treatment status.
Results: A total of 89 studies involving 263,262 participants were included in the meta-analysis. Prevalence estimates were reported in 41 studies on hypertension (HTN), 29 on type 2 diabetes mellitus (T2DM), 14 on metabolic syndrome (MS), 9 on cardiovascular disease (CVD) and 22 on CKD. The reported
prevalence estimates varied greatly within countries, between countries and within regions: HTN (5.2% to 45.0%), T2DM (0.9% to 28.1%), MS (2.1% to 20.4%) and CKD (0.6% to 53.3%). There was no significant difference in the prevalence of HTN and T2DM between HIV-infected and -uninfected participants. The prevalence of MS (OR=1.66, 95% CI 1.01 to 2.72, 2 studies) and CKD (OR=2.30, 95% CI 1.12 to 4.72, 6 studies) were higher in HIV-infected participants than HIV-uninfected participants.

Conclusions: The burden of CVMD and CKD among PWH in SSA is high, although there are wide variation within and across countries and regions. A better understanding of the complex interplay of genetic, environmental and HIV-factors in the pathogenesis of these comorbidities is essential. Furthermore, rigorous implementation science to determine optimal screening, prevention and treatment strategies in PWH in SSA is also critical.

PE9/75

APOL1 high risk genotype has an adverse impact on kidney function in African HIV-infected patients with high viral load

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Purpose: To determine the impact of APOL1 high-risk genotype (HR) on kidney function in African HIV patients starting a second line antiretroviral treatment (ART).

Method: Patients from Africa were randomized to receive one of three second line combinations (randomized phase 3 trial ANRS 12169). In this sub-study, we genotyped the APOL1G1 and G2 risk alleles through Taqman and defined HR by the carriage of two risk alleles (G1/G1, G1/G2 or G2/G2) vs. low-risk genotype (LR: G0/G0, G0/G1 or G0/G2). The kidney function was assessed by the CKD-EPI estimated glomerular filtration rate (eGFR). Logistic regression and mixed linear models were implemented to test the association of APOL1 HR with rapid eGFR decline (>5 mL/min/1.73 m²/year) and eGFR evolution over time, respectively.

Results: 370 patients (71% female) from Cameroon (294), Burkina Faso (47) and Senegal (29) were included. 27(7.3%) patients had hypertension and 11 (3.0%) had an eGFR<60 mL/min/1.73 m² at baseline. Median (interquartile-range) baseline characteristics were 38.4 (33.2–46.3) yo, 176(78–288) CD4 T-cells/µl, 4.5 (4.1–5.1) log(viral load)/mL and 95.7 (80.9–111.2) mL/min/1.73 m² for eGFR. 12 patients (3.2%) were APOL1 HR. Patients were on the second line ART for 57.9 (46.7–64.7) months. During follow-up, eGFR increased of 2 (95% CI: 2.4; 2.6) mL/min/1.73 m² per year. Patients with baseline high viral load (>2 log/mL) and APOL1 HR had higher risk of rapid decline in eGFR (adjusted OR=24.9[1.5;419.5]) and tend to have a lower improvement in eGFR over time (adjusted b=–3.2;–6.8;0.4)mL/min/1.73 m²/year than patients with baseline low viral load and APOL1 LR (figure).

Conclusion: Compared to previous reports, the APOL1 HR prevalence was low in our cohort (Estrella, 2015; Ekuw, 2019). In patients with baseline high viral load, those with APOL1 HR exhibit a suboptimal improvement in kidney function on second line ART.

Individual and predicted longitudinal estimated glomerular filtration rate (eGFR) by APOL1 high-risk
Comparison of 2 frailty scores in PLWHIV aged 50 and over: SOF index and FRIED phenotype

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Purpose: The overall life expectancy of people living with HIV (PLWHIV) is increasing mainly due to access to highly active antiretroviral treatment and multidisciplinary care. The prevalence of frailty among PLWHIV is frequent and begins earlier compared to the general population. The measurement of frailty in PLWHIV is currently recommended but the best identification tool remains to be defined. The objective of this study was to compare the frailty criteria according to the FRIED phenotype and the SOF index (Study of Osteoprototic fractures) in PLWHIV.

Method: This multicentre, cross-sectional study included 509 PLWHIV aged 50 and over treated in 12 French hospitals. Demographic data, comorbidities, HIV data, geriatric parameters, Fried phenotype fragility markers and the SOF index were collected.

Results: Among the 509 PLWHIV (73% male, mean age 58.4 ± 7 years), according to the Fried phenotype 58.8% were pre-fragile and 8.2% were fragile; according to the SOF index, 37.1% were pre-fragile and 11.2% were fragile. The SOF index was weakly correlated with Fried’s phenotype, with a Kappa score=0.267 ± 0.042 for patients classified as “fragile and pre-fragile” versus “robust” patients. In multivariate analysis, the presence of Fried’s phenotype fragility markers was associated with the risk of depression, falls and a history of cancer. Frailty according to the SOF index was significantly associated with precariousness, incapacity for activities of daily living, risk of depression and falls.

Conclusion: In PLWHIV, over the past five years the SOF index and Fried’s phenotype are low correlated scores. The use of Fried’s phenotype identifies more pre-fragile and fragile patients and therefore to be potentially more useful in identifying fragility in this population. Prospective studies assessing frailty and the risk of adverse change in morbidity and mortality are crucial in order to define relevant screening tools for this population.

PE9/78

Could we consider the intima-media thickness (c-IMT)>1 mm as a risk factor for cardiovascular diseases in HIV+ subjects chronically treated with antiretrovirals?

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Background: HIV patients have a higher risk to develop cardiovascular diseases, which may be related to chronic inflammation and associated endothelial dysfunction. The relationship between carotid intima-media thickness (c-IMT) and cardiovascular risk has not been fully explored in HIV patients on antiretroviral therapy (cART).

Methods: A cross-sectional study on 130 HIV+ on cART was performed to evaluate the relationship between c-IMT and several parameters: epidemiological, immunological (CD4 nadir, CD4/CD8 ratio), virological (HIV-RNA), metabolic (total cholesterol, HDL, LDL, triglycerides) and clinical (time from HIV diagnosis, time on treatment, hypertension, diabetes or dyslipidemia). Mean value of the bilateral cIMT was considered for the quantitative analysis, whereas the greatest value for the qualitative analysis (cut-off 1 mm). Cardiovascular risk was assessed using ASCVD risk calculator.

Results: Data of our population are resumed in Tables 1 and 2. Among 130 patients, 56 (43.1%) had c-IMT>1 mm. These patients are older, have a longer history of infection and treatment, with lower CD4 nadir (p=0.0009). Furthermore, we observed a negative correlation between c-IMT and Framingham score (r=-0.13 p=0.005).

Conclusions: Annexin levels were significantly correlated with high risk CVD. We work demonstrate a correlation between the inflammatory annexins and the results obtained from the cardiovascular risk scores in HIV population. This work highlight how inflammation participates in the pathogenesis of cardiovascular damage and circulating levels of Annexins will be useful in improving cardiovascular risk calculation.

PE9/77

Annexin V, Annexin A1 and cardiovascular risk in HIVpopulation

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Background: Whereas HIV-related mortality has decreased, rate of CVD death has increased(1). The endothelium plays a pivotal role in the pathogenesis of atherosclerosis. Several studies suggest that endothelial dysfunction is an independent predictor of adverse events in CVD patients(2). Annexins are one of the classes of proteins regulated by Ca2+ levels, characterized by a unique architecture that allows them to regulate different cellular events such as membrane morphology and organization, cytoskeletal activity. The presence of extracellular annexins, such as Annexin A1 (AnxA1) and Annexin V (AnxV), is particularly evident in inflammation, a condition in which the annexins play an anti-inflammatory role. In addition, low AnxV levels are related to a greater atherosclerotic and thrombotic risk in systemic diseases.

The aim of this study is to evaluate the relation between plasmatic AnxV and AnxA1 and cardiovascular risk scores in patients with HIV infection in viro-immunological stability.

Methods: We enrolled 222 HIV-positive outpatients in cART at the Infectious Diseases Clinics of Chieti and Roma. Demographic and anamnestic data were collected, blood and immunological parameters were measured and AnxA1 and V1 were analyzed. Framingham and DADS as CVD Risk scores were calculated.

Results: Levels of AnxA1 was 16.74 ± /-19.02 ng/mL and AnxV was 1.4 ± /-1.9 ng/mL; DADS was 2.27 ± 2.54 and Framingham was 8.52 ± 6.5. We found a negative association between DADS score and AnxV (r=-0.17 p=0.008) and AnxA1(r=-0.17 p=0.01). Furthermore, we observed a negative correlation between AnxA1 and Framingham score (r=-0.13 p=0.05).

Conclusions: Annexins levels were significantly correlated with high risk CVD. Our work demonstrate a correlation between the inflammatory annexins and the results obtained from the cardiovascular risk scores in HIV population. This work highlight how inflammation participates in the pathogenesis of cardiovascular damage and circulating levels of Annexins will be useful in improving cardiovascular risk calculation.
**Table 1. Epidemiological, clinical, virological data**

<table>
<thead>
<tr>
<th>Variables</th>
<th>N=130</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (IQR) Age (years)</td>
<td>47.50 (40–53.35)</td>
</tr>
<tr>
<td>Median (IQR) Years of Infection (years)</td>
<td>9 (5–19)</td>
</tr>
<tr>
<td>Median (IQR) Time on Treatment (years)</td>
<td>7.5 (4–18)</td>
</tr>
<tr>
<td>Media ± DS Zetin HIV – RNA (log copies/mL)</td>
<td>5.0 ± 0.7</td>
</tr>
<tr>
<td>Median (IQR) Nadir CD4 (cell/μL)</td>
<td>259 (119.50–375)</td>
</tr>
<tr>
<td>Median (IQR) CD8 (cell/μL)</td>
<td>765.50 (579.25–1112.75)</td>
</tr>
<tr>
<td>Median (IQR) CD4/CD8 (ratio)</td>
<td>0.91 (0.57–1.1)</td>
</tr>
<tr>
<td>Median (IQR) right cIMT (mm)</td>
<td>0.80 (0.60–1.10)</td>
</tr>
<tr>
<td>Median (IQR) left cIMT (mm)</td>
<td>0.80 (0.60–1.03)</td>
</tr>
</tbody>
</table>

**Table 2. Comparison between data collected in subjects with IMT more than or below 1 mm (univariate analysis)**

<table>
<thead>
<tr>
<th>Variables</th>
<th>ClMT ≤ 1 mm: 74 (56.9%)</th>
<th>ClMT &gt; 1 mm: 56 (43.1%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male 61 (82%)</td>
<td>48 (85.7%)</td>
<td>ns</td>
</tr>
<tr>
<td>Risk Factors</td>
<td>MSM 47 (63.5%)</td>
<td>27 (48%)</td>
<td>ns</td>
</tr>
<tr>
<td></td>
<td>IDU 6 (8%)</td>
<td>6 (10.7%)</td>
<td>ns</td>
</tr>
<tr>
<td>Age</td>
<td>Years 43 (35–50)</td>
<td>52 (47–57.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Time from HIV</td>
<td>Years 7 (3.75–12)</td>
<td>16 (8.25–21)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Time on cART Years 6 (3–10)</td>
<td>14 (7.25–19)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>HIV-RNA VL</td>
<td>Cases 67 (90.5%)</td>
<td>48 (85.7%)</td>
<td>ns</td>
</tr>
<tr>
<td></td>
<td>value (%)</td>
<td>(%)</td>
<td>(%)</td>
</tr>
<tr>
<td>Nadir CD4</td>
<td>321 (168.5–425)</td>
<td>146.5 (73–306)</td>
<td>0.01</td>
</tr>
<tr>
<td>ASCVD risk</td>
<td>Cases 11 (16%)</td>
<td>20 (35.7%)</td>
<td>0.011</td>
</tr>
<tr>
<td></td>
<td>value &gt;7.5%</td>
<td>(%)</td>
<td>(%)</td>
</tr>
</tbody>
</table>

**PE9/79 Immune reconstitution inflammatory syndrome (IRIS) in HIV–infected hospitalized patients with advanced disease**

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**Purpose**: The purpose of this study is to describe clinical characteristics of HIV–infected hospitalised patients who develop IRIS between January 2009 and December 2018 in a tertiary Public Health System hospital of Madrid (Spain).

**Method**: Retrospective single-centre study of HIV patients treated with HAART.

**Results**: During the study period, 678 hospital admissions of 313 HIV patients were registered. Of them, 141 patients (45%) had detectable viral load, most of whom (60%) were not receiving ART at baseline. 48 patients (34%) did not know HIV diagnosis before admission (of which 70% was diagnosed with advanced disease stage). 75% were men, median age was 45 years old (IQR 39–51) and the most probable way of HIV acquisition was IDU (27%). IRIS was related to Mycobacterium (27%), cytomegalovirus (27%), Pneumocystis jiroveci (13.6%), progressive multifocal leucoencephalopathy (9%), Castleman’s disease (9%), Kaposi sarcoma (4.5%), histoplasmosis (4.5%), and leishmaniasis (4.5%). Baseline CD4 + T-cell count were 70/mm3 (IQR 23–167) and 107/mm3 (IQR 26–320), respectively, IRIS occurred in 22 patients (15.6%). IRIS was defined as a value of BMI affects 5% of HIV-population and is associated with increased mortality.

**Objectives**: Assess the proportion of patients naive to antiretroviral treatment (ART) with low BMI at treatment start; describe their demographic and clinical features; evaluate immunological, virological, clinical and therapeutic outcomes.

**Methods**: Naive subjects who started any ART in 2008–2018 within the ICONA cohort and with a measure of BMI available before ART were included. Descriptive statistics and non-parametric (Chi-square and Kruskal-Wallis)
tests were used; KM probability curves and multivariable Cox regression models for virological failure, treatment discontinuation and clinical events were used. Mean changes in CD4 and CD8 cell count from fitting a linear mixed model after ART start were estimated.

Results: 5,921 subjects were included: 315 individuals (5.3%) showed a BMI below 18.5. Subgroups stratified according to BMI resulted different in terms of demographic, clinical and social features (Table 1). In the unadjusted analysis, baseline BMI class was associated with a significantly different risk of virological failure and treatment discontinuation with a worse trend for the group with BMI<18.5, while no correlations with clinical events were observed (Figure 1). The difference in risk of virological failure and treatment discontinuation was attenuated after controlling for key confounding factors (mainly age and CD4 count). CD4 count and CD4/CD8 ratio trend over time had no correlation with BMI, while CD8 count showed a steeper slope of decrease during ART in low and obese BMI classes.

Conclusion: BMI<18.5 is uncommon in ART naive subjects but is related to virological failure and treatment discontinuation, although age and pre-ART CD4 count played the pivotal role. Low BMI is an indicator of vulnerability and might be considered as a predictor of treatment failure.

Figure 1. KM estimates for virological failure, drug discontinuation and clinical events

PE9/81
Sistatin C, KIM1 and NGAL as biological markers for detecting early kidney injury in HIV positive patients
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Purpose: HIV positive people are at increased risk for kidney damage because of the disease itself, comorbidities and drugs used. Proteinuria and eGFR are not enough for early diagnosis. In this study our aim is to investigate the role of Cystatin C, Kidney Injury Molecule-1 (KIM1) and Neutrophil Gelatinase-Associated Lipocalin (NGAL) in early kidney damage.

Method: Sample size was calculated and 88 HIV positive patients who admitted to Infectious Diseases Outpatient Clinic and were willing to participate the study were enrolled. 81 control patients were selected among healthy volunteers. Patient demographics, underlying conditions, treatments were recorded. Cystatin C, Kidney Injury Molecule-1 (KIM1) and Neutrophil Gelatinase-Associated Lipocalin (NGAL) were studied by ELISA from serum and urine samples.

Results: Mean age was 38.5 ± 12.6 and 67.5% (n=114) was male totally. There was no difference between ages of patient and control groups (p=0.05) but more women were included in the control group (13.6% vs 51.3%, p<0.001). There was a correlation between eGFR and urine NGAL (p=0.001). Mean Cystatin C, Kidney Injury Molecule-1 (KIM1) and Neutrophil Gelatinase-Associated Lipocalin (NGAL) levels of patient and control groups are shown in Table 1. eGFR, serum Cystatin C, serum and urine NGAL, and serum KIM-1 was significantly lower in the patient group.

Conclusion: Serum levels of Cystatin C, NGAL, KIM-1 and urine NGAL were found lower in HIV positive patients and these biochemical markers are candidates for the diagnosis of early kidney damage in this patient population.

Mean Cystatin C, Kidney Injury Molecule-1 (KIM1) and Neutrophil Gelatinase-Associated Lipocalin (NGAL) levels of patient and control groups

<table>
<thead>
<tr>
<th>Patient (n=88)</th>
<th>Control (n=81)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>Standard</td>
</tr>
<tr>
<td>eGFR</td>
<td>107.9081</td>
</tr>
<tr>
<td>Serum_Cystatin_C</td>
<td>36.53</td>
</tr>
<tr>
<td>NGAL_serum</td>
<td>835.24003</td>
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<tr>
<td>NGAL_urine</td>
<td>111.02</td>
</tr>
<tr>
<td>KIM1_serum</td>
<td>3.94591</td>
</tr>
<tr>
<td>KIM1_urine</td>
<td>0.58628</td>
</tr>
</tbody>
</table>

PE9/82
Long-term AIDS survivors: comorbidities and polypharmacy: a new challenge
S Vela1, C Bea2, A Belmonte1, A De Gracia1, C Pinto1, MR Oltra1, R Ferrando1, A Ferrer1 and MJ Galindo Pueyo1
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Purpose: There are many people living with HIV (PLWHIV) diagnosed in the 80s and early 90s when there was no efficacious antiretroviral treatment (ART) who are still alive. They have also survived the era of lipodystrophy and other adverse events and are getting older. The objective of our study is to characterize the comorbidities and their treatment in PLWHIV of our cohort who were diagnosed before 1997.

Method: Single-centre observational, retrospective, non-interventional study carried out in a third level hospital in Spain. Our cohort included PLWHIV diagnosed before 31 December 1996 visited in the outpatient clinics at least once from January 1, 2017 to December 31, 2018. Baseline sociodemographic, clinical characteristics, ART, comorbidities and concomitant medication were analyzed using STATA 14.

Results: We included 374 patients with a mean age of 54 ± 6.14 years old of which 262 (70.05%) were men. The mean time of follow up was 27.56 ± (3.28) years. The main risk factor of transmission was the use of intravenous drugs (55.8%). 39% of them (10.5%) where diagnosed of HIV and AIDS at the same time. The most common comorbidities were: lipodystrophy 70 (77.54%), HCV coinfection 216 (57.75%), dyslipidaemia 178 (47.59%) and hypertension 93 (24.87%). Only 30 patients (8.02%) didn’t have any comorbidity. 161 (43%) had 3 or more comorbidities and 114 (30.48%) had two comorbidities. The mean Charlson Comorbidity index was 3.3 (SD 2.9) and VACS index was 23.9 (SD 15.4). The mean of treatments per patient was 4.1 ±(3) (23% of our patients ≥5 drugs). Nervous system drugs are the most frequently prescribed (35.29%) followed by alimentary tract and metabolism (21.95%) and cardiovascular system (18.78%) drugs.

Conclusion: The long-term AIDS survivors have a high prevalence of comorbidities and polypharmacy. The right management of comorbidities is a challenge to improve their quality of life and their survival.

<table>
<thead>
<tr>
<th>Comorbidities (n, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
</tr>
<tr>
<td>HCV coinfection</td>
</tr>
<tr>
<td>Hepatic steatosis</td>
</tr>
<tr>
<td>Lipodystrophy</td>
</tr>
<tr>
<td>Non AIDS malignancy</td>
</tr>
<tr>
<td>Osteopenia/osteoporosis</td>
</tr>
<tr>
<td>COPD</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
</tr>
</tbody>
</table>
Risk Factors associated to immune reconstitution inflammatory syndrome (IRIS) in HIV-infected hospitalized patients with advanced disease

A Díaz-de Santiago1, P Gonzalez-Merino2, S De La Fuente3 and A Angel-Moreno Maroto4

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2Universidad Autónoma de Madrid, Madrid, Spain

Purpose: The purpose of this study is to determine risk factors associated to IRIS in HIV-infected hospitalised patients between January 2009 and December 2018.

Method: Retrospective single-centre study of HIV patients treated with HAART.

Results: During the study period, 678 hospital admission of 313 HIV patients were registered. Of them, 141 patients (45%) had detectable viral load, most of whom (80%) were not receiving ART at baseline. IRIS occurred in 22 patients (15.6%). There were no differences by sex (12.5% of males Vs 12.9% of women, \( p = 0.061 \)). There were no differences between lopinavir, atazanavir and darunavir. Dolutegravir was most related to IRIS in INSTI group (75%; \( p = 0.0001 \)). Rapid decline in HIV viral load (2.72 log) resulted significant (95% CI 2.4–3.1; \( p < 0.00001 \)), unlike for increase in CD4 + T cell count (\( p = 0.037 \)). 42% were taking NNRTI, 10% PI and 47% INSTI (\( p = 0.023 \)). Inside NNRTI family efavirenz was most associated to IRIS (\( p = 0.061 \)). There were no differences between lopinavir, atazanavir and darunavir. Dolutegravir was most related to IRIS in INSTI group (75%; \( p = 0.017 \)). Factors associated to IRIS in multivariate analysis were: undetectable viral load before admission: aOR 0.035 (95% CI from -0.065 to -0.005; \( p = 0.021 \)). AIDS cause of hospitalization: aOR 14.7 (95% CI 5.5–45.1; \( p = 0.0001 \)). Known HIV infection duration was inferior in patients with IRIS (median difference of 10 years, 95% CI 5.5–15.1). 21% showed HCV-co-infection, vs 46% of patients without IRIS (\( p = 0.033 \)). 95% suffered from an AIDS-disease as cause of admission; IRIS was developed in 22% of patients with AIDS cause of hospitalization and 0.5% of non-AIDS reasons (\( p < 0.00001 \)). 54% did not know HIV status (6% with patients without IRIS; \( p < 0.0001 \)). 87% of patients with IRIS had severe (6% of patients without IRIS; \( p = 0.0001 \)). Rapid decline in HIV viral load (2.72 log) resulted significant (95% CI 2.4–3.1; \( p < 0.00001 \)), unlike for increase in CD4 + T cell count (\( p = 0.037 \)). 42% were taking NNRTI, 10% PI and 47% INSTI (\( p = 0.023 \)). Inside NNRTI family efavirenz was most associated to IRIS (\( p = 0.061 \)). There were no differences between lopinavir, atazanavir and darunavir. Dolutegravir was most related to IRIS in INSTI group (75%; \( p = 0.017 \)). Factors associated to IRIS in multivariate analysis were: undetectable viral load before admission: aOR 0.035 (95% CI from -0.065 to -0.005; \( p = 0.021 \)). AIDS cause of hospitalization: aOR 14.7 (95% CI 5.5–45.1; \( p = 0.0001 \)). Known HIV infection duration was inferior in patients with IRIS (median difference of 10 years, 95% CI 5.5–15.1). 21% showed HCV-co-infection, vs 46% of patients without IRIS (\( p = 0.033 \)). 95% suffered from an AIDS-disease as cause of admission; IRIS was developed in 22% of patients with AIDS cause of hospitalization and 0.5% of non-AIDS reasons (\( p < 0.00001 \)). 54% did not know HIV status (6% with patients without IRIS; \( p < 0.0001 \)). 87% of patients with IRIS had severe (6% of patients without IRIS; \( p = 0.0001 \)).

Conclusion: Detectable viral load, AIDS cause of admission and unknown HIV infection were associated to IRIS in our cohort. Efavirenz and dolutegravir could be more related drugs to IRIS but further investigations are needed.
Conclusion: Clustering analysis identified contrasted inflammation profiles with distinct associations with age, smoking and HIV-related endpoints. We found, as already shown in the literature, a cluster composed of smokers with a high degree of inflammation and a cluster of older people developing a different type of inflammation. The novelty here is the identification of a cluster of relatively young subjects, non-smokers, but developing a particular inflammatory profile.

Maps (SOm) with proposed boundaries defining clusters - Inflammatory profiles

PE9/86
Cognitive impairment in patients with HIV in a Mexican hospital
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Instituto Mexicano del Seguro Social, Infectious Diseases, Cdmx, Mexico

Purpose: To describe the clinical characteristics of patients with HIV and cognitive impairment.

Method: We conducted a pilot study in 104 patients with VIH that were seen in outpatient care at Infectious Diseases Hospital in LA Raza National Medical Center during March to December 2018. We studied 21 patients with Montreal Cognitive Assessment (MOCA) test equal or inferior to 26 points. Brain magnetic resonance, lumbar puncture and neurologic evaluation were performed.

Results: We found 12 (57.14%) female patients and 9 (42.8%) males. Most of the patients were being treated with protease inhibitors (71.42%) plus nucleoside analogue reverse transcriptase inhibitor (61.90%) by the time of the study. The incidence of HIV viral load in (CSF), which present 13% of the serum undetectable HIV patients. We divided patients into two groups, one with undetectable HIV viral load in CSF [15 patients (71.42%)] and the second one with detectable viral load in CSF [6 patients (28.57%)]. In regard to HIV duration, the first group had an average of 22.66 years with HIV, the second one with 21.73 years. Amongst CD4/CD8 relation, this was higher in the first group with a value of 0.90, versus 0.74 in the second group. The most prevalent abnormalities on magnetic resonance were small vessel disease (62.5%), followed by hippocampal atrophy (56.25%). At evaluation by neurologist the most prevalent impairment was dysmetria in 6 patients (62.5%), followed by hippocampal atrophy (56.25%).

Conclusion: The prevalence of detectable CSF HIV load in patients with undetectable serum HIV load was higher than reported by international studies, which could be related to viral scap and cognitive impairment.

In other series the most sensible brain abnormality for HIV cognitive impairment was brain atrophy unproportioned to age. In this study more than half of the patients presented hippocampal atrophy.

PE9/87
Clinical management of ageing people living with HIV in Europe: The view of the care providers
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Purpose: Although guidelines for the management of HIV infection include recommendations for ageing people living with HIV (PLWH), clinical practice of European HIV care providers may vary. We aimed at investigating the clinical management of ageing PLWH from the perspective of the care provider.

Method: We performed a study using a 3-phase Delphi methodology by involving a panel of clinicians with expertise in HIV infection clinical management. The first phase involved 10 clinicians to identify HIV comorbidities of interest. The second and third phases recruited clinicians virtually via a web-based questionnaire that included 137 questions focussed on 11 comorbidities (e.g. cardiovascular disease, pulmonary disease, etc).

Results: Ninety-seven and 85 responses were collected in phase 2 and 3, respectively. While we observed general agreement in the relevance of assessing cardiovascular risk, smoking and allergy history, lipids, renal parameters, bone health via FRAX calculation or BMD scan, depression and anxiety and sexual health screening, there was disagreement in determining the best marker for diagnosis of impaired glucose tolerance (fasting glucose versus HbA1c) and responders did not seem to evaluate frailty or menopause in their clinical practice.

Conclusion: High levels of agreement were found among clinical care providers across Europe and with the European AIDS Conference Society (EACS) guidelines regarding key items of clinical management of comorbidities in ageing PLWH. However, we identified some important gaps, such as the lack of standardisation or implementation of the assessment of frailty or menopause, which are emerging as important factors to optimise ageing PLWH clinical care. Further studies are warranted to confirm whether intensified screening translates into HIV morbidity advances.
PE9/89
Long-term lipid-lowering-therapy in HIV is clinically effective
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1VA North Texas Health Care System, Medicine, Dallas, USA 2University of Texas Southwestern Medical Center, Medicine, Dallas, USA 3University of Texas Southwestern Medical Center, Dallas, USA

Table 1

<table>
<thead>
<tr>
<th>Long-Term Exposures</th>
<th>Patient years</th>
<th>Death</th>
<th>New CVD Event</th>
<th>Acute CVD Event</th>
<th>Infection</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statins only</td>
<td>140,130</td>
<td>51.0%</td>
<td>0.51</td>
<td>0.00001</td>
<td>0.00001</td>
<td>0.00001</td>
</tr>
<tr>
<td></td>
<td>7,752</td>
<td>0.51</td>
<td>0.037–0.70</td>
<td>0.00001</td>
<td>0.00001</td>
<td>0.00001</td>
</tr>
<tr>
<td>Non-Statin LLT only</td>
<td>2,493</td>
<td>0.29</td>
<td>0.17–0.51</td>
<td>0.00001</td>
<td>0.00001</td>
<td>0.00001</td>
</tr>
<tr>
<td>Combined LLT</td>
<td>6,150</td>
<td>0.35</td>
<td>0.23–0.53</td>
<td>0.00001</td>
<td>0.00001</td>
<td>0.00001</td>
</tr>
<tr>
<td>Mono AHT</td>
<td>19,910</td>
<td>1.39</td>
<td>1.21–1.60</td>
<td>0.00001</td>
<td>0.00001</td>
<td>0.00001</td>
</tr>
<tr>
<td>Dual AHT</td>
<td>11,351</td>
<td>1.24</td>
<td>0.98–1.57</td>
<td>0.011</td>
<td>0.00001</td>
<td>0.00001</td>
</tr>
<tr>
<td>Cardiac ASA</td>
<td>4,472</td>
<td>*</td>
<td>joint recent use [see Table 2]</td>
<td>0.00001</td>
<td>0.00001</td>
<td>0.00001</td>
</tr>
</tbody>
</table>

Table 2. (Hazard Ratios (95% Confidence interval), multiplicity-corrected p-values)

<table>
<thead>
<tr>
<th>Recent/Remote Exposures</th>
<th>Patient Years</th>
<th>Death</th>
<th>New ASCVD event</th>
<th>Acute ASCVD event</th>
<th>Severe Infection</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recent LLT</td>
<td>23,701</td>
<td>0.65</td>
<td>0.57–0.74</td>
<td>0.00001</td>
<td>1.57 (1.40–1.77)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Remote LLT</td>
<td>9,044</td>
<td>1.04</td>
<td>0.87–1.24</td>
<td>0.70</td>
<td>0.89 (0.71–1.10)</td>
<td>0.037</td>
</tr>
<tr>
<td>Recent AHT</td>
<td>28,438</td>
<td>2.17</td>
<td>1.96–2.40</td>
<td>0.00001</td>
<td>2.36 (2.10–2.64)</td>
<td>0.00001</td>
</tr>
<tr>
<td>Remote AHT</td>
<td>15,157</td>
<td>1.23</td>
<td>1.07–1.42</td>
<td>0.0001</td>
<td>1.10 (0.90–1.35)</td>
<td>0.46</td>
</tr>
<tr>
<td>Recent ASA</td>
<td>15,437</td>
<td>1.58</td>
<td>1.40–1.77</td>
<td>0.00001</td>
<td>4.84 (4.41–5.53)</td>
<td>0.00001</td>
</tr>
<tr>
<td>Remote ASA</td>
<td>16,691</td>
<td>1.19</td>
<td>1.05–1.36</td>
<td>0.0001</td>
<td>1.20 (1.02–1.42)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

ASCVD-outcomes of statins in HIV have not been studied in conjunction with other health outcomes and those of other cardiovascular preventive medications (CVPIM), particularly non-statin (NS) lipid-lowering therapy (LLT). We analyzed the clinical impact of CVPIM use in all HIV-infected US-veterans after their first undetectable HIV-viral load on HAART from 1995–2011, examining LLT (statins, fibrates, fish-oil, ezetemibe, and nicain), antihypertensives (AHT), and cardiac Aspirin (ASA) in relation to mortality, cardio- or cerebrovascular (ASCVD) events, severe infections, and cancer. We applied marginal structural models for each outcome controlling for all exposure levels within each CVPIM class. Exposure models for all antiretrovirals (ARVs), and CVPIMs were based on weekly-updated VA-pharmacy out-and-inpatient data. We used: demographics, calendar year, hospital-size, follow-up frequency, HCV-status, smoking, drug-use, 1-year HAART/ARV possession rates, prior-year HIV-CD4 and CD4-averages, liver and kidney function, hemoglobin, BMI, blood-pressure, and 1-year cholesterol averages (total and HDL) to build individual propensity scores for each exposure level and outcome. We defined long-term exposure as ≥11/12 months, recent exposure as ≤11 months exposure in the past year, and remote exposure as last use ≥1-year ago. Non-death clinical events were defined by ICD-9-codes, except for acute CVD events that also used ICD procedural codes and evidence of neuroimaging for new cerebrovascular insults. We followed 23,267 patients (97% male, 46% black) for median 5.2 years (IQR:2.5–9.2). Median age was 53 years (IQR:46–60). 42% were ever exposed to LLT. The tables contain the hazard ratios for clinical outcomes. Mortality findings were similar when restricting the analysis to ≥2006 (not shown). Our analysis confirms a substantial mortality benefit for HIV patients taking long-term LLT. The statin effect is likely driven by reduced infection and cancer risk while NS-LLT only exerts a protective effect on ASCVD risk. In contrast, neither AHT nor ASA seemed to confer clinical benefits.
Gender issues

PE10/1
Patient, clinical and virus genetic characteristics of female migrants from Eastern, Central and Western Africa enrolled in the SHCS

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1University Hospital Zurich, Zurich, Switzerland 2University of Zurich, Zurich, Switzerland 3Lausanne University Hospital, Lausanne, Switzerland 4University of Basel, Basel, Switzerland 5University of Geneva, Geneva, Switzerland 6University Hospital Basel, University of Basel, Basel, Switzerland 7Inselspital Bern, Switzerland 8University of Bern, Bern, Switzerland 9Kantonsspital St.Gallen, St. Gallen, Switzerland 10Regional Hospital Lugano, Lugano, Switzerland

Purpose: We aim at identifying patient, clinical and virus genetic characteristics of female migrants in Switzerland; a group with a high HIV prevalence known to be vulnerable and important.

Method: Our study population consisted of female Swiss HIV Cohort Study (SHCS) participants of black ethnicity coming from Eastern, Central or Western Africa. The study population was compared to a control population of white female SHCS participants infected with HIV subtype B, matched by median SHCS registration year. Both, study and control population, were infected with HIV through heterosexual contacts and had at least one sequence in the SHCS resistance data base. A phylogenetic tree including one sequence per SHCS participant and blasted Los Alamos background sequences was built.

Results: Compared to our control population, our study population had a comparable number of median follow-up visits per year, a higher median ability to work 100% and fewer reported psychiatric problems (Table). Adherence to antiretroviral treatment (ART) was considerably poorer (p<0.001) and in line with this, the mean log10 RNA values after the first initiation of ART was significantly higher for the study population compared to the control population. First CD4 cell counts were lower for our study population (p<0.001), and fewer participants were diagnosed during primary infection (p<0.001). Our study population was infected with a wide range of HIV-subtypes, greatly differing for the respective regions of patient origin, and less than half had a SHCS participant as the closest neighbor on the phylogeny.

Conclusion: Awareness and accessibility to HIV-testing should be raised in the population of female migrants from Eastern, Western and Central Africa to capture infections early. However, the phylogenetic clustering with Los Alamos sequences along with the subtypes detected in the study population indicates that the contribution to the ongoing HIV epidemic originating from these migrant women is rather low.

PE10/2
Menopause impacts drug use and mental health in women with HIV in Switzerland

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Purpose: We aimed to assess age at menopause and factors associated with early menopause in HIV-positive women, and to explore its impact on HIV viral load, behaviour changes and mental health disorders.

Methods: We performed a retrospective analysis of HIV-positive women followed in the Swiss HIV Cohort Study (SHCS) with documented menopause between 01/2010 and 12/2018. We investigated age at onset of menopause according to different sociodemographic variables and fitted logistic regression models with the respective indicator variable for the behavioural characteristic, and used interrupted time series analysis (ITS) to identify time dependent peri- and postmenopausal trends.
Results: Between 2010 and 2018, 1130 women within the SHCS experienced menopause and the percentage of postmenopausal women tripled from 11.5% (n=274) in 2010 to 36.1% (n=961) in 2018. Median age at menopause was 50, early menopause (<45) occurred in 115 (10.2%) and premature menopause (<40) y in 23 (2%) patients. Early menopause was associated with black ethnicity (52.2% versus 21.6%, p=0.001), but not with HIV acquisition mode, CDC stage, viral suppression, CD4, HCV, smoking or active drug use.

We identified a number of trends in the 2–5 year timeframe prior to menopause; both, viral blips (OR 1.69 [95% CI 1.13, 2.55], p=0.007), and intravenous drug use (OR 1.65 [95% CI 1.02, 2.67], p=0.04), Figure 1 and 2 increased. Odds of needing psychiatric care increased until 1 year after menopause (OR 1.04 [95% CI 1.00, 1.09], p=0.07), and decreased afterwards (OR 0.95 [95% CI 0.90, 1.00], p=0.05).

Conclusion: The median age of HIV-positive women at menopause is around 2 years earlier than reported for HIV-negative women in Switzerland. Of note, most relevant behavioural changes occurred in the years before menopause with relevant increases in viral blips, intravenous drug use and mental health disorders requiring psychiatric care.

PE10/3

Gender-specific analysis of a German cohort of HIV-infected patients onRaltegravir-based therapy shows distinctive baseline co-morbidity profiles of women versus men but no impact on treatment outcomes

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1MSD Sharp & Dohme GmbH, Medical Affairs, Haar, Germany 2UBIN/Praxis, Berlin, Germany

HIV-infected women are facing specific needs in the context of antiretroviral therapy. For a better understanding, we performed a gender-specific post-hoc analysis for patients on Raltegravir (RAL)-based therapies in the German real-life cohort WIP.

The WIP study was a prospective, observational, multicenter cohort study in routine clinical care with data collection between 2010 and 2014. Safety and efficacy outcomes of RAL-based antiretroviral therapy in a population enriched for aging patients (274, 61% ≥50 years) were documented. Detailed methods are described elsewhere (Naumann et al., J STD AIDS 2016). The cohort included 69 (15%) female and 382 (85%) male HIV-infected patients. Mean age at 51 years in both groups. At RAL initiation women and men were 13% vs. 23% therapy-naïve, 49% vs. 51% pretreated with virologic suppression and 33% vs. 23% without virologic suppression. At baseline, female patients suffered more frequently from depression (23% vs. 16%) as well as chronic hepatitis C virus infection (20% vs. 9%) and male patients more often from cardiovascular diseases including hypertension (15% vs. 20%) as well as lipid abnormalities such as hypercholesterolemia (6% vs. 11%) and hyperglycemia (1% vs. 6%). Concomitant medications at baseline were consistent with these comorbidity profiles. No gender-specific differences in RAL-based therapy were observed in women versus men: RAL was combined with PI in 17% vs. 16%, with NRTI in 64% vs. 64% and with others in 19% vs. 20%. Regarding treatment outcomes, virologic response rates were comparable between women and men (Table 1).

Table 1. Therapeutic outcomes at week 48

<table>
<thead>
<tr>
<th>Therapy Status</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>VL&lt;50 c/mL N (%)</td>
<td>VL&lt;50 c/mL N (%)</td>
<td>early DC N (%)</td>
</tr>
<tr>
<td>Therapy-naïve</td>
<td>Therapy-naïve</td>
<td>Therapy-naïve</td>
</tr>
<tr>
<td>7 (78%)</td>
<td>0 (0%)</td>
<td>2 (22%)</td>
</tr>
<tr>
<td>29 (85%)</td>
<td>2 (6%)</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>Pretreated suppressed</td>
<td>Pretreated suppressed</td>
<td>Pretreated suppressed</td>
</tr>
<tr>
<td>15 (65%)</td>
<td>4 (17%)</td>
<td>4 (17%)</td>
</tr>
<tr>
<td>Pretreated failing</td>
<td>Pretreated failing</td>
<td>Pretreated failing</td>
</tr>
<tr>
<td>1 (33%)</td>
<td>2 (67%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>Total</td>
<td>Total</td>
</tr>
<tr>
<td>52 (75%)</td>
<td>8 (12%)</td>
<td>9 (13%)</td>
</tr>
</tbody>
</table>

In this German real-life cohort, characterization of female versus male patients demonstrated divergent co-morbidity profiles and minor differences in utilization patterns of RAL-based therapy. Nevertheless, in both women and men similar and high response rates comparable to clinical trial results could be observed.

PE10/4

Menopausal symptoms, sleep disorders and anxiety/depression among premenopausal and postmenopausal HIV-infected women: a multicenter cohort study in Spain

I Suarez1, B Alejos2, N Sanz3, A Henderson4, J Berenguer5, JA Iribarren6, JL Gomez-Sivrient1, J Santos7, F Vidal8, E Bernal9, V Acensi11, J Larín1, V Henderson10 and CoRIS1,2Hospital InfantilSofía, San Sebastian de los Reyes, Spain 3Institute of Health Carlos III, Madrid, Spain 4Asociacion CoRIS, Madrid, Spain 5Hospital Universitario 12 de Octubre, Madrid, Spain 6Hospital Universitario Gregorio Marañon, Madrid, Spain 7Hospital Universitario Donostia, Donostia, Spain 8Hospital Universitario de Canarias, Santa Cruz de Tenerife, Spain 9Hospital Universitario Virgen de la Victoria, Malaga, Spain 10Hospital Universitario Joan XXIII, Tarragona, Spain 11Hospital Universitario Reina Sofia, Murcia, Spain 12Hospital Central de Asturias, Oviedo, Spain

Purpose: To assess menopausal symptoms, sleep disorders and depression/ anxiety among premenopausal and postmenopausal HIV-infected women aged 45–60 years from the cohort of Spanish HIV/AIDS Research Network (CoRIS).

Method: Menopause was defined as 12 consecutive months without menstruation. Menopause Rating Scale was used to evaluate menopausal symptoms (Psychological, Somatic and Urogenital subscales), 3-items Jenkins Sleep Scale for sleep disorders and the 4-item Patient Health Questionnaire-4 for anxiety/depression. Multivariable logistic regression models were used to evaluate the impact of menopause in the different outcomes.

Results: Of 251 women included, 137 (55%) were postmenopausal. Median age at menopause was 48 years (IQR: 45–50). 66% of postmenopausal and 54% of premenopausal had any menopausal symptoms. The most frequent symptoms were: muscular discomfort (66% vs 62%, postmenopausal and premenopausal, respectively), physical/mental exhaustion (63% vs 52%), sleep problems (58% vs 52%) and depression (51% vs 42%). Prevalence for psychological symptoms was 64% vs 50%; for somatic 61% vs 50% and for urogenital 61% vs 48%, among menopausal and premenopausal women, respectively. In multivariable analysis, postmenopausal women had a two-fold increased risk of suffering from urogenital symptoms than premenopausal women (table 1).

Prevalence of moderate-to-severe anxiety/depression was 22% vs 16% among post and premenopausal women, respectively. The corresponding prevalences for sleep disorders were 67% vs 52%. Only sleep disorders were significantly associated with menopausal status in multivariable analysis (table 1).

Overall, 19% of the women had moderate to severe anxiety and/or depression and 60% had sleep disorders. When considering menopausal and premenopausal women, these percentages were 22% vs 16% for anxiety/depression and 67% vs 52% for sleep disorders, respectively.

Conclusion: HIV-infected women showed a high prevalence of menopausal symptoms, anxiety/depression and sleep disorders. Urogenital symptoms sleep disorders were more frequent in postmenopausal women. There were no significant differences in the presence of somatic or psychological symptoms, nor anxiety/depression.

Adjusted OR for the association between postmenopausal status and the presence of menopausal symptoms, anxiety/depression and sleep disorders

<table>
<thead>
<tr>
<th>MRS</th>
<th>Psychological</th>
<th>Anxiety/depression</th>
<th>Sleep disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Menopause</td>
<td>1.58 (0.93–2.69)</td>
<td>1.49 (0.78–2.84)</td>
<td>2.40 (1.61–3.57)</td>
</tr>
<tr>
<td>0.98 (0.51–1.86)</td>
<td>1.88 (1.19–2.97)</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

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Conclusion: This cohort of women is very distinct as their rates of smoking, alcohol and recreational drug use are extremely low; they also had low cardiovascular risk scores when calculated. However they have a high prevalence of co-morbidities and unmet health needs and are at high risk of disengagement. Evaluation of emotional well-being was low despite evidence of higher prevalence of depression and anxiety in WLWHIV. This study highlights the need for more tailored, women-focused assessment frameworks to be incorporated into clinical care.

Table 2. Presence of co-morbidities and high risk indicators

<table>
<thead>
<tr>
<th>Cardiovascular</th>
<th>Assessment conducted</th>
<th>Bone health</th>
<th>Assessment conducted</th>
<th>Reproductive</th>
<th>Assessment conducted</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>87 (95%)</td>
<td>FRAX score calculated</td>
<td>14 (15%)</td>
<td>Menstruation/ menstrual discussed</td>
<td>68 (74%)</td>
</tr>
<tr>
<td>Total cholesterol (mmol/l)</td>
<td>88 (96%)</td>
<td>DEXA scan performed</td>
<td>14 (15%)</td>
<td>Smear performed</td>
<td>55/80 (69%) ***</td>
</tr>
<tr>
<td>BP (mmHg)</td>
<td>86 (93%)</td>
<td>Emotional Health</td>
<td>42 (45%)</td>
<td>Breast screening ***</td>
<td>12/37 (32%)</td>
</tr>
<tr>
<td>10-year CV risk (QRisk3)</td>
<td>32 (35%)</td>
<td>Informal assessment**</td>
<td>7 (8%)</td>
<td>Contraception use discussed</td>
<td>72/92 (78%)</td>
</tr>
<tr>
<td>Smoking</td>
<td>89 (97%)</td>
<td>Formal mental health assessment</td>
<td>3 (3%)</td>
<td>HbA1C</td>
<td>8 (9%)</td>
</tr>
<tr>
<td>Renal health</td>
<td>Sleep quality assessment**</td>
<td>89 (97%)</td>
<td></td>
<td>Medication Review</td>
<td>84 (91%)</td>
</tr>
<tr>
<td>Renal profile - bloods</td>
<td>88(96%)</td>
<td>*Only performed among those with proteinuria on urinalysis. **Patient asked informally by clinician during visit (e.g. ‘how are you feeling, emotion-wise?’)</td>
<td>79 (86%)</td>
<td>Bone health</td>
<td>80 (91%)</td>
</tr>
<tr>
<td>Urinalysis*</td>
<td>79(85%)</td>
<td>*Only performed among those with proteinuria on urinalysis. **Patient asked informally by clinician during visit (e.g. ‘how are you feeling, emotion-wise?’)</td>
<td>68 (74%)</td>
<td>Menstrual status</td>
<td>55 (69%)</td>
</tr>
</tbody>
</table>

| | Median (IQR) or N (%) | High risk | | Median (IQR) or N (%) | High risk |
|--------------------------|----------------------|----------|--------------------------|----------------------|
| Cardiovascular | | | Renal health | | |
| BMI (kg/m²) | 29.7 (25.0–34.5) | >30: 42/87 (48%) | CKD stage (CKD-EPI) | Normal: 60 (CKD1 and 2) 30–60-30 | 85 (97%) | 2 (2%) 1 (1%) |
| Total cholesterol (mmol/l) | 4.9 (4.1, 5.4) | >4.5: 8/88 (9%) | Urinalysis - proteinuria present uPCR (n=20)* | 42/79 (53%) | 1 (1, 19) |
| BP (mmHg) | 6 (7%) | 81 (73, 88) | Bone health | | n/a |
| 10-year CV risk (QRisk3) | 125 (116–135) | >140: 13/86 (15%) | DEXA scan Normal Osteopenia Osteoporosis | 7/14 (50%) | 5/14 (11%) 2/14 (4%) |
| Smoking Current/Ex Never | 8/89 (9%) | >10%; 5 (6%) | Reproductive | | n/a |

Table 1. Annual health review in 2018

PE10/5
An evaluation of the care given to older women attending an HIV clinic in London
C Williams* and P Farrugia*
1Guy’s and St Thomas’ NHS Foundation Trust, Harrison Wing HIV Outpatients, London, UK

Purpose: Although HIV-related outcomes are regularly assessed, the wider health needs of women living with HIV (WLWHIV) are often overlooked. We evaluated the cardiovascular, renal and bone health of women living with HIV aged 40–55 in a central London HIV unit and whether their reproductive and emotional needs were being assessed in clinical care.

Method: An audit was conducted of a random sample of 1 in 6 WLWH under follow-up in 2016 aged 40–55. Data collected included demographics, presence of co-morbidities and adherence to British HIV Association (BHIVA) standards of care.

Results: 92 women (median age 48 years; 78% black African; median 14 years since diagnosis) were included. 79(86%) had VL nadir and current CD4 counts were 195 (110–120) and 589 (424–758). 42 (46%) did not attend at least one appointment during 2018. 11 (12%) had a period of non-attendance of >1 year in the past 5 years.

Menstrual status was discussed in 76% women and contraception in 78%. Emotional well-being was only assessed in 56% of patients and mainly consisted of informal enquiry. 48% of the cohort had a BMI>30. HbA1C was measured in 9%. Cardiovascular assessments were performed on 35% despite 98% having necessary data for evaluation. FRAX scores were calculated on 15% despite 53% being on Truvada.

Conclusion: Although HIV-related outcomes are regularly assessed, the wider health needs of women living with HIV (WLWHIV) are often overlooked. We evaluated the cardiovascular, renal and bone health of women living with HIV aged 40–55 in a central London HIV unit and whether their reproductive and emotional needs were being assessed in clinical care.

PE10/6
Anti–Mullerian hormone a plausible indicator of cardiometabolic risk in HIV-infected women
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1Centro Hospitalar Universitário de Lisboa Central (CHLC), Lisboa, Portugal
2Chronic Diseases Research Centre, CEDOC, NOVA Medical School/Faculdade de Ciências Médicas, Universidade NOVA de Lisboa, Lisboa, Portugal
3Centro Hospitalar de Setubal EPE, Setubal, Portugal
4Hospital Prof. Doutor Fernando Fonseca (HFF), Amadora, Portugal

Purpose: The definition of a biological aging-profile is of major importance for risk stratification in women living with HIV (WLWHIV). Follicle Stimulating Hormone (FSH), Luteinizing (LH) and Estradiol (E2) hormones have been classically related to menopause, but recently Anti–Mullerian Hormone (AMH) has emerged as a novel indicator. Lower AMH associates with cardiovascular risk markers and represents a possible modulator of cardiovascular system. We compared AMH levels in WLWHIV with those reported in non–HIV population for
the same age. Also we have investigated the impact of AMH levels in markers of cardiovascular risk.

Methods: A panel of cardiovascular biomarkers was compared between groups of women with the same age and accordingly the appropriateness of AMH levels to their age. Plasma protein cysteinilation levels were quantified as a novel aging marker associated with cardiometabolic diseases.

Results: Our study included 269 WLHIV and 35% had AMH levels below the 10th percentile expected for their age. A total of 106 women were aged 25–44 years old (yo), 63% caucasian. In this group nine had undetectable AMH; 66 were in low AMH group (below median expected values for their age) and 31 in high AMH group. FSH (p<0.01) LH (p<0.01) were lower and E2 (p<0.05) higher in low and AMH groups in comparison to undetectable AMH group. However, the classical hormone profile was not different between low and high AMH groups. Moreover, high AMH group had lower total cholesterol (p<0.05), lower plasma protein cysteinilation (p<0.01) and higher eGFR (p<0.05) than women with undetectable AMH. No differences were found for triglycerides or HDL-c.

Conclusions: WLHIV have lower AMH levels than expected for their age. AMH might have a better predictive value on cardiovascular risk assessment than female hormone classic profile.

HIV and marginalised groups

PE11/1

Sexual behaviors and seroprevalence of HIV, HBV, and HCV among hill tribe youths of Northern Thailand

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Purpose: To examine sexual behaviors and assess the seroprevalence of HIV, HBV, and HCV among hill tribe youths.

Method: A cross-sectional study was conducted (The participants were recruited from 60 randomly selected hill tribe villages in Chiang Rai Province, Thailand. A validated questionnaire and 5 mL blood specimen were used to collect data. Data were collected by a self-reporting method. Rapid immunochromatographic tests were used to detect anti-HBs, HBsAg, anti-HCV, and anti-HIV-1 and -2. Chi-square and Fisher's exact test were used to detect the associations between variables at alpha of 0.05.

Results: A total of 1,325 participants were recruited forthe analysis. The majority were females (60.5%), aged 15–17 years (58.9%), and 72.5% graduated high school. A total of 14.5% smoked, 22.4% drank alcohol, 14.2% were tattooed, and 61.4% had their ears pierced. Among the 30.3% who had sexual experience, 42% experienced one-night stands, 26.9% had sexual contact with a prostitute within one year prior to the study, 18.9% used alcohol prior to having sexual intercourse, and 15.7% had been tested for HIV/AIDS previously. Among males, 11.5% were males who have sex with males (MSM), and 4.6% were bisexual. Among females, 83.0% were females who have sex with males, and 5.0% were females who have sex with female. Different sexual tribes and groups were found to have significantly different risk behaviors and sexual behaviors. Among the 836 obtained blood samples, none were positive for HIV/AIDS, 19.9% were positive for HBsAg, and 0.2% were positive for anti-HCV.

Conclusion: Hill tribe youths in Thailand are at risk of HIV, HBV, and HCV infections according to their risk behaviors and sexual behaviors, which differ between sexes and tribes. Effective behavioral interventions should be promoted among hill tribe youths to minimize the risk for these diseases in the future.

PE11/2

Rapid HIV tests and linkage of people who inject drugs (PWID) to health facilities for antiretroviral therapy (ART) in Nigeria

KT Owosio1 and AC Ottoo2

1Foundation for Sustainable Health Promotion and Development (FOSHPAD), Community Mobilization, Ado-Ekiti, Nigeria
2African Center for Training, Research and Development, Abuja, Nigeria

Purpose: The National HIV/AIDS and Reproductive Health Survey 2012 shows low uptake of HIV testing in Nigeria especially among the key population. In Nigeria, People who inject drugs (PWID) face discrimination, criminalization that prevent them from accessing health care and inclusion in the society. HIV prevalence among PWID in Nigeria was 3.4% in 2017. Women who inject drugs are particularly affected with prevalence of 13.9% compared to 2.6% among men. Female sex workers who inject drugs face highest HIV prevalence (43%). It is thought that 9% of new HIV infections in Nigeria every year are among people who inject drugs according to 2017 The Joint United Nations Programme on HIV/AIDS (UNAIDS) statistics.

Method: The study was conducted among PWID living in Ati-Akankan area of Ado-Ekiti. This area is a slum characterized by the presence of homeless
shelters, drug peddlers trading openly, commercial sex workers, runaway teenage girls being used as sex slaves in exchange for drug and little cash. 78 PWID’s were examined consisting of 67 males and 11 females between the ages of 15–47 years. They were provided with HIV testing services between October - December 2018, utilizing multiple HIV test kits for screening and confirmatory tests to improve quality. Positive clients were counseled and referred to health centers for free Antiretroviral Treatment.

Results: 2.34% were confirmed to be HIV positive and were successfully referred for ART. There was low turnout of PWID’s to events promoting HIV prevention, testing and treatment.

Conclusion: Participants reported that fear of being handed to police as a major reason for not seeking HIV testing and services. PWID’s and other key populations need adequate access to HIV/AIDS prevention, treatment and support services.

Screening via rapid HIV tests need to target Key Populations if the 90–90–90 target of the UNAIDS is to be achieved.

PE11/3

The blind spot: high HIV burden among slum-dwelling school-age girls in Kampala, Uganda

JT Ssenyonga 1, M Nakafu 1, DM Ssemakula 2, R Ssenyonga 3 and J Nhakate 4

1Makerere University College of Health Sciences, Community Health, Kampala, Uganda 2Center for Innovations in Health Africa, Kampala, Uganda 3Makerere University College of Health Sciences, Department of Epidemiology and Biostatistics, Kampala, Uganda

Background: Adult and youthful slum dwellers have been documented to have a higher prevalence of HIV compared to the general population. However, there is paucity of information on the extent of this infection among slum-dwelling school age (5–14 years) children in Uganda. This study explored the burden of HIV among slum-dwelling school-age children (SDSAC) of Namuwongo, Kampala, Uganda.

Methods: We analyzed data derived from HIV counselling and testing records of school-age children that tested at Kisugu HC III between 2011 and 2016. A total of 555 anonymised records were analyzed for: residence, HIV, religious, and sex status. Using STATA version 13; bi-variate analysis was conducted to obtain joint distribution and the two-sample test of proportions test; to elicit associations and their significance.

Results: The overall study population burden of HIV was 2%, with girls (2.6%) more affected than boys (0.9%). SDSAC had a higher HIV burden (3.3%) compared to non-slum dwellers (1.2%). HIV was more prevalent among slum-dwelling girls (5.2%) compared to their non-slum dwelling counterparts (0.9%). A positive HIV result was associated with being a slum dwelling girl (95% CI: [0.3%-8.3%], p=0.0013) and belonging to the 10–14 year age group (95% CI: [0.002-0.065], p=0.015).

Conclusions: There is a high burden of HIV among slum-dwelling school-age girls in Kampala. SDSAC should be included among the blind spot population and we recommend expansion of school age friendly preventive, promotive and therapeutic HIV services to these areas.

PE11/4

Research of behavioral models of transgender people leading to high rates of HIV prevalence in Ukraine

I Medvid 1

1All-Ukrainian Civil Society Organization (Community Based), Kyiv, Ukraine

Purpose: Study of behavioral models of transgender people leading to high rates of HIV prevalence in Ukraine.

Methods: A quantitative study using the RDS method. This is the largest of its kind in the EECA countries: 438 transgender people were surveyed across Ukraine, including Crimea and the eastern regions of the country where military operations are taking place.

Results: 69% of transgender people in Ukraine did not use a condom during their most recent sexual intercourse. The main reasons for this were that sexual partners insisted on sex without condoms (28%) and the lack of condoms (23%). According to respondents’ own reports, HIV prevalence among transgender people could be as high as 21%. At the same time, HIV infection specialists and other doctors in AIDS centers in Ukraine do not receive special training to work with transgender people, and transgender people with HIV are registered in health facilities according to their biological gender.

Conclusions: The data obtained suggest that, as in other countries, the risk of HIV transmission among transgender people in Ukraine is 50 times higher than among the general population.

The lack of knowledge about HIV/AIDS and STI among transgender people needs to be raised, by means of targeted interventions, and access for transgender people to HIV services needs to improve, including through awareness training for doctors. There is also a need for advocacy work to improve the meaningful participation of trans people and their organizations in national anti-epidemic action.

The next steps should aim to ensure that the state recognizes the vulnerability of transgender people and explicitly includes transgender people in the list of groups with an increased risk of HIV infection. Transgender people should be included in national coordination mechanisms, in particular, the National Council for Countering Tuberculosis and HIV/AIDS.

PE11/5

Outreach services for HIV testing and prevention among female transgender commercial sex workers in Milan: different approaches for different populations?

G Lapadula 1, E Lumeg 1, A Monopoli 2, N Squillace 1, A Soria 1, M Comolatti 1, E Beretta 1, A Vecchi 1, P Columpi 1, F Sabbatini 1, GM Migliorino 1, M Modesti 1 and V Cristiano 1

1Ospedale San Gerardo - ASST Monza, Infectious Diseases Unit, Monza, Italy 2ALA Milano Onlus, Milan, Italy

Purpose: Female-transgender commercial sex workers (FTG-CSW) are disproportionately affected by HIV and have reduced access to HIV-testing and PREP. We describe two different testing strategies: an outreach program and an outpatient clinic dedicated to FTG-CSW.

Methods: In collaboration with a non-governmental organization (NGO) providing counseling and help to TG persons, we organized (i) a mobile unit, one night a week, in TG prostitution sites in Milan, offering rapid oral tests and counseling about HIV prevention; (ii) a weekly evening outpatient clinic in the NGO headquarters, offering fingerstick tests and PREP care. The staff included a FTG peer-educator, a counselor, a psychologist and HIV-specialists. FTG-CSW were interviewed about sexual habits, history of STI, health needs and barriers.

Results: 57 FTG-CSW accessed our services between February and June 2019. First contact was the mobile unit in 39 and the outpatient clinic in 18 subjects. Table 1 shows their characteristics. Those reached on the street were younger than those self-presenting to the outpatient clinic. More than half of the subjects reported 6 months since their last HIV-test. The most commonly
reported reason for delayed testing were difficult/uncomfortable access to testing-facilities (54%) and fear of stigma/discrimination (27%). Condomless sex was frequent and higher among self-presenting TG-CSW.

Method: Street-based rapid oral HIV testing in outreach settings among FTG-CSW is useful and brings to a significant number of new HIV-diagnoses. Creating a dedicated outpatient clinic was useful to implement PREP in this fragile population, but the benefit in terms of new diagnosis was null.

PE11/6
The impact of unstable housing on HIV treatment outcomes in people living with HIV/AIDS in an urban setting of Southern Europe
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1Hospital Del Mar, Infectious Diseases, Barcelona, Spain. 2ISCIB, Barcelona, Spain. 3Hospital Del Mar, Pharmacy, Barcelona, Spain. 4Autonomous University of Barcelona, Barcelona, Spain

Purpose: People living with HIV (PLHIV) with unstable housing (UH) face several barriers hindering access to care, adherence to antiretroviral therapy (ART), retention in care, and treatment success. Despite being on the rise, this phenomenon has been scarcely characterized in Southern Europe.

Method: A retrospective cohort study was conducted among all PLHIV>18-year-old who started or resumed ART between 2012 and 2018 in Hospital del Mar, Barcelona. Unstable housing was defined as living in the street or in temporary residences due to financially insecure situations. Multivariate Cox regression models were used to identify independent risk factors associated with a composite outcome of treatment failure, loss to follow-up and death (TF).

Results: We included 570 patients, contributing 1014 person-years of follow-up, with a median time of 21.35 months. Among them, 115 (20.17%) had UH. The baseline characteristics of people with UH included: mean age 41.81 years; male gender 77.4%; median HIV-RNA viral load 4.76 log10 copies/mL; median CD4 count 257 cells/μL; STR 47.8%; HIV acquisition through injection drug use 67%; alcoholism 29.6%; current drug use 64.3%; psychiatric disorder 36.5%; idiomatic/cultural barrier 24.3%; and patient pre-judgment 5.2%.

75.7% were non-adherent, 47% had inadequate immune recovery and 48.7% presented TF, compared to 20.7%, 21% and 18.2% in the non-UH group (P<0.001). UH independently predicted TF (HR: 1.87; 1.22–2.85), after adjusting for HIV-RNA (HR: 1.27 per log10 increase; 95% CI 1.00–1.61); current recreational drug use (HR: 2.09; 95% CI 1.40–3.12) and patient pre-judgment (HR: 2.16; 95% CI 1.23–3.80).

Conclusion: The proportion of UH was common in this Southern European urban cohort of PLHIV. PLHIV with UH had a high comorbidity burden and suboptimal ART outcomes, including poorer adherence, retention in care, adequate immune recovery and treatment success. Specific interventions are needed for this neglected population.

PE11/7
Reflection of sex work criminalization in court judgements targeting to protect health, sanitary and epidemiological well-being
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1Forum of Sex Workers, Executive Committee, Saint Petersburg, Russian Federation. 2Forum of Sex Workers, Executive Committee, Krasnoyarsk, Russian Federation

Purpose: Sex workers remain a population severely affected by HIV epidemics, which is widely recognized. To expose the court practice in accordance with Article 6.11 of the Administrative Code of the Russian Federation, which provides for punishment of a fine for engaging in sex work, we looked into the contents of court decisions.

Method: We applied the content analysis to 250 magistrate’s court judgements under the Article 6.11 made from June to December 2017 accessed online through an aggregator of court decisions ‘Rospravosudiy’. Results: The offender’s request was stated only in 0.04% of the decisions; in 73% the accused women were physically absent in the court hearings. Witness testimonies were collected in 16.8% (42) judgements; in the court hearings, there were no testimonies by a witness or police officer who drew up a report on detention. The presence of a lawyer was mentioned in two court judgements. In 92% (230) protocols, the offender did a guilty plea, that is, gave written confessions or pleaded guilty during a court hearing, and in 92.8% (232) judgements women received a fine of 21 – 28 Euros. The mass distribution of sexually transmitted diseases and HIV infection was referred as harm of prostitution in one of the 250 judgements. One case was initiated against a man, which indicates that under this article women are disproportionately prosecuted.

Conclusion: Although the public harm of sex work is interpreted as a cause a massive spread of sexually transmitted diseases and HIV infection, the court practice under Article 6.11 for engaging in prostitution has lost its original meaning to protect public health and focuses only on vague notion of morality. This legal uncertainty leads to deliberately unjust decisions by courts: the proof of guilt is practically absent, and the court practice focuses on guilty verdicts against women.

PE11/8
Caring for the Transgender HIV-positive patient
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Purpose: The stigma attached to gender nonconformity in many societies can result in the so called “minority stress”, that may make transgenders more likely to avoid medical care and to escape the retention in care when suffering from chronic diseases. A health monitoring system targeting this population doesn’t exist yet and data on demographics are lacking due to the fact that not every transgender person pursue an open medical path that leaves a record. The aim of this study is to describe the state of health of male-to-female HIV-positive transgender population attending the Infectious Diseases Outpatient Service of our University Hospital in order to identify their needs and to improve their retention in care.

Methods: We collected data from all the HIV-positive transgender male-to-female patients attending the Infectious Diseases Outpatient Service of our Clinic from 1988 to 2018 with more than one access to the clinic, reviewing their outpatient clinical records and then performed a descriptive analysis.

Results: We collected data from 78 patients; 48.7% (N=38) had<1 year of follow up. 51.3% had>1 year of follow-up with median follow-up of 11 years (IQR 7.1–16.4). Of total population, 53.8% ranged from 18 to 30 years old; 43.6% presented comorbidities (Table 1). Median CD4 cell count at HIV diagnosis was 212 (IQR 72–350); 30.8% (N=24) of the population presented for the 1st time to our center with AIDS-defining events mostly tuberculosis.

Demographic characteristics of the population

<table>
<thead>
<tr>
<th>Total population N=78 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (categorical)</td>
</tr>
<tr>
<td>18–30</td>
</tr>
<tr>
<td>31–40</td>
</tr>
<tr>
<td>&gt;40</td>
</tr>
<tr>
<td>Nationality</td>
</tr>
<tr>
<td>Brazil</td>
</tr>
<tr>
<td>Colombia</td>
</tr>
<tr>
<td>Argentina</td>
</tr>
<tr>
<td>Peru</td>
</tr>
<tr>
<td>Ecuador</td>
</tr>
<tr>
<td>Others</td>
</tr>
<tr>
<td>HCV co-infected</td>
</tr>
<tr>
<td>4 (5.1%)</td>
</tr>
<tr>
<td>Comorbidities</td>
</tr>
<tr>
<td>34</td>
</tr>
<tr>
<td>Types of comorbidities</td>
</tr>
<tr>
<td>Cardiovascular/ Diabetes</td>
</tr>
<tr>
<td>16.6%</td>
</tr>
<tr>
<td>Dyslipidemia</td>
</tr>
<tr>
<td>15%</td>
</tr>
<tr>
<td>Lipodystrophy</td>
</tr>
<tr>
<td>13.3%</td>
</tr>
<tr>
<td>GERD</td>
</tr>
<tr>
<td>11.6%</td>
</tr>
<tr>
<td>Psychiatric</td>
</tr>
<tr>
<td>8.3%</td>
</tr>
<tr>
<td>(diagnosed)</td>
</tr>
<tr>
<td>Others</td>
</tr>
<tr>
<td>35.2%</td>
</tr>
</tbody>
</table>
HIV infection-related characteristics

<table>
<thead>
<tr>
<th>CDC Group at HIV diagnosis</th>
<th>A</th>
<th>30 (38.5%)</th>
<th>B</th>
<th>24 (30.8%)</th>
<th>C</th>
<th>24 (30.8%)</th>
</tr>
</thead>
</table>

AIDS-defining events at diagnosis

<table>
<thead>
<tr>
<th>(CDC C N=24)</th>
<th>Tuberculosis (pulmonary, other sites)</th>
<th>43.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cerebral Toxoplasmosis</td>
<td>10.2%</td>
</tr>
<tr>
<td></td>
<td>Pneumocystis pneumonia</td>
<td>10.2%</td>
</tr>
<tr>
<td></td>
<td>Cryptococcosis</td>
<td>7.6%</td>
</tr>
<tr>
<td></td>
<td>CMV systemic disease</td>
<td>7.6%</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>20.5%</td>
</tr>
</tbody>
</table>

Results: 308 transwomen were included; median age was 31 years (interquartile range – IQR=25–38), 53.8% had HIV infection. Among current hormone users (40.8%), the most frequent were estradiol (26.53%), ethinylestradiol (5.15) or a combination of both (9.18%). Median cIMT was 0.57 mm (IQR=0.52–0.64). In participants with increased cIMT, 11 (3.97%) and 24 (8.66%) were classified as high risk by the Framingham equation and ASCVD, respectively. In the final adjusted model, age (OR=1.14, 95% CI=1.08–1.20), systolic blood pressure (OR=1.05, 95% CI=1.01–1.09) and estradiol use (OR=0.34 95%CI=0.11–0.92) were associated with cIMT.

Conclusion: A negative association between cIMT and current estradiol use was found in transgender women. While conflicting results exist in the literature about estrogen replacement therapy in women, these data suggest cardioprotective effects of estradiol use without medical supervision in younger transwomen. Follow up studies are needed to confirm its safety and it might be considered as a choice of hormone for transwomen.

PE11/10

HIV and migrants: a demographic and clinical characterization of migrants under follow-up at an Infectious Diseases Department in Lisbon, Portugal

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Purpose: Characterize the migrant population currently on follow-up at the Infectious Diseases Department of a Central Hospital (IDD) in Lisbon, Portugal, for Human Immunodeficiency Virus Infection (HIV).

Method: All patients currently attending follow-up appointments were identified, and cohort based on nationality was selected. Patient’s charts were reviewed for confirmation of migrant status and characterization of HIV infection and clinical outcomes.

Results: Of the 348 patients identified, accounting for 11.5% of all patients under follow-up for HIV infection (n=3013), 230 were men with an average age of 49 years. Most of the patients are from Portuguese speaking countries, 49% from Brazil and 51% from African Portuguese Speaking Countries. Two-hundred and sixteen patients, 62%, were identified as economic migrants, and 6.9% (n=24) entered the country under health protocols between countries. The patients have been in Portugal for nine years on average, and 60.3% (n=210) were diagnosed in the year prior to entering the country or in the year of entrance. Regarding HIV infection, 94.25% (n=328) are HIV type 1 and three present HIV type 1 and 2 co-infection, mostly of probable sexual transmission, 79% (n=275), and 41% (n=143) of these of heterosexual risk. Sixty-two patients (17.8%) presented with opportunistic infections (OI) on diagnosis, in most cases active tuberculosis (6.3%), n=22, and more than one simultaneous OI in 4.6% (n=16). A hundred and thirty-two patients (37.9%) present co-infections of those 76 (57.6%) with Hepatitis B Virus. When first evaluated at IDD 67.8% of patients (n=236) were naive. All patients are currently under anti-retroviral therapy (ART), 67.4% (n=304) of whom have undetectable viral load.

Conclusion: Access to health care allows early diagnosis and adequate treatment. The migrant population’s engagement in follow-up care leads to both good therapy adhesion and good immunovirological status contributing to control the HIV epidemic.

HIV cure

PE12/1

Comparison of three commercial kits for quantitative analysis of HIV-1 RNA produced in Russia

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Purpose: Viral load (VL) measuring is one of the main methods of HIV cure efficiency control. Unfortunately, the main viral variant used in design of quantitative PCR-kits is HIV-1 subtype B. However A6 subtype dominates in Russia and CRF03_AB, CRF02_AG and CRF63_02A1 are wide spreading as well.
In this study we compared three Russian Real-Time-quantitative PCR-kits: AmpliSens HIV-Monitor-FRT (Monitor-FRT), RealBest RNA HIV quantitative (RealBest) and recently developed AmpliSens HIV-monitor-Duo-FL (Monitor-Duo).

Method: Plasma clinical samples with VL 500–2,050×10^6 copies/mL was analyzed. All samples (n=125) were tested using Monitor-FRT and Monitor-Duo. Using RealBest the part of collection (n=84) were tested as well. The simple linear regression and Bland-Altman analyses were carried out. Precision of kits was tested by analysis of NIBSC HIV-1 Standard 97/650, in three dilutions.

Effectiveness of different HIV-1 subtypes and CRFs quantification was tested using NIBSC References panels 12/224 and 13/214.

Results: In analysis of clinical samples a statistically significant correlation between all kits was found (with R²=0.8) (Fig. 1). The highest convergence was found between Monitor-FRT and Monitor-Duo. For 2nd WHO International Standard all assays demonstrated VL lower than real concentration (0.19, 0.34 and 0.53 log copies/mL for Monitor-Duo, Monitor-FRT and RealBest correspondingly). The best precision in HIV-1 subtypes' and CRFs testing was found for Monitor-Duo. The median VL-delta (real minus obtained) of log copies/mL for this kit was 0.19 (-0.13–0.91). For Monitor-FRT VL-delta was 0.49 (0.18–1.17) and for RealBest - 0.74 (0.32–1.75). The highest discordance was found for CRF13_cpx sample (1.17, 0.91 and 0.55 for Monitor-FRT, Monitor-Duo and RealBest correspondingly).

Conclusion: All three Russian HIV-1 VL-quantitative kits studied demonstrated high level of correlation and precision for HIV cure efficiency control. All kits revealed different HIV-1 group M subtypes and CRFs. Apparently high rate of VL delta for CRF13_cpx sample is result of mosaic structure of its genome.

![Figure 1. Comparison of kits by a simple linear regression (left) and Bland-Altman (right) analyses](image)

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Darunavir resistance among patients exposed to protease inhibitors failing ARV therapy

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Purpose: Darunavir is the main protease inhibitor (PI) antiretroviral for salvage therapy, but previous PI use may limit treatment response to this drug. 

Method: The HIV-1 RNA partial pol sequences (Sanger) from 1,696 patients failing antiretroviral regimen, genotyped from 2014 to 2017, were evaluated at Stanford db for drug resistance mutations (DRM) and genotypic susceptibility score (GSS) and at rega and NCBI for HIV subtype. Logistic regression analyses were performed to access clinical and laboratory variables associated to decrease of darunavir GSS. 

Results: Mutations to NRTI (69.6%, 1181/1696) and to NNRTI (59.9%, 1016/1696) drug classes were common, and 27.5% (466/1696) had at least one major PI-DRM, most commonly M46 (14.7%, 250/1696), V82 (13.8%, 234/1696) and I54 (13.3%, 225/1696). Full activity to darunavir was predicted for 88% of the patients, but only 57% for those with at least one PI-DRM. Presence of a PI-DRM was strongly associated (p<0.001) to older age, use of more than two regimens, longer total time on treatment and presence of a PI-DRM. A lower GSS to darunavir was independently associated to subtype F, NRTI mutations and exposure to darunavir and previous use of older PI (e.g. saquinavir, indinavir, nevirapin).
Conclusion: Among patients with PI-DRM, full activity to darunavir was compromised in many cases and efforts to detect failure at earlier time is warranted, particularly for cases treated in early HAART era or infected with HIV-1 subtype F, both associated to darunavir resistance. NRTI mutations may serve as a proxy for a minimal level of therapy adherence necessary for PI-DRM emergence.

Table 1. Logistic regression to evaluate the association of demographic and laboratory variables to DRV susceptibility

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted Odds Ratio P</th>
<th>Adjusted Odds Ratio P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95% CI</td>
<td>95% CI</td>
</tr>
<tr>
<td>Age above 36 years</td>
<td>2.07 0.001</td>
<td>1.37–3.11 1.98 0.082 0.92–4.28</td>
</tr>
<tr>
<td>CD4+ T count &gt;500 cells/µm³</td>
<td>0.77 0.190</td>
<td>0.52–1.14 0.60 0.146 0.30–1.20</td>
</tr>
<tr>
<td>Time on treatment &gt;7 years</td>
<td>2.70 0.000</td>
<td>1.70–4.30 1.11 0.769 0.60–2.24</td>
</tr>
<tr>
<td>Number of regimens &gt;2</td>
<td>2.95 0.000</td>
<td>1.86–4.70 1.19 0.651 0.57–2.50</td>
</tr>
<tr>
<td>Exposure to IDV, SQV, NFV</td>
<td>3.75 0.000</td>
<td>2.54–5.33 3.11 0.000 1.65–5.85</td>
</tr>
<tr>
<td>LPV treatment</td>
<td>2.04 0.001</td>
<td>1.36–3.07 1.68 0.098 0.91–3.11</td>
</tr>
<tr>
<td>DRV treatment</td>
<td>8.17 0.000</td>
<td>4.96–13.37 3.95 0.000 1.83–8.54</td>
</tr>
<tr>
<td>HIV-1 polymerase subtype F</td>
<td>1.48 0.083</td>
<td>0.95–2.30 2.23 0.021 1.13–4.40</td>
</tr>
</tbody>
</table>

Association of darunavir genotypic susceptibility score (full activity, GSS=1 vs some degree of resistance, GSS=0–0.75) to variables at genotyping collection. Due to space constrain only variables with p<0.2 at unadjusted analyses are shown. Presence of NRTI resistance mutation is not included in the table as there was no case of darunavir resistance without a NRTI mutation (100% x 59%, p<0.0001).

Figure 1. Detection of M184V/I or K65R/N/E in population sequencing (PS) and next generation sequencing (NGS) in proviral DNA

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Total population [n=102]</th>
<th>Historical mutations M184V/I or K65R/N/E [n=52]</th>
<th>No historical mutations M184V/I nor K65R/N/E [n=50]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, n (%)</td>
<td>77 (75.4)</td>
<td>36 (69.2)</td>
<td>41 (82.0)</td>
</tr>
<tr>
<td>Age (years), median</td>
<td>51.2 (45.3–56.3)</td>
<td>52.3 (49.0–58.4)</td>
<td>47.6 (41.8–54.2)</td>
</tr>
<tr>
<td>Route of HIV transmission, n (%)</td>
<td>43 (42.1)</td>
<td>15 (28.8)</td>
<td>28 (56.0)</td>
</tr>
<tr>
<td>- MSM</td>
<td>0.028</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Heterosexual</td>
<td>27 (26.4)</td>
<td>15 (28.8)</td>
<td>12 (24.0)</td>
</tr>
<tr>
<td>- IDU</td>
<td>24 (23.5)</td>
<td>17 (32.7)</td>
<td>7 (14.0)</td>
</tr>
<tr>
<td>- Other/Unknown</td>
<td>8 (7.8)</td>
<td>5 (9.6)</td>
<td>3 (6.0)</td>
</tr>
<tr>
<td>Time since HIV- infection diagnosis (years), median (IQR)</td>
<td>18.4 (11.8–23.3)</td>
<td>21.9 (17.5–24.7)</td>
<td>12.7 (6.7–20.3)</td>
</tr>
<tr>
<td>Current ART, n (%)</td>
<td>0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Including 3TC or FTC</td>
<td>71 (69.6)</td>
<td>24 (46.2)</td>
<td>47 (94.0)</td>
</tr>
<tr>
<td>- 2NRTIs + NRTI or bPPI</td>
<td>56 (54.4)</td>
<td>21 (40.4)</td>
<td>35 (70.0)</td>
</tr>
<tr>
<td>- 1NRTI + bPPI</td>
<td>27 (26.4)</td>
<td>15 (28.8)</td>
<td>12 (24.0)</td>
</tr>
<tr>
<td>bPPI monotherapy</td>
<td>19 (18.6)</td>
<td>16 (30.8)</td>
<td>3 (6.0)</td>
</tr>
<tr>
<td>Time on current ART (years), median (IQR)</td>
<td>4.1 (2.6–6.9)</td>
<td>4.5 (3.0–7.1)</td>
<td>3.2 (2.2–6.5)</td>
</tr>
<tr>
<td>Time of HIV viraemia suppression (years), median (IQR)</td>
<td>7.7 (5.1–12.1)</td>
<td>8.8 (5.7–12.3)</td>
<td>6.3 (4.2–10.9)</td>
</tr>
</tbody>
</table>

PE13/2

Prevalence and factors associated to the detection (population and next generation sequencing) of archived 3TC resistance mutations in aviremic HIV-infected adults (GEN-PRO)

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Purpose: To evaluate in aviremic patients the frequency of M184V/I and K65R/E/N in proviral DNA (pvDNA) by population sequencing (PS) and next generation sequencing (NGS), the concordance between techniques and predictive factors for persistence of mutations.

Methods: We analyzed pvDNA of HIV-infected participants on stable ART and virologically suppressed for ≥1 year by PS (whole blood) and NGS (PBMCs). Mutations were identified and quantified using the PASEq system (InsiCaixa). Results: 102 participants (Table 1); 50 without M184V/I and/or K65R/E/N in historical resistance genotype in plasma, and 52 with prior history. In the group with historical resistance, pvDNA analysis by PS showed M184V/I and/or K65R/E/N in 14/52 (26.9%). NGS detected mutations in >1%, >5% or >20% in 42/48 (87.5%), 36/48 (75%) and 22/48 (45.8%) respectively. (Figure 1) Univariate analysis of factors associated to persistence of 3TC mutations in pvDNA/PS analysis showed that current ART including 3TC/FTC or 2NRTIs + NRTI or bPPI were associated to clearance while time on ART >per year was associated with persistence [OR 1.14 (95% CI:0.99–1.33; p=0.77)]. Using NGS>20%, current treatment with triple therapy was associated with clearance [OR 0.13 (95% CI:0.03–0.60; p=0.009)], regimen including 3TC/FTC had a trend towards association with clearance [p=0.07] and time since HIV diagnosis with persistence [p=0.06]. When analyzed with NGS>5%, predictive factors for persistence were time since HIV diagnosis [OR 1.16 (95% CI:0.93–1.42; p=0.23)] and IDU risk factor [OR 1.26 (95% CI:1.29–1.34; p=0.029)]. By NGS>1%, no predictive factors were found.

Conclusion: Historical 3TC mutations are not detected in pvDNA in the majority of patients using PS. NGS increases sensitivity, but with the 5% cutoff NGS still misses one quarter of historical mutations. A regimen including 3TC is associated with clearance of resistance mutations. The therapeutic relevance of detecting 3TC mutations in pvDNA by NGS requires further research (ART-PRo clinical trial, NCT03539224).
PE13/3
Accumulation of integrase strand-transfer inhibitor resistance mutations confers high level resistance to dolutegravir in HIV-1 non-B subtype viruses from patients failing raltegravir in Uganda

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Purpose: There are limited data on susceptibility of HIV to integrate strand-transfer inhibitors (INSTIs) in low- and middle-income countries, mostly due to rare reports of failure on INSTI-based regimens and scarcity of patients with INSTI drug resistant mutations (DRMs).

Method: HIV non-B subtype infected patients (n=10) failing raltegravir (RAL)-based third-line treatment were selected for the study. Patient-derived HIV isolates with INSTI DRMs, and a control lacking DRMs were used to test for phenotypic susceptibility to INSTIs (DTG, RAL, and EVG). Cross resistance was assessed by Spearman’s correlation coefficient test.

Results: Viruses with one primary mutation and accessory mutations (AMs) were susceptible to DTG but highly resistant to both RAL and EVG. For example, viruses with N155H and AMs (T97A, L74I, E157Q, G163R, M50L, and/or V151I) were susceptible to DTG but resistant to EVG (FC 56.7 to >100) and RAL (FC 29.1 to 44.7). Presence of Y143R/G with AMs (T97A, M50I, L74I, G163R, D232N) had FC of 0.5 to 1.1 (DTG), 15.9 to >100 (EVG), and >100 (RAL). A virus with E138A, G140A, G146R, and G163R showed resistance to all three INSTIs, FC of <111 for DTG and >1000 to either EVG or RAL. Among AMs, G163R conferred high level resistance to all INSTIs in presence of Y143R/S or N155H. The strong cross resistance was only observed between DTG and EVG (r=0.88, p=0.00075).

Viral infectivity assay showed a 56% average loss in infectivity with mutant G140A, Q148R, and G163R showed resistance to all three INSTIs, FC of >1.4, 21.4 to 77.6, and 10.1 to 18.7 to DTG, EVG, and RAL respectively. Viruses were susceptible to DTG but highly resistant to both EVG and RAL. For example, viruses with E138A, G140A, G146R, and G163R showed resistance to all three INSTIs, FC of <111 for DTG and >1000 to either EVG or RAL. Among AMs, G163R conferred high level resistance to all INSTIs in presence of Y143R/S or N155H. The strong cross resistance was only observed between DTG and EVG (r=0.88, p=0.00075).

Cross resistance was assessed by Spearman’s correlation coefficient test.

Conclusions: Patients failing RAL are susceptible to DTG, but resistant to EVG and RAL. Multiple primary INSTI DRMs seem to confer high-level resistance to DTG. Thus, precaution is needed when switching RAL failures with multiple primary INSTI DRMs.

PE13/4
Monitoring the prevalence of transmitted HIV-1 drug resistance in Hungary

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1National Public Health Center, Budapest, Hungary 2Eötvös Loránd University, Budapest, Hungary 3Semmelweis University, Budapest, Hungary 4South-Pest Central Hospital, Budapest, Hungary 5University of Szeged, Szeged, Hungary

Purpose: Transmitted HIV-1 drug resistance (TDR) may affect the success of first-line antiretroviral treatment. The aim of this study was to monitor the presence of HIV-1 strains carrying transmitted drug resistance-associated mutations (TDRMs) in newly diagnosed, treatment-naive patients in Hungary. Extensive implementation of integrase inhibitors into the medical care initiated to investigate TDR of this drug class as well.

Method: 274 HIV-infected individuals diagnosed between 2013 and 2018 were included in the study; most of them belonged to the MSM (men who have sex with men) group. HIV-1 subtypes and TDRMs were determined by sequencing partial protease, reverse transcriptase and integrase coding regions of the pol gene. The sequences were analysed using the Stanford HIV Drug Resistance Database algorithm. Transmission clusters among patients were identified using phylogenetic analysis.

Results: Although subtype B HIV-1 strains were predominant (84.7%) in the study, non-B subtypes including A, F, CRF01 AE, CRF02 AG, C, D and G were also recorded. The overall prevalence of TDR was 9.1% (25/274; 95% CI: 6.3–13.1%). Most of TDRMs were detected in subtype B HIV-1 strains. Nucleoside reverse transcriptase inhibitor (NRTI)-associated mutations were the most frequent indicators of TDR (21/274; 7.7%; 95% CI: 5.1–11.4%), followed by mutations conferring resistance to protease inhibitors (PIs) (3/274, 1.1%; 95% CI: 0.4–3.2%) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) (2/274; 0.7%; 95% CI: 0.2–2.6%). Drug resistance of integrase inhibitors were tested in 136 newly diagnosed, untreated patients. Major integrase resistance mutation (T66A) was detected in 1 case (1/136; 0.7%; 95% CI: 0.1–4.1%). Cluster analysis revealed potential transmission clusters with TDRM carrying samples.

Conclusion: Onward transmission of drug resistant subtype B HIV-1 strains accounted for the majority of TDR observed among treatment-naïve HIV-infected individuals in Hungary.

PE13/5
Prevalent reverse transcriptase resistance mutations as barriers to achieving elimination of mother-to-child transmission of HIV in South Africa

OV Adeniy1

Walter Sisulu University, East London, South Africa

Purpose: The emergence of HIV drug resistance poses a significant threat to achieving the goal of elimination of mother-to-child transmission. In this study, we assessed the burden of HIV-1 drug resistance mutations (DRMs) within the context of the public sector prevention of mother-to-child transmission (PMTCT) programme in the Eastern Cape, South Africa.

Method: We conducted genetic analysis on vaginal isolates (n=80) from plasma samples of women with probable virological failure at delivery between January and May 2018 from two large maternity centres in the Eastern Cape using standard protocols. Partial pol gene covering 1030 bp were amplified and sequenced according to previously reported protocol. DRMs were determined by submitting the generated partial pol sequences to the Stanford drug resistance database for query on mutations associated with drug resistance in HIV viruses. We examined the correlates of DRMs using bivariate analysis.

Results: The age of parturient women ranged from 16–43 years. The majority of the parturient women were currently on Efavirenz-based regimen (first line ART) (82.5%) and had been on ART for more than 12 months (65.0%). The prevalence of DRMs was 72.5% (n=58). The CD4 count demonstrated a negative linear association with the DRMs (p=0.002).

The predominant DRMs were K103N (n=43; 74.1%), M184V (n=28; 48.3%) and K65R (n=11; 19%). Among the parturient women on current treatment of EFV-based regimen; 79.1% already had K103N while nine patients on protease inhibitor-based regimen still harboured K103N. The majority of the M184V mutations were observed in parturient women on first line regimen (n=23; 82.1%).

Conclusion: We found a high prevalence of DRMs in women delivering their index babies at high viral loads in the study settings. Future studies should explore the point-of-care technology for reverse transcriptase-PCR for screening for common resistance mutations to guide appropriate neonatal prophylaxis and maternal therapy.
PE13/6
Virologic failure and human immunodeficiency virus drug resistance in adolescents on antiretroviral therapy in Yaounde and Douala

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Purpose: HIV is a leading cause of death, among adolescents, likely due to poor monitoring and high risk of therapeutic failure in resource-limited settings. We sought to determine the rates of virologic failure (VF) and HIV-1 drug resistance (HIVDR) among adolescents receiving antiretroviral therapy (ART).

Method: A cross-sectional study was conducted among adolescents receiving ART in 10 Health Facilities of Douala and Yaounde in Cameroon from November 2018 to May 2019. Sociodemographic characteristics, ART regimens, adherence level and viral load (VL) were obtained from medical files. Genotypic HIVDR testing was performed for those experiencing VF (VL≥1000 copies/mL) with available sample and interpreted using the Stanford HIVdb algorithm. Bivariate analyses were performed, with p<0.05 considered statistically significant.

Results: Out of 1,316 adolescent files on ART, 233 (17.7%) had missing records of VL. Among those with VL results, adherence level ranged from 81.6% to 91.8% using different adherence assessment methods. Interestingly, 276/1083 (25.5%) were experiencing VF versus 807/1083 (74.5%) reported with viral suppression (VL<100 copies/mL). HIVDR testing was successfully done for 45/57 (79%) available samples from those experiencing VF. Of relevance, VF was associated to suboptimal adherence (OR:0.039, p=0.000), distant residence (OR:1.5, p=0.01) and category one health facility (OR:2.8, p=0.02), age at ART initiation (OR:2.5, p=0.01) and baseline CD4 percentages (OR:2.1, p=0.001). Overall rate of acquired HIVDR was 93.3% (42/45), with a high rate of multiclass HIVDR-mutations (80%).

Conclusion: In Cameroon, VF is high among adolescents receiving ART, mainly attributed to poor adherence. Acquired HIVDR is frequent adolescents experiencing VF, with consistent rate of multi-drug resistance strains, which in turn limit future therapeutic options for transition to adult care. Thus, scale up of VF monitoring, timely detection of VF and prompt switching to PI-based second-line ART would limit the accumulation of HIVDR and ensure successful viral suppression.

PE13/7
Selection of integrase inhibitor (INI) resistance mutations in an INI experienced patient treated by Bictegravir

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Purpose: Very few data are available about the viral genetic resistance pathways in case of failure to Bictegravir (BIC).

Method: We described a case of an INI experienced patient with baseline N155H INI resistance mutation who had a virologic rebound while on Bictegravir containing regimen.

Results: A 30-year-old African American patient, diagnosed with HIV in 2008 and started HIV treatment in 2015 with TDF/FTC/EVG/c. This first ARV line was stopped due to poor adherence related to GI side effects. Genotypic testing performed after failure of TDF/FTC/EVG/c evidenced a M501 + N155H profile in HIV integrase gene and M184V in RT.

The patient reengaged in care in November 2018 and was treated with TAF/FTC/BIC and was followed at M1, M2 and M3 (Table 1). At M1 and M2, he harbored a good virologic plasma HIV RNA response, then failed at M3. At M3, Integrase gene sequencing showed selection of E138K, S147G, and R263K mutations in addition to the M501 and N155H resistance mutations already present at baseline. He received as subsequent regimen of TAF/FTC/DRV/c with a good virologic response.

Conclusion: This case report suggests that TAF/FTC/BIC should not be used in patients with previous selection of INI resistance mutation and this kind of patient should receive only Dolutegravir (DTG) 50 mg twice a day if an INI based regimen has to be used. Bictegravir is able to select various INI resistance mutations at least in viruses already harboring INI resistance.

Table 1.

<table>
<thead>
<tr>
<th>Date</th>
<th>Plasma HIV RNA</th>
<th>CD4 cell count</th>
<th>Resistance testing</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>467,000</td>
<td>8</td>
<td>RT: M184V; Integrase: M501-N155H</td>
<td>TAF/FTC/BIC</td>
</tr>
<tr>
<td>M1</td>
<td>32,000</td>
<td>30</td>
<td>TAF/FTC/BIC</td>
<td>TAF/FTC/BIC</td>
</tr>
<tr>
<td>M2</td>
<td>2,850</td>
<td>52</td>
<td>TAF/FTC/BIC</td>
<td>TAF/FTC/BIC</td>
</tr>
<tr>
<td>M3</td>
<td>88,400</td>
<td>RT: M184V; Integrase: M501+R138K+5147F+N155H+R263K</td>
<td>TAF/FTC/BIC</td>
<td></td>
</tr>
<tr>
<td>M4</td>
<td>1,650</td>
<td>86</td>
<td>TAF/FTC/DRV/c</td>
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<tr>
<td>M6</td>
<td>83</td>
<td>147</td>
<td>TAF/FTC/DRV/c</td>
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PE13/8
Impact of HIV-1 subtypes and integrase natural polymorphisms on virological response to first–line integrase inhibitors based regimens

D Armeni1,2, C Gori1, V Micheli1, A Bertoli1, G Berno1, S Cicalini3, C Pinetti1, R Galgani2, A Vergoni1, B Bruzzone3, AP Callegaro1, M Lichtner4, F Maggiolo5, A Di Biagio5, A Latin1, G Rizzardini1, M Andreoni6, A D’Arminio Monforte7, C Mussini1, A Antonini5, F Ceccherini-Silberstein1, CF Perino7, MM Santoro8 and On Behalf of Italian INI-Surveillance Group
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Purpose: We evaluated the virological response to first-line integrase-inhibitor (INI) based treatment in HIV-1 infected drug-naive patients followed in Italy.

Methods: The impact of HIV-1 subtype and integrase polymorphisms on virological success (VS, HIV-RNA <50 copies/mL after ART-start) and virological rebound (VR, see Figure) was evaluated by survival analysis.

Results: 515 patients were analyzed: 336 infected with B subtype (65.2%), 65 F (7.0%), 28 C (5.4%), 24 CRF02_AG (4.7%) and 91 with other subtypes (17.7%). 222 (43.1%) patients were treated with dolutegravir, 166 (32.2%) with raltegravir, 36 (6.9%) with elvitegravir, 29 (5.6%) with raltegravir and 29 (5.6%) with raltegravir.

Two patients (0.4%) harbored one INI-major resistance mutation (MMR) at baseline (R263K and Y143YCHR, respectively), while 29 (5.6%) harbored ≥1 accessory INI RM (ARM).

Overall, by 12 months of treatment, the probability of VS was 94%. F-infected patients showed the lowest probability of VS (65.1%); others: 91%; C: 96%; B: 96%; CRF02_AG: 100% (p=0.131). No associations with VS probability and the presence of ARMs or polymorphisms were found.

Overall, by 24 months after VS, the probability of VR was 12%. F-infected patients harbored the highest probability of VR (37%; p<0.001) (Figure, Panel A). By evaluating the integrase polymorphisms, patients harboring B, T124S and T218I had a significantly higher probability of VR (Table; Figure, Panels B–F).
By Cox multivariable analysis, adjusting for demographic, viro-immunological and treatment parameters, F-infected patients showed a higher relative hazard (95% C.I.) of VR (4.37 [1.77–10.79], p=0.001) compared to B-infected patients, regardless to the INI used.

Conclusion: Patients infected with CRF02_AG and B subtype showed the best virological control under first-line INI-based treatment, while F-infected patients showed a poorer virological control. The presence of F subtype-related polymorphisms may correlate with this phenomenon. Further investigations are needed to clarify these observations.

Funding for this study was provided by ViV Healthcare.

Figure

Table

PE13/9
HIV-1 integrate inhibitor resistance associated mutations defined by majority and minority populations among individuals failing therapy
S Gudipati1, I Brar1, Z Osborn1, JE McKinnon1, T Loss1, S Brar1, AM Golembieski1 and N Markowitz3
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Purpose: Integrate inhibitors (INIs) are recommended for ART-naïve individuals and are increasingly employed in switch and salvage regimens. This study examines the occurrence of INI major Resistance Associated Mutations (mRAMS) for both majority and minority populations and their impact on INI resistance (INI-R) in patients failing treatment.

Method: Genotypic antiretroviral resistance testing was performed using next generation sequencing for detection of mRAMS for majority and minority populations and their impact on INI resistance (INI-R) in patients failing treatment.

Results: From 10/2015–12/2019, 293 individuals were prescribed INI regimens; 63 were considered treatment failures. Median age was 43 years (IQR: 30–51); 82.5% male; 88% African American; median HIV RNA: 41,426 (IQR: 10,749–97,942); median CD4: 281 (IQR: 110–385). Of those failing therapy, 40% had INI mRAMS. Minority INI mRAMS were found in 37.1% of INI-R defined by majority mRAMS was 7.9% for both first (G1) and second (G2) generation INIs and 60% for G1 INIs only. Intermediate and high level INI-R defined by majority mRAMS was observed in 6.3% for G1 INIs and 0% of G2 INIs. With the inclusion of minority mRAMS, INI-R was 19% and 3.2% for G1 and G2 INIs.

Conclusion: Nearly all INI-R patients failing therapy had INI mRAMS; although INI-R remained low, particularly for G2 INIs. The clinical impact of minority INI mRAMS remains unclear. Long-term outcome studies are needed to resolve the clinical significance of minority mutations that impact susceptibility profiles of INIs.

PE13/10
HIV-1 diversity and antiretroviral resistance among Bulgarian citizens infected abroad and foreigners registered with HIV/AIDS in Bulgaria from 2012 to 2017 (preliminary analysis)
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Purpose: The aim of our study was to analyze HIV-1 diversity and the prevalence of antiretroviral resistance mutations among Bulgarian citizens who reported to be infected abroad and foreign individuals diagnosed and registered with HIV/AIDS in Bulgaria from 2012 to 2017.

Methods: In Bulgaria 274 individuals (190 Bulgarians and 84 foreigners) infected with HIV-1 abroad were diagnosed and registered from 2012 to 2017. 149 (54.4%) of them were heterosexuals (HET), 99 (36.1%) men who have sex with men (MSM), 20 (7.3%) people who inject drugs (PWIDs) and 6 (2.2%) MSM who inject drugs. Resistance mutations and HIV-1 diversity was analyzed in 108 (39.4%) randomly selected individuals.

Results: The overall prevalence of the resistance mutations was 20.4% (22/108), comprising 6 (5.6%) to nucleoside reverse transcriptase inhibitors (NRTI) and 16 (14.8%) to non-nucleoside reverse transcriptase inhibitors (NNRTI). Dual resistance mutations were identified in 1 (0.9%) patient with both NRTI and NNRTI. The main HIV-1 clade was subtype B (54.9%) followed by subtype A1 (13.9%), unassigned (10.2%), F1 (8.7%), CRF01_AE (6.3%) and 6 other subtypes and CRFs comprising 6% in total. Phylogenetic analysis identified phylogenetic clusters in different subtypes involving individuals infected abroad as well as patients infected in the country.

Conclusions: High genetic diversity of HIV-1 subtypes have been introduced and disseminated in the country. Phylogenetic clusters demonstrate distribution of HIV-1 among different transmission groups of the populations. The prevalence of resistance mutations among analyzed individuals diagnosed with HIV/AIDS in Bulgaria is low.
PE13/11

Analytical treatment interruption and its association with reappearance of peripheral archived resistance mutations

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Purpose: Little is known about the impact of short-analysys antiretroviral-treatment interruption (ATI) and subsequent re-initiation of antiretroviral-therapy (ART) might have on archived major resistance mutations (MRMs).

Methods: Seven chronically HIV-1 infected patients with HIV-RNA <50 copies/mL for ≥10 years, undergoing towards ATI (APACHE-study) were analysed for HIV-DNA (ddPCR) and pol-sequences (Illumina-MiSeq) before ATI, at viral-rebound (VR) during ATI and at achievement of undetectability after ART-resumption (post-ATI). These parameters were evaluated at three similar time-points in seven triple-ART-treated patients with HIV-RNA <50 copies/mL for ≥1 year (MODAT-study). Intra-patient prevalence of archived MRMs (Stanford-list), including Apobec3-related MRMs, was assessed at each time-point. Wilcoxon signed-rank and Mann-Whitney tests were used to test changes in MRM prevalence at different time-points, as appropriate.

Results: APACHE subjects experienced VR after ATI at a median (IQR) time of 41(3–7) weeks and, after ART resumption, achieved HIV-RNA <50 copies/mL in 24(4–29) weeks. Median (IQR) HIV-DNA was 892(692–1286) copies/10^6CD4^+T cells at T1, 1892(146–3798) at T2, and 992(553–2183) at T3, with no significant change in HIV-DNA overtime (p>0.37). At baseline, 5/7 APACHE and 3/7 MODAT subjects carried HIV-DNA-MRMs with a median (IQR) intra-patient prevalence of 38.1(6.2–99.6) and 90.0(47.1–99.5) [p=0.46, Table]. In APACHE, MRMs persisted during ATI in 2/7 (28.6%) and in 4/7 (57.1%) individuals at plasma level and in peripheral reservoir, respectively. Post-ATI, MRMs completely reverted in 2 individuals. Comparing pre- and post-ATI HIV-DNA sequences, MRMs with a baseline intra-patient prevalence <80% significantly decreased from pre- to post-ATI [intra-patient prevalence: 7.2 [1.8–29.8] vs. 0.0 [0.0–0.6], p<0.01]. This decrease occurred mainly in APOBEC3-related MRMs (Table).

In MODAT-patients, no differences in MRM prevalence were found between baseline and follow-up (p=0.18).

Conclusion: This proof-of-concept study confirms that ATI does not affect the amount of post-ATI peripheral HIV-DNA but suggests that ATI may be associated with reappearance of peripheral archived MRMs, and in some cases with their complete reversal.

PE13/12

A low level of darunavir resistance-associated mutation emergence in patients with virological failure during long-term use of darunavir in people living with HIV, the French ANRS CO3 Aquitaine cohort

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Purpose: Ritonavir-boosted darunavir (DRV/r) is a protease inhibitor (PI) indicated for the treatment of naive and pretreated HIV infected patients since 2007. Our study aims to describe DRV/r treated-patients experiencing virological failure (VF) documented with HIV resistance testing.

Method: Data from patients belonging to the ANRS CO3 Aquitaine cohort treated with a regimen including DRV/r between February 2007 and December 2015 were analyzed. Baseline characteristics of patients with VF (defined by ≥2 consecutive plasma viral load (VL) >50 copies/mL) were compared to those without VF. We then described factors associated with VF as emergence of IAS DRV resistance-associated mutations (RMs).

Results: 1458 patients treated with a DRV/r based regimen were included. Among them, 270 (18.5%) patients experienced VF with genotypic resistance tests performed during follow-up. DRV RMs were detected in 29 patients (12%) at VF. These 29 patients had received a median of 10 lines of treatment before DRV/r initiation compared to 5 lines for patients without DRV RMs (p=0.0001). Analysis of previous genotyping tests revealed that 25/29 patients had DRV RMs before DRV initiation: 10, 9 and 6 patients had 2, 3 and 4 or more DRV RMs respectively. VF had occurred under previous PI treatments. Dose of boosted DRV at VF was 1200 mg/day for 80% of patients. For half of them, DRV was maintained after VF and controlled viremia was restored after modification of DRV-associated antiretroviral molecules or increased DRV dose. Finally, only 4/29 patients selected DRV RMs after DRV/r initiation. All of them experienced previous VF with other PIs without selecting DRV RMs. Conclusion: These results highlight the efficacy and the robustness of boosted darunavir since emergence of DRV RMs appeared in less than 0.3% of patients receiving a DRV based regimen in our large cohort.

PE13/13

Patients infected with multi-class resistant HIV-1 and with viral suppression treated with no more than one active drug: comparison of viral resistance reports and drug resistance in proviral DNA

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1ICH Study Center, Hamburg, Germany 2University of Schleswig-Holstein, Kiel, Germany 3MUC Research CRO, Munich, Germany 4PZB, Aachen, Germany 5Infektionikum, Frankfurt, Germany 6ifi Institute, Hamburg, Germany 7MVZ Karlsplatz, Munich, Germany 8University Hospital of Essen, Essen, Germany 9Zentrum für Infektiologiek Prezlaurer Berg, Berlin, Germany 10Praxis Ebertplatz, Cologne, Germany 11Private Practice, Stuttgart, Germany 12MOP, Mannheim, Germany 13University Hospital of Bonn, Bonn, Germany 14Institute of Immunology and Genetics, Kaiserslautern, Germany

Objective: Archived drug resistance-associated mutations (DRMs) may compromise virologic efficacy of antiretroviral therapy (ART). With deep sequencing (DS) assays, mutation patterns can be analyzed in proviral DNA at low frequencies. However, current data indicate that resistance testing
performed on HIV DNA lacks sensitivity compared with cumulative DRMs available from historical resistance testing (HRT) using plasma RNA. 

Methods: LOWER is a multicenter study of patients with major DRMs (using Stanford-HIVdb v8.6.1) in ≥3 ART classes (of NRTIs, NNRTIs, PIs, INSTIs). This subanalysis describes mutational patterns in proviral DNA (after APBECF filtering) in patients with viral suppression (~50 copies/mL) whose ART consisted of ≤1 active agent based on HRTs.

Results: In 16/195 patients with viral suppression, HRTs indicated that the genotypic susceptibility score (GSS) of current ART was ≤1. In 9 patients with a GSS of 1, fully active drugs were INSTIs (n=5), boosted PIs (n=2), and entry inhibitors (n=2). Among the 7 patients with a GSS <1, 3 cases were found to have a GSS=0. Median time of viral suppression in the 16 patients was 9.7 years. Even with a DS cut-off of <2%, many DRMs were not re-detected by DS and mean GSS increased from 0.69 (range 0–1) to 1.66 (0–3). In 11/16 patients, proviral drug resistance yielded a GSS increase of ≥0.5 for current ART, compared to HRTs. Only 1 patient had a GSS of <1 both in HRTs and in the proviral DNA.

Conclusion: Long-lasting viral suppression is possible in some patients with multi-class resistance, even when historical resistance reports suggest only one active agent (or even less) in the current ART regimen. GSS was higher using DS from proviral DNA, indicating that at least some DRMs could have been cleared from the latent reservoir over time.

PE13/14

Non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance in people living with HIV-1 (PLWH) subtype non-B from the Swiss HIV Cohort Study (SHCS)

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Purpose: The roll-out of antiretroviral therapy (ART) in resource limited settings (RLS), increases the spread of non-nucleoside reverse transcriptase inhibitors (NNRTI) drug resistance. With immigration of people living with HIV-1 (PLWH) with subtype non-B, similar consequences could arise also in Western Europe.

Method: PLWH enrolled before March 2019 in the Swiss HIV Cohort Study (SHCS) and infected with HIV-1 non-B subtype (A, C, F, CRF01 AE, and CRF02 AG) were included. We analysed 790 PLWH that were treatment naïve (n=50) or experienced patients (n=5) at diagnosis. The HIV-1 sequences from PLWH were analysed with HIVseq established by Bennett et al., 2009. Logistic regression was used to identify the associations with NNRTI resistance.

Results: The prevalence of transmitted NNRTI resistance in the SHCS was 2.53% for non-B subtypes. We found that having an NNRTI resistance is associated with subtype A and F compared to CRF01_AE (odds ratio (OR)adj上赛季 [95% confidence interval (CII)] = 6.42 [1.02, 123.55], 15.21 [1.9, 311.66]) (see Figure A). Including the subtypes and the year of diagnosis with splines, the logistic regression model significantly improved the quality of the fit (p-value = 0.01), indicating a time dependence of NNRTI resistance in Switzerland for non-B subtypes (see Figure B).

Conclusion: This study shows that an increase of NNRTI resistance occurs not only in RLS but also in resource rich settings like Switzerland for non-B subtypes. Consequently, due to immigration from high HIV-1 prevalence countries, public health problems related to DR in RLS are also increasingly relevant in Western Europe. Close surveillance of transmitted drug resistance (TDR) remains important, given the ongoing widespread roll-out of integrate inhibitors in RLS, this may also apply to integrate inhibitors.

PE13/15

HIV-1 from antiretroviral-naïve and experienced patients lack capsid substitutions associated with GS-6207 in vitro resistance

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Purpose: HIV capsid (CA) plays an essential role in multiple stages of the viral replication cycle. In vitro characterization of the CA inhibitor GS-6207 revealed the high potency of the compound (0.1 nM EC50). Resistance selection experiments identified seven amino acid substitutions in CA protein associated with resistance to GS-6207 in antiretroviral therapy (ART)-naïve or –experienced people living with HIV (PLWH).

Method: Sanger sequencing was used to study the presence of GS-6207 in vitro-selected mutations (L56I, M66I, Q67H, K70N, N74D, N74S, and T107N) associated with in vitro resistance to GS-6207 in antiretroviral therapy (ART)–naïve or –experienced people living with HIV (PLWH).

Results: The prevalence of transmitted NNRTI resistance in the SHCS was 2.53% for non-B subtypes. We found that having an NNRTI resistance is associated with subtype A and F compared to CRF01_AE (odds ratio (OR)adj上赛季 [95% confidence interval (CII)] = 6.42 [1.02, 123.55], 15.21 [1.9, 311.66]) (see Figure A). Including the subtypes and the year of diagnosis with splines, the logistic regression model significantly improved the quality of the fit (p-value = 0.01), indicating a time dependence of NNRTI resistance in Switzerland for non-B subtypes (see Figure B).
None of the seven GS-6207 resistance mutations identified during in vitro selection experiments was detected among the 1500 patients studied. Conclusion: In our large database (n=1500) of ART-naïve and experienced PLWH with various subtypes, no GS-6207 in vitro-associated mutations were observed. Therefore, previous PI failure and emergence of PI resistance mutations are not anticipated to impact potential resistance to GS-6207 in HIV-1 CA. This suggests a very low likelihood of pre-existence of resistance mutations to GS-6207 in the PLWH population and that GS-6207 has the potential to be effective regardless of treatment history or prior PI use.

<table>
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<th>HIV-1 Subtype distribution, % (n)</th>
<th>ARV-Naive (n=500)</th>
<th>ARV-Experienced no PI use (n=500)</th>
<th>ARV-Experienced PI failure history (n=500)</th>
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<tr>
<td>B</td>
<td>37% (185)</td>
<td>42% (210)</td>
<td>56% (280)</td>
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<td>CRF02_AG</td>
<td>46% (230)</td>
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<td>F1</td>
<td>4.6% (23)</td>
<td>2.4% (12)</td>
<td>-</td>
</tr>
<tr>
<td>CRF06</td>
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<td>3.9% (19)</td>
<td>3.4% (17)</td>
</tr>
<tr>
<td>A1</td>
<td>2.8% (14)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>D</td>
<td>2.2% (11)</td>
<td>2.2% (11)</td>
<td>1.6% (8)</td>
</tr>
<tr>
<td>Other non-B</td>
<td>3.0% (15)</td>
<td>1.6% (8)</td>
<td>1.0% (5)</td>
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</tbody>
</table>

PE13/17
Clinical impact of minority mutations in patients failing an integrase inhibitor-based regimen: what do clinicians do?
S Gudipati, I Brar, Z Osborn, JE McKinnon, T Loss, S Brar, AM Golembieski and N Markowitz
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Purpose: Next Generation Sequencing (NGS) is increasingly used to describe HIV antiretroviral drug resistance. However, the clinical consequences of minority mutations remains unclear. We examine how the addition of minority mutations affects the overall interpretation of genotype resistance reporting for Integrase Inhibitors (INIis) in INI-experienced (INI-E) patients failing INI-based ART.

Method: HIV genotypes for patients on ART therapy have been performed using NGS for detection of major HIV Resistance Associated Mutations (rMAMS) for majority and minority populations and INI-resistance (INI-R), defined by the Stanford University HIV drug resistance database. Assays were done on INI-E viremic persons (HIV RNA >200 copies/mL) failing therapy. Thresholds for rMAMS were defined as ≥10% for majority and 1-<10% for minority populations.

Results: Of 293 INI-E patients seen from 10/2015–12/2018, 63 were identified with presumed treatment failure. Median age: 43 years (IQR: 30–51); 82.5% male; 88% African American; median HIV RNA: 41,426 (IQR: 10,749–97,942); median CD4: 281 (IQR: 110–385). At failure, counting majority rMAMS only, 21 patients had INI-R (low level) and INI-E patients with intermediate or high level resistance. Of these four patients, two had changes to their regimen, one was lost to follow up and one patient had no changes to their regimen. At failure, including both majority and minority rMAMS, 39 patients had INI-R (low level) with 13 having intermediate or high level resistance. Within these 13 patients, 54% of them had changes to their regimen, 31% had no changes and 15% were lost to follow up.

Conclusion: Using NGS to identify minority rMAMS led to considerable changes in INI-R interpretation. The addition of minority genotypic susceptibility to the resistance report led clinicians to reject first or second generation INIs in 54% of patients. The clinical use of minority population mutations was inconsistent and further studies are needed for guidance.

PE13/18
Identification of HIV-1 transmission clusters in Croatia, 2014–2017: evidence for the forward spread of HIV-1 resistant variants
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Purpose: Phylogenetic analysis is a useful tool for identification of HIV-1 transmission clusters and analysis of biological characteristics of individual clusters. The aim of the study was to determine and characterize transmission networks that are responsible for the forward spread of HIV-1 infection and resistant variants in Croatia.

Method: We analyzed 403 (95.9%) of 428 newly HIV-diagnosed persons who entered clinical care at the University Hospital for Infectious Diseases, Zagreb. The entire protease HIV-1 gene (PR, codons 1–99) and a part of the reverse transcriptase HIV-1 gene (RT, codons 1–240) were sequenced by using a validated in-house method. Mutations were determined by using Surveillance Drug Resistance Mutation list. HIV subtype was determined with Rega HIV-1 subtyping tool, version 3.0. Sequences subtyped as B were selected for phylogenetic inference. For each sequence in the dataset 10 closest sequences were determined with BLAST search. Phylogenetic trees were constructed with
PhyML 3.0, while the FigTree version 1.4.3 was used for tree visualization. Transmission clusters were defined as sequences ≥3 patients from Croatian cohort with the approximate likelihood ratio test value >0.90.

Results: Subtype B was found in 368 (91%) of patients. The overall prevalence of transmitted drug resistance (TDR) was 16.4% (n=66/403). The most prevalent TDR patterns were T215S, 7.2% (n=29/403); K101E, 3.5% (n=14/403); T215S + L210W, 2.2% (n=9/403); V32I + E138A + L100I + K103N, 1.9% (n=8/403); M41L + T215L, 0.7% (n=3/403). Phylogenetic analysis identified 19 local transmission clusters, of which 5 (26%) clusters were responsible for the forward spread of resistant HIV-1 viral strains. Patients in clusters (n=347) were more frequently MSM (319/358 vs. heterosexuals 24/39, p<0.001), of younger age (median: 35 vs 39 years, p<0.02) and had a recent infection (77/81 vs. chronic 270/222 p<0.001).

Conclusion: In this study we found a high prevalence of TDR and identified 5 transmission clusters responsible for the spread of HIV-1 resistant strains.

PE13/19

High levels of resistance among HIV-1 treatment naive patients in Greece, a nationwide study: evidence for country and regional level transmission networks

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Purpose: The prevalence of HIV drug resistance among drug-naive HIV-infected individuals (baseline resistance) was previously estimated at 27.9% during 2006–2015, in Northern Greece. To investigate the prevalence of resistance in the era of limited resistance testing in Greece

Method: We analyzed protease (PR) and partial reverse transcriptase (RT) sequences from 103 treatment naive patients obtained between 2016 and 2018 in Northern Greece. The dispersal patterns of viruses with resistance were estimated by phylogenetic analysis using as references sequences sampled during 2006–2015, in Greece

Results: The overall prevalence of resistance was at 37.9% (39/103), with the highest prevalence to be for the NNRTIs (35.0%). For the NRTI RTIs and PSs low levels of resistance were detected at 2.9% and 1.0%, respectively. The dominant resistance mutations for NNRTIs were E138A (17.5%), and K103N (10.7%). Notably, the overall prevalence of resistance between 2016 and 2018 was higher than the previous ten years (37.9% versus 27.9%, p=0.04). Phylogenetic analyses showed that viruses with E138A and K103N resistant mutations originated from previous strains with the same resistance pattern found within the phylogenetic clusters from Greece (local transmission networks, LTNs).

Pooled Analysis of Pre-existing M184V/I among Virologically Suppressed Clinical Trial Participants who Switched Regimens to B/F/TAF

Table 1: Study 1844 Study 1878 Study 4030 Study 4449 Study 1474 Pooled B/F/TAF

<table>
<thead>
<tr>
<th>Prior Regimen</th>
<th>DTG/ABC/3TC</th>
<th>Boosted PI + 2 NRTIs</th>
<th>DTG + F/TDF or DTG + F/TAF</th>
<th>EVG/COBIB/TAF or any TDF-containing 3-drug regimen</th>
<th>Any 3rd agent + 2 NRTIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median/B/F/TAF treatment duration (weeks)</td>
<td>117 (group 1); 50 (group 2)</td>
<td>116 (group 1); 71 (group 2)</td>
<td>48</td>
<td>54</td>
<td>48</td>
</tr>
<tr>
<td>Number switched to B/F/TAF</td>
<td>545</td>
<td>532</td>
<td>283</td>
<td>86</td>
<td>75</td>
</tr>
<tr>
<td>HIV-1 RNA &lt;50 c/mL, at last visit</td>
<td>99% (537/545) 96% (526/545)</td>
<td>99% (525/532) 93% (497/532)</td>
<td>99% (282/283) 84% (238/283)</td>
<td>100% (86/86) 98% (84/86)</td>
<td>99% (74/75) 15% (13/75)</td>
</tr>
<tr>
<td>Baseline genotype available</td>
<td>99% (526/545) 93% (497/532)</td>
<td>99% (525/532) 93% (497/532)</td>
<td>99% (282/283) 84% (238/283)</td>
<td>100% (86/86) 98% (84/86)</td>
<td>99% (74/75) 15% (13/75)</td>
</tr>
<tr>
<td>Baseline M184V/I</td>
<td>3.3% (17/522) 12% (62/497)</td>
<td>3.3% (17/522) 12% (62/497)</td>
<td>20% (47/238) 3.6% (3/84)</td>
<td>23% (3/13) 9.7% (132/1354)</td>
<td>98% (129/132)</td>
</tr>
<tr>
<td>M184V/I HIV-1 RNA &lt;50 c/mL at last visit</td>
<td>100% (117/117) 95% (59/62)</td>
<td>100% (117/117) 95% (59/62)</td>
<td>100% (47/47) 100% (3/3)</td>
<td>100% (3/3) 98% (129/132)</td>
<td>100% (3/3) 98% (129/132)</td>
</tr>
<tr>
<td>Treatment emergent resistance</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

a. Group 1: participants switched to B/F/TAF on Day 1 of study randomized phase; group 2: participants continued baseline regimen during randomized phase and switched to B/F/TAF in open-label extension phase

Conclusion: Our study showed that in the era of limited resistance testing, transmitted resistance (TDR) to NNRTIs continues to occur at increasing prevalence in Northern Greece. TDR originated from previously existing clusters of resistance. The existence of extensive local transmission networks in some areas, raise concern about the risk of TDR to other drug classes.
Conclusion: E/C/TAF offers an effective, well tolerated switch option for patients with M184V/I. These data on continued virologic suppression despite pre-existing resistance are encouraging and warrant further follow-up.

Baseline Characteristics (n=64)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years (range)</td>
<td>52 (22–76)</td>
</tr>
<tr>
<td>Female, % (n)</td>
<td>27% (17)</td>
</tr>
<tr>
<td>Race, % (n)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>69% (44)</td>
</tr>
<tr>
<td>Black</td>
<td>31% (20)</td>
</tr>
<tr>
<td>Median CD4 count, cells/µm³, (range)</td>
<td>655 (107–1503)</td>
</tr>
<tr>
<td>Median weight, kg (range)</td>
<td>76 (44–164)</td>
</tr>
</tbody>
</table>

Resistance Mutations

<table>
<thead>
<tr>
<th>Resistance mutations based on screening historic genotype</th>
<th>PVR at W24</th>
</tr>
</thead>
<tbody>
<tr>
<td>M184V or M184I only</td>
<td>83% (53)</td>
</tr>
<tr>
<td>M184V/I + 1 TAM [M41L (1), K70R (2), T215Y/F (4), K219E (1)]</td>
<td>12% (8)</td>
</tr>
<tr>
<td>M184V/I + 2 TAMs [M41L=T215Y/F (3)]</td>
<td>5% (3)</td>
</tr>
<tr>
<td>Regimen prior to switching: 2 NRTIs + PI + ritonavir or cobicistat</td>
<td>53% (34)</td>
</tr>
</tbody>
</table>

**PE13/21**

**Sustained viral suppression among participants with pre-existing M184V/I who switched to bictegravir/emtricitabine/tenofovir alafenamide**

K Andreatta, R Acosta, ML D’Antoni, DP Porter, S Chang, R Martin, M Willkom, I McNicholl, J Gallant, C Pikora, H Graham, S Collins, H Martin and KL White

Gilead Sciences Inc., Foster City, USA

**Purpose:** Pre-existing resistance can affect antiretroviral therapy efficacy in people living with HIV. One of the most common treatment-emergent resistance substitutions is M184V/I. This substitution can be transmitted, archived in the viral reservoir, and reactivated, even when genotyping shows wild-type virus. Studies 1844, 1878, 4030, 4449, and 1474 demonstrated the safety and efficacy of switching stably suppressed HIV-1-infected individuals to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF). In this pooled analysis, we investigated the prevalence of pre-existing M184V/I and impact on virologic outcomes.

**Method:** Participants enrolled were aged ≥18 years (studies 1844, 1878, and 4030), ≥65 years (study 4449), or 6 to <18 years (study 1474). Pre-existing drug resistance was assessed by historical genotypes and/or retroviral DNA genotyping (GenoSure Archive™ assay, Monogram Biosciences). Virologic outcomes were based on last available on-treatment HIV-1 RNA, where early discontinuation with HIV-1 RNA <50 copies/mL was considered suppressed.

**Results:** Altogether, 1521 participants switched to B/F/TAF and were treated for a median of 63 weeks (range 1–145 weeks; Table 1). Cumulative baseline genotypic data from historical and/or proviral genotypes were available for 89% (1354/1521). Pre-existing M184V/I was detected in 9.7% (132/1354) of participants: by proviral genotyping only (83%), 109/132, historical genotype only (9%), 12/132, or both (8%), 11/132. At baseline, participants with pre-existing M184V/I were 15–78 years old. At the time of analysis ≥68 weeks of B/F/TAF treatment, 98% (129/132) of participants with pre-existing M184V/I were suppressed compared to 99% (1504/1521) of the overall B/F/TAF study population. No B/F/TAF-treated participant developed new drug resistance.

**Conclusion:** Pre-existing M184V/I was detected in nearly 10% of suppressed participants’ baseline genotypes, the majority of which was previously undocumented. High rates of virologic suppression in participants who switched to B/F/TAF, and the absence of treatment-emergent resistance, indicate B/F/TAF may be an effective and durable treatment for suppressed patients with archived M184V/I.

**PE13/22**

**Absence of naturally existing resistance against the HIV-1 capsid inhibitor GS-6207 in HIV-1 primary isolates**

N Margot, R Ram, M Rhee and C Callebaut

Gilead Sciences Inc., Foster City, USA

**Purpose:** GS-6207 is a first-in-class HIV capsid (CA) inhibitor in clinical development as a long-acting agent. Processing of the gag polyprotein is linked to multiple stages of the viral life cycle, and natural gag polymorphisms found in viral isolates could be linked to loss of potency, as seen for maturation inhibitors (MI), also targeting gag. Here we studied the potency of GS-6207 in HIV-1 primary isolates from people living with HIV (PLWH) in the context of gag polymorphisms.

**Method:** The HIV-1 gag-protease fragment from 55 HIV-1 primary isolates from treatment-naive (TN; n=18) and treatment-experienced (TE; n=37) PLWH were cloned into the pXLA1 proviral DNA. HIV-1 constructs were transfected into 293T cells and viral isolates were harvested after 48 hours. Susceptibility (EC50) of the HIV-1 isolates to GS-6207 and controls was measured in a 5-day multi-cycle assay in MT-2 cells and compared to wild-type.

**Results:** GS-6207 displayed potency with an EC50 of 95 pM, with minimal variability across all 55 isolates tested (Table). In contrast, resistance to the protease inhibitors (PI) darunavir and atazanavir was high in TE isolates with PI resistance mutations. Antivirals from the MI class (bevirimat [BVM] and GS-3532798) displayed reduced potency in isolates with naturally occurring gag polymorphisms known to affect MI activity. NRTI control displayed limited variation from wild-type, reflecting the wild-type sequence in reverse transcriptase in these HIV isolates.

**Conclusion:** GS-6207 exhibited high potency that was not affected by the presence of gag polymorphisms and/or protease mutations present in primary isolates, underscoring the absence of naturally occurring resistance against GS-6207, in contrast to maturation inhibitors. This confirms that the mode of action of GS-6207 is distinct from that of maturation inhibitors. Additionally, viral isolates from TN and TE PLWH were equally susceptible to GS-6207, underlining its potential for treatment in PLWH regardless of their treatment history.

**Mean Drug Susceptibilities**

<table>
<thead>
<tr>
<th>Patient Isolates</th>
<th>GS-6207</th>
<th>BVM</th>
<th>GSK-3532795</th>
<th>ATV</th>
<th>DRV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment-Naive</td>
<td>0.8 [0.5–1.2]</td>
<td>&gt;46 [2.3–67]</td>
<td>&gt;39 [1.1–176]</td>
<td>0.8 [0.5–1.8]</td>
<td>0.8 [0.4–1.3]</td>
</tr>
<tr>
<td>(n=18)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-Experienced</td>
<td>0.8 [0.5–1.2]</td>
<td>&gt;36 [0.5–47]</td>
<td>&gt;35 [0.5–171]</td>
<td>148 [0.5–791]</td>
<td>99 [0.5–555]</td>
</tr>
<tr>
<td>(n=37)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PE13/23**

**Impacts assessment of home based care program over adherence to ART among adolescence living with HIV and AIDS in Blantyre Malawi**

L Samson Kapile1, B Mkomo2, S Mulole3, C Tsonga4 and S Chiomba5

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**Purpose:** To assess the impacts of home based care program over promoting adherence among adolescence on ART and viral load suppression. To identify factors that influence adherence among adolescence on ART. Adherence to HIV antiretroviral therapy (ART) is a critical determinant of HIV-1 RNA viral suppression and health outcomes. However, HIV infected adolescents and youth tend to be less adherent to antiretroviral therapy (ART) and have significantly lower rates of virological suppression which results in re-infecting others.

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Method: A sample of 2157 adolescence on ART in different health centres in Blantyre rural was selected assessed from 2016 and 2018. These were in 30 support groups under Senior Chief Kapeni, Blantyre. Weekly home visits were done to provide counselling and sanitation trainings where we targeted parents and guardians, at least 45 focus group discussions were done, 25 key informant interviews with parents, guardians, adolescence on ART, health service providers. Data were collected three times, during baseline, mid and end line. Data was analysed by using excel.

Results: 56% of adolescence who were provided care and support by their parents or guardians reported in improved health than before starting ART, 14% of adolescence living without parental care or guardians, reported little change, the fact be, they have little time to concentrates on medication, rather they use time for searching everyday basic need. 653 adolescence defaults were identified and retained on care. At least 1981 adolescence were vitally suppressed. Health service providers reported that, at adolescence that has no close relative likely miss the dates for collecting medication. Misbehaviour of health services providers hinders adolescence access the medication.

Conclusion: Adherence to ART can be achieved if the whole family where one is on ART treatment take part in treatment and linked with health service providers. Families has to be supported.

PE13/24
Correlation of results analysis drug resistance of HIV-1 among patients with virological failure by next-generation sequencing and traditional population sequencing
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Central Research Institute of Epidemiology, Moscow, Russian Federation

Purpose: Achieving the goal “90-90-90” requires a significant increase the number of HIV-1 infected patients on ART. It entails an increase of viral drug resistance (DR) testing application. For this aim traditional “Sanger”-sequencing is used in Russia. However, the implementation of next-generation sequencing (NGS) approach may be used for DR-testing as well. Nonetheless, NGS must be validated before. The purpose of this study was to compare the results of DR-analysis HIV-1 pol-gene (protease and reverse transcriptase) 2083–3344 obtained by NGS and “Sanger”-sequencing for viruses derived from patients with virological failure.

Method: Plasma samples from 45 HIV-infected patients who experienced virological failure were analyzed by “Sanger”-sequencing and NGS with 1%/5%/10%/20% sensitivity thresholds to minor viral populations. Analysis of pol-sequences obtained and DR-analysis were carried out using BioEdit, MEGA and HIVdb program of Stanford database.

Results: DR to at least one antiretroviral drug was detected in 45 patients by NGS with 1% threshold and in 43 patients by NGS5%/10%/20% and “Sanger”-sequencing.DR to PI was found in 15 patients by NGS1%, in 10 patients by NGS5%/10%/20% and in 9 patients by “Sanger”-sequencing.DR to NRTI was detected in 42 patients using NGS1% and in 40 patients using all the other sequencing methods. Finally, DR to NNRTI was detected in 35 patients using NGS1%, in 31 using NGS5%/10%, in 30 using NGS20% and in 29 patients using “Sanger” sequencing. All mutations detected by “Sanger”-sequencing were found using NGS1%. Altogether 377,288,268 and 241 DR mutations were detected by NGS 1%/5%/10%/20% respectively. Altogether 377,288,268 and 241 DR mutations were detected by NGS1% and in 40 patients using all sequencing methods.

Conclusion: Adherence to ART can be achieved if the whole family where one is on ART treatment take part in treatment and linked with health service providers. Families has to be supported.

Figure 1. DR mutations identified by “Sanger” and NGS

PE13/25
Analysis of the latent reservoir of a patient infected with HIV under PrEP by single full-length HIV-1 amplification
M Damagnez1, S Scholten1, V di Cristianzano1, S Sierra1, M Böhme3, M Däumer3, A Thielken1, R Kaiser1, E Knops1 and E Heger3
1Institute of Virology, University of Cologne, Faculty of Medicine and University Hospital of Cologne, Cologne, Germany 2Praxis Hohenstaufenring, Cologne, Germany 3Institute for Immunology and Genetics, Kaiserslautern, Germany

Purpose: Antiretroviral therapy fails to cure HIV-1 leading to a life-long disease. The reason for the failure is the latent reservoir which is established shortly after initial infection. The latent reservoir is characterised by replication-competent proviruses inside CD4+ cells which do not display active viral gene expression during ART. It demonstrates a remarkably strong long-term stability for which the reasons are not entirely clear. A better understanding of the latent reservoir could lead to a functional cure for the disease.

Method: In this work two single genome amplification approaches (published by Lee et al. 2017 and Brunner et al. 2016) were compared concerning to efficiency and success rate. The assay published by Lee was less complex and faster to implement than the assay proposed by Brunner, so it was validated and extensively performed for one patient who experienced an HIV-1 infection during pre-exposure prophylaxis by SGA and next-generation sequencing of full-length HIV-1 DNA.

Results: We demonstrated that the assay by Lee was highly sensitive for single genome amplification (SGA) by using a specialised cell-line containing integrated provirus. Overall, 22 proviruses generated by the assay were extensive analysed with respect to clonality, deletion/insertion, hypermutations and stop mutations, intact open reading frames, and resistance mutations. The proviral landscape involved resistance associated mutations M184I and M184V inside the reverse transcriptase, which indicates a new developing resistance against 3TC/FTC and not a transmitted 3TC/FTC resistance. In summary, 14% of the analysed population were genome intact, 9% had extensive hypermutations, and 50% contained large internal deletions.

Conclusion: This proviral full-length HIV-1 SGA implements a promising new rapid method which circumvents the limitation of the viral outgrowth assay. By intensive sequence analysis this assay allows a precise characterization of the latent reservoir to advance and improve cure strategies.

PE13/26
Drug resistance profile according to HIV-1 viral load after long–term exposure to antiretroviral treatment in the absence of routine virological monitoring: results from a programmatic cohort in sub-Saharan Africa
G Villa1,2, A Abdullahi1, D Ousu1, C Smith3, M Azumah1, L Sayeed4, H Austin1, D Awuah5, A Beloukas1,7, D Chadwick6, R Phillips3,5 and AM Geretti1
1University of Liverpool, Institute of Infection & Global Health, Liverpool, UK 2University of Sussex, Department of Global Health & Infection, Falmer, Brighton, UK 3Kwame Nkrumah University of Science and Technology, Kumasi, Ghana 4University College London, Institute of Global Health, London, UK 5Kamto Anokey Teaching Hospital, Department of Medicine, Kumasi, Ghana 6James Cook University Hospital, Centre for Clinical Infection, Middlesbrough, UK 7University of West Attica, Department of Biomedical Sciences, Athens, Greece

Purpose: To assess the extent of HIV-1 drug-resistance according to the viral load in a programmatic cohort in Ghana.

Method: The study recruited consecutive patients from 4 out-patient clinics in 2018. HIV-1 RNA was quantified with Xpert HIV-1 Viral Load (Cepheid, Sunnyvale, USA). Plasma samples underwent population sequencing if the viral load was >200 copies/mL. Major resistance-associated mutations (RAMs) and genotypic susceptibility scores (GSS) were determined using the Stanford HIV Drug Resistance database (v8.8).

Results: The study included 333 subjects on ART. Median ART exposure was 8.9 years (IQR 5.7–11.3) and most (297/333, 89.2%) were on a NNRTI-based regimen. HIV-1 RNA was quantifiable (≥40 copies/mL) in 164/333 (49.2%).

Figure 1. DR mutations identified by “Sanger” and NGS
transfecting HEK293T cells with plasmid DNA. YREGR and GIRGK, were constructed. SDM viral stocks were obtained by mutations, as well as insertions after codon 231 (231ins): GK, GYKGK, SREGK, A Bachelard3, V Ferr

patterns was common especially in patients with viral load

Conclusion: Co-existence of high viral loads and complex drug resistance

CRF02_AG was the most prevalent subtype (66/87, 75/87/C19/35/65 (53% respectively. Prevalence of NNRTI or PI RAM was 53/87 (60.9%), 59/87 (67.8%) and 3/87 (3.4%), resistance (median 2 RAMs; IQR 1–3). Patients with viral load ≥1000 copies/mL, 4 (33%–3%) had ≥1 RAM, most commonly M184V/I and K103N/S. Patients with viral load ≥1000 copies/mL had more extensive resistance (median 2 RAMs; IQR 1–3), and more complex resistance patterns: 35/65 (53.8%) had M184V/I and K103N/S, 20/65 (30–8%) had ≥1 discriminatory RAM (other than M184V/I), and 24/65 (36-9%) had ≥1 TAM. CRF02_AG was the most prevalent subtype (66/87, 75-9%).

Conclusion: Co-existence of high viral loads and complex drug resistance patterns was common especially in patients with viral load ≥1000 copies/mL, whose ART should be promptly managed.

PE13/27

In vitro analysis of replicative capacity and phenotypic susceptibility of integrase mutant HIV–2 viruses

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1AP-HP, Hôpital Bichat-Claude Bernard, Laboratoire de Virologie, Paris, France
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3AP-HP, Hôpital Bichat-Claude Bernard, Service de Maladies Infectieuses et Tropicales, Paris, France

Purpose: We aimed to assess replicative capacity and phenotypic susceptibility to INSTI of various resistance profiles observed in INSTI-experienced HIV–2-infected patients.

Method: Site-directed mutants (SDM) harboring T97A, E92Q+T97A, T97A+N155H, N155H, E92Q+T97A+N155H INSTI resistance-associated mutations, as well as insertions after codon 231 (231ins): GK, GYKGK, SREGK, YREGR and GIRGK, were constructed. SDM viral stocks were obtained by transfecting HEK293T cells with plasmid DNA. In vitro SDM phenotypic susceptibility to INSTI was measured, using the ANRS peripheral blood mononuclear cells (PBMC) assay. Viruses were co-cultured with fresh uninfected phytohemagglutinin-stimulated PBMC, with 10-fold dilutions of the antiretroviral drug, ranging from 1000 to 0.1 nM. Supernatant HIV–2 viral load was quantified at 3 and 4 days post-infection. Replicative capacity of SDMs with 231ins was assessed by measuring HIV–2 viral load at day 3, 7 and 14.

Results: Mutant viruses harboring 231ins did not present impaired replicative capacity, except 231insGIRGK mutant which exhibited a 43-fold lower viral replication than the wild-type virus at day 14 (Figure 1). SDM with 231insGK was resistant to raltegravir and cabotegravir, but remained susceptible to dolutegravir and bictegravir (Table 1). SDMs harboring a 5–amino-acids insertion were resistant to all integrase inhibitors. Phenotypic susceptibility to cabotegravir and raltegravir was impaired in presence of E92Q and/or N155H (6–to–75 fold-change), while bictegravir remained active on the 5 mutants.

Conclusion: Viruses with N155H mutation pathway, which is the most commonly observed mutation in INSTI-experienced HIV–2-infected patients, remained susceptible to bictegravir, offering a therapeutic option for patients infected by such viruses. Through this work, we also obtained new data on the recently described 231ins resistance pathway, using site-directed mutagenesis, showing no impact on viral fitness, and confirming the decreased susceptibility to first-generation INSTI and cabotegravir.

Resistance to second-generation INSTI occurred only for mutants with 5–amino-acids insertion, limiting their use in clinical practice.

Table 1. Phenotypic susceptibility to INSTI of HIV–2 site-directed mutants

<table>
<thead>
<tr>
<th>Mutant</th>
<th>Bictegravir, IC50, nM (Fold-change)</th>
<th>Cabotegravir, IC50, nM (Fold-change)</th>
<th>Dolutegravir, IC50, nM (Fold-change)</th>
<th>Raltegravir, IC50, nM (Fold-change)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R0D (wild-type)</td>
<td>3.0</td>
<td>3.3</td>
<td>2.9</td>
<td>2.4</td>
</tr>
<tr>
<td>231insGK</td>
<td>3.5 (1.2)</td>
<td>68 (21)</td>
<td>4.5 (1.6)</td>
<td>172 (72)</td>
</tr>
<tr>
<td>231insGYKGK</td>
<td>118 (39)</td>
<td>139 (42)</td>
<td>78 (27)</td>
<td>182 (76)</td>
</tr>
<tr>
<td>231insSREGK</td>
<td>25 (8.3)</td>
<td>70 (21)</td>
<td>14 (4.8)</td>
<td>39 (16)</td>
</tr>
<tr>
<td>T97A</td>
<td>4.2 (1.4)</td>
<td>6.6 (2.0)</td>
<td>3.3 (1.1)</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>E92Q+T97A</td>
<td>2.0 (0.7)</td>
<td>248 (75)</td>
<td>Not done</td>
<td>Not done</td>
</tr>
<tr>
<td>T97A+N155H</td>
<td>0.9 (0.3)</td>
<td>51 (15)</td>
<td>64 (22)</td>
<td>48 (20)</td>
</tr>
<tr>
<td>E92Q+T97A+N155H</td>
<td>0.8 (0.3)</td>
<td>29 (8.8)</td>
<td>33 (11)</td>
<td>15 (6.3)</td>
</tr>
<tr>
<td>N155H</td>
<td>1.7 (0.6)</td>
<td>42 (13)</td>
<td>1.1 (0.4)</td>
<td>24 (1.0)</td>
</tr>
</tbody>
</table>

Figure 1. Replicative capacity of HIV–2 site-directed mutants harboring an insertion after codon 231
Treatment simplification with two-drug regimens: impact of transmitted drug resistance mutations in residents of South–East Austria

E Stefl1, HH Kessler1, A Blazic1, SR Mehta2, AS Benzezer1, B Santner1, A Chaillon2 and M Hoenigl1,3

1Medical University of Graz, Diagnostic and Research Center for Molecular Biomedicine, Graz, Austria 2University of California San Diego, Division of Infectious Diseases and Global Public Health, San Diego, USA 3Medical University of Graz, Division of Pulmonology and Section of Infectious Diseases, Graz, Austria

Purpose: Two-drug regimens may be preferable to induce and/or maintain viral suppression, while decreasing lifetime cumulative drug exposure and potential long-term toxicities. In this study, the prevalence of transmitted drug resistance mutations (DRMs) to dobutegravir (DTG), lamivudine (3TC), and rilpivirine (RPV) currently used in two-drug regimens was investigated in residents of South-East Austria representing an area with a population of more than 1 million. The local HIV-1 transmission network was reconstructed to gain deeper insight into transmitted HIV-1 DRMs in this population.

Method: The study population included 192 ART-naive residents of South-East Austria with newly diagnosed HIV-1 infection between 2013 and 2018. Before initiation of ART, resistance testing based on Sanger sequencing data of the reverse transcriptase (RT) and integrase (IN) genes was performed using the Stanford University Genotypic Resistance Interpretation tool. The genetic transmission network was reconstructed; shared DRMs were defined as any DRM present in genetically linked individuals.

Results: The frequency of any clinically relevant DRM against DTG, 3TC, and/or RPV at time of diagnosis was 15.6% (30/192 patients). Of 192 patients, one (0.5%) showed resistance against DTG, 8 (4.2%) patients against 3TC, and 25 (13.0%) patients against RPV. Transmission network analysis found 42.7% (82/192) genetically linked patients forming 26 clusters, ranging in size from 2 to 10. Of the 30 patients harboring any DRM, 18 (60%) were members of 6 different clusters. Of those, 15/18 (83.3%) were shared DRMs.

Conclusion: In residents of South-East Austria, two-drug regimens may be used in the majority of patients. More than half of patients harboring any clinically relevant DRM were found to be part of clusters.

Baseline resistance to Doravirine depends on the algorithm used for interpretation


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Purpose: We report the prevalence of clinically relevant resistance to first-line regimens recommended by EACS in the newly diagnosed patients in Spain in 2018.

Method: The latest version (8.8) of Stanford HIV Drug Resistance Algorithm was used to investigate clinically relevant resistance, defined as any level of resistance different from susceptible or potential low-level resistance, to the latest update of EACS first-line regimens. Depending on the availability of fasta sequences in RT, Pro and Integrase, we studied resistance to ABC/3TC/DTG, TDF/FTC/DTG, TDF/FTC/BIC and TDF/FTC/RAL in 320 patients, TDF/FTC/RPV in 694 patients and TDF/FTC/DRV in 457 patients.

Results: Clinically relevant resistance to ABC and TAF/TDF was 0.7% (5/694), to 3TC/FTC was 0.3% (2/694), to RPV was 5.8% (40/694), and to RAL was 1.3% (5/394). No clinically relevant resistance to DRV, DTG or BIC was found.

Clinically relevant resistance to first-line regimens recommended by EACS in 2018 was as follows:

- a) ABC/3TC/DTG, TDF/FTC/DTG and TDF/FTC/BIC: two patients (0.6%) showed resistance to at least 1 drug in the regimen, and 1 patient (0.3%) resistance to 2 drugs;
- b) TDF/FTC/RAL: 6 patients (1.8%) showed resistance to at least 1 drug, and 1 patient (0.3%) to 2 drugs;
- c) TDF/FTC/DRV: 4 patients (0.9%) showed resistance to 1 drug in the regimen, and 1 (0.2%) to 2 drugs;
- d) TDF/FTC/RPV: 45 patients (6.5%) were resistant to 1 drug in the regimen, and 2 (0.3%) to 2 drugs.

No patient shared resistance to all 3 drugs in the regimen.

Conclusion: Clinically relevant baseline resistance to EACS protease- and integrase inhibitors-based regimens in HIV newly diagnosed patients in Spain remains very low. On spite of NNRTI resistance levels, caution on baseline resistance must be taken when starting a Rilpivirine based regimen.
A retrospective evaluation of a national home infusion provider’s approach to medication adherence of parenteral ibalizumab-uiyk in the alternate-site and homecare setting

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Purpose: Ibalizumab-uiyk (ibalizumab), is a parenteral CD4-directed post-attachment HIV-1 inhibitor, approved in the United States 2018, for treatment of HIV-1 infection heavily treatment-experienced adults with multidrug resistant HIV-1 in combination with oral anti-retroviral therapy (ART), who are failing their current ART regimen. (Package Insert).

The objective of this study was to demonstrate that medication adherence strategies would impact both the oral ART regimen compliance and ibalizumab infusions. The clinical infusion pharmacists’ expertise would synergistically focus on medication adherence for the total regimen.

Methods: A retrospective analysis evaluated medication compliance using this care management model. Data collected began in May 2018. Dosing was given per manufacturer guidelines: a loading dose followed by a maintenance dose every 2 weeks. If a maintenance dose is missed 3 plus days beyond 2 weeks, an additional loading dose is required. Scheduling, clinical management, and adherence to both oral ART and ibalizumab regimen was imperative. Adherence to oral ART was based on documented patient assessments and confirmation of refill history. Coordination of care and communication data was collected.

Results: Data from 73 patients representing a total of 1005 intravenous infusions of ibalizumab was studied. Seventeen patients missed 19 doses for reasons listed in Table 1. 62 of 73 patients (85%) continued to receive ibalizumab infusions as scheduled. Eleven patients discontinued treatments listed in Table 1. Only two patient discontinued the regimen due to non-compliance. Three patients discontinued due to side effects. Oral ART compliance achieved was 89% listed in Table 2.

Conclusions: Patients receiving Ibalizumab can be successfully treated at home or in an alternate-site setting. Eighty-five percent (85%) of studied patients continued to receive treatments every 2 weeks as planned. Medication adherence strategies were inclusive of oral ART. Ibalizumab provides a new treatment for oral ART resistant patients.

Prevalence of HIV-1 drug resistance among patients with antiretroviral therapy failure in Moscow region, Russia

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Purpose: In the Moscow region HIV-infected people accessible to public health reached 33,340 by the beginning of 2019, and ART coverage was 69%. The increase in number of people receiving antiretroviral therapy requires monitoring of acquired HIV drug resistance (DR) and enhancing surveillance of transmissible resistance

Method: We analyzed demographic and virological data from 896 ART patients attended the Moscow Regional AIDS Center in 2012–2019. Plasma samples were genotyped using ViroSeq™ HIV-1 test-system and interpreted using the Stanford HIV DR database

Results: The average age of patients was 35 years (range 1–67). The proportion of men and women was 58.5% and 41.5%, respectively. The duration of treatment in all patients was at least 6 months, and all had a virological failure in the history. For all the years studied, the virological failure was not associated with resistance-associated mutations (RAMs) in 143 (16%) patients. Among these cases, no dependence on gender or transmission route was detected. The proportion of ART-resistant patients was 84% (766 patients).

753 (84%) patients had single or multiple RAMs, resulting in HIV DR to one or more classes of ART.

Among those with HIV DR mutations identified, 54% had NRTIs + NNRTIs mutations, 32% — NRTIs only, 8% — NNRTIs only, 3% — NRTIs + PI, 2% — NNRTIs + NNRTIs + PI and 1% — PI only. The most common RAMs were M184V/I (11.5%), K65R (7.6%) to NRTIs, G190A/S/E (39.3%), K103S/S (28.0%) to NNRTIs and M46I/46L/V/LVML (32.8%) to PI.

Conclusion: High prevalence of circulating NRTIs + NNRTIs, NRTI- and NNRTI-resistant HIV-1 variants was observed in experienced HIV-1-infected patients in Moscow Region. HIV DR surveillance in the Moscow region should be strengthened to prevent the spread of multi-drug resistance and cross drug resistance and to strengthen the long-term success of ART.
predominant HIV-1 subtype with 71% of cases and 62.46% of our patients were exposed to last six ARV molecules. The prevalence of resistance to different classes of ARV was as follows: 65.37% to NRTI, with M184V (61.81%), 61.49 to NNRTI with Y181C/I/V (22.98%), and V82FT (2.3%) and L74V (0.05%).

Conclusion: These data show a high prevalence of NRTIs and NNRTI but less than 10% of PI resistance. The LPV remain sensitive in many patients this suggests the use better virological monitoring and good tools for poor adherence detection.

HIV-associated and non HIV-associated tumours

PE14/1
Prevalence of anal dysplasia among persons living with human immunodeficiency virus (HIV)
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Purpose: The study aimed to investigate the prevalence of anal dysplasia and describe the clinical characteristics of HIV-infected patients with anal dysplasia enrolled in services at a primary HIVSTI treatment hospital in the Philippines, a country experiencing one of the fastest growing HIV epidemics.

Method: This cross-sectional study was conducted from November 2017 to April 2018. Data were obtained through patient interview and chart review after informed consent. Anal pap smear using the conventional technique was performed and interpreted by a single pathologist.

Results: 371 patients were included in the analysis. The mean age was 32 years and more than 90% were male. The overall prevalence of abnormal anal cytology was 25.1% (n=93), of which 51.6% were classified as atypical squamous cells of undetermined significance (ASCUS), 37.6% low-grade squamous intraepithelial lesion (LSIL), 8.6% atypical squamous cells cannot rule out HSIL (ASC-H), and 2.2% high-grade squamous intraepithelial lesion (HSIL). There was a higher prevalence of anal dysplasia among HIV patients who identified themselves as homosexual (p = 0.002) or bisexual (p = 0.002), practiced receptive anal intercourse (p = 0.015), had ≥ 5 lifetime sexual partners (p = 0.052), had a CD4 T cell count ≤ 200 cells/mm³ (p = 0.388), and with WHO HIV clinical stages 3 and 4 (p = 0.014).

Conclusion: Results of this study were comparable and consistent with previous studies. Findings underscore the need for further investigation on routine screening of anal dysplasia among HIV-patients in the Philippines, especially male having sex with male (MSM).

PE14/2
HIV infection is associated with reduced survival among hepatocellular carcinoma cases from an urban referral hospital: Kampala, Uganda
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Purpose: Hepatocellular carcinoma (HCC) rates appear to be increasing with prolonged survival among HIV infected patients. This study described the impact of HIV-infection on HCC prognosis.

Methods: Eligible HCC patients attending the Mulago National Referral Hospital in Kampala, Uganda, were enrolled into a case–control study between March 2015 and February 2018. Standardized methods were used to collect clinical, ultrasound and laboratory data at enrolment and a follow-up telephone call was made at one, three, six and twelve months post-enrolment to determine vital status of HCC cases. Kaplan Meier curves and Cox regression analyses were used to assess determinants of HCC survival.

Results: Of 372 HCC cases, 18% were HIV-infected. HCC cases generally presented with multifocal disease (72%) with a median duration of symptoms of 4 months (IQR 1–84). None of the cases had received any curative treatment for HCC. Overall, 310 (83.3%) HCC case deaths were reported within one year following diagnosis. Median survival was 5 months from symptom onset and 1.5 months from diagnosis. HIV infected HCC cases had a median survival of 4 months. In multivariable analysis after adjusting for age, sex and ALT levels, HIV infection was independently associated with a 47% increased mortality risk (HR 1.47, 95% CI:1.08–1.99, p 0.012).

Conclusion: Despite overall rapid mortality, HIV-infected HCC cases had a poorer prognosis compared to HIV negative HCC patients. Clinical and ultrasound-based screening algorithms which are relatively affordable should be explored for early HCC diagnosis and linkage to care, in these resource-limited settings where HIV is prevalent.

PE14/3
High prevalence of anal and cervical dysplasia in a cohort of HIV-infected women, but low prevalence of concomitant lesions
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Purpose: Incidence of Anal Intraepithelial Neoplasia is higher in HIV-1 women compared with HIV-uninfected women. HIV–1 infected women have an increased risk of an invasive anal squamous cell carcinoma (AASC) compared to HIV-uninfected women. Published data on prevalence of anal intraepithelial lesions are scarce in these women. The aim of this study was: estimate prevalence of anal–cervical lesions, prevalence of concomitant lesions and the associated predictive factors in a cohort of HIV-1 women.

Methods: Cross sectional study performed between 2008–2018. HIV–1 infected women from single tertiary care center in Catalonia-Spain were included. Anal/cervical cytology was performed, High-resolution anoscopy/colposcopic biopsy was performed in women with ASCUS, LSIL, HSIL anal/cervical cytology.

Results: 514 HIV-1-infected women were included: mean (SD) age, 42 (10) years; median (SD) of HIV diagnosis time, 14.1 (6.9) years; 261 (53%) women has a CD4 T-cells <200 cells/μL. Anal cytology [n (%)]: normal [280 (54%)], ASCUS [61(12%)], LSIL [81(16%)], HSIL [37(7%)] and unsatisfactory [55(11%)]. Cervical cytology: normal [16(3%)], AIN1 [51(8%)], AIN2 [21(19%)], AIN3 [12(11%)], non-evaluable [3 (3%)]. Cervical cytology was not available in 20 women: normal [313(63%)], ASCUS [60 (12%)], LSIL [99(20%)] and HSIL [20 (4%)] and unsatisfactory [20(4%)], 67 cervical biopsies were performed: normal [16(24%)], CIN1 [28(42%)], CIN2 [15 (22%)], CIN3 [6(9%)]. Other diagnosis [2 (3%)]. The prevalence of concomitant SIL in anal and cervix was 5%, correlation coefficient: 0.377. No predictive factor was associated with concomitant lesions, Conclusion: Prevalence of anal canal intraepithelial lesions was similar to the prevalence of cervical intraepithelial lesions in HIV-1 women. The prevalence of concomitant lesions in anal and cervix was low. In front of the lack of results on effectiveness of the screening programs for cancer prevention in anal canal, our results suggest that this preventive strategy in anal canal (and cervix) is advisable for HIV-1-infected women.
PE14/4
Malignant and benign skin lesions in HIV-1 infected people
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Purpose: In cART era, the incidence of AIDS-defining cancers decreased while there is a persistence of non-AIDS defining cancers. Whether HIV patients are at increased risk of melanoma and non-melanoma skin cancer (NMSC) is not well documented. Compared with HIV-uninfected persons, the HIV-infected counterparts have a higher risk for subsequent squamous cell carcinoma (SCC) but not basal cell carcinoma (BCC), with a dose-response relationship with lower CD4 count and higher viral load. Aim of this study was to assess the presence of cutaneous malignancies in HIV-1 patients.

Methods: A monocentric cross-sectional study was conducted on HIV-infected patients consecutively visited (February-May 2019). A single expert dermatologist assessed the presence of skin lesions. All suspicious lesions were biopsied and evaluated by a dermatopathologist. Clinical history of HIV infection and laboratory data were recorded. The characteristics of the patients with or without NMSC were compared by chi-square test for categorical variables and T-test for independent samples for continuous variables.

Results: NMSC was diagnosed in 17/96 patients (17.7%, 15 SCC and 2 BCC), melanoma in 2 patients (2.1%). Other lesions were: 6 actinic keratoses (6.2%), 7 seborrheic keratoses (7.3%), 5 atypical nevi (5.2%). Patients with NMSC were older (mean difference 7.8 years, SD 2.6, p = 0.003) than non-NMSC patients, while no differences were found regarding photodamage, family history for NMSC/melanoma, CDC class, time from HIV diagnosis, nadir CD4 cell count, log10 zenith viral load, current CD4 cell count, time on antiretroviral therapy, exposure to different antiretroviral drug classes.

Conclusions: Our study showed that SCC was more common than BCC regardless of the state of immunological reconstitution, time of HIV diagnosis, nadir or current CD4 cell count. Two patients were diagnosed with melanoma (a Superficial Spreading Melanoma and a nodular melanoma), suggesting that dermatological evaluation can be very important for early diagnosis of non-AIDS related skin cancers.

PE14/5
Results of HPV-testing for anal screening in HIV-infected women
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Introduction: Occurrence rate of anal cancer is comparatively rare and accounts for approximately 1–2% of all tumors of the gastrointestinal tract in the general population. The cancer of the anal canal is usually associated with the human papillomavirus (HPV). The risk group for this disease is women with HPV-infected in cervix. HIV-infected women have a higher risk of papillomavirus infection, malignancy and persistence than HIV-negative women.

Purpose: to study the prevalence of HPV high carcinogenic risk (HCR) in anus among HIV-infected women.

Method: We examined 99 HIV-infected women from Moscow region during 2018–2019. There was performed HPV-test from anus and cervix (with the determination of 14 types of HPV HCR - 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) for all women.

Results: Young women up to 40 years predominated in the study group. There were diagnosed with HPV of HCR in anus in 47 (47.5%) of them: 62% (29/47) HPV detection was in cervix (maximum 7 genotypes in one sample) and 38% (18/47) without HPV in cervix (maximum 3 genotypes in one sample). Frequency of determination types of HPV HCR in anus is: 16 – 32.2%, 18 – 25.5%, 31 – 23.4%, 33 – 14.9%, 35 – 52–12.8%, 39 – 10.6%, 45 – 10.6%, 51 – 10.6%, 52 – 10.6%, 56 – 8.5%, 58 – 7.9%, 59 – 8.5%, 66 – 6.4%, 68 – 6.4%.

Conclusion: HIV-infected women have a high incidence of HPV infection and a wide range of detectable genotypes of HCR HPV with the highest incidence of HPV infection. The results should be used to develop anal screening using HPV testing for at least 13 HCR HPV genotypes.

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PE14/6

COHORT SDT (Granada): decrease of the incidence of HSIL+ in the anal mucosa of HIV+ patients MSM after the performance of a screening, diagnostic and therapeutic program (2010–2018)

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Purpose: Our main objective was to analyze the incidence of HSILs and ASCC (HSIL+) in anal mucosa of HIV+ MSM, and the risk factors related.

Method: The study included consecutive HIV-infected MSM between May 2010 and December 2018. Data were gathered at baseline and annually on their sexual behavior, CD4 and CD8 levels, HIV viral load of HIV, and anal cytology, HPV PCR, and high-resolution anoscopy. Patients with normal anoscopy and LSIL were evaluated annually. There were two options for patients with HSIL: mucosectomy with electric scalpel by the coloproctology service or 3 doses (0, 2, 6 months) of 9 valent vaccine (Gardasil9 MSD). Antibodies against HPV vaccine genotypes and HIV parameters are measured at baseline and during vaccination and further vaccination was discontinued because it had affected the patient’s daily activities. In all other cases, headaches were of minor severity (requiring paracetamol intake in 10/17 episodes) and vaccination was pursued. At month 7, median CD4 was 699/μL and 95% had HIV RNA <50 cp/μL.

Conclusion: Vaccination against HPV with the 9 valent vaccine is safe and well tolerated in HIV-positive women with the same tolerance profile as in HIV-negative women. HPV vaccination does not impact the control of HIV infection.

PE14/8

Cancer trends and outcomes in a cohort of people living with HIV

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Purpose: the aim of our study was to evaluate cancer cases in terms of diagnoses, management and outcomes in our cohort of people living with HIV (PLWHIV) in the HAART era.

Method: we performed a retrospective study including PLWHIV with a diagnosis of cancer in the last 15 years. We collected data about diagnosis, type of cancer, staging, treatment and cause of death. We considered four groups depending on the year of diagnosis (<2010, 2010–2012, 2013–2015, 2016–2018). Furthermore, we divided cancers in AIDS-defining cancer (ADC), virus-related non-AIDS-defining cancer [(HCV, HBV, EBV and HPV), VR-NADC] and not-virus-related and non-AIDS-defining cancer (NVR-NADC).

Results: we enrolled 83 patients for a total of 92 cases of cancer. Seven patients had two different cancer, and one patient had three. Demographic, clinical and virologic data have been summarized in Table 1. Although the number of cases was similar in each group, the temporal distribution was different (Figure 1). ADC diagnoses were more frequent before 2010. On the contrary, NVR-NADC showed an increasing trend in the last 3 years-period. VR-NADC were, instead, stable during the years. Sixteen (17.4%) subject were naive at the diagnosis of cancer and 14 of them had an ADC (11 Kaposi’s Sarcoma, 3 Non-Hodgkin Lymphoma) and 2 a testicular cancer.

We observed 38 (45.78%) deaths with a median survival of 6.2 (IQR: 1.4–14.4) months. Thirtytwo (84.21%) patients died in the first 2 years after the diagnosis. NVR-NADC showed the highest mortality rate (51.6%), especially when diagnosed late (81.2%). An advanced cancer at the diagnosis was the strongest predictor of mortality (aHR 23.59, CI 3.08–180.67).

Conclusion: NVR-NADC showed a progressive increase in the last years-period. VR-NADC were, instead, stable during the years. Sixteen (17.4%) subject were naive at the diagnosis of cancer and 14 of them had an ADC (11 Kaposi’s Sarcoma, 3 Non-Hodgkin Lymphoma) and 2 a testicular cancer.

PE14/7

Prospective longitudinal study on immunogenicity and safety of vaccination against human papillomavirus (HPV) with the 9valent vaccine in HIV-positive women, the Papillon study: preliminary results on tolerance and safety

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Purpose: Guidelines on HPV vaccination in HIV-positive women recommend preferentially 9valent vaccine in 3 doses but there are currently no data on this strategy. We present preliminary results on tolerance/safety of this vaccine in women with well-controlled HIV infection.

Method: The Papillon study (EUDRACT 2018-000228-33/NCT NCT03391921) is an ongoing prospective trial in HIV-positive women, aged 15–40 years, on cART with HIV RNA <400 cp/mL, randomized to receive either 2 (0.6 months) or 3 doses (0, 2, 6 months) of 9 valent vaccine (Gardasil9 MSD). Antibodies against HPV vaccine genotypes and HIV parameters are measured at baseline and month 7 (one month after last vaccine dose). Vaccine tolerance/safety is evaluated by a specific questionnaire performed once between day 2 and 7 after each dose.

Results: Between June 2018 and June 2019, 90 women were vaccinated with 188 doses (3 doses n=41, 2 doses n=57, 1 dose n=90 women). At baseline, median age was 35 years, CD4 656/μL, 93% had HIV RNA <50 cp/mL. After a median follow-up of 165 days, there was no serious adverse event; 62% (56/
PE14/9

Rate of HCC occurrence and associated risk factors in a multicentric cohort of HIV/HCV co-infected patients treated with DAAs

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Purpose: After the introduction of direct-acting antivirals (DAAs), the natural history of HCV infection has changed, with effects on HCV-related outcomes. Our study aimed to determine the rate and the predictors of HCC in a HIV/HCV co-infected population of cirrhotic individuals treated with DAAs-regimens.

Method: We retrospectively studied all cirrhotic HIV/HCV individuals treated with DAAs, from October 2014 to January 2017 at the Departments of Infectious Diseases in five Italian hospitals, observing our patients from the first day they started DAAs therapy, and analyzed their characteristics with multivariate COX regression to find independent prognostic factors for HCC occurrence.

Results: We included 178 HIV/HCV co-infected patients: 76.4% were male and the median age was 52 (IQR 49–55) years. After a median of 13 months, HCC occurred in 15 patients (8.4%), 3 of them being recurrences, with a rate of HCC recurrence of 50% and median disease-free survival of 14 months. At the univariate analysis we found that HCV genotype, Child Pugh Turcot (CPT) score, CD4-linfocytes nadir and cART administration at baseline were significantly different between patients who developed HCC and patients who did not. Furthermore, patients with a previous history of HCC showed a higher risk of developing a second event (Table 1). After adjusting for confounders, HCV genotype 1b, higher CPT score and history of HCC remained independently associated with HCC occurrence (p-value 0.005, 0.01 and <0.001 respectively), otherwise cART administration at baseline was a protective factor (p-value 0.03; Table2).

Conclusions: As we expected, in our cohort, HCC occurrence was associated to the severity of liver disease, HCV genotype 1b, and previous history of liver cancer. What moreover came out is the need of a deeper investigation of the role of immunovirological control of HIV as a protective factor for HCC.

Table 2. Factors independently associated with HCC occurrence at COX multivariate regression

<table>
<thead>
<tr>
<th>Variable</th>
<th>HR (95%)</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>Age 1.09 (0.96–1.24)</td>
<td>0.178</td>
<td></td>
</tr>
<tr>
<td>Male 1.76 (0.22–14.09)</td>
<td>0.592</td>
<td></td>
</tr>
<tr>
<td>CPT score 1.55 (1.1–2.18)</td>
<td>0.012</td>
<td></td>
</tr>
<tr>
<td>HCV genotype 1b 12.82 (2.18–75.19)</td>
<td>0.005</td>
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<tr>
<td>HCV genotype 3 3.72 (0.87–16)</td>
<td>0.077</td>
<td></td>
</tr>
<tr>
<td>Naive to HCV therapies 0.47 (0.14–1.64)</td>
<td>0.238</td>
<td></td>
</tr>
<tr>
<td>HCC history 16.47 (3.52–76.98)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>cART administration 0.12 (0.02–0.80)</td>
<td>0.034</td>
<td></td>
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</tbody>
</table>

PE15/1

Genetic characterization of the near full-length genome of an HIV-1 A1/C/D/K/B unique recombinant form from the Eastern Cape, South Africa: a case report

OV Adeniyi

Walter Sisulu University, East London, South Africa

Purpose: HIV-1 sub-type C is the predominant circulating virus in South Africa, a country with the world’s largest HIV epidemic. There have been anecdotal reports of non-C subtypes of HIV-1 in different parts of the country in the past two decades. Though, Eastern Cape has the third largest HIV epidemic by province in South Africa, very little information exists on the genetic diversity of HIV in this understudied region of the country.

Method: This paper presents the genetic analysis of a mosaic recombinant variant of HIV-1 from a pregnant woman from Mdantsane, Eastern Cape, South Africa. Preliminary analysis of the partial Pol gene of the RNA sequence showed inter-subtypes recombination of C and D, thus, prompting a detailed analysis of the full-length genomic sequence. The REGA HIV sub-typing tool version 3.0 was used to analyse the full sequence for recombination pattern. Sequences were multiply aligned with Clustal X and phylogenetic trees generated by the neighbour-joining method.

Results: The full sequence analysis revealed a mosaic pattern comprising recombinant C/D (in the pol gene), recombinant A1/C/D (in the gag gene) and predominant B subtype in the env- nef gene. The accessory genes consist of: recombinant B/K in the Vpu gene and other subtypes: C (Vpr and Vif genes) and B (Nef gene).

Conclusion: This is the first report of this mosaic pattern of HIV-1 in South Africa. However, the clinical and epidemiological implications of this variant remains unclear. More studies are needed to fully understand the genetic diversities of HIV in the country.

Table 1. Baseline characteristics of overall population, with comparison of patients with and without HCC through COX univariate regression

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall N=178</th>
<th>No HCC N=163</th>
<th>HCC N=15 (8.4%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (expressed as median and interquartile range or absolute)</td>
<td>52 (49–55)</td>
<td>52 (49–55)</td>
<td>52 (50.2–55)</td>
<td>0.472</td>
</tr>
<tr>
<td>Male</td>
<td>136 (76.4%)</td>
<td>123 (75.5%)</td>
<td>13 (86.7%)</td>
<td>0.334</td>
</tr>
<tr>
<td>HCV genotypes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td>14 (7.9%)</td>
<td>11 (6.7%)</td>
<td>3 (20%)</td>
<td>0.03 (HR 5.71)</td>
</tr>
<tr>
<td>1b</td>
<td>72 (40.4%)</td>
<td>69 (42.3%)</td>
<td>3 (20%)</td>
<td>0.03 (HR 5.71)</td>
</tr>
<tr>
<td>2</td>
<td>4 (2.2%)</td>
<td>4 (2.4%)</td>
<td>0 (0%)</td>
<td>0.998</td>
</tr>
<tr>
<td>3</td>
<td>59 (33.1%)</td>
<td>52 (31.9%)</td>
<td>7 (46.7%)</td>
<td>0.111</td>
</tr>
<tr>
<td>4</td>
<td>28 (15.7%)</td>
<td>26 (16%)</td>
<td>2 (13.3%)</td>
<td>0.529</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.6%)</td>
<td>1 (0.6%)</td>
<td>0 (0%)</td>
<td>0.99</td>
</tr>
<tr>
<td>Naive to HCV therapies</td>
<td>100 (56.2%)</td>
<td>94 (57.7%)</td>
<td>6 (40%)</td>
<td>0.171</td>
</tr>
<tr>
<td>CPT score (23 missing)</td>
<td>5 (5–6)</td>
<td>5 (5–6)</td>
<td>6 (5–7.5)</td>
<td>0.01 (HR 1.43)</td>
</tr>
<tr>
<td>CP-A</td>
<td>125 (80.6%)</td>
<td>116 (62.9%)</td>
<td>9 (60%)</td>
<td>0.01</td>
</tr>
<tr>
<td>CP-B</td>
<td>28 (18.1%)</td>
<td>23 (16.4%)</td>
<td>5 (33.3%)</td>
<td></td>
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<tr>
<td>CP-C</td>
<td>1 (1.3%)</td>
<td>1 (1.3%)</td>
<td>0 (0%)</td>
<td>0.99</td>
</tr>
<tr>
<td>HCC history</td>
<td>3 (3.4%)</td>
<td>3 (1.8%)</td>
<td>3 (20%)</td>
<td>&lt;0.001 (HR 8.58)</td>
</tr>
<tr>
<td>Nadir CD4 (56 missing)</td>
<td>151 (98–289)</td>
<td>148 (68–266)</td>
<td>328 (126–408.5)</td>
<td>0.009 (HR 1.01)</td>
</tr>
<tr>
<td>ART administration</td>
<td>173 (97.2%)</td>
<td>160 (98.2%)</td>
<td>13 (86.7%)</td>
<td>0.029 (HR 0.13)</td>
</tr>
</tbody>
</table>
PE15/2

Impact of KIR and their ligands (HLA allele) on susceptibility to selected viral opportunistic conditions and HIV plasma viral load in HIV+ patients

M Leszczyszn-Pynka, B Aksak-Was, A Urbariska and M Parczewski
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Purpose: To assess the influence of KIR/HLA allele on occurrence of Herpesvirus AIDS-defining conditions, HPV infection, pretreatment TCD4+ cell count and HIV-RNA, baseline TCD4+/TCD8 ratio as well as nadir TCD4+ count.

Method: Study included 310 HIV-positive patients. Among them 70 (22.6%) had the history of shingles, 36 (11.6%) – HPV clinical manifestation, 38 (12.3%) - CMV, EBV, HHV-8 and HSV diseases defining AIDS. Genotyping of 16 variants of KIR, HLA-A Bw4+, HLA-B Bw4+He80, HLA-B Bw4+Thr80, HLA-C1 Asn80 and HLA-C2 Lys80 was performed with PCR-SSP, statistical analysis with chi-square test and U Mann-Whitney test.

Results: Patients with a history of HPV infection were found significantly more likely to carry KIR2D53 (p = 0.002), KIR2DL5aIl (p = 0.004) or KIR2DL5r2 (p = 0.0003) alleles. Among these patients HLA-C1Asn80, KIR2DL3 and compound KIR2DL3/HLA-C2 were less frequent compared to those without HPV manifestation (p = 0.03, p = 0.02 and p = 0.003, respectively). Expression of compound KIR3DS1/HLA-B Bw4+ and genotype HLA-C1/HLA-C2 tended to link with lower frequency of shingles (p = 0.05 and p = 0.06, respectively). No significant differences in frequency of the analysed KIR and HLA genotypes between patients with and without AIDS-defining illnesses with CMV, HSV, EBV and KS-HV were found. Higher pretreatment HIV-RNA was found in patients expressing KIR2DS1 (p = 0.038), KIR2DS2 (p = 0.041), KIR3DS1 (p = 0.023), KIR2DL2 (p = 0.018), KIR2DL5ex (p = 0.019), KIR3DS1/3DL1 (p = 0.008) and following compounds - KIR2DL2/HLA-C1 (p = 0.0006), KIR2DL2/HLA-C2 (p = 0.023), KIR2DS1/HLA-C1 (p = 0.015), KIR2DS1/HLA-C2 (p = 0.004), KIR2DL2/3DL1/HLA-C1 (p = 0.01). The only genetic variant connected with lower baseline viral load was haplotype A of KIR (p = 0.0003). KIR2DL5r2 was related to lower nadir TCD4+ cell count (p = 0.038).

Conclusion: 1. Six variants of KIR and HLA allele both alone and in pairs were found to influence/modify the occurrence of HPV-related diseases among HIV-infected patients.
2. Expression of selected KIR variants, compounds and KIR haplotype A is affecting HIV replication.

PE15/3

The identification and causal analysis of aberrant CD4 counts in an HIV cohort in Southern Alberta, Canada

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1University of Calgary, Department of Medicine, Calgary, Canada 2National HIV Reference Laboratory, National Microbiology Laboratory, Winnipeg, Canada 3Alberta Health Services, Department of Lab Medicine, Calgary, Canada 4University of Calgary, Department of Medicine, Calgary, Canada

Background: The CD4 count is used as the most robust surrogate marker for HIV disease immunosuppression. A potential confounder (genetic diversity of the OKT4 receptor) in the correct enumeration of CD4 cells was described in 1981 but has subsequently received little attention. We report on a series of cases where this mutation compromised the results of a new commercially available monoclonal antibody leading to highly aberrant results.

Methods: After a routine satisfactory comparative analysis (200 samples) a new commercial monoclonal antibody (BioLegend: T4-FITC anti-human CD4 antibody) was introduced in flow cytometry CD4 testing. In 5/1980 patients receiving care at the Southern Alberta HIV Clinic who had, despite clinical and virologic stability, experienced an apparent sudden reduction in immunofluorescence. We also identified heterozygosity leading to correct count but a 50% reduction in immunofluorescence.

Results: All cases had central to east African ethnic background. Their CD4 measurement was aberrant with only one commercially monoclonal product. A homozygous mutation of the OKT4 epitope in the V3 domain of the CD4 explained the complete absence of CD4 cell recognition in these five patients. We also identified heterozygosity leading to correct count but a 50% reduction in immunofluorescence.

Conclusions: HIV care programs need to be aware that reagents and assays reflect a changing profile of the HIV epidemic, noting host genetics. Despite significant developments in laboratory methods, allowing for more accurate and efficient CD4 reporting, ongoing vigilance is required of both lab professionals and clinicians to identify false test results and pursue programmatic improvements.

PE15/4

Placental gene expression profiles and pathways in HIV-1 positive Cameroonian women under ART

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Purpose: A major consequence of in-utero exposure to HIV/ART is increased morbidity and mortality in infants during postnatal life. The causes and mechanism(s) underlying these conditions are not well understood. The placenta plays a key role in the development of a healthy fetus, and normally functioning placentas increases the chances of improved health later on in their childhood. We hypothesized that HIV-1 infection causes alterations in the functioning of the placenta, which impedes the holistic development of the fetus. The aim of this study was to conducted a genome-wide study investigating changes in the gene expression and pathways in women infected by HIV-1 under ART.

Method: In a cross-sectional survey, 102 women (31 HIV-1 positive under ART, and 71 uninfected woman) were enrolled. Median viral load was 682 copies/ul and women were on variable lengths of treatment. Placenta biopsies

DNA chromatogram homozygous wild type CD4

DNA chromatogram homozygous OKT4 deficient. The arrow denotes position 868 in the CD4 gene
excised from 9 HIV-1-positive women and 8 HIV-uninfected women were carefully selected and gene expression was measured using Illumina Human HT-12 v 4.0 BeadChip microarray. Next, genes presenting a 2-fold ratio as compared to the control group were entered into Ingenuity Pathway Analysis (IPA) in order to determine genes specifically regulated in the placenta of HIV-1-infected women.

Results: Over 61,47323 genes were significantly dysregulated in placenta from HIV-1+ women compared to the HIV- controls. These genes encoded components of canonical signaling pathways: “Epithelial Adherens Junction”, “Phagosome Maturation”, “Gni12/13”, “14–3–3–mediated”, “HIF1a”, “CDK5”, and the “Remodeling Epithelial Adherens”. Predictor networks indicated that the placenta of HIV-1-infected had upregulations in genes that confer organisinal injury and abnormalities.

Conclusion: The gene expression in the placenta is different between HIV-1/ART and uninfected counterparts, and highlights specific genes such as those related to injury. This might underwhelm the sound development of the fetus and consequently the well-being of the off-spring in later life.

PE15/5
Functional clustering and association of HLA class I alleles to viral load in HIV-positive and ART-naive participants from the INSIGHT START study

AG Zucco1, M Bennedebk1, C Ksenberg1, M Gabrielaite2, DD Murray3, C MacPherson4, MH Losso5, MN Polizzotto5, R Paredes5, V Kan6, AG Babiker7, HC Lane8, JD Neaton9, JD Lundgren1 and INSIGHT START Study Group

1 Rigshospitalet, University of Copenhagen, Centre of Excellence for Health, Immunity and Infections (CHIMP), Department of Infectious Diseases, Copenhagen, Denmark 2 Rigshospitalet, Copenhagen University Hospital, Center for Genomic Medicine, Copenhagen, Denmark 3 Hospital General de Agudos JM Ramos, Buenos Aires, Argentina 4 University of New South Wales, Kirby Institute, Sydney, Australia 5 Hospital Universitari Germans Trias i Pujol, Infectious Diseases Service & irisiCaixa AIDS Research Institute, Badalona, Spain 6 George Washington University, Veterans Affairs Medical Center, Washington D.C, USA 7 University College London, Medical Research Council, Clinical Trials Unit, London, UK 8 National Institute of Allergy and Infectious Diseases, Division of Clinical Research, Bethesda, USA 9 University of Minnesota, Division of Biostatistics, School of Public Health, Minneapolis, USA

Background: Previous studies on host-viral genomics in HIV+ patients found associations between HIV-1 viral load (VL) and HLA class-I alleles. Statistical analyses of HLA alleles have been challenging due to high polymorphism and variable allele frequencies among populations. To overcome this, we explored functional clusters of HLA class-I alleles based on predicted epitopes to increase statistical power.

Methods: Viral sequencing data from 3785 HIV+ participants enrolled in the START study was used to assemble HIV consensus sequences from 35 countries. We translated these sequences into 1.03 million putative HIV-1 peptides (9-mers) and predicted their binding affinities to 259 HLA class-I alleles using netMHCpan 4.0. This predicted cohort-specific immunopeptidome was used to group alleles by hierarchical consensus clustering into a single high-confidence tree of functional relationships (Fig. 1). Associations of log10(VL) to each functional cluster were tested by linear regression using a q-value <0.05 to identify significant functional clusters, only two (HLA-B*57:01 and B*57:03 Fig. 2) were detected at individual allele level.

Conclusions: Consensus clustering of HLA alleles based on predicted epitopes provides functional groups to efficiently explore associations with VL. Three significant functional clusters were found containing both previously reported HLA alleles (HLA-B*57) and novel candidates whose predicted epitope profiles closely resemble those of other alleles affecting HIV-1 VL that were not detected at individual allele level.

Figure 1. Dendrogram of 259 HLA class I alleles based on predicted binding affinities to HIV

Figure 2. Boxplots and violin plots of HIV-1 VL in carriers and non-carriers of reported HLA nodes

PE15/6
miRNA expression profiling in subcutaneous adipose tissue of monozygotic twins discordant for HIV infection: validation of differentially expressed miRNA and bioinformatic analysis

N squillace1, E Bresciani2, V Orsini2, L Rizzii2, R Meanti2, A Soria1, G Lapadula1, A Bandera1, A Gori3,4, V Locatelli2, G Migliorino1 and A Torsello2

1 San Gerardo Hospital, Infectious Diseases Unit, Azienda Socio Sanitaria Territoriale di Monza, Monza, MB, Italy 2 University of Milano Bicocca, Medicine and Surgery Department, Monza, Italy 3 Fondazione IRCCS Ca’ Granda Ospedale Maggiore Policlinico, Infectious Diseases Unit, Department of Internal Medicine, Milano, Italy 4 School of Medicine and Surgery, University of Milan, Department of Pathophysiology and Transplantation, Milano, Italy

Purpose: Variability in metabolic complications of combination Antiretroviral Treatment (cART) has been linked not only to therapy, but also to host genetic factors. MicroRNAs (miRNAs) are small noncoding RNAs regulating gene expression. The model of two monozygotic twins differing only for HIV-infection could allow to better comprehend cART miRNAs regulation, independently of genetic background.

Methods: A profiling of 2577 mature miRNA in subcutaneous adipose tissue (SAT) of twins was investigated by GeneChip® miRNA 4.1 array. Real-time PCR was performed to validate differentially expressed miRNAs. Target genes of deregulated miRNA were predicted by miRDB database (prediction score >70) and enrichment analysis was carried out with Panther, a platform using Gene Ontology and Panther pathways as annotation data set.
Results: Twin A, HIV+ on therapy with tenofovir, emtricitabine and efavirenz, was affected by peripheral and face lipoatrophy; no comorbidity was reported for Twin B, HIV-. They differed significantly for BMI (21.8 vs 27.3, twin A vs twin B) but not for glucose, lipid profile, liver enzymes and blood pressure. 95% mature miRNAs differentially expressed (FC ≥ 2 or ≤2) in the twin A respect to the B were identified: 30 were up-regulated, whereas 65 were down-regulated. mir-15b-5p, mir-127-3p (upregulated), mir-122-5p and mir-3620-5p (downregulated) were validated by Real-Time PCR. Prediction target analysis identified 914 genes. Pathway enrichment analysis of genes targeted by miRNAs showed their involvement in Cadherin signalling (a key protein in the adhehers junction), Fibroblast Growth Factor, Notch signalling (a critical pathway for kidney development), T cell activation and Wnt signaling (involved in pathogenesis of neuroinflammation in the Central Nervous System).

Conclusions: This analysis could provide some preliminary information on genes targeted by mir-15b-5p, mir-127-3p, mir-122-5p and mir-3620-5p in SAT. Further researches could deepen the link between deregulated miRNAs and comorbidities reported in people HIV-affected.

PE16/2
New T- and B-lymphocytes production and T-cell receptor diversity in young adults perinatally infected by HIV

M Properzi1, S Paghera2, L Imberti2, A Sottini2, F Castelli2 and E Quiros-Roldan1

1University of Brescia and ASST Spedali Civili Brescia, Department of Infectious and Tropical Diseases, Brescia, Italy 2Centro di Ricerca Emato-Oncologica AIL (CREA), Diagnostic Department, ASST Spedali Civili di Brescia, Brescia, Italy

Objectives: To evaluate immunosenescence (defined as reduced production of new lymphocytes, restriction of T-cell receptor repertoire and telomeres shortening) in perinatally-infected children with very long-lasting HIV infection.

Methods: We compared thymic and bone marrow output (quantifying the number of T-cell receptor excision circles (TRECs) and K-deleting recombination excision circles (KRECs)), telomere length (TL) and T-cell repertoire (analyzed by means of CDR3 spectratyping analysis) of 21 perinatally HIV-infected subjects (pHIVy), with a mean of 27 years of infection, with those of 19 age-matched non-perinatally HIV-infected patients (np-HIVy), with a mean duration of HIV infection of 4.5 years, and of 40 age-matched healthy controls (HC).

Results: TRECs and KRECs levels were similar among pHIVy, npHIVy and HC (Fig. 1), while median TL in peripheral blood cells was significantly lower in both pHIVy and npHIVy than in HC (Fig. 2). The mean proportion of human T cell receptor beta variable (TRBV) subgroups with normal profiles was significantly lower in samples obtained from HIV-infected patients compared to HC (16.8% and 18.8% vs 27.5%). The proportion of TRBV chains with shifted profiles was not different, while that with restricted TRBV profiles was significantly higher in pHIVy than in HC (49.5% vs 35.5%) and mono/ oligoclonal TRBV cells were higher in npHIVy than in HC (11.4% vs 2.9%). A negative correlation was found between the percentage of TRBV perturbations and CD4/CD8 ratio (r = −0.81; P = 0.001) and CD4+ cell count (r = −0.63; P < 0.05).

Conclusions: A normal thymic output together with an increased telomere length and a reduced T-cell diversity in perinatally HIV-infected subjects could be explained by the shift of newly produced cells into memory subsets. This phenomenon may allow to control viral infection and maintain peripheral homeostasis.
inflammation and immune activation may contribute to morbidity and mortality in chronic treated HIV-1 infection. However, the mechanisms of HIV-1 related M/M dysfunction remain poorly defined in vivo.

Method: Using the Bone Marrow/Liver/Thymus humanized mouse (BLT), we assessed the direct early effect of the HIV-1 clone 89.6 on expression of (co) receptors important for HIV-1 pathogenesis and/or M/M function. Protein expression and function (endocytosis) in human monocyte subsets (CD14+, CD14+CD16+, CD14+CD16-) was assessed at baseline and after 4 weeks of HIV-1 infection using flow cytometry. Pairwise group comparisons used Wilcoxon rank-sum tests.

Results: Over 4 weeks of HIV-1 infection, expression (% of parent (not shown) and/or Median Fluorescence Intensity (MFI) of CD4 and CXCR2 declined in all monocyte subsets in the HIV+ group (n=10). CXCR4 MFI increased only in hCD14+CD16+ monocytes in the HIV+ group. % CCR5 expression increased only in hCD14+CD16+ monocytes in the HIV+ group. % CD16 expression increased similarly in monocytes of both the HIV+ and HIV-1 group (n=10) (not shown). CCR2 expression did not change in any monocyte subset in both groups. % CX3CR1 increased only in hCD14+CD16+ monocytes in the HIV+ group. The most notable effects in the HIV+ group were increase in CCR5 expression in hCD14+CD16+ monocytes, decrease in CD4 and CXCR2, increase in CX3CR1 and reduction in % PhRhodo in hCD14+CD16+ monocytes (Table).

Conclusion: HIV-1 directly downregulates CD4 and CXCR2 in monocytes, impairs monocyte function and upregulates CX3CR1 in proinflammatory CD14+CD16+ monocytes. Our data complement prior in vitro data that CD14+ monocytes are preferentially susceptible to HIV-1 entry and demonstrate the direct impact of HIV on human M/M function and chemokine expression in vivo.

Table

<table>
<thead>
<tr>
<th>Parameter (selected)</th>
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PE16/4
Lectin-like oxidized low-density lipoprotein (LOX-1) is elevated in proinflammatory monocytes in chronic treated HIV

W Mu, P Hamid, A Kossyvakis, H Nguyen, S Sen Roy and T Kelesidis
University of California, Los Angeles, Medicine, Los Angeles, USA

Purpose: The mechanisms of HIV-1 related Monocyte/macrophage (M/M) dysfunction remain poorly defined in vivo. Both oxidized lipids and HIV-1 are known to impact M/M and lipid rafts, specialized membrane domains enriched in signalling machinery important for atherogenesis. Proinflammatory CD14+CD16+ monocytes have higher content of lipid rafts compared to classic CD14+CD16- monocytes. We hypothesized that scavenger receptors that bind oxidized lipids such as the Lectin-like oxidized low-density lipoprotein (LOX-1) is expressed on proinflammatory monocytes.

Goal: To assess LOX-1 expression in chronic treated HIV patients in comparison to healthy controls.

Method: Using the Bone Marrow/Liver/Thymus humanized mouse (BLT), we assessed the direct effect of the HIV-1 clone 89.6 on expression of LOX-1 in human monocytes. LOX-1 expression was assessed at baseline and after 4 weeks of HIV-1 infection using flow cytometry. Pairwise group comparisons used Wilcoxon rank-sum tests.

Results: Over 4 weeks of HIV-1 infection, expression of LOX-1 increased in proinflammatory monocytes in chronic treated patients compared to healthy controls. The most notable effects in the HIV+ group were increase in LOX-1 expression in hCD14+CD16+ monocytes, decrease in CD4 and CXCR2, increase in CX3CR1 and reduction in % PhRhodo in hCD14+CD16+ monocytes (Table).

Conclusion: HIV-1 directly regulates LOX-1 expression in proinflammatory monocytes, impairs monocyte function and upregulates CX3CR1 in proinflammatory CD14+CD16+ monocytes. Our data complement prior in vitro data that CD14+ monocytes are preferentially susceptible to HIV-1 entry and demonstrate the direct impact of HIV on human M/M function and chemokine expression in vivo.

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PE16/3
In Vivo modelling of mechanisms of HIV-1-related monocyte dysfunction

W Mu, P Hamid, A Kossyvakis, H Nguyen, S Sen Roy and T Kelesidis
University of California, Los Angeles, Medicine, Los Angeles, USA

Purpose: Monocyte/macrophage (M/M)-related (rather than T-cell) inflammation and immune activation may contribute to morbidity and
lipoprotein (LOX-1) are upregulated in lipid raft enriched CD14+CD16+ proinflammatory monocytes in chronic treated HIV and this receptor may drive proinflammatory properties of CD14+CD16+ monocytes.

**Method:** Using the Bone Marrow/Liver/Thymus humanized mouse (BLT), we assessed the direct effect of the HIV-1 clone 89.6 on expression of LOX-1. BLT mice (n=32) were split in 3 groups: A) HIV uninfected (n=8), B) HIV infected viremic, no antiviral therapy (ART) (n=12), C) HIV infected aviremic, on potent ART (n=12). Protein expression in monocyte subsets was assessed after 12 weeks of HIV-1 infection and potent antiviral therapy using flow cytometry and whole blood staining with anti-human antibodies. Group comparisons used Wilcoxon rank-sum tests.

**Results:** Over 12 weeks of HIV-1 infection, expression [% of parent (not shown) and/or Median Fluorescence Intensity (MFI) of LOX-1 in CD14+CD16+ monocytes increased in the HIV-1+ART group compared to the HIV- group by a mean of 22-fold (Figure). Protein membrane levels of LOX-1 in CD14+CD16- monocytes decreased in the HIV-1+ group compared to the HIV- group. LOX-1 in CD14+CD16+ monocytes remained elevated in the HIV/ART group by a mean of 8-fold compared to the HIV- group.

**Conclusion:** HIV-1 directly upregulates LOX-1 in CD14+CD16+ monocytes. Despite potent ART, elevated levels of LOX-1 in these monocytes persist and may drive their proatherogenic properties by binding oxidized lipids.

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**Figure 1**

**In vivo dissection of the impact of HIV-1 versus antivirals on systemic inflammation in chronic treated HIV**

**W Mu, R Heymans, E Ritou, P Hamid, A Kossyvakis, S Sen Roy and T Kelesidis**

**University of California, Los Angeles, Medicine, Los Angeles, USA**

**Purpose:** Monocyte/macrophage (M/M)-related (rather than T-cell) inflammation and immune activation may contribute to morbidity and mortality in chronic treated HIV infection. Observational human studies cannot dissect the differential effects of HIV versus ART on inflammation. We used a physiologically relevant humanized mouse model of chronic treated HIV to dissect in vivo HIV- and/or ART-driven impact on human cytokines and chemokines.

**Method:** The C57BL/6 Rag2−/−; CD47−/− Bone Marrow/Liver/Thymus mice do not develop early graft versus host disease. After 4 weeks of infection with the dual-tropic 89.6 HIV-1 virus, mice were treated with daily emtricitabine (200 mg/kg), tenofovir (208 mg/kg), raltegravir (80 mg/kg) for up to 12 weeks. The groups were: A (n=5): uninfected (HIV-); B (n=10): HIV+; C (n=15): HIV+/ART. Biomarkers of human M/M activation sCD163 and sCD14 were determined by Luminex Assays. Results are described as mean and SEM and t-test was used for statistical analysis.

**Results:** HIV-1 induced a mean 59% and 56% reduction in plasma h-sCD14 and h-sCD163, respectively, in infected compared to uninfected mice (p<0.05). Potent ART for 12 weeks suppressed viremia within 4 weeks and induced a mean 49% and 38% increase in h-sCD14 and h-sCD163 (p<0.05) in HIV+/ART+ compared to HIV+ mice (p<0.05).

**Conclusion:** Our in vivo model provided unique mechanistic insight about differential effects of HIV-1 versus potent ART on M/M activation. HIV-1 reduced biomarkers of M/M activation (possibly due to cytotoxic effects of HIV-1), whereas ART increased h-sCD163 and h-sCD14. These mechanistic data complement prior data from observational human studies that biomarkers of M/M activation remain elevated in chronic treated HIV despite potent ART and suggest that ART rather than HIV-1 per se drives the increase in plasma levels of sCD163 and sCD14.

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**Figure 2**

**PE16/6**

**Differential impact of HIV-1 versus antivirals on systemic inflammation in chronic treated HIV**

**R Heymans, W Mu, E Ritou, P Hamid, A Kossyvakis, S Sen Roy and T Kelesidis**

**University of California, Los Angeles, Medicine, Los Angeles, USA**

**Purpose:** Despite potent antiviral therapy (ART), increased inflammation persists in chronic treated HIV-1 infection and may contribute to morbidity. Observational human studies cannot dissect the differential effects of HIV versus ART on inflammation. We used a physiologically relevant humanized mouse model of chronic treated HIV to dissect in vivo HIV- and/or ART-driven impact on human cytokines and chemokines.

**Method:** The C57BL/6 Rag2−/−; CD47−/− Bone Marrow/Liver/Thymus mice do not develop early graft versus host disease. After 4 weeks of infection with the dual-tropic 89.6 HIV-1 virus, mice were treated with daily emtricitabine (200 mg/kg), tenofovir (208 mg/kg), raltegravir (80 mg/kg) for up to 12 weeks. The groups were: A (n=5): uninfected (HIV-); B (n=10): HIV+; C (n=15): HIV+/ART. Human and murine cytokines and chemokines were determined by Luminex Assays. Results are described as mean and SEM and t-test was used for statistical analysis.

**Results:** HIV-1 induced a mean >45% reduction in plasma h-IL-1b, h-IL-6, h-IL-8, h-IL-10, h-IL-18 and h-TNF-a and a mean >20% increase in plasma h-CCL3, h-CCL5, h-CXCL1 and h-CXCL10 in infected compared to uninfected mice (p<0.05, Table). Potent ART for 12 weeks suppressed viremia within 4 weeks and induced a mean >20% increase in human cytokines. ART induced a mean >20% increase in h-CCL2 and hCXCL1 and a mean 55% increase in murine TNF-a in HIV+/ART+ compared to HIV+ mice (p<0.05).

**Conclusion:** Our in vivo model provided unique mechanistic insight about differential effects of HIV-1 versus potent ART on human cytokines and chemokines. HIV-1 reduced human cytokines (possibly due to cytotoxic effects of HIV-1 on human immune cells), whereas potent ART did not affect or even increased human chemokines and m-TNF-a. These mechanistic data complement prior data from observational human studies and suggest that ART contributes to systemic inflammation in chronic treated HIV.
Correlation between blood telomere length and CD4+ CD8+ T-cell subsets in HIV-1-positive individuals with long-term virological suppression on antiretroviral therapy

J Rodriguez-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernardino1, JM Castro1, RD de Miguel1, J González-Centeno1, A Esteban-Cantos1, N Stella-Ascariz1, R Montejano1, R de Miguel1, B Alejos2, B Mena-Garay1, B Rodes1, JI Bernin...
PE16/9
Phenotypical recovery of the T-cell pool following switch to dual and triple INSTI-based cART
C Tincati, D Mondatore, M Allegri, A Tavelli, I Nekrasova, M Sala, A d’Arminio Monforte and G Marchetti
University of Milan, Department of Health Sciences-San Paolo Hospital, Milan, Italy

Purpose: Integrase strand transfer inhibitors (INSTIs) are used in first-line and switch strategies as dual combination therapy, yet their impact on the persistent immunological changes of treated HIV infection is unknown. We evaluated T-cell homeostasis in subjects switching to dual and triple INSTI-based therapy during viral undetectability.

Method: Retrospective study on HIV-infected subjects on suppressive NNRTI- or PI-based triple cART regimens switched to dual or triple INSTI-containing therapies.

T-cell immunophenotype was studied pre-switch and at 6 (T6) and 12 months (T12) after switch during stable viral suppression. Peripheral blood was stained with the fluorochrome-based antibodies to study T-cell naive (CD45RA), memory (CD45R0), activated (CD38), and CD127-expressing subpopulations. Mann-Whitney and Wilcoxon tests were used for statistics.

Results: 45 dual-INSTI and 164 triple-INSTI individuals were identified (Table 1). Despite CD4+ count increases in triple-INSTI (Fig. 1A), stable CD4/CD8 ratio was registered in both groups (Fig. 1B).

Analysis of T-cell homeostasis revealed the selective expansion of naive CD4+ T-cells in dual-INSTI (Fig. 1C) and stable kinetics of naive CD8+ T-cells in both groups (Fig 1D). Sustained increases of CD127-expressing CD4+ cells were detected in dual- and triple-INSTI subjects (Fig. 1E), yet growth of the CD8+CD127+ subset was observed only in the former (Fig. 1F). In contrast, a contraction of memory CD8+ T-cells was noted in triple-INSTI (Fig. 1G), coupled with the increase of the activated CD8+ pool which translated into significantly higher CD8+CD38+ cells compared to dual-INSTI at T12 (Fig. 1H).

Conclusion: Switching to a dual INSTI-based regimen in the course of viral suppression may aid immunological recovery of the T-cell pool, featuring the expansion of the CD127-expressing and naive CD4+ T-cell subsets. Future studies need to confirm these preliminary findings which appear to support the immunologic efficacy of dual INSTI-based regimens in sustaining a more favourable T-cell immunophenotype in peripheral blood.

Table 1. Demographic Characteristics of Study Subjects

<table>
<thead>
<tr>
<th></th>
<th>Dual INSTI</th>
<th>Triple INSTI</th>
<th>p value (Dual vs Triple)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (M) n(%)</td>
<td>13(77)</td>
<td>127(75)</td>
<td>0.0005</td>
</tr>
<tr>
<td>Age in years (median, IQR)</td>
<td>34(29-55)</td>
<td>31(23-57)</td>
<td>0.1</td>
</tr>
<tr>
<td>HIV epidemiology</td>
<td>11(4)</td>
<td>13(4)</td>
<td>0.2</td>
</tr>
<tr>
<td>Homosexual, n(%)</td>
<td>12(77)</td>
<td>59(56)</td>
<td>0.4</td>
</tr>
<tr>
<td>NTCT, n(%)</td>
<td>12(77)</td>
<td>56(58)</td>
<td>0.2</td>
</tr>
<tr>
<td>AIDS, n(%)</td>
<td>12(77)</td>
<td>42(27)</td>
<td>1</td>
</tr>
<tr>
<td>CD4+V patients, n(%)</td>
<td>12(71)</td>
<td>10(71)</td>
<td>0.4</td>
</tr>
<tr>
<td>Diabetes, n(%)</td>
<td>3(1)</td>
<td>5(3)</td>
<td>0.7</td>
</tr>
<tr>
<td>smoker, n(%)</td>
<td>5(31)</td>
<td>24(15)</td>
<td>0.4</td>
</tr>
<tr>
<td>Patients on HAART</td>
<td>13(77)</td>
<td>117(74)</td>
<td>0.6</td>
</tr>
<tr>
<td>Time of HAART (median, IQR)</td>
<td>78(48-138)</td>
<td>70(48-141)</td>
<td>0.7</td>
</tr>
<tr>
<td>Time of CD4+ (median, IQR)</td>
<td>78(50-138)</td>
<td>70(48-141)</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Figure 1. T-Cell Homeostasis in dual- and triple-INSTI treated subjects

PE16/11
Expression of PD-1 in a population of double-negative T cells (CD3+CD4+CD8-) in HIV-infected patients - the preliminary study results
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Purpose: Double-negative T cells (CD3+CD4+CD8-; DNT) are heterogeneous populations; in healthy people they account for approximately 1–3% of all CD3+ cells in peripheral blood. Their function has not yet been fully understood, but it is believed that they play a role in regulatory processes, and the PD-1+ subsets generate the majority of proinflammatory cytokines.

Method: Fifteen HIV infected individuals on antiretroviral treatment, with undetectable HIV-RNA, were included to the study (12 men [80.00%], 3 women [20.00%]; mean age 41 years [SD: 7], mean CD4+ cells 441/μL [SD: 213]). DNT were selected from PBMC with flow cytometry: CD3-V450, CD4-PerCP-Cy5.5, CD8-APC-H7, TCRαβ-FITC, TCRγδ-PE-CY7, PDI-V500. Amount of study cells in blood volume were calculated from complete blood count test. U Mann-Whitney test were used for statistical analysis. Applying the Bonferroni correction the significant p-value was established as p< 0.016.
Results: Table 1 presents the results.
Conclusions: The TCDγδ+ subpopulation predominates among DNT cells in HIV infected patients treated with antiretroviral therapy. The PD-1 is the surface protein of most DNT cells, but is more common in TCRγδ+ subpopulations than TCRγδ+

Table 1. DNT cells subpopulations and frequency of PD-1+ cells

<table>
<thead>
<tr>
<th></th>
<th>All DNT cells</th>
<th>DNT TCR γδ+ cells</th>
<th>DNT TCRγδ+ cells</th>
<th>P (DNT TCR γδ+ vs DNT TCRγδ+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cells/μL</td>
<td>mean 54.5 (SD: 36.7)</td>
<td>median 9.2 (IQR: 7.0-15.9)</td>
<td>median 37.4 (IQR: 7.0-69.2)</td>
<td>0.0235</td>
</tr>
<tr>
<td>% CD3+</td>
<td>mean 5.3 % of</td>
<td>median 24.0 % of</td>
<td>median 75.9 % of</td>
<td>0.0014</td>
</tr>
<tr>
<td>DNT (SD: 2.2)</td>
<td></td>
<td>(IQR: 9.9–45.8)</td>
<td>(IQR: 54.4–90.1)</td>
<td></td>
</tr>
<tr>
<td>PD1+ (%)</td>
<td>mean 60.1 (SD:16.0)</td>
<td>median 70.9 (IQR: 68.0-80.2)</td>
<td>median 51.6 (IQR: 41.6-67.2)</td>
<td>0.0023</td>
</tr>
</tbody>
</table>

PE16/13

Poor recovery of T-cell receptor repertoire despite long-term antiretroviral therapy

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Purpose: Despite antiretroviral therapy (ART), people living with HIV (PLWH) remain at greater risk of several infectious and non-communicable comorbidities. Persisting immunological deficits might contribute to this excess burden of non-AIDS disease. Previous work has suggested that the T cell receptor (TCR) repertoire is highly disordered in untreated HIV infection and does not recover after three months of ART. We sought to establish whether these T-Cell receptor repertoires normalise with long-term antiretroviral therapy.

Methods: Peripheral blood samples from HIV positive participants using ART and HIV negative individuals participating in a prospective cohort study were analysed. TCR receptor sequences were amplified and sequenced and bioinformatic pathways were followed using previously established TCR assignation software.

Results: Samples were analysed from 27 HIV positive and 22 HIV negative individuals and compared to data from 16 PLWH before and after initiation of antiretroviral therapy analysed in previous work. The HIV positive group on ART had evidence of good immune reconstitution, with median (IQR) CD4 counts of 685 (457–848) cells/μL and undetectable HIV viral loads. TCR repertoires remained abnormal when compared to HIV negative individuals, with a lower diversity and greater inequality of receptor repertoires. This had not normalised after more than 10 years of ART. In a specific evaluation of the population of Mucosal-Associated Invariant T (MAIT) cells, these were found to be severely depleted in HIV infection prior to ART and had not recovered with ART.

Conclusions: These results suggest that the disrupted TCR repertoire associated with HIV infection does not normalise with long-term ART. Possible explanations could be permanent changes in T cell populations that do not recover with antiretroviral therapy, or on-going chronic inflammation causing bias in the TCR repertoire. If confirmed in larger studies, these findings help explain the greater incidence of infectious and non-communicable comorbidities among PLWH.

Moderated ePosters I: basic science

PE17/1

Abdominal adipose tissue is associated with alterations in tryptophan–kynurenine metabolism and markers of systemic inflammation in people living with HIV

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Purpose: While both adipose tissue accumulation and tryptophan (Trp) metabolism alterations are features of HIV infection, their interplay is unclear. The primary aim was to evaluate associations between abdominal adipose
tissue, alterations in the kynurenine (Kyn) pathway of Trp metabolism, and systemic inflammation in people living with HIV (PLWH). Exploratively, we investigated possible associations between Kynurenines and lipids.

**Method:** 864 PLWH and 75 uninfected controls were included from the COCOMO study. Abdominal adipose tissue was measured using waist-to-hip ratio. Venous blood was collected and analyzed for Kyn and Kyn catabolites, neopterin, high-sensitivity CRP (hs-CRP), and lipids. Linear regression models were used to test associations in PLWH. The ratio between quinolinic and kynurenic acids (QA/KYNA) was used as measure of the flux through the branch of the kynurenine pro-inflammatory pathway catalyzed by kynurenine 3-monooxygenase.

**Results:** PLWH had higher KTR than uninfected individuals (p-value < 0.001). In PLWH, increase in waist-to-hip ratio was associated with higher KTR (p-value 0.0009), QA/KYNA ratio (p-value 0.006), markers of systemic inflammation (p-value < 0.001) and with lower KYNA concentration (p-value 0.019) (Table 1). Increase in QA/KYNA ratio was associated with higher hs-CRP (p-value < 0.001) and neopterin concentrations (p-value < 0.001) (Figure 1). In contrast, KYNA concentration was associated with lower hs-CRP (p-value 0.025) and neopterin concentrations (p-value 0.034) (Figure 1). Kyn metabolites were associated with lower concentrations of LDL and total cholesterol after controlling for confounders (Figure 2).

**Change in % of outcome per 0.5 unit increase in waist-to-hip ratio**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Crude β-coefficient [95% CI]</th>
<th>p-value</th>
<th>Adjusted β-coefficient [95% CI]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>KTR</td>
<td>31 [17; 46]</td>
<td>&lt;0.001</td>
<td>19 [5; 37]</td>
<td>0.009</td>
</tr>
<tr>
<td>QA/KYNA</td>
<td>44 [22; 69]</td>
<td>&lt;0.001</td>
<td>33 [8; 66]</td>
<td>0.006</td>
</tr>
<tr>
<td>KYNA</td>
<td>11 [-21;42]</td>
<td>0.050</td>
<td>-18 [-31; -3]</td>
<td>0.019</td>
</tr>
<tr>
<td>QA</td>
<td>52 [30; 76]</td>
<td>&lt;0.001</td>
<td>9 [-3; 34]</td>
<td>0.151</td>
</tr>
<tr>
<td>hs-CRP</td>
<td>431 [232; 740]</td>
<td>&lt;0.001</td>
<td>232 [80; 504]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Neopterin</td>
<td>19 [1; 37]</td>
<td>0.033</td>
<td>15 [-6; 40]</td>
<td>0.160</td>
</tr>
</tbody>
</table>

Abbreviations: PLWH, people living with HIV; KTR, kynurenine-to-tryptophan ratio; QA/KYNA, quinolinic acid-to-kynurenic acid ratio; QA, quinolinic acid; KYNA, kynurenic acid; hs-CRP, high sensitivity CRP. Confounders included in multivariable models were age, sex, smoking, origin, BMI, and Kyn (only when QA/KYNA, KYNA, and QA as dependent variables).

**Conclusion:** In PLWH, abdominal adipose tissue was associated with increased QA/KYNA ratio, suggesting activation of pro-inflammatory pathway of Kyn metabolism, with reduction of anti-inflammatory molecules, and increase of markers of systemic inflammation. Interestingly, Kyn metabolites concentrations were negatively associated with lipid levels. Taken together, our results suggest dysregulation of Kyn metabolism associated with abdominal adipose tissue accumulation to be a potential source of inflammation in HIV infection.

**Abbreviations:** KTR, kynurenine-to-tryptophan ratio; QA/KYNA, quinolinic acid-to-kynurenic acid ratio; QA, quinolinic acid; KYNA, kynurenic acid; hs-CRP, high sensitivity CRP.

**Abstract Book**

**HIV Medicine**

**ª**

**EACS 2019 – Abstract Book**
Results: Susceptibility scores dropped significantly from 0.5 (IQR= [0.25,1]) before EAC to 0.25 (IQR= [0.25,1], p=0.008) after EAC. Forty individuals (85.1%) experienced no change in susceptibility, while 7 (14.9%) had a decreased score after the EAC period (Figure). Susceptibility was low already before EAC, with 59.6% of participants harbouring HIV-1 that was not fully susceptible to any of the drugs in their regimen. Conclusion: Levels of HIVDR were high before starting EAC, indicating unnecessary regimen switches should be critically assessed against the risk of developing (additional) HIVDR.

PE17/4
Replication-competent HIV-1 reservoirs form in mucosal macrophages of patients under antiretroviral therapy
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Purpose: HIV-1 eradication requires the elimination/reduction of the HIV-1-reservoir pool mainly characterized within T-cells. However, residual viremia in HIV-1-infected cART-suppressed individuals originates from T-cells but also from macrophages that posses all required characteristics to form an additional long-lived HIV-1 reservoir. Hence, macrophages, initially targeted by HIV-1 upon genital mucosa infection, are tissues-resident cells that resist the cytopathic effects of HIV-1 infection, are long-lived, can self-renew, accumulate infectious virus in intracellular virus-containing compartments (VCC), and produce infectious virus upon stimulation in-vitro.

Methods: We used whole penile tissues from HIV-1-infected cART-suppressed individuals with undetectable plasma viral load obtained upon transgender-surgery and searched by PCR, FISH and microscopy for HIV-1 DNA, RNA, p24 and intact virions. Tissue viral outgrowth was used to detect infectious reactivation-competent viruses.

Results: We show that urethral macrophages contain integrated HIV-1 DNA, RNA, proteins and intact virions in VCCs, whereas viral components remain undetectable in urethral T-cells. Moreover, urethral cells release replication-competent infectious HIV-1 following specific re-activation with the macrophage activator lipopolysaccharide (LPS), while the T-cell activator phytohaemagglutinin (PHA) is ineffective. HIV-1 urethral reservoirs localize preferentially in a newly identified subset of intermediate M1/M2 macrophages, highly expressing CD206, IL-1 and IL-4-receptors, but not CD163. Finally, macrophage reservoirs form long-lasting conjugates with CD8+ T-cells resisting killing suggestive of a mechanism of enhanced inflammation that participates in reservoir persistence.
Conclusions: Altogether, we demonstrate that tissue-macrophages establish replication-competent reservoir in cART-suppressed patients, thereby challenging the dogma that HIV-1-reservoirs principally reside in T-cells. As the molecular and cellular characteristics of HIV-1-reservoir in tissue-macrophages differ from that in T-cell, we anticipated that reservoir dynamic and eradication strategies in this two cell types will diverge. Systematic investigation of the presence of HIV1-reservoirs in other human tissues is now clearly necessary, especially for shock and kill strategies aimed at reservoir elimination.

PE17/5
Skin tissue resident memory T cells (TRMs) are depleted in HIV infection and reconstituted by an early begin of ART
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Purpose: PLWHIV have increased risk of skin and mucosal cancer, like HPV-related neoplasia, despite of ART. TRM, are abundant in the skin and widely recognized for their anticancer role in peripheral tissues. Our project aims at investigating the effect of HIV infection on the skin TRM.

Method: We collected skin biopsies from individuals of two cohorts: (1) patients with a long history of HIV and a late begin of cART, currently under therapy; (2) recently diagnosed patients who received ART and were re-biopsied one year after infection. We quantified TRM via immunofluorescent staining and automated in situ analysis (Tissue-FAXS). We performed DNA And RNA-Scope on the skin of HIV+ patients and SIV chronically infected untreated macaques.

Results: Skin TRM were strongly depleted in both human cohorts, indicating that the depletion happens early in the course of HIV infection. The number of TRM correlated with the nadir, suggesting that skin TRM are lost in advanced HIV disease and never reconstituted. Surprisingly, our most recent results show that if ART is started early, the skin TRM population is reconstituted one year after ART begin. Moreover, we could recently detect HIV-DNA by DNA-Scope in the cells of the papillary dermis of patients with a long history of HIV. Finally, skin of SIV chronically infected macaques showed the presence of SIV RNA and DNA in the cells of the papillary dermis.

Conclusion: Skin TRMs are severely depleted upon HIV infection but can be properly reconstituted if ART is started early. Our DNA and RNA-Scope staining in untreated macaques suggest the presence of SIV RNA and DNA in the cells of the papillary dermis.

PE17/6
Baseline and emergent genotypic and phenotypic results in HIV-1-infected, heavily treatment-experienced (HTE) participants meeting protocol-defined virologic failure (PDVF) criteria through week 96 in the fostemsavir (FTR) phase 3 BRIGHT study
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Purpose: FTR is a prodrug of temsavir (TMR), a first-in-class, investigational attachment inhibitor that binds to HIV-1 gp120, preventing viral attachment and entry into host CD4+ T-cells. Here, we present Baseline and emergent virologic results among participants experiencing PDVF through 96-weeks of FTR-based therapy.

Method: BRIGHT is a Phase 3 trial evaluating FTR in HTE patients with multidrug resistant HIV-1. Participants were assigned to the Randomized (RC; 1–2 ARV classes remaining) or Non-randomized Cohort (Non-RC; zero classes remaining). Glycoprotein (gp)-120 substitutions that potentially influence susceptibility to TMR include: S357HI/M, M426LP, M434I/K, M475I.

Results: Overall, 45% (162/358) of participants had relevant gp120 substitution(s) at Baseline, and median TMR IC50FC was 0.99-fold from reference. Through WK96, 23% (63/272) of RC and 49% (49/99) Non-RC patients met PDVF criteria. Rates of PDVF among RC participants were
comparable regardless of Baseline virologic factors: 22% (31/141) without vs. 25% (31/122) with relevant gp120 substitutions, and 22% (29/132) with IC50FC ≤1-fold vs. 29% (10/34) with TMR IC50FC >100-fold (Table 1). 52% (26/50) of RC and 25% (11/44) Non-RC participants with PDVF had no treatment-emergent gp120 substitutions of interest, among whom median change in Baseline TMR IC50FC was < 1-fold. Median increase in IC50FC in participants with emergent gp120 substitutions at failure was 511-fold for RC and 2260-fold for Non-RC (Table 2).

Conclusion: Through WK96, PDVF in RC participants was comparable to previous ARV trials conducted in similar populations. Pre-treatment gp120 substitutions of interest and TMR IC50FC were not reliably predictive of PDVF among RC participants. Non-RC participants, with zero fully active ARVs, experienced higher rates of PDVF, emergent gp120 substitutions of interest, and greater median increase in Baseline TMR IC50FC. Overall, emergent gp120 substitutions of interest correlated with higher median increase in TMR IC50FC. A clinical cut-off for FTR has not yet been determined.

**Moderated ePosters II: clinical science**

**PE18/1**

Are women living with HIV in increased risk of complications to birth when planning elective caesarean section? A Danish nation wide population based study

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Objectives: Regardless of viral suppression two-thirds of women living with HIV (WLWH) in Denmark deliver by caesarean section (CS) and half of the elective CS (ECS) are performed due to mothers request. The aim of the study was to investigate if planning ECS increases risk of obstetric complications compared to planning vaginal delivery in WLWH.

Method: Retrospectively, all WLWH in Denmark giving birth to live born singletons from 2002–2014 were included. Data was retrieved from medical records and national registries. The risk of obstetric complications comparing planning ECS to vaginal birth was estimated through multivariate logistic regression adjusted for mode of delivery, viral load, year of birth and maternal age.

Results: 389 WLWH were included. All were in antiretroviral treatment at delivery, 86% had HIV-RNA < 40 copies/mL and 21% had previously had a CS. No MTCT was seen. During pregnancy and in collaboration with a gynaecologist 50.4% planned ECS, 44% without medical indication. Children born by WLWH planning vaginal delivery did not have increased risk of low APGAR-scores (<7) (3% vs. 2%, aOR 1.7, 95% CI 0.1–22.7, p=0.68) or prolonged hospitalization (>3 days) (21% vs. 52%, aOR 1.9 95% CI 0.8–4.3, p=0.12) compared to children born by WLWH planning ECS. No differences between groups were observed regarding postpartum bleeding (38% vs. 20%, aOR 0.6, 95% CI 0.2–1.6, p=0.29), infections (2% vs. 3%, aOR 1.5, 95% CI 0.2–14.6, p=0.72) or prolonged maternal hospitalization (>3 days) (37% vs. 69%, aOR 1.6, 95% CI 0.7–3.4, p=0.26). WLWH planning ECS had lower risk of emergency CS (32% vs. 20%, aOR 0.5, 95% CI 0.29–0.85, p=0.01) compared to WLWH planning vaginal delivery.

Conclusion: To a high extent WLWH still plan to give birth by ECS without medical indication. No increased risk of most obstetric complications was however seen when comparing WLWH planning vaginal delivery to planning ECS. Overall WLWH can safely plan a vaginal delivery.

**PE18/2**

Cesarean section is still the most common mode of delivery among HIV-positive women in Central Poland

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Background: In the context of effective ART and viral suppression (VS) it is expected that cesarean section (CS) would be less common mode of delivery for HIV-positive pregnant women. At the same time the proportion of CS deliveries in general Polish population increased from 19.6% in 2000 to 42.2% in 2014 (Euro-Persista). Here we investigate the trends over time in CS among HIV-positive women under integrated gynecological care in Warsaw.

Methods: We reviewed medical records of all pregnancies in 2006–2017. We compared indications for mode of delivery as identified by HIV clinic's gynecologist (HGC) and the final delivery mode (FDM). In statistical analyses we used kappa agreements and non-parametric tests as appropriate.

Results: Of 112 births with known mode of delivery (70.9% of all pregnancies) 103 were with known indication for mode of delivery. 70 (62.5%) mothers were on cART before pregnancy, 6 (5.3%) started after 28th week of pregnancy, 96 (85.7%) had VS before delivery. In total 83 (74.1%) of deliveries were by CS, but HGC indicated the need for CS in 58 (51.8%). The proportion of CS deliveries did not vary over the calendar years (p=0.969). The proportion of women with HIV RNA<50 copies/mL varied from maximum of 23.5% in 2013 to zero in 2016 and 2018 (0.68%), figure. In 77 (68.7%) cases of CS indication by HGC and FDM agreed (kappa agreement of 0.49 [CI 0.32–0.66]). Of 20 cases of CS performed contrary to HGC recommendation 18 were explained by gynecological/obstetrical indication.

Conclusions: Despite most women being on ARV before pregnancy and predominant VS before delivery CS remains the most common mode of delivery among HIV-positive pregnant women. This was could be explained by obstetrical indications and reflects the trends in overusing and liberalization of indications for CS in general Polish population.
The Swiss Mother and Child HIV Cohort Study (MoCHiV), a unique opportunity to monitor and adapt measures to prevent HIV mother to child transmission

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Background: The Swiss Mother and Child HIV Cohort Study (MoCHiV) is an on-going multicenter, interdisciplinary and prospective observational cohort study, providing longitudinal data on HIV-infected mothers and children in Switzerland. Here we describe the study’s coverage of changes in recommendations for the prevention of HIV mother-to-child transmission (MTCT) and assess these changes on patients data.

Methods: We evaluated data from MoCHiV and the linked Swiss HIV Cohort Study (SHCS) database and describe changes at different time points when recommendations were changed.

Results: The study includes a total of 1248 mother-and-child pairs, 281 HIV-infected children and 1571 HIV-exposed uninfected (HEU) children. The most common mode of acquisition of maternal HIV-infection was heterosexual (77%). In 2016, 42 deliveries were registered and all of them received combined antiretroviral therapy (cART) during pregnancy and 40 (95%) had a non-detectable HIV viral-load (pVL) at time of delivery. 36% of children were born by vaginal delivery, 45% by elective cesarean-section and 19% by secondary cesarean section. Since 2009 when vaginal delivery in women with undetectable pVL was recommended, the rate in elective cesarean section has steadily decreased. In 2018 new recommendations were changed.

Discussion: Mode of delivery in HIV-infected women 2000–2016

Conclusion: The MoCHiV study offers a unique longitudinal data-collection and contributes to national and international HIV research and to changing recommendations. Thanks to the very high effectiveness of maternal treatment, any other preventive measure, including treatment of the newborn, could be abandoned, when mother HIV pVL is undetectable at birth.

Figure 2/3. MTCT and changes of Swiss guidelines/Changes of pVL over time

Influence of HCV co-infection and hepatitis C treatment on risk of chronic kidney disease in HIV positive persons

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11 Institute of Tropical Medicine, Antwerp, Belgium
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13 Infectious Diseases, AID8S and Clinical Immunology Research Center, Tbilisi, Georgia
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Purpose: HCV infection has been associated with increased risk of chronic kidney disease (CKD). We investigated the impact of HCV cure
on the risk of CKD in HIV/HCV co-infected individuals in the EuroSIDA study.

Method: HIV-positive persons with known HCV status and ≥3 serum creatinine measurements after 1/1/2004 were included in five groups based on time-updated HCV-RNA and use of HCV treatment: 1) HCV-uninfected 2) spontaneously resolved HCV, 3) Chronic untreated HCV, 4) Successfully treated HCV, 5) HCV-RNA positive after starting HCV treatment. Poisson regression was used to compare incidence rates of CKD between HCV groups.

Results: We included a total of 14,499 HIV-positive persons; 5254 (36.2%) were anti-HCV positive at baseline. The majority were male (74%), White (85%), and on cART (88%) with a median age of 43 years and CD4 cell count of 467 cells/µL. During 104,816 person-years of follow-up (PYFU); median 6.6 (IQR 3.0–11.6) per person, 982 (6.8%) developed CKD; crude incidence rate/1000 PYFU (95% CI) was 9.4 (8.8–10.0). After adjustment, all groups had lower rates of CKD compared to group 4, although this was marginally significant for groups 3 and 5 (Figure). Analysis in those without F3/F4 fibrosis showed similar results. Excluding persons treated with DAA-only therapy in groups 4 and 5 attenuated the differences in CKD incidence between group 3–5. After adjustment, compared to group 4, group 3 had a 5% decreased incidence of CKD (aIRR 0.95; 95% CI 0.65–1.38) and a 16% reduced incidence in group 5 (aIRR 0.84; 95% CI 0.52–1.36).

Conclusion: This large study of >5000 HIV/HCV co-infected persons found no evidence that successful HCV treatment reduced the incidence of CKD. Confounding by indication, where those with highest risk of CKD were prioritized for HCV treatment, especially in the DAA era, may contribute to these findings.

Univariate and Multivariate Incidence Rate Ratios of Chronic Kidney Disease

PE18/5

The hepatitis C continuum of care among HIV-infected individuals in Austria

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Purpose: The use of DAAs in the Austrian HIV Cohort Study was strongly associated with clinics providing DAAs directly compared to clinics who have to refer patients to hepatologists (Fig. 1). Here, we evaluated whether this difference diminished 18 months later.

Method: Patients seen after 2013 were studied up to March 2019. Stages of the continuum included patients HCV-antibody tested, anti-HCV positive, HCV-RNA tested, ever HCV-RNA positive, remaining HCV-RNA positive without therapy, treatment, the composite of ongoing therapy and SVR occurred in 579(70.5%) patients and 547(66.6%) achieved SVR (Fig. 2). Significant differences between HIV clinics, according to providing DAAs directly or not were found for all treatment related stages. DAA use was strongly associated with clinics providing DAAs (OR 3.89; 2.55–5.93) and with older age (<30 OR 0.18; 0.08–0.39; 30–50 OR 0.35; 0.24–0.51) compared to being 50 years of age or older, but was not associated with transmission category, sex, origin and HCV genotype.

Conclusion: Despite being "en route" to eliminate HCV from HIV/HCV co-infected individuals, there is still a difference in access to DAA use. To improve and hasten this process a "no matter who provides HCV therapy" strategy is warranted.

Results: Among 6152 HIV positive patients, HCV antibody test was not performed in 360(5.9%) and 1223(19.9%) had a positive antibody test, of whom 1208(98.8%) were HCV-RNA tested and 975(79.7%) were ever HCV-RNA positive (55.6% with genotype 1 and 23.9% with GT3). Among the 821 individuals that remained HCV-RNA positive, 606(73.8%) initiated HCV treatment, 403(66.5%) received DAAs without interferon and 203(33.5%) interferon based regimens. The composite endpoint of ongoing therapy and SVR occurred in 579(70.5%) patients and 547(66.6%) achieved SVR (Fig. 2).
Untreated HCV in HIV/HCV-coinfected US population remains common despite the availability of curative therapies

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Purpose: To determine the HIV/HCV population never treated for HCV since the availability of direct-acting antivirals (DAAs) in a US network of HIV treatment centers.

Method: We collected EMR data specific to coinfected patients in care between 1 Jan 2014 to 31 Oct 2018 from 10 HIV treating clinics in the US. Index date was set as the latter of confirmed coinfection or 1 Jan 2014. Patients were classified as “treated”, “lost to follow up (LTFU)” (no evidence of treatment or cure and no longer in care at practice), or “untreated” (no evidence of treatment or cure, in care with detectable HCV).

Results: Of 3,896 patients, 1,479 were diagnosed as HIV/HCV-coinfected prior to 2014 and the remaining 2,417 were new cases. Median (IQR) follow was 28.5 (23.5, 32.2) months. For treated patients, median (IQR) time from index to treatment was 32.2 (10.1, 54.1) months. For patients classified as LTFU, median (IQR) time from index to date was 10.2 (1.8–27.9) months with observation of 39.0 (23.5–54.2) months. For treated patients, median (IQR) time from index to treatment was 14.2 (3.9–28.5) months.

Conclusion: Despite the availability of highly effective HCV therapies, in this cohort of HIV/HCV-coinfected patients, less than half had evidence of receiving treatment. Given the more rapid progression of liver disease among people with coinfection, better strategies are needed to optimize patient engagement and provide timely HCV treatment to this population.
HepEd, 241 HCPs were trained on HCV management during 3 educational HCV Masterclasses. HCV informative flyers and booklets were created and disseminated to patients and peers. Peer support sessions (HepFriend) were successfully attended by 64 (38%) patients.

Conclusion: HIV/HCV co-infection was high among IDUs and associated with multiple risk factors and increased HCV-RNA levels. Socio-economic barriers and the lack of pangenotypic DAAs limited the treatment and outcomes in this group. This is the first pilot study on managing patients with HIV/HCV from key population in Romania.

PE19/3
Prelib: evaluating a newly launched Canadian provider of innovative internet-based services for self-directed HIV and STI screening
M Regimbal-Ethier1,2, K Benomar1,2, V To1 and M Quesnel1

Method: Technology-enabled STI screening paradigms are promising for addressing barriers to testing uptake, yet few such services exist. Prelib, a new clinic in downtown Montreal, aims to provide accessible, convenient, and judgement-free screening by innovatively combining internet-based risk assessment with on-site self-sampling. Being one of the first of its kind, Prelib offers a unique opportunity to evaluate the uptake, feasibility, and acceptability of this model.

Purpose: To assess employment in the Swedish HIV cohort over twenty years compared to the HIV-negative population (HNP).

Method: From the Swedish Total Population Registry we identified all people born between 1940 and 2000 (n=8 587 629) in Sweden and linked them with the Swedish National HIV Registry (n=9 492) and the Longitudinal Integration Database for Health Insurance and Labor Market Studies. Prevalence ratios (PR) of employment were calculated using Poisson regression. Predictors of employment (age, sex, education, origin and civil status) were adjusted for (adjPR).

Table 1. Summary of screening completion rates

<table>
<thead>
<tr>
<th>Step of screening process</th>
<th>N</th>
<th>% of previous</th>
<th>% overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Created profile</td>
<td>708</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Completed questionnaire</td>
<td>664</td>
<td>93.8%</td>
<td>93.8%</td>
</tr>
<tr>
<td>Scheduled appointment (all)</td>
<td>502</td>
<td>75.6%</td>
<td>70.9%</td>
</tr>
<tr>
<td>Scheduled appointment within study period</td>
<td>492</td>
<td>n/a</td>
<td>69.5%</td>
</tr>
<tr>
<td>Attended an appointment</td>
<td>471</td>
<td>95.7%</td>
<td>66.5%</td>
</tr>
</tbody>
</table>

Table 2. HIV and STI prevalence among those tested with results available during the study period

<table>
<thead>
<tr>
<th></th>
<th>N/N tested</th>
<th>Prevalence (%)</th>
<th>N/N tested</th>
<th>Prevalence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any HIV/STI</td>
<td>29/443</td>
<td>6.5%</td>
<td>11/113</td>
<td>9.7%</td>
</tr>
<tr>
<td>CT (any)</td>
<td>16/443</td>
<td>3.6%</td>
<td>1/106</td>
<td>0.9%</td>
</tr>
<tr>
<td>CT (urogenital)</td>
<td>11/442</td>
<td>2.5%</td>
<td>10/112</td>
<td>8.9%</td>
</tr>
<tr>
<td>CT (anal swab)</td>
<td>7/106</td>
<td>6.6%</td>
<td>4/430</td>
<td>0.9%</td>
</tr>
<tr>
<td>NG (any)</td>
<td>12/442</td>
<td>2.7%</td>
<td>1/213</td>
<td>0.5%</td>
</tr>
<tr>
<td>NG (urogenital)</td>
<td>3/441</td>
<td>0.7%</td>
<td>0/121</td>
<td>0%</td>
</tr>
<tr>
<td>HIV</td>
<td>0/425</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Among 471 appointment attendees, mean number of partners in the past 2 months was 2.6[median=2], 25.5% were men who have sex with men, 74.1% reported condomless anal or vaginal sex, and 23.6% reported first-time screening. STI prevalence was 6.5%, driven by NG and CT (Table 2). Extragenital NG and CT were most prevalent. No HIV or HCV infections were identified.

Conclusion: Prelib demonstrated feasibility and acceptability following launch, based on high screening completion rates and STI prevalence comparable to local clinical practice, and reached many high-risk and first-time testers.

PE19/4
Employment of people living with HIV approaching that of the HIV-negative population irrespective of migrant status and sexual orientation
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Purpose: To assess employment in the Swedish HIV cohort over twenty years compared to the HIV-negative population (HNP).

Method: From the Swedish Total Population Registry we identified all people born between 1940 and 2000 (n=8 587 629) in Sweden and linked them with the Swedish National HIV Registry (n=9 492) and the Longitudinal Integration Database for Health Insurance and Labor Market Studies. Prevalence ratios (PR) of employment were calculated using Poisson regression. Predictors of employment (age, sex, education, origin and civil status) were adjusted for (adjPR).

Results: PLWH were less likely to be employed than HNP but with decreasing difference over time (adjPR 0.6, 95% CI 0.6–0.6 in 1996, adjPR 0.7, 95% CI 0.7–0.7 in 2006 and adjPR 0.9, 95% CI 0.9–0.9 in 2016) (Fig. 1). Migrant women with HIV had the largest increase of employment (Fig. 2) and the negative association between migrant status and employment decreased between 1996 (adjPR 0.7, 95% CI 0.6–0.9) and 2016 (adjPR 0.9, 95% CI 0.9–1.0). Low CD4 count (<200 copies/mL) and mode of HIV-transmission. Trends in employment were illustrated in scatterplots with overlaid prediction plots.

Results: PLWH were less likely to be employed than HNP but with decreasing difference over time (adjPR 0.6, 95% CI 0.6–0.6 in 1996, adjPR 0.7, 95% CI 0.7–0.7 in 2006 and adjPR 0.9, 95% CI 0.9–0.9 in 2016) (Fig. 1). Migrant women with HIV had the largest increase of employment (Fig. 2) and the negative association between migrant status and employment decreased between 1996 (adjPR 0.7, 95% CI 0.6–0.9) and 2016 (adjPR 0.9, 95% CI 0.9–1.0). Low CD4 count (<200) associated with reduced employment (adjPR 0.7, 95% CI 0.6–0.8). Employment of PLWH with present/former intravenous drug use (IVDU) was persistently low (Fig 2).

Figure 1. MLWH: men living with HIV, WLWH: women living with HIV, HNM: HIV-neg men, HNW: HIV-neg women
Conclusion: To our knowledge, this is the first study of employment in PLWH including a whole nation. Employment of PLWH increased over time, particularly in migrants, and was associated with suppressive ART and high CD4 count. People with former IVDU are an important target group for policies promoting employment.

Figure 2. Employment in PLWH. MSM: men who have sex with men, IVDU: former/present intravenous drug use

PE19/5
Retention in care and virological suppression in naive HIV-infected transgender women initiating treatment in Argentina: 48-week results (TRANSViV study)
C Frota1,2, V Zalazar3, P Radusky1,2, N Cardoso1,2,4, M Duarte1,2,4,5, S Fabian1,2, I Figueroa1, A Gun1, I Aristegui1,7, P Cahn1 and O Sued1
1Fundacion Huesped, Research Department, Buenos Aires, Argentina 2Hospital Juan A. Fernandez, Infectious Diseases Unit, Buenos Aires, Argentina 3Universidad de Buenos Aires, Buenos Aires, Argentina 4Asociación de Travestis, Transexuales y Transgéneros de Argentina (A.T.T.T.A.), Buenos Aires, Argentina 5REDLACTRANS, Buenos Aires, Argentina 6Asociación Civil Gondolín, Buenos Aires, Argentina 7Universidad de Palermo, Buenos Aires, Argentina

Purpose: Prevalence of HIV infection in transgender women (TGW) in Argentina is 34%. Stigma and discrimination in the health sector hinder access and retention. We aimed to evaluate retention in care and antiviral efficacy among naive TGW initiating first-line therapy in a trans-sensitive HIV service. ClinicalTrials.gov Identifier NCT03033836.

Method: Naive TGW without NRTI resistance (IAS-USA) with any value of plasma viral load HIV-1 (pVL) initiated dolutegravir 50 mg plus tenofovir/emtricitabine OD, and were followed at weeks 4, 8, 12, 24, 36 and 48. Psychosocial questionnaires and adherence were administered at admission, weeks 24 and 48. The trans-sensitive HIV service included a multidisciplinary team. Retention (primary outcome) was defined based on the proportion of individuals retained along the 48 weeks of the study. Viral suppression at baseline (median): age 28 years, HIV-1 RNA 46,908 copies/mL (40% < 50 copies/mL, median CD4 383 cells/mm3 (19% < 200). At week 48, 77% were retained, and 72% had pVL HIV < 50 copies/mL (97% per-protocol). 48-weeks median adherence was 86.3%. Fourteen patients (22%) were discontinued or lost to follow-up, however 79% of them had undetectable pVL at the last visit. Median CD4 cell count was 685 cells/mm3. Incidental syphilis was diagnosed in 29.5% of the participants. One patient died due to meningeval TB. No major tolerability/toxicity issues were observed. Preliminary analysis at week 24 of the factors associated with failure of retention were: police harassment and drug/alcohol-related problems.

Conclusion: Retention is the major issue among TGW initiating treatment. Most defaults were due to external factors, without association of HIV treatment. Strategies to increase retention in care are urgently needed to achieve 90/90/90 among this specific population. Supported by a ViV-IIR-grant

PE19/6
Addressing the needs of female sex workers in Switzerland: model of care beyond STI testing
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Purpose: In Switzerland, sexwork is legal and regulated with an estimated 20 000 female sexworkers (FSW) in the country, FSW are at high risk of sexually transmitted infections (STI), but have reduced access to prevention and treatment because of stigmatization, language barriers, and financial concerns. We aimed to identify a suitable model to engage FSW in health care.

Method: The Basel AIDS center (www.ahlb.ch) opened an anonymous “walk in clinic” called “lady-check” for one afternoon per week. This clinic includes translation, a gynecologist, a specialist nurse and a collaborating pharmacy. Clients pay only 20 Euro at registration for counselling, screening for STIs, contraception advice, a full gynecological examination including cervical cancer smear and vaccination against hepatitis B. The service is anonymous.

Results: From March 2016 to July 2019, 350 women attended comprising 872 clinical visits during 328 office hours. 125 (36 %) women were from Eastern Europe and 118 (34%) from South America and the Caribbean. 23 (8.4%) of cervical cytologies were abnormal necessitating referral for colposcopy. There were 11 unprepared pregnancies requesting referral for medical abortion. STIs were identified and treated in 43/350 (15%) of women: Chlamydia 30/382 (7.8%), Gonorrheoa 15/382 (3.9%) and Syphilis 8 (2.4%). No FSW (504 tests) were HIV positive. All women were counselled on HIV/STI prevention and condom use. In addition, oral hormonal contraception, implants or IUDs were prescribed as indicated. Overall, we administered 187 Hepatitis B vaccine doses.

Conclusion: FSW are willing to engage in health care services including gynecological care, if these are easily accessible, affordable and anonymous. FSW had high rates of asymptomatic bacterial STIs, requiring antibiotic treatment and many FSW were not previously vaccinated against Hepatitis B.

Morbidity/mortality in the era of cART
PE20/1
The association of rare HLA alleles with clinical disease progression in HIV-positive cohorts with varied treatment strategies
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1Centre of Excellence for Health, Immunity and Infections (CHIP), Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark 2Division of Biostatistics, School of Public Health, University of Minnesota, Minneapolis, USA 3Medical Research Council, Clinical Trials Unit in University College London, London, UK 4Veterans Affairs Medical Center and George Washington University, Washington, USA 5National Institute of Allergy and Infectious Diseases, Division of Clinical Research, Bethesda, USA

Purpose: The Strategic Timing of Antiretroviral Treatment (START) and The Strategies for Management of Antiretroviral Therapy (SMART) trials demonstrated that ART can partly reverse clinically defined immune dysfunction induced by HIV replication. Control of HIV replication is influenced by human leukocyte antigen (HLA) alleles. Whether HLA alleles also independently influence risk of clinical events reflecting immune dysfunction is unknown and is explored here.

Method: In HIV+ individuals from the START and SMART trials, we assessed associations between imputed HLA alleles (102 class I and 83 class II alleles), and the following endpoints: AIDS, infection-related cancer, herpes virus-related AIDS events, chronic inflammation-related conditions and bacterial pneumonia. We used Cox regression to estimate the hazard ratios (HRs) for the
risk of clinical events for HLA allele carriers versus non-carriers. Models were adjusted for sex, age at trial entry, geographical region, race, time-updated CD4+ count and HIV viral load and stratified by trial treatment groups. HLA class I and II alleles were analysed separately, and the Benjamini-Hochberg procedure was used to limit the false discovery rate (FDR) to <5%. (q-value <0.05).

Results: Among 4,829 participants, there were 132 AIDS events, 136 chronic inflammation-related conditions, 167 bacterial pneumonias, 45 infection-related cancers and 44 herpes virus-related AIDS events. After FDR correction, we found several associations with a q-value <0.05 (Table 1): HLA-DQB1*06:04 and HLA-DRB1*13:02 for AIDS (HR [95% CI] 2.63 [1.54–4.6] and 2.25 [1.43–3.7], respectively), HLA-B*15:17 and HLA-DRB1*15:01 for bacterial pneumonia [4.93 [2.30–10.7] and 4.33 [2.01–9.31], respectively], and HLA-A*69:01 for infection-related cancer [15.26 [3.56–66.2]]. The carriage frequencies of all alleles with a q-value <0.05 were ≤10% (Table 1).

Conclusion: This hypothesis-generating study suggests that certain rare HLA alleles may influence risk of specific, clinical immune dysfunctional phenotypes irrespective of the effect of ART. Validation of these observations in other larger cohorts is required.

Table 1. Adjusted Cox regression model for time to first non-AIDS event

<table>
<thead>
<tr>
<th>Age at ART initiation (per 10 years)</th>
<th>HR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1.27 (1.09–1.59)</td>
<td>0.0280</td>
</tr>
<tr>
<td>Female</td>
<td>1.00 (Reference)</td>
<td>Reference</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>0.0360</td>
<td>0.0884</td>
</tr>
<tr>
<td>Caucasian</td>
<td>0.95 (0.34–2.98)</td>
<td>0.9072</td>
</tr>
<tr>
<td>Non-Caucasian</td>
<td>0.62 (0.36–1.07)</td>
<td>0.0114</td>
</tr>
<tr>
<td>Mode of HIV transmission</td>
<td>0.1318</td>
<td>0.8184</td>
</tr>
<tr>
<td>Non-injecting drug use</td>
<td>0.81 (Reference)</td>
<td>Reference</td>
</tr>
<tr>
<td>Injecting drug use</td>
<td>1.00 (0.90–2.18)</td>
<td>1.80 (0.14–2.84)</td>
</tr>
<tr>
<td>Pre-event CD4+/CD8+ ratio</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>≤0.26</td>
<td>4.05 (2.42–9.70)</td>
<td>0.0000</td>
</tr>
<tr>
<td>≥0.27</td>
<td>3.62 (1.77–7.41)</td>
<td>0.0000</td>
</tr>
<tr>
<td>0.44±0.59</td>
<td>2.10 (1.04–4.24)</td>
<td>0.0300</td>
</tr>
<tr>
<td>0.60±0.86</td>
<td>1.99 (0.94–4.24)</td>
<td>0.0600</td>
</tr>
<tr>
<td>2.08±3.02</td>
<td>1.80 (0.14–2.84)</td>
<td>0.0000</td>
</tr>
</tbody>
</table>

Table 2. Harrell C statistics for Cox regression models predicting events during follow-up

<table>
<thead>
<tr>
<th>Test Statistic</th>
<th>Unadjusted Cox Model</th>
<th>Adjusted Cox Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>C Statistic</td>
<td>0.67 (0.62–0.71)</td>
<td>0.67 (0.62–0.71)</td>
</tr>
<tr>
<td>C Statistic*</td>
<td>0.73 (0.69–0.76)</td>
<td>0.73 (0.69–0.76)</td>
</tr>
</tbody>
</table>

PE20/2

Neutrophil-to-lymphocyte ratio compared to CD4+/CD8+ T-cell ratio as a predictor of non-AIDS events in treated people living with HIV

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Purpose: In the ART era non-AIDS events have emerged as the leading cause of morbidity and mortality for people living with HIV (PLWH). CD4+/CD8+ T-cell ratio has been shown to be incrementally associated with non-AIDS events in treated people living with HIV. Neuro-immune dysfunction and inflammation-related conditions are the most common causes of non-AIDS events. The neutrophil-to-lymphocyte ratio (NLR) is a simple, non-invasive method of assessing systemic inflammation. Additionally, the NLR has been shown to predict cardiovascular mortality in the general population, and has previously been related to infection-related cancer (15.26 [3.5–66.2]). The NLR increased in unadjusted models, both lower pre-event CD4+/CD8+ T-cell ratio and higher NRL were associated with increased NADES (p<0.001, p=0.05 respectively, Figure 1). After adjustment for confounders, only CD4+/CD8+ T-cell ratio remained independently associated with the incidence of NADES (Table 1). Models containing pre-event CD4+/CD8+ T-cell ratio predicted NADES better than pre-event NLR (C-statistic; 0.73 vs 0.68 respectively, Table 2).

Conclusion: This study suggests NLR does not have predictive value for NADES in PLWH. Further studies are needed to assess its clinical utility for specific NADES in this population.
Factors associated with virologic failure in women with HIV: Condesa specialized clinics, Mexico City

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Purpose: To identify factors associated with virologic failure (VF) in women with HIV, patients of two clinics in Mexico City.

Method: An observational cross-sectional study. Carried out among women patients at the Condesa Clinics between January 2014 and December 2018. All patients were pregnant (Cohort pregnant women) and had been undergoing HAART (highly active antiretroviral treatment) for at least six months and possessed complete medical records. Convenience sampling, prevalence, odds ratio, chi² and attributable risk were analyzed using SPSS24.

Results: 169 women with HIV from the Condesa Specialized Clinic (CSC) and CSC-Iztapalapa. 143 in statistical analysis. 15% (n=16) failed to follow up. Median age, 28 years (SD 6.1). Education: 47% completed middle school. Unpaid employment: 78%. 74% have a stable partner. 85% with virologic suppression and 15% with virologic failure (VF). Women with chronic HIV (n=67), 41% with VF at the time of first medical consultation in pregnancy: VL 16,355 copies/mL (SD 261891 c/mL, at the third quarter before birth 97% with VL <200 c/mL, at present 85% VL <200 c/mL; CD4 (cells/mm³): 361 c/mm³ (SD 224), 432 c/mm³ (SD 185) and 427 c/mm³ (SD 241) respectively, 61% serodiscordant couples. Women with recent diagnosis of HIV (pregnancy scrutiny, n=76) first viral load 22,106 c/mL (SD 41285 c/mL), before birth 95% with VL<1000 c/mL, at present 95% VL<200 c/mL, 5% in VF. CD4 (cells/mm³): 302 c/mm³ (SD 214), 375 c/mm³ (SD 257) and 581 c/mm³ (SD 332) respectively; 47% concordant couples. In both, the probability of VF in women who experienced domestic violence was 3.1 OR (SD 1.3-9.9, p 0.01) and in those receiving antiretroviral therapy with protease inhibitor (PI) the probability of VF was 2.9 OR (SD 1.7-7.5, p 0.003).

Conclusion: In this study we observed two factors associated with VF; identifying the associated factors is useful in developing intervention strategies. If we eliminate domestic violence, the VF decreases 73% and if we change HAART without PI, VF decreases 66%.

Causes of death among a cohort of HIV-infected adults in rural Tanzania

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Purpose: Nearly half of AIDS-related deaths occur in East and Southern Africa, yet data on causes of death (COD) are scarce. We determined COD and factors associated with cause-specific mortality among HIV-infected persons in rural Tanzania.

Method: We included adults (≥15 years) enrolled in the Kilombero and Ulanga Antiretroviral Cohort (KIULARCO) in 2005–2006, with follow-up through 2016. We classified COD as HIV-related or non-HIV-related with subclassification into comprehensive classes. Among adults enrolled from 2013 onwards (when COD were systematically recorded), we assessed cause-specific mortality using cumulative incidences, and associated factors using Cox proportional hazard models.

Results: Among 8409 adults, 816 (10%) had died by the end of 2016, among whom COD were available for 358 (44%), with missing COD mainly before 2013 (Figure 1). The leading identified COD were tuberculosis (107 (30%)), non-AIDS-related infections (58 (16%)), and AIDS-related infections (52 (15%)). Among 2574 adults enrolled from 2013 onwards, 74 (3%), 24 (1%) and 22 (1%) died from HIV-related, non-HIV-related and unknown causes, respectively. One-year cumulative incidences of HIV-related and non-HIV-related mortality were 0.03 (95% confidence interval 0.02–0.04) and 0.009 (0.006–0.01), respectively (Figure 2). Factors associated with HIV-related mortality were hospitalisation, not having an HIV-positive partner, advanced WHO stage, lower CD4 count, and not initiating ART at enrolment. Factors associated with non-HIV-related mortality were older age, living closer to the clinic, and hospitalisation.

Conclusion: Despite access to ART, HIV-related mortality rates were higher than non-HIV-related mortality rates. Tuberculosis was the leading identified COD, emphasising the need for continued improvements in screening and management. Documentation of COD improved over time; methods to uniformly capture deaths and causes are recommended. The lower non-HIV-mortality rates among those living further from the clinic may be due to undocumented deaths; further efforts to track and retain participants in care are needed.
documented. In addition, predictors of this phenomenon among adult HIV-infected patients in pastoralist communities in Kenya are largely unknown.

**Method:** This was a retrospective cohort study carried out between January 2014 and December 2017 among HIV-infected patients being followed up at the Baringo County Referral Hospital, Kabarnet, Kenya. Patient files were used to extract the required patient information. Kaplan-Meier, as well as Cox proportional hazards regression models, were used to assess for independent predictors that contributed to mortality of these patients over time.

**Results:** 332 patients were studied over a median follow-up period of 27.6 months (IQR: 18.5–36.2 months), with a female to male predominance of 1.4:1, a median age of 41 years (IQR: 35–48 years), and a median pre-treatment CD4 count of 207 cells/mm³ (IQR: 81–316 cells/mm³). Overall, 6.6% (n=22) of the patients were documented to have died during the study period, with estimated mortality at 3.1% (n=11; 95% CI: 1.9–5.9%) in month 3, 5.1% (n=2; 95% CI: 3.2–8.1%) in month 12, 7.1% (n=5; 95% CI: 4.7–10.6%) in month 24, and 7.1% (n=0; 95% CI: 4.7–10.6%). Independent predictors of mortality were male sex [aHR: 4.90; 95% CI: 1.81–12.72], CD4 ≤ 100 cells/mm³ [aHR: 2.93; 95% CI: 1.24–6.91], and WHO stage III & IV [aHR: 2.80; 95% CI: 1.20–6.55], and TB/HIV co-infection [aHR: 18.39; 95% CI: 4.71–71.81].

**Conclusion:** Mortality was noted to be high, especially among the first three months of follow-up, mostly due to immunosuppression and TB/HIV co-infection. Hence, early diagnosis, with expeditious commencement of therapy and frequent follow-up is vital to minimize these numbers.

**PE20/6**

**Trends in underlying causes of death in HIV – infected patients from 2016 to 2018 in Ukraine: a cohort study**

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3Poltava Regional Nercological Dispersary, Poltava, Ukraine

**Purpose:** Death level in PLHIV in Ukraine remains high. We aimed to examine changes in causes of death in PLHIV over the period 2016–2018.

**Method:** A retrospective cohort study was conducted at Poltava Regional HIV Center in which routinely collected data for PLHIV enrolled and followed up between January 2016 and December 2018 were abstracted from the clinic’s database. Patient follow up was initiated from the day of the first visit in clinic until exit by death, transfer out or loss to follow up. Percentage of deaths for each cause across calendar years was analyzed using Chi-square test.

**Results:** 268 of the 3559 study participants died during 9706 person-years of follow-up [crude incidence mortality rate, 2.7 per 100 person-years [95% CI: 2.2–3.3]]. 147 people were transferred out and 85 lost-to-follow-up. Compared with those that survived (n=3059), we recorded a higher proportion of deaths in men – 176 (66%) vs 153 (50%), intravenous drug use risk for HIV acquisition – 94 (35.1%) vs 885 (28.9%), presented for care late in course of their HIV infection 192 (47.1%) vs 793 (25.9%), hepatitis C virus-positive – 185 (60.5%) vs 1850 (59.5%), previous AIDS diagnosis – 173 (64.5%) vs 1070 (34.9%) (p<0.001), never exposed to ART92 (34.3%) vs 176 (5.6%) (p<0.001). The most common causes of death were AIDS-related causes, followed by liver disease, and cardiovascular disease.

**Table 1. Specific causes of death, 2016–2018**

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Number of deaths (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total death</td>
<td>268 (100%)</td>
</tr>
<tr>
<td>AIDS-related, including:</td>
<td>164 (61.2%)</td>
</tr>
<tr>
<td>- tuberculosis</td>
<td>80 (29.8%)</td>
</tr>
<tr>
<td>- toxoplasmosis of brain</td>
<td>33 (12.3%)</td>
</tr>
<tr>
<td>- pneumocystis pneumonia</td>
<td>12 (4.5%)</td>
</tr>
<tr>
<td>Liver-related (chronic viral hepatitis)</td>
<td>59 (22.0%)</td>
</tr>
<tr>
<td>Cardiovascular disease (CVD)-related</td>
<td>16 (5.9%)</td>
</tr>
<tr>
<td>Other or unknown, including:</td>
<td>29 (10.9%)</td>
</tr>
<tr>
<td>- drug overdose</td>
<td>17 (6.4%)</td>
</tr>
</tbody>
</table>

**Conclusion:** Low CD4/CD8 measured over time was associated with increased risk of AE, NAE and mortality regardless of CD4+ cell count. These preliminary findings supports the predictive role of variation of CD4/CD8 over time and the need for further research on therapeutic tools, whether antiretroviral therapy or not, to improve the recovery of the CD4/CD8.

**PE20/7**

**Dynamic of CD4+/CD8+ ratio in late presenters: impact on clinical outcomes**

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5University Hospital of the Canary Islands, Tenerife, Spain
6San Carlos Clinic Hospital, Madrid, Spain
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8Vall d’Hebron University Hospital, Barcelona, Spain
9Hospital Universitario Ramón y Cajal, IRYCS, Department of Infectious Diseases, Madrid, Spain

**Purpose:** To evaluate whether CD4+/CD8+ cell ratio (CD4/CD8) measured over time is associated with the development of AIDS-defining events (AE), non-AIDS defining events (NAE) and mortality in HIV+ late presenter (LP) individuals from the cohort of the Spanish HIV/AIDS Research Network (CoRIS).

**Method:** Late presentation was defined as HIV diagnosis with CD4+cell count ≤350 cells/μL or an AIDS defining event within 6 months of enrolment. Cox proportional hazard models allowing time-varying covariates were used to estimate hazard ratios (HR) for the association between time-varying CD4/CD8 and the first AE, the first NAE (cardiovascular, kidney, liver, neoplasms, bone, neuropsychiatric, metabolic or other event) and death. Models were adjusted for CD4+ cell count and age, as time-varying covariates, transmission category, country of origin, educational level, presence of HIV antibodies, presence of HBV surface antigen and HIV-RNA at age enrolment.

**Results:** Of the 10,486 out of 15,509 CoRIS participants by November 2018 included in the study, 4,643 were LP [prevalence: 44.3% [95% CI: 43.3–45.2]]. Among LP, 159 patients had at least one AE [incidence: 0.91 [95% CI: 0.52–0.72]/100 person-years], 593 experienced at least one NAE [incidence: 2.53 [95% CI: 2.33–2.74]/100 person-years] and 213 died [mortality rate: 0.19 [95% CI: 0.12–0.26]/100 person-years]. CD4/CD8>0.4 over time was associated with an increased risk of AE [HR: 1.79 (95% CI: 1.09; 2.96)] and NAE [HR: 1.25 (1.01; 1.55)], mainly cardiovascular events, as detailed in table 1 and with all-causes mortality [HR: 1.37 (0.96, 1.95)].

**Association between CD4+/CD8+ ratio and the first non-AIDS event in late presenters (N=4,643)**

<table>
<thead>
<tr>
<th>N of HIV+ late presenter individuals with at least one NAE and CD4/CD8 &lt;0.4/CD4/CD8 ≥0.4</th>
<th>Incidence rate x 100 person-years (95%CI)</th>
<th>Adjusted HR for CD4/CD8+&lt;0.4 vs ≥0.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular events</td>
<td>38/45</td>
<td>0.35 (0.28; 0.44) 1.97 (1.18, 3.29)</td>
</tr>
<tr>
<td>Kidney events</td>
<td>18/38</td>
<td>0.24 (0.18, 0.31) 0.87 (0.41, 1.84)</td>
</tr>
<tr>
<td>Liver events</td>
<td>15/18</td>
<td>0.14 (0.10, 0.20) 0.60 (0.27, 1.37)</td>
</tr>
<tr>
<td>Neoplasms</td>
<td>58/83</td>
<td>0.00 (0.01; 0.71) 1.06 (0.68, 1.64)</td>
</tr>
<tr>
<td>Bone Events</td>
<td>32/62</td>
<td>0.40 (0.32, 0.49) 1.31 (0.78, 2.18)</td>
</tr>
<tr>
<td>Neuropsychiatric events</td>
<td>47/62</td>
<td>0.46 (0.38; 0.56) 1.45 (0.87, 2.40)</td>
</tr>
<tr>
<td>Metabolic events</td>
<td>38/61</td>
<td>0.42 (0.34, 0.51) 1.57 (0.93, 2.65)</td>
</tr>
<tr>
<td>Other events</td>
<td>6/3</td>
<td>0.04 (0.02, 0.07) 0.78 (0.20, 2.90)</td>
</tr>
</tbody>
</table>

**Conclusion:** While AIDS remained the most common cause of death throughout the period 2016–2018 (62.6%–63.5%), the percentage of liver-related deaths increased (12% to 25.3%) and CVD-related deaths increased (2.6% to 10.6%), p<0.05, χ² test.** Conclusions:** AIDS remained the most common cause of death over the period 2016–2018 in Ukraine. The percentage of liver-related and CVD-deaths increased, making it the joint leading non-AIDS cause of death with AIDS-related deaths.
PE20/8
Retrospective investigation into the causes of death in HIV-infected patients from Bonn in the era of combined Anti-Retroviral Therapy

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Purpose: Countless investigations have attested to the decline of deaths attributed to AIDS in HIV positive patients since the introduction of combined Anti-Retroviral Therapy (cART). The goal of this investigation was to examine this transition and systematically determine the causes of death in the previous decade in the Bonn cohort of HIV infected people.

Method: For the purposes of this investigation 81 patients from Bonn who died between 2010 and 2018 were recorded. Along with the underlying causes of death, patient data such as pre-mortem laboratory parameters, comorbidities and comedications were collected and descriptively analyzed.

Result: The median age at death was 51 years (IQR 45.8–60.0), 81% were men. The median lifespan with HIV infection was 15.66 years. 88.9% of the patients received antiretroviral therapy until the time of their death. 70% of the patients had an undetectable HIV viral load at last check. The median of the last CD4 Helper Cell count before death (~12 Months) was 260.5 Cells/µL. In 17.2% of the cases the cause of death was an AIDS defining illness: 6.1% Pneumocystis jirovecii Pneumonia, 4.9% other AIDS defining illness, 3.7% Non-Hodgkin-Lymphoma and 1.2% Wasting Syndrome. Non-AIDS associated malignancies (19.8%) were the most common cause of death. Cardiovascular disease represented 13.6% of the deaths respectively before Non-HIV associated infections (12.3%). 7.4% of the patients, all of whom were coinfected with chronic hepatitis, suffered from diseases of the liver. 6.2% of the patients committed suicide, 8.6% died of other causes, and in 14.8% of the cases the cause of death remained unknown.

Conclusion: Non-AIDS associated malignancies and cardiovascular disease are increasingly leading to the death of HIV infected people in the area of Bonn. The trend of decreasing mortalities attributed to AIDS was confirmed. These results are due to consistently implemented antiretroviral therapy and highlights their importance.

PE20/9
Reduced utility of early procalcitonin in HIV febrile patients admitted to the emergency department

C Picarelli1, A Dusina1, M Covino2, A Emiliozzi1, D Farinacci1, G Merra2, L Carbone2, C Picarelli1, A Dusina1, M Covino2, A Emiliozzi1, D Farinacci1, G Merra2, L Carbone2, C Picarelli1, A Dusina1, M Covino2, A Emiliozzi1, D Farinacci1, G Merra2, L Carbone2, C Picarelli1, A Dusina1, M Covino2, A Emiliozzi1, D Farinacci1, G Merra2, L Carbone2

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2Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, Italy

Purpose: To investigate the role of procalcitonin (PCT) in the Emergency Department (ED) as early assessment of febrile patients and to investigate its prognostic role in in-hospital mortality.

Method: We retrospectively evaluated data of all HIV-infected patients who were admitted to ED and then hospitalized with fever as the main symptom from 2008 to 2017. QSOFA score was used to assess the severity of clinical presentation. Chi-square test and logistic regression were used to assess the factors independently associated to the use of PCT and to assess the prognostic prediction value of PCT assessment in terms of in-hospital mortality rate.

Results: Study population consisted in 579 patients: 65.3% males; median age 47 years (IQR 40–53). Median length of hospital stay after ED admission was 11 days (IQR 6–20). At ED admission, median CD4 cell count was 222 cells/mm³ (IQR 64–445) and median plasma HIV-RNA was 1612 cp/mL (IQR 19–139431). In 52% of the cases, HIV serostatus was already known at ED admission (60% of them were on cART from at least 6 months) and in 13% of cases the patients presented with AIDS defining events. QSOFA score was >0 in 8% of the population (N=47). PCT was performed in 144/105 patients (N=82). At multivariate analysis, factors associated with the use of PCT were: to be female (p=0.029), of older age (p=0.012), already diagnosed with HIV infection (p=0.04) and to have presented positive blood cultures at admission (p=0.025).

Conclusion: The decision to perform early PCT in HIV febrile patients is guided by the clinical presentation and by some demographic characteristics such as female gender, older age, known HIV infection. The prognostic relevance of early determination of PCT is poor. An integrated approach including biomarkers dosage, validated sepsis scores, and involvement of antibiotic stewardship team, is desirable to improve outcome in this kind of patients.

In-hospital deaths according to QSOFA in HIV positive patients admitted to Emergency Department (ED) with fever tested or not with Procalcitonin (PCT)

<table>
<thead>
<tr>
<th>QSOFA</th>
<th>PCT in ED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO PCT in ED N (%)</td>
</tr>
<tr>
<td>QSOFA=0</td>
<td>In-hospital death</td>
</tr>
<tr>
<td></td>
<td>Yes N (%)</td>
</tr>
<tr>
<td>QSOFA=0</td>
<td>In-hospital death</td>
</tr>
<tr>
<td></td>
<td>Yes N (%)</td>
</tr>
<tr>
<td>Total N (%)</td>
<td>37 (100)</td>
</tr>
</tbody>
</table>

PE20/10
Patients with HIV and HCV in intensive care treatment: admission criteria and trends in the intensive care unit (ICU) at the University Hospital of Bonn 2014–2019

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Purpose: Patients with chronic HIV- and HCV-infection require specialized, multidisciplinary intensive care in case of uncontrolled HIV infection/ opportunistic infections and/or decompensated liver disease. Here we analyze admission characteristics and trends over time in HIV, HCV and HIV/HCV co-infected patients admitted to the intensive care unit (ICU) at University Hospital of Bonn during January 2014 to June 2019.

Method: We performed a retrospective survey of all patients admitted to the ICU with HIV infection and chronic/recent history of HCV infection. Available clinical data of all patients with regard to sex, age, medical history, admission criteria, duration of stay and outcome were analyzed.

Results: Overall, 210 patients were included (median age 51.3 years, female/male 60/150) with a total of 286 ICU admissions. Median duration on ICU was 3 days. 48 patients died on ICU. Admission criteria differed in HIV, HCV and HIV/HCV co-infected patients. HIV patients (42 patients, 58 admissions) were predominantly admitted due to opportunistic infections (37.9%), sepsis (24.1%) and cardiopulmonary disease (18.9%). HCV patients (148 patients, 205 admissions) were mostly admitted due to liver disease (22.9%), sepsis (21.9%) and intoxication/drug abuse (20.0%). 20 HIV/HCV co-infected patients were admitted because of sepsis (32.0%), opportunistic infections (20.0%) and intoxication/drug abuse (20.0%).

During the observation period we saw a constant trend of admissions of HIV patients due to infectious diseases. Admissions of HCV patients due to complications of liver disease was considerably decreasing.

Conclusions: The high number of HIV patients admitted to ICU due to acute infections reflects the ongoing high proportion of HIV late presenters. The decreasing trend of HCV patients admitted due to sequelea of liver disease probably shows the impact of DAA therapy on clinical course of HCV infection reducing morbidity and mortality.
Burden of disease in PLWH harboring a 4-class drug resistant virus: data from PRESTIGIO Registry

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Istituto Scientifico di Modena, Infectious Diseases, Modena, Italy
Azienda Scuola di Verona, UOS Malattie Infettive, Verona, Italy
Azienda Scaligera di Verona, UOS Malattie Infettive, Verona, Italy
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Università degli Studi di Firenze, Dipartimento di Medicina clinica e Sperimentale, Firenze, Italy
ASST Cremona, Cremona, Italy
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Università degli Studi di Firenze, Dipartimento di Medicina clinica e Sperimentale, Firenze, Italy
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Università degli Studi di Roma “Tor Vergata”, Department of Experimental Medicine, Rome, Italy
University of Siena, Siena, Italy
Istituto Scientifico San Raffaele-Vita-Salute San Raffaele University, Clinic of Infectious Diseases, Milan, Italy

Purpose: To date, there are no data on survival and burden of disease in people living with HIV-1 (PLWH) harboring a 4-class drug resistant (4DR) virus (NRTI, NNRTI, PI, INSTI).

The aim of the study was to evaluate the survival and the incidence of AIDS and non-AIDS-related events in this fragile population.

Method: Cohort study on PLWH, recorded in the PRESTIGIO Registry, with a documented 4DR virus.

We estimated the incidence of death, AIDS and non-AIDS-related clinical events recorded after 4DR occurrence (baseline, BL).

Non-AIDS related events included: non-AIDS-defining malignancies, major adverse cardiovascular events (MACE), cirrhosis, chronic kidney disease (CKD), diabetes.

Incidence rates (IR) were expressed per number of person-years of follow-up (PYFU) since BL and estimated by univariate Poisson regression.

Results: Overall, 148 PLWH were evaluated; median age was 49 years (IQR = 44–53), 78% males. Patients’ characteristics are reported in Table 1.

During a median follow-up of 47 months (IQR = 32–84), 38 PLWH had 62 events/death for any cause (12 died, 17 non-AIDS-defining malignancies, 3 AIDS-defining malignancies, 15 AIDS events, 6 MACE, 6 CKD and 3 cirrhosis): IR = 9.12/100-PYFU (95% CI = 6.85–11.39).

Fifteen PLWH developed 24 new AIDS events or had AIDS-related death: IR = 3.52/100-PYFU (95% CI = 2.12–4.94).

Twenty-six PLWH developed 38 non-AIDS events or non-AIDS-related deaths: IR = 5.59/100-PYFU (95% CI = 3.81–7.37).

Time to any clinical event/death for any reason, AIDS event/AIDS-related death or non-AIDS event/non-AIDS-related death are shown in Figure 1.

Conclusion: Among PLWH with 4DR, the burden of disease due to both AIDS and non-AIDS related events is still an issue, even in recent years.

Interestingly, 32% of the recorded clinical events were malignancies, 27% non-AIDS-defining malignancies.

Figure 1: Time to occurrence of ≥ 1 event/death (panelA), AIDS event/death (panelB) and non-AIDS event/death (panelC).

Baseline characteristics of the 148 PLWH and 4-class drug resistant virus.
PE20/12
Changing pattern of hospital admissions due to medical conditions in HIV-infected subjects in a European public health care system with free access to antiretroviral treatment
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2Hospital Universitari Germans Trias i Pujol, Pharmacy, Badalona, Spain
3Hospital Universitari Germans Trias i Pujol, Infectious Diseases, Badalona, Spain

Purpose: Reasons for hospitalizations in HIV-infected subjects might vary along recent years due to universal ART and achievement of high rates of HIV suppression, particularly in developed countries with universal free ART and access to health-care.

Method: We analyzed admissions of HIV-infected subjects to internal medicine/infectious diseases Dept. from October 2016-September 2018 in a University tertiary hospital in Barcelona.

Results: We identified 243 admissions (1.5 admissions/subject) with a mean stay of 11.2 days. Of them, 73.2% were male, median age 49.8 years, median 361 CD4+ cells. Alcohol or drug (including IV) abuse was present in 24.7% and 23.5%, respectively, and 56.4% had prior HCV coinfection. Most (93%) subjects were previously diagnosed of HIV, only 5.4% were newly diagnosed during the admission. Mortality was 4.9%, and was associated with neoplasia (p=0.026). Plasma HIV-1 RNA was <50 copies/mL in 53.1% (129/243), and 40.0% had >200 copies/mL. Having an AIDS-defining illness (p=0.007) or lower CD4 count (p=0.026) were associated with longer hospital stays. Being female (p=0.069) or having an undetectable HIV-1 plasma RNA (p=0.14) were associated with trends towards shorter hospitalizations. Last ART retrieval from the pharmacy was significantly shorter in those with undetectable plasma HIV-1 RNA compared to those with detectable (IQR: 5–13 vs 13–21 days, p<0.001). The main diagnoses were infections not related to HIV (n=133, 53.9%), of which 69.2% were respiratory infections. Only 14.6% had AIDS-defining illnesses.

Conclusion: The main diagnostics were respiratory infections not related to HIV. Mortality was 5% and was only associated with neoplasia. AIDS-defining illnesses and lower CD4 counts had longer hospital stays. Most subjects were already diagnosed of HIV and had lost their link to health care and withdrawn their ART. These subjects not only fuel hospital admissions but also HIV transmission to the general population. Active public health strategies should be designed to relink them to viral suppression.

PE20/13
Association of non-adherence to antiretroviral therapy with cardiovascular outcomes in virologically suppressed persons living with HIV: the Swiss HIV Cohort Study
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2Lausanne University Hospital, Infectious Disease Service, Lausanne, Switzerland
3University of Geneva, School of Pharmaceutical Sciences, Lausanne, Switzerland
4Bern University Hospital, Department of Infectious Diseases, Bern, Switzerland
5University Hospital Geneva, Division of Infectious Diseases, Geneva, Switzerland
6University Hospital Basel, Division of Infectious Diseases, Basel, Switzerland
7University Basel, Basel, Switzerland
8Kantonsspital St. Gallen, Division of Infectious Diseases, St. Gallen, Switzerland
9Ospedale Regionale di Lugano, Division of Infectious Diseases, Lugano, Switzerland
10University Hospital Zurich, University of Zurich, Zurich, Switzerland
11Swiss Tropical & Public Health Institute, Department of Medicine, Basel, Switzerland

Purpose: Suboptimal adherence to antiretroviral therapy (ART), even if enough to achieve and sustain viral suppression, has been associated with enhanced residual inflammation. We aim to investigate whether incomplete ART adherence in the persons living with HIV (PLWH) with virologic suppression is associated with increased cardiovascular disease (CVD) outcomes.

Method: PLWH prospectively enrolled in the SHCS were included in this analysis if they started ART between 2003 and 2017, had at least 6 months of viral suppression (RNA<50 copies/mL) and no history of CVD. The association between incomplete adherence to ART, defined as any missed doses by self-report, and a composite outcome for a CVD event (myocardial infarction [MI], revascularization, death due to cardiovascular event), was evaluated using Cox proportional hazard ratio (HR) models. Models were adjusted for the Framingham 10-year risk score (FRS), family history of CVD, ethnicity, HIV transmission group, and CD4+ T-cell count, and HIV-1 RNA upon ART initiation.

Results: A total of 6,188 PLWH were included in the analysis (74% male) with a median age of 39 (range: 17–80). FRS was 10–20% and >20% in 18% and 9% of participants, respectively. Median participant follow-up was 8 years (IQR: 5–11), with a median of 13 adherence questionnaires (IQR: 7–21). In total, 181 (3%) participants experienced a CVD event: revascularization (43%), stroke (22%), MI (20%), death (12%), and hemorrhage (3%). After adjusting for confounders, suboptimal adherence was associated with an increase in CVD events (HR: 1.35, 95% CI: 0.85–2.17).

Conclusion: Among PLWH with virologic suppression, there was a trend towards incomplete ART adherence being associated with an increased risk of a CVD event, emphasizing the possible role of non-adherence to ART as a driver of clinical non-AIDS outcomes. Future studies in other cohorts should further confirm this association to understand its clinical implications.

PE20/14
Differences in social and mental well-being of long-term survivors among people who inject drugs and other participants in the Swiss HIV Cohort Study: 1980–2011
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2University Hospital Zurich, Zurich, Switzerland
3Arud, Centre for Addiction Medicine, Zurich, Switzerland
4University Hospital Basel, University of Basel, Basel, Switzerland
5Regional Hospital Lugano, Lugano, Switzerland
6Geneva University Hospital, Geneva, Switzerland
7Lausanne University Hospital, Lausanne, Switzerland
8Cantonal Hospital St Gallen, St. Gallen, Switzerland
9University of Zurich, Zurich, Switzerland
10University of Basel, Basel, Switzerland
11University of Lausanne, Lausanne, Switzerland
12Bern University Hospital, University of Bern, Bern, Switzerland

Purpose: People living with HIV who were diagnosed before highly active antiretroviral therapy (HAART) was available and who survived at least 15 years after HIV diagnosis, termed pre-HAART long-term survivors (LTS), form a particularly vulnerable population. We study social, clinical and mental factors of LTS in the Swiss HIV Cohort Study, with a particular focus on people who inject drugs (PWID).

Method: We compared PWID LTS with those LTS, who were most likely infected through sexual contact, i.e., men who have sex with men (MSM) and heterosexuals (HET). By using phylogenetic methods, we selected an additional group of heterosexual LTS who most likely shared a social network with PWID (presumed because of phylogenetic HIV clustering) at the time of HIV infection, termed clusteredHET. Social and clinical factors at the time when the HIV diagnosis was at least 15 years ago were compared among these three study groups using logistic regression.

Results: Overall, 1,663 of 5,686 (29.2%) PWID were LTS. We found significant differences between PWID LTS and MSM/HET LTS regarding self-reported depression (59.4% vs 43.9%, OR=1.8, p<0.001), being in prison (30.6% vs 7.3%, OR=5.1, p<0.001), and work ability of less than 50% (59.6% vs 28.9%, OR=5.1, p<0.001). ClusteredHET were less vulnerable with respect to these variables than PWID LTS but more at risk compared to MSM/HET LTS, indicating that clusteredHET are closer to PWID with regard to social and mental aspects compared to all MSM/HET.

Conclusion: Despite the overwhelming success of harm reduction programs for PWID in Switzerland, special care for HIV-infected PWID is still needed today, with emphasis on mental health and social integration of PWID LTS.
Results from Cox proportional hazards or Fine & Gray models for competing risks. All estimates are adjusted for potential confounders.

<table>
<thead>
<tr>
<th>CD4 at cART initiation (cells/µL)</th>
<th>aHR</th>
<th>95% CI</th>
<th>p</th>
<th>aHR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS/AIDS-death or SNAE</td>
<td></td>
<td></td>
<td></td>
<td>SNAE (AIDS/AIDS-death as compet. risk)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>350–499/500+</td>
<td>1.268</td>
<td>(0.786, 2.046)</td>
<td>0.331</td>
<td>1.194</td>
<td>(0.709, 2.011)</td>
<td>0.504</td>
</tr>
<tr>
<td>200–349/500+</td>
<td>1.336</td>
<td>(0.885, 2.063)</td>
<td>0.192</td>
<td>1.082</td>
<td>(0.677, 1.728)</td>
<td>0.742</td>
</tr>
<tr>
<td>&lt;200/500+</td>
<td>2.225</td>
<td>(1.422, 3.481)</td>
<td>&lt;0.001</td>
<td>1.826</td>
<td>(1.133, 2.942)</td>
<td>0.013</td>
</tr>
<tr>
<td>AIDS/AIDS-death (SNAE as compet. risk)</td>
<td></td>
<td></td>
<td></td>
<td>Total mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>350–499/500+</td>
<td>1.184</td>
<td>(0.377, 3.718)</td>
<td>0.772</td>
<td>0.996</td>
<td>(0.489, 2.027)</td>
<td>0.991</td>
</tr>
<tr>
<td>200–349/500+</td>
<td>2.015</td>
<td>(0.786, 5.168)</td>
<td>0.145</td>
<td>1.209</td>
<td>(0.651, 2.245)</td>
<td>0.549</td>
</tr>
<tr>
<td>&lt;200/500+</td>
<td>3.161</td>
<td>(1.159, 8.619)</td>
<td>0.025</td>
<td>2.032</td>
<td>(1.049, 3.933)</td>
<td>0.035</td>
</tr>
</tbody>
</table>

PE20/15

Low pre-ART CD4 count is associated with increased risk of clinical progression or death even after reaching 500 CD4 cells/µL on ART

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6General Hospital of Athens G. Gennimatas, 1st Dept. of Internal Medicine and Infectious Diseases Unit, Athens, Greece
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Purpose: Although the clinical disadvantages of initiating ART at low CD4 counts have been clearly demonstrated, it is unclear whether any excess risk remains after reaching relatively safe CD4 levels. We explore whether persons who started ART with <500 CD4 cells/µL but increased their CD4 count above this level, have from this point onwards, similar risk of clinical progression/death with persons starting ART with ≥500 CD4 cells/µL.

Method: Data were derived from a multicenter Greek cohort study (AMACS). Adults, starting boosted PI, NNRTI or INSTI based ART, ≥2000 were eligible, provided they either started ART with ≥500 CD4 cells/µL ("High CD4") or started with <500 CD4 cells/µL but surpassed this threshold while on ART ("Low CD4"). Baseline was ART initiation ("High CD4") or the date of first exceeding 500 CD4 cells/µL ("Low CD4" group). Survival analysis, allowing for competing risks, was used to explore the risk of clinical progression/death (AIDS/AIDS-death or serious non-AIDS events-SNAEs i.e. Myocardial Infarction, Stroke, End-Stage Renal Disease, non-Decompensated Liver Disease, non-AIDS Malignancies, non-AIDS deaths).

Results: The study included 3,819 persons: 645 in the "High CD4" and 3,174 in the "Low CD4" group. Median (IQR) follow-up time was 43 (25,83) and 61 (32,98) months, respectively. In total, 223 events (93 fatal, 130 non-fatal; 39 AIDS related and 184 SNAEs) were observed. Overall, there was no significant difference in disease progression between the two groups but further stratification of the "Low CD4" group revealed that those initiating ART with <200 CD4 cells/µL were at higher risk for clinical progression or death after baseline, compared to those in the "High CD4" group (Table).

Conclusion: Individuals starting ART with <200 cells/µL remain on increased risk of clinical progression/death even after reaching or surpassing 500 CD4 cells/µL. These patients should be closely followed.
the population of L0. The cause-of-death data on HIV-infected were analyzed for better understanding the urgent clinical and public health interventions.

**Method:** Causes of mortality in HIV type 1 infected patients in the largest infectious diseases hospital in St. Petersburg in the year 2015 and associations of prognostic factors with cause-specific mortality were analyzed.

**Results:** Among 2,516 patients died 383 (15.2%), 257 males, 126 females; mean age 36 years; SD:7.5.

Among the dead, the advanced HIV/AIDS stage (CDC category C3) was diagnosed in 319 out of 355 (92.7%). CD4-positive count varied 0-665 (median 33 cell/ml [10;97]). In 116 (30.3%) patients HIV-infection were diagnosed for the first time. In 256 (66.8%) it lasted more than one year, but only 6 (2.3%) of them received effective antiretroviral therapy (ART). In total, 96 (25.1%) patients had started but 54/96 (56.3%) interrupted ART.

The most frequent opportunistic infection was tuberculosis (n=176, 45.9%), with the generalization in 149 (38.9%) patients, caused by mono/polyresistant Mycobacteria in 40 from 47 (85.0%) analyzed cases. Tuberculosis became the main reason of death (135, 35%), following with pneumonia (n=180, 20.9%), encephalitis (n=65, 17%), and cancer (n=24, 6.7%).

In total, cancers were detected in 31 (8.1%) patients. Patients with CD4≥55/L had higher risk for development of cancer (adjusted by age and sex OR=2.2, 95% CI: 1.00–4.78) and dying from it (adjusted OR=3.2, 95%-CI). No association between cancers and gender, HIV-infection stage and duration and ART was observed.

**Conclusion:** An active program for early detection of HIV, initiation of ART, detection of associated diseases and precancers will help prevent the development of diseases and deaths related to HIV/AIDS, which will lead to an increase in the life expectancy of HIV-infected in Russia.

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**PE20/18**

**Dynamics and structure of mortality of HIV-positive people in Ukraine**

N Bugaienko

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**Purpose:** Analysis of dynamics, structure of HIV-positive people mortality, effectiveness of antiretroviral therapy in Ukraine during the period of 2014–2018.

**Method:** A retrospective descriptive epidemiological analysis based on the national report forms.

**Results:** During 2014–2018, the mortality rate of HIV-positive people in Ukraine increased (from 5.9 to 6.8 thousand), with 28449 people deceased. In the age–gender structure, 65% of deaths occurred among men, 35% – among women, 80% of all deaths were reported in the 25 to 49 age group. 56% people that died were infected with the HIV virus due to unprotected sexual contacts, and 41% – as a result of injecting drug use. Of all deaths, 60% were HIV - associated, 37% were diseases not related to HIV-infection and other causes - 3%. Among HIV-associated deaths 58% occurred due to AIDS. On average, 3.3 thousand AIDS-deaths are recorded annually. The mortality rate increased from 8.0 per 100,000 population in 2014 to 8.9 in 2018. HIV/TB was the leading cause AIDS-related deaths: 64% in 2014 and 51% in 2018. The mortality rates not related to HIV-infection diseases increased from 36% to 38%. The number of deaths from tuberculosis decreased by 1.7 times. 43% of people who died were receiving antiretroviral therapy. Treatment coverage raised from 39% in 2014 to 46% in 2018. The proportion of patients who died of HIV/TB while receiving therapy was 51.0%.

The highest levels mortality being registered in Dnipropetrovska, Odeska, Mykolaivska oblasts.

**Conclusion:** It is necessary to optimize preventive measures aimed at early detection of HIV-positive people, their linkage to medical care, improvement of epidemiological surveillance system, completeness and quality of collected data regarding the causes of death, taking into account the existing tendency of increasing AIDS mortality rate against the background of significant spread of tuberculosis among deceased, their insufficient coverage by antiretroviral treatment.

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**Mother-to-child transmission**

**PE21/1**

**HIV infection in pregnant women and children in Switzerland: how effective are measures for preventing mother-to-child transmission?**

M Gebhardt

Federal Office of Public Health, Bern, Switzerland

**Purpose:** In 2004, recommendations were published in Switzerland in order to prevent mother-to-child transmission (MTCT) of HIV of (Bulletin FOPH 53/ 2004:1008–1011). The recommendations were approved by the Swiss Federal Commission for Sexual Health and included combination antiretroviral therapy, caesarean section and avoidance of breastfeeding. The objective was to evaluate the effectiveness of MTCT-prevention in women with Swiss versus non-Swiss nationality (distribution of nationalities see Table 1).

**Method:** Analysis of Swiss HIV notification data on (a) children infected by MTCT in 1990–2018 and (b) women diagnosed during pregnancy in 2004–2018.

**Results:** Rates of HIV infections in children were substantially lower after 2004, particularly in children with Swiss nationality (Table 2). The overall rate was higher for non-Swiss than for Swiss children (Odds Ratio non-Swiss vs. Swiss: 2.46 [1.87–3.21], p<0.0001). During 2004–2018, HIV diagnoses declined in both Swiss and non-Swiss women (Figures 1 and 2). 5.0 % of HIV-diagnosed Swiss women (N=716) were pregnant at diagnosis, compared to 18.8 % of non-Swiss women (N=1778; z=8.4, p<0.0001). The rate of HIV diagnoses in women who were pregnant at diagnosis was 2.11 per million Swiss women, versus 46.4 per million non-Swiss women (Odds Ratio Swiss versus non-Swiss 0.044 CI [0.031–0.061], p<0.0001; reference population are the 15–44 year-old women in Switzerland).

**Conclusion:** MTCT of HIV in Switzerland declined following the recommendations published in 2004. However, rates of HIV infections were twelve times higher in non-Swiss children than in Swiss children. This is partly explained by non-Swiss women being three times more likely to be diagnosed with HIV than Swiss women when tested during pregnancy. The results indicate that prevention of MTCT is less effective in non-Swiss than in Swiss women.

**Prevention measures need to be improved for foreign women in order to further reduce MTCT of HIV in Switzerland.**

**Table 1. Nationality of women diagnosed with HIV during 2004–2018**

<table>
<thead>
<tr>
<th>Nationality</th>
<th>Number of HIV diagnoses</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swiss</td>
<td>717</td>
<td>28.7%</td>
</tr>
<tr>
<td>European (non-Swiss)</td>
<td>209</td>
<td>8.4%</td>
</tr>
<tr>
<td>African</td>
<td>1073</td>
<td>43.0%</td>
</tr>
<tr>
<td>American (North, Middle, South)</td>
<td>119</td>
<td>4.8%</td>
</tr>
<tr>
<td>Asian</td>
<td>158</td>
<td>6.3%</td>
</tr>
<tr>
<td>Oceanian</td>
<td>34</td>
<td>1.4%</td>
</tr>
<tr>
<td>Unknown</td>
<td>186</td>
<td>7.4%</td>
</tr>
</tbody>
</table>

**Table 2. Rate of HIV infected children per 100,000 live births in Switzerland by nationality of the children and birth period**

<table>
<thead>
<tr>
<th>Nationality</th>
<th>Birth period</th>
<th>Mean rate</th>
<th>Odds ratio [CI]*</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swiss</td>
<td>1990–2003</td>
<td>13.6</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Swiss</td>
<td>2004–2018</td>
<td>0.54</td>
<td>0.042 [0.017–0.103]</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>non-Swiss</td>
<td>1990–2003</td>
<td>28.0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>non-Swiss</td>
<td>2004–2018</td>
<td>6.3</td>
<td>0.225 [0.139–0.364]</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*2004–2018 versus 1990–2003; CI: 5% Confidence interval
No evidence for induced glucuronidation of dolutegravir in HIV-infected pregnant women

V Bukkens1, P Bollen1, J Freriks1, D Konopnicki2, K Weizäcker3, CH Tenorio4, J Molto5, G Taylor6, I Alba-Alejandre7, R van Crevel1, A Colbers1, D Burger1 and on behalf of the PANNA Network

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Purpose: Dolutegravir (DTG) exposure is moderately decreased (by approximately 30%) during pregnancy. One possible explanation for this decrease could be increased glucuronidation through induction of UGT1A1, which has been described in pregnancy. Therefore, we examined the molar metabolic ratio of DTG-glucuronide (DTG-gluc)/DTG in plasma during pregnancy and postpartum.

Methods: An open-label, multi-centre, observational, phase IV study was conducted in HIV-infected pregnant women recruited in HIV treatment centers in Europe (PANNA Network). We collected intensive steady-state 24-h pharmacokinetic (PK) curves during the third trimester of pregnancy and 3–7 weeks postpartum for women treated with once daily 50 mg DTG as part of antiretroviral treatment. The geometric mean (GM) DTG-gluc AUC0-24 h and DTG AUC0-24 h were determined with non-compartmental analysis. Next, the molar metabolic ratio of DTG-gluc AUC0-24 h/DTG AUC0-24 h in pregnancy was compared to postpartum. It is unlikely that induction of UGT1A1 is the major driver of decreased DTG exposure in pregnant women.

Results: 14 third trimester and 9 postpartum PK curves were available to determine the AUC0-24 h of both DTG-gluc and DTG. GM (%CV) AUC0-24 h of DTG-gluc was 4.60 (65) h·mg/L in the third trimester and 3.94 (44) h·mg/L postpartum. Geometric mean ratio (90% CI) AUC0-24 h for DTG-gluc in third trimester vs. post-partum was 1.04 (0.83–1.31). The median (IQR) molar metabolic ratio was 0.11 (0.07–0.12) in the third trimester and 0.08 (0.05–0.09) postpartum (third trimester vs. postpartum; p=0.164).

Conclusion: No significant difference in the molar metabolic ratio DTG-gluc AUC0-24 h/DTG AUC0-24 h in pregnancy vs. postpartum was observed. It is unlikely that induction of UGT1A1 is the major driver of decreased DTG exposure in pregnant women.

PE21/3

Comparative analysis of clinic and laboratory parameters and frequency of mother-to-child transmission of HIV among HIV-positive pregnant women with marked immunodeficiency and normal immunological status

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Purpose: Comparative analysis of clinic and laboratory parameters and frequency of mother-to-child transmission among HIV-positive pregnant women with marked immunodeficiency or without it.

Methods: Comparative retrospective and prospective evaluation of clinic and laboratory test values for 1333 women with HIV that gave birth in the time period between 2014 and 2017 in Saint-Petersburg. All pregnant women were divided into two groups: 1st group - 139 women with marked immunodeficiency (CD4 <200 cells/µL), 2nd group - 1194 patients without immunodeficiency (CD4 >201 cells/µL and more). Statistical analysis was done with the analytics software Statistica 10.

Results: One pregnant woman in ten (10.4%, n=139) had the marked immunodeficiency. The number of pregnant women with immunodeficiency has declined between 2014 and 2017 (p<0.001). The groups are similar in age (1st group - age 28±3.7, 2nd group - age 31±4.7), way of transmission (sexual transmission – 61.2% of pregnant women in the 1st group, 70 % in the 2nd group). Certain differences were identified for some parameters (see the table).

Conclusions: For the HIV-positive pregnant women the marked immunodeficiency is a risk factor for development of anemia, preterm delivery and mother-to-child transmission. Timely diagnosis of HIV and immunodeficiency for women of reproductive age together with early administration of HAART before pregnancy allow to lower significantly the frequency of preterm delivery and mother-to-child transmission.

Clinical and laboratory parameters in groups of pregnant women

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group I</th>
<th>Group II</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug injecting during pregnancy, %</td>
<td>9</td>
<td>3.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Pregnant women with HCV coinfection, %</td>
<td>53</td>
<td>42</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Anemia in Pregnancy, %</td>
<td>77</td>
<td>62</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Beginning of HAART before pregnancy, %</td>
<td>19</td>
<td>34</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CD-4 lymphocyte count on the date of pregnancy registration at healthcare institution, cells/µL (%)</td>
<td>126.6 (12)</td>
<td>517 (27.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CD-4 lymphocyte count before delivery, cells/µL (%)</td>
<td>242.4 (18.4)</td>
<td>615.8 (36.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Percentage of preterm delivery, %</td>
<td>26</td>
<td>17</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Frequency of HIV mother-to-child transmission, %</td>
<td>2.2</td>
<td>0.6</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
PE21/4

Analysis of perinatal HIV transmission cases in St. Petersburg
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Purpose: To analyze the causes of perinatal HIV transmission in St. Petersburg for the period from 2014 to 2018, to determine the risk factors for mother-to-child transmission of HIV infection and ways to reduce this indicator.

Method: A retrospective analysis of 86 medical records of HIV-infected children with perinatal transmission, born 2014–2018 in St. Petersburg and other regions of the Russian Federation, as well as medical records of their mothers, was carried out.

Results: Of the 86 cases of perinatal HIV transmission, 49 children were born to HIV-infected mothers in St. Petersburg, 23 children infected through breastfeeding, and 14 children are from other regions of Russia. The majority of mothers who gave birth to children in St. Petersburg and infected them in utero or during childbirth, HIV infection was diagnosed before pregnancy (58%), 22% during pregnancy, 12% during childbirth and 6% - time of infection detection is unknown. The sexual way of infection was the main one in the mothers of the group under discussion - 63% (n=31), half of the mothers sought medical help (49%), the average duration of treatment was 21 weeks of gestation. 13 women (27%) actively consumed drugs. ARVD violation of adherence to ARV in the mothers of the group under discussion - 63% (n=31), half of the mothers sought medical help (49%), the average duration of treatment was 21 weeks of gestation. 13 women (27%) actively consumed drugs. ARVD of HIV-infected pregnant women before delivery was 86,397 copies/mL. Abandoned of mothers seeking medical help (49%), the average duration of treatment was 5 weeks. The average level of HIV RNA in the blood of mothers before delivery was 86,397 copies/mL. Abandoned of ARVD during pregnancy received 27% of mothers, starting at an average of 24.5 weeks of pregnancy, 72% of them had impaired treatment adherence. The average time of receiving HAART was 5 weeks. The average level of HIV RNA in the blood of mothers before delivery was 86,397 copies/mL. Abandoned of antiretroviral medicine - 49% (n=24). 29 mothers (59%) received prophylaxis at birth. 23 out of 86 children were infected during breastfeeding, 74% of women were seronegative during pregnancy.

Conclusions: The main reasons for the implementation of perinatal HIV transmission is the refusal to prevent socially prosperous women or the violation of adherence to ARV.

PE21/5

Geopolitical assessment and relevance for acceptance of vaginal delivery in good controlled HIV-infected pregnant women in Japan

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Purpose: The aim of this study was to examine and identify relevance of acceptance of vaginal delivery, as the delivery mode in good controlled HIV-infected pregnant women in Japan, in comparison with conventional elective cesarean section delivery from some geopolitical points (number of patients, medical assurance system et al.) of view.

Method: This study was researched by the Group of Epidemiological Study on P-MTCT in Japan. This group is a multicenter prospective observational study group in which 983 HIV-infected pregnant women are enrolled and their pregnancies were followed at “Grigorios AIDS Clinic” in Cyprus. The majority were of European origin (17/29), followed by those of African origin (11/29) and one patient from Asia. Patients’ age at pregnancy diagnosis was 28.73 (±4.06) years (mean±95% CI), whereas gestational age at time of pregnancy confirmation was 14.65 (±2.97, 95% CI) weeks. Mean CD4+ T-cell count at time of pregnancy diagnosis was 544.64 (±92.59, 95% CI). Viral load (VL) was undetectable in only 3/34 pregnancies; the remaining 31/34 had a mean VL of 1.017×10^4 (±0.67×10^4, 95% CI) copies/mL. All patients were initiated on antiretroviral therapy (ART). At time of delivery, 27/34 pregnancies had undetectable VL whereas the remaining 7 had a mean VL of 8.172×10^4 copies/mL. Mean CD4+ T-cell count was 749.76 (±145.48, 95% CI). Mode of delivery was scheduled cesarean section regardless of VL. Both mother and newborn received AZT during and following delivery respectively. Out of 35 newborns (one twin pregnancy), 33 were HIV-negative at 24 months of age whereas one was found HIV-positive. Positivity was attributed to mother’s poor compliance to ART. One newborn is currently at 6 months of age and is HIV negative.

Conclusion: This is the first report of Cyprus’ national data on pregnancy outcomes of HIV-positive women. Between 1986 and 2019, one case of perinatal HIV transmission has been recorded and attributed to mother’s poor compliance to ART.

PE21/7

New-born infants from HIV positive women: five years experience of Infectious Diseases Hospital Iasi

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1Infectious Diseases Hospital, Iasi, Romania 2Infectious Disease Clinic Hospital, Iasi, Romania 3Université of Medicine and Pharmacy Grigore T. Papa, Iasi, Romania

Purpose: In the North-Eastern region of Romania most of the female HIV-positive population is sexually active at a child-bearing age. In Romania, there is a strict protocol regarding HIV vertical transmission. We aim to evaluate the efficiency of this protocol and the degree of appliance, reflected in the HIV status of new-born infants from HIV-positive mothers for a period of 5 years.

Method: Of the 1442 patients actively monitored in the HIV/AIDS Regional Center in Iasi, Romania, 46.5% are female. We evaluated retrospectively the files of all new-born infants from HIV-positive mothers for a period of 5 years (January 2012–December 2016).
Results: In the period mentioned above, 163 children were born (36 in 2012, 38 in 2013, 26 in 2014, 27 in 2015, 36 in 2016); one death occurred 10 days after birth, due to multiple organ malformations; the lowest weight at birth was 750 g; three of the children (1.8%) had a detectable viral load at birth; in two cases we could not evaluate the viral load; 161 children were born through cesarean section; two were born through natural labour (1.2%), one of which at home. Mothers received treatment with lopinavir/ritonavir +zidovudine/lamivudine through the whole pregnancy in 111 cases, other antiretroviral regimens in 43 cases, and in 9 cases the mothers did not receive any treatment, being tested for HIV at birth. For all new-borns prophylaxis was made with zidovudine+lamivudine for 6 weeks. Three children remained positive at 18 months, and therapy for them consisted of zidovudine+lamivudine+nevirapine.

Conclusion: Evaluation of pregnant HIV-positive women and prophylaxis for new-born infants in the evaluated period was conducted according to protocols, which resulted in a small percentage of HIV-positive children (1.8%).

PE21/8 Risk factors for peripartum virological failure in South African pregnant women on anti-retroviral therapy: East London Prospective Cohort Study

OV Adeniyi and East London Prospective Cohort Study Group
Walter Sisulu University, East London, South Africa

Background: South Africa government implemented the World Health Organization Option B+ (life-long highly active anti-retroviral therapy – HAART) in 2015 as a strategy towards achieving the goal of elimination of mother-to-child transmission of HIV. This study investigated the HIV-1 RNA plasma viral load suppression at delivery in a cohort of pregnant women on HAART, and risk factors for per-partum virological failure in Eastern Cape Province, South Africa.

Methods: This is a sub-analysis of the East London Prospective Cohort Study database designed to monitor the treatment outcomes of mother-infant pairs across three large maternity services in Eastern Cape, South Africa. Quantitative PCR assays (viral load) were conducted within 24 hours of delivery and categorised as: full suppression (lower than limit of detection), low level viraemia (VL=20-999 RNA copies/mL and virological failure (VL≥1000RNA copies/mL). Logistic regression model analysis was performed to determine the risk factors for peripartum virological failure.

Results: Among all the participants (N=1709), 57.2% achieved full viral suppression at delivery, 25.3% had low level viraemia and 17.5% had virological failure. Younger age ≤ 25 years, unemployment, pre-conception awareness of HIV status, poor adherence, partner non-disclosure and lifestyle behaviors (alcohol consumption and cigarette smoking during pregnancy) were significantly associated with peri-partum virological failure. In multivariate (LR) analysis, after adjusting for confounding factors, poor adherence, pre-conception awareness of serostatus and unemployment were the independent significant determinants of peri-partum virological failure with consequent 20 cases of in-utero MTCT of HIV (1.2%).

Conclusion: Significant progress towards elimination of MTCT has been achieved in the study settings. However, health system strengthening and social support will be crucial towards addressing the identified risk factors of virological failure in South Africa.

NASH

PE22/1 Assessment of non alcoholic fatty liver disease in a cohort of HIV mono-infected patients

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2IRCCS Policlinico San Matteo di Pavia, Infectious Diseases, Pavia, Italy
3University of Pavia, Pavia, Italy

Introduction: NAFLD is a substantial social problem in Western countries due to metabolic syndrome increasing and lack of effective treatment. Early recognition and risk stratification of asymptomatic patients could lead to a significant challenge. Considering HIV population NAFLD is commoner, progress faster and cause non-AIDS related disease. Despite the availability of the new noninvasive techniques and serologic markers of fibrosis there is a lack of systematic study for their validation among those patients.

Purpose: Aim of this study is to assess the performance of non-invasive tools for screening and diagnosis of NAFLD among HIV patients, identify the associated risk factor and identify a diagnostic algorithm.

Methods: This is a retrospective observational study involving HIV clinics of Pavia’s Policlinico San Matteo. We collected data of 128 HIV patients without viral coinfection, history of alcoholic abuse or other liver abnormalities between 2014 and 2016. Steatosis and fibrosis evaluation has been performed by the biochemical scores Fatty Liver Index (FLI), NAFLD fibrosis score and by controlled attenuation parameter (CAP) evaluated with FibroScan.

Results: 42% of patients resulted positive for NAFLD presence at Fibroscan with CAP evaluation and 22% at FLI. 41% of patients in positive CAP group had a positive FLI score. Contrary, only 8% in CAP negative group presented a positive FLI. We found a significant statistical correlation between FLI and CAP: FLI score was positive and higher in CAP positive patients, with an AROC of 0.758. Multivariate model showed that higher BMI and triglycerides levels were significantly associated with NAFLD.

Conclusion: Latest scores and non-invasive diagnostic techniques, CAP particularly, are promising tools requiring further study to obtain a validation also among HIV patients. Between the score Fatty Liver Index is the most useful to identify people at risk of NAFLD which deserve to be investigated and successively examine with CAP.

Non-alcoholic fatty liver disease (NAFLD) and related metabolic disorders among HIV-positive patients in the country of Georgia

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2Vane Javakhishvili Tbilisi State University, Tbilisi, Georgia
3Hepatology clinic HEPA, Tbilisi, Georgia
4HIGH MEDICAL TECHNOLOGIES CENTRE, Tbilisi, Georgia

Background and Purpose: The burden of liver-related morbidity and mortality remains high among HIV-infected patients. Whilst prevalence and mortality rates associated with viral hepatitis in HIV-infected individuals have been declining, rates associated with NAFLD are increasing. NAFLD is emerging concern for individuals with HIV. Pathogenesis of NAFLD and reasons for progression to NASH and ESLD are not fully elucidated, but metabolic disorders seem to be main drivers. Importantly, HIV and NAFLD are both associated with increased risk of cardiovascular disease (CVD).

Methods: Total of 187 HIV mono-infected patients with NAFLD were studied. NAFLD was diagnosed based on ultrasound and Controlled Attenuation Parameter (CAP) by transient elastography (TE-FibroScan). Among patients with moderate (S2) (CAP >280 dB/m) and severe steatosis (S3) (CAP >300 dB/m) following metabolic parameters were studied: Central obesity (waist circumference ≥94 cm (males), ≥80 cm (females) or BMI=30 kg/m²), Triglycerides ≥150 mg/dL, Total Cholesterol-TC ≥200 mg/dL, LDL-cholesterol≥130 mg/dL, HDL-cholesterol ≤40 mg/dL in males, ≤50 mg/dL in females, blood pleasure (BP=130/85 mmHg), fasting plasma glucose (FPG)=100 mg/dL, or previously diagnosed T2DM/prediabetes.

Results: Among 187 HIV mono-infected NAFLD patients 151 (80.7%) had moderate (S2) or severe steatosis (S3). Mean age =46 years, 81% - males, mean CD4+ cell count - 590 cells/µL, 98.5% on ART. Among 151 NAFLD patients dyslipidemia was revealed in 121 subjects (80%), 67% (n=81) had atherogenic dyslipidemia defined as elevated triglycerides and decreased HDL-c, mixed dyslipidemia in 21 subjects (17.5%), IFGG/T2DM in 19 subjects (13%), hypertension in 52 (35%) patients and overweight/obesity in 37 subjects (25%). No significant metabolic changes were associated with mild steatosis (S0–S1).

Conclusion: TE can be considered as useful tool for early detection of NAFLD in HIV-infected patients and timely intervention might reduce liver-related morbidity and even CVD risk. Further studies emphasizing ART’s association with metabolic disorders are needed.
PE22/3
Non-alcoholic fatty liver disease is a significant predictor of cardiovascular risk in HIV-infected patients

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Purpose: The association between non-alcoholic fatty liver disease (NAFLD) and cardiovascular disease in the general population has been largely confirmed while in people living with HIV (PLWH) has not been assessed yet. We aimed to evaluate the impact of NAFLD and liver fibrosis on cardiovascular risk in PLWH.

Method: 982 HIV-monoinfected patients from three retrospective cohorts (LHiPA in Palermo; LIVEHIV in Montreal; MHHMC in Modena) were included. All patients underwent FibroScan. NAFLD was defined as controlled attenuation parameter (CAP) ≥288 db/m in the absence of significant alcohol intake (>20 g/die), which was excluded for all the included patients. Significant fibrosis was defined as liver stiffness measurement (LSM) >7 kPa. Cardiovascular risk was evaluated with Atherosclerotic Cardiovascular Disease (ASCVD) Risk Estimator, according to American College of Cardiology and American Heart Association guidelines. Patients with previous cardiovascular events were considered as high risk.

Results: The mean age of the population was 53 years, 74% were males, 450 (46%), 130 (13%), 264 (27%) and 138 (14%) were in low, borderline, intermediate and high ASCVD risk classes, respectively. The prevalence of previous cardiovascular events was 8.4%. NAFLD and liver fibrosis were found in 20% and 17% of the population, respectively. The distribution of ASCVD risk classes by NAFLD and fibrosis category is depicted in the Table.

Conclusion: NAFLD is a strong predictor of cardiovascular disease in PLWH. Early recognition of NAFLD may allow to implement life-style modification and treatment to prevent cardiovascular disease.

PE22/4
Non alcoholic fatty liver disease diagnosed by non-invasive markers in HIV-infected patients

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1HIV Unit. Hospital Universitario La Paz. IdiPaz, Madrid, Spain 2Hepatology Unit, Gastroenterology Service. Hospital La Paz, Madrid, Spain 3HIV unit. Internal Medicine. Hospital Universitario La Paz. IdiPaz, Madrid, Spain

Purpose: After curing chronic hepatitis C, non-alcoholic fatty liver disease (NAFLD) is the main cause of liver damage in HIV-infected subjects. The identification of subjects with NAFLD with simple tools is an important challenge for HIV-infected subjects nowadays. Our objective was to screen a large cohort of stable HIV-infected subjects for liver steatosis with available non-invasive markers.

Method: Cross-sectional study in a 4009 HIV-infected subjects from a single Clinical Unit. We analysed the demographic, clinical and last analytical recordings of all patients with HIV infection followed regularly in our cohort. We calculated steatosis markers (HSI, TyG), fibrosis markers (APRI, FIB4) and attenuation parameter (CAP) whose value ≥288 db/m diagnoses liver steatosis ≥5%, and transient elastography (TE) by Fibroscan™. Non-invasive markers were calculated with the last available laboratory test records done no earlier than 6 months before the cross-sectional study date, in February 2019.

Results: The main clinical and demographic characteristics: females 20%, transmission route MSM 47%, hetero 22%, IDU 23%, ethnicity 85% Caucasian, CDC stage C 23%, median nadir CD4 cell count 697 (505-914), 93% with undetectable HIV viral load, median BMI 25 kg/m2 (23–28). Less than 1% of subjects have a non-treated chronic hepatitis B or C. Non-invasive markers and metabolic parameters are shown in table 1.

Conclusion: Currently at least one out of every 3 patients infected with HIV has hepatic steatosis. Insulin resistance and hypertriglyceridemia, key components of metabolic syndrome, have a very high prevalence in this population. Although advanced fibrosis is not very prevalent at present, the

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Table 1: Non-invasive markers and metabolic parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Mellitus</td>
<td>335/4009 8%</td>
</tr>
<tr>
<td>Diabetes Mellitus or abnormal fasting glucose</td>
<td>509/4009 13%</td>
</tr>
<tr>
<td>Dyslipemia</td>
<td>1937/4009 48%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1313/4009 33%</td>
</tr>
<tr>
<td>HTA</td>
<td>1136/4009 28%</td>
</tr>
<tr>
<td>Metabolic syndrome</td>
<td>637/4009 16%</td>
</tr>
<tr>
<td>NAFLD (CAP&gt;288 db/m)</td>
<td>n=982</td>
</tr>
<tr>
<td>Low</td>
<td>196</td>
</tr>
<tr>
<td>Borderline</td>
<td>76 (39%) 14 (7%)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>70 (36%) 36 (19%)</td>
</tr>
<tr>
<td>High</td>
<td>36 (19%)</td>
</tr>
<tr>
<td>Without NAFLD</td>
<td>n=786</td>
</tr>
<tr>
<td>(CAP&gt;288 db/m)</td>
<td>37 (48%)</td>
</tr>
<tr>
<td>Significant liver fibrosis (LSM&gt;7 kPa)</td>
<td>n=168</td>
</tr>
<tr>
<td>Low</td>
<td>57 (34%) 23 (13%)</td>
</tr>
<tr>
<td>Borderline</td>
<td>59 (35%) 29 (17%)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>107 (13%) 205 (25%)</td>
</tr>
<tr>
<td>High</td>
<td>109 (14%)</td>
</tr>
<tr>
<td>Without liver fibrosis (LSM&gt;7 kPa)</td>
<td>n=814</td>
</tr>
<tr>
<td>Low</td>
<td>393 (49%)</td>
</tr>
<tr>
<td>Borderline</td>
<td>107 (13%) 205 (25%)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>109 (14%)</td>
</tr>
<tr>
<td>High</td>
<td>238 dB/m</td>
</tr>
<tr>
<td>Transient elastography</td>
<td>CAP&gt;238 db/m</td>
</tr>
<tr>
<td>Low</td>
<td>1031      53%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>272/2153 13%</td>
</tr>
</tbody>
</table>

Overall, intermediate and high risk classes were more frequent in patients with steatosis (p<0.001). Notably, by multivariate ordinal regression analysis, NAFLD (OR 1.50, 95% CI 1.05–2.14, p=0.03), BMI≥30 (OR 1.85, 95% CI 1.38–2.49, p<0.001) and time since HIV diagnosis (OR 1.03, 95% CI 1.03–1.06, p=0.001) were independent factors associated with a higher ASCVD risk. No association was found between fibrosis and ASCVD risk classes.

Conclusion: NAFLD is a strong predictor of cardiovascular disease in PLWH. Early recognition of NAFLD may allow to implement life-style modification and treatment to prevent cardiovascular disease.
high prevalence of insulin resistance and NAFLD would cause it to increase significantly in the coming years. Non-invasive markers of hepatic steatosis and fibrosis are an easy-to-use tool what should be routinely implemented in the care of patients infected with HIV.

PE22/5
Global prevalence of liver impairment in HIV population in direct antiviral agents (DAA) era: the role of fatty liver disease
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Purpose: Our objectives are to analyze the global prevalence and causes of hepatic impairment in the HIV-infected population and to know the role of NAFLD in this population

Methods: Cross-sectional study was conducted in our HIV outpatient clinic between March and May 2017. Sociodemographic, clinical, analytical, and abdominal ultrasound (US) performed in the 24 previous months were collected.

Results: 373 consecutive HIV-infected patients were included. Median age 50 (IQR 42–65); 75.1% men, median CD4 691 cells/mm3 (IQR 488–891). Undetectable HIV viral load in 89.8%. Hepatic impairment triggers were: HCV (+) 146 (39%) 82 of them already cured with DAAAs, AgVHBs(+) 3.7%. We found persistently abnormal high transaminase levels in 108 patients (28.9%), which was significantly associated with male gender [OR (IC95%), 2.1(1.1–3.9)] and having fatty liver in US [DR (IC95%), 2.1(1.2–3.2)]. In 79 (21%) some grade of NAFLD was described in abdominal US. We managed to identify the underlying cause of liver impairment in 59/108 patients, albeit it remains unclear in 49/108 (13.1% of the whole population). We found significant association with abdominal ultrasound fatty liver and the duration of antiretroviral treatment exposure (p<0.005) and age (p<0.001).

Conclusion: Even though 1/3 of the HIV-infected population has persistently elevated transaminases, in 13% of them, the cause remains unclear. Taking into account that fatty liver is described in 21% of this population, we must consider NAFLD of paramount importance in this population. NAFLD is associated with duration of antiretroviral exposure and age. We need further research that will allow us to understand this emerging problem in the HIV-infected subjects.

Novel consultations, remote care – telemedicine, mobile applications
PE23/1
Harnessing mobile technology for health worker capacity building to improve quality of care in resource-constrained settings
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Purpose: With the high health worker: patient ratio, there has been increased task-shifting of physician responsibilities to mid-level practitioners but the corresponding capacity building for these health workers to provide quality HIV care is limited and costly. The Infectious Diseases Institute (IDI), a private non-profit organisation affiliated to Makerere University, is bridging this capacity development gap through its flagship innovation – the Advanced Treatment Information Centre (ATIC). ATIC provides a toll-free line through mobile applications that health workers are linked to in-house medical officers, physicians, pharmacists, and laboratory experts for interactive telephonic consultation on HIV and infectious diseases patient management.

Method: In December 2016, ATIC extended working hours through a mobile app, to include after-office hours, weekends and public holidays in a bid to increase health worker access to this resource.

Results: Since 2004, ATIC has handled over 20,000 information requests – the majority (70.1%) are on clinical management of patients with specific interest in ART initiation (8.5%); ARV administration and dosing (39.4%); drug interactions (2.4%); adverse drug reaction management (13.1%); management of treatment failure (6.7%); ARV logistics 2.6%; while 3.7% inquire about laboratory investigations for HIV and other infectious diseases. In December 2018 ATIC received 1,456 information request compared to 907 in December 2016 – a 60.5% rise.

Conclusion: Mobile technologies can facilitate effective linkage between experts and health workers to enhance their capacity in clinical patient management, accurate diagnosis and health supplies management. The ATIC toll-free call centre provides an effective model for capacity building in resource-limited settings. However, the efficacy and cost-effectiveness of call centres for health worker capacity building hasn’t been determined and data from similar resource-constrained settings is limited. We aim to evaluate impact and cost effectiveness of this service in the future.
PE23/3
Attracting people who use drugs to HIV prevention and care programs via darknet and messengers: evidence from St. Petersburg, Russia

A Lakhov

Charitable fund ‘Humanitarian Action’, Saint-Petersburg, Russian Federation

Purpose: Darknet online-platform for selling illegal psychoactive substances (IPS) Hydra, as well as Telegram and KakaoTalk messengers, have become the main sources of IPS for people who use drugs in St. Petersburg. Also, the drug scene has been rapidly changing since 2015. The most popular IPS, apart from cannabinoids, are new psychoactive substances (mephedrone, x-PVP, etc.), as well as amphetamine, methamphetamine, MDMA. The use of heroin and methadone has been decreasing steadily. It means that HIV prevention and care programs aimed at intravenous drug users who had been using opioids mainly should be updated.

Method: Charitable fund “Humanitarian Action” has been working in the field of HIV prevention among PWIDs and sex workers since 2001. Each year more than 5,000 people receive services of the fund, including syringes exchange, HIV, HCV and HBV testing, linkage to HIV care, etc. The fund sought to update its methods of attracting PWIDs to HIV prevention and care. The deputy director of the fund contacted Hydra to provide this platform with the information on the fund’s activities. Also, he gave 2 interviews to the Telegram channel of Hydra. An active drug user – one of the clients of the fund – created and developed chats and public channels of the fund in Telegram and KakaoTalk messengers.

Results: 2 interviews for Hydra generated more than 100,000 views. Telegram chat has more than 820 members, public channel – more than 960 subscribers. Case managers and peer counselors of the fund connect with clients via these messengers directly to remind them of ARV intake, of a visit to the doctor, etc.

Conclusion: Darknet, as well as Telegram and KakaoTalk messengers, should be actively used by harm reduction and HIV prevention and care programs to attract PWIDs to testing and linkage to care.

PE23/4
People living with HIV (PLHIV) and their doctors: adopters and sceptics, and those opened to e-health

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Purpose: To identify profiles of PLHIV and doctors regarding e-health. Methods: Multicenter online survey conducted in October 2018 in France including 279 PLHIV and 229 physicians. A multiple correspondence analysis followed by a mixed unsupervised classification was implemented.

Results: Three groups of PLHIV were identified: group 1 “adherent to e-health” N=121 (43%) more often over 60 (G1 8% G2 28% G3 40%), more likely to receive other treatments than antiretrovirals (G1 25% G2 47% G3 54%); group 2 “technology sceptics” N=86 (31%) more often women and having at least one child (G1 29% G2 56% G3 41%); group 3 “Internet adopters” N=72 (26%) more often under 49 (G1 65% G2 30% G3 27%) and MSM (G1 64%, G2 24% G3 44%), more likely to use mobile applications for wellness/health (G1 64%, G2 19%, G3 10%) and connected objects (G1 47% G2 13% G3 13%).

Among doctors, three groups emerged: group 1 “strongly confident in e-health” N=95 (41%) more often men, more often over 50 (G1 50% G2 61% G3 72%); group 2 “strongly opposed to e-health” N=80 (35%), more numerous to agree that e-health challenges confidentiality (G1 64% G2 39% G3 27%); group 3 “open to e-health” N=44 (19%) more often infectiousologists (G1 63% G2 86% G3 73%), more likely to believe that medical applications are useful for patient information/education (G1 58% G2 91% G3 87%).

No link was found between the groups of PLHIV and doctors.

Conclusion: While world literature about e-health describes adopters and sceptics, a third profile appears in both PLHIV and doctors, but without a direct link: those who pay attention to e-health to improve their health condition and doctors who find a benefit to patients and/or for their exercise.

PE23/5
Fitness tracking wearable devices and a dedicated smart phone app (MySAWtH App) to predict quality of life in PLWH: a multi-centre prospective study

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1Modena HIV Metabolic Clinic, University of Modena and Reggio Emilia, Modena, Italy 2DataRiver Srl, Modena, Italy 3University of Modena and Reggio Emilia, Modena, Italy 4Clinical and Experimental Medicine PhD Program, University of Modena and Reggio Emilia, Modena, Italy 5Department of Mathematics, University of Modena and Reggio Emilia, Modena, Italy 6Faculty of Medicine, The Chinese University of Hong Kong, Modena, Italy 7Holdsworth House Medical Practice, Sydney, Australia

Objective: My Smart Age with HIV (MySAWtH) is a multi-centre prospective ongoing study based on collection of physical function data and patient-related outcomes through a dedicated smart-phone app (MySAWtH App). Our objective was to describe health changes assessed with frailty index (FI), collected by health professionals, and a health measure called intrinsic capacity (IC) index which explores 5 different health domains: locomotion, vitality, sensory, cognition, psychosocial. FI and IC were used to predict quality of life (QOL) and health score (HS) at follow-up.

Methods: We included 261 PLWH >50 years from Italy (128), Australia (100) and Hong Kong (33). Baseline and follow-up (6 months) were performed. Frailty was measured with a 36-item FI, while 27-item IC index was self-assessed with fitness tracking wearable devices and a MySAWtH app. QoL and HS were evaluated with EQ5DSL questionnaire.

Results: Mean age was 56.94 years; 88.12% men. Median CD4 was 657 c/µL (480–817 IQR) and 252 (98.05%) patients had undetectable HIV viral load. Mean FI at baseline and follow-up were 0.22 (± 0.1) and 0.20 (± 0.09) respectively, p<0.001. Mean IC at baseline and follow-up were 0.80 (± 0.12) and 0.71 (± 0.12), p<0.27. Median QoL at baseline and follow-up were 0.88 (0.8–1 IQR) and 0.9 (0.83–1 IQR), p<0.03. Mean HS at baseline and follow-up were 7.62 (± 1.68) and 7.63 (± 1.56), p<0.001. In a multivariate logistic model, predictors for a good HS at follow-up were baseline IC (OR=6.74, 3.86–11.77) and recruitment site (Hong Kong (OR=1.25, 1.01–1.54)). Predictors for QoL were baseline IC (OR=7.62, 4–14.51) and recruitment site (Hong Kong (OR=1.33, 1.05–1.69)).

Conclusion: FI and IC are performative tools that can be used in research and clinical setting to describe respectively disease and health status in PLWH. IC score in comparison to FI displayed higher sensitivity to predict both QoL and self-perceived health in PLWH.

PE23/6
The efficiency of introducing the EmERGE Pathway of care for stable Croatian PLHIV

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1NPMSS-HHC CIC, London, UK 2London School of Hygiene and Tropical Medicine, London, UK 3University Hospital for Infectious Diseases, Zagreb, Croatia

Purpose: Estimate the cost-effectiveness of introducing a mHealth supported Pathway of Care for clinically stable people living with HIV in Zagreb. The EmERGE Pathway enables individuals to receive HIV treatment information on their smart-phone via the mHealth App.

Method: 293 study participants predominantly used HIV outpatient services, the focus of the costing study. Unit costs were linked to mean per patient year (MPY) service use of HIV services. Data on use of services were collected after the introduction of the mHealth Pathway, enabling annual cost of HIV service provision to be estimated. Annual costs were combined with outcome data, changes in CD4 count and Viral Load one-year before and after the introduction of the mHealth Pathway. Costing were calculated in Croatian Kuna and converted to Euros.

Results: Mean outpatient visits decreased from 5.2 (95% CI: 4.9 to 5.5) to 4.75 (95% CI: 4.5 to 5.0) MPY. The annual costs of service provision were €8,885.30 (95% CI: €8,833.90 to €8,938.60) pre-mHealth and €8,716.20 (95% CI: €8,673.40 to €8,761.40) post-mHealth; clinic visits and tests comprised
10% of total costs, ARVs 55% and other pharmacy costs 35% of annual costs. No significant differences in CD4 counts were observed between periods and Viral Load remained undetectable during each period with no significant difference between pre-mHealth and post-mHealth values.

Conclusion: Annual cost pre- and post- mHealth Pathway decreased by 2%. Cost for ARVs and Pharmacy services were the greatest cost drivers. Participants remained clinically stable after the introduction of mHealth Pathway of Care, which has been an efficient intervention. Future efficiencies can be anticipated with introduction of the Pathway across the clinical site. Additional analyses will include other outcomes such as quality of life (PROQOL-HIV), self-management (PAM13) and patient out-of-pocket expenditures.

PE23/7

'The 4th 90': a preliminary assessment of change in quality of life over 1 year of the EmERGE study: PROQOL-HIV and EQ-5D-5L, a descriptive analysis

C Jones1, S Bremmer1, A Leon2, J Begovac3, L Apers4, M Borges5, S Zekan3, E Teofilov3, F Garcia2, M Durancky1, J Whetham2 and on behalf of the EmERGE Consortium

1Brighton & Sussex Medical School, Brighton, UK 2Fundació Clinic per la Recerca Biomèdica, Barcelona, Spain 3Klinika za Infektnive Bolesti, Zagreb, Croatia 4Institut voor Tropical Geneeskunde, Antwerp, Belgium 5Centro Hospitalar de Lisboa Central, Lisbon, Portugal 6Paris Diderot University, Paris, France 7Brighton & Sussex University Hospitals NHS Trust, Brighton, UK

Purpose: To assess the potential effect on Quality of Life (QoL) of a co-designed reduced visit pathway of care for individuals living with stable HIV.

Methods: People living with stable HIV across five diverse clinical sites in Europe were invited to take part in the EmERGE study – whereby individuals are seen once instead of twice a year by their clinician – with interim visits supported via an mHealth platform.

We report descriptively on QoL outcomes at baseline (M0) and month 12 (M12) available to May 2019. For PROQOL-HIV, the mean change in score is reported by domain. For EQ-5D-5L, some vs. no problems (as proportions) are reported by dimension.

Results: PROQOL-HIV was completed by N=1688/2230 (73.8%) at M0 and 986/1439 (69.2%) at M12. At M0, domain scores were generally high across sites (median score for each: 75/100), except for stigma (median=50, IQR: 25–80) with some variation by site. Mean differences (M12-M0) for all domains were small relative to their SDs, indicating little change (Table 1).

Participants' general health was good at M0. 28.6% rated their health as <fair while at M12 had improved for N=151/912 (16.6%), worsened for 261 (28.6%), unchanged for 500(54.8%).

EQ-5D-5L was available on N=2115/2230 (95.5%) at M0, and N=1018/1439 (70.1%) at M12. Mean health today was 84.3 (SD=21.1) at both M0&M12, lower at M12 than at M0.

The majority of participants had a high level of empowerment at baseline. Over 60% of respondents in the lowest categories of PAM-13 (L1&2) for self-management (PAM13) and patient out-of-pocket expenditures.

Table 1. Mean (SD) of changes between M0 & M12 for domains fo PROQOL-HIV by site

Table 2. Number (%) of respondents (n) reporting no problems per domain of EQ-5D at M0 & M12

PE23/8

Measuring empowerment in EmERGE mHealth platform users: a descriptive analysis of interim data

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Purpose: To assess the potential effectiveness of a co-designed reduced visit pathway of care for individuals living with stable HIV in terms of empowerment (which encapsulates patient confidence, skills and knowledge to self-manage health and care).

Methods: People living with stable HIV across five diverse clinical sites in Europe were invited to take part in the EmERGE study – whereby individuals are seen once, instead of twice, a year by their clinician – with their interim visit supported via an mHealth platform.

We report here on preliminary data on the primary outcome, empowerment, measured by PAM-13 (Patient Activation Measure-13) at baseline (M0) and 12 months (M12).

Results: PAM-13 was available on 2112/2251 (93.8%) of participants at M0 and 1026/1439 (72.3%) at M12. The overall proportion of participants at low activation Levels (L1 & 2) was 12.2% (261/2112) at baseline, ranging from 10.5% in Antwerp to 13.5% in Zagreb. At M12, the overall proportion was 11.1% (145/1026), ranging from 9.0% in Zagreb and 17.1% in Barcelona.

Change in activation from L1&2 at baseline to L3&4 at M12 was achieved by 63/101 (62.4%) L1&2 baseline participants whilst 93/891 (10.4%) of baseline participants at L3&4 had dropped to L1&2 by M12; 836/992 (84.3%) did not switch between L1&2 and L3&4.

The proportion of participants across each of the four levels of PAM-13 was similar across sites at baseline with 28% of participants with the highest levels of activation. At four out of five sites, the proportion at L3&4 is currently lower at M12 than at M0.

Conclusions: The majority of participants had a high level of empowerment at baseline. Over 60% of respondents in the lowest categories of PAM-13 (L1&2) at baseline shifted to L3&4 in M12. The proportion of participants at low activation levels was similar between sites. Follow-up continues until October 2019.

Other coinfections/sexually transmitted infections

PE24/2

High rates of ocular and neurosyphilis in a large German, city-based university hospital: lessons learned on ocular syphilis

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Purpose: Incidence of syphilis is rising, mainly among the high-risk group of men having sex with men (MSM). Syphilis can range from uncomplicated to more complicated clinical infections, including ocular syphilis (OS). A stage-adopted treatment is standard of care and recommendations advise to treat OS according to neuro-syphils-treatment. However, data on detailed understanding of OS remain sparse.

Method: Retrospective cohort study of sero-active syphilis cases at University Hospital Klinikum rechts der Isar, Munich from 08/2008 to 06/2018 with focus on ocular involvement. Cases were defined according to definition of Centers for Disease Control (CDC).

Results: In total, data sets of 90 patients (93% male), average age 47 years (IQR 38–54 years) were analyzed. Patients positive for HIV (PLWH) accounted for 48% and 51% were MSM. 24 (27%) were diagnosed with OS, resulting in 36 affected single eyes. Visual acuity reduction was the most frequent symptom (96%). Papillitis (61% of affected eyes), vasculitis (44%) and intermediate uveitis (42%) were the most frequent diagnostic findings (Table 1). In total (in cases with OS), 11% (0%) were in primary, 13% (13%) in early secondary, 53% (83%) in late secondary, 17% (0%) in latent and 6% (4%) in tertiary stage of infection. 48% of the patients underwent lumbar puncture, of which 54% were defined as neurosyphilis cases (57% of OS). Overall treatment regimens (treatment in OS) consisted of 20% (33%) intramuscular ceftriaxone, 42% (13%) intramuscular benzathine penicillin, 20% (33%) intravenous penicillin G, 7% (13%) combination of penicillin G, intramuscular benzathine penicillin and ceftriaxone and 3% (0%) doxycycline. In 8% (8%) the patients were lost for treatment.

Conclusion: The majority of syphilis patients were male and PLWH. Around one quarter presented with OS, almost all cases had visual acuity reduction. This finding highlights OS as a relevant and probably often undiagnosed complication of secondary syphilis.

Table 1. Detailed description of ocular syphilis and eye involvement

<table>
<thead>
<tr>
<th>Classification of uveitis/eye involvement</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior uveitis</td>
<td>5 (14)</td>
</tr>
<tr>
<td>Intermediate uveitis</td>
<td>5 (14)</td>
</tr>
<tr>
<td>Posterior uveitis</td>
<td>15 (42)</td>
</tr>
<tr>
<td>Panuveitis</td>
<td>4 (11)</td>
</tr>
<tr>
<td>Papillitis</td>
<td>22 (61)</td>
</tr>
<tr>
<td>Vasculitis</td>
<td>16 (44)</td>
</tr>
<tr>
<td>Chorioretinitis/Retinitis</td>
<td>12 (33)</td>
</tr>
<tr>
<td>Vitritis</td>
<td>7 (19)</td>
</tr>
<tr>
<td>Iridocyclitis</td>
<td>5 (14)</td>
</tr>
</tbody>
</table>

PE24/5

Prevalence of syphilitic hepatitis among HIV-infected patients in Istanbul, Turkey, a region with increasing incidence of syphilis and HIV infection

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Purpose: The aim of this study is to determine the prevalence of syphilitic hepatitis among HIV-infected individuals diagnosed with acute syphilis.

Method: Between January 2016 and June 2019, a retrospective analysis of HIV-infected individuals who regularly attended a tertiary clinic in Istanbul, was performed. - Cases of syphilitic hepatitis were identified according to the following criteria: (I) VDRL/RPR-confirmed T. pallidum infection occurring after or simultaneously diagnosed with HIV infection (II) elevated liver enzyme laboratory tests, including alkaline phosphatase (ALP), that resolved after penicillin treatment, and (III) exclusion of other causes of hepatitis

Results: Among 933 HIV-infected patients, 74 (7.9%) were diagnosed with any stage of syphils based on RPR and TPHA results, 72 of them were male, and all patients were Caucasian. Concurrent syphils and HIV infections were diagnosed in 7 of 74 patients. Out of 74 patients 6 (8.1%) had syphilitic hepatitis. Moreover, 2 of these 6 patients were simultaneously diagnosed with syphilis and HIV infection. Within the cohort demonstrating syphilitic hepatitis, all of them selfidentified as men who have sex with men (MSM). All of the 6 patients were diagnosed in the early stage of syphilis and they were treated with a single dose of benzathine penicilin. The following symptoms were recorded: mucocutaneous lesions (n=5), chancre (n=4), pharyngitis (n=2) and jaundice (n=1). Rapid remission of clinical and biochemical abnormalities following treatment were seen in all hepatic involved patients.

Conclusion: The rates of hepatic involvement in HIV-syphilis coinfection were higher in predominantly MSM populations. Immune dysregulation and entry of spirochetes into a reticulum are possible mechanisms to explain an increased risk of hepatic involvement in HIV-syphils co-infected population. Therefore, all syphilis hepatitis patients were MSM in our cohort. Lower rates of MSM

Decreasing HIV/HBV co-infection incidence rate according to the birth year of 5 year intervals
individuals may contribute to the lower prevalence observed in our patients as compared to previous reports in the literature.

PE24/6
Seroconversion rate after yellow fever vaccine in HIV-positive patients
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2Institute of Tropical Medicine, Antwerp, Belgium 3Institut Robert-Koch, Centre for Biological Threats and Special Pathogens – Highly Pathogenic Viruses-ZBS-1, Berlin, Germany

Background: Yellow fever (YF) vaccine is a live attenuated vaccine inducing protective Neutralizing Titters of antibodies (NT Ab) in 99% of immunocompetent vaccines at one month. Data on seroconversion rate in HIV-positive patients (p) are scarce.

Objectives: To assess seroconversion rate by measuring NTAb in HIV (p) in the year before and after YF vaccine and to identify risk factors for lack of seroconversion.

Methods: A retrospective study in two Belgian AIDS Reference Center. Demographics, HIV history and YF immunization data were extracted from HIV databases. Plasma samples from the year before and after YF vaccination (≥30 days after immunization) were analyzed for YF NTAb by plaque reduction neutralization test (PRNT90). Primary endpoint was seroconversion rate (YF NTAb increasing from undetectable to ≥1/10).

Results: Hundred HIV p., negative for YF at baseline and immunized with one dose of vaccine, should be considered in such circumstances. A multicentric study to assess seroconversion rate and duration of protection after YF vaccine, were included: 51% female, 68% African, median age at vaccination 38 years; 79% on antiretroviral therapy (ART), 65% with undetectable viral load before immunization, median CD4 509/μl, median nadir CD4 211/μl. After YF vaccine 84/100 p. developed protective NTAb. Age, ethnicity, nadir CD4 count, duration of HIV infection, CD4 in the year before immunization had no influence on seroconversion rate, while not being on ART or having a detectable viral load before or during immunization was a risk factor for lack of seroconversion (p = 0.0005).

Conclusions: Not being on ART or with undetectable viral load was the only identified risk factor for lack of seroconversion after YF vaccine. A second dose of vaccine, should be considered in such circumstances. A multicentric study to assess seroconversion rate and duration of protection after YF immunization in HIV patients on a larger scale is currently underway.

PE24/7
Low seroprevalence of syphilis infection among key populations in Togo in 2017: a national cross-sectional survey
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Purpose: To estimate the seroprevalence of syphilis among males who have sex with males (MSM), female sex workers (FSW) and drug users (DU) in Togo.

Methods: A cross-sectional bio-behavioral study was conducted in the largest HIV reference center and STI clinic of Brussels. Inclusion criteria were adult patients with a new episode of syphilis. Both patient and physician filled a survey. Data on demographics, socioeconomic, sexual behavior, chemsex, stage of syphilis, clinical manifestation, concomitant STI, PrEP use, CD4 and viral load in HIV+ patients were analysed. Descriptive statistics were used with Wilcoxon or Fisher’s exact tests.

Results: Between October 2017 and May 2019, 136 patients were included: 62 HIV+ and 74 HIV-. Most were men (97%), 90% MSM. There was no difference in gender, sexual orientation, origin and socioeconomic status between the 2 groups. HIV- were slightly older than HIV+ (40 vs 36 years, p = 0.02). High risk sexual behaviors including chemsex were frequent in both groups (see Table 1). Among HIV+, 71% (60/82) were treated with a VL <200 cp/ml. Among HIV-, 30% were on PrEP and 19% started PrEP after syphilis diagnosis. Two-thirds of patients had symptoms of primary or secondary syphilis. Proportion of neurosyphilis was similar in both groups. Among asymptomatic patients, HIV+ had more frequently early latent syphilis while HIV- had more late latent syphilis or of unknown duration (p < 0.01). Previous syphilis infection was more frequent in HIV+ (74% vs 37% in HIV-, p < 0.01). Median RPR was similar in both groups.

Conclusion: HIV+ and HIV- patients with syphilis have a similar profile with high risk sexual behavior including infrequent condom use, sex under influence and multiple partners. Among asymptomatic patients, HIV+ were diagnosed at earlier stage probably due to regular blood test. Strategies to detect syphilis earlier should be developed, such as more frequent testing, particularly in HIV- MSM not on PrEP.

PE24/8
Socio demographics, sexual behavior and clinical manifestations of HIV+ and HIV- patients diagnosed with syphilis, Brussels 2017–2019
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Purpose: To compare patient characteristics, sexual behavior and clinical manifestations of HIV positive (HIV+) and HIV negative (HIV-) patients with syphilis.

Method: Prospective observational study performed in the largest HIV reference center and STI clinic of Brussels. Inclusion criteria were adult patient with a new episode of syphilis. Both patient and physician filled a survey. Data on demographics, socioeconomic, sexual behavior, chemsex, stage of syphilis, clinical manifestation, concomitant STI, PrEP use, CD4 and viral load in HIV+ patients were analysed. Descriptive statistics were used with Wilcoxon or Fisher’s exact tests.

Results: Between October 2017 and May 2019, 136 patients were included: 62 HIV+ and 74 HIV-. Most were men (97%), 90% MSM. There was no difference in gender, sexual orientation, origin and socioeconomic status between the 2 groups. HIV- were slightly older than HIV+ (40 vs 36 years, p = 0.02). High risk sexual behaviors including chemsex were frequent in both groups (see Table 1). Among HIV+, 71% (60/82) were treated with a VL <200 cp/ml. Among HIV-, 30% were on PrEP and 19% started PrEP after syphilis diagnosis. Two-thirds of patients had symptoms of primary or secondary syphilis. Proportion of neurosyphilis was similar in both groups. Among asymptomatic patients, HIV+ had more frequently early latent syphilis while HIV- had more late latent syphilis or of unknown duration (p < 0.01). Previous syphilis infection was more frequent in HIV+ (74% vs 37% in HIV-, p < 0.01). Median RPR was similar in both groups.

Conclusion: HIV+ and HIV- patients with syphilis have a similar profile with high risk sexual behavior including infrequent condom use, sex under influence and multiple partners. Among asymptomatic patients, HIV+ were diagnosed at earlier stage probably due to regular blood test. Strategies to detect syphilis earlier should be developed, such as more frequent testing, particularly in HIV- MSM not on PrEP.

Table 1. Sexual behaviors in patients with syphilis

<table>
<thead>
<tr>
<th>Sexual behavior</th>
<th>HIV+ positive (n=62)</th>
<th>HIV+ negative (n=74)</th>
<th>HIV+ positive (n=62)</th>
<th>HIV+ negative (n=74)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>27/62(=43)</td>
<td>22/74(=30)</td>
<td>0.05</td>
<td>0.15</td>
</tr>
<tr>
<td>Oral</td>
<td>13/62(=21)</td>
<td>10/74(=13)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
<tr>
<td>Anal</td>
<td>12/62(=19)</td>
<td>10/74(=13)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
<tr>
<td>Vaginal</td>
<td>9/62(=14)</td>
<td>9/74(=12)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
<tr>
<td>Genital</td>
<td>9/62(=14)</td>
<td>9/74(=12)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
<tr>
<td>Oral with glove</td>
<td>8/62(=13)</td>
<td>4/74(=6)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
<tr>
<td>Oral with cuff</td>
<td>6/62(=10)</td>
<td>1/74(=1)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
<tr>
<td>Oral with ring</td>
<td>4/62(=6)</td>
<td>1/74(=1)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
<tr>
<td>Oral with string</td>
<td>2/62(=3)</td>
<td>1/74(=1)</td>
<td>0.23</td>
<td>0.59</td>
</tr>
</tbody>
</table>

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PE24/9

Risk factors and prevalence of syphilis, gonorrhea and chlamydia infections in the Swiss HIV cohort study

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Purpose: To assess risk factors and prevalence of sexually transmitted infections (STIs) in the Swiss HIV Cohort Study (SHCS).

Methods: STIs reported by patients or treating physicians within the last 6 months of study visit are recorded in the SHCS since October 2017. Demographic, clinical and behavioral characteristics were prospectively collected at the 6-monthly follow-up visits. We calculated prevalence and used logistic regression to assess risk factors for episodes of STIs.

Results: Between October 2017 and March 2019, 728 SHCS participants reported 1,001 episodes of STIs among 9,824 patients under follow-up. The most frequent STI was syphilis, with 368 reported episodes, followed by gonorrhea (309), chlamydia (255) and others (not specified, 69). Half of STI episodes were asymptomatic (501, 50%). Patients reporting an episode of STI were predominantly male (96%), men who have sex with men (MSM) (89%) and younger (median age 44 vs 52) than those without STI. Prevalence of ever having an STI among MSM was 14% and ranged between 1.0% and 4.4% among other transmission groups.

In univariable analysis, the strongest risk factors for STIs were having had occasional partners (odds ratio (OR) 18.1, 95% confidence interval [11.5–16.1]) and condomless sex with an occasional partner (OR 13.6 [14.0–23.0]) (Figure). In multivariable analysis, risk factors included MSM (adjusted odds ratio (aOR) 3.6 [2.8–4.7]), having occasional partners (aOR 4.5 [3.3–6.0]), condomless sex with an occasional partner (aOR 3.3 [2.7–4.1]) or steady partner (aOR 1.2 [1.0–1.4]), as well as being younger than 50 years (aOR 2.2 [1.9–2.6]) and injecting and non-injecting drug use (aOR 1.4 [1.2–1.7]), and were similar across different STIs (Figure).

Conclusion: Prevalence of STIs in the SHCS was 14% among MSM and less than 5% among other transmission groups. Risk for STIs exceeded 3-fold among MSM compared to any other transmission group, and 4-fold among participants having occasional partners.

PE24/10

Predictors of serofast state after treatment for syphilis in HIV-infected patients

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Objectives: Nontreponemal serologic tests such as rapid plasma reagin (RPR) tests are used to monitor treatment response, because they usually correlate with disease activity. Syphilis and human immunodeficiency virus (HIV) coinfected patients may experience slower decline in RPR titers which is referred to as serofast state. Risk factors for serofast status in which nontreponemal antibodies persist after treatment are not completely understood. Goal of this study was to evaluate risk factors for serofast state after treatment in HIV-infected patients.

Methods: From April 2016 to June 2018 671 HIV+ patients were tested for syphilis using Treponema pallidum particle agglutination assay (TPPA). Among the TPPA positive patients, medical records were screened for documented syphilis infections with evaluable data. Serofast state was defined as lack of 4-fold decrease in RPR titers during a 6 months follow-up period in the absence of symptoms of syphilis. Baseline characteristics were tested as predictive factors of serological failure using univariable analysis.

Results: 224 patients (33.4%) were tested positive in TPPA assay and in 135 patients at least one previous syphilis infection was documented in case records. 53 out of 135 patients (39.3%) experienced serological failure. Serofast state was associated with higher number of previous infections (p=0.01) and fewer usage of adjunctive therapy with corticosteroids (p=0.001). Adjunctive corticosteroids, used for the prevention of the Jarisch-Herxheimer reaction and not for treatment of syphilis, led more often to serological cure in late syphilis (p=0.002), while it had no influence in early syphilis (p=0.15). Type of syphilis treatment (one versus three doses of benzathine penicillin-G) did not affect serological cure rates.

Conclusion: Corticosteroid usage for prevention of the Jarisch-Herxheimer reaction was associated with serological cure. Although serological response is the most commonly used surrogate method to assess the efficacy of syphilis treatment, the biological significance of the serofast state remains unclear.
PE24/11
A proactive approach to assess rising STIs among different at-risk groups of MSM in the early era of PrEP: a real-world clinical care setting

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Purpose: MSM are at particular risk of STIs due to sexual behavior and substance use. HIV PrEP may increase this risk, mainly by means of risk compensation. In our center, a proactive approach combining education about STIs has been proposed to all patients PrEP users. Our aim was to comparatively assess incident STIs among different at-risk groups—PLWHIV, HIV-negative (HIV-neg) PrEP and no-PrEP users—seen at our center early after PrEP implementation, as well as to evaluate different types and sites of STI in these groups.

Method: Clinical data were retrospectively collected on all consecutive MSM seen at the Infectious Diseases Department (European Hospital Marseille, France), between September 2016 and October 2018. STI screening is performed systematically among all at-risk patients followed in our center. STI incidence rate (IR) was assessed among groups of patients for the whole period (P), as well as separately for the first (P1) and second year (P2) of the study period.

Results: Medical records of 636 MSM participants were reviewed, of whom 447 were PLWHIV, and 189 were HIV-neg, including 105 PrEP-users. Overall STI incidence rate (IRR) was higher in HIV-neg (irrespective of use of PrEP) when compared to that of PLWHIV. In multivariate analysis, STI risk was significantly higher among HIV-neg no-PrEP users compared to PLWHIV, while not different between PLWHIV and PrEP users.

STI incidence globally increased during the first 2 years after PrEP approval among PLWHIV and no-PrEP users while it remained rather stable for HIV-neg PrEP users. The HIV-neg no-PrEP group remained at higher risk of STI than PLWHIV and PrEP users during the two periods.

Conclusion: These results underline that a proactive approach of an efficient follow-up of and information on MSM participants since PrEP approval may have prevented an increase of the incidence of STIs among HIV-neg individuals.

PE24/12
Profiles of multidrug resistant gonorrhea in HIV-infected patients attending an urban hospital in Uganda

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Purpose: There’s increasing anti-microbial resistance of Neisseria gonorrhoea to conventional anti-microbial therapy. There’s limited data on N. gonorrhoea resistance among HIV-infected patients in developing countries. The objective of this operational research was to estimate the prevalence of culture positive N. gonorrhoea resistance among HIV-infected patients diagnosed with culture positive N. gonorrhoea.

Method: Prospective observational study carried out from June 2018 to July 2019, in HIV-infected persons who presented with either an abnormal vaginal discharge or penile discharge and tested culture positive for N. gonorrhoea. A total of 511 HIV-infected patients accessed services from the STI program. Of 511 patients, 279 (54%) presented with either an abnormal vaginal discharge or penile discharge. Among the 279 samples that were cultured, N. gonorrhoea was isolated in 23 (8.2%) cultures. Although N. gonorrhoea was more amongst the male participants compared to their female counterparts: 65.2% vs. 34.8%, this was not statistically significant (p=0.84). Median age of the participants diagnosed with N. gonorrhoea was 33 years (IQR: 28.5–39.0) and 12 (52.2%) with WHO clinical stage III/IV. Six (26.1%) sensitivity profiles were unavailable due to inability of the N. gonorrhoea isolate to grow on subculture. In 15/17 (88.2%) N. gonorrhoea cultures, there was sensitivity to either Cefoxitine, Augmentin, Ceftriaxone, Cefuroxime, Penicillin, Chloramphenicol or Streptomycin. Ceftriaxone resistance, the current recommended first-line therapy was present among 3/17 (17.6%) of the patients. Interestingly, 2/17 (11.8%) cultures showed total antimicrobial resistance.

Conclusion: Development of MDR N. gonorrhoea is especially concerning as it is difficult to treat, provides long term risks of gonorrhoea and increases HIV drug resistance to partners. There’s need for continued N. gonorrhoea sensitivity surveillance in HIV patients, as well as the general public to inform management choices, especially in resource-limited settings where syndromic management of STIs is performed.

PE24/13
Sexually transmitted diseases clinic in a Portuguese Infectious Diseases unit

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Introduction: Sexually transmitted diseases (STDs) represent a major risk factor for HIV infection. Their prevention and treatment have a significant impact in individual and public health.

Objectives: To characterise the patients attending our consultation and their STDs.

Methods: Review of clinical records of patients attending the STD consultation between June 2017 and June 2019. Statistical analysis was performed using IBM SPSS25.

Results: A total of 425 patients attended the STD consultation. Their mean age was 30.5 yo (min 18, max 68), mostly male (n=376; 88.5%) from which 78.8% were men who have sex with men (MSM). Five (1.2%) were transgender females. Two thirds (n=284, 66.8%) were Portuguese. Most of the patients (n=297; 69.8%) had a high education level. Six patients were sex workers. The main reasons for consultation were: symptoms compatible with STDs (35.6%), evaluation for PrEP (31.3%), high risk sexual exposure (24.9%), positive screening for a STD (6.7%).

We diagnosed a total of 188 infections in 148 patients: Syphilis, 55 cases (incidence of 12.9%); Gonorrhoea, 53 cases (12.5%); Chlamydia 48 cases (11.3%); Condyloma acuminatum 11 cases (2.6%); Mycoplasma genitalium 10 cases (2.4%); Candidiasis 5 cases (1.9%); Genital herpes 2 cases (0.5%) and Molluscum contagiosum 1 case (0.23%). HIV infection was diagnosed in three patients. At the first visit, 31 patients had two STDs diagnosed and 10 had three STDs diagnosed. Sixty-one patients met criteria and started PrEP during follow-up; nine patients met criteria and were informed but did not want to start PrEP.

Conclusion: Approximately one third (34.8%) of the patients that attended our consultation were diagnosed with at least one STD. We proposed PrEP in 47% of them. The incidence of HIV was 0.7%. Target-based campaigns can be an important measure to alert people in other risk groups beside MSM.
PE24/14

Quantification of DNA human papillomavirus 16 and 18 in anal cells improves the prediction of high grade anal intraepithelial neoplasia in HIV patients

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Objectives: To analyze the value of quantitative HPV-DNA16 and 18 in anal cells for screening of high grade anal intraepithelial neoplasia (HGAIN) in HIV patients.

Methods: Cross sectional study between 2017–2019. Inclusion criteria: HIV infection, >18 years-old and risk factors for anal cancer. Exclusion criteria: previous HPV-vaccine. HGAIN was diagnosed by biopsy (AIN II–III) and guided by a high resolution anoscopy (HRA). We determined anal cytology, quantitative DNA-HPV 16,18 and other high risk (HR) subtypes (Cobas®-4800); quantitative DNA-HPV16,18 (qDNA-HPV) (Taqman-primer) in all patients. To calculate DNA-HPV16/cp/human-cells, we quantified 18S rRNA in anal cells (ThermoFisher-Scientific). ROC areas were calculated for best cut-off of qDNA-HPV16 and qDNA-HPV18. Sensitivity (S), specificity (Sp), positive predictive values (PPV), negative predictive value (NPV) were calculated to the different screening tests with their Kappa coefficients and p-value.

Results: 56 patients were included. Age 43.2±8.5 years; 48.2% smokers; 19.6% previous AIDS; CD4+<500 cells/μl; HIV-VL<50 cop/mL 96.5%; previous STI 71.4%. HR-HPV, HPV-16 and HPV-18 was detected in 85.7%, 42.9% and 17.9% respectively; Cytology was abnormal (ASCUS, LSIL or HSIL) in 42.9% and 17.9% respectively; Cytology was abnormal (ASCUS, LSIL or HSIL) in 42.9% and 17.9% respectively. Abnormal cytology and DNA-HPV-16 and 18 were significantly more frequent in HGAIN-biopsies (p<0.05). qDNA-HPV16 was higher in HGAIN-biopsies: 864 cop./human-cells (IQR:80–3941) vs non-HSIL: 40 cop./human-cells (2–693), p=0.09 (Table 1). In Table 2, we show the S, Sp, PPV, NPV of cytology and virological variables for the prediction of HGAIN.

Conclusions: A qualitative DNA-HPV detection in anal cells is high sensitive for HGAIN diagnosis, but shows a low specificity and low PPV. Quantification of viral load of qDNA-HPV16 or qDNA-HPV18 in anal cells increases the specificity and PPV for HGAIN diagnosis. DNA-HPV viral load in anal cells could be a new tool to be included in anal cancer screening programs.

PE24/15

Primary prophylaxis against Pneumocystis jirovecii

Pneumonia may be effective in preventing severe bacterial pneumonia in HIV-positive patients: findings from a large Italian center

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Purpose: We aimed to determine if HIV-infected patients taking trimethoprim-sulfamethoxazole (TMP-SMZ) or aerosolized pentamidine (AP) as primary prophylaxis for Pneumocystis jiroveci Pneumonia (PJP), presented a lower risk of developing bacterial pneumonia compared to others who don't.

Method: We retrospectively evaluated a monocentric cohort of HIV-positive patients, all of whom presented a CD4+ cell count under 200/mm³. Follow-up was censored when CD4+ cell count became >200/mm³ or in the event of a diagnosis of bacterial pneumonia (based on clinical, microbiological and/or radiological findings). Chi-square test and logistic regressions were used to compare parameters and assess predictors.

Results: We analyzed 1053 patients: 745 were males (70.8%), with a median age of 39 years (IQR 12–84). Full patients' characteristics are available in Table 1. Six-hundred and fifty patients (61.7%) took TMP-SMZ while 116 (11%) took AP as prophylaxis against PJP. During 1438 Patient-Years of Follow-up, there were 49 diagnoses of bacterial pneumonia requiring hospitalization, with a median duration of hospital stay of 12 days (6–31). Overall, prophylaxis against PJP was negatively associated with developing pneumonia (Odds Ratio 0.54, 95% CI 0.30–0.97, p=0.045), after adjusting for age and the presence of a previous AIDS-defining event. In a dedicated sub-analysis, we observed that prophylaxis against PJP resulted protective against pneumonia in patients with a previous AIDS event (p=0.036), while its association was not significant in patients without a previous AIDS-defining event (p=0.672). In patients with over a year since HIV diagnosis, only TMP-SMZ resulted protective against pneumonia (p=0.025) compared with AP, whose association was not significant (p=0.152).

Conclusion: Our study seems to suggest that the use of prophylaxis against PJP may have a role also in preventing bacterial pneumonia, a potentially life-threatening event in immunocompromised patients. Other studies, with larger sample size, are needed to properly assess the matter.

Patients’ characteristics at baseline

| Age (years), median (IQR) | 39 (34–47) |
| Males, n (%) | 745 (70.8) |
| CDC Stage C, n (%) | 502 (47.7) |
| HIV Risk Factor, n (%): 1. MSM 2. Heterosexual 3. Others | 1. 447 (42.5) 2. 291 (27.6) 3. 244 (23.2) |
| HIV Risk Factor, n (%): 4. Other/Unknown | 4. 71 (6.8) |
| Nadir CD4+ cell count (cell/mm³), median (IQR) | 67.5 (28.0–129.3) |
| Zenith HIV-RNA (log10 copies/mL), median (IQR) | 5.12 (4.37–5.56) |
| Cases of severe Bacterial Pneumonia, n (%) | 49 (4.7) |
| Patients taking TMP-SMZ, n (%) | 650 (61.9) |
| Patients taking AP, n (%) | 116 (11.0) |
| Time from HIV diagnosis (months), median (IQR) | 16.4 (3.9–73.2) |
**PE24/16**

**HHV-8 salivary shedding in individuals with different HIV status and sexual behaviour**

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Human gammaherpesvirus 8 (HHV-8), the etiological cause of Kaposi sarcoma, multicentric Castleman's disease and primary effusion lymphoma, is mainly sexually transmitted. However, saliva is suggested to play an important role in transmission of the virus.

**Objectives:** To determine the frequency of HHV-8 salivary shedding in HIV-infected (HIVpos) and non-infected (HIVneg) individuals with different sexual behavior in Russia.

**Methods:** The study involved 165 patients: 120 male и 45 female with the median age of 36 (20–66) years. Four groups were formed: HIVpos men who have sex with men (MSM/HIVpos), MSM/HIVneg, HIVpos heterosexual men and women, HIVneg heterosexual men and women. The HHV-8 DNA in saliva was detected by a single time PCR assay. Fisher’s exact Test was used to evaluate the association between HHV-8 persistence and HIV status and sexual behavior, as well as Odds Ratio was calculated to assess risk for HHV-8 salivary shedding in different groups.

**Results:** HHV-8 DNA was detected in saliva in 5.5% (9/165) cases. The prevalence was found among MSM/HIVpos - 31.8% (7/22), MSM/HIVneg - 4.0% (2/50) cases. The concentration of viral DNA was 3.78–6.19 (median 4.98); 2.00 and 3.11 lg GE HHV-8/ml, respectively. HHV-8 in saliva was not found among heterosexual individuals. MSM are at higher risk of HHV-8 salivary shedding than heterosexual men and women, OR = 27.97 (p<0.05, CI 95% 1.59–489.33). HIV-infected individuals also have an increased risk of HHV-8 persistence in saliva, OR = 5.91 (p<0.05, CI 95% 1.19–29.42). Both factors significantly enhance the risk of HHV-8 shedding, OR = 48.87 (p<0.05, CI 95% 2.64–405.03).

**Conclusions:** This is the first data on prevalence of HHV-8 in saliva among Russian individuals with different HIV status and sexual behavior. HHV-8 was found in saliva of 2.0% non-HIV-infected and 10.8% HIV-infected persons. The highest prevalence of HHV-8 in saliva was found in HIV-infected MSM (31.8%).

**PE24/17**

**Insights into syphilis reinfection in HIV patients: predictors and role of serofast condition**

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**Purpose:** An increasing proportion of cases of syphilis in people living with HIV (PLWHA) worldwide are reinfections, mainly in men who have sex with men (MSM). The objectives of this study were: to describe the occurrence of laboratory confirmed cases of syphilis reinfections among PLWHA observed from 2000 to 2019, analyze cofactors of reinfection, identify the impact of serological response in reinfection.

**Methods:** All PLWHA in a single clinical center with a 1st episode of syphilis infection were included. Reinfection was serologically defined according to CDC definitions. Treatment failures were not included. Kaplan-Meier survival curves were generated to describe the cumulative incidence and time to first reinfection. Factors independently associated to the probability of reinfection were identified by Cox regression analysis.

**Results:** 751 pts had a 1st diagnosis of serological syphilis; 173 (23%) had a reinfection. Median age at reinfection was 42 years (IQR37–50) compared to 46 (IQR37–54) of those without reinfection; 168 pts (97.1%) were males; 75.3% MSM; 85.5% Caucasian. Median CD4cell count at first reinfection was 581/ mmc, median HIV-RNA1.5 log c/mL. Median time of follow-up: 6.3 years (IQR2.4–10.6) and 3.4 years (IQR1.7–6.6) at reinfection. Probability to be reinfection-free after5y from the first episode was 83% (±0.3). Serofasts’ proportion was similar (48% vs45%) in those who presented a reinfection and those who didn’t (p=0.944). Factors associated with reinfection were being

**PE24/18**

**Infective endocarditis, a current health problem in Romanian injecting drug users**

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**Purpose:** The use of new injectable psycho-stimulant drugs (NPS) in the last decade led to an increased risk of invasive bacterial infections, including infective endocarditis (IE). The aim of our study was to assess risk factors, clinical characteristics and survival in injecting drug users (IDUs) diagnosed with IE in a Romanian tertiary care facility.

**Method:** Retrospective study on IDUs hospitalized with IE at “Victor Babes” Hospital, Bucharest, between January 2008 and December 2018. Statistical analysis was performed using SPSS vs. 20.0.

**Results:** A total of 112 IE were diagnosed in 101 IDUs [55 IE in HIV-positive, 57 in HIV-negative IDUs]. The majority were males (80.1%), from urban areas (95.0%), with a median age of 30 years (IQR 28, 34), 99% co-infected with HCV. IDUs were NPS (55.4%), opioids (20.7%) and mixed (22.7%) abusers. Right-sided IE was diagnosed in 78.5% cases. Staphylococcus aureus was isolated in 70.4% cases (42.8% MSSA, 27.6% MRSA), followed by Streptococcus spp (26%). Eleven cases of IE reinfections occurred, more often in NPS users (p=0.02), after a median period of 1.9 years (IQR 6, 4.1). IE was more frequent in HIV-positive IDUs between 2013–2018 compared to
Preventable risk factors and predictors of hepatic and non-hepatic co-morbidities among PLHIV

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Objective: Nigeria has the third highest burden of HIV/AIDS in the world. We sought to identify the preventable hepatic risk factors, and the prevalent hepatic and non-hepatic co-morbidities among people living with HIV (PLHIV).

Method: HIV-positive patients aged 18 years and above were consecutively enrolled. Descriptive statistics and logistic regression analyses were conducted to determine the pattern and predictors of hepatic and non-hepatic comorbidities.

Results: One hundred and twenty-four HIV positive patients were enrolled. Four patients (3.23%) had at least one form of hepatic disease, primarily hepatocellular cancer (100%). None had alcoholic or fatty liver disease. Majority (63.4%) had at least one risk factor for liver disease. The most predominant risk factors were current alcohol use (23.8%), herbal drug use and hepatitis B virus co-infection, both 16.1% and current tobacco use (5.7%). None had concurrent HCV co-infection. Only 3.3% and 0.81% had ever received vaccinations for HBV and HAV respectively. The proportion of respondents with at least one HBV risk factor was 68.6%. The most predominant HBV risk factor was high-risk sex (62.6%). Other HBV risk factors present in the population were an MSM sexual orientation, injecting drug use, previous blood transfusion with 6.6% each and prenatal exposure (5.0%).

Conclusion: Preventable risk factors for liver disease are prevalent among these PLHIV. Integrating the prevention of these risk factors into HIV care is recommended.

Preventable risk factors and predictors of hepatic and non-hepatic co-morbidities among PLHIV

PE24/19

Prevalent Risk factors for HAV infection and reinfection among MSM living with HIV in South-Western Poland

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Objectives: Poland was the country with the highest increase of acute hepatitis A incidence during an outbreak in 2016–17 in Europe according to ECDC reports. Despite the lack of country-wide epidemiological data, MSM is the most affected population. The aim was to assess the rate of asymptomatic HAV seroconversion among HIV-infected MSM in HIV care center in Wroclaw, Lower Silesia region.

Method: Retrospective, single-center analysis of epidemiological and serological data concerning HAV infection and other STIs among MSM living with HIV. Total anti-HAV were tested in two timepoints: at baseline before the significant increase of hepatitis incidence in Poland (till the beginning of 2017) and after the end of 2017. Patients with history of acute hepatitis A, vaccinated or with unclear history of HAV vaccination were excluded.

Results: Among 485 MSM under care 159 individuals were included, median age 34 years (range 21–65). 133 patients were anti-HAV total negative at baseline. In 14 cases (10.53%) anti-HAV total turned positive at the second timepoint, without any symptoms, signs or biochemical markers of acute hepatitis between two tests. Median CD4 at baseline was 594 (IQR 413–743), nadir CD4 was 336.5 (IQR 234–437). All patients were on cART during the observation period except 3 individuals who had interrupted therapy. In 87
patients at least one past and current episode of other STI (eg. syphilis, gonorrhea, chlamydiosis, genital warts, acute hepatitis C) was reported, in 41 cases – more than 1 episode. No statistically significant correlation of HAV seroconversion with age, current CD4, CD4 nadir, neither episodes of current or past other STI was found.

Conclusion: Asymptomatic HIV infection rate among HIV-infected MSM was relatively high, although not related to other STI as markers of risky sexual behaviours. The proper access to anti-HAV vaccines is strongly needed in the vulnerable MSM population.

We estimated prevalence and incidence of syphilis infections (newly positive TPHA/TPPA or ≥4-fold VDRL increase) for each of the four previously inferred clusters and compared it to their respective proportions of men reporting nsCAI.

Results: Incidence of syphilis increased from 0.08 infections per person-years in 2005 to 0.12 in 2018. Overall syphilis prevalence differed significantly among clusters. This finding was consistent with differences in average nsCAI proportion among clusters (OR:6.0, p<0.0001). Trajectories of syphilis incidence over time differed between clusters (Figure): Clusters with increasing nsCAI proportion also exhibited recent increases in syphilis incidence. However, increases in syphilis incidence were delayed compared to those in nsCAI proportion. The increase in syphilis incidence was particularly pronounced for clusters 3 and 4, two groups characterised by recent nsCAI increases. In 2018, these clusters contributed over half of the syphilis cases while making up less than one third of the population.

Conclusion: Our preliminary results suggest that syphilis incidence over time differs between behavioural clusters and that specific clusters could be targets for potential interventions to control syphilis infections.

PE24/22
Evaluation of a systematic sexually transmitted infections screening pilot programme in HIV-positive men who have sex with men (MSM)

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Purpose: To describe prevalence of asymptomatic sexual transmitted infections (STI) in a cohort of MSM-HIV+ and risks factors associated; to assess the effectiveness of a risk-reduction counselling intervention and an enhanced partners management strategy.

Method: 100 MSM-HIV+ attending an HIV outpatient-clinic in Barcelona were evaluated at baseline (BL), month 6(M6) and month 12(M12), between December 2017–June 2019. Study visits included: STI screening; self-administered questionnaire about sexual behavior; risk-reduction counselling intervention. STI screening included serologic tests (Syphilis-HCV-HBV), RT-PCR for Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG) in urine (U) rectal (R) and pharyngeal (P) samples. Sexual partners (SP) notification/contact strategies included written information delivered by patients and software tool-based phone messages by health professionals.

Results: Median (IQR) age was 40 years (34–47), CD4-count 725µL (543–975), 90% on ART. Median number of SP (last year) was 8(3–20), 74% reported condomless sex, 58% recreational drugs use, and 32% chemsex use (3% slamming).

A total of 54 STI were diagnosed in 40 subjects. At baseline, 20% had at least one positive result: syphilis 10%, CT 7% (R 7%, P 1%), NG 7% (R 3%, PH 5%). A non-significant decrease in STI prevalence was observed during the follow-up (BL 20%, M6 19%, M12 17%; p=1). No risk factors were significantly associated with STI, although a higher percentage of chemsex use was observed (24.5% vs 39.5%, p=0.222).

An increasing trend in condom use was observed overtime (BL 26% vs M12 36%, p=0.14), without differences in recreational and chemsex drugs use and number of SP.

Although subjects with STI reported a total of 2385 SP, only 612(25.2%) could be notified and 7/61(11.5%) attended our clinic.

Conclusion: Prevalence of asymptomatic STI in this MSM-HIV+ population was high. Systematic periodical screening and counselling was not effective to reduce significantly STI prevalence. Greater efforts are needed to control STI in this high-risk population, to promote safe sex and to improve partners management.
Chemsex in Barcelona: a descriptive approach about men who have sex with men (MSM) who use recreational drugs in a sexual context

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Purpose: “Chemsex” refers to the intentional use of recreational drugs to enhance sexual experience in MSM. Little is known about this phenomenon in the city of Barcelona; the aim of this study is to characterize a Chemsex users cohort from our city, by analyzing socio-demographical and clinical characteristics, sexual behaviors, type of drugs and pattern of consumption and sexually transmitted diseases (STDs).

Methods: Cross-sectional study of a series of MSM patients Chemsex users. Patients were recruited between March 2018 and May 2019, at the Hospital Clinic of Barcelona. Clinical and epidemiological characteristics were evaluated based on the information obtained from the clinical history and a questionnaire answered by the patient. Likewise, screening for HIV, HCV and STDs was carried out.

Results: 161 MSM and transgender patients were included. 48% were Latin-Americans. 94% were HIV positive and 36% of them were HCV positive (24% had detectable HCV-RNA). The median of sexual partners was 20 (IQR 10; 30). 94% were HIV positive and 36% of them were HCV positive (24% had detectable HCV-RNA). The median of sexual partners was 20 (IQR 10; 30). 94% were HIV positive and 36% of them were HCV positive (24% had detectable HCV-RNA). The median of sexual partners was 20 (IQR 10; 30).

161 MSM and transgender patients were included. 48% were Latin-Americans. 94% were HIV positive and 36% of them were HCV positive (24% had detectable HCV-RNA). The median of sexual partners was 20 (IQR 10; 30). 95% reported unprotected anal sex. 50% were polydrug users and 20% reported slamming. The individual frequency of drug use and the most prevalent drug combinations are reported in graphic 1 and graphic 2. The screening of asymptomatic STDs reported 91 positive PCR: Neisseria gonorrhoeae (55%), Mycoplasma genitalium (28%) and Chlamydia trachomatis (17%). 13% of HIV patients had detectable viral load. 70% were concerned about drug use in this context and 60% would like help to address this issue.

Conclusions: High prevalence of unprotected sexual risk practices, polydrug use and slamming are found in our MSM chemsex users cohort. The prevalence of HCV and other asymptomatic STDs is very common in this population. Specific risk reduction strategies are necessary in this population.

Analysis of serum metabolite changes in early syphilis patients with or without serologic response after treatment

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Purpose: The treatment success of syphilis depends on 4-fold decrease of rapid plasma reagin (RPR titer) according to current treatment guideline. However, the change of RPR titer is not sensitive. We aim to screen treponemal metabolomics response of early syphilis after treatment among HIV-infected and HIV non-infected patients.

Method: Adult patients aged 20 years or older who presented with early syphilis (primary, secondary and early latent syphilis) with RPR titers of 4 or greater were included. The serum was collected in week 1, 2, 3, 4, 8, 12 after treatment with 2.4 MU benzathine penicillin G. Serologic response was defined as decline of RPR titre by 4-fold or greater at each time point compared with baseline. We used a combined liquid chromatography MS/MS assay and direct flow injection assay for the metabolomics analyses of the samples.

Results: Total 24 patients were included between January 2015 and March 2018 while 18 subjects had HIV infection. The median baseline RPR titer were 1:128 among HIV-uninfected patients while 1:256 among HIV-infected patients. After treatment, 19 patients achieved serologic response after treatment within 12 weeks and 13 of them were HIV-infected. In the metabolomic analysis, two metabolites were identified with significant changes according to the treatment response that SDMA were significantly lower and taurine had early decline change in those who had achieved treatment response.

Conclusion: In our study, we found that lower SDMA level and early decline of taurine level were associated with the treatment response of Treponema pallidum. Further larger scale analysis should be done to identify the potential role of these metabolites as markers to evaluate treatment success of syphilis.
Stable transmission of amoebiasis among newly diagnosed HIV-positive patients in Taiwan, 2009–2018

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Purpose: Entamoeba histolytica infection is an emerging sexually transmitted disease among men who have sex with men in the Asia-Pacific region. This study aims to investigate the overall and temporal change of the seroprevalence of amoebiasis among HIV-positive patients in Taiwan and its associated factors.

Method: We reviewed medical records of newly diagnosed HIV-positive patients who received HIV care at five medical centers across Taiwan between 2009 and 2018. Patients who had tests for indirect hemagglutination antibody (IHA) within 6 months before or after their HIV diagnoses were included for analyses. The trend of IHA seropositivity over time was tested by chi-square test for trend. The demographics, clinical presentations, and baseline laboratory test results were analyzed for the association with positive IHA (defined by an IHA titer ≥1:32) in multivariable regression models.

Results: Among 3539 newly diagnosed HIV-positive patients in the 10-year study period, 2122 (60%) had IHA titers determined. Overall, 202 (9.5%) patients tested positive for IHA and 83 (3.9%) had clinical diagnoses of invasive amoebiasis. The annual seroprevalence of IHA fluctuated, ranging from 5.9% in 2012 to 16.5% in 2009, without a statistically significant trend from 2009 to 2018 (p = 0.278). The IHA seropositivity was associated with positive rapid plasma reagin (RPR) titers over time (adjusted odds ratio [aOR] 1.07, 95% confidence interval [CI] 1.04–1.11), an older age (aOR 1.002, 95% CI 1.00–1.003) and symptoms of diarrhea (aOR 1.20, 95% CI 1.16–1.24).

Conclusion: Seropositivity for E. histolytica infection was not uncommon among newly diagnosed HIV-positive individuals in Taiwan and the seroprevalence remained stable over the past 10 years. To facilitate early diagnosis and treatment of amoebiasis and to prevent further transmission, IHA testing should be included in the routine HIV care of HIV-positive patients in Taiwan, particularly those who present with diarrhea and RPR titers ≥4.

Mycoplasma genitalium resistance against macrolide antibiotics in the Berlin MSM cohort tested with the Allplex MG & AzIR Assay (SeeGene)

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Purpose: Due to the high rate of sexual transmitted infections (STI) there is a rise in awareness and in STI-testing. Mycoplasma genitalium (MG) is one important cause of non-gonococcal urethritis and emerging macrolide resistance is a major concern. A standardized real-time-PCR test is the favoured method for this hard to culture bacterium in routine diagnostics. We tested here the Allplex MG&AzIR Assay on MG positive samples.

Method: Screening MSM for MG from mainly urethral/anal swabs or urine was performed with the Hologic Panther system (Aptima MG Assay target capture and isothermal amplification TMA). Total nucleic acid extraction from 96 MG positive samples was done with the Abbott M2000sp system, followed by testing for macrolide resistance with the Allplex™ MG&AzIR Assay in a RUO version. This test differentiates the SNP mutations A2058C/G/T and A2059C/G/T of the 23S rRNA-gene region-V of MG.

Results: 69.8% (N = 67) of MG positive screened samples were also positive in the Allplex™ MG&AzIR Assay. In a very high proportion of these samples (80.6%, N = 54) resistance mutations could be detected. A2059G was the mutation detected with the highest frequency (74.1%; N = 40) followed by A2058G (24.1%; N = 13). One sample had an A2058T mutation. No sample showed an A2058C or A2059C/T mutations.

Conclusion: As expected not all Aptima assay positive samples tested positive with the Allplex assay due to the known very high sensitivity of the TMA test. Of 80.6% resistant MG detected, 74% showed resistance against Azithromycin and 26% against Azithromycin alone. Usual second line option in Germany is Moxifloxacin despite increasing numbers of reported clinical resistance (fluorochinolone resistance assay Seegene launch in summer, first data will be added). Resistance guided therapy is crucial for sufficient treatment success and addition of molecular resistance testing against Fluoroquinolones is an additional requirement.
PE24/29

The prevalence of high-risk anal HPV in HIV-positive MSM in Lebanon

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Purpose: Infection with HPV is associated with ano-genital cancers and potentially preventable through vaccination. 90% of anal cancers are related to HPV16 and HPV18. Concomitant infection with HPV doubles the risk of anal malignant transformation in affected MSM. To our knowledge, this is the first study to examine the prevalent anal HPV strains and anal STIs among asymptomatic HIV-positive MSM in a Middle Eastern country.

Methods: We performed a cross-sectional study at a well-established HIV clinic in Beirut. 38 participants were included; they were all men who had sex with men, asymptomatic at recruitment. EuroArray STI kits were used for screening STIs by PCR and EuroArray HPV kits for HPV PCR determination and typing.

Results: The median age of the participants was 30 (range 20–71). 82.35% of them had an undetectable HIV viral load. Only 28.95% had prior HPV vaccination; 13.15% had prior anal Pap smear testing. 75% were not aware of the association between HIV, HPV and anal dysplasia and cancer. 34 participants (89.47%) tested positive for any type of anal HPV, among them, 91.17% harbored high-risk HPV (HR-HPV) strains distributed as such: 55.8% HPV16, 26.32% HPV56 and 23.68% HPV18. The majority of the participants (81.58%) had multiple HPV types (median of 4 types) and 34.21% had at least one concomitant STI, most of which were Mycoplasma species.

Conclusion: We found a high rate of HR-HPV anal infections but a low rate of HPV vaccination among this young HIV-positive population. HPV56 was the second most common high-risk strain, a finding not reported from other regions; HPV56 is not included in the 9-valent HPV vaccine. The prevalence of asymptomatic rectal carriage of Mycoplasma species was elevated. It is crucial to explore the epidemiology of anal HPV and STIs among HIV-positive MSM in this region to guide future cancer prevention efforts.

Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (IQR)</td>
<td>30 (27–33)</td>
</tr>
<tr>
<td>History of HPV vaccination</td>
<td>11 (28.35%)</td>
</tr>
<tr>
<td>Currently on ART</td>
<td>36 (94.74%)</td>
</tr>
<tr>
<td>Duration of ART, median (IQR)</td>
<td>3 (1.875–3.5)</td>
</tr>
<tr>
<td>Current CD4 count, mean (SD)</td>
<td>641.8 (335.91)</td>
</tr>
<tr>
<td>Nadir CD4 count, median (IQR)</td>
<td>305 (169–448)</td>
</tr>
<tr>
<td>Current undetectable HIV VL</td>
<td>28/34 (82.35%)</td>
</tr>
</tbody>
</table>

Table 2. Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any HPV type</td>
<td>34/38 (89.47%)</td>
</tr>
<tr>
<td>High risk HPV</td>
<td>31/34 (91.17%)</td>
</tr>
<tr>
<td>Multiple HPV (n=34)</td>
<td>31/34 (91.17%)</td>
</tr>
<tr>
<td>Any STI (n=38)</td>
<td>13/38 (34.21%)</td>
</tr>
<tr>
<td>Mycoplasma species</td>
<td>10 (26.31%)</td>
</tr>
<tr>
<td>Ureaplasma urealyticum</td>
<td>7 (18.42%)</td>
</tr>
<tr>
<td>Chlamydia trachomatis</td>
<td>1 (2.63%)</td>
</tr>
<tr>
<td>Neisseria gonorrhoea</td>
<td>3 (7.89%)</td>
</tr>
</tbody>
</table>
Paediatric, adolescent

PE25/1

Effect of cluster of differentiation (CD4) on viral respiratory infection in children, between 0–5 years of age. A study conducted in Kwazulu-Natal, South Africa

T Famoroti1 and W Sibanda2

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Purpose: Viral respiratory tract infections (RTI) contribute significantly to morbidity and mortality among children in resource-poor countries. Cell mediated immunity plays a central role in disease modification and viral clearance and individuals with defective cellular immunity are likely to have prolonged viral shedding and increased frequency of infections. Human immunodeficiency virus (HIV) infected children are likely to have higher incidence of RTI than HIV negative children.

Method: A retrospective data analysis of respiratory specimens results of children between 0–5 years of age collected between 1st January 2011 and 31st July 2015 from hospitals. Respiratory specimens were tested for viral pathogens using multiplex polymerase chain reaction (PCR) and non-viral pathogens using appropriate culture media. HIV testing was performed either by serological or PCR methods. The objectives were to analyze respiratory pathogens isolated from specimens of both HIV Positive and HIV negative and to determine the role cluster of differentiation (CD4%) plays in RTI.

Results: Out of 1264 respiratory results, 621 (49.1%) were viral isolate results and 643 (50.9%) were non-viral isolate results. Respiratory syncytial virus was the most detected pathogen 218 (35.1%). HIV results were available for all 621 (100%) with 122 (19.6%) HIV positive. The prevalence of viral and non-viral RTI between HIV negative and HIV positive pathogens detected among children. The study highlighted the difference in prevalence of viral and non-viral RTI between HIV negative and HIV positive children and it further showed the effect CD4% has on susceptibility to RTI.

Conclusion: This study identified the common respiratory viral and non-viral pathogens detected among children. The study highlighted the difference in prevalence of viral and non-viral RTI between HIV negative and HIV positive children and it further showed the effect CD4% has on susceptibility to RTI. Upscaling the HIV treatment will likely have an impact on RTI in children. The study outcome has implications for the rational design of public health programs. Further studies is needed in understanding respiratory infection in children.

Table 1. Respiratory multiplex respiratory viruses with HIV and CD4 results.

<table>
<thead>
<tr>
<th>Variables (total number of specimens) 1264, median age 3 months</th>
<th>Gender (Total=1264)</th>
<th>Male=687 (54.4%)</th>
<th>Female=562 (44.5%)</th>
<th>Gender not stated 15 (1.2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated non viral pathogen total</td>
<td>394</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 results linked to non viral results ≤25% Total</td>
<td>55 (51.9%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 results linked to non viral results ≤25% Total=51 (48.1%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total=51</td>
<td>12</td>
<td>2</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>p values</td>
<td>&lt;0.05</td>
<td>0.9908</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Viral respiratory pathogens</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total=621</td>
<td>25</td>
<td>25</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>p values</td>
<td>0.9908</td>
<td>0.05</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>CD4 results linked to viral respiratory results ≤25% Total</td>
<td>66 (65.3%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 results linked to viral respiratory results ≤25% Total=35 (34.7%)</td>
<td></td>
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PE25/2

Adolescent HIV and asymptomatic malaria parasitemia (AMP) co-infection

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Purpose: In this study, we sought to determine the prevalence of AMP in a population of Adolescents HIV positive patients on antiretroviral therapy (ART). We also seek to know the correlation of this co-infection on the %CD4 and HIV viremia of the study population.

Method: 153 adolescents on ART at the APIN Laboratory of the Jos University Teaching Hospital (JUTH) in Plateau State, North Central Nigeria, participated in this study. The mean age of the participants was 14(±4) years. Participant's venous blood were drawn; with two (2) thick blood smears made and air-dried for each participant. The slides were stained with Giemsa and Field stains for malaria microscopy. %CD4 of the study population was analyzed using the Partec® Cyflow Counter II; while the separated plasma was assayed for HIV viral load using the Roche® Cobas Amplicope/Cobas Taqman 96 System. Collected data analysis was done using a simple percentage.

Results: Of the 153 participants in this study, 66% (101/153) were virally suppressed (<1,000 copies/mL); while 34% (52/153) were virally unsuppressed (>1,000 copies/mL). 65% (99/153) of the study population have AMP. 54% (55/101) of the virally suppressed population have AMP; with a mean %CD4 value of 28%, while the virally suppressed population without AMP (46/101) have a mean %CD4 value of 30%. 85% (44/52) of the virally unsuppressed population have AMP; with a mean %CD4 value of 19%; while the virally unsuppressed population without AMP have a mean %CD4 value of 16% respectively.

Conclusion: This study shows that there is a high prevalence of AMP among adolescent HIV patients (65%). The high prevalence of AMP among the virally unsuppressed population (85%), with a mean %CD4 value of 19%, points to the fact that malaria parasitemia in HIV infection fosters increased plasma HIV viremia and a dysregulated immune response to this co-infection.
PE25/3

Clinical features of viral diarrhea in the children of HIV women of childbearing age: a case-control study

A Beun1, T Grammens2, M Hainaut3, P Barlow4, S Van den wijngaert5, M Delforge1, S De Wit6 and N Dauby1

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Purpose: Rubella infection is a vaccine preventable disease. Maternal infection during pregnancy may lead to congenital infection and severe fetal malformations. Nowadays, perinatally HIV-infected women (PHIV) have better prognosis and are frequently experiencing pregnancy at a young age. We aimed at evaluating the rate of rubella seronegativity in a cohort of PHIV of childbearing age.

Methods: Perinatally-infected women of childbearing age with a documented rubella serological testing were retrospectively identified and age-matched to HIV-positive non-perinatally infected women (nPHIV). Vaccination history with the measles-mumps-rubella vaccine (MMR) was retrieved from the hospital files in the PHIV group. Conditional logistic regression was used for comparison between the PHIV and nPHIV subjects.

Results: Twenty-nine PHIV (cases) and fifty-eight nPHIV (controls) were identified. There was no significant difference between cases and controls considering country of birth (Belgium vs. outside Belgium), proportion of Sub-Saharan African origin, ART proportion, CD4+ T cell count >350 cells/µL and HIV viral load <50 copies/mL at time of rubella testing and CD4+ T cell count nadir >200 cells/µL. Median duration of living in Belgium was significantly different in the two groups: 15.9 years vs. 2 years for the nPHIV group (p value <0.01). A high rate of seronegativity was found in the PHIV group as compared to nPHIV group (34.5% vs. 6.90%, p<0.01). MMR administration before rubella testing was identified in 75.8% of PHIV women (22/29) with a mean of 2 doses (range: 1–3 doses).

Conclusions: High rubella seronegativity rate was found in PHIV with high MMR vaccine coverage, reflecting defective vaccine-induced immunity. This is of particular concern for the ongoing rubella eradication strategy. We recommend that perinatally HIV-infected women of childbearing age should be regularly screened for rubella immunity.

PE25/4

High rate of rubella seronegativity in perinatally-infected HIV women of childbearing age: a case-control study

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Purpose: To study was to investigate the clinical features of viral diarrhea in children with HIV.

Method: The study involved 30 children aged between 1 and 18 years who were treated at the Republican AIDS Center. Clinical, virological, bacteriological, serologic (PCR) methods were used.

Results: The study showed that viral diarrhea is more prevalent in children under the age of 3 years with HIV. 21 (70%) of the 30 children with diarrhea have been diagnosed with viral etiology. Viral diarrhea was caused in 16 children (76.2%) by rotavirus while normal diarrhea with normal Herpes type 2 (9.5%) and adenovirus diarrhea 1 (4.78%), 2 (9.5%) patients had mixed etiologic viral diarrhea. The most severe diarrhea was rotavirus diarrhea, with strong symptoms of intoxication and symptoms of multiple vomiting in children. Catarrhal signs in the rotavirus diarrhea were more susceptible to adenovirus diarrhea. The body temperature rose slowly and reached 39.1°C until 4–5 days before the onset of the disease. In the diarrhea clinic with a normal herpes virus, multiple seizures (more than 10 times) occurred suddenly on the background of sub-febrile body temperature. The return was 5.2±1.8 days, the fecal matter was fluid and was observed 1–2 times a day.

Conclusions: Thus, according to the results of the study, ethylogically rotavirus was the leading cause of viral diarrhea in HIV-infected children. Diarrhea syndrome prevailed over vigor and vomiting.

PE25/5

Health outcomes in adolescents and young adults living with HIV before and after transition to adult care in Barcelona

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Purpose: To describe the demographic and HIV related data of patients who transferred from paediatric to adult care in two centres of Barcelona and compare the quantitative health outcomes before and after the referral process.

Method: An observational, prospective study with retrospective data collection was conducted with 53 adolescents living with HIV who had transitioned from Hospital Sant Joan de Déu (HSJD) to Hospital Clinic (HCB) in Barcelona between 2006 and 2017. Data was collected from clinical records before transition, right after it and at the last control visit. Risk factors for detectable viral load were evaluated with a regression model that included sex, socioeconomic status, absence of virological failure during adult care and low educational level.

Results: 53 patients successfully transitioned from HSJD to HCB during the time of the study, 15 (28.3%) of them were no longer linked to care (3 deaths, 5 transferred to another centre and 7 lost-to-follow-up). Most of the patients (75%) with undetectable viral load during paediatric care were found to remain undetectable during adult care. Importantly, the results obtained with the multivariable regression model showed that low educational level was found to carry a 27-fold increase in the risk of having a detectable viral load in the last visit (aOR of 27.39 with a 95% CI of 1.5–487.48), while the absence of virological
failure during adulthood could be a potential protective factor, as it reduced the risk of being detectable by 88% (aOR of 0.12 with a 95% CI of 0.001–0.170).

Conclusion: While not showing a clear impact of the transition process on the health of this cohort, these findings align to those reported in similar studies. Patients with virological failure during adulthood and low educational level should be followed up more closely.

PE25/6
Correction of lipid abnormality by integrase inhibitor among children taking ART

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Objectives: Boosted PIs are milestones of HIV management in pediatric practice. Long-term ARV treatment is associated with lipid abnormalities. The statins and fibrates are routine co-medications for adults but its are not alloyed in pediatric practice. The purpose of the study was to estimate a possibility of correction laboratory abnormalities (increased level of cholesterol and/or triglycerides in blood of HIV-positive children) by switch the boosted PI to HIV integrase inhibitor (Raltegravir).

Methods: The retrospective study was conducted in group of 58 HIV-positive children (less 18 years). Inclusion criteria were hypercholesterolemia (>5.0 mM) and/or the hypertriglyceridaemia (>2.3 mM) on ART with boosted PI. The ART scheme was changed for all children (n=58). Boosted PI was replaced by integrase inhibitor (RAL). RAL formulation (chewable tablets, 25 mg and 100 mg) used accordingly weight. Time horizon of observation and laboratory assessment after switch was 24 months.

Results: Lab abnormalities in study group (n=58) after switch to RAL were corrected: reliable decrease of level of cholesterol (p<0.01), triglycerides (p<0.001), viral load (p=0.001) and growth CD4 count (p=0.05).

Conclusion: Boosted PI switch to integrase inhibitor is providing long-term and effective HIV management and improvement of lipid abnormalities among children.

Key words: HIV positive children, HIV treatment of children, lipid disorders among children, lipid management, adverse events during ART among children.

Table 1. Patient Demographics and Baseline Characteristics, n=58

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>M±m</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of ART start, years ± SD</td>
<td>2.5±3 m</td>
<td>2.5±8 m</td>
</tr>
<tr>
<td>Average time to II switch, years ± SD</td>
<td>3.1±2 m</td>
<td>3.1±4.1 m</td>
</tr>
<tr>
<td>Average time of hypercholesterinemia, years ± SD</td>
<td>3.1±2 m</td>
<td>3.1±4.1 m</td>
</tr>
<tr>
<td>Average time of triglyceridemia, years ± SD</td>
<td>2.3±2 m</td>
<td>2.3±4.5 m</td>
</tr>
<tr>
<td>Average cholesterol, mM</td>
<td>5.95±0.15</td>
<td>5.8–6.10</td>
</tr>
<tr>
<td>Average triglyceride, Mm</td>
<td>1.99±0.15</td>
<td>1.84–2.14</td>
</tr>
<tr>
<td>Average VL, copies/mL</td>
<td>400.55±224.61</td>
<td>175.94–625.16</td>
</tr>
<tr>
<td>Average CD4, cells</td>
<td>963.91±84.34</td>
<td>879.57–1048.25</td>
</tr>
<tr>
<td>AE on PI boosted schemes, %</td>
<td>17.2</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. 24 months lab assessment after boosted PI switch to integrase inhibitor, n=58

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Boosted PI (95% CI)</th>
<th>Integrase inhibitor (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol, mM</td>
<td>5.95 (5.6–6.10)</td>
<td>4.1 (3.87–4.33)</td>
<td>0.01</td>
</tr>
<tr>
<td>Triglyceridemia, Mm</td>
<td>1.99 (1.84–2.14)</td>
<td>0.99 (0.76–1.22)</td>
<td>0.001</td>
</tr>
<tr>
<td>VL, copies/mL</td>
<td>400 (175–625)</td>
<td>40 (140–60)</td>
<td>0.001</td>
</tr>
<tr>
<td>CD4, cells</td>
<td>963 (879–1048)</td>
<td>1276 (1094–1458)</td>
<td>0.05</td>
</tr>
</tbody>
</table>
contact (41.7%) than MSM (23.0%; p=0.0023). Late diagnoses among adolescents decreased over time but not in last 15 years: 21/67 (31.3%) in 2003–2017 vs 32/111 (28.8%) in 2013–2017 (p=0.74).

Conclusion: There is an increasing contribution of sexual transmission and MSM in new HIV diagnoses in adolescents. HIV-newly infected adolescents are younger, with a growing rate of 15–17 year-old. More than 1/3 present late diagnosis and did not decrease in last 15 years. This emphasizes the vulnerability of this population and the need to develop more effective preventive actions.

PE25/8
Factors associated to late presentation of HIV newly diagnosed adolescents in Spain
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Purpose: Adolescents represent a growing share of new HIV diagnoses. Late presenters (LP) is a universal challenge that also affects adolescents. Nevertheless, data are scarce.

Method: Retrospective study of LP (<350 CD4/ul or AIDS-defining events at diagnosis) in HIV newly diagnosed adolescents (12 to <20 years-old) included in CoRIS and CoRISpe Spanish cohorts until end 2017. CoRIS enrols HIV-naïve patients from adult units and CoRISpe from pediatric units. Demographic, clinical data and way of transmission were analysed.

Results: From 357 HIV newly diagnosed adolescents, 123 (34.5%) were late presenters with a median CD4 rate of 235/µl at diagnosis. LP were mainly male (69.9%) and median age was 18.7 years, similar to general cohort. The main way of infection in LP was sexual (64.2%; 35.8% men who have sex with men (MSM) and 28.4% by heterosexual contact), 21.1% were injection drug users, 7.3% vertical transmission, 3.3% hemoderivates receivers. LP was significantly more frequent for heterosexual transmission (41.7%) than for MSM (23%), p=0.0023. Regarding the origin, 30.4% of MSM born outside Spain were LP vs 18.4% of Spanish MSM (p=0.0757). Foreign women with heterosexual transmission was a vulnerable group with 50% of LP vs 18.4% in Spanish MSM (p=0.0006). Despite mainly behaviourally transmission and younger age, LP rate for middle adolescents (15–17.9 years-old) was as high as for late adolescence (18–19.9 years-old): 34.6% vs 32%; p=0.694. LP among adolescents decreased over time but not in the last 15 years: 34.3% in 2003–2007 vs 28.8% in 2013–2017 (p=0.504).

Conclusion: More than 1/3 of HIV newly diagnosed adolescents were late presenters, with no decline in last 15 years. Adolescents with heterosexual transmission, foreign MSM and heterosexual foreign women presented higher LP rates. Specific approaches are needed to tackle this situation.

PE25/9
Comparison of antiretroviral treatment initiation in HIV newly diagnosed adolescents in Spain
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Purpose: Adolescents represent a growing share of new HIV diagnoses. However, data about antiretroviral treatment (ART) and viral suppression in this population is scarce.

Method: Description of HIV new diagnosed patients 12–20 years-old included in CoRIS (adult) and CoRISpe (pediatric) Spanish cohorts between 1996 and 2017. Comparison of time to initiation of ART and viral suppression depending on sociodemographic and clinical data was performed.

Results: 270 HIV newly diagnosed adolescents were included, 75.6% were male and median age was 18.8 years-old. The way of infection was essentially sexual (89%), in men who have sex with men (61%), mainly born in Spain (58%) and Latin America (29%). 86.3% of adolescents were initially followed up in adult units, while 12.5% in pediatric ones. 88.9% have ever received ART; the rest being mainly early loss of follow-up. Time to ART initiation from diagnosis significantly decreased over time according to evolution of guidelines, but remained 55 days from 2014, period of universal treatment. Median time from ART indication to initiation was significantly lower in early adolescents (12–14 years-old) than older patients (11 vs 26 days, p=0.025), but was similar if followed up in pediatric or adult units.

Conclusion: Despite being a challenging population, adolescent almost achieved 90% in treated and 90% in first viral suppression in our cohort. Younger patients started treatment earlier but achieved suppression later.

PE25/10
Oral self-testing for adolescents and young adults absent or declining to test during home-based HIV testing—a mixed-method study embedded in a cluster-randomized trial in Lesotho (ADORE study)
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1Swiss Tropical & Public Health Institute, Basel, Switzerland 2University of Basel, Basel, Switzerland 3University Hospital Basel, Division of Infectious Diseases and Hospital Epidemiology, Basel, Switzerland 4SolidarMed Lesotho, Butha-Buthe, Lesotho 5SolidarMed Lesotho, Mokhotlong, Lesotho 6SolidarMed Lesotho, Maseru, Lesotho 7Molecular Virology, Department of Biomedicine, University of Basel, Basel, Switzerland

Purpose: Home-based testing, widely used in sub-Saharan Africa, fails to reach high coverage among adolescents and young adults (AYA). ADORE (Adolescent ORal tEsting) is a mixed-method nested study, embedded in a cluster-randomized trial, measuring effectiveness and acceptability of secondary distributed oral HIV self-tests in Lesotho.

Methods: In intervention village-clusters, self-tests were left for absent/declining household members during home-based testing. One present household member was trained on self-test use. Distributed self-tests were followed up by village health workers (VHW). The quantitative outcome was testing coverage among AYA (age 12–24) within 120 days, defined as a confirmed HIV test result or known status, using adjusted random-effects logistic regression. Qualitatively, we conducted in-depth interviews among AYA who did (control–interviews) or did not (case–interviews) use the self-test, following the concept of saturation, coded and analyzed according to the Framework Method. Trial registration: NCT03598686.

Results: 1,065 consenting households with 2,685 AYA were enrolled (intervention arm: 56 clusters; 572 households; 1,447 AYA; control arm: 47; 538; 1,236). In the intervention arm, 937 AYA were absent or declined. Self-tests were left for 790 eligible AYA, and 487 (62%) were returned. In the control arm, 860 AYA were absent or declined; 7 (1%) subsequently tested at a VHW. 2,234 eligible self-tests were left for 790 absent/declining members: 739 (37%) were returned. The intervention effect was greater (37% intervention; 17% control; p=0.001). The intervention effect was greater in males (70% versus 24%; 7.5%), and was particularly successful among males (79% versus 50%; 3.96 [2.81–5.59]; p-interaction <0.001). 11 case- and 10 control-interviews were performed. In-person assistance during and after self-testing, and convenience of testing emerged as key qualitative themes.

Conclusion: Secondary distribution of oral self-tests among AYA increased HIV testing coverage by >35%, and was particularly successful among males. Training of a present household member and the VHW on self-testing is key.
Preterm births in women living with HIV in Switzerland: a 13-year evaluation

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Children’s Hospital of Eastern Switzerland, Infectious Diseases and Hospital Epidemiology, St. Gallen, Switzerland 2Cantonal Hospital St. Gallen, Infectious Diseases and Hospital Epidemiology, St. Gallen, Switzerland 9Bern University Hospital, Department of Pediatrics, Bern, Switzerland 8Lausanne University Hospital, Hospital, Division of Infectious Diseases and Hospital Epidemiology, Zurich, Switzerland 1Institute of Medical Virology, University of Zurich, Zurich, Switzerland 10University Hospital Basel, Department of Obstetrics, Basel, Switzerland 11University Hospital Geneva, University of Geneva, Department of Obstetrics and Gynecology, Geneva, Switzerland 12University Hospital Basel, Basel, Switzerland 13University Children’s Hospital, Division of Infectious Diseases and Hospital Epidemiology, Bern, Switzerland 14Regional Hospital Lugano, Division of Infectious Diseases, Lugano, Switzerland 15Lausanne University Hospital, Service of Pediatrics, Department Women-Mother-Child, Lausanne, Switzerland 5University Hospital Basel, Department of pediatrics, Basel, Switzerland 4Institute of Medical Virology, University of Zurich, Zurich, Switzerland 12Children’s Hospital, Geneva University Hospital, University Basel, Basel, Switzerland 13University Children’s Hospital Zurich, Children’s Research Center, Zurich, Switzerland

Purpose: Combined antiretroviral treatment (cART) and advanced HIV infection are associated with negative pregnancy outcomes, particularly preterm birth. About 10 years ago, we identified a prematurity rate of 24–26% in women with HIV under cART. Here we assess the recent years during more than a decade to identify changes.

Method: We analysed all pregnant women included in the Swiss Mother and Child HIV Cohort Study (MoCHIV) and the linked Swiss HIV Cohort Study (SHCS) from 2005–2017. Preterm births by elective cesarean section were excluded. Gestational age (GA) was available in weeks and additional days within the following week, e.g. GA 37+0 which is equivalent to a term birth.

Results: We evaluated a total of 798 pregnancies in 581 women including 16 twins that were counted separately. 78% (621) of the pregnancies achieved at least GA ≥ 24.86% (536) of them were exposed to the same cART regimen for at least 90 days. Over time, this rate increased from 70% in 2005 to 93% in 2017. 156 pregnancies ended before GA 24, of which 38% (59/156) were spontaneous abortions and 37% (58/156) pregnancy terminations (see Figure 1). 70% (557/621) of neonates were term born. The rate of preterm birth was 10% (64/621) whereof 63% (40/64) were late preterm deliveries (GA > 36 = 36+6). We observed a reduction of preterm deliveries since 2005 from 14.3% in 2005 to 7.3% in 2017 (p < 0.04, see Figure 2).

Conclusion: The rate of preterm births has decreased compared to our previous analysis in 2010 and is now close to the rate in the total population of Switzerland, which declined from 7.4% in 2007 to 7.0% in 2017. It is thus necessary to identify determinants that explain changes in preterm birth, such as e.g. modifications in cART regimens.

Figure 1. Overview of pregnancy outcomes

Figure 2. Gestational age of live born infants from mothers with HIV 2005–2017

PE25/12

Poor clinical outcomes in HIV-infected children who start antiretroviral therapy at an older age

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Purpose: The current standard of care in pediatric HIV is to start antiretroviral therapy (ART) as soon as possible after diagnosis. However, this strategy was only recently implemented in Tanzania and many children in care were started on ART based on clinical or immunological criteria.

Method: A retrospective chart review was performed among children (0–19 years) on ART and attending an HIV clinic in Mbeya, Tanzania from 2015–2018. Children were grouped according to age at ART-initiation and comparison was made of clinical characteristics on their last clinic visit with labs as well as their status by the end of 2018.

Results: This study included 1,813 children (Table 1). Those who initiated ART at earlier ages were currently younger (p < 0.0001) and children who initiated ART by 6 months of age were on ART for less time (p = 0.00075) and were more likely to be on a protease inhibitor (p = 0.00001). Average VL was higher in the <6-month category than the 1–5-years category (p = 0.038727) and on multivariable analysis, the >5-year category had lower odds of having VL < 1000 (AOR, 0.4 [95% CI, 0.2–0.8]). CD4 counts and percentages were lower in the >5-years category (p = 0.0001). More children initiating ART later had both a WHO stage 3/4 condition at initiation (p = 0.000499) and a WHO T-stage (current WHO stage) of 3/4 (p = 0.011239) plus lower odds of having WHO stage 1 at initiation (AOR, 0.2 [95% CI, 0.1–0.5]). Older age groups were found to have worse clinical outcomes (lost to follow-up or death) (p = 0.009529).

Conclusion: Children starting ART later were more likely to have severe clinical disease both at initiation and at time of clinic visit. They were also more likely to have greater immunosuppression and worse clinical outcomes. VL alone may not be a good indication of the clinical status of children on ART.

Table 1. Client characteristics

<table>
<thead>
<tr>
<th>Group (age at initiation)</th>
<th>&lt;6 months</th>
<th>6–12 months</th>
<th>1–5 years</th>
<th>&gt;5 years</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Number</td>
<td>102</td>
<td>86</td>
<td>560</td>
<td>1065</td>
<td></td>
</tr>
<tr>
<td>Female (%)</td>
<td>57 (44)</td>
<td>49 (57)</td>
<td>289 (52)</td>
<td>565 (53)</td>
<td>0.724023</td>
</tr>
<tr>
<td>Age in years</td>
<td>4.56</td>
<td>5.72</td>
<td>8.14</td>
<td>15.11</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Months on ART</td>
<td>50.6</td>
<td>58.8</td>
<td>65.5</td>
<td>62.2</td>
<td>0.00075</td>
</tr>
<tr>
<td>VL in copies/mL</td>
<td>70,435</td>
<td>36,770</td>
<td>13,844</td>
<td>32,520</td>
<td>0.038727</td>
</tr>
<tr>
<td>CD4 in cells/mm³ (#)</td>
<td>1539 (66)</td>
<td>1464 (64)</td>
<td>1139 (401)</td>
<td>656 (756)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>CD4% (#)</td>
<td>34.9 (65)</td>
<td>37.7 (64)</td>
<td>34.7 (391)</td>
<td>27.5 (738)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>WHO stage 3 or 4</td>
<td>72 (71)</td>
<td>75 (87)</td>
<td>462 (83)</td>
<td>805 (76)</td>
<td>0.000499</td>
</tr>
<tr>
<td>Outcome LTIFU or death</td>
<td>2 (96)</td>
<td>1 (76)</td>
<td>3 (508)</td>
<td>12 (237)</td>
<td>0.009529</td>
</tr>
</tbody>
</table>
Prevalence and predictors of unintended pregnancies among HIV positive young adults (14–24 years) attending an urban HIV clinic in Uganda

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Purpose: To assess the predictors of unintended pregnancies among HIV positive young adults attending an urban HIV clinic.

Method: The Infectious Diseases Institute (IDI) adults’ HIV clinic provides care and treatment to over 8,000 patients about 400 of which are young adults. We abstracted data from electronic medical records of all young women aged between 14 and 24 years enrolled at the IDI sexual and reproductive health clinic from January 2012 to December 2018. Descriptive statistics were used to explore baseline characteristics and a logistic regression model was fit at the multivariate analysis to assess factors associated with unintended pregnancies.

Results: A total of 255 women were included in the study. The prevalence of unintended pregnancy was 37.7%. Median (IQR) age, parity and duration on ART was 22 (21–24), 2 (1–2) and 8 (0–28) months respectively; majority of the women were married or cohabiting 160/255 (62.8%); on a first line ART regimen 174/255 (68.2%) and had attained above secondary level education 100/255 (39.2%). At the multivariate level adjusting for age, parity, duration on ART, marital status and education level, young women who were widowed or separated had increased odds (OR=2.9; 95% CI=1.09–7.54; p=0.03) of unintended pregnancy compared to single women. Young women on Efavirenz based regimen had increased odds (OR=1.6; 95% CI=0.95–2.80; p=0.07), with a borderline statistical significance. Age, duration on ART, ART regimen, and education level were not associated with unintended pregnancies.

Conclusion: The prevalence of unintended pregnancies among HIV positive young adults is lower than that in the general population of adolescents in Uganda. Young adults is lower than that in the general population of adolescents in Uganda.

Influence of maternal parameters on birth outcome in HIV-exposed newborns – 11 year observation

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Purpose: The perinatal status of neonates is affected by a range of conventional and HIV-infection related risk factors. Therefore, to study the correlation, we reviewed information on maternal parameters during pregnancy and neonatal parameters at birth.

Method: HIV Out-Patient Clinic of the Hospital for Infectious Diseases in Warsaw is providing integrated gynaecological and HIV care since its constitution in 1994. In collaboration with Department of Children’s Infectious Diseases, we reviewed all pregnancies and neonates occurring between 2006 and 2017 in the clinic. Data on neonates were collected from medical documentation analysis.

Results: In the investigated period, there were 187 pregnancies. Of 159 with known birth outcome, 18 (11.3%) were preterm births, only 1 neonate was very preterm. Median mother’s age at delivery was 31 (IQR: 27.5–34) years, median gestation week at delivery was 38 (37–39). Of 148 children with known HIV status, one patient born in term was HIV-positive (0.7%). In the group of newborns with birth weight <10 percentile (defined as intrauterine growth restriction), the median last CD4 count in women during pregnancy was lower, 318 (113–800) compared to 488 (37–1254) in neonates >10 percentile (p=0.0008). There was a tendency towards a higher risk of neonatal birth weight <10 percentile in the older mothers (p=0.077).

Conclusion: Insufficient maternal immune status is a risk factor for intrauterine growth restriction. Advanced maternal age at delivery may have a probable effect on birth weight. Due to limited study sample, further investigations should be considered.

Microbiota richness and diversity in a cohort of underweight HIV-positive children aged 24–72 months in Cape Town, South Africa

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Introduction: Elements of the human gut microbiome have been found to impact on a range of pathological conditions.Human immunodeficiency virus (HIV) infection disturbs the microbiota-mucosal immune system balance and disrupts the stable microbiome which results in inflammation and chronic HIV pathogenesis.Globally there is a 68.7% prevalence of malnutrition amongst children who are HIV positive. Limited data exists on microbiome diversity of underweight, HIV-infected children in developing countries. This study describes the microbial diversity within a cohort of underweight children on Antiretroviral therapy (ART) & highlights implications for practice.

Methods: This data forms part of a larger randomized control trial of which HIV-positive children aged 24–72 months were recruited from high disease burden areas within Cape Town. Fecal samples, anthropometric data (weight/height) and venous blood (CD4) were collected at baseline and at follow-up visits. Only baseline data was analysed for this study. The microbiota was analysed by culture and molecular-based methods. Anthropometric data was converted to percentiles. Biomedical raw data was exported to STATA for statistical analyses.

Results: More than half the cohort were on the 5th percentile WFA (52%; p=0.03). 65% of children had a CD4 >1,000 cells/µL (p=0.02). The microbiota was enriched with Bacteroides, Clostridium Perfringes, Bifidus, Enterobacteria, Enterococcus and Lactobacilus. Nine children had Fungi growth, indicative of bacterial microbiota disruption. Diminished growth of Clostridium Perfringes and increased growth of Enterobacteria was shown, which is common in the HIV adult population due to inflammation. Enterobacteria has been linked to immune activation and pathogenic activities. Compared to studies of healthy children, this cohort had low diversity of microbiota. Firmicutes, a Bacterial Phyla that is commonly depleted in the HIV population was reasonably well represented in this cohort, which is possibly associated with ART, as ART has been shown to allow for recovery of the microbiota in the HIV adult population.

Conclusion: The potentially pathogenic microbiota contributes to ongoing mucosal inflammation resulting in microbial changes/disease progression. Microbiota manipulation can reduce inflammation, improve absorptive capacity of the GIT overall health of the child which will reduce morbidity and mortality.

Pathogenesis and immunopathogenesis

SHIV162P3 transmission by semen leukocytes is efficiently inhibited by a combination of broad neutralizing antibodies

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Background: The semen of HIV-1 infected subject contains either free infectious virus or cell-associated virus (infected leukocytes). Although the semen of HIV-1 infected subjects contains both free and cell-associated virus, transmission by cell-free virus particles, transmission by seminal leukocytes has been overlooked in studies of cell-cell transmission and related inhibitory factors.
ability of a combination of bNAbS to protect from SHIV162P3 cell–cell transfer by semen leukocytes was tested in vitro in a TzmBL assay. To confirm the data and to extend the panel of bNAbS, neutralization assays using TzmBL and PBMC as target cells were developed using infected splenocytes as surrogate of semen cells.

Results: A combination of 1st generation bNAbS 2F5+2G12+4E10 inhibited cell–cell transmission with equal efficiency when both semen leukocytes and splenocytes were used as donor cells in a TzmBL assay. Protection was highly reduced when the same bNAbS were used in double combination or individually. Interestingly, a series of the so-called “2nd generation bNAbS” (10–1074, PGT128, PGT151 and N6) even when used individually, revealed to be as efficient against cell–cell transmission as the triple combination of the 1st generation bNAbS. Moreover cell-free infection inhibition was achieved with 1 log lower IC50 values compared to cell-associated transmission, whatever it was the bNAb used.

Conclusion: A subset of bNAbS could efficiently prevent cell–cell transmission by semen infected leukocytes, and this property should be considered an important characteristic defining antibody potency for therapeutic or prophylactic antiviral strategies.

PE26/2
Colonic microbiota exhibits disparate associations with HIV-infection and sexual practices

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Purpose: Effective antiretroviral therapy (ART) has prolonged survival and shifted the morbidity spectrum for people living with HIV (PLWH) from AIDS-associated opportunistic infections and malignancies towards age-associated noncommunicable comorbidities (AANCCs), with these being more prevalent in PLWH compared to in age-matched HIV-uninfected individuals. A key contributor to the current disease spectrum includes HIV-associated inflammation and immune activation, the etiology of which in PLWH remains incompletely defined. Gut microbial dysbiosis is thought to be a potential important contributor, but data thus far are conflicting regarding the role that lifestyle factors, including sexual orientation and behavior, and HIV-infection itself have on gut microbial dysbiosis.

Methods: Using 16S rRNA gene sequencing, we profiled the microbiota from fecal samples of PLWH with suppressed viremia on ART and HIV-uninfected individuals. A key contributor to the current disease spectrum includes HIV-associated inflammation and immune activation, the etiology of which in PLWH remains incompletely defined. Gut microbial dysbiosis is thought to be a potential important contributor, but data thus far are conflicting regarding the role that lifestyle factors, including sexual orientation and behavior, and HIV-infection itself have on gut microbial dysbiosis.

Results: Our data provide unique evidence that colonic microbiota exhibit disparate associations with HIV-infection and sexual practices.

Abundance trends differ significantly in both comparison of MSM vs. MSW and PLWH vs. HIV-negatives.

PE26/3
Zonulin indicates loss of intestinal integrity and microbial translocation in HIV+ patients

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Purpose: Damage of the gastrointestinal (GI) mucosa in HIV infection leads to microbial translocation and immune activation, which in turn contributes to non-infectious comorbidities. Combined antiretroviral therapy (cART) leads to only partial restitution of this gut damage. Several biomarkers of the epithelial barrier have been identified, however, some are not specific and others are impacted by cART. Zonulin is a modulator of epithelial tight junctions. Some studies reported an increase of Zonulin in the blood during HIV infection while others reported a decrease. We quantified Zonulin and compared it to inflammatory markers and the viral reservoir in blood, ileum and rectum from HIV patients and controls.

Methods: Biopsies from terminal ileum (TI), rectum (R) and blood (PB) were collected from 5 treatment naive (HIV+ naïve) and 10 cART-treated (HIV+ cART) HIV+ individuals and 11 controls (CTRL). Median time on ART was 6 (9–10). ELISA (ImmunoDioskistix) was used to measure Zonulin in serum. CD4+ T cells and total HIV DNA was quantified in PB, TI and R. Ultrasensitive digital ELISA (Simoa; Quanterix) was used to measure IFN-α in serum and tissue supernatants.
Results: The median CD4+ T cell count [cells/µL] in HIV+ naïve was 70 (30-256) versus 426 (293–787) in HIV+ cART. Zonulin levels [ng/mL] were highest in treatment-naïve HIV+ when compared to cART-treated HIV+ (p=0.004) or CTRL (p=0.0087; HIV+ naïve>HIV+ cART-CTRL). Similarly, HIV+ naïve showed higher IFN-α and HIV-DNA levels in PB when compared to HIV+ cART (IFN-α: p=0.0039; HIV-DNA: p=0.00420). Zonulin was correlated negatively to CD4+ T cell frequencies (r=-0.58, p=0.04) and positively to IFN-α (r=0.65, p=0.05) in the TI.

Conclusion: Zonulin was highest in HIV+ naïve patients. In addition, its levels in blood were associated with loss of intestinal CD4 T cells and increased inflammation in the gut, suggesting that increased levels of systemic Zonulin correlate with intestinal damage.

**PE26/4**

Distinct pro-inflammatory and cardio-protective effects of antiretroviral drugs in vascular endothelial cells

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**Purpose:** Studies have linked cardiovascular disease (CVD) in people living with HIV (PLWH) with certain antiretroviral drugs (ARVs); however, a causative link has not been established. CVD is driven by inflammation of the vascular endothelium leading to increased leukocyte/platelet adhesion and pro-coagulant activity. In addition, the endothelium has cardio-protective, anti-thrombotic properties. Our objective was to compare the effects of different ARVs upon endothelial inflammatory responses to better understand the causes of increased CVD in PLWH.

**Method:** Human umbilical cord vein endothelial cells were treated with ARVs and inflamed with TNF-α. Inflammation was evaluated as cell adhesion molecule (intercellular adhesion molecule [ICAM]-1) and coagulation factor (tissue factor [TF]) expression by flow cytometry. We also determined the molecule (intercellular adhesion molecule [ICAM]-1) and coagulation factor (tissue factor [TF]) expression by flow cytometry. We also determined the endothelial cardio-protective (tissue factor [TF]) expression by flow cytometry. We also determined the molecule (intercellular adhesion molecule [ICAM]-1) and coagulation factor (tissue factor [TF]) expression by flow cytometry. We also determined the molecule (intercellular adhesion molecule [ICAM]-1) and coagulation factor (tissue factor [TF]) expression by flow cytometry.

**Results:** Abacavir sulphate (ABC) increased ICAM-1 and TF expression compared to both tenofovir disoproxil fumarate (TDF, +4.16±1% and +15.4%, p<0.05) and tenofovir alafenamide when compared to both tenofovir disoproxil fumarate (TDF, +4.16±1% and +15.4%, p<0.05). Microparticles isolated from ABC-treated endothelium significantly enhanced collagen-evoked platelet activation (integrin activation and α-granule release). The ability to breakdown the platelet activator ADP was enhanced by TDF and TAF (+44.4% and +46.0%, p<0.05) but ABC had no significant effect.

**Conclusion:** ABC, TDF and TAF differentially impact the endothelial inflammatory response. ABC induces effects that are pro-inflammatory and would be expected to increase CVD, whereas TDF and TAF have anti-thrombotic and therefore potentially cardio-protective effects. Further work is required in more relevant cell types and in clinical settings with licensed ARV combinations to establish whether these inflammatory changes elucidate mechanisms by which ARVs may affect CVD in PLWH.

**PE26/5**

Bacterial translation kinetics in HIV-1 infection: from acute to chronic stages

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**Purpose:** In acute HIV infection (AHI), viral load (VL) increases and the virus reaches gut, where intestinal epithelial barrier disruption occurs, resulting in bacterial translocation (BT) and the following immune activation. The aim of this study is to evaluate the BT kinetics during the different AHI stages (defined by Fiebig classification).

**Method:** In this retrospective study, 10 subjects diagnosed during AHI (4 in Fiebig II, 3 in Fiebig III and 3 in Fiebig IV) were included (8/10 were male with a median age of 22 years at the time of diagnosis). In addition to these 10 plasma samples, other 39 plasma samples were analysed from diagnosis until antiretroviral therapy (ART) and VL suppression. 40 samples from ART-suppressed late-chronic (LC) infected subjects were analysed as control. Days post-infection were estimated according to Fiebig stage at the time of diagnosis. sCD14, IFABP and LPS BT biomarkers were measured on all plasma samples by ELISA.

**Results:** sCD14 levels were higher in Fiebig III stage (median: 5.99 µg/mL, LPS levels were higher in Fiebig IV stage (median: 6.25 EU/mL) while IFABP levels were higher in Fiebig VI stage (median: 0.86 ng/mL) than in other Fiebig stages (Table1). IFABP had highest levels at 28-80 days post-infection (p=0.04), sCD14 levels were higher at 15–30 days post-infection (p=0.001), while LPS showed similar trend to sCD14 (p=0.51). sCD14, IFABP and LPS medians of LC infected subjects are showed in Table1.

**Conclusion:** sCD14 and LPS have the highest values during the first stages of infection. While LPS decreases along time, sCD14 shows similar dynamic to LPS, but finally increases at LC infection. Moreover, we show that IFABP increases along time and establishes at LC infection. These results suggest that BT occurs in large-scale at the first term of infection and is stable at LC stage, independently of an increase of other inflammation biomarkers (as sCD14).

**Table 1.** Samples median and IQR values

<table>
<thead>
<tr>
<th></th>
<th>Fiebig II</th>
<th>Fiebig III</th>
<th>Fiebig IV</th>
<th>Fiebig V</th>
<th>Fiebig VI</th>
<th>LC</th>
</tr>
</thead>
<tbody>
<tr>
<td>N samples</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>25</td>
<td>14</td>
<td>40</td>
</tr>
<tr>
<td>N subjects</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>7</td>
<td>40</td>
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<tr>
<td>Log VL</td>
<td>6.64 (6.61, 7.637, 7)</td>
<td>6.80 (6.58, 7.675)</td>
<td>6.90 (7.492, 8.944)</td>
<td>1.96 (1.70, 1.5)</td>
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<td></td>
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<tr>
<td>CD4 (cell/µL)</td>
<td>586 (577, 595)</td>
<td>NA</td>
<td>NA</td>
<td>615 (663, 750)</td>
<td>727 (598, 978)</td>
<td></td>
</tr>
<tr>
<td>CD8 (cell/µL)</td>
<td>940 (875, NA)</td>
<td>NA</td>
<td>NA</td>
<td>954 (816, 971)</td>
<td>860 (631, 1185)</td>
<td></td>
</tr>
<tr>
<td>sCD14</td>
<td>2.92 (2.81, 5.98)</td>
<td>4.73 (3.78, 3.31)</td>
<td>7.24 (6.68, 7.37)</td>
<td>2.44 (2.24, 2.59)</td>
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<tr>
<td>IFABP</td>
<td>0.33 (0.15, 0.30)</td>
<td>0.25 (0.17, 0.83)</td>
<td>0.36 (0.31, 0.86)</td>
<td>0.65 (0.55, 1.03)</td>
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<tr>
<td>LPS</td>
<td>2.52 (1.95, 3.06)</td>
<td>2.47 (6.58, 6.29)</td>
<td>2.99 (2.26, 3.22)</td>
<td>2.06 (0.69, 1.47)</td>
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</tr>
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</table>

**PE26/6**

Mitochondrial antioxidants attenuate In vivo liver fibrosis in chronic treated HIV

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**Purpose:** Elucidating mechanisms of HIV-related liver fibrosis will set the basis for therapies that can lessen its impact including cirrhosis and mortality. As mitochondria are the main source of cellular oxidative stress, the mitochondrial antioxidant MitoQ may target HIV-related liver fibrosis. We used a physiologically relevant humanized mouse model of chronic treated HIV to study whether MitoQ attenuates in vivo HIV- and/or ART-driven liver fibrosis.

**Method:** The C57BL/6 Rag2−/−−/−cl−−/−CD47−/− Bone Marrow/Liver/Thymus mice do not develop early graft versus host disease and thus HIV- and/or ART-driven changes on liver fibrosis can be dissected in vivo. After 4 weeks of infection with the dual-tropic 89.6 HIV-1 virus, mice (n=20) were treated with daily emtricitabine (200 mg/kg), tenofovir (208 mg/kg), ritelgravir (80 mg/kg) for up to 12 weeks. MitoQ was given in water at 250 µM daily. The groups were: A (n=5): uninfected (HIV-); B (n=10): HIV+; ART; C (n=10): HIV+/ART+ MitoQ. Liver fibrosis was assessed histopathologically by Picrosirius red staining of fibrotic mouse liver. Real time PCR was used to determine mRNA levels of key mediators of liver fibrosis (TIMP-1, TGF-beta, MMP-9). Results are described as mean± SEM and t-test was used for statistical analysis.

**Results:** Potent ART suppressed viremia within 4 weeks. HIV+ mice exposed to HIV/ART for 12 weeks demonstrated a ~12-fold increase in fibrosis (Figure).
In the liver of HIV-1+ART+ mice there was a mean 22%, 16%, 18% and 12.3% increase in Picrosirius Red signal, TGF-β, TIMP-1 and MMP-9 mRNA levels, respectively, compared to uninfected mice (p<0.05). MitoQ attenuated HIV/ART-induced increase in Picrosirius Red signal, TGF-β, TIMP-1 and MMP-9 (p<0.05).

Conclusion: MitoQ attenuated HIV/ART-driven increase in collagen content and molecular mediators of fibrosis in the liver. Further studies are needed to determine whether MitoQ can be a novel therapeutic strategy for liver fibrosis in chronic treated HIV.

**PE26/7**

Mitochondrial antioxidants attenuate in vivo mitochondrial dysfunction and exhaustion in T cells in chronic treated HIV

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**Purpose:** Elucidating how oxidative stress and mitochondrial dysfunction contribute to T cell impairment in chronic HIV infection despite potent antiretroviral therapy (ART) could provide new therapies to reduce aging of the immune system related to morbidity and mortality. Oral MitoQ has successfully been tested in vivo (animals, clinical trials) for oxidative damage-related states and T cell exhaustion in chronic viral infections such as hepatitis. We used a physiologically relevant humanized mouse model of chronic treated HIV to study whether MitoQ attenuates in vivo HIV- and/or ART-driven mitochondrial and T cell dysfunction (exhaustion).

**Method:** After 4 weeks of infection with the dual-tropic 89.6 HIV-1 virus, C57BL/6 Rag2−/−γc−/−CD47−/− Bone Marrow/Liver/Thymus humanized mice (n=20) were treated with daily emtricitabine (200 mg/kg), tenofovir (208 mg/kg), raltegravir (80 mg/kg) for up to 12 weeks. MitoQ was given in water at 250 μM daily. The groups were: A (n=5): uninfected [HIV-]; B (n=10): HIV−/ART−; C (n=10): HIV−/ART/MitoQ. Multicolor flow cytometry was used to assess human T cell (CD3+) exhaustion (PD-1+) and Mitochondrial membrane potential (MMP) (staining with the fluorochrome TMRE). Reduced fluorescence signal of TMRE suggests reduced MMP and mitochondrial dysfunction. Results are described as mean± SEM and t-test was used for statistical analysis.

**Results:** Potent ART suppressed viremia within 4 weeks. HIV+ mice exposed to HIV/ART for 12 weeks demonstrated a mean 36% increase in PD-1 expression and a mean 35% reduction in MMP in CD3+ T cells compared to uninfected mice (Figure) (p<0.05). MitoQ attenuated HIV/ART-induced increase in PD-1 MFI and decrease in TMRE MFI in CD3+ T cells (p<0.01).

**Conclusion:** MitoQ attenuated HIV/ART-driven increase in exhaustion and mitochondrial dysfunction in T cells. Further studies are needed to determine whether MitoQ can be a novel therapeutic strategy for immune dysfunction in chronic treated HIV.

**PE26/8**

Inhibition of caspase 1 reduces viral load, CD4 T cell depletion and immune activation in HIV-1 infected humanized mice

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**Purpose:** HIV-1 infection results in the activation of inflammasome involving IFI16, NLRP3, caspase-1 and release of IL-1β and IL-18. Early inflammasome activation may facilitate viral spread and establishment of viral reservoirs. We evaluated the effect of the caspase-1 inhibitor VX-765 on virological and immunological parameters after HIV-1 infection in humanized mice.

**Method:** NSG mice engrafted with human CD34+ hematopoietic stem cells were infected with HIV-1 JRCSF. 15 mice were first sacrificed serially to investigate kinetics of the HIV-1 related inflammasome activation. Infected mice (n=24) were then treated daily injected with VX-765 or vehicle from day 1 post infection on, for 21 days. Blood and organs were collected at different time points and analysed for inflammasome genes expression, cytokines levels, viral load and CD4 cell count.

**Results:** HIV-1 RNA disseminated within 3 days post-infection in different organs, in concomittance with increased expression of NLRP3 and IL1-β such as in lymph nodes (fold change of 3.1 and 1.84) and bone marrow (fold change of 2.74 and 4.96), respectively (p<0.001). IFI16 expression peaked at D24 in lymph nodes and Bone marrow (fold change of 1.49 and 1.64, p<0.05) and coincides with increased IL-18 levels in plasma (6.89 vs. 83.19 pg/mL, p<0.004). Treatment with VX-765 significantly reduced TNF-α at day 11 (0.47 vs. 2.2 pg/mL, p=0.045), IL-18 at day 22 (7.8 vs 23.2 pg/mL, p=0.04), CD4+ T cells (44.3% vs. 36.7%, p=0.01) and the CD4/CD8 ratio (0.92 vs 0.67, p=0.005) after 21 days of infection in plasma. Importantly, viral load and total HIV DNA were decreased in VX-765-treated mice (4.26 vs. 4.89 log 10 copies/mL, p<0.027).

**Conclusion:** We report early inflammasome activation associated with HIV replication in tissues. Inhibition of the inflammasome activation early upon infection with HIV-1 improves CD4+ T cell homeostasis, viral loads as well as immune activation.
Effect of early initiation of ART on alterations in natural killer cells in HIV infected pediatric patients

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Purpose: HIV disease progression is faster in children. According to the recent NACO guidelines, all children diagnosed HIV-1 positive and below the age of two should be initiated on ART therapy, irrespective of their CD4 counts. However, on antiretroviral therapy, the viruses in the infected individuals develop resistance mutations, as is observed in the ART non-responders. Whether early initiation of ART helps to preserve immune cells like NK cells, which play a key role in inhibiting viral replication and also in regulating the host adaptive immune response to HIV infection from early loss or promote their recovery is yet not known and therefore it is important to assess the effect of early initiation of ART on the immune responses in the HIV-1 infected children (ART responders and non-responders).

Methods: In a longitudinal study on 30 HIV infected pediatric patients <5 years and uninfected pediatric healthy controls, alterations in NK cell subset along with their activating, inhibitory and cytotoxic receptor were enumerated and functionally characterized by flow cytometry and correlated with CD4 count, viral load, neutralization response and plasma ADCC activity before and after early initiation of ART at every 6 month follow-up.

Results: Circulating NK cells were significantly increased after first follow up of ART initiation and the activating (NKG2D, NKG2C), cytotoxic (NKp30, Nkp44, Nkp40) and inhibitory receptor (NKG2A, KIR) of NK cells were also restored to the normal level. The CD4 counts were increased and viral load decreased as compared to the ART naive patients. Neutralization response and plasma ADCC activity is improved after 6 months of ART initiation.

Conclusion: Our study suggest that early initiation of ART is beneficial to the patients, since our study is a longitudinal study results will be further confirmed after a long follow ups.

HIV-DNA levels, HLA-B*27 and HLA-DRB1*13 among LTNP, ECs and HIV controllers

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Background: The aim of this study was to determine the association of HLA B*27 and HLA-DRB1*13:03 with HIV-DNA in Elite Controllers, Long-Term Non-Progressors, HIV Controllers, ART-naive and ART treated patients (pts).

Methods: We evaluated 231 HIV-1 pts from the ICONA and the Elvis Cohorts categorized in 5 distinct groups: 20 EC (ART-naive pts, always with HIV-RNA <50 cps/mL); 35 long-term non-progressors (LTNP; ART-naive pts for >28 years, with VL <1,000 cps/mL and CD4+ ≥500 cells/µL); 17 HIV controllers (ART-naive pts, always with HIV-RNA 50–1000 cps/mL); 122 ART-naive pts (pts who started ART, with HIV RNA >50 cps/mL and CD4+ <500 cells/µL); 37 pts with suppression of ART (HIV-RNA <50 cps/mL). Total HIV-DNA was extracted from PBMCs by droplet digital PCR (ddPCR) and classified as undetectable if below the detection limit. HLA-B*27 rs4349859 and HLA-DRB1*13:03 rs424232 genotypes were determined. Multivariable linear regression was performed to assess SNP’s association with HIV-DNA values.

Results: rs 4349859 GG genotype was found in 16%, 6%, 14%, 8% and 9% of EC, HIV-controllers, LTNP, ART-naive and ART-treated pts, respectively (p=0.819, Table 1).

Table 1. Characteristics at HIV-DNA determination of unmatched HIV-1 infected subjects

Table 2. Multivariable linear regression: factors associated with HIV-DNA.

Macromolecule uptake across intestinal epithelia in HIV infection

C Grunhagen1, SM Knug2 and H-J Eppe1


Purpose: Increased serum levels of microbial macromolecules are associated with chronic immune activation, disease progression and comorbidity in HIV infection. Although they have been attributed to a pathological influx across the gut mucosa, it is unknown how these microbial components cross the intestinal mucosal barrier. Prior studies demonstrated an increased permeability to small solutes such as electrolyte or monosaccharides.
Therefore, the mechanisms described cannot be attributed to the mucosal translocation of macromolecules. In this study, we quantified macromolecule translocation across the gut mucosa of HIV infected patients and performed mechanistically studies on the translocation processes involved. Methods: Epithelial barrier function and transepithelial transport of macromolecules (FITC-Dextran 4000 (FD4, 4 kDa) and horseradish peroxidase (HRP, 44 kDa)) were quantified by means of Ussing chamber experiments on duodenal and colon mucosa endoscopically obtained from HIV-infected individuals and uninfected controls. The contribution of epithelial apoptosis and transcytosis to macromolecular transport was investigated by transwell flux measurements in monolayers of cultured intestinal cells (T84) using inducers and inhibitors of apoptosis at 37 °C and 14 °C. Epithelial apoptosis was quantified by the SensoLyte®3C Homogenous AFC Caspase-3/7-Assay. Results: FD4 and HRP fluxes across the mucosa as well as epithelial apotoses were increased in untreated HIV+ patients compared to controls but tended to normalize in patients on antiretroviral therapy. In cultured epithelial cells, induction of apoptosis increased permeability to both macromolecules. Inhibition of active transcytosis at 14 °C revealed a reduced in translocated HRP in both control as well as treated T84 cells. Conclusion: For the first time, an increased mucosal macromolecule translocation has been directly demonstrated in intestinal mucosa obtained from HIV-infected patients. Our data indicate that epithelial apotoses represent an unspecific translocation pathway for both, medium and large size macromolecules, whereas large size macromolecules seem to predominantly translocate via active transcytosis.

**PE26/12**

**Immune cell activation as a risk factor for hypertension in people living with HIV in Sub-Saharan Africa using the recent American Heart Association and American College of Cardiology Guidelines**

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Purpose: This study was aimed at determining factors associated with hypertension and the role of immune activation in People living with HIV (PLWH) using the new hypertension guidelines by the American Heart Association (AHA) and the American College of Cardiology (ACC) in Sub-Saharan Africa.

Methods: We conducted three cross-sectional, one systematic and one prospective study. The World Health Organization Stepwise approach to Surveillance (WHO STEPS) and the international physical activity questionnaire (IPAQ) were used to collect data for cross-sectional studies while Preferred reporting items for Systematic reviews and meta-analyses was employed for the systematic study. FlowJo for flowcytometry analysis and Statistical evaluations were employed to elucidate relationships between hypertension and response variables.

Results: Factors significantly associated with increased odds for developing hypertension among 226 PLWH after adjustments in multivariate logistic regression were waist circumference, sedentary lifestyle, age, body mass index, employment status, fasting blood sugar, table salt consumption and moderate physical activity respectively (p<0.05). 94% had uncontrolled blood pressure. The new AHA/ACC criteria for hypertension shifted 26% of the originally normotensives into hypertension category. Hypertension was associated with higher neutrophil, white blood cell counts and neutrophil lymphocyte ratio (p=0.06).

Conclusion: Elevated levels of Gal-9 in perinatally HIV-infected children sustain even during ART. The demonstrated loss of tight junction integrity by rGal-9 along with elevated sCD14 suggest the role of Gal-9 in microbial translocation and chronic inflammation observed in ART-treated children. Targeting Gal-9 either by exploiting its secretory pathways or competitive blockade may serve as novel therapeutic approach to control HIV-driven inflammation that persists during ART.

**PE26/13**

**Increased level of plasma Galectin-9 is associated with microbial translocation in perinatally HIV-infected children**

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Purpose: Perinatal HIV infection is distinct from chronic HIV infection in adults in terms of rapid disease progression, higher viral load and increased depletion of CD4+ lymphocytes. Galectin-9 (Gal-9) is a component of the first waves of cytokine storm in acute HIV infection that remains elevated in antiretroviral therapy (ART)-suppressed HIV-infected individuals. The elevated levels of Gal-9 in chronic HIV infection despite viral suppression in adults suggest that it may contribute to ongoing inflammation. Here we seek to investigate the levels of Gal-9 in treated and untreated HIV-infected children compared to healthy controls and its role in microbial translocation and inflammation.

Methods: Gal-9 and soluble CD14 (sCD14) were measured in the plasma of 15 treated and 15 untreated HIV-infected children, and 10 healthy controls by sandwich ELISA. The effect of rGal-9 on tight junction proteins, Claudin-4 and ZO-1, was studied in gut epithelial cell-line HT-29, using immunofluorescence and qRT-PCR.

Results: Increased levels of Gal-9 were found in treated (Median = 10.7 ng/mL) and untreated (Median = 13.6 ng/mL) HIV-infected children as compared to healthy controls (Median = 6.7 ng/mL). Plasma levels of Gal-9 showed a strong positive correlation (Spearman r = 0.64, p < 0.0001) with sCD14, a marker of microbial translocation, both in treated and untreated HIV-infected children. Immunofluorescence revealed disruption of Claudin-4 tight junctions after 24 h of stimulation of HT-29 cells with 500 nM rGal-9. qRT-PCR results also showed 4 folds downregulation of Claudin-4 (p<0.03) and ZO-1 (p<0.01) tight junctions.

Conclusion: Elevated levels of Gal-9 in perinatally HIV-infected children sustain even during ART. The demonstrated loss of tight junction integrity by rGal-9 along with elevated sCD14 suggest the role of Gal-9 in microbial translocation and chronic inflammation observed in ART-treated children. Targeting Gal-9 either by exploiting its secretory pathways or competitive blockade may serve as novel therapeutic approach to control HIV-driven inflammation that persists during ART.

**Pharmacology, pharmacogenomics and drug interactions**

**PE27/1**

**Efficacy and safety of artemether-lumefantrine as treatment for Plasmodium falciparum uncomplicated malaria in adult patients on efavirenz based antiretroviral therapy in Zambia: an open label non-randomized interventional trial**

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1Tropical Diseases Research Centre, Clinical Sciences, Ndola, Zambia

2University of Malawi, College of Medicine, Blantyre, Malawi

3Tropical Diseases Research Centre, Biomedical Sciences, Ndola, Zambia

Purpose: HIV-infected (HIV+) individuals on antiretroviral therapy (ART) require treatment with artemisinin-based combination therapy (ACT) when infected with malaria. Artemether-lumefantrine (AL) is the most commonly-used ACT for treatment of Plasmodium falciparum (Pf) malaria in Africa but there is limited evidence on the safety and efficacy of AL in HIV+ individuals on ART, among whom drug-drug interactions are expected. We assessed the day 42 adequate clinical and parasitological response (ACPR) and incidence of adverse events (AEs) in HIV+ individuals on efavirenz-based ART with uncomplicated Pf malaria treated with AL.
Method: We conducted a prospective open label non-randomized interventional clinical trial at St Paul’s Hospital, in northern Zambia involving 152 patients aged 15–65 years with uncomplicated HIV who were on efavirenz-based ART. They received a 3-day directly-obtained standard treatment of AL and were followed up until day 63.

Results: Enrolled patients had a baseline geometric mean (95% CI) parasite density of 1,108 (841–1,463). 16.4% (25/152) of the participants had a recurrent malaria episode by day 42. PCR data was available for 17 of the patients with recurrences and demonstrated re-infection in all making the PCR-adjusted day 42 APCR 100% in the 144 patients who could be evaluated. Even when patients with missing PCR data were considered very conservatively as failures, the day 4 APCR was over 94%. None of the participant, disease or treatment characteristics, including day 7 lumefantrine concentrations, predicted the risk of malaria recurrence by day 42. AL was well tolerated following administration.

Conclusion: AL was well tolerated and efficacious in treating uncomplicated HIV-infected adults on efavirenz-based ART. However, a fairly high proportion of participants experienced a recurrent malaria infection which highlights the need for additional malaria prevention measures in this sub-population after treatment with AL.

PE27/2

Ritonavir-boosted darunavir plus two nucleoside reverse transcriptase inhibitors versus other regimens for initial antiretroviral therapy for people with HIV infection: a systematic review

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¹American University of Armenia, Yerevan, Armenia ºUniversity of California, San Francisco, USA

Background: Darunavir is a second-generation protease-inhibitor used with ritonavir (DRV/r) and two nucleoside reverse-transcriptase inhibitors as an option in first-line antiretroviral treatment (ART).

Methods: We systematically reviewed randomized controlled trials (RCTs) of DRV/r versus other regimens in patients initiating ART. We searched five bibliographic databases and other key resources. We had no language limitations. We assessed bias risk with the Cochrane tool and used GRADE to assess evidence quality. We report findings in terms of risk ratio (RR) with 95% confidence intervals (CI).

Findings: Three RCTs met inclusion criteria. In plasma viral load suppression, DRV/r underperformed ritonavir-boosted lopinavir at 48 weeks (RR 1.13, 95% CI 1.03–1.25), 96 weeks (RR 1.11, 95% CI 1.02–1.21), and 192 weeks (RR 1.20, 95% CI 1.07–1.35). DRV/r was similar to dolutegravir at 48 weeks (RR 0.96, 95% CI 0.87–1.06) but less effective at 96 weeks (RR 0.84, 95% CI 0.75–0.93). At 96 weeks, DRV/r underperformed raltegravir (RR 0.94, 95% CI 0.88–0.99) but was similar to ritonavir-boosted atazanavir (RR 1.02, 95% CI 0.96–1.09). Overall bias risk was moderate. Evidence quality was also moderate. Interpretation. Initial ART regimens using DRV/r should be considered in future World Health Organization guidelines.

PE27/3

Towards individualization of antiretroviral therapy – more cost-effective than dose intensification in patients

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¹National Institute of Immunohaematology, Transfusion Transmitted Diseases, Mumbai, India ºK.E.M. Hospital, Medicine, Mumbai, India

Background: As a result of the policy shift to “test and treat”, an exponential increase in the number of people receiving ART may be expected in the near future. Moreover, there is no pharmacogenetic algorithm strategy for decreasing the quantity of active pharmaceutical ingredients required to cover the need of ART regimens.

Objectives: To explore the role of gene polymorphisms in drug metabolism enzymes and drug transporters in ART associated adverse toxicities in HIV patients in India. To measure plasma ART concentration in patients using HPLC and its correlation with genotypes.

Method: Sixty-six HIV-1 patients on Zidovudine and hundred on Tenofovir based combinational therapy were enrolled from the KEM Hospital in Mumbai. Genotype analysis was performed with the SEQUENOM MassARRAY iPLEX pro PGx 74 panel. ART drug levels were quantified by HPLC. The Olerup SSP was used for HLA typing. Odds ratios (OR) with 95% confidence intervals were calculated to assess patient’s increased risk of developing rash in comparison with Tolerant.

Results: Patients with allele G in ABCB1 gene whereas allele T in CYP2B6 gene is associated with EFV toxicity like neuropathy. CYP2B6-516 G/G, Q/T and T/T genotypes were found in 68%, 21% and 11%, respectively. (Fig. 1). The median EFV plasma concentration was 3,238 ng/mL 10 (10%), 72 (72%) and >4,000 ng/mL, respectively. (Fig. 2) The NVP/EVF rash risk appears to depend on the presence of the predisposing alleles HLA-DRB1*14, HLA-DQB1*05 and HLA-DQB1*02 (Table 1). Also, alleles HLA-A*11, HLA-B*56:01:01:01, HLA-B*52:01:01:01 and HLA-C*12 may play a protective role in EFV/NVP hypersensitivity reaction (Table 2).

Conclusion: The various genetic factors will aid in designing effective dosing/treatment strategies. The strong association between HLA alleles and ART induced hypersensitivity reaction can be utilized to avoid life threatening consequences in HIV infected patients in India.

Association of MHC Non-classical markers in Tolerant and Non-tolerant groups

<table>
<thead>
<tr>
<th>HLA-Non-classical markers</th>
<th>Tolerant</th>
<th>EFV/NVP Rash</th>
<th>p value</th>
<th>odds ratio</th>
</tr>
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<tr>
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<td></td>
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</tr>
<tr>
<td>*14 0/17</td>
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<tr>
<td>HLA-DQB1</td>
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<tr>
<td>*05 3/17</td>
<td>11/16</td>
<td>0.005</td>
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<td>*02 1/17</td>
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Association of MHC classical markers in Tolerant and Non-tolerant groups

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<thead>
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<th>MHC Classical marker</th>
<th>Tolerant</th>
<th>EFV/NVP Rash</th>
<th>p value</th>
<th>odds ratio</th>
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<td>HLA-C*12</td>
<td>9/17</td>
<td>0/16</td>
<td>0.001</td>
<td>0.001</td>
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<tr>
<td>*03 1/17</td>
<td>4/16</td>
<td>0.17</td>
<td>5.33</td>
<td></td>
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</tbody>
</table>
The valproic acid–dolutegravir drug–drug interaction is based on displacement of protein binding and unlikely to be clinically relevant.

Purpose: Previous literature suggests that there is a drug-drug interaction (DDI) between dolutegravir (DTG) and valproic acid (VPA) that leads to >80% decreased DTG plasma concentrations1. Possible explanations include induction of DTG's metabolizing enzymes by VPA, impaired DTG absorption due to complexation of DTG by excipients in VPA, or competition for binding sites on plasma proteins. In this pharmacokinetic (PK) sub study, we evaluated DTG-PK in HIV-infected subjects on DTG-containing regimens participating in the “LRAs United as a Novel Anti-HIV strategy” (LUNA) study.

Methods: Intrasubject comparisons were made for DTG PK (50 mg QD) with and without co-administration of VPA (30 mg/kg BID for 14 days). Trough samples for total DTG, free DTG, and DTG-glucuronide plasma concentrations were taken on Day 0 (upon start of VPA and after 6 h), on Day 1, 7, 14, and finally 28 days after VPA was stopped on Day 42 (table 1). Subjects in study arms without VPA served as controls.

Results: Ten subjects on DTG were included six of whom received VPA. Preliminary results of four subjects (three on VPA) showed total DTG trough levels (geometric mean (GM)) prior and after VPA of 1.8 mg/L on Day 0 and 1.5 mg/L on Day 42. During VPA administration total GM DTG levels decreased sharply to 0.53–0.69% without VPA administration as 0.29–0.30% without VPA administration (figure B). All free DTG concentrations were above the proposed in vitro EC90 value for unbound DTG of 0.9 microg/L2 (not shown).

Conclusion: Our data confirm the reported decrease in total DTG plasma concentrations after addition of VPA. It can be explained by displacement of protein binding of DTG by VPA. This DDI is probably not clinically relevant.

Table 1. DTG sampling

<table>
<thead>
<tr>
<th></th>
<th>Day 0</th>
<th>Day 1</th>
<th>Day 7</th>
<th>Day 14</th>
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<td>Yes</td>
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<td>6-hour sample</td>
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Median efavirenz (EFV) plasma concentrations, by CYP2B6-516 genotype

PE27/5

BESIDE – clinical relevance and implications for management of antiretroviral therapy due to recreational drug use in PLWH in Germany

B Funke1, K Martin2, CD Spinner3, S Christensen2, H Heiken4, H Knechten5, S Usadel2, T Wünsche7 and V Witte1

1. MSD Sharp & Dohme GmbH, Haar, Germany 2. Technical University of Munich, School of Medicine, University Hospital rechts der Isar, Department of Medicine II, Munich, Germany 3. Center for Interdisciplinary Medicine (CIM), Munich, Germany 4. Praxis Georgstrasse, Hannover, Germany 5. PZB Aachen, Medical Center for Infectious Diseases, Aachen, Germany 6. Infektionsmedizin Freiburg, Freiburg, Germany 7. Praxis Wünsche, Berlin, Germany

Recreational drug use among PLWH in Germany is common [EACS 2017]. This puts patients at risk for drug–drug interactions potentially leading to adverse events and/or loss of efficacy of antiretroviral therapy (ART). Here, we assessed the clinical relevance of illicit drug consumption and potential implications for management of ART.

BESIDE was a cross-sectional study, evaluating the prevalence of concomitant diseases and co-medications including OTC and illicit drugs in PLWH on ART. Regional distribution of study sites (n=20), consecutive recruitment and age-stratified sampling ensured a representative sample of the PLWH population in Germany. Data on recreational drug use were gathered via anonymized patient questionnaires.

Between 09/2016 and 12/2018, centers collected data of 453 PLWH on ART. A high proportion of patients with data available (76%: 223/293) consumed recreational drugs, 21% [47/223] to stimulate sexual activities. 71% [207/223] of patients had been asked about drugs by their doctors and 66% [149/223] had been educated on potential risks and interactions. However, no more than 29% [65/223] of patients sought consultation with their doctor about their drug use and only 7% [15/223] saw a problem in the use of drugs in combination with ART. Strikingly, 39% [86/223] of patients had undergone medical treatment and 36% [81/223] had been hospitalized due to their drug consumption, with even more concerning numbers in patients aged <30 years.
Drug-drug interactions between antiretrovirals and carbamazepine or oxcarbazepine: a real-life investigation

D Cattaneo, S Baldelli, V Cozzi, M Fusi, A Tzori, V Micheli and C Gervasoni

Purpose: Carbamazepine and oxcarbazepine are strong inducers of metabolic enzymes. For this reason, potential drug-drug interactions (DDIs) may take place between these two drugs and antiretrovirals. Here, we aimed to assess the relevance of these DDIs in real life clinical settings.

Methods: Patients treated concomitantly with carbamazepine or oxcarbazepine and contraindicated antiretrovirals for at least three months were considered. Data on therapeutic drug monitoring (TDM) of both antiepileptic and antiretrovirals trough concentrations were collected and compared with those from HIV-positive patients regularly followed in our hospital not taking antiepileptic drugs.

Results: Eleven HIV-positive patients given carbamazepine or oxcarbazepine were identified (8 men, 3 women, mean age 52±8 years). These patients were given oxcarbazepine or carbamazepine from 3,126±2,267 days for idiopathic epilepsy (n=6), post-infection epilepsy (n=2), post ischemic stroke epilepsy (n=1), and trigeminal neuralgia (n=2).

The TDM evaluations for carbamazepine and oxcarbazepine resulted within the therapeutic ranges, a task reached by wide distribution in the daily drug doses (Figure 1). Tenofovir trough concentrations measured in HIV-infected patients given concomitantly one of the two antiepileptics with tenofovir disoproxil fumarate (49±13 vs. 109±62 nm/L; p=0.115) or with tenofovir alafenamide (11.4±3.5 nm/L vs. 17.8±7.8; p=0.246) showed drug concentrations comparable with values usually measured in the overall population of HIV-infected patients routinely followed in our hospital not taking antiepileptic drugs.

Conclusions: Coadministration of carbamazepine or oxcarbazepine with atazanavir or dolutegravir should be avoided; for these two drugs, the adoption of TDM is strongly advisable, eventually combined with increased antiretroviral doses.

Drug-drug interactions between dolutegravir (DTG) and immunosuppressant drugs (IS) in HIV-infected patients with solid organ transplantation (SOT): a single-arm clinical trial (DTGSOT)

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¹HIV Unit. Arnau de Vilanova & Santa Maria University Hospitals –IRB, Lleida, Spain ²Hospital Clinic – IDIBAPS, University of Barcelona, Barcelona, Spain

Purpose: Dolutegravir (DTG) is a non-boosted integrase inhibitor, metabolized primarily by UGT1A1, playing CYP3A a minor role, neither inducer nor inhibitor of cytochrome P450 or glucuronidation. Therefore, DTG could avoid drug–drug interactions (DDI) with calcineurin and mTOR inhibitors, although a potential DDI could exist with mycophenolic acid (MPA) which also is glucuronidated (UGT1A9). However, there is limited information in the transplantation setting.

The aim was to know the pharmacokinetic (PK) profiles of IS and DTG (plus two NRTIs) in HIV-infected SOT recipients.

Method: Single-arm trial including 12 consecutive HIV-infected SOT adult recipients on stable and effective ART who were switched from RAL-based to DTG-based ART. Patients maintained the same doses of IS drugs during the study period. The areas under the concentration-time curve (AUC), maximum (Cmax) and trough concentrations (Cmin) of DTG and RAL were determined by UPLC/MS/MS and HPLC/Fluorescence detector methods, respectively. The same PK parameters were analyzed for tacrolimus, cyclosporin and MPA prior to and two weeks following ART switch, using standard immunoassays.

Results: There were six kidney, five liver and one cardiac HIV-infected transplant recipients. One kidney recipient left the study due to neurocognitive DTG side effects. Median (IQR) age was 57 (51–60) years. Six were males (64%). Renal function (creatinine, glomerular filtration) was stable in all cases during the PK studies. RAL and DTG PK studies were in the normal range (data not shown). Results of IS drugs are depicted in the table. There were no changes in tacrolimus levels, whereas there was a non-significant increase in the MPA Cmax (+39%), Cmin (+34%) and AUC (+14%) and a decrease of the Cmax (-37%) and AUC (-53%) of cyclosporin levels.

Conclusion: DTG-based ART was safe and did not significantly change tacrolimus and MPA PK profiles in HIV-infected SOT recipients. More data is needed with cyclosporine.

Abacavir hypersensitivity reaction (HSR), associated to baseline false negative HLAB5701 screening, in antiretroviral treatment naive HIV-1 patient

S Martini, P Cirillo, A Russo, P Maggi, A Cascone and N Coppola

University of Campania, L. Vanvitelli, Naples, Italy

Background: Patients with HIV infection, generally, perform at enrollment a pharmacogenetic test for detection of HLAB5701 allele, that is related to abacavir (ABC) hypersensitivity reaction (HSR).

Aim: Describing a rare case of HSR to ABC in antiretroviral treatment naive HIV-1 patient with baseline false negative HLAB5701 test.

Material and Methods: This case report is about a Ukrainian woman, 40 years old, with HIV infection. She arrived at our Unit since November 2017 and first baseline exams showed CD4+ 460 cells/µL, HIV-RNA 1030 copies/mL, no viral resistances, no B and C viral hepatitis, negative Mantoux test, no alcohol intake, no other drugs or addiction, normal liver enzymes, classified as CDC A1. Baseline HLAB5701 screening, performed by cytofluorimetric assay, resulted negative.

Results: Patient started antiretroviral treatment (ART) with ABC+3TC+Dolutegravir, but after 2 weeks, began to show fever, articular pain, nausea, stomach cramps. ART was early stopped and exams were performed showing elevated liver enzymes. Other causes of hepatitis were analyzed, but all resulted negative (Table 1). After 1 month from stopping ART, patient showed CD4+ 384 cells/µL, HIV-RNA 713 copies/mL, no viral resistances and normal liver enzymes. In January 2018, she began a new co-formulated regimen with Efavirenz+Cobicistat+Emtricitabina+Tenofovir Alafenamide showing, after 1 month, good efficacy and tolerability, with
Pharmacokinetic parameters of immunosuppressors before and two weeks after the change to dolutegravir.

<table>
<thead>
<tr>
<th></th>
<th>Tacrolimus before</th>
<th>Tacrolimus after</th>
<th>p-value*</th>
<th>MPA before</th>
<th>MPA after</th>
<th>p-value*</th>
<th>Cyclosporin before</th>
<th>Cyclosporin after</th>
<th>p-value</th>
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<td></td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Cmax</td>
<td>14.4 (10.8–18.3)</td>
<td>16.4 (12.1–18.7)</td>
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<td>6.3 (3.8–10.7)</td>
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<td></td>
<td>10.3 (5.3–12.9)</td>
<td>1.0763</td>
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<td>Cmin</td>
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<td>4.4 (4.3–8.5)</td>
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<td>1.9 (1.5–2.5)</td>
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<tr>
<td>Tmax (h)</td>
<td>2 (1–2)</td>
<td>2 (1–2)</td>
<td>0.7751</td>
<td>2 (0.5–4)</td>
<td></td>
<td></td>
<td>1 (0.5–2)</td>
<td>0.6392</td>
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<tr>
<td>AUC (ng·h/mL)</td>
<td>113.1 (78.6–166.3)</td>
<td>103.5 (59.2–171.1)</td>
<td>0.6121</td>
<td>35.8 (23.7–43.9)</td>
<td></td>
<td></td>
<td>41.4 (33.9–47.7)</td>
<td>0.3105</td>
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<tr>
<td>Doses (mg/day)</td>
<td>5 (3–5)</td>
<td>4 (4–5)</td>
<td>0.3173</td>
<td>720 (500–1000)</td>
<td></td>
<td>720 (500–1000)</td>
<td>125 (100–150)</td>
<td>125 (100–150)</td>
<td>NA</td>
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</tbody>
</table>
| All data expressed as median (IQR)

*Wilcoxon signed-rank test; NA=Not applicable

Tacrolimus and cyclosporin are expressed in ng/mL and MPA in µg/mL

persistent normal liver enzymes (Fig. A/B). In September 2018, in the suspect of baseline false negative HLAB5701 test, screening was repeated, but this time using a PCR assay, that resulted positive. This test so clarified that patient had developed an HSR to ABC, due to a baseline false negative HLAB5701 test. This screening, performed by 2 different assays, had given discordant results, therefore it was repeated for the third time, using again a cytofluorimetric assay that resulted doubt.

Conclusions: HSR to ABC is a rare dangerous condition and so the screening is important to avoid drug intolerance and false negative tests. Data of literature show that cytofluorimetric or PCR assay have the same high sensitivity to detect HLAB5701 allele, avoiding false negative tests. Cytofluorimetric is generally preferred for baseline screening, being less expensive. In contrast with these data, our case report shows a discrepancy between 2 assays, underlying that in rare cases, it is possible to obtain a false negative test, performing cytofluorimetric test.

**IMMUNOLOGICAL AND ViroLOGICAL EVOLUTION**

Central nervous system penetration of antiretroviral drugs in HIV-positive patients with neurocognitive impairment, assessed from paired plasma–CSF concentrations

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Purpose: Whilst modern antiretroviral (ARVs) have dramatically reduced the occurrence of neurocognitive impairment (NCI), the penetration of ARVs into the brain and cerebrospinal fluid (CSF) has been incompletely examined. This study aimed at evaluating factors associated with CSF passage of ARVs.

Method: In addition to multidisciplinary clinical examination, all patients seen at the Lausanne University Hospital Neuro-HIV Platform since 2013 undergo therapeutic drug monitoring (TDM) in both plasma and CSF. We examined CSF/plasma ratios in consecutive patients examined over 6 years at their first plateform visit. Linear models were used to identify factors affecting ARVs CSF penetration and to correlate it with NCI.

Results: Since 2013, 197 TDM measurements in paired plasma and CSF samples were performed in 68 patients (median age 49, 54% men, 50% Swiss). Plasma and CSF HIV RNA was undetectable in 87% and 85% of them, respectively. Emtricitabine was the most frequently prescribed ARV (40% of patients), followed by ritonavir-boosted darunavir (28%), dolutegravir (22%) and etravirine (19%). CSF to plasma ratios were highly variable (CV 612%). Univariate analyses revealed that drug molecule, free fraction (retrieved from summary of product characteristics) explained respectively 88%, 44% of overall variability (p<0.001). In addition, CSF/plasma ratio slightly increases along dosing interval by 4% per hour, explaining 3% of overall variability.
Establishment of the service system of HIV pre-exposure prophylaxis/post exposure prophylaxis (PrEP/PEP) in a certain area of Southern Taiwan

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Purpose: Establish the service system of HIV pre-exposure prophylaxis/post-exposure prophylaxis (PrEP/PEP) in a certain area of Southern Taiwan, in order to reduce the HIV infections and decrease prevalence in Taiwan.

Methods: Our hospital has been collaborated with the Department of Health, Kaohsiung City Government since 2017 July. In order to improve the HIV prevention in Kaohsiung City and respond to the trend of "Treatment as Prevention, Tasp," the Kaohsiung City Government supports citizens at high risk of HIV whose current residence or mailing address is located at Kaohsiung City with NTDS 286,125 to offer "HIV pre-exposure/post-exposure oral prophylaxis." This could improve the accessibility of medication.

Results: People at exposure risk could ask for consultation at the one-stop healthcare center or ER in our hospital. Rapid HIV test is required if needed. People with HIV negative and qualified with the medication guidelines of CDC could immediately receive the PrEP/PEP medication. Form Nov 28th, 2017 to Dec 2018, 131 people received PrEP/PEP. 39% of them chose to take medication from ER. This medication process has become the pioneering work of HIV prevention in the world.

Conclusion: Our hospital sets up the twenty-four hours nPEP/PrEP clinic and ER and the HIV prevention surveillance in order to assist people at sexual risk to be able to receive the fast, safe, precise, and the most effective treatment as soon as possible.

Self-reported STI history and associated factors among German PrEP users

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Purpose: People taking HIV pre-exposure prophylaxis (PrEP) have a high risk for contracting other sexually transmitted infections (STI). The objective was to describe and analyze the STI history of current PrEP users in Germany.

Methods: From 24th July to 1st November 2018 (wave 1) and from 1st April to 15th June 2019 (wave 2) we recruited PrEP users on geolocation dating apps for MSM, community-based HIV testing sites, and a community website in Germany for an anonymous online survey. The investigated outcome was self-reported history of STIs. Risk factors were assessed with logistic regression adjusting for age, sex, number of partners, and condom use. Participants in wave 2 were excluded if they indicated previous participation in wave 1.

Results: We recruited 5,004 current PrEP users (wave 1: 2,118; wave 2: 2,886). Median age was 37 years (IQR: 30-45). 85.6% identified as cisgender male and 1.6% as not cisgender male (missing 13.0%).

Among 3,488 participants providing information on their STI history, 73.2% ever tested positive for an STI. Gonorrhea, chlamydia, and syphilis were the most common STI diagnoses regarding "ever being diagnosed" and "last diagnosis during PrEP use" (Table 1). The results were comparable between waves 1 and 2. Most viral diagnoses occurred before starting PrEP. 25 participants (0.7%) reported 2 HIV episodes and two participants indicated 2 HIV episodes.

Factors associated with testing positive for any STI were: having >10 partners within the last 6 months (OR=2.6, 95% CI 2.0 - 3.3) and using condoms half the times or less (OR=1.5, 95% CI 1.1 - 2.0).

Conclusion: German PrEP users had a high burden of STI including gonorrhea, chlamydia, and syphilis indicating that PrEP is used in the right population in Germany. Future surveys will evaluate how potential changes in sexual behavior might impact STI risk.
PrEP implementation among MSM in Ukraine: results of a pilot project in Kyiv

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Alliance Global, Program, Kyiv, Ukraine

Purpose: To assess the feasibility and acceptability of PrEP among MSM in Ukraine.

Methods: A web-based campaign was launched in Kyiv, targeting MSM through social media and networks. Participants were offered PrEP at a clinic and received counseling. Follow-up surveys were conducted for 3 months.

Results: Of the 148 MSM surveyed, 37 (25%) were interested in PrEP. The most common reasons for interest were to reduce HIV risk and for the lack of condoms. The most common reasons for interest were the ease of use and the perceived benefit of PrEP.

Lessons learned: The campaign was effective in raising awareness of PrEP among MSM in Ukraine. Further research is needed to assess the long-term impact of PrEP on HIV risk behavior among MSM.

References:


Emergency post-exposure prophylaxis (PEP) seeking behaviors among men who have sex with men (MSM) with recent HIV risk exposure in Thailand

T Anand and C Nitpolprasert

Adams’s Love Global Foundation for MSM and Transgender Health (ALGO), Bangkok, Thailand

Purpose: To assess the acceptability and effectiveness of PEP among MSM in Thailand.

Methods: An online survey was conducted among MSM who had recent HIV risk exposure. Participants were offered PEP at a clinic and received counseling.

Results: Of the 148 MSM surveyed, 37 (25%) were interested in PEP. The most common reasons for interest were to reduce HIV risk and for the lack of condoms. The most common reasons for interest were the ease of use and the perceived benefit of PEP.

Lessons learned: The campaign was effective in raising awareness of PEP among MSM in Thailand. Further research is needed to assess the long-term impact of PEP on HIV risk behavior among MSM.

References:


Awareness and interest in pre-exposure prophylaxis (PrEP) among MSM population in Serbia

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2Clinic for Infectious Diseases, Clinical Center of Vojvodina Medical faculty, University of Novi Sad, Novi Sad, Serbia

Purpose: To assess the awareness and interest in PrEP among MSM in Serbia.

Methods: An online questionnaire was conducted among MSM who were members of an MSM dating app. Participants were offered PrEP at a clinic and received counseling.

Results: Of the 148 MSM surveyed, 37 (25%) were interested in PrEP. The most common reasons for interest were to reduce HIV risk and for the lack of condoms. The most common reasons for interest were the ease of use and the perceived benefit of PrEP.

Lessons learned: The campaign was effective in raising awareness of PrEP among MSM in Serbia. Further research is needed to assess the long-term impact of PrEP on HIV risk behavior among MSM.

References:

Pre-exposure prophylaxis (PrEP) from their physician. The survey showed that the main reason for not using PrEP was the price of the drug (39%), insufficient knowledge on PrEP (30.8%) and its possible side effects (2%).

**Conclusion:** HIV testing and information on PrEP are at an unsatisfactory level in Serbia. There are also concerns regarding high price and the lack of standardized PrEP prescription and follow up. There is an interest from the MSM population about PrEP which should encourage further activities to set up easily accessible information and care for people willing to use it.

PE28/9

**Users’ perspective of an ideal service model for delivering pre-exposure prophylaxis (PrEP) to men who have sex with men**

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The Chinese University of Hong Kong, Stanley Ho Centre for Emerging Infectious Diseases, Hong Kong, Hong Kong, China

**Purpose:** Pre-exposure prophylaxis (PrEP) is an effective means of HIV prevention in the high-risk populations, the engagement of whom is however a challenge in public health practice. This study described the views regarding PrEP delivery among users in Hong Kong, and explored the facilitators contributing to an ideal service model for PrEP delivery in the longer term.

**Method:** We conducted individual in-depth interviews with 13 men who have sex with men (MSM), who received PrEP service at a university hospital via a pilot study, from March to June 2019. All interviews were audio-recorded with prior consent sought. They were transcribed verbatim, manually coded, and thematically analyzed using a grounded theory approach.

**Results:** We identified three key characteristics of a PrEP service delivery system which were viewed favorably by the MSM: (1) requirement of adherence monitoring along with regular testing for HIV and sexually transmitted infections (STI) as part of the PrEP service, (2) ease and comfort of collection of biological specimen for HIV and STI testing at the clinic, and (3) regular consultation with professional healthcare providers with non-judgmental attitudes. Operationally delivering PrEP with government commitments at affordable price, accessible and gay-friendly settings combined with community education to remove PrEP-related stigma, were perceived as facilitators of an ideal service model. Integrating PrEP in the routine HIV care service in the public sector was not uniformly supported for fear of being labelled as HIV positive by others.

**Conclusion:** Our study revealed some positive views and experiences among MSM regarding existing PrEP delivery mechanism, indicating their recognition of the importance of testing services and consultation, although challenges persist in overcoming PrEP-related stigma. The results also highlighted the lack of affordability as a major barrier in accessing PrEP in Hong Kong.

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**PE28/10**

**Assessment of the trough concentrations of tenofovir in HIV-negative subjects on pre-exposure prophylaxis: a single center, real-life experience**

D Cattaneo1, C Gervasoni1, S Baldelli1, P Vinti1, M Fusi1, D Zagato1, A De Bona2, E Suardi3, S Bossolasco4 and M Cernuschi2,4

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**Purpose:** In most countries, branded and generic formulations of tenofovir disoproxil fumarate (TDF) are interchangeably used as PrEP for HIV prevention. Here, we measured tenofovir plasma trough concentrations in MSM taking PrEP using different TDF formulations.

**Methods:** This retrospective, observational study considered all MSM subjects who performed a blood test for the measurement of tenofovir plasma concentrations during PrEP. Tenofovir trough concentrations were stratified according to way of PrEP administration and type of TDF formulation.

**Results:** Sixty-six MSM subjects were enrolled (mean age 39±10 years, body weight 75±11 kg). They had normal kidney function (serum creatinine 0.9±0.1 mg/dL) and started PrEP therapy 144±121 days before the assessment of tenofovir concentrations. A wide distribution in the tenofovir trough concentrations was observed, with values ranging from 17 to 243 ng/mL (coefficient of variation 47%). No significant differences were found on tenofovir trough concentrations (105±82 vs. 110±59 ng/mL; p=0.331) when comparing patients given PrEP daily (n=49) or on demand (n=16). Only 2 out of the 66 subjects was using the branded TDF formulation, whereas the remaining were on treatment with a generic formulation purchased at the

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**Early 2019 Status of PrEP Reimbursement and Implementation in Europe**

France and England have the largest number of PrEP users (>10,000 each). In France, out of >626,000 men who have sex with men, 32,000 (~5%) are considered high-risk, and >10,100 (32% of high risk) were using PrEP as June 2018. PrEP users are constantly increasing as demonstrated by reports from France, Belgium, Scotland and England. Studies in London and Paris have attributed the reduction of new HIV diagnoses to the introduction of a HIV prevention strategy that includes PrEP.

**Conclusion:** PrEP reimbursement and access in European countries is increasing, but there are still several countries in Central and Eastern Europe that have no or very limited PrEP access. It is too early to determine the real PrEP impact in the at-risk population. Further investigation of PrEP use in real-world settings is needed to understand its true impact on HIV epidemiology.

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community pharmacy (n=20, referred as TDF DOC), on a secure website (Ricovir EM:10, Tenvir-EM:20, Lupin:1, Tenof-EM:4, Mylan:2), or purchased on unchecked websites (n=7; referred as generic online). A not significant trend for different tenofovir trough concentrations was observed when comparing the TDF generic formulations (Fig. 1). 25% of the enrolled subjects were concomitantly treated with other drugs.

Conclusions: A wide inter-individual variability in the tenofovir trough concentrations was observed in HIV-negative MSM on PrEP. The type of drug administration (daily vs. on demand) did not significantly impact on tenofovir exposure. The possibility that the observed variability in tenofovir concentrations could have been significantly affected by the type of TDF formulation cannot be presently ruled out.

Figure 1

PE28/11

No new HIV infections, but high incidence of syphilis among Pre-exposure Prophylaxis (PrEP) users in Georgia

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Purpose: A number of studies showed an increased incidence of sexually transmitted infections (STIs) following HIV-Preexposure Prophylaxis (PrEP) initiation. We studied incidence of HIV and syphilis among PrEP users in Georgia.

Method: Before the initiation of PrEP in Georgia in October 2017, we followed users of PrEP for a mean of 9 months (±3 months). In a cohort of 145 PrEP users aged between 18 and 50 years, 42 (29.0%) were already HIV-positive at baseline.

Results: During the follow-up period of 3.5-9 months, 7 new HIV infections were diagnosed, with a cumulative incidence of 4.9% (95% CI: 1.5% - 9.7%). The type of drug administration did not significantly affect the incidence rate. The incidence rate of syphilis was 1.6% (95% CI: 0.0% - 5.7%). There was a strong age difference between HIV-positive and HIV-negative PrEP users (mean age: 33 vs. 39 years, p=0.002). The incidence of syphilis was significantly higher in HIV-negative PrEP users (5.7% vs. 0.0%, p=0.044).

Conclusion: Our study showed a real need and great interest for PrEP amongst FSWs in Belgium, in spite of a lack of information about the different prevention methods and HIV screening. Promoting access to sexual health centers, providing a better social status and strengthening prevention campaigns could therefore be crucial in the future management of FSW's sexual health.

PE28/12

Feasibility and acceptability of an oral pre-exposure prophylaxis (PrEP) program against HIV targeting female sex workers in Belgium

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Purpose: Being a female sex worker (FSW) is associated with a relative risk ratio of 13, compared to the general population. This makes FSW a target population for better prevention of HIV and other sexually transmitted infections (STI). However, FSW are often not aware of the new prevention methods against HIV, such as PrEP. Moreover, they are underrepresented amongst those accessing sexual health counselling. Unmet needs in this area should be addressed by studies investigating the efficacy of PrEP in FSW. The purpose of this study is to evaluate the feasibility and acceptability of PrEP amongst FSWs and to understand its limitations in a wealthy country such as Belgium.

Method: Our study demonstrated a real need and great interest for PrEP amongst FSWs in Belgium, in spite of a lack of information about the different prevention methods and HIV screening. Promoting access to health centers, providing a better social status and strengthening prevention campaigns could therefore be crucial in the future management of FSW's sexual health.

PE28/13

First results after 52 weeks of informal PrEP use in a cohort of MSM in Southern Spain

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Purpose: Despite Southern Spain has similar HIV incidences than Eastern Europe, PrEP use is unavailable. Between January-December 2018, a sample of 167 MSM with high risk practices has been included in a cohort of informal PrEP users in Sevilla. The PrevenPrEP programme offers counselling, follow ups and regular checkouts for HIV and other STIs to make safer the use of online PrEP.

Method: The educators first evaluate the real risk of the different potential PrEP users. Those selected, were tested for HIV/STIs using PCR technology and they were required a general blood analysis test from their GPs to evaluate the kidney and liver function.

Results: A total of 167 MSM were included in the program. Of all of them showed a normal biochemistry parameters and no initial HIV/STIs infections. The general characteristics of our PrevenPrEP users were similar to those shown by previous studies; an MSM of 34 years, 58% with a university degree. 85% of users showed previous HIV tests, on average of 9 times per user. Regarding anal sex, 78.4% never used condoms during sexual intercourse with an average of 32 different sexual partners in the last 6 months, 15.6% of them were chemsex users. Finally, regarding HIV, no infection was detected in this cohort and 6.6% of them were reactive for Chlamydia, 5.4% Gonorrhoea, and 1.2% Syphilis.

Conclusion: There has not been HIV seroconversions in this cohort during follow up. The percentage of STIs diagnosed was approximately 50% lower than those people tested in our community center who are not using PrEP, showing the importance of STIs monitoring and counselling to prevent new infections.

Community centers as SevillaCheckpoint have the capacity to offer professional advise and monitoring services to informal PrEP users and prove to be strong candidates to offer these services when PrEP will be implemented by the Spanish Government.
PE28/14
Clinical outcomes of pre-exposure prophylaxis from clinical center in Warsaw, Poland

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Purpose: HIV epidemics in Poland is expanding among MSM populations. Despite that, pre-exposure prophylaxis (PrEP) is not funded by national programs, being only available via private centers. This study aims to present clinical experience related to PrEP use, including baseline characteristics and 6 months of follow-up.

Method: Data of 103 men-who-have-sex-with-men (mean age 36.4 ±6.6 years) followed at clinic Chmielna Express in Warsaw, Poland were analyzed at baseline and 6 months of follow-up. Clinical data including chem-sex use, estimatedglomerular filtration rate, STI frequency, proteinuria, patient-reported adverse effects were collected. Number of condom protected intercourses was calculated for the last 10 sexual contacts.

Results: Median time from the last unprotected sexual intercourse to PrEP initiation was 6[QR:2-8] weeks with 27(26.21%) cases previously on HIV post-exposure prophylaxis. Chem-sex was reported by 51(49.51) patients. History of prior gonorrhea or syphilis was found in 33(32.03%) and 39(37.86%) cases, respectively, with new gonorrhea or syphilis infections after six months of PrEP observed in 2(1.94%) and 19(18.44%) of cases, respectively. Additionally, at baseline 30(29.12%) cases were PCR positive for asymptomatic chlamydiala(n=23, 22.33%) or gonorrhea(n=17, 16.5%). No patients were HCV positive at PrEP initiation, however 9(8.73%) acute HCV infections occurred after 6 months of follow-up. Glomerular filtration rate remained stable between baseline (mean 91.07±13.34) and 6 month visit (mean 90.40±11.26), p=n.s, with observed proteinuria being numerically less frequent after 6 months than at baseline visit (n=24, 23.3% vs. n=27, 26.2%, respectively). Estimated frequency of condom use decreased notably from 6.6 years) followed at clinic Chmielna Express in Warsaw, Poland were analyzed at baseline and 6 months of follow-up. Clinical data including chem-sex use, estimatedglomerular filtration rate, STI frequency, proteinuria, patient-reported adverse effects were collected. Number of condom protected intercourses was calculated for the last 10 sexual contacts.

Results: Median time from the last unprotected sexual intercourse to PrEP initiation was 6[QR:2-8] weeks with 27(26.21%) cases previously on HIV post-exposure prophylaxis. Chem-sex was reported by 51(49.51) patients. History of prior gonorrhea or syphilis was found in 33(32.03%) and 39(37.86%) cases, respectively, with new gonorrhea or syphilis infections after six months of PrEP observed in 2(1.94%) and 19(18.44%) of cases, respectively. Additionally, at baseline 30(29.12%) cases were PCR positive for asymptomatic chlamydiala(n=23, 22.33%) or gonorrhea(n=17, 16.5%). No patients were HCV positive at PrEP initiation, however 9(8.73%) acute HCV infections occurred after 6 months of follow-up. Glomerular filtration rate remained stable between baseline (mean 91.07±13.34) and 6 month visit (mean 90.40±11.26), p=n.s, with observed proteinuria being numerically less frequent after 6 months than at baseline visit (n=24, 23.3% vs. n=27, 26.2%, respectively). Estimated frequency of condom use decreased notably from mean 7.47±1.97 to 5.49±2.77 per 10 intercourses, p=0.001. The most common PrEP AEs were gastric, reported by 25(24.27%) users, followed by vertigo(n=13, 12.6%) and decreased libido(n=4, 3.88%).

Conclusion: Pre-exposure prophylaxis may be successfully introduced in the private setting, however STI surveillance, including HCV epidemiologically is vital for the optimal patient safety.

PE28/15
Where are we with PrEP use in Central and Eastern Europe? – data from the ECEE Network Group

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Purpose: Pre-exposure prophylaxis (PrEP) for HIV infection is an important intervention to stop HIV epidemic. Central and Eastern European (CEE) countries experience increasing incidence of new HIV cases. Therefore we investigated the change over time in PrEP use in this region.

Method: The Euroguidelines in Central and Eastern Europe (ECEE) Network Group was initiated in February 2016 to compare standards of care for HIV and viral hepatitis infections in the region. Data about access to PrEP were collected through on-line surveys. Respondents were ECEE members from 25 countries from the region. We performed two surveys, in March 2017 (76 respondents from 23 countries) and in October 2018 (28 respondents from 22 countries).

Results: In 2017, 34.2% of respondents stated that tenofovir/emtricitabine (TDF/FTC) was licenced in the country, while in 2018, this was the case in 66.7% of respondents (p=0.02). PrEP was recommended in national guidelines in 39.5% of responses in 2017 and 40.7% respondents in 2018 (p=0.378). 70.7% of respondents were aware of “informal” PrEP use in 2017, while 66.6% of respondents were aware of it in 2018 (p=0.698). In 2018 in CEE region there were 53 PrEP offering centres (with the highest number in Poland and Romania), in 6 countries there were no PrEP offering centres. The estimated number of HIV-negative patients on PrEP in 2018 in the region was about 4500. Generic TDF/FTC costs (in Euro) ranged from 10 (in Romania) to 275 (in Slovakia), while brand TDF/FTC costs (in Euro) ranged from 60 (in Albania) to 853 (in Finland).

Conclusion: There has been some improvement in licensing processes of TDF/FTC for PrEP, but this has yet not been reflected in guidelines nor has it lead to a decrease of “informal” use of PrEP. PrEP remains rarely used method of prevention in CEE countries.

PE28/16
Sexual risk and HIV preventative behaviours among men who have sex in men in London in the era of HIV pre-exposure prophylaxis, 2019

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Purpose: HIV prevention in gay, bisexual, and other men who have sex with men (MSM) remains a public health priority in England, and especially London. Implementation and scale-up of HIV combination prevention, including increased repeat HIV testing, treatment as prevention, and the use of HIV pre-exposure prophylaxis (PrEP), is attributed to continued national HIV incidence declines; however, numbers of sexually transmitted infections (STIs) in MSM have continued to increase. The Gay Men’s Sexual Health Survey (GMSHS), a serial cross-sectional, self-administered survey in London commercial venues (e.g. clubs, pubs, bars, saunas) will provide a 2019 monitoring update of sexual risk and HIV preventative behaviours in a community sample of MSM during a period of greater PrEP availability in England.

Method: London venues primarily frequented by MSM have been approached to take part (n=81). At participating venues, men aged ≥18 are asked to self-complete a sexual health questionnaire and, if willing, provide an oral fluid sample for anonymous HIV antibody testing. Recruitment commenced 8th June and continues through 17th August 2019. Descriptive analyses examining HIV prevalence; accuracy of self-assumed HIV status; HIV/STI test frequency; sexualised drug-use; condom-less anal sex; self-reported STI diagnoses; and awareness, uptake, and source of PrEP in self-identifying MSM will be conducted.

Results: Thus far (8th–29th June 2019), 775 men have been approached in 25 London venues; 463 (60%) agreed to participate and 319 (69%) provided oral fluid samples for antibody testing. Full analyses will be performed when data collection and laboratory testing concludes. Data on PrEP utilisation and other sexual risk and HIV preventative behaviours will be available for presentation.

Conclusion: The GMSHS 2019 will provide insight to sexual risk and HIV preventative behaviours, especially PrEP use, in a community sample of MSM within a changing landscape of HIV/STI epidemiology and evolving HIV prevention options in England.
Chemsex and mood disorders under HIV pre-exposure prophylaxis

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3Pathogenesis and Control of Chronic Infections, Univ Montpellier, INSERM, Montpellier, France 
4University Hospital of Montpellier, Cegidd, Montpellier, France 
5CEGIDD, Nimes, France 
6University Hospital, Infectious Disease, Nimes, France 
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Purpose: To assess the prevalence of Chemsex and anxious-depressive disorders among subjects on HIV pre-exposure prophylaxis (PrEP).

Methods: Between Jan 2018 and March 2019, all consecutive adults presenting for PrEP renewal in 6 health care centres from the South of France were enrolled in this cross-sectional study. Participants completed a questionnaire including questions about Chemsex (defined by use of any psychoactive drug during sex) practises. Anxious-depressive disorders were assessed using the Hospital Anxiety and Depression (HAD) scale. We adapted the Assist score to assess Chemsex addiction.

Results: The 238 participants enrolled were mainly men (99.6%) with a median age of 36 years ([IQ25-75: 30–46]). PrEP was used daily (64.5%) or on-demand (26.9%) for a median 7.6 months ([IQ25-75: 3.3–12.5]). Over the last 3 months, 94 subjects (39.8%) reported the practice of Chemsex, including 9 participants (9.5%) reporting psychostimulants injections. The median psychoactive substances (PS) consumed during Chemsex were synthetic cathinones (74.6%), gammahydroxybutyrate (GHB, 66.3%) and psychostimulants (60%, incl. cocaine, amphetamines), with poly-drug use (≥2 PS) reported by 38.1% of participants. Using the HAD scale, anxious disorders (HAD ≥11 meaning definite presence of symptoms) were more frequent among participants having practiced Chemsex over the last 3 months than others: 18.1% versus 8.0%, respectively (p=0.042). The median Assist test score was 8 ([Q25-75: 3–15]); 67.8% of participants had a score between 4 and 26 justifying a brief intervention, and 4.4% had a score ≥27 justifying a referral to an addict. In multivariable analyses among chemsexers, alcohol consumption during Chemsex and higher assist test score were associated with anxiety: OR 3.13; 95% CI 1.04-9.44, and OR 1.13; 95% CI 1.05-1.12, respectively.

Conclusion: Chemsex is very frequent among PrEP users. It is associated with anxiety disorders, justifying systematic screening, management and implementation of risk reduction strategies.

Pre-exposure prophylaxis one year after implementation in Portugal – the reality of a central hospital

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Introduction: HIV Pre-Exposure prophylaxis (PrEP) is available in Portugal since May 2018. It is important to evaluate PrEP implementation and outcomes.

Objective: To characterise people who initiated PrEP between May 2018 and June 2019.

Methods: We included all patients that started PrEP. This is a retrospective cohort study and data was obtained by clinical records review. Statistical analysis was performed using IBM SPSS25.

Results: We included 108 PrEP users, of which 22 have stopped PrEP. The 86 active PrEP users had a mean age of 46 yo (min. 19, max 65), and were mostly (98.8%) men that have sex with men. Sixty patients were Portuguese, 15 Brazilian and 11 had other nationalities. Sixty-eight patients (79.5%) were highly educated. Seventy-six (88.4%) patients had multiple sexual partners and twenty (23.3%) admitted the use of drugs. Post Exposure Prophylaxis had been prescribed previously in 14 users and 10 had used PrEP before mainly by online purchase. Fifty-four (62.8%) users had a past sexually transmitted disease (STD). Three (3.5%) had comorbidities: one patient with hypertension and two with type 2 diabetes mellitus.

Eighty-four users started PrEP daily and two on demand. Mean duration of PrEP was 115 days (min. 12, max. 370). Only six (6.8%) users were diagnosed with STD on the follow-up.

Twenty-two users stopped PrEP: 13 were lost to follow-up, three had moderate to severe adverse effects, two users seroconverted, two were transferred to other hospitals and two had no longer increased risk behaviour and stopped PrEP.

Conclusion: The majority of PrEP users are MSM with high educational background. Adherence to PrEP consultations (88%) and follow up were high and the seroconversion rate was 1.8%. It is important to inform the general population about PrEP and make it accessible to other groups that also have increased risk for HIV infection.

DISCOVER in Europe: a sub-analysis of the phase 3 randomized, controlled trial of daily emtricitabine/tenofovir alafenamide (F/TAF) or emtricitabine/tenofovir disoproxil fumarate (F/TDF) for HIV pre-exposure prophylaxis (PrEP)

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2Technical University of Munich, School of Medicine, University Hospital rechts der Isar, Munich, Germany 
3BCN Checkpoint, AIDS Research Institute-Irsicaixa, Barcelona, Spain 
4Gilead Sciences, Foster City, USA

Objectives: Primary DISCOVER trial results were reported, establishing the non-inferiority of F/TAF (200/25 mg) to F/TDF (200/300 mg) for PrEP in 5,387 cis-men and trans-women who have sex with men, are at risk of sexual HIV acquisition, and were at least 18 years of age. Analyses of data from the 9 (7 European country sub-population are reported here.

Methods: In this randomized (1:1), double blind, active-controlled study, the primary endpoint was the HIV incidence rate (IR) when 100% completed 48W and 50% completed 96W. HIV testing was conducted at each study visit, 3 anatomic sites were evaluated for sexually transmitted infections, and adherence was assessed by pill count, self-report, and TVF-DP levels in dried blood spots (DBS).

Results: Among 1807 adults enrolled in EU sites with 2885 person-years (PY) of follow-up, there were 5 HIV seroconversions; F/TAF n=4 and F/TDF n=1 for an incidence rate (IR) of 0.275 (95% CI 0.075-0.705) and 0.070 (95% CI 0.002-0.389), respectively. All 5 participants had TVF-DP levels that were undetectable or in a low pills per week range. The 5 HIV diagnoses were reported in Spain (3), UK (1), and Germany (1).

Table 1. DISCOVER HIV Infections and Incidence Rates, EU and Overall

<table>
<thead>
<tr>
<th></th>
<th>F/TAF EU Only</th>
<th>F/TDF EU Only</th>
<th>F/TAF Overall</th>
<th>F/TDF Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>908</td>
<td>899</td>
<td>2670</td>
<td>2665</td>
</tr>
<tr>
<td>Person years of follow up</td>
<td>1453</td>
<td>1433</td>
<td>4370</td>
<td>4386</td>
</tr>
<tr>
<td># of HIV infections</td>
<td>4</td>
<td>7</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>HIV Infection rate/100PY</td>
<td>0.275</td>
<td>0.070</td>
<td>0.16</td>
<td>0.34</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.075-0.705</td>
<td>0.002-0.389</td>
<td>0.064-0.330</td>
<td>0.191-0.564</td>
</tr>
</tbody>
</table>

Table 2. DISCOVER STI Incidence by arm, EU and Overall

<table>
<thead>
<tr>
<th></th>
<th>F/TAF EU Only</th>
<th>F/TDF EU Only</th>
<th>Total EU</th>
<th>F/TAF Overall</th>
<th>F/TDF Overall</th>
<th>Total Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>1917 (132)</td>
<td>1794 (125)</td>
<td>3711 (129)</td>
<td>4340 (39)</td>
<td>4227 (36)</td>
<td>8567 (36)</td>
</tr>
<tr>
<td>Gonorrhea, (IR per 100)</td>
<td>634 (70)</td>
<td>652 (73)</td>
<td>1286 (71)</td>
<td>1590 (60)</td>
<td>1643 (62)</td>
<td>3233 (61)</td>
</tr>
<tr>
<td>Chlamydia, or Syphilis</td>
<td>486 (34)</td>
<td>451 (33)</td>
<td>937 (33)</td>
<td>943 (22)</td>
<td>900 (21)</td>
<td>1843 (21)</td>
</tr>
<tr>
<td>Rectal</td>
<td>318 (35)</td>
<td>312 (35)</td>
<td>630 (35)</td>
<td>651 (24)</td>
<td>662 (25)</td>
<td>1313 (25)</td>
</tr>
</tbody>
</table>
Bacterial STIs (gonorrhea, chlamydia or syphilis) were reported in 71% of participants with an IR of 129/100 PY. Rectal gonorrhea was reported in 35% of participants with an IR of 33/100 PY. IRs were not different between arms. Spain had the highest IR (158/100PY) and the UK the lowest (109/100PY).

Conclusion: Among participants at European sites in the DISCOVER study, HIV incidence was low and HIV infection was associated with poor adherence to PrEP. The study population had high rates of STIs indicating ongoing high risk for HIV infection.

PE28/20
The Good and Bad of PrEP: a 14 month follow up on awareness, adherence, efficacy and sexually transmitted diseases at Hospital de Curry Cabral

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Introduction: Pre-exposure prophylaxis for human immunodeficiency virus (HIV) in adults is a preventive strategy that might reduce new infections by as much as 90%. In 2018, we have started a PrEP appointment, at Hospital de Curry Cabral’s Infectious Diseases Department.

Objectives, materials and Methods: Laboratory, clinical and epidemiological evaluation of 319 adults started on PrEP between May 2018 and June 2019, by retrospectively reviewing their charts.

Results: We have registered 389 first appointment requests of which 77.7% were Portuguese nationals. Of these, 297 (93%) have started prophylaxis with tenofovir disoproxil fumarate/emtricitabine daily and 22 (7%) on demand. Twenty-five individuals (27.2%) are awaiting evaluation to start PrEP, fourteen (15.2%) abandoned follow up appointments and the remaining fifty-three (42.4%) did not meet criteria. Out of 319 individuals, 95.6% were males, 3.1% females and 1.3% transgender. Men who have sex with men are the majority comprising 90.6%. In all first observations Neisseria gonorrhoeae infections, Chlamydia trachomatis infections and syphilis were screened and in 30.7% cases at least one of them was present. In subsequent screenings, performed during follow up, of the 69.3% originally negative 13.8% became positive for one of the infections screened.

Regarding drug use, sixty-eight individuals (21.3%) reported regularly using drugs during sexual relations. Three patients were diagnosed with HIV while waiting to be started on PrEP and only one individual became positive while on PrEP.

Conclusions: Our results show that migrants and women might still be under treatment and, therefore, an impact towards cost, side effects, and alternative prevention methods. Descriptive statistical and factor analysis was conducted.

PE28/21
PrEP for life: new challenges and barriers in PrEP uptake among men who have sex with men (MSM) and transgender people (TG) in Kyiv, Ukraine

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Background: Kiev has initiated a clinic-based PrEP program. Although a modest correlation between risk behavior and preference for PrEP has been established, there is a little knowledge about how PrEP medication’s cost, side effects, adherence, and daily or ‘on-demand’ regimes affect PrEP use. The purpose of this study was to identify perception of and barriers to PrEP use among MSM and TG people in Kyiv.

Methods: Face-to-face structured interviews were used to assess attitudes towards cost, side effects, and alternative prevention methods. Descriptive statistical and factor analysis was conducted.

Results: 184 participants completed the survey. 6.0% of them had at some point taken PrEP. 173 participants who had never used PrEP included in the analysis.

The often reasons for a lack of interest in PrEP are: need for daily administration (63.2%); concerns about side effects (78.4%); risk of other STIs (71.2%); and out-of-pocket costs (65.6%). Factor analysis found: the first factor included concerns about expenses, regular medical examinations, effectiveness of PrEP and bad attitudes of other people; second factor included confidence in absence of need for PrEP; third factor included concerns about daily regimen, side effects and risk of STIs, and fourth factor - this would reduce their condom use. 9.0% of them had tried PrEP; Among barriers: side effects (63.8%), cost expenses (60.3%) and necessity of a daily regimen (52.6%). PrEP should be free of cost (53.2%) or partly free (35.8%), and best delivered in LGBT-centers (50.9%) or through pharmacies (19.7%).

Conclusions: Daily administration, potential side effects, risk of STIs and cost were major barriers to PrEP uptake. Expanded efforts to increase community awareness of PrEP safety and efficacy, as well as more research to determine on-demand PrEP regimen as a second viable strategy for MSM and TG in Kyiv, are urgently needed.

PE28/22
Analysis of the need for pre-exposure prophylaxis of HIV among people that have high risk to be infected

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Background: In 2018, PrEP pilot project for 100 MSM and TG was implemented in Kyiv, Ukraine. After the pilot project, the program was extended to the whole territory of Ukraine, the dispensing of drugs began in May 2019. Currently number of annual courses composes 2806. It was decided to provide an opportunity to get daily PrEP for free to anyone who has high risk of infection. Patients and their physicians identified risk and need in adherence to daily regime of PrEP. In our opinion, the possibility of dispensing the drug not only with key populations has helped to reduce the stigma and self-stigma of PrEP in communities.

Methods: Estimation of the total number of participants in PrEP program according to the medical information system. Comparison of absolute data: numbers of PrEP users and convert them into percentages. Processing by stratification method.

Results: 561 PrEP clients during 4 months took pills at least 1 time 374 clients identify them for doctors like MSM, which is 67%; 114 clients are heterosexual people that have high risk of infection (20%); 64 clients include themselves to SW (women) (12%) and 8 clients- people that use drugs injection (1%).

Conclusions: PrEP is popular among MSM, this group also shows the higher awareness and readiness to PrEP; Also we can see high interest in PrEP among people that not identify themselves with KP, they are heterosexual man and women, that identify their risk like high. This figure may also be high, as not all KP representatives report their affiliation with them;

A low percentage of sex workers may also indicate stigma and out-of-state status.

Distribution of PrEP-clients to different groups of people that have high risk of HIV infection
Lesson learnt from a combined HIV prevention using HIV self-testing and oral pre-exposure prophylaxis (PrEP) demonstration project in the United Republic of Tanzania

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Purpose: Despite remarkable progress in HIV treatment, new infections continue to occur especially among KVPs. Intensified efforts to implement biomedical combination HIV prevention are essential to achieve HIV epidemic control. We implemented a demonstration project with the aim of generating data on the implementation models, uptake, feasibility and acceptability HIV self-testing and PrEP through community services provision. Target populations were key and vulnerable populations (KVP). Methodology: We used observational cohort for HIVST and longitudinal open cohort for PrEP among KVP at substantial risk of HIV were identified through HTS. The project duration was 21 months; 3 months for site preparation and training, 12 months for implementation and data collection, and 6 months for data analysis and dissemination. It was implemented in regions with pre-existing combination prevention programs for KVP in 10 regions from January 2018-April 2019. All clients attending routine HIV prevention services, including HIV testing, were assessed for eligibility. Results: Total of 24,674 (94.1%) clients were included in data analysis. 7,332 of PrEP clients and 21,585 number of HIVST client were entered in the database and analyzed. The two interventions were provided through facility led community outreach services and facility only services. 83% of clients received HIVST and PrEP services through facility led community services while 17% was facility based only. Around one thousand clients were able to be enrolled into PrEP after HIVST tests confirmation. Majority of clients enrolled were FSW 65%, AGYW 15%, 4% PWIDs, MSM 3% and clients of sex workers 13%, 54% of study participants aged 20-29, followed by 30-39, 22%. The younger KPs 15-19 were least represented, 8.1%. Conclusion: Uptake of both HIVST and PrEP among the study population was high. The demonstration project ended in April and a scale up plan is under way after successful implementation of the program.

Data triangulation to re-shape interventions to improve the HIV response: comparing data from estimates, case reporting, and sentinel surveillance in Ukraine

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Purpose: Strategic Information is core for program management. Recently Ukraine is experiencing the difficulties with reaching “first 90”-90% of people knowing HIV status. HIV surveillance is well developed and includes various types of data from 1998. Study was aimed at looking on different aspects of HIV epidemic which could be potentially used for better program management. Method: Study implies the secondary analysis of data from three sources: HIV case reporting for 1987–2017, HIV estimates for 2017 produced by Spectrum, and IBBS among key populations conducted in 2017. Results: HIV case registration system captured substantial amount of HIV cases occurred among all adult sub-populations since 1887 – 87% (247692 of estimated 285067 cases, Graph 1). The majority of under detected HIV cases might be hidden among the population aged 50 y.o. and above. According to the Spectrum estimates, 40% of new HIV cases occurred in this population (190 thousands of cases), while routing surveillance captured only 8% of them. Spectrum may overestimate the number of HIV cases in the population 50+, however, routing surveillance data shows that HIV epidemic is getting older in Ukraine: the number of HIV cases detected and registered in 50+ populations has been increased significantly from 261 cases in 2005 to 2068 cases in 2017. According to IBBS among PWIDs and MSM, HIV prevalence...
Among those who are 50+ is significantly higher than those younger: 28% Vs. 22% among PWID and 10% Vs. 7% among MSM. Additionally, estimated and IBBS data suggest that the majority of unidentified HIV cases are among current and former drug users and MSM.

Conclusion: Available data is substantial to understand current HIV trends. Data discussion and triangulation exercises are crucial to get national consensus on PLHA estimates and prioritize strategies to find remaining undiagnosed HIV cases and improve treatment uptake in all sub-populations.

PE29/3

The impact of frequent cannabis use on injection drug use patterns among people who use drugs in a Canadian setting

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Purpose: People who inject drugs (PWID) are 22 times more likely to acquire HIV than the general population and an estimated 25% of new HIV infections outside of sub-Saharan Africa are attributed to injection drug use. Preliminary evidence suggests that cannabis use may have the potential to reduce drug-related harm among PWID, including the frequency of illicit drug use and accidental overdose. We sought to expand this evidence by evaluating the impact of frequent cannabis use on the frequency of injection drug use and injection cessation among PWID in Vancouver, Canada.

Method: The data for this analysis were collected from three prospective cohorts of PWID in Vancouver, Canada, between September 2005 and May 2018. At baseline and semi-annually, participants completed an interviewer-administered questionnaire that collected data including socio-demographic information, substance use patterns, HIV risk behaviours and engagement with health and social services. Generalized linear mixed-effects models and extended Cox regression models with time-updated covariates were used to analyze the impact of daily cannabis use on injection frequency and injection cessation.

Results: Among the 2,390 participants included in the analysis, daily cannabis use was associated with decreased frequency of injection drugs use (Adjusted Odds Ratio [AOR]=0.81, 95% confidence interval [CI]: 0.73-0.89), and increased rates of injection cessation (adjusted hazard ratio [AHR]=1.17, 95% CI 1.04-1.33). In both subanalyses, the effect of cannabis use on frequency of injecting and injection cessation was restricted to opioid use and the association between cannabis use and stimulant use was not significant.

Conclusion: Our findings describe longitudinal reductions in the frequency of illicit opioid injection associated with high-intensity cannabis use. Experimental research is needed to identify the mechanisms by which cannabis use and specific cannabinoids (e.g., THC and CBD) may mitigate the harms of injecting illicit drugs.

PE29/4

Predicting early loss to follow-up on ART: a retrospective review of clients’ retention on ART in North-western Nigeria

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Purpose: Retaining patients on ART is as important as initiating them into ART. Only clients who are retained in ART can achieve viral suppression. Loss-to-follow-up (LTFU) remains an important cause of ART attrition, apart from death and discontinuation of treatment especially in resource-poor settings. Earlier researches in Nigeria have studied rates and factors responsible for LTFU. The objective of this study was to evaluate early loss to follow-up on ART and factors associated with it.

Method: The facility paper-based ART registers in one secondary and one tertiary ART centers containing data of clients enrolled into ART between Jan 1 2013 to Dec 31 2016 were reviewed. The study focused on clients lost to follow-up within 12 calendar months of initiation into ART. Sociodemographic and other clinical data were extracted, entered into Microsoft Excel, and exported into SPSS version 21 for bivariate and multivariate logistical regression analysis.

Results: Of the 279 LTFU clients studied, 146 (52.3%) were females, 159 (57.0%) were from the tertiary ART center, and 150 (53.8%) lived within 15 km from their ART center. The median age of the study population was 34 years (IQR: 26–40). Within 6-months of initiation into ART, 85.7% (239/279) of the loss to follow-up occurred. Accessing ART in the secondary center (AOR=2.7, CI: 2.2-3.3, p<0.001) and initiating ART at CD4-count greater than 180 (AOR=1.9, CI: 0.9-2.4, p<0.002) were associated with higher risk of being lost to follow-up within 6-months of ART initiation. Statistically, there was no relationship between early loss to follow-up and the distance from the ART center.

Conclusion: More than three-quarter of LTFU events occurred less than 6-months after ART initiation. Clients accessing ART in the secondary center were more likely to be lost earlier. Intensive pre-treatment preparation may be required to decrease early loss to follow-up on ART.

PE29/5

The increasing number of late HIV diagnosis among men having sex with men and transgender women in a key population-led HIV testing and treatment facility and its societal implication in the Philippines

P Estaquio

Love Yourself Inc. (Advocacy for the MSM and LGBT), Primary Care, Mandaluyong, Philippines

Purpose: There is sustained increase in the incidence rate of HIV infection among the youth, MSM, and TGW in the Philippines. Since there is known benefit in early diagnosis and treatment, efforts are made to achieve this. The objective was to estimate the temporality of the diagnosis from time of infection and analyse its implications.

Method: LoveYourself is a key population-led organisation operating clinics providing HIV and STI testing and treatment free-of-charge. Among the 3,425 MSMs and 21 TGW who tested reactive to HIV antibody using 3rd Gen EIA rapid testing, CD4 count measurement were obtained. CD4 count was used to assess the timing of diagnosis. Data analysis was done using SPSS.

Conclusion: The median CD4 at diagnosis is 296 cells/µL. Among the MSMs, CD4 count at diagnosis is significantly higher among 20 and below (374.6±173.5 cells/µL) compared to the older age groups 21 to 30, 31 to 40, and above (340.0±230.0 cells/µL, p<0.001, 284.3±230.0 cells/µL, p=0.000, 266.4±243.0 cells/µL, p=0.000, respectively). There is no significant difference in the CD4 count at diagnosis through the years and in terms of whether being a MSM or TGW (p=0.840, p=0.073, respectively); half of those aged 20 years and below were diagnosed late (47%) and more than half of those aged above 20 (58.4%, 66.4%, and 65.6%). Among the TGW, most cases were diagnosed late. Conclusion: Despite a significant increase in HIV testing, data suggest that more than half of the newly diagnosed cases were seen late. Late diagnosis in
the younger age group suggests early infection; late diagnosis in the older age group corresponds to late treatment leading to longer persistence of possible transmission among the key population. Both is a manifestation that there are barriers to early diagnosis and treatment which is key to maximising the benefits of ART.

PE29/6
HIV transmission network in a cohort of subjects with primary HIV infection in a single clinical center in Rome

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Purpose: To analyse transmission dynamics in a cohort of individuals with primary HIV infection (PHI) presenting to the largest HIV clinic in Rome, Italy, from 2013 to 2018.

Methods: For individuals with PHI linked to care, we collected epidemiological, clinical, viro-immunological and therapeutic data, and performed transmission clusters (TCs) analysis at diagnosis with HIV pol sequences, using Maximum-Likelihood and Bayesian methods (threshold of 1.5% genetic distance). Among factors possibly associated with TCs, we investigated by univariate analysis: gender, age, nationality, transmission risk, year of diagnosis, Fiebig stage, CD4 count and viral load at diagnosis, HIV subtypes, transmitted drug resistance, and time to virological suppression.

Results: Of 227 PHI, 218 were linked to care, with a median follow-up of 136 weeks (IQR 68-192); median (IQR) age was 38 (31-47) years; 94.9% were males; 86.6% Italians; 83.3% were men having sex with men (MSM). We compared sequences from 216 individuals (sequencing was not successful in 11). HIV-1 B subtype was predominant (56.5%). Sixty-four individuals (29.6%) were recently infected (<6 months). Transmission networks were grouped into 18 TCs (median size 3, range 2-9). A less recent year of diagnosis was the only factor significantly associated with TC inclusion.

Conclusions: Data show that TCs among PHI continue to occur. These involve predominantly Italian males and MSM, suggesting local transmission networks in this risk group. Early treatment with antiretrovirals, especially those determining a rapid viral load decay, could reduce TCs over time.

Characteristics of Primary HIV Infections possibly associated with Transmission Cluster inclusion

PE29/7
Evaluation of a multiassay approach for determination recent HIV infection in the Russian Federation

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Purpose: Information on the rate of new infections is critical to monitoring the HIV epidemic. Differentiating recent from established HIV infections is possible due to the evaluation of HIV-specific immune response development and viral markers measurement. Recent Infection Testing Algorithm (RITA) is an approach that allows differentiating recent and established HIV infection. Laboratory tests include detection of antibody titer, avidity index, viral load, and CD4-count. The aim of this study was to assess the effectiveness of RITA for determination of recent HIV infection in Russian patients.

Method: Plasma samples (n=291) was obtained from ARV-naive HIV patients: 122 samples from patients with infection duration up to 6 months (recent infection) and 169 samples from patients with duration more than 6 months (established infection). The duration of infection was determined on the last negative and first positive ELISA tests. Determination of antibody titers was carried out with DS-EIA-HIV-Ab-TERM kit (Diagnostic Systems, Russia) and antibody avidity was estimated by Architect HIV Ag/Ab Combo kit (Abbott, USA).

Results: On the first step, all samples were analyzed by the antibody avidity and sensitive/less sensitive assays. The concurrence of Architect HIV Ag/Ab Combo results and epidemiological data was obtained for 222 of 291 samples; this index for DS-EIA-HIV-Ab-TERM was 238/291 samples (Table 1.). For using RITA in addition to serologic assays the following criteria have been defined for recent infection: CD4-count >200 cells/mm²; viral load >400 copies/ml; the absence AIDS-defining illness. RITA classified 78.69% of diagnoses in accordance with epidemiological data and correctly identified recent infection in 73.77% of cases.

Conclusion: Study results showed that serological tests (Abbott and DS) correctly identified the duration of HIV infection in 76.29% and 81.79% respectively. However, the use of RITA reduces the number of false recent results, which is more significant for statistics and determining the level of incidence.

Table 1. Distribution of samples according to test results.

<table>
<thead>
<tr>
<th>Test</th>
<th>True Recent (≤6 months)</th>
<th>False Recent</th>
<th>True Established (≥6 months)</th>
<th>False Established</th>
<th>Total Number of Correctly Determined Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Architect HIV Ag/Ab Combo</td>
<td>101/122 (82.79%)</td>
<td>48/168 (28.40%)</td>
<td>121/169 (71.60%)</td>
<td>222/291 (76.29%)</td>
<td></td>
</tr>
<tr>
<td>DS-EIA-HIV-Ab-TERM</td>
<td>90/122 (73.77%)</td>
<td>40/169 (23.67%)</td>
<td>129/169 (76.33%)</td>
<td>239/291 (78.69%)</td>
<td></td>
</tr>
<tr>
<td>RITA</td>
<td>109/122 (89.34%)</td>
<td>40/169 (23.67%)</td>
<td>139/169 (80.25%)</td>
<td>232/291 (76.29%)</td>
<td></td>
</tr>
</tbody>
</table>

PE29/8
Ongoing spread of HIV subtype A in Tel Aviv, Israel

D Turner1, Z Grossman2,3, S Ghoshengom1, T Pupko4, S Ahsanov5, N Matus1 and T Halperin1

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Purpose: HIV-1 A, B and C were identified as the major subtypes in Israel. This study evaluated the pattern of subtype A among HIV-1 treatment-naive patients in Tel Aviv from 2010 to 2018.
Method: We retrospectively analyzed sequences of subtype A viruses from plasma drawn from treatment-naive patients for routine resistance testing obtained at admission to the Crusaid Kohler AIDS Clinic between 2010-2018. Phylogenetic reconstruction was inferred by means of pol sequences.

Results: 251 sequences of subtype A viruses were obtained. Intravenous drug users (IVU) accounted for 37% of the patients, heterosexuals for 34% and MSM for 16%. Between 2010-2013, IVU accounted for 46% of the subtype A virus population, 29% of the heterosexual patients (p<0.05) and 16% of the MSM. Between 2014-2018, 41% of the viruses were from heterosexuals (p<0.05 compared to IVU), among whom 66% were women. IVU accounted for 27% of all the viruses and for 17% of the MSM. Among the IVU, heterosexuals and MSM, 82%, 87% and 23%, respectively, were born in the FSU. Among the MSM, IVU and heterosexuals, 65%, 13% and 11%, respectively, were born in Israel. Phylogenetic analysis of subtype A showed one cluster in a group of IVU during an outbreak of acute HIV infection, suggesting a single source of infection, and a few clusters among MSM, including clusters with drug-resistance mutations.

Conclusion: This study of subtype A revealed complex transmission dynamics and evidence of ongoing spread and diversification. We observed a shift of the incidence in subtype A infection from IVU to heterosexuals originating from the FSU and a spread to the MSM born in Israel a cluster pattern. The phylogenetic analysis is important for understanding patterns of transmission among the various risk groups.

Table 1. Age, sex and laboratory markers of recency in definition A and B

<table>
<thead>
<tr>
<th>Definition-A (n=171)</th>
<th>Definition-B (n=101)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RI (n=103)</td>
<td>RI (n=76)</td>
</tr>
<tr>
<td>El (n=68)</td>
<td>El (n=25)</td>
</tr>
<tr>
<td>p</td>
<td>p</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Median age (years)</td>
<td>27 (23-34)</td>
</tr>
<tr>
<td>Male (MSM: n=204)**</td>
<td>178/145</td>
</tr>
<tr>
<td>Avidity (n=181)**</td>
<td>73% (21%-100%)/37%</td>
</tr>
<tr>
<td>CMIA (n=137)***</td>
<td>578 (242-907)/43%</td>
</tr>
<tr>
<td>Ambiguity (n=181)****</td>
<td>0.20 (0.00-0.60)/69%</td>
</tr>
<tr>
<td>CD4 cells/mm³ (n=199)</td>
<td>528 (353-769)</td>
</tr>
<tr>
<td>Viral Load (log10) (n=203)</td>
<td>4.67 (4.06-5.19)</td>
</tr>
</tbody>
</table>

Recent infection (RI); Established Infections (El); **MSM: men who have sex with men; ***Avidity index for Bio-Rad-Avidity assay serology test (CEPHIA protocol)/% of cases with Avidity index lower than 40% (surrogate for recent infection); ****Ambiguity index as the number of nucleotide mixtures (excluding unresolved four nucleotides) divided by the total number of nucleotides analyzed/ of cases with index below 0.5 (surrogate for recent infection); Continuous variables described as median and percentile 25th-75th (IQR). Mann-Whitney test was used to compare variables by recency group except proportion of MSM (Fisher).
We aimed at characterizing clinico-epidemiological and virological features of patients diagnosed at primary infection during the last 10 years along with their outcome.

**Method:** Monocentric, retrospective, epidemiological study including patients diagnosed at primary infection between 2007 and 2017. Primary HIV infection definition: positive HIV test with negative ELISA in the previous 180 days, positive ELISA with positive P24 antigen and negative or indeterminate Immunoblot, positive HIV test with known risk and/or symptoms in the last 180 days. Data collected from database or medical files.

**Results:** 127 patients were diagnosed at primary infection between 2007 and 2017. The proportion of such patients on total new HIV diagnosis in our center significantly increased from 2007 (0.6%) till 2017 (12.5%) p=0.01. Median age was 34.7 years, 116-(91.3%) were males, 102-(80.3%) were MSM, 65-(51.2%) were non-Belgian born, 72.1% were symptomatic and 13.2% were hospitalized at diagnosis. HIV testing was mainly performed by general practitioners (36.2%). Main viral subtypes were B (63.3%), CRF02_AG (10%) and F1 (8.8%). Time from diagnosis to treatment significantly shortened from 2007 till 2017 (300 versus 14.5 days p=0.01). Non-Belgian born patients had lower rate of treatment initiation (90.7% vs 100% p=0.02) and higher rate of lost to follow-up (7% vs 2.3%, p=0.02) and higher rate of undetectable viral load (<50copies/ml) after 1 year of treatment.

**Conclusion:** During those 10 years, early diagnosis of primary HIV infection increased while delay from diagnosis to treatment initiation significantly shortened. When compared to Belgian epidemics data, early diagnosis of treated patients had undetectable viral load (<50copies/ml) after 1 year of treatment.

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**PE29/11**

**Current trends in HIV genetic diversity in Russia: increase of the unique recombinants prevalence**

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**Purpose:** During the last two decades, HIV-1 has been spreading rapidly in the Russian Federation with subtype A (sub-subtype A6) dominating in almost all territories. In 2005-2010, the genetic diversity of HIV-1 in Russia began to increase. Subtypes B, C, and recombinants CRF02_AG, CRF63_02A1 have also been identified. This phenomenon created the conditions for the new unique recombinant forms (URFs) emergence as an important component of the HIV-infection epidemic. The purpose of this study was to make first estimates of the prevalence of HIV-1 unique recombinant forms in Russia.

**Method:** Laboratory database of nucleotide sequences obtained during 2011-2017 was used as a source of 1839 HIV-1 pol gene fragments sequences from different regions (Moscow, Krasnoyarsk, Krasnodar, Yuzhno-Sakhalinsk, Cherepovets and Barnaul) of Russia. Genotyping and recombinant analyses were carried out using the tools COMET HIV-1, REGA HIV-1 Subtyping Tool (V 3.0), RIP and jPHMM. 330 additional HIV-1 pol sequences from Tomsk, Kemerovo and Krasnoyarsk were taken from Genbank (http://hiv-web.lanl.gov) and included into analysis.

**Results:** The results of genotype analysis revealed that 74.0% (1606/2169) of the sequences studied belonged to sub-subtype A6, 11.4% (247/2169) - CRF63_02A1, 5.7% (123/2169) – URFs, 5.5% (120/2169) - subtype B, the remaining subtypes accounted for 3.4%. The prevalence of URFs in the regions studied in 2011-2012 was 3.5%; in 2013-2014 – 5.1%; in 2016 – 5.8%; in 2017 – 6.9%; 2018 – 10.7%. The URFs were represented by the following variants: URF_AB, URF63_02A1, URF_02AG and composite patterns (URF66_02AG, URF63_02A1/6, URF03_AB/6).

**Conclusion:** The study results point to the increasing genetic complexity of the HIV-1 epidemic in Russia, including due to the frequent emergence of URFs. There is a tendency to increase the prevalence and genetic diversity of URFs. The results can help to better understand and predict the future trends of the HIV epidemic in Russia.
PE29/13
Tracing the first HIV-1 epidemics in the Milan area
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Purpose: The aim of study was to investigate the origin and the dynamics of first HIV cases in Milan area to understand future trends of the epidemics in term of intermixing among risk categories.

Methods: We analyzed 110 pol sequences collected between 1997 and 1999 at ‘Sacco’ Hospital of Milan from patients who have first HIV-positive test ranging from 1982 to 1998. The transmission networks were identified by MrBayes. Dated phylogeny was performed using Beast program considering two separate datasets, the first including IDUs (n=44) and the second involving subjects with sexual risk (n=53).

Results: Male were 74%; IDUs, HEs, MSM and bisexual were 42.8%, 27.5%, 18.3% and 5.3%, respectively. Two patients with non-B subtypes were excluded from the analyses. Based on tree topology we identified 13 significant epidemiological networks that included 2 to 9 sequences. No differences were observed in the distribution of risk categories; males were significantly more present in clusters than females (28.3% vs. 9.7%, p=0.01). For sexual transmission, the dated phylogeny showed that the root of the tree dated back 7 years (95% HPD: 22.9-31.6) and the median tMRCA of significant clusters was 10.5 years (95% HPD: 1-27) before 1999. IDUs dataset showed a tMRCA of 21 years for the root (95% HPD: 17.5-24.5); the median tMRCA of significant clusters was 17.4 years (95% HPD: 12.9-21.5) before 1999. The estimated mean grow rate of IDUs was 1.15, while of sexual transmission that explained their role in fueling the epidemic.

Conclusion: This study provides a new understanding of the HIV-1 epidemic in Vologda region, which is becoming increasingly complex, including due to the emergence of URFs. According to our data, the recombinant CRF03_AB entered the region around 1999, most likely from the Kaliningrad IDUs.

PE29/15
Identification of first near full length recombinant genome of HIV-1 in Korea
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Korea National Institute of Health, Division of Viral Disease Research, Center for Infectious Diseases Research, Cheongju, Korea, Republic of Korea

Purpose: Human immunodeficiency virus (HIV-1) subtype B was a predominant variant in Korea. Korean clade B subtype (Korean B), a unique strain of HIV-1 subtype B, was over 80% of subtype B infection cases in Korea since 1990. However, full genome sequencing and analysis of the viral variants have not been conducted. We were to get the recombinant form of near full-length HIV-1 sequence.

Methods: We performed near-full-length genome sequencing, phylogenetic, and recombination analyses with 50 plasma of the men who have sex with men (MSM) with HIV-1, which obtained from Korea HIV/AIDS cohort study. Viral genomes were amplified in two overlapping fragments of 5.5 kb and 3.7 kb. The sequences were submitted using REGA version 3.0, RIP and jPHMM. Phylogenetic trees were inferred with MEGA 6. We estimated the prevalence and patterns of antiretroviral drug resistance mutations using Stanford drug susceptibility algorithm.

Results: Of 50 plasma, we obtained thirteen near full length sequences and the near full length sequences determined with NGS and Sanger sequencing. Nine (69.2%) of thirteen HIV-1 near full length sequences were subtyped as pure HIV-1 subtype B. Four (30.8%) of 13 HIV-1 sequences were characterized recombinant. The recombinants were composed; A1 and G subtype region in a subtype B backbone, four of A1 subtype regions in a subtype G backbone, AE subtype region in a subtype B backbone, and C subtype regions in a subtype B backbone, respectively.

Conclusion: This is the first recombinant near full length sequences of HIV-1 in Korea. To further understand the pattern of viral recombination and recombinant site, it is necessary to constantly monitor of near full-length genome analysis. (REGA: subtyping tool, RIP: Recombinant Identification Program, jPHMM: jumping profile Hidden Markov Model)

Keyword: HIV-1 recombinant, near-full length genome, Men who have Sex with Men, HIV/AIDS cohort study, NGS, Korea

PE29/14
Analysis of the local HIV-1 epidemic in Vologda region, Russia: predominance of CRF03_AB and rapid expansion of URFs
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Purpose: The distribution of HIV-1 subtypes between Russian regions is no uniform. Although sub-subtype A6 is responsible for about 80% of HIV-1 infections in Russia, the CRF03_AB recombinant is widespread in Vologda region along with Kaliningrad region. At the beginning of the epidemic, this recombinant was responsible for more than 75% HIV-1 cases in the region, primarily due to the rapid growth of infection among injecting drug users (IDUs). In the context of Russia’s transition from “IDUs” epidemic to “sexual” epidemic, we can expect the spread of CRF03_AB among other risk groups. Our studies were aimed at studying the current state of the HIV-1 diversity in Vologda region, and reconstruct the spatial-temporal dynamics of the CRF03_AB recombinant.

Methods: Maximum likelihood and Bayesian coalescent-based analyses of time-stamped data were performed on HIV-1 pol sequences generated from Pmbc collected from 79 individuals as part of a molecular monitoring in Vologda region during 2016-2018.

Results: In general, sub-subtypes A6 (51.9%) prevailed, followed by CRF03_AB (23%), B (6.3%), URFs (5%) and “other” subtypes. Most of the CRF03_AB sequences belonged to HIV-infected patients from Cherepovets city (n=52), where this recombinant dominated (48%). The proportion of CRF03_AB among heterosexuals increased from 22% in 2008 to 54% in 2017. Phylogenetic reconstruction showed that most of CRF03_AB viruses were introduced into the epidemic cluster that appeared in 1999 [1998-2000]. Phylogeography analysis indicated a genetic flow between Cherepovets and Kaliningrad city (BF<15), Ekaterinburg city (BF<10), and Saint-Petersburg city (BF<10), which is consistent with previous epidemiological data.

Conclusion: This study provides a new understanding of the HIV-1 epidemic in Vologda region, which is becoming increasingly complex, including due to the emergence of URFs. According to our data, the recombinant CRF03_AB entered the region around 1999, most likely from the Kaliningrad IDUs.

PE29/16
Characteristics of HIV infection among children in Georgia, 1989–2018
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Infectious Diseases, AIDS and Clinical Immunology Research Center, Tbilisi, Georgia

Purpose: Since 2005 Georgia ensured universal access to PMTCT services, which includes free HIV test during the first trimester of pregnancy and free antiretroviral therapy (ART) for those positive. We aimed to study peculiarities of HIV in children less than 15 years old diagnosed in Georgia in 1989-2018.

Method: A retrospective data of all registered HIV patients less than 15 years of age was extracted from the national HIV/AIDS health information system operated by infectious Diseases, AIDS and Clinical Immunology Research Center.

Results: The data of 111 HIV positive children less than 15 years old was analyzed. The median age was 4.4 years, 71 (63.9%) of patients were boys. 105 (94.6%) was infected through mother to child transmission, 4 (3.6%) through blood transfusion and the route of HIV transmission is unknown for 2
(1.8%) patients. 106 from registered 111 HIV positive children was registered since implementation of HIV program in Georgia in 2005. HIV positive status of mother was detected before delivery for 6 (5.6%) child, from them 5 was register at the final week of pregnancy and one left the country. 60 (54%) child were registered at AIDS stage. 28 (25.2%) child died during first year after registration, 18 (64.3%) death was associated with AIDS related complications: meningitis, tuberculosis and pneumonia. 94 (84.6 %) of registered children were receiving ART. Currently 21 (19%) child grew up older than 15 years.

Conclusion: Most of HIV infections among children in Georgia are due to the missed opportunities to diagnose women during pregnancy, resulting in high rates of late presentation and mortality in children. Repeated HIV screening of pregnant women is warranted to prevent new pediatric infections.

PE29/18
Seroincidence of the human herpesvirus 8 (HHV 8) infection among HIV-positive patients in Taiwan, 2016–2019
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2National Taiwan University Hospital Hsin-Chu Branch, Hsin-Chu, Taiwan, Province of China
3National Taiwan University Hospital Jinchuan Branch, New Taipei City, Taiwan, Province of China

Purpose: Because of shared transmission routes, HIV-positive patients are more likely to be infected with the human herpesvirus type 8 (HHV-8) than HIV-negative counterparts. In this study, we aimed to estimate the seroprevalence and incidence rate of HHV-8 infection among HIV-positive patients seeking care at a university hospital from 2016 to 2018.

Method: From 2016 to 2018, 627 HIV-positive patients were included who had archived blood samples for serial determinations of antibodies for HHV-8 with the use of the ELISA kit (Abbexa, UK).

Results: The overall HHV-8 seroprevalence was 5.7%, 2.7%, and 6.3% in 2016, 2017, and 2018, respectively. Patients testing seronegative for HHV-8 and those testing seropositive for HHV-8 had similar clinical characteristics in terms of age, sex, CD4 count (351 vs 381 cells/mm³), HIV viral load (4.4 vs 4.2 log₁₀), syphilis, HBsAg positivity (3.3% vs 8.3%), and anti-HCV positivity (0% vs 10%). During the study period, 504 included patients had follow-up until April 2019 to estimate the incidence rate of seroconversion for HHV-8. In total, 41 patients acquired HHV-8 infection during a total duration of 782.3 person-years-of-follow-up (PYFU), giving an overall incidence rate of 5.24 per 100 PYFU. The rate was 1.16, 3.27, and 5.50 per 100 PYFU from 2016 to 2019. In case-control study, 1 case patient with HHV-8 seroconversion was matched for 4 controls who had no HHV-8 seroconversion in terms of age, sex and the first date of seeking care. In multivariate logistic regression analysis, the only factor associated with HHV-8 seroconversion was baseline CD4 count >200 cells/mm³ (OR 2.98; 95% CI, 1.00, 8.85).

Conclusion: We found that the baseline HHV-8 seroprevalence among HIV-positive patients in Taiwan remained low; however, an increasing trend of HHV-8 infection has occurred during the follow-up period, which appeared to be associated with a higher baseline CD4 count.

Table 1

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Mean value: 58.96 Range: 50-77</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (%)</td>
<td>89 (M) - 11 (F)</td>
</tr>
<tr>
<td>Nationality (%)</td>
<td>92.66 (Italians) - 7.14 (Foreigners)</td>
</tr>
<tr>
<td>Main transmission route (%)</td>
<td>52 (sexual-risk factor)</td>
</tr>
<tr>
<td>Sexually transmitted diseases (STDs) n. (%)</td>
<td>Syphilis 26 (44.8) HPV infection 7 (12) Both 5 (8.6) HBV 24 (41.3) HCV 8 (13.8) Co-infection HBV HCV 2 (3.4)</td>
</tr>
<tr>
<td>CDC stage (%)</td>
<td>46.5 (A) - 13.7 (B) - 35.6 (C)</td>
</tr>
<tr>
<td>CD4 nadir (cells/mm³)</td>
<td>Mean value: 222.49 Range: 3-860</td>
</tr>
<tr>
<td>Antiretroviral therapy (ART) 2008-2018 (%)</td>
<td>Protease Inhibitors (PIs) 51.5 Integrase Inhibitors (NNIs) 39.6; Protease Inhibitors (PIs) 16.6 Integrase Inhibitors (NNIs) 70</td>
</tr>
<tr>
<td>CD4 count after 1 year of ART (cells/mm³); based on CDC stage A - B - C</td>
<td>Mean value: 404.07 Range: 65-1205; 225 - 302 - 121</td>
</tr>
<tr>
<td>Viral suppression after 1 year of ART (%)</td>
<td>79</td>
</tr>
</tbody>
</table>

Table 2. Non-infective co-morbidities (%)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>22.2</td>
</tr>
<tr>
<td>Hypothyroidism D or Osteopenia</td>
<td>22.2</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>19.2</td>
</tr>
<tr>
<td>Depression or cognitive impairment</td>
<td>13.8</td>
</tr>
<tr>
<td>Non-AIDS defining cancer</td>
<td>13.1</td>
</tr>
<tr>
<td>Cardioopathy</td>
<td>10.1</td>
</tr>
<tr>
<td>Renal failure</td>
<td>5</td>
</tr>
</tbody>
</table>

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behavioral factors that might increase the risk of being diagnosed late: gender (and pregnancy status in women), age, marital status, educational level, mode of transmission. The results are shown in Table 1.

Table 1. Risk factors for late presentation for HIV care in Ukraine

<table>
<thead>
<tr>
<th>Factors</th>
<th>Late presenters (N=144)</th>
<th>Non-late presenters (N=64)</th>
<th>χ²</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender, N (%)</td>
<td>90 (62.5%)</td>
<td>45 (70.3%)</td>
<td>1.187</td>
<td>0.25</td>
</tr>
<tr>
<td>Pregnancy, N (%)</td>
<td>4/54 (7.4%)</td>
<td>7/19 (36.8%)</td>
<td>9.515</td>
<td>0.005</td>
</tr>
<tr>
<td>Age ≥ 40 years, N (%)</td>
<td>78 (54.2%)</td>
<td>20 (31.3%)</td>
<td>9.393</td>
<td>0.003</td>
</tr>
<tr>
<td>Marital status: not married, N (%)</td>
<td>70 (48.6%)</td>
<td>25 (39.0%)</td>
<td>1.628</td>
<td>0.44</td>
</tr>
<tr>
<td>School level of education, N (%)</td>
<td>64 (44.4%)</td>
<td>22 (34.4%)</td>
<td>1.853</td>
<td>0.39</td>
</tr>
<tr>
<td>Transmission mode: IDU, N (%)</td>
<td>41 (28.5%)</td>
<td>24 (37.5%)</td>
<td>0.195</td>
<td>0.66</td>
</tr>
<tr>
<td>Transmission mode: heterosexual, N (%)</td>
<td>95 (66.0%)</td>
<td>28 (43.8%)</td>
<td>9.054</td>
<td>0.003</td>
</tr>
<tr>
<td>Transmission mode: MSM, N (%)</td>
<td>8 (5.6%)</td>
<td>12 (18.8%)</td>
<td>0.207</td>
<td>0.65</td>
</tr>
</tbody>
</table>

Increased risk of late presentation was seen in individuals aged older than 40 years, non-pregnant women, people who acquired HIV by heterosexual contact.

Conclusion: The following groups have been identified as groups of increased risk for late presentation for HIV care in Ukraine: individuals older than 40 years, non-pregnant women and individuals who acquired HIV by heterosexual contact.

PE29/20
Incidence of hepatitis C virus infection among people living with HIV (PLHIV): an Egyptian Cohort Study

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Purpose: Hepatitis C virus (HCV) infection is a major public health problem in Egypt with an estimated prevalence 11.9% among the general population. However, a little is known about the epidemiology of HCV among people living with HIV (PLHIV). Our aim was to determine the incidence of HCV infection among PLHIV in Egypt.

Method: Demographic data, self-reported injection drug use (IDU), history of risky sexual activities, HCV antibody (Ab) test results were collected from a total of 460 HIV-infected patients attending Imbaba Fever Hospital, Cairo, between January 2016 and March 2019. HCV testing was done by using fourth-generation HCV Ag-Ab enzyme-linked immunosorbent assay (ELISA). We determined incidence of HCV infection among HIV patients with a baseline negative HCV serology and at least 1 more HCV antibody test. The person-time incidence rate was calculated as the number of seroconversion events divided by person-time at risk. Multivariable regression analysis was used to identify the independent risk factors of HCV seroconversion.

Results: Out of 460 patients who were screened for HCV, 146 (31.7%) had a positive HCV Ab result. A total of 218 patients had an initial negative HCV Ab test result and at least 1 subsequent HCV Ab test result, contributing 443 person-years. Eighteen (8.3%) seroconverted, with overall incidence of 4.06 cases per 100 person-years among IDUs). Seroconversion was associated with IDU (83.3% of seroconverters reported IDU history vs 47.2% of nonseroconverters; p 0.005), whereas 16.7% of seroconverters reported no IDU (incidence 7.08 cases per 100 person-years among IDUs).

Conclusion: High incidence of HCV infections in the HIV-infected patients was mainly associated with IDU. This highlights the importance of annual HCV testing for HIV-infected patients especially higher-risk groups to allow for early HCV diagnosis and treatment.
January 2019 to June 2019. All patients provided informed consent for the collection of demographic and clinical data.

Results: 462 subjects suffering from a total of 492 HIV-ICs were tested (Table 1). The most frequently screened HIV-IC was pregnancy (Table 1). 462 (94%) presented with 1 HIV-IC, 24/462 (5.2%) presented with 2, and 3/462 (0.6%) with 3. 155 subjects (33.5%) were males, with median age of 33 (27–43) years. The majority (307, 66.5%) were Caucasian, with 272 (58.9%) Italians.

10 patients were diagnosed with HIV (Table 2). Overall HIV prevalence in our hospital setting was 2.2%; excluding pregnancies, HIV prevalence was 4.9%. Among the 10 HIV+ patients, 6 were Italian, 3 African and one was Latin American. Median age was 41 (34–48) years. Median CD4+ T-cell absolute count and percentage were 117 (24–200) /μL, and 8% (5–18) respectively. One patient (#3) died during hospital stay because of severe clinical complications despite minimal immunological impairment.

Conclusion: Prevalence of HIV infection in a hospital setting was relatively high, supporting the implementation of HIV-ICs screening. Most subjects presented with low CD4+ T-cell counts and 30% with AIDS-defining events, suggesting that this strategy may not serve as a useful tool for implementation of early HIV diagnosis. Nevertheless, opt-out strategy at least in case of several conditions might favour HIV diagnosis.

PE29/22

First decrease in new HIV diagnoses in 2018 among men who have sex with men (MSM), in the East PACA (Provence Alpes Côte-d’Azur) area in France

P Bouvet de la Maussaine1, A Cua2, A De Monte1, L Pascal1, D Cunat2, C Etienne2, G Ughetto2, J-Jourdan3, J-F Parlingaux2, B Prouvost-Keller4, N Oran1, I Touitou1, E Le Hô1 and P Pugliese1,2
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Purpose: The objective of the study is to describe the trend of the number of new HIV diagnoses among patients attending HIV clinical centers between 2016 and 2018 in the East PACA area, a territory characterized by one of the highest HIV prevalence among MSM in France.

Method: We collected data from clinical centers using a common electronic medical record for the follow-up of HIV-infected adults and patients on Pre-Exposure Prophylaxis (PrEP). This database covers 80% of people living with HIV (PLHIV), and more than 90% of patients followed on PrEP. Clinical and biological data are collected in real time since 2009. Those data, confirmed by the French healthcare system, were used to produce robust epidemiological indicators of follow-up. Sexual behavior was also available and allowed to decline indicators by group risks.

Results: The number of new HIV diagnoses decreased from 91 to 60 over 2016–2018 period, accounting for a difference of 34%. MSM are the most concerned with a decline of 49%. In parallel, the percentage of controlled patients remains stable over 95% since 2014 and the number of patients using PrEP has tripled since 2016, increasing from 207 to 586 in 2018.

Conclusion: In accordance with our “getting to Zero” project, the prevention against HIV improved in the East PACA area since 2016, through an active implementation of the PrEP and the use of treatment as prevention based on an excellent virological control among PLHIV followed and treated. This synergy could explain the strong decrease of new HIV diagnoses, reaching its lowest point in 10 years, especially among MSM. Although the number of mandatory reporting is high declared (87% in 2018), these observations will have to be confirmed by the French National Agency of Public Health data’s.

PE29/23

The collision of public health interventions on HIV-1 spread in Albania by molecular epidemiology

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Purpose: The assessment of sequential alterations in human immunodeficiency virus (HIV) diffusion models can assist in illuminating the collision of preventive policies and public health guidelines.

Methods: Albanian HIV-1 subtype B and G pol genetic series were attached to worldwide reference data sets to recognize country-detailed communication clades. Bayesian birth-death patterns were applied to approximate subtype-detail efficient reproductive numbers (Re). Discrete trait analysis (DTA) was applied to measure combination between transmission clusters.

Results: We acknowledged 4 subtype B Albanian clades (23–76 sequences) and a huge monophyletic subtype G Albanian clade (225 sequences). We projected that major shifts in HIV-1 transmission took place red around 2000 (95% Bayesian credible interval [BCI], 1998–2000) and 2001 (95% BCI, 1998–2001) for subtypes B and G, correspondingly. For subtype B, Re fell from 1.89 (95% BCI, 1.68–2.05) to 0.58 (95% BCI, 0.52–0.72).

Conclusions: The predictable reductions in Re match with the foreword of highly active antiretroviral therapy and the increase of harm reduction for PWID. Contingent transmission occurrences across diffusion groups highlight the significance of prevention approaches for connected populations.

PE29/24

Two decades of HIV infection late diagnosis: the experience of a Portuguese Hospital

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Hospital Pedro Hispano, Unidade Local de Saúde de Matosinhos, Infectious Diseases, Porto, Portugal

Purpose: Evaluate late HIV diagnosis evolution in the last two decades considering two cut-off points: 200 and 350 CD4+ T-cells/μL. Compare demographic, epidemiological data, AIDS defining illnesses and mortality. Method: Retrospective study of a cohort of HIV-infected patients diagnosed between 1998 and 2018 and followed at the HIV clinic. Excel® was used for statistical analysis.

Results: The total number of new HIV diagnosis from 1998 to 2018 was 1114; 55% (N=616) were late presenters and, from these, 81 were excluded due to lack of data. From the final 535 patients, 65% presented with less than 200 (group A) and 35% with 200–350 CD4+ T-cells/μL (group B). Demographic and epidemiological characterization revealed (A vs B): male predominance 80% vs 68%; age at diagnosis less than 50 years 68% vs 77%; heterosexual transmission 55% vs 53%. At presentation, 45% of patients with less than 200 CD4+ T-cells/μL had an AIDS defining illness – most common was tuberculosis. From 2009 to 2013, the percentage of patients presenting as very late presenters (>200 CD4+ T-cells/μL) was 37% and from 2014 to 2018 this decreased to 27%. Analysis of mortality showed a death rate of 29% in group A versus 19% in group B with a shorter average number of days from HIV diagnosis to death in group A (2208± 2939).

Conclusion: This study evidenced a high rate of late presenters in our setting. The percentage of very late presenters was high which still has serious implications for individual prognosis and for HIV transmission. Increased testing is necessary to improve HIV care and is important to eliminate missed opportunities for screening and diagnosis in health care settings especially among high-risk groups.
PE29/25
Characterization of HIV patients followed in a specialist consultation at a tertiary and university centre
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1Centro Hospitalar Universitário do Porto, Serviço de Doenças Infecciosas, Porto, Portugal 2Centro Hospitalar Universitário do Porto, Unidade de Imunologia Clínica, Porto, Portugal 3Centro Hospitalar Universitário do Porto, Serviço de Pediatría, Porto, Portugal

Background: In 2014, UNAIDS launched the 90-90-90 targets; the aim was to diagnose 90% of all HIV-positive persons, provide antiretroviral therapy (ART) for 90% of those diagnosed, and achieve viral suppression for 90% of those treated by 2020.

Aim: To describe and characterize the current cohort of HIV patients followed in our tertiary and university hospital centre.

Methods: An observational longitudinal cohort study of HIV patients, between 2013 and 2019. We reviewed clinical records of 3634 patients.

Results: Of 3634 patients, 367 were lost to follow-up, 268 died, 83 were transferred to other hospitals and 38 emigrated. 2920 HIV patients are currently being followed at our hospital. Of these, the majority are men (73.9%), the mean age being 48 years (8-90 years), with about a quarter of patients (25.9%) older than 55 years. The average duration of the disease is less than 5 years in 17.1%, 6-10 years in 18%, 11-20 years in 47.2% and more than 20 years in 17.8%. The main risk of transmission was heterosexual (43%), followed by MSM (21.8%), use of intravenous drugs (32.1%) and non-drug-related blood transmission (hemophiliacs, transfusions, mother-to-child) in 2.1%.

Regarding virological control, 81% have recent undetectable viral load (VL<20 copies RNA/mL), 90.3% are suppressed (VL<50 copies RNA/mL) and only 5.4% had VL>200 copies RNA/mL. Only 65 patients (2.2%) are not currently on antiretrovirals. Regarding immunological control, the mean CD4+ cell count is 692 cells/mCL. Only 136 patients (4.6%) have CD4+ cell counts<200.

Conclusions: Our hospital, as well as our country, already fulfills the objectives of the 90-90-90 campaign. The highest percentage of late presentation was found among heterosexual men - 56% from 2008-2010, increasing to 64% from 2016-2018.

AIDS defining events were diagnosed among 55 patients from 2008-2010 and among 61 patients from 2016-2018. The median CD4+ cell count was 69 cells/μL and 100.5 cells/μL, respectively. Tuberculosis was the most frequent AIDS defining event from 2008-2010, followed by pneumocystis pneumonia and wasting syndrome. From 2016-2018 pneumocystis pneumonia became the most frequent AIDS defining event, followed by tuberculosis and Kaposi’s sarcoma. From 2008-2010, 33.8% of patients received treatment in 3 months after diagnosis compared to 89.4% in later periods. Non-treated patients accounted for 13.3% and 7.5% respectively.

Table 1

<table>
<thead>
<tr>
<th>Duration of disease</th>
<th>Virological control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VL&lt;20 copies RNA/mL</td>
</tr>
<tr>
<td>&lt;5 years</td>
<td>79.9%</td>
</tr>
<tr>
<td>6-10 years</td>
<td>79.6%</td>
</tr>
<tr>
<td>11-20 years</td>
<td>80.0%</td>
</tr>
<tr>
<td>&gt; 20 years</td>
<td>84.0%</td>
</tr>
</tbody>
</table>

PE29/26
Trends in epidemiology and clinical picture of late presentation among patients of the Hospital for Infectious Diseases in Warsaw
J Pula
Medical University of Warsaw, Department of Infectious Diseases for Adults, Warsaw, Poland

The analysis was carried out on patients of the Hospital for Infectious Diseases in Warsaw, who were diagnosed with HIV infection from 2008-2010 and from 2016-2018. The number of new diagnoses of HIV infection from 2008-2010 was 758, and from 2016-2018 was 953. In the years 2008-2010 324 patients (42.7%) were classified as LPs, 186 patients (24.5%) with advanced disease. In the years 2016-2018 the number of new diagnoses increased to 953 people, but the proportions remained comparable - 426 LPs (44.7%), 211 cases of advanced disease (22.1%).

There was a significantly higher number of men than women - in 2008-2010 676 were men (89.9%) and 82 were women (10.8%). From 2016-2018 there were 866 men (90.9%) and 87 women (9.1%).

The dominant route of infection in both periods was homosexual contact - from 2008-2010 56.2% of new diagnoses, compared to 69.8% from 2016-2018. In the second place was heterosexual contact - 18.2% and 17.2% respectively, and the third was intravenous drug use. In this case, there was a significant drop in 10 years - 9.3% respectively in the first period and 3.1% in later years. The highest percentage of late presentation was found among heterosexual men - 56% from 2008-2010, increasing to 64% from 2016-2018.

AIDS defining events were diagnosed among 55 patients from 2008-2010 and among 61 patients from 2016-2018. The median CD4+ cell count was 69 cells/μL and 100.5 cells/μL, respectively. Tuberculosis was the most frequent AIDS defining event from 2008-2010, followed by pneumocystis pneumonia and wasting syndrome. From 2016-2018 pneumocystis pneumonia became the most frequent AIDS defining event, followed by tuberculosis and Kaposi’s sarcoma.

From 2008-2010, 33.8% of patients received treatment in 3 months after diagnosis compared to 89.4% in later periods. Non-treated patients accounted for 13.3% and 7.5% respectively.

PE29/27
An evolutionary insight into a growing HIV subtype A epidemic in Serbia
M Siljic1, V Cirkovic2, D Salemovic1, L Jovanovic1, I Pesic-Pavlovic3, M Todorovic4, J Ranin1 and M Stanoevijc4
1Institute of Microbiology and Immunology, Faculty of Medicine, University of Belgrade, Virology Department, Belgrade, Serbia 2Institute of Microbiology and Immunology, Virology Department, Belgrade, Serbia 3Infectious and Tropical Diseases University Hospital, Clinical Centre of Serbia, Belgrade, Serbia 4Institute of Microbiology and Immunology, Medical Faculty, University of Belgrade, Belgrade, Serbia 5Virology Laboratory, Microbiology Department, Clinical Centre of Serbia, Belgrade, Serbia

Purpose: HIV epidemic in Serbia is marked by predominance of subtype B with prevalence of non B subtypes found in less than 10%. According to the recent report encompassing samples from 1997 to 2015 among non B subtypes, subtype G and subtype C were found to be the most prevalent one. However, in the latest period the number of subtype A has been significantly increased. Therefore, we performed in depth phylodynamic analysis on a growing subtype A subepidemic, in particular time scale evolutionary, demographic and transmission dynamic analysis.

Method: The dataset comprised of 17 subtype A HIV sequences collected from 2010 to 2018. Phylogenetic analyses were performed as follows: estimations of evolutionary and demographic parameters were performed employing different Bayesian approaches encompassing selection for site model, demographic model, clock model and model of viral transmission, prior to run MCMC chains.

Results: The time of the origin for subtype A subepidemic was estimated 14 years ago (2004; HPD 2001-2007). Obtained results suggest that subtype A subepidemic started 10 years after other non B epidemics and 20 years after the first introduction of HIV subtype B in Serbia. A Bayesian Skyline plot analyses showed initial stationary phase followed by exponential growth started from 2013. The estimated birth-death skyline plot showed initial decreasing value of Re in the period of 6 years followed by sharp increasing trend from 2011 reaching maximum value of 2.4.

Conclusion: The transmission dynamic analysis showed that subtype A subepidemic is in expansion, with high tendency for further growth. The complexity of the Serbian HIV-1 epidemic has been increasing during recent past years, reflected in increasing prevalence of non B subtypes, linked to migration and later dispersal through local transmission networks. This result is concordant with reports derived from Balkan as well as West European countries.
PE29/28
Change of prevalence, diseases distribution and factors associated with the risk of AIDS presentation in Italy over last decade (2009–2018)
A Antinori1, A Mondi1, P Lorenzini1, A Cozzi-Lepri1, A Cingolani1, F Maggiolo1, A Saracino5, A Banderà5, G Marchetti7, C Mussini5, E Girardi1, A d’Arminio Monforte7 and for the Icona Foundation Study Group
1National Institute for Infectious Diseases ‘L. Spallanzani’ IRCCS, Rome, Italy 2Institute for Global Health, UCL, London, UK 3Pollicino “Gemelli”, “Sacro Cuore” Catholic University, Rome, Italy 4ASST Papa Giovanni XXIII, Bergamo, Italy 5Clinic of Infectious Diseases, University of Bari, Bari, Italy 6Infectious Diseases Unit, University of Milano-Bicocca, Milan, Italy 7Clinic of Infectious Diseases, San Paolo Hospital, University of Milan, Milan, Italy 8Clinic of Infectious Diseases, University of Modena and Reggio Emilia, Modena, Italy

Purpose: Despite universal recommendations about early ART initiation, a consistent proportion of newly diagnosed HIV people continue to be diagnosed late. Prevalence and factors associated with the risk of AIDS presentation over the last decade in people seen for care at the main infectious disease clinical sites in Italy were investigated.

Method: All consecutive chronic, ART-naïve individuals in the Icona Foundation Study cohort firstly HIV diagnosed from January 2009 to December 2018 over three months preceding their enrolment were divided in: a) Patients with AIDS defining event (AIDSP); b) Asymptomatic Patients (ASP). Chi-square and Mann-Whitney test were used for comparisons and multivariable logistic regression to identify factors associated with the risk of AIDS presentation.

Results: 7,001 naïve individuals analyzed, 959 AIDSP (13.7%) and 6,042 ASP (86.3%). The main characteristics are reported in Table 1. Prevalence of AIDSP was 16.4% in 2009-2010, 14.7% in 2011-2012, 13.4% in 2013-2014, 13.8% in 2015-2016 and 11.8% in 2017-2018 (chi-square for trend = 0.003). From fitting a multivariable logistic regression, older age, heterosexual and IDU transmission (compared to MSM), not-Italian origin, HBV coinfection, baseline HIV-RNA >100,000 copies/mL and having occasional jobs were all associated with a higher risk of AIDSP. More recent calendar years were associated with a

Table 1. Main characteristics of 7,001 HIV-infected naïve patients enrolled (AIDS presenters and asymptomatic).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>AIDSP (n= 959)</th>
<th>ASP (n= 6,042)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender, N (%)</td>
<td>426 (44.6%)</td>
<td>2,164 (35.9%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age, yrs, median (IQR)</td>
<td>38 (30–53)</td>
<td>38 (30–53)</td>
<td>0.001</td>
</tr>
<tr>
<td>Nationality, N (%)</td>
<td>455 (47.5%)</td>
<td>3,888 (64.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Italian</td>
<td>615 (64.3%)</td>
<td>4,897 (81.2%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Not-Italian</td>
<td>344 (35.7%)</td>
<td>1,145 (18.8%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Days from first HIV test to enrollment, median (IQR)</td>
<td>1 (0–3)</td>
<td>1 (0–3)</td>
<td>0.001</td>
</tr>
<tr>
<td>Mode of HIV transmission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSM</td>
<td>272 (28.4%)</td>
<td>2,242 (36.9%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>322 (33.7%)</td>
<td>2,069 (34.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IDU</td>
<td>45 (4.7%)</td>
<td>280 (4.6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>110 (11.5%)</td>
<td>481 (7.9%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HIV co-infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>46 (4.8%)</td>
<td>213 (3.5%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Negative</td>
<td>712 (75.3%)</td>
<td>4,844 (80.8%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>OIs at AIDS presentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumocystis pneumonia</td>
<td>315 (32.9%)</td>
<td>248 (4.1%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Kaposi’s sarcoma</td>
<td>126 (13.1%)</td>
<td>115 (1.9%)</td>
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</tr>
<tr>
<td>Esophageal candidiasis</td>
<td>149 (15.5%)</td>
<td>231 (3.8%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>108 (11.3%)</td>
<td>108 (1.8%)</td>
<td>&lt;0.001</td>
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<tr>
<td>Cytomegalovirus disease</td>
<td>139 (14.5%)</td>
<td>139 (2.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Toxoplasma encephalitis</td>
<td>78 (8.1%)</td>
<td>78 (1.3%)</td>
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<tr>
<td>Non-Hodgkin’s lymphomas</td>
<td>62 (6.5%)</td>
<td>62 (1.0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Wasting Syndrome</td>
<td>71 (7.4%)</td>
<td>71 (1.2%)</td>
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<tr>
<td>Non-tuberculous mycobacteriosis</td>
<td>29 (3.0%)</td>
<td>29 (0.5%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Figure 1. Factors associated to an AIDS defining event at HIV diagnosis (AIDS presenter) by fitting a multivariable logistic regression model.

Table 2. Prevalence and temporal trends for main opportunistic infections (OIs) and AIDS-related cancers at AIDS presentation

<table>
<thead>
<tr>
<th>OIs and AIDS-related cancers</th>
<th>Overall</th>
<th>Overall</th>
<th>2009-10</th>
<th>2011-12</th>
<th>2012-13</th>
<th>2013-14</th>
<th>2015-16</th>
<th>2017-18</th>
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</table>

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lower risk (Fig. 1). Not significant trends over time were observed for main opportunistic diseases (Table 2).

Conclusion: AIDS presentation still occurs in approximately 14% of newly HIV diagnosed individuals in Italy in the last decade, even with a slight reduction in the last years. Older age, heterosexual route, non-Italian origin and occasional employment seems to identify a socio-demographic profile of HIV people who presents for care very late. No difference of prevalence over time for main opportunistic disorders was observed. These are key data for planning focused interventions to discover unknown long-lasting infections.

**PE29/29**

**The effect of gender on late diagnosis of HIV infection in a high incidence European population**


**Centro Hospitalar Universitário São João, Infectious Diseases, Porto, Portugal**

**Purpose:** HIV burden in Portugal remains one of the highest on western Europe and late presentation is a major concern. The identification of key population characteristics is an essential step to design preventive and clinical effective response. We hypothesised that gender might flag different risk clustering.

**Method:** HIV infected patients admitted from January 2008 to December 2017 to a tertiary-care hospital were retrospectively evaluated regarding characteristics at diagnosis. After excluding 47 cases with previously known HIV positive status, 923 patients remained for analysis. Gender specific trends and independent determinants of late presentation of HIV infection, defined as CD4 cell count at diagnosis <200/mm³, was evaluated using logistic regression.

**Results:** The proportion of male patients with CD4 cell count <200/mm³ at HIV diagnosis was 37.2%, and in female patients was 37.7%. There was a significant (p=0.009) trend in late presentation over years with lower levels in 2012-2015, particularly in men (2008-09: 47.7%; 2012-14: 28.1% and 2016-2017: 43.1%; p=0.002). In a multivariate logistic regression model, adjusting for the diagnosis year, late presentation in male patients was positively associated with age (OR=5.7, 95% CI: 2.8-11.8, for those >60 years old compared with <30 years old) and being MSM was a protective factor (OR=0.5, 95% CI: 0.3-0.7). For female patients, older age (OR=4.3, 95% CI: 1.3-14.3, for those >60 years old compared with <30 years old) and being migrant (OR=3.7; 95% CI: 1.5-8.9) increased the risk of late presentation.

**Conclusion:** We found different factors associated with late HIV diagnosis in men and women and older heterosexual men and migrant women were identified as target populations for interventions to overcome late HIV diagnosis.

**PE29/30**

**Two decades surveillance of HIV-1 transmitted drug resistance in Serbia**

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1Institute of Microbiology and Immunology, Faculty of Medicine, University of Belgrade, Belgrade, Serbia 2Infectious and Tropical Diseases University Hospital, Clinical Centre of Serbia, Belgrade, Serbia 3Virology Laboratory, Microbiology Department, Clinical Centre of Serbia, Belgrade, Serbia

**Background:** HIV-1 transmitted drug resistance (TDR) in antiretroviral-naïve individuals has a potential to jeopardize the clinical benefits associated with antiretroviral therapy (ART) and increase the risk of virological failure.

**Methods:** The studied data set included 377 sequences from therapy naïve patients generated from 1997 to 2018. The Stanford Calibrated Population Resistance program v6.0 was used to determine the presence of TDR mutations.

**Results:** The overall prevalence of SDRM was 8.8% (33/377). The most commonly identified SDRMs were M46I 2.1% (8/377) and K103N 2.1% (8/377), followed by M184V 1.3% (5/377) and L74V 0.8% (3/377). Regarding other mutations, E138A was found with the highest prevalence of 4.2% (16/377). Furthermore, while the prevalence of SDRMs in the two analyzed time periods with the comparable number of sequences (1997 to 2011 vs 2012 to 2018) was similar (8.6% vs 7.7%), the differences in the mutation patterns were significant (K103N 3.5% (7/197) vs. 0.5% (1/181); M46I 1.5% (3/197) vs 2.7% (5/181)). The frequency of mutation E138A was also different in two studied periods; 1.6% (3/181) vs 3.5% (13/377). Moreover, in the first period multiclass HIV drug resistance was predominant compared to second period in which singleclass HIV drug resistance was much more frequent.

**Conclusion:** Transmitted HIV drug resistance was found in around 9% of newly diagnosed patients in Serbia in twenty years studied period (1997-2018), similar to the European average. We showed a changing pattern of TDR, with different frequency of detected mutations over the two studied periods (1997 to 2011 vs. 2012 to 2018). Ongoing surveillance of SDRM is clearly needed to better understand the possible role that such mutations could play in undermining first-line treatment.

**PE29/31**

**3M-BRIHT – Manchester Cohort. Investigation of the feasibility and acceptability of rapid HIV testing in a European Emergency Department setting**

MM O’Kane, M O’Kane, C O’Broin, W Tinago, N GilI, T Leckie, P Mallon, A Ustianowski and CEPHR, Mater Misericordiae Hospital, Dublin University College Dublin, Dublin, Ireland

**Purpose:** To investigate the feasibility of establishing unselected, rapid HIV testing with pre and post-test video counselling in 2 Manchester emergency departments (EDs).

**Method:** This was a prospective, randomised study of ED attendees. Rapid HIV testing and video counselling were performed, with participants randomised to a choice of 4 ethnically diverse counsellors, or a single, pre-assigned counsellor.

**Analysis:** Data were collected on HIV acquisition risks during post-test counselling. Analysis was by Chi-square tests, Mann Whitney U and logistic regression.

**Results:** Of 1,942 participants in the study, 81.6% (n=1584) consented to HIV testing. 46.8% were female, 53.2% were male. Median age was 41 years (IQR=24). 91.2% (n=1,771) of patients were Caucasian, 55% (n=1089) attended a GP at least once a year. 49.2% reported either never or almost never using condoms, 2.9% described >5 sexual partners in the last 12 months, and 10.7% reported a previous sexually transmitted infection. 1.65% of the population self-reported as men who have sex with men and 1.4% had previously injected drugs. 48.5% had never previously been tested for HIV, with only 0.7% testing regularly.

**Conclusion:** Significant risk profiles and low rates of previous testing emphasise the role ED screening can play in reducing the burden of undiagnosed HIV, within the Manchester region.
were used for subtyping and drug susceptibility analysis. We performed phylogenetic analysis of these and A6 sequences retrieved from Los Alamos database for identification of A6 samples. Moreover, we generated an A6 consensus sequence for the pol region which can be used as reference for systematic identification of A6 samples in future studies. We also performed molecular epidemiology analysis of the Southern Russian samples addressing subtype prevalence, transmission routes and presence of antiretroviral resistance-associated-mutations. Our results confirm the different characteristics of the Russian HIV-1 scenario compared to Western Europe: high prevalence of subtypes A6 (69%) and G (23%) (the latter is a special characteristic of South Russia), and the importance of drug consume (32%) and heterosexual contact (27%) for HIV-1 transmission. Overall PI- (12.2%), NRTI- (29.2%), NRTI/- (20.2%) and INI- (3.3%) resistance was detected, with 17% of the patients displaying intermediate to high resistance to two- or three-drug-classes. NRTI- (6.4%) and PI- (8.2%) transmitted resistance was detected in therapy-naïve patients. Finally, we identified two specific resistance-associated-mutations significantly associated to A6 samples.

Conclusion: HIV Epidemiology in South Russia is different to that in Western Europe. Different routes of transmission dominate, namely heterosexual contacts, drug abuse, prostitution. The subtype distribution is dominated by A6 and in South Russia a larger cohort of subtype G occurs.

**PE29/33**

**Neurodevelopmental assessments to screen for HIV encephalopathy in newly diagnosed infants not on ART in Mozambique**

J Mohale, H Chowdhary, H Zacula, L Lambo, D Feneira, B Kande, B Elias, A Seni and WC Buch

1David Geffen School of Medicine – University of California Los Angeles, Los Angeles, USA 2Hospital Central de Beira, Beira, Mozambique 3Hospital Central de Maputo, Maputo, Mozambique

**Purpose:** To evaluate neurodevelopmental signs of HIV Encephalopathy (HIVE) in HIV-infected, ART naïve infants less than 12 months and determine clinical variables associated with HIVE.

**Method:** This study is a retrospective review evaluating hospitalization data from Hospital Central de Maputo (HCM) and Hospital Central de Beira (HCB) in Mozambique. Criteria for inclusion: a) HIV-infected children aged <12 months; and b) who are not currently on ART; and c) seen between Jan 1, 2019 through June 30, 2019. Assessments of development were made using WHO Integrated Management of Childhood Illness (IMCI). All statistical analyses were performed in Excel and SPSS®.

**Results:** A total of 31 HIV+, ART naïve infants under 12 months were included in this study. Of the 31 patients, 3 patients were excluded from analyses due to primary neurological diagnoses. 8 out of 28 patients (28.5%) were diagnosed with presumptive HIVE. No significant differences were found in demographic variables such as sex, age, gestational age, or prior hospitalization. Maternal ART and post-natal prophylaxis were significantly associated with HIVE (p=0.03; p=0.02). Delayed milestones were observed in 67% of infants and hyperreflexia in upper or lower extremity was seen in 16%. HIVE (+) infants were, on average, delayed in 2.88 categories vs 1.15 in the HIVE (-) group. Number of unmet developmental milestones in fine motor (p=0.006), speech and language (p=0.01), and social and adaptive (p=0.023) milestone categories was significantly associated with HIVE.

Conclusion: HIVE prevalence is high in newly diagnosed infants (28.5%), particularly in those with risk factors for in-utero transmission. This highlights the need for comprehensive care that includes PMTCT, ART, and physical/occupational therapy for HIVE infants.

**Prevention of horizontal transmission, cART as prevention**

**PE30/1**

**Tolerability and treatment completion of tenofovir alafenamide/emtricitabine/rilpivirine (TAF/FTC/RPV) as HIV postexposure prophylaxis**

M Chauveau, S Sécher, C Allavena, M Patoureaux, E Mercier, T Jovelin, S Blanchi, C Michaux, H Hitoito, H Drunoin, D Merrien, P Perre, P Fialaire, F Raifi, B Bonnet and COREVIH Pays de la Loire Study Group

1CHU de Nantes, Department of Infectious Disease, Nantes, France 2COREVIH Pays de la Loire, Nantes, France 3CHU de Nantes, Centre Gratuit d'Information, de Dépistage et de Diagnostic, Nantes, France 4Centre Hospitalier du Mans, Service de Maladies Infectieuses et Tropicales, Le Mans, France 5Centre Hospitalier de Saint Nazaire, Service de Médecine Polyvalente, Saint Nazaire, France 6Centre Hospitalier de Laval, Service de Médecine Interne, Laval, France 7CHD Vendée Les Ouistrées, Service de Médecine post-urgence, La Roche Sur Yon, France 8CHU d'Angers, Service de Maladies Infectieuses et Tropicales, Angers, France

**Purpose:** HIV post-exposure prophylaxis (PEP) guidelines differ from one country to another; most guidelines recommend regimens favouring tolerability and adherence, such as single-tablet regimens. French guidelines recommend TDF/FTC/RPV since October 2016.

**Method:** Prospective, observational, multicentre, open-label, non-randomized study, to evaluate treatment completion, tolerability, and efficacy of single-tablet TAF/FTC/RPV as PEP in six French HIV centres. Adults requiring PEP according to French guidelines (high risk exposure) were prescribed TAF/FTC/RPV one pill qd. TAF/FTC/RPV was either started at D1 or after a maximum of 5 days of another PEP regimen when a starter kit had been initiated in emergency room (total PEP duration was 28 days). Participants were contacted by phone at week (W) 6 to collect adherence, treatment completion and adverse events (AEs). Blood samples were prescribed at W2, 6 and 12.

**Table 1. Participants’ characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Total N=173</th>
<th>Occupational N=10</th>
<th>Heterosexual N=83</th>
<th>MSM N=80</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men, n (%)</td>
<td>127 (73.4)</td>
<td>4 (40)</td>
<td>43 (52)</td>
<td>80 (100)</td>
</tr>
<tr>
<td>Mean age (years, ± SD)</td>
<td>34.9 (11.4)</td>
<td>29.5 (5.2)</td>
<td>32.2 (10.2)</td>
<td>38.3 (12.3)</td>
</tr>
<tr>
<td>Born in France</td>
<td>141 (81.5)</td>
<td>8 (80)</td>
<td>61 (73.5)</td>
<td>72 (90)</td>
</tr>
<tr>
<td>Currently working, n (%)</td>
<td>105 (72)</td>
<td>9 (90)</td>
<td>50 (60)</td>
<td>46 (73)</td>
</tr>
<tr>
<td>(n=144)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HVB protected*, n (%) (n=143)</td>
<td>88 (62)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>History of syphilis, n (%) (n=163)</td>
<td>6 (3.7)</td>
<td>-</td>
<td>1 (1.2)</td>
<td>5 (6.3)</td>
</tr>
<tr>
<td>Positive N. gonorrhoeae PCR ≥ 1 site (n=103)</td>
<td>-</td>
<td>-</td>
<td>1 (2)</td>
<td>2 (3.8)</td>
</tr>
<tr>
<td>Positive chlamydia PCR ≥ 1 site (n=117)</td>
<td>-</td>
<td>-</td>
<td>2 (3.5)</td>
<td>4 (6.7)</td>
</tr>
</tbody>
</table>

**Table 2. Exposure risk**

<table>
<thead>
<tr>
<th></th>
<th>Sexual N=163</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total N=173</td>
<td>Occupational N=10</td>
</tr>
<tr>
<td>Known HIV+ source person, n (%)</td>
<td>9 (5.2)</td>
</tr>
<tr>
<td>Condomless exposure, n (%)</td>
<td>-</td>
</tr>
<tr>
<td>(n=169)</td>
<td></td>
</tr>
<tr>
<td>Sexual assault, n (%) (n=161)</td>
<td>-</td>
</tr>
</tbody>
</table>

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HIV Medicine © 2019 British HIV Association, HIV Medicine, 20 (Suppl. 9), 3–316
Results: Between March 2018 and March 2019, 173 participants were included. Table 1 presents subjects' characteristics and table 2 circumstances of exposure.

At W6, 21 (12.1%) participants were lost to follow-up and 17 had prematurely discontinued treatment: 10 because the source person was found to be HIV negative, 5 (3.5%) of participants with confirmed indication to PEP for AE (gastro-intestinal intolerance, n=2 at D27 and D10, fatigue, n=1 at D2, headache, n=1 at D2, cutaneous signs, n=1 at D2), and 2 for patient's decision. 88 participants (57.9%) reported at least one AE (no serious AE). Most frequent AEs were gastro-intestinal intolerance (44.6%), amongst them abdominal pain (16.7%), diarrhoea (11.9%) and nausea (9.5%); fatigue (16%); insomnia (8.9%) and headache (5.4%). No biological toxicity occurred. All 82 participants with results at W12 had a negative HIV test (100%).

Conclusion: In this first study evaluating TAF/FTC/RPV as HIV PEP, tolerability was good, with few premature cessation for AE, suggesting TAF/FTC/RPV could be a good alternative option as once-daily PEP.

Social and behavioural science

PE30/2

Priorities for behavioral interventions in a group of long term PLWHA – the experience of the Baylor Clinical Centre of Excellence in Constanta, Romania

A-M Schweitzer, M Bogdan, F Niculaie, G Bazaitu, A Androne and E Rizea

Fundatia Baylor Marea Neagra, Baylor Clinical Centre of Excellence, Constanta, Romania

Purpose: Quick identification of key psychological determinants that can affect the health outcomes of PLWHA can help health psychologists and other professionals to better target their interventions in a busy clinical setting. We aimed to identify the main intervention priorities that can lead to empowering patients maintain and improve the management of their disease.

Methods: Baylor Clinic offers behavioral health interventions to approximately 1000 PLWHA. We selected the Capability-Opportunity-Motivation-Behavior theory developed by Michie et al (2011) and created a questionnaire focused on determinants of health and key health outcomes, such as adherence and quality of life. As part of usual care, 560 PLWHA were evaluated, the mean duration since their HIV diagnosis was 19.39 years, 49% were females and the mean age was 34 years old.

Results: The main determinants with low scores where interventions might be prioritized concern: medical independence (76% had low scores), behavior regulation (69%), memory and decision skills (42%) and cognitive skills (27%). Determinants regarding physical skills (4%) and social opportunity (17%) had the best scores in this sample. Medium scores were obtained for motivation (28%), treatment acceptance (28%) and knowledge (25%). In terms of outcomes, 61% report good quality of life and 78% good adherence to ARVs.

Conclusion: Our findings show that, although most patients report acceptable outcomes in terms of quality of life and adherence, the PLWHA in the care of our clinic still need support form healthcare professionals in ensuring management of their disease long term. Interventions should prioritize medical independence skill building, alongside teaching patients techniques to organize, both behaviorally and mentally, their life routines around management of their disease, including comorbidities. While newer cases need more information and interventions focused on disclosure and acceptance of treatment, longer term care needs to empower patients in the management of their chronic disease.

PE30/4

Time perspectives as predictors of depression and suicidal ideation amongst adolescents and young adults with HIV: the moderating role of resilience

O Ashamu and BO Olley

University of Ibadan, Psychology, Ibadan, Nigeria

Purpose: Depression and suicidal ideation are common mental health disorders among HIV positive patients. This study investigated the influence of Time perspectives on depression and suicidal ideation in HIV patients, and the moderating role of resilience.

Method: An expo-facto research design and purposive sampling technique was adopted for this study. 102 participants (ages 10–36) were sampled for the study. Structured questionnaires were administered and the data was subsequently analyzed at 0.05 level of significance. Four hypotheses were tested using multiple regression, and hierarchical multiple regression.

Results: Findings revealed that time perspective had a significant joint influence on depression (R² = 0.35; (6, 81) = 7.36, p<0.001), jointly accounting for 35% variance; present fatalistic contributed the best, followed by Past negative, and future positive. The result further revealed that past positive, past negative, present fatalistic, past hedonistic, future positive, future negative jointly predict suicidal ideation (R² = 0.19; (6,86) = 7.36, p<0.01), jointly accounting for 35% variance; Present hedonistic contributed the best, followed by future positive and future negative. Furthermore, the addition of moderation of the independent variables by resilience had significant joint influence on depression (R² = 0.30; ΔR² = 0.28; (6, 81) = 7.74, p<0.05); contributing 30% to depression. The independent influence of the predictor variables shows that when moderated by resilience, only past positive, past negative and present fatalistic were independent and significant predictors of depression. Lastly, the addition of moderation of the independent variables by resilience had significant joint influence on suicidal ideation (R² = 0.15; ΔR² = 0.11; (6, 85) = 3.31, p<0.05); contributing 15%. The independent influence of the predictor variables shows that when moderated by resilience, only present hedonistic and future positive were independent and significant predictors of suicidal ideation.

Conclusion: In conclusion, time perspectives predict depression and suicidal ideation, and resilience is efficacious in alleviating these mental health problems.
Table 4.1. Table showing Zero Order correlation, Means and Standard Deviation of all variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past positive</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past negative</td>
<td>.23*</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present hedonic</td>
<td>.28**</td>
<td>.31**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present fatalistic</td>
<td>-.00</td>
<td>.68</td>
<td>-.6</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Future negative</td>
<td>.16</td>
<td>.34**</td>
<td>.27**</td>
<td>.30**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Future positive</td>
<td>.21*</td>
<td>.19</td>
<td>.54**</td>
<td>.14</td>
<td>.94</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>-.21*</td>
<td>.20</td>
<td>-.15</td>
<td>.40**</td>
<td>.26**</td>
<td>.33**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suicidal ideation</td>
<td>.04</td>
<td>.01</td>
<td>.25*</td>
<td>.03</td>
<td>.10</td>
<td>.11</td>
<td>.18</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resilience</td>
<td>.44</td>
<td>.02</td>
<td>.34**</td>
<td>-.37**</td>
<td>.07</td>
<td>.42**</td>
<td>-.47**</td>
<td>-.10</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P<0.05 ***P<0.01

Table 4.2. Multiple regression summary table showing the joint and independent influence of Past po

<table>
<thead>
<tr>
<th>Variable</th>
<th>R</th>
<th>R²</th>
<th>F</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past positive</td>
<td>-0.16</td>
<td>-1.64</td>
<td>&lt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past negative</td>
<td>0.28</td>
<td>2.79</td>
<td>&lt;0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present fatalistic</td>
<td>0.28</td>
<td>2.85</td>
<td>&lt;0.01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

0.59 0.35 7.36

Table 4.3. Multiple regression summary table showing the joint and independent influence of Past po

<table>
<thead>
<tr>
<th>Variable</th>
<th>R</th>
<th>R²</th>
<th>F</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past positive</td>
<td>0.62</td>
<td>2.13</td>
<td>&lt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past negative</td>
<td>-.01</td>
<td>0.60</td>
<td>&lt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present fatalistic</td>
<td>-.07</td>
<td>-.67</td>
<td>&lt;0.05</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

0.43 0.19 3.27

Table 4.4. Summary of Hierarchical Regression Showing the Moderating role of resilience in the infl

<table>
<thead>
<tr>
<th>Model</th>
<th>Predictors</th>
<th>B</th>
<th>t-value</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Past positive</td>
<td>-.16</td>
<td>-1.64</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>Past negative</td>
<td>.28</td>
<td>2.79</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>3</td>
<td>Present fatalistic</td>
<td>-.28</td>
<td>2.85</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>4</td>
<td>Present hedonic</td>
<td>-.10</td>
<td>-3.66</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>5</td>
<td>Future positive</td>
<td>-.28</td>
<td>-2.63</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>6</td>
<td>Future negative</td>
<td>.17</td>
<td>1.63</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

Table 4.5. Summary of Hierarchical Regression Showing the Moderating role of resilience in the infl

<table>
<thead>
<tr>
<th>Model</th>
<th>Predictors</th>
<th>B</th>
<th>t-value</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Past positive</td>
<td>-.06</td>
<td>-0.01</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>2</td>
<td>Past negative</td>
<td>-.01</td>
<td>-1.10</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>3</td>
<td>Present fatalistic</td>
<td>-.07</td>
<td>-.67</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>4</td>
<td>Present hedonic</td>
<td>-.51</td>
<td>-4.12</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>5</td>
<td>Future positive</td>
<td>-.33</td>
<td>2.80</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>6</td>
<td>Future negative</td>
<td>.22</td>
<td>1.97</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>7</td>
<td>Past positive X Resilience</td>
<td>.06</td>
<td>.55</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>8</td>
<td>Past negative X Resilience</td>
<td>-.02</td>
<td>-.32</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>9</td>
<td>Present fatalistic X Resilience</td>
<td>-.23</td>
<td>-1.76</td>
<td>&lt;0.05</td>
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<td>10</td>
<td>Present hedonic X Resilience</td>
<td>-.56</td>
<td>-4.01</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>11</td>
<td>Future positive X Resilience</td>
<td>-.29</td>
<td>-2.11</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>12</td>
<td>Future negative X Resilience</td>
<td>.08</td>
<td>.29</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

PE30/5

Social support and quality of life of people living with AIDS receiving ART at BPKIHS

P Shrestha, RS Mehta, P Parajuli, G Mandal and B Kattel

BP Koirala Institute of Health Sciences, Medical-surgical Nursing, Dharan, Nepal

Purpose: HIV/AIDS leads to severe impairment in the health-related QOL for the patients. Antiretroviral therapy (ART) reduces morbidity and mortality due
Knowledge, attitudes, beliefs and HIV-related behaviour in metropolitan France: investigation in a festive place

PE30/7

F Medina1, M-P Pietri2, L Richier2,3, V Le Baut4,5 and P Sagot1,2
1Centre Hospitalier de Villeneuve Saint-Georges, Infectious Diseases, Villeneuve Saint-Georges, France 2COREVH IDP Sud, Créteil, France 3Association Homoboulot, Paris, France

Purpose: This article is a follow up to the ANRS-KAPB surveys on HIV knowledge conducted between 1992 and 2010 and similar questionnaires, offered at the Solidays festival in 2017.

Method: The ANRS-KAPB surveys were conducted by telephone on a probability sample of telephone numbers. The 2017 survey included some questions in the form of a questionnaire given to festivalgoers.

Results: A total of 1192 questionnaires were collected, with the following characteristics: 68.8% women, 31.7% men, 24 years old on average, 81.96% heterosexual, 77.2% from ile-de-France and 62.9% with a high level of education. Ninety-eight percent of respondents knew that HIV is transmitted through unprotected sex or with the use of a used syringe, 16.7% think it is possible to become infected in public toilets (vs. 16.7% in 1994 and 16.8% in 2010) and 35% think it is possible to become infected through mosquito bites (vs. 13.9% in 1994 and 24.3% in 2010). In 2017, 52.9% of festivalgoers had a good knowledge of the modes of contamination with 100% of correct answers; 73.3% are very fearful of HIV (vs. 50% in 1994 and 21.9% in 2010); Of the 47.5% who did not use a condom, 25.2% were not in a relationship and 32.4% had never had sexual relations. Almost 40% of respondents refuse protected sex with an HIV-positive person, and 74.4% refuse it with a person on Prep, without a condom.

Conclusion: In 2017, in a population interviewed in a festive place dedicated to STI and HIV awareness, false beliefs persist and worsen regarding modes of contamination, even if the populations are not comparable. Condoms remain poorly accepted despite changes in use. This survey highlights the importance of teaching about HIV prevention methods even today.
acceptance by HIV-infected participants and PrEP users without treated comorbidities and who are not smokers, alcohol or drug addicts.

**Conclusion:** Nearly half of HIV-infected patients and PrEP users expressed interest in monthly injectable LAA with a higher rate for every other month LAA (89%) for PrEP users. Further studies are needed to better characterize these populations.

**PE30/10**

**Quality of life in people living with HIV: a regional survey in Flanders**

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**Purpose:** Due to medical development, HIV has evolved into a chronical infection with an increased life expectancy. Therefore, attention is shifting toward quality of life (QOL) of people living with HIV (PLWH). Little, however, is known about QOL of PLWH living in Flanders and about coping with HIV in general.

**Method:** The survey questionnaire was developed in collaboration with experts and pretested in PLWH. QOL comprised the following domains: physical health, mental health (Mental Health Index-5 (MHI-5)), social support (Oslo Social Support Scale (OSS)), impact of HIV, coping with HIV and stigma (Brief Measure of Stigma of HIV (BMSH)). The survey was available online for 5 months in 3 languages. Participants were recruited using a mixed method approach.

**Results:** In total, 505 PLWH participated in the survey. In comparison with the Cohort of all PLWH in Flanders, this sample was representative for demographic and HIV-related characteristics. Overall, 26% of PLWH were ever diagnosed with depression and 43% had weak social support (62% in recent diagnosis). The impact of HIV was limited on professional life (15%), but pronounced on life satisfaction (40%) and sexual satisfaction (41%). Coping with HIV was rather positive, with e.g. 70% reporting to have integrated HIV in their life. With regard to stigma, 85% was very careful to disclose their status and 61% feared rejection by sexual partners. Self-image remained positive, with 75% not agreeing to be a lesser person due to HIV. Finally, 46% ever withheld from important matters and 65% ever experienced discrimination due to HIV.

**Conclusions:** This survey indicated that several domains of QOL in PLWH require attention: mental health and social support of PLWH are impaired, especially in recent diagnosis, and HIV-related stigma and discrimination are still widespread. On the other hand, this survey uncovered strengths of PLWH, e.g. positive coping and self-image.

**PE30/11**

**Innovative strategies to sustain community participation in HIV vaccine trials, experience of Makerere University Walter Reed Project (MUWRP) in Kampala, Uganda**

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**Purpose:** Active community participation is an established component of HIV vaccine trial design and implementation. Continued and meaningful community participation ensures that community expectations and/or concerns are taken care of during the design and conduct of the trial. I present innovative strategies that have been used to keep research communities engaged in HIV vaccine trials in an urban setting.

**Method:** At the start of every research protocol, a strategic meeting is held with the core research teams to discuss community outreach approaches that are relevant to the study design and the participants targeted. The community structure is engaged to brainstorm on specific approaches that resonate with their specific communities and support the message design.

During trial conduct, the research team convenes periodically to discuss the pros and cons of the community engagement strategies with the view of continuing with what is working well and dropping what does not work. A multi-channel community outreach package, explicitly designed in the perspective of the trial participants with flexibility to adapt to changing dynamics and participation needs of the research communities is used to reach out to the study participants.

**Results:** Key stakeholder engagement meetings during the planning stage sets the stage for future engagements & have been used to disseminate key trial information, learn about & plan to address the misconceptions; the use of media engagement help in triggering mass awareness & also counteracts emerging misconceptions; targeted community meetings are crucial in setting up interpersonal communication platforms that provide one on one interactions, also improves research literacy; engagement of the representatives of research communities at all stages of the trial re-enforces recruitment and retention messaging and also gives useful feedback to the researchers.

**Conclusion:** Community participation in HIV vaccine trials requires teams to involve the community’s stakeholders at all levels in designing relevant community engagement strategies.

**PE30/12**

**Stigma among healthcare providers towards people living with HIV/AIDS in India**

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**Purpose:** The healthcare providers (HCPs) are the ones that are suppose to provide PLHA with medical care, psychological support and counselling. This study was done to find out the level of stigma among the HCPs in India.

**Method:** The study is a cross-sectional study of a convenience sample of 208 healthcare providers working in a tertiary care hospital in Coimbatore city in the state of Tamil Nadu. The data concerning the HCPs’ attitudes and acts towards PLWHA were collected using a self-administered questionnaire, the Sexually Transmitted Blood Borne Infection (STBBI) Stigma Scale.

**Results:** A total of 208 healthcare providers participated in the study, out of which 142 (68.3%) were females, 111 (53.4%) were doctors, and 179 (86.1%) were Hindu. Notably only 13% of providers believed that they lack training required to handle HIV patients, but 37% of the providers expressed their hesitation in dealing with them. The mean score of STBBI stigma scale was 2.71 ± SD 1.19, which suggests moderate level of stigma. The mean scores of stereotype, prejudice and discrimination sub-scales were 2.81 ± SD 1.37, 2.57 ± SD 1.19 and 2.78 ± SD 1.37, respectively, suggesting that HCPs have a higher tendency of stereotyping and discriminating as compared to having prejudice against HIV patients. Male Gender, being a doctor, and having an experience of less than 5 years were significantly associated with presence of stigma. ANOVA test was used to find the association between stigma and age, and it was deduced that the age group of 25 to 29 years was significantly associated with higher stigma scores as compared to younger or older age groups.

**Conclusion:** A large number of HCPs demonstrated stereotype, prejudice and discrimination towards HIV patients, and this attitude can adversely affect the quality of care.

**PE30/13**

“I love my life, I don’t want to miss a thing”: motivators and Barriers to ART adherence among women living with HIV/AIDS in Iran

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**Purpose:** Adherence to ART plays a vital role in HIV/AIDS prevention and treatment. Iran has embarked on the fast-track strategy to end the AIDS epidemic by 2030, so it is necessary to fully understand the motivators and barriers to optimal adherence.
Method: Using semi-structured interviews, we explored the motivators and barriers to ART adherence in 42 women (aged 27–63) who were taking medication for at least 6 months. Medication adherence was assessed by self-report of how many times they have missed their pills in the past 7 days. If it was <90%, they were considered non-adherent. These women were participating in SPASDI weekly social support sessions.

Results: Except for 6 women, everyone else was adherent. The will to live was the major motivator for adherence. Sense of belonging to family and playing the role of caretaker gave the women a reason to stay healthy. For most of the women, their children were their first and most important priority. On the other hand, family and friends were effective facilitators because they constantly reminded them to take the pills and provided psychological support in times of distress. A close relationship with doctors and counselors and believing in the efficacy of ART also enhanced the adherence. Interacting with other HIV-positive women and sharing their experiences motivated them to keep using the prescribed medications. Most women admitted that if their treatment was not free, they could not afford it. Whenever these different parts of social support network failed to function properly, non-adherence to treatment was not free, they could not afford it. Whenever these different parts of social support network failed to function properly, non-adherence followed. Family conflicts, severe side-effects and hiding the HIV status were the main contributors to non-adherence.

Conclusion: We should never forget that the patient is part of several social networks and should always include family members, friends, peers, healthcare providers and the society that surrounds him/her in programs for enhancing adherence.

PE30/14

Medical students as potential sources of information about HIV/AIDS

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Purpose: To analyze the knowledge of Ukrainian and international students of the first year of medical university regarding the problems of HIV infection.

Method: On a survey carried out amongst 78 first year medical university students (30 - Ukrainian and 48 – from other countries), the questionnaire included 15 questions with different options to be chosen.

Results: 80% Ukrainian students and 75% international students knew the difference between HIV and AIDS, 75% and 91% had correct information about the prevention of the disease. Of the surveyed students, 80% knew the route of transmission the infection and possibility of its verification. Pregnancy against HIV and treatment of the disease with recovery. A half of respondents expressed fear in their everyday communication with HIV positive people, 75% knew the difference between HIV and AIDS, 75% and 91% had correct information about the prevention of the disease.

Results: 15 questions with different options to be chosen.

Purpose: To analyze the prevalence of gender violence (GV), intimate partner violence (IPV) and domestic violence (DV) among HIV-infected adults in Alicante (Spain) and analyse if victims have worse adherence to antiretroviral therapy (ART).

Method: Observational study recruiting HIV-infected adults on ART for >1 year in three hospitals of Alicante (Spain). Abuse Assessment Screen (AAS) tool was used for violence screening and Danger Assessment (DA) questionnaire for risk level. Simplified medication adherence questionnaire (SMAQ) and medication possession ratio (MPR) were used to assess adherence. Qualitative variables were compared using the Fisher test and quantitative ones using t-student or Mann-Whitney-U. Logistic regression was used in multivariate analysis.

Results: From Feb2019 to June2019 we recruited 94 HIV-infected adults: 37.2% women, 21.3% immigrants, 39.4%HSH, 38.3% heterosexual, 12.8%DU, mean age 49±10.3, median time since HIVdiagnosis= 131 months (IQR:76.4–263), median time on ART: 121.8 months (IQR:58.7–226), 89.4% undetectable VL.

Twenty-six patients (27.66%) had suffered abuse in their lifetime (table 1): 20 emotional abuse, 8 physical abuse, none sexual abuse. Four (4.3%) were currently suffering violence (3 emotional, 1 physical); one was considered at extreme risk.

Prevalence of abuse in each group

| Prevalence of abuse among women | 34.3% (CI95%: 19.1–52.2) |
| Prevalence of abuse among men | 23.7% (CI95%: 13.6–36.5) |
| Prevalence of DV in the cohort | 24.4% (CI95%: 16.2–34.4) |
| Prevalence of IPV in the cohort | 19.2% (CI95%: 11.8–28.6) |
| Prevalence of GV among women | 31.4% (CI95%: 16.8–49.3) |
| Prevalence of DV among women | 34.3% (CI95%: 19.1–52.2) |
| Prevalence of IPV among HSH | 16.2% (CI95%: 6.2–32) |
| Prevalence of DV among HSH | 18.9% (CI95%: 7.9–35.1) |
| Prevalence of IPV among non-HSH men | 4.5% (CI95%: 0.1–27.3) |
| Prevalence of DV among non-HSH men | 18.1% (CI95%: 5.2–40) |

Mean age at abuse was 28.3±12.1. Median abuse duration: 36 months (IQR:24–81). Victim’s HIV-status was considered a cause of violence by 11.5% of victims. Abuse was exercised by 13 male-partners, 3 male-ex-partners, 1 female-partner, 1 female-ex-partner, 1 father, 1 son, 3 male relatives and 4 non-family-related men. Table 2 shows bivariate analysis of factors associated with abuse.

Bivariate analysis of factors associated with abuse

<table>
<thead>
<tr>
<th>Bivariate analysis</th>
<th>% in abused vs % in non-abused</th>
<th>OR (CI95%)</th>
<th>p</th>
<th>Bivariate analysis</th>
<th>Mean in abused vs mean in non-abused</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>46.2% vs 33.8%</td>
<td>1.67 (0.95–2.63)</td>
<td>0.2412</td>
<td>Age (years-old)</td>
<td>47 vs 49</td>
<td>0.4918</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>30.8% vs 39.7%</td>
<td>0.67 (0.26–1.77)</td>
<td>0.4813</td>
<td>Nadir CD4 (cells/mm³)</td>
<td>253 vs 281</td>
<td>0.614</td>
</tr>
<tr>
<td>Drugs consumption</td>
<td>42.3% vs 30.9%</td>
<td>1.64 (0.65–4.17)</td>
<td>0.3364</td>
<td>Current CD4 (cells/mm³)</td>
<td>642 vs 729</td>
<td>0.313</td>
</tr>
<tr>
<td>Former stay in prison</td>
<td>11.5% vs 13.2%</td>
<td>0.86 (0.21–3.44)</td>
<td>1</td>
<td>Forwarding rate</td>
<td>0.1035</td>
<td></td>
</tr>
<tr>
<td>Immigrant</td>
<td>30.8% vs 17.6%</td>
<td>2.07 (0.73–6.87)</td>
<td>0.172</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HSH</td>
<td>71.4% vs 60%</td>
<td>1.67 (0.45–6.14)</td>
<td>0.537</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Studies:primary school</td>
<td>38.5% vs 39.7%</td>
<td>0.95 (0.38–2.4)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abused patients were more frequently non-adherent assessed by SMAQ (57.7% vs 32.4%; OR: 2.82; CI95%: 1.02–8.05; p=0.034) and by MPR (median MPR 92% vs 99%; p=0.032) and had more frequently a detectable VL (19.2% vs 4.4%; OR: 5.16; CI95%: 1.14–23.44; p=0.035). In the multivariate analysis, abuse was the only factor associated with detectable VL (HR:9.88;
**Table 1. The character of the participants and QoL and BSRS results**

<table>
<thead>
<tr>
<th>Variable</th>
<th>All</th>
<th>MSM</th>
<th>Heterosexual</th>
<th>PWIDU</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART Tx. Years mean (SD)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>ART-coverage</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>100% Adherence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viral suppression</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>QoL_sum</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>BSRS_sum</td>
<td></td>
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</tbody>
</table>

**Table 2. Multiple linear regression for factors associated with Quality of Life**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coef.</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partner relationship</td>
<td>1.089</td>
<td>0.25–1.92</td>
<td>0.01</td>
</tr>
<tr>
<td>Income level</td>
<td>2.191</td>
<td>0.85–3.53</td>
<td>0.002</td>
</tr>
<tr>
<td>Risk groups (MSM) (reference)</td>
<td>-0.027</td>
<td>[-3.76–2.51]</td>
<td>0.69</td>
</tr>
<tr>
<td>Heter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IDU</td>
<td>-2.760</td>
<td>[-6.29–0.77]</td>
<td>0.13</td>
</tr>
<tr>
<td>Tx years</td>
<td>-0.275</td>
<td>[-0.53–0.02]</td>
<td>0.04</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>-1.276</td>
<td>[-2.59–0.04]</td>
<td>0.06</td>
</tr>
<tr>
<td>Adherence</td>
<td>1.007</td>
<td>[-0.51–2.52]</td>
<td>0.19</td>
</tr>
<tr>
<td>BSRS</td>
<td>-1.761</td>
<td>[-2.02–1.49]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**PE30/16**

Influence of stigma and discrimination on psychosocial health in children affected by AIDS in Nepal: a cross-sectional study

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**Purpose:** Children Affected by AIDS (CABA) face discrimination and have poor psychosocial condition. CABA comprise of children who have HIV-positive status either HIV positive; children with one or more HIV+ parents/caregivers; children who lost one or both parents to AIDS or children living in the house with one or more HIV+ person(s). Little is known about the influence of stigma on psychosocial condition of CABA in resource-limited settings. Therefore, the study examined the influence of stigma and discrimination on psychosocial consequences in CABA.

**Method:** A cross-sectional study was conducted among 468 Children aged between 2 to 14 years who were affected by AIDS from March to April 2019 in Nepal. Children’s psychosocial problems were measured using questionnaires and scales developed by AIDS Psychosocial metrics. Stigma and discrimination perceived by children were measured using stigma, discrimination inventory for AIDS Affected Children. The associations between stigma and discrimination with psychosocial consequences were analyzed using multiple regression and logistic regression analysis.

**Results:** Of 468 children, 38% reported that they experienced any form of stigma from the community. Those who experienced stigma were more likely to have fear of isolation compared to those who did not experience stigma (AOR: 2.48, 95% CI: 1.50, 4.11, p=0.001). CABA were more likely to have lower score for support seeking for psychosocial support (β=−0.55, p=0.021) when they experienced stigma. Additionally, children were more likely to have higher scores for psychological distress if they had stigma and discrimination (β=1.30, p=0.005).

**Conclusion:** CABA experienced high stigma and discrimination that resulted in poor psychosocial well being and fear of isolation in Nepal. The results highlight the need of psychosocial counselling and support services to children at their school and in the mutual support groups to improve their psychosocial well-being.

**PE30/17**

The quality of life among people living with HIV in Taiwan in the era of STR

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**Purpose:** We have adopted single tablet regimen (STR) for treating people living with HIV in Taiwan in recent years. The STR has largely increased the compliance and also viral suppression rate. However, the study of impact on quality of life (QOL) is lacking in Taiwan.

**Method:** This is a cross-sectional study by self-administrated structured questionnaire. The people living with HIV treated in National Taiwan University Hospital (NTUH) and Yun-Lin branch, NTUH were invited to participate the web-based questionnaire of WHOQoL-HIV BREF and BSRS. We aim to analysis the participants’ QOL and risk of depression.

**Results:** During April 1 to June 30, 2019, there were 212 participants responded the questionnaire. The mean age was 39.31±9.66 and 183(86.32%) were male. There were 126 participants were mamm sex with mamm (MSM), 43 heterosexual and 43 persons with injection drug use (PWIDU). The ART coverage rate, 100% adherence and viral suppression were significant different among the three risk groups (p<0.001, 0.009 and 0.01 respectively) and lowest among the PWIDU group. PWIDU also had lowest QOL, even though no statistical significantly difference among the three risk groups. There was a trend for BRBS difference (p<0.07), which is higher in the MSM group. By multiple linear regression we noted that partner relationship, income level, treatment duration, BSRS level were independent factors associated with QOL after adjusted by risk groups, adherence and comorbidities.

**Conclusion:** Most people living with HIV in Taiwan can achieve viral suppression under STR. The QoL among PWIDU need more attention. We suggest caregiver should still note high tendency of depression among MSM groups even while they have good viral control. Whether the partner relationship can improve after same marriage law issued since 2019 in Taiwan and improve QOL in turn warrants further study.

**PE30/18**

Experiences of and factors influencing physical activity in people living with HIV: a qualitative systematic review

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**Purpose:** Despite proven benefits of physical activity (PA) for physical, mental and social wellbeing to people living with HIV, and in preventing co-morbidities, uptake of PA in this population remains low. Understanding the reasons is critical to effecting behaviour change. This systematic review of qualitative research aimed to synthesise evidence of experiences, barriers, and facilitators of PA in people living with HIV using the Theoretical Domains Framework (TDF) for behaviour change.

**Method:** A systematic search of six electronic databases. Screening of results by two independent reviewers with adjudication by a third reviewer. Qualitative and mixed methods studies that reported perceptions and/or experiences of engaging with PA were included. Two quality appraisal tools
were used to assess risk of bias in individual papers and judge confidence in review findings. Study findings were extracted to populate the TDF domains and then condensed and summarised.

Results: 22 studies were included, 33 factors related to 13 of the 14 TDF domains were identified. Confidence in findings was judged high or moderate for 27 of the 33 factors. Most commonly reported barriers to PA, with at least moderate confidence, were; lack of knowledge about types of exercise and how to access them, low motivation resulting from depression or fatigue, and low confidence and perceived physical limitations. The most common facilitators to PA, with at least moderate confidence, were support from friends and family, group settings, buddy systems, and experiencing the potential benefits of PA in terms of prevention or delay of symptoms and comorbidities.

Conclusion: This systematic review indicates the key barriers and facilitators to uptake of PA reported by people living with HIV. Incorporating these findings into development and delivery of interventions could improve uptake and continuation of PA, potentially increasing the likelihood of effectiveness, and contributing to improved health outcomes in this population.

PE30/20
Perception of condom use in the era of pre-exposure prophylaxis (PrEP): a qualitative analysis
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Purpose: Risk compensation by reducing condom use has become a new focus of considerable concern in the course of delivering pre-exposure prophylaxis (PrEP) for preventing HIV infection. The development of effective PrEP programs will require an understanding of perception of condom use that can be explained by how high-risk individuals perceive their personal risks. This study aimed to explore the perceptions of early adopters of PrEP towards condom use in Hong Kong.

Method: This is part of a larger study involving in-depth interviews with men who have sex with men (MSM) between March and June 2019. All were PrEP users attending a pilot PrEP service in Hong Kong. Audios were transcribed verbatim, manually coded, and categorized with themes emerging using inductive approach.

Results: A total of 13 MSM between 22 and 59 year-old were interviewed. Four themes arose from self-reported data: (1) "Condoms provide better protection than PrEP to prevent HIV" among those perceiving relatively unchanged level of risk due to poor PrEP adherence; (2) "Condoms are less essential" among those perceiving substantial decreased risk resulted from good PrEP adherence, coupled with personal preference for condomless sex; (3) "Condoms are still essential" among those emphasizing the need to respect partner’s preferences for condom use, and those perceiving irregular sexual encounter as a higher-risk behavior than regular sexual encounter; and (4) "Condoms are actually essential" among those who wanted better protection after diagnosis of sexually transmitted infections (STIs) during the study.

Conclusion: The estimation of self-perceived HIV risk based on an MSM’s views towards PrEP’s efficacy, relationship status with partner, and experiences of STIs, strongly influences perception of condom use. While HIV risk has been redefined varying from individual experience, advice on risk assessments through risk-reduction counselling would need to be tailored to the changing behavioral practices in PrEP users.

PE30/21
Recommendations for enabling timely pregnancy disclosure to clinical staff of women living with HIV
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1Fundation Baylor Maria Neagra, Baylor Clinical Centre of Excellence, Constanta, Romania 2Universite Lumiere Lyon 2, Lyon, France 3Universite Claude Bernard Lyon 1, Health Services and Performance Research, Lyon, France

Purpose: The Baylor clinic in Romania initiated a quality improvement program, starting from the observation that several women living with HIV (WLH), enrolled into care for longer than 12 months, have not informed the clinical staff about the ongoing pregnancy, endangering both their health and their infants. We aimed to identify improvement areas in the clinic operations, based on lessons learnt from interviews with WLH.

Method: WLH were interviewed about their experiences regarding pregnancy disclosure and subsequent care received in the clinic (n=39, 14% did not disclose, 86% disclosed). Three independent coders classified responses facilitators and barriers using the RQDA software. Quality improvement recommendations were inferred from the barriers listed by patients.

Results: The WLH had mean age 30 and were from 53% rural area. Recommendations to overcome barriers include: ensuring communication of roles and responsibilities of all staff especially to newer patients; displaying and communicating guaranteed confidentiality, to decrease apprehension about negative consequences; shortening and streamlining duration of service delivery to affect less patients’ schedule; improving personnel’s attitude, towards a more neutral and judgement-free, to increase discussions on difficult topics, such as abortions or casual sex encounters; clarifying patients’ roles in shared decision making.

Conclusion: The willingness to disclose pregnancy is dependent upon favorable external circumstances. To positively alter the clinic circumstances, we plan to create information-education-communication materials for WLH to encourage patients disclose and anticipate their journey in case of pregnancy. Ways of effectively communicating roles and responsibilities of staff in the clinic need to be assessed and deployed. Healthcare providers’ communication skills will be diversified with other tools, such as the teach back technique and it’s use in clinical encounters will be assessed regularly. Communication around confidentiality and patients rights, including reproductive rights, will be prioritized among WLH, regardless of number of years since enrollment into care.

PE30/22
Health-related quality of life in a single center cohort of people living with chronic diseases: comparison between HIV and other clinical conditions
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Purpose: To perform a comprehensive assessment of patient’s reported outcomes measures (PROMs) among PLWH and patients affected by other chronic conditions (OC) such as diabetes mellitus type 1, rheumatoid arthritis, breast cancer in hormonal therapy and to investigate factors associated with different PROMs outcomes.

Methods: Cross-sectional observational study. Questionnaires investigating quality of life (Medical Outcomes Study Short Form 36-item Health Survey), work productivity (WPI), adherence (Morisky), health status (Eq-SD-3L), treatment satisfaction (TSG) were administered to pts consisently observed at a single Universitary Hospital during a 2 month-period (march-may, 2019). Inclusion criteria: age=70 y, history of chronic disease= 1 y, being in a stable therapy=6 months, clinician-based life expectation >2 y, absence of main functional impairment (ADL>=8).

Logistic regression analysis was used to analyze the association between disease group (HIV vs OC) and PROMs.

Results: 132 patients were enrolled (51 PLWH, 81 OC). Mean age: 49 y (SD 11), mean time of disease 12y (10), 96% were Caucasian, 35% assumed polypharmacy, 42% of male were PLWH vs 16% OC (p<0.001), 19% PLWH vs 6% OC had clinical complications (p<0.001). Differences in specific PROMs means are reported in figure 1. PLWH showed greater values in all domains considered. At multiple regression analysis after controlling for variables in the legend, older age, polypharmacy and HIV infection were independently associated with most of domains. In particular, HIV infection was associated with all except for mental health and work productivity.
Conclusions: In this cohort of patients with chronic conditions followed within the same health setting, PLWH showed better self-reported health outcomes compared to other chronic conditions considered as a whole, with comparable characteristics of chronicity. The independent detrimental role of older age and polypharmacy in most outcomes suggests the need of longitudinal assessment of PROMs in clinical practice.

Significative correlations between PROMs and sociodemographic and clinical characteristics

Figure 1. Mean values of PROMs according to chronic conditions (HIV vs OC)

PE30/23
Experiences of Dutch obstetric healthcare providers with HIV-positive pregnant women: a qualitative study
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Purpose: HIV-related stigma is still present among healthcare providers, which potentially endangers the quality of care for all HIV-positive people. In case of pregnancy, this stigma negatively influences mental health during pregnancy, and during and after birth. The aim of this study is to assess the experiences of Dutch obstetric healthcare providers in providing care to HIV-positive pregnant women, and the role of HIV-related stigma in that.

Method: This was a qualitative study. Semi-structured individual interviews and duo-interviews were conducted with 16 Dutch obstetric healthcare providers, varying from cleaner to gynaecologist.

Results: Through thematic analysis, five themes emerged: transmission, knowledge, assumptions based on society’s view, compassion with HIV-positive pregnant women, and culture differences as source for conflicting values. The first two themes belong to ‘care for yourself as healthcare provider’, while the resting themes belong to ‘care for pregnant women’. A frequently mentioned motif was extra awareness to prevent HIV transmission, which was related to not having adequate knowledge about HIV. There seems to be a difference in level of knowledge among the healthcare providers, where the gynaecologist and midwives had the highest level of up to date knowledge. Besides, healthcare providers struggled with non-disclosure of HIV-status of the pregnant women to their partner, where contrasts with other perceived cultures took a central place. Another recurrent theme was the perspective of the partner, including the rights of the father. Overall, healthcare providers reported behaviour that arose from certain negative connotations related to considerations about HIV, which can be considered as unintended stigmatizing behaviour resulting from existing stigma.

Conclusion: This study provides insight into the experiences of obstetric healthcare providers in providing care to HIV-positive pregnant women. These findings suggest a need to increase knowledge about HIV among obstetric healthcare providers, and to increase culture comprehension in healthcare settings.

PE30/24
Evaluation of knowledge, attitudes and practices among HIV positive pregnant women and their partners in four healthcare facilities in Malawi
I Triulzi, S Orlando, I Palla, F Ciccacci, H Sangare, S Mancinelli, G Torchetti and L Palombi
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2Università Tor Vergata, Roma, Italy 3Community of Saint Egidio, Blantyre, Malawi

Purpose: In Malawi, HIV prevalence in the adult population is one of the highest in the world, especially in young women (11.7% vs 7.4%-UNAIDS). Understanding knowledge, attitudes and practices (KAP) is crucial to plan proper interventions to reduce the spread of HIV and overcome cultural barriers.

Method: HIV+ pregnant women accessing 4 health DREAM facilities in Malawi (Machinjiri, Chileka, Blantyre and Balaka) were invited to answer a KAP questionnaire with their partners on the PMTCT process. A KAP questionnaire (27 questions) was developed exploring the level of knowledge about HIV (route of transmission, modes of prevention and treatment), of attitude (way of being and of taking care of HIV+ people) and of practices (behaviours).

Results: 79 subjects from 4 DREAM centres (Balaka 8, Blantyre 2, Chileka 23, Machinjiri 46) participated; 48.1% were female. Regarding knowledge of HIV, (14 questions) males showed a higher number of correct responses than women (13±0.3 vs 11.6±0.3, p=0.001), on attitude (7 questions) male and women reported similar number of positive answers (5.7±0.2 vs 5.4±0.2,ns) whereas risky practices were more often reported by women (68.4% vs 42.5%, OR 2.9 [1.15–7.40]), with significant differences on condom use (36.8% vs 60.0%, p=0.046) (ns). Associations of knowledge with attitudes and practices (logistic regression): with increasing knowledge scores responders were likely to have positive attitudes (OR=1.06, p=0.001) and safe practices (OR=1.08, p=0.03). Moreover, distinguishing by gender, the association between knowledge and attitude was significant both in male (OR=1.08, p=0.02) and female respondents (OR=1.06, p=0.02), but the association between knowledge and practices was significant only in males (OR=1.08, p=0.03).

Conclusion: Rates of knowledge and attitudes are still particularly poor in HIV+ patients in Malawi, especially women. The scarce association between KN and practices in female patients underscores the need for a deeper understanding of behavioural mechanisms in HIV+ patients in Malawi, especially women.

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PE30/24
Evaluation of knowledge, attitudes and practices among HIV positive pregnant women and their partners in four healthcare facilities in Malawi
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Towards the 4th 90, measuring multi-dimensional quality of life in people living with HIV in Aquitaine, France: psychometric properties of the French version of the WHOQOL-HIV BREF

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Purpose: To assess the psychometric properties of the French version of the WHOQOL-HIV BREF instrument in adults living with HIV-1 (PLWH) in Nouvelle Aquitaine.

Method: We conducted a cross-sectional study nested within the ANRS CO3 Aquitaine cohort. From July 2018 – May 2019, participants were consecutively enrolled at their HIV-consultations and completed a web-based (n = 583 PLWH) or paper self-administered questionnaire (n = 402) or completed measures at a HIV primary care clinic in Birmingham, Alabama.

Results: 583 PLWH were enrolled: median age 56, 73% male, 85% French descent, 99% currently treated and 91% virally suppressed. Floor effects were explored known-group validity based on CDC clinical categories. 4 of 6 domains demonstrated adequate internal consistency (Table 1).

Conclusion: The French version of the WHOQOL-HIV BREF in an older, treatment-experienced but virally suppressed population showed adequate internal consistency for six domains. The CFA showed good concurrent, convergent and discriminant validity and evidence of known-group validity.

Table 1. Internal consistency of the French version of the WHOQOL-HIV BREF

<table>
<thead>
<tr>
<th>Domain</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Range (Min)</th>
<th>Range (Max)</th>
<th>Cronbach’s α</th>
<th>Coeff.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Physical health</td>
<td>571</td>
<td>14.15</td>
<td>2.97</td>
<td>4</td>
<td>20</td>
<td>0.63</td>
<td></td>
</tr>
<tr>
<td>II. Psychological health</td>
<td>566</td>
<td>13.70</td>
<td>2.78</td>
<td>4.8</td>
<td>20</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>III. Level of independence</td>
<td>557</td>
<td>14.65</td>
<td>3.49</td>
<td>20</td>
<td>0.72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV. Social relations</td>
<td>554</td>
<td>13.91</td>
<td>3.03</td>
<td>4</td>
<td>20</td>
<td>0.70</td>
<td></td>
</tr>
<tr>
<td>V. Environmental health</td>
<td>554</td>
<td>14.37</td>
<td>2.58</td>
<td>6</td>
<td>20</td>
<td>0.79</td>
<td></td>
</tr>
<tr>
<td>VI. Spirituality/personal beliefs</td>
<td>567</td>
<td>15.04</td>
<td>3.35</td>
<td>20</td>
<td>0.64</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The CFA results (Figure 1) showed that the six-domain structure of the WHOQOL-HIV BREF produced an acceptable fit to the data (CFI = 0.833; RMSEA = 0.071 [90% CI 0.067 – 0.075]). Items were correlated with their domain (r = 0.45 – 0.82). All but one item were more highly correlated with their respective domains. Scores were higher among asymptomatic compared to symptomatic participants but no differences were detected between B and C categories (Table 2).

Conclusion: The French version of the WHOQOL-HIV BREF in an older, treatment-experienced but virally suppressed population showed adequate internal consistency for six domains. The CFA showed the original structure produced an acceptable fit to the data. It showed good concurrent, convergent and discriminant validity and evidence of known-group validity.

Table 2. Known–groups validity of the WHOQOL-HIV instrument according to CDC clinical categories for HIV infection (N=583)

<table>
<thead>
<tr>
<th>Overall Qol. Health</th>
<th>A (N=330)</th>
<th>B (N=136)</th>
<th>C (N=117)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
<td>Mean 95% CI</td>
</tr>
<tr>
<td>General Qol. Status</td>
<td>3.79 (3.70–3.87)</td>
<td>3.57 (3.44–3.71)</td>
<td>3.50 (3.35–3.66)</td>
</tr>
<tr>
<td>General Health Status</td>
<td>3.67 (3.57–3.77)</td>
<td>3.36 (3.19–3.53)</td>
<td>3.43 (3.25–3.60)</td>
</tr>
<tr>
<td>VI. Spirituality/personal beliefs†</td>
<td>15.30 (14.95–15.66)</td>
<td>14.53 (13.95–15.11)</td>
<td>14.90 (14.26–15.55)</td>
</tr>
</tbody>
</table>

Figure 1. The structure of the French version of the WHOQOL-HIV BREF based on CFA

Body size modifies the relationship between internalized HIV stigma and pain in people with HIV in the Southeastern USA

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Purpose: Pain and obesity have emerged as common co-morbidities with HIV. Meanwhile, HIV-related stigma poses a significant barrier to improving health for people with HIV (PWH). Research supports an association between stigma and pain. Obesity is also associated with pain, but may interact with other variables. In the present analysis, we investigated the role of body size as a moderator of the association between internalized HIV stigma and acute pain.

Method: Participants (N = 180 PWH not currently using substances) completed measures at a HIV primary care clinic in Birmingham, Alabama.
Internalized HIV stigma was measured using the revised HIV Stigma Scale, self-stigma subscale. Height and weight measures were collected. BMIs were categorized as “Healthy” (BMI=18.5–24.9), “Overweight” (BMI=25–29.9), and “Obese” (BMI=30+). Current pain was reported one week following initial study measures using a numerical rating scale from 0: “none,” to 10: “worst imaginable.” Covariates included age, sex, race, sexual orientation, socioeconomic status, and months on antiretroviral medications.

**Results:** Participants included 31% with healthy range BMI, 39% with overweight range, and 30% with obese range. Both internalized HIV stigma and BMI category were positively associated with pain. The interaction of stigma with weight category was significant (B=-1.02, SE=0.45, 95% CI [-1.90, -0.13]). Upon examination of simple slopes, among PWH with lower BMIs internalized HIV stigma was positively associated with pain (B=1.48, SE=0.55, 95% CI [0.40, 2.56]). Internalized HIV stigma was not associated with pain for PWH in the overweight range (B=-0.46, SE=0.36, 95% CI [-0.24, 1.17]), or the obese range (B=-0.55, SE=0.60, 95% CI [-1.73, 0.62]). Significant covariates included female sex, and lower socioeconomic status.

**Conclusion:** Findings support HIV stigma relates to greater perceptions of pain. The association may depend on body size. Research is needed to understand individuals’ body size and composition perceptions in relation to HIV stigma, which can inform health communication for PWH managing their weight or pain.

**Standard of care**

**PE31/1**

**Exploring the attitudes of HIV-positive patients on single-tablet antiretroviral regimens towards generic de-simplification**

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**Purpose:** The majority of HIV-positive outpatients attending the Mater Hospital in Ireland are prescribed single tablet antiretroviral regimens (STRs). However, generic equivalents of the most commonly-prescribed STRs are not yet available. In order to switch to generic antiretrovirals, the majority of patients on STRs would therefore be required to ‘de-simplify’ their regimen. Although the potential exists to realise substantial medication cost savings through generic de-simplification, barriers to its widespread adoption include potential effects on adherence and quality of life. The study aim was to establish the perspectives of patients on STRs regarding generic de-simplification.

**Method:** A questionnaire was completed by 287 Mater Hospital outpatients on STRs. IBM® SPSS® was used for further analysis. Descriptive statistics were used to summarise participants’ characteristics and non-parametric tests were used to test for statistical significance between groups.

**Results:** The highest proportion of patients were non-Irish national, employed males with a college degree or higher (n=132/286) and 59.1% (n=169/286) when participants were unsure, or unwilling, were asked if generic de-simplification would be acceptable to them for cost saving reasons or re-investment into HIV care respectively. Having excess medication bottles was the main reason for reluctance to switch at 53.6% (n=105/196), followed by adherence concerns (n=85/196, 43.4%).

**Conclusion:** It appears the majority of participants would not oppose generic de-simplification for the benefit of society or HIV care. Patient engagement and effective communication may aid acceptance. Generic de-simplification could result in significant cost savings without compromising patient care.

**PE31/2**

**Comparison of Immunological and virological response to cART between HIV-1/O and HIV-1/M patients followed-up in France:**

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Therapeutic outcomes for patients infected by genetically divergent HIV-1/O are not well-known, due to scarce data and lack of comparison with patients infected by pandemic HIV-1/M. Our aim was to compare the response to cART between HIV-1/O and HIV-1/M patients followed-up in France. All naïve HIV-1/O subjects initiating cART in France in the ANRS-ORIVAO study were compared to naïve HIV-1/M initiating cART in the ANRS-COPANA cohort. Piecewise linear mixed-effect models and Kaplan-Meier survival curves were used to analyze immunological and virological response to cART, in the overall population (n=65 HIV-1/O vs 279 HIV-1/M), and in two subpopulations: patients originating from sub-Saharan Africa (African population), as most HIV-1/O patients are of Cameroonian origin, and patients initiating 2INI+1IP/r (2IR population).

In the overall population, baseline plasma viral load (pVL) was 0.7 log10 copies/mL lower in HIV-1/O than in HIV-1/M patients (p=0.003), but no difference was found for occurrence of pVL<200 cp/mL after cART initiation (log-rank test, p=0.57). Baseline median CD4 count was lower in HIV-1/O (179/mm3) vs. HIV-1/M (248/mm3) (p=0.002). Between baseline and 4 months, CD4 increase did not differ (p=0.87), but was significantly lower for HIV-1/O after 4 months of treatment (p=0.04). The African population showed no difference between HIV-1/O vs HIV-1/M for baseline pVL, occurrence of pVL<200cp/mL and CD4 increase. For the IP/r population, baseline pVL was 1 log10 copies/mL lower in HIV-1/O vs HIV-1/M patients (p=0.003), leading to occurrence of pVL<200cp/mL significantly faster for HIV-1/O vs HIV-1/M (log rank test: p<0.001), but immunological response to cART was similar.

pVL differences between HIV-1/O and HIV-1/M existed at baseline, in the overall population and IP/r population. However, HIV-1/O and HIV-1/M immunological and virological responses to cART did not differ when patients’ geographical origin was taken into account. In France, treating HIV-1/O following HIV-1/M defined criteria leads to similar therapeutic outcomes.

**PE31/3**

**From HIV diagnosis to antiretroviral therapy initiation in Croatia from 2013 to 2018**

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1University Hospital for Infectious Diseases ‘Dr. Fran Mihaljevic’, Zagreb, Croatia 2School of Medicine, University of Zagreb, Zagreb, Croatia

**Purpose:** We describe where the HIV diagnosis was made, linkage to care and the time from HIV diagnosis to antiretroviral therapy (ART) initiation in Croatia, 2013 to 2018.

**Methods:** Croatia has a centralized system of care and all HIV patients are treated at the University Hospital for Infectious Diseases (UHID) in Zagreb. Data on persons entering care were extracted from the electronic database at UHID. Included were the persons that were nationals or residents of Croatia that have previously not been in care elsewhere.

**Results:** Overall 587 patients entered care from 2013 to 2018. The first HIV-positive test was done at: hospitals (other than UHID) in 150 (25.6%) persons, voluntary counselling and testing settings in 147 (25.0%), UHID in 103 (17.5%), community-based settings in 85 (14.5%), other places in 62 (10.6%) and unknown sites in 40 (6.8%) persons. For the period 2014–2018, linkage to care among those who entered care, was within 7 days of the first HIV-positive test in 53%, within 14 days in 78% and within one month in 91% persons. The median CD4+ cell count at entry into care ranged from 255/μL in 2017 to 341/μL in 2018. It was very low when HIV was diagnosed in hospital settings (median, 84/μL) and highest when HIV was diagnosed at community-
based settings (median, 413/μL). In 2017 and 2018 ART was initiated within 24 hours from the first clinical visit in 78% and 71% persons respectively, whereas in 2014–2016 it was initiated in 36–62% persons.

Conclusion: Community-based HIV testing contributed to earlier HIV diagnosis. Linkage to care was very good and rapid ART initiation is currently a common practice in Croatia. Expanding community-based HIV-testing accompanied by prompt linkage and early ART might contribute to the decrease of new HIV-infections in Croatia.

**PE31/4**

Effective management of symptoms – a nursing intervention

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**Purpose:** Effective symptom management is considered an essential component of nursing care practice for different clinical conditions, but it is particularly important in chronic diseases (Sidani, 2001), as is the case with HIV infection.

**Method:** Thus, the purpose of this research was to develop a nursing intervention program that demonstrates its effects on symptom management and consequently adherence to antiretroviral therapy in the person with HIV infection.

**Results:** This is a study who the sample was 73 participants with symptoms of anxiety, fatigue, fear, depression and headaches. The majority of participants (96.9%) reported never having failed the therapy, 24.7% took the therapy as they learned, “every time”, 57.5% reported adhering to instructions, 91.8% said didn’t forget, 28.8% reported “never having stopped”. As for the reason for not taking at, 15% was simply forgetting. Regarding evaluation pre and post intervention of the manual of symptom management strategies use, by the Wilcoxon test, the differences were shown to be statistically significant in the symptoms anxiety, fear and fatigue confirming the theoretical construct that the use of the manual improved these three symptoms. On the other hand, the use of the manual helped to reduce the failures in antiretroviral therapy, with statistically significant differences.

**Conclusion:** Nursing consultation as a care context, where nursing intervention has contributed to a better management of symptoms and adherence to antiretroviral therapy in the person with HIV infection, should receive greater attention at the hospital level, but also, and especially at the level of the organization of primary health care. The study showed that symptom management is a sensitive indicator of nursing care, where the intervention of the nurse, wherever it takes place, privileges the quality of communication and relation with the sick person and helps to improve the management of its symptoms, as well as adherence to antiretroviral therapy.

**PE31/5**

Tetanus seroprotection in HIV-positive subjects living in Belgium: risk factors for seronegativity, evaluation of medical history and a rapid dipstick test

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1CHU Saint-Pierre, Infectious Diseases, Brussels, Belgium 2LHUB-ULB, Brussels, Belgium

**Purpose:** Tetanus is a deadly but vaccine preventable infectious disease. The objectives of this work are, in a population of HIV-positive patients: 1) Determine the prevalence of tetanus-toxoid (TT) seroprotection, 2) identify the risk factors for TT seronegativity and 3) evaluate the accuracy of vaccination history and a rapid dipstick test.

**Methods:** HIV-positive patients attending the outpatient clinic of Saint-University Hospital AIDS Reference center were recruited between 04/01/2018 and 15/02/2019. TT-specific antibodies were measured by ELISA and a level >0.15 IU/mL was considered protective. The Tetanus Quick Stick (TQS), a rapid bedside immunochromatographic test, was evaluated in a subgroup of patients. A questionnaire was used to collect risk factors associated with seronegativity: socio-demographics features, education level, insurance data, current and nadir CD4+ T cell count, viral load & ART use. Fisher’s exact test was used for categorical variable univariate hypothesis testing and logistic regression for multivariate hypothesis tests. The Mann Whitney test was used to compare continuous variables. A p-value <.05 was considered statistically significant.

**Results:** Three hundred forty-four patients were included. TT seroprotection rate was 84.9%. After multivariate analysis, two factors were independently associated with TT seronegativity: being born outside Europe (OR: 3.02, 95% CI (1.35–6.76)) and education level lower or equivalent to high school (OR: 2.35, 95% CI (1.14–4.85)). Vaccination history report was shown to be unreliable (Sensitivity 43.79%, Specificity 76.47%, Positive predictive value 91.37% and Negative predictive value 19.31%) while TQS performance was good (Sensitivity 86.42%, Specificity 96.00%, Positive predictive value 99.29% and Negative predictive value 52.17%).

**Conclusion:** HIV-positive patients born outside Europe and those with a lower education level should be prioritarily targeted for TT booster. As in the general population, vaccination history is not reliable and TQS could represent a useful tool for screening.

**PE31/6**

The prevalence of virologic failure and resistance associated mutations in single and multi-tablet HIV treatment regimens


Taiyuan General Hospital, Ministry of Health and Welfare, Taoyuan City, Taiwan, Province of China

**Purpose:** The availability of once-daily fixed dose single tablet regimen (STR) would benefit 2nd and 3rd goals of 90 in population with HIV. This study aims to evaluate the prevalence of virologic failure and resistance associated mutations in patients taking STR.

**Method:** We conducted a retrospective study to compare virologic outcomes of STR and MTR since January 2016 to December 2018, and 1861 HIV-infected patients ever took combination antiretroviral therapy (cART) more than 6 months. There were TDF/FTC/ ATV, TDF/FTC/PV, TAF/FTC/ EVG/c and ABC/3TC/ DTG in single-tablet HIV regimens in the study site. Virologic failure was defined as plasma viral load (PVL) ≥200 copies/mL after 6 months of cART or confirmed PVL ≥200 copies/mL after achieving PVL <50 copies/mL. Population sequencing was retrospectively performed to detect emergent resistance associated mutations (RAMs). RAMs were interpreted using the International AIDS Society–USA 2016 mutations list.

**Results:** The proportion of patients on STR was significantly increased from 20.7% (202/977) to 91.0% (1759/1934) (p <0.001) since 2016 to 2018 (Figure 1). However, 4.3% (53/1232), 4.3% (73/1701) and 1.5% (27/1861) of patients were diagnosed virologic failure in 2016, 2017 and 2018, respectively. Moreover, 56.5% (30/53), 41.1% (30/73) and 63% (17/27) of patients were detected RAMs. Patients on STR had significantly less virologic failure when compared to patients on MTR in 2016 (odds ratio [OR]: 0.07 [95% CI: 0.03, 0.18], p =0.001), 2017 (OR: 0.17 [95% CI: 0.1, 0.28], p =0.001) and 2018 (OR: 0.17 [95% CI: 0.08, 0.38], p =0.001), respectively. (Figure 2) Of 201 patients diagnosed virologic failure, patients on STR had similar risk of being detected RAMs when compared to patients on MTR (OR: 0.57 [95% CI: 0.3, 1.11], p =0.1).

**Conclusion:** These findings may help healthcare authority and physicians to plan for optimal HIV disease management when the choice of both STRs and MTRs are available.
PE31/7
Development and validation of a risk score for predicting non-adherence to antiretroviral therapy
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1Hospital Del Mar, Infectious Diseases, Barcelona, Spain 2Hospital Del Mar, Pharmacy, Barcelona, Spain 3ISGlobal, Barcelona, Spain 4Autonomous University of Barcelona, Barcelona, Spain 5IMIM Hospital del Mar Medical Research Institute, Barcelona, Spain

Purpose: Despite factors influencing ART-adherence are known, a practical tool to predict non-adherence at ART initiation is lacking. Method: A model to predict non-adherence to ART was developed and validated using a cohort of people living with HIV (PLHIV) starting or resuming ART at Hospital del Mar, Barcelona, in 2012–2015 (derivation cohort) and in 2016–2018 (validation cohort). Adherence was evaluated bimonthly by pharmacy refills and self-reports. Non-adherence was defined as taking <90% of prescribed dose and/or ART interruption >one week. Predictors of non-adherence were identified by logistic regression. β coefficients were used to develop a predictor model. Optimal cut-offs were identified through bootstrapping methodology and performance was evaluated through C statistic.

Results: Overall, 574 patients were enrolled, including 349 and 225 in the derivation and validation cohorts respectively. 104/349 patients in the derivation cohort (29.8%) were non-adherent. Non-adherence predictors included: alcohol use (adjusted OR (aOR) 5.53; 95% CI 2.44–12.55) [20 points]; current substance use (aOR 2.43; 95% CI 1.16–5.21) (11 points); language barrier (aOR 7.44; 95% CI 2.78–19.95) (24 points); unstable housing (aOR 3.11; 95% CI 1.43–6.77) (13 points); ART preclusion (aOR 11.05; 95% CI 1.81–67.53) (28 points); missed appointments (aOR 10.50; 95% CI 4.36–25.31) (28 points); psychiatric disorder (aOR 2.10; 95% CI 1.00–4.61) (9 points) no factor (6 points). A score cut-off of 26.3 points identified non-adherence (sensitivity 0.87, specificity 0.86, positive predictive value (PPV) 0.73, and negative predictive value (NPV) 0.94, C statistic 0.86 (0.82–0.94)). In the validation cohort, 78/225 (34%) were non-adherent. The model predicted non-adherence with a sensitivity, specificity, PPV and NPV of 0.87, 0.86, 0.77, and 0.93 respectively (C statistic 0.91 (0.86–0.95)).

Conclusion: This easy-to-use highly sensitive and specific tool could be used at ART initiation to identify patients in need of higher resources to achieve optimal treatment goals.

PE31/8
Measles seroprevalence among HIV infected patients in central part of Poland – vaccination proposal
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Purpose: In 2018, there was 5x increase in measles in Poland with 335 cases confirmed. The majority of measles cases in Europe were reported in Ukraine (bordering with Poland), with more than 54 000 cases. The aim of study was to check the presence of measles antibodies in HIV-infected patients and establish local vaccination recommendations in this group of persons. Method: HIV(+) patients with no prior history of measles vaccination or with one dose of measles-containing vaccine (MCV) in the past were tested for measles IgG antibodies (IgGAb) between March and May 2019. They were divided into two groups: Group I – patients born before 1975 (before the introduction of measles vaccine in Poland) and Group II – patients born in 1975–1990 (received only 1 dose of MCV). Medical documentation of epidemiological data (age, sex, vaccination) and laboratory tests (CD4 and VL HIV) were analyzed.

Results: Measles IgGAb were analyzed for 161 patients (844 male), median age 41 [36, 49] with VL HIV<40 (94%). In Group I - 63 patients – never vaccinated measles IgGAb were found in 56 (89%) people, after natural infection. In Group II, 98 patients, vaccinated with 1 dose of MCV in childhood, specific IgGAb were found in 36 (37%) subjects. 11 (16%) persons without measles immunity were vaccinated with MMR vaccine. Table 1.

Conclusion: Among patients who received only one dose of MCV, the presence of measles IgGAb is quite low, only 37%. Such group of patients should be vaccinated without prior specific IgGAb testing. In group of older patients over 45 years the measles seroprevalence is high, about 90%; vaccination should be considered after testing for specific antibodies.

Patient characteristics associated with IgG measles

<table>
<thead>
<tr>
<th>Measles antibodies</th>
<th>HIV(+) patients</th>
<th>Gender</th>
<th>last CD4 clul. median [IQR]</th>
<th>MMR vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG+</td>
<td>6 (89%)</td>
<td>36 (37%)</td>
<td>&lt;0.0001 78 (85%)</td>
<td>644 [503,1013] 0</td>
</tr>
<tr>
<td>IgG-</td>
<td>7 (11%)</td>
<td>62 (63%)</td>
<td>&lt;0.0001 52 (75%)</td>
<td>534 [392,838] 11 (16%)</td>
</tr>
</tbody>
</table>

PE31/9
Nurse-led annual health review – one year follow up
M-P Klein1, S Obene-Adomako2 and I Samuel1
1King’s College Hospital, HIV and Sexual health, London, UK 2Coldcote Centre, London, UK

Objectives: People living with HIV require an annual health monitoring and assessment according to BHIVA guideline, to improve the quality of care. We developed an annual health pro-forma in 2018, for nurses to assess and monitor the prevalence and outcomes of co-morbidities in patients attending the nurses-led clinic. With this audit, we evaluated the cardiovascular, renal, bone, emotional, sexual and women’s health for 55 patients aged 31–87.

Methods: We conducted an audit of 55 PLWHIV attending a large South-East London HIV clinic in the UK, all selected via our annual health Nurse-Led clinics in June 2019. A retrospective case note review was undertaken to evaluate the annual health pro-forma the nurses introduced in July 2018.

Results: 55 patients were identified (65% male and 35% Female; median age 50 years [IQR 44–55]; 56% Black, 38% white and 5% mixed ethnic background).

- 42/47 (90%) had a 10-year Q-Risk3 assessment, 7/47 (15%) assessed scored ≥ 10% and 5/7 (71%) require an ART review.
- 32/55 (58%) patients on TDF base regimen are currently receiving ARVs associated with nephrotoxicity (TDF, LPV, and ATV), however 5/32 (13%) did not have yearly urinalysis as per BHIVA guidelines.
Table 1. Annual health review in 2018

<table>
<thead>
<tr>
<th>Annual Health Review</th>
<th>Assessment conducted (n=55)</th>
<th>BHIVA Target % (Achieved)</th>
<th>Outcome : Sign-posted</th>
<th>Outcome : Referred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular BMI (kg/m²)</td>
<td>51 (91%)</td>
<td>90% (Y)</td>
<td>25%</td>
<td>50%</td>
</tr>
<tr>
<td>Blood Pressure (mmHg)</td>
<td>55 (100%)</td>
<td>90% (Y)</td>
<td>68%</td>
<td>36%</td>
</tr>
<tr>
<td>10-year CV risk (QRisk3)</td>
<td>42 (90%)</td>
<td>90% (Y)</td>
<td>46%</td>
<td>54%</td>
</tr>
<tr>
<td>Renal health</td>
<td>55 (100%)</td>
<td>100% (Y)</td>
<td>87%</td>
<td>None</td>
</tr>
<tr>
<td>Urinalysis - bloods</td>
<td>47 (85%)</td>
<td>100% (N)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Bone health</td>
<td>26 (93%)</td>
<td>90% (Y)</td>
<td>93%</td>
<td>None</td>
</tr>
<tr>
<td>FRAX score calculated</td>
<td>51 (93%)</td>
<td>90% (Y)</td>
<td>89%</td>
<td>9%</td>
</tr>
<tr>
<td>Emotional</td>
<td>51 (93%)</td>
<td>90% (Y)</td>
<td>89%</td>
<td>5%</td>
</tr>
<tr>
<td>Health</td>
<td>51 (93%)</td>
<td>90% (Y)</td>
<td>89%</td>
<td>5%</td>
</tr>
<tr>
<td>Woman</td>
<td>18 (95%)</td>
<td>95% (Y)</td>
<td>95%</td>
<td>5%</td>
</tr>
<tr>
<td>Health discussed</td>
<td>26 (93%)</td>
<td>90% (Y)</td>
<td>93%</td>
<td>7%</td>
</tr>
<tr>
<td>Sexual Health</td>
<td>55 (100%)</td>
<td>95% (Y)</td>
<td>31%</td>
<td>67%</td>
</tr>
<tr>
<td>Alcohol</td>
<td>54 (98%)</td>
<td>95% (Y)</td>
<td>91%</td>
<td>7%</td>
</tr>
<tr>
<td>Smoking</td>
<td>51 (93%)</td>
<td>90% (Y)</td>
<td>85%</td>
<td>15%</td>
</tr>
<tr>
<td>Recreational Drugs</td>
<td>48 (87%)</td>
<td>90% (N)</td>
<td>96%</td>
<td>None</td>
</tr>
</tbody>
</table>

CV risk preform to patient over 40 years old.

FRAX score was done to all patients over 50 years old.

Table 2. Presence of co-morbidities and high-risk indicators

<table>
<thead>
<tr>
<th>Co-morbidities</th>
<th>Number of patients and N (%)</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular BMI (kg/m²)</td>
<td>≤18.5 kg/m²</td>
<td>1 (2%)</td>
</tr>
<tr>
<td></td>
<td>18.5 to 24.9 kg/m²</td>
<td>12 (24%)</td>
</tr>
<tr>
<td></td>
<td>25 to 29.9 kg/m²</td>
<td>25 (49%)</td>
</tr>
<tr>
<td></td>
<td>30 to 39.9 kg/m²</td>
<td>13 (25%)</td>
</tr>
<tr>
<td></td>
<td>Systolic BP (mmHg)</td>
<td>9 (16%)</td>
</tr>
<tr>
<td></td>
<td>Diastolic BP (mmHg)</td>
<td>11 (20%)</td>
</tr>
<tr>
<td></td>
<td>Receiving anti-hypertensive (n=55)</td>
<td>20 (43%)</td>
</tr>
<tr>
<td></td>
<td>10-year CV risk (QRisk3)</td>
<td>3 (n=47)</td>
</tr>
<tr>
<td></td>
<td>≥ 4.9%</td>
<td>7 (15%)</td>
</tr>
<tr>
<td></td>
<td>≥ 5% to 9%</td>
<td>30 (55%)</td>
</tr>
<tr>
<td></td>
<td>Not assessed</td>
<td>N/A</td>
</tr>
<tr>
<td>Smoking</td>
<td>n=55</td>
<td>1 (2%)</td>
</tr>
<tr>
<td></td>
<td>current or Never o Ex-smoker</td>
<td>49 (89%)</td>
</tr>
<tr>
<td></td>
<td>Recreational drugs</td>
<td>1 (2%)</td>
</tr>
<tr>
<td></td>
<td>n=55</td>
<td>49 (89%)</td>
</tr>
<tr>
<td></td>
<td>Never o Ex-user</td>
<td>5 (9%)</td>
</tr>
<tr>
<td>Renal health</td>
<td>CKD stage (CKD EPI)</td>
<td>48 (87%)</td>
</tr>
<tr>
<td></td>
<td>n=55</td>
<td>7 (13%)</td>
</tr>
<tr>
<td></td>
<td>Normal: 60 mmol/L</td>
<td>≤15 mmol/L</td>
</tr>
<tr>
<td></td>
<td>(CKD1 and 2)</td>
<td>(CKD1) and 2</td>
</tr>
<tr>
<td></td>
<td>&lt;30 mmol/L</td>
<td>10 (18%)</td>
</tr>
<tr>
<td></td>
<td>Urinalysis - proteinuria present (n=55)</td>
<td>27 (84%)</td>
</tr>
<tr>
<td></td>
<td>Urinalysis on TDF (n=32)</td>
<td>4 (7%)</td>
</tr>
<tr>
<td></td>
<td>Urinalysis - not done but required (n=55)</td>
<td>24 (92%)</td>
</tr>
<tr>
<td></td>
<td>Bone health</td>
<td>2 (8%)</td>
</tr>
<tr>
<td></td>
<td>FRAX score (n=26)</td>
<td>2 (8%)</td>
</tr>
<tr>
<td></td>
<td>3 Over 40 years old; 4eGFR was corrected for black ethnicity</td>
<td></td>
</tr>
</tbody>
</table>

- Of those with normal blood pressure, 11/55 (20%) are receiving anti-hypertensive, however 5/11 (45%) have uncontrollable blood pressure (>140/90 mmHg).

Introduction: The annual health review has enabled the majority of the BHIVA target attainment except for urinalysis and recreational drugs, however overall results has improved over 30%.

Conclusion: One year on, the uptake of the annual health review has dramatically improved. We identified high prevalence of comorbidities and psycho-social issues using the Nurse-led annual pro-forma, and they were referred and addressed appropriately. Due to the high complexity of care, urinalysis and recreational drugs falls short of the BHIVA target which is being addressed by the multi-disciplinary team.

PE31/11

Viral hepatitis in HIV-positive patients – testing, prophylaxis and treatment in Central and Eastern Europe


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Objectives: Because of shared routes of transmission hepatitis C (HCV) and hepatitis B (HBV) are the most common co-infections in people living with HIV (PLWH). All PLWH should be vaccinated against HBV and hepatitis A virus (HAV) and treated for HBV and HCV due to increased risk of developing end-stage liver disease. We aimed to describe testing, prophylaxis and treatment of viral hepatitis in PLWH in Central and Eastern Europe.

Method: Data was collected from 18 countries of Euroguidelines in Central and Eastern Europe Network Group (ECEE): Serbia, Turkey, Bosnia and Herzegovina, Romania, Bulgaria, Croatia, Estonia, Ukraine, Hungary, Greece, Albania, Armenia, Czech Republic, Georgia, Belarus, Slovakia, Lithuania, Poland, four countries had information from two centers.

Results: In total 21 of 22 (85%) centers in ECEE screen all PLWH for HCV antibodies and for HBsAg. In 20 centers (91%) HCV testing is free of charge either covered by governmental programs (five centers (23%)) or by health insurance (15 centers (68%)), in two centers (9%) PLWH have to pay. All centers have access to DAAs but only six centers (27%) have no limitations for treatment access. HbsAg testing is covered by governmental programs in four centers (18%), by health insurance in 15 centers (68%), in three centers (14%) HBsAg screening is available as paid service. 13 centers (59%) vaccinate all PLWH against HBV, it is free of charge in 11 centers (50%). In HIV/HBV co-infected patients 20 centers (91%) use tenofovir-based regimen. Only 12

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Late HIV diagnosis is associated with significant mortality in people living with HIV (PLWH) and high numbers of missed opportunities (MOs) for earlier testing have been identified. A pilot of a national late diagnosis review process (LDRP) was undertaken in 15 HIV services evaluating the feasibility and effectiveness.

**Purpose:**

Late HIV diagnosis is associated with significant mortality in people living with HIV (PLWH) and high numbers of missed opportunities (MOs) for earlier testing have been identified. A pilot of a national late diagnosis review process (LDRP) was undertaken in 15 HIV services evaluating the feasibility and effectiveness.

**Method:**

15 HIV services across England and Wales participated in the pilot between July and December 2018. All patients presenting to HIV service with CD4 count <200 cells/mm³ at diagnosis were included. Healthcare attendances within 5 years were reviewed for MOs, and safety reviews and feedback to external services where MOs occurred undertook if MOs and patient harm was identified. A structured survey was completed for each lead evaluating the pilot.

**Results:**

Of 127 very late diagnoses identified, 40 (31.5%) had 79 possible or definite MOs identified for earlier testing. Clinical indicator conditions were present in 58.2% of MOs episodes. PLWH with MOs were more likely to be white, UK-born (Table 1), have lower CD4-counts and AIDS-defining conditions and suffer significant harm at diagnosis (Table 2). There were no differences in age, gender, and route of HIV acquisition between those with MOs or without (Table 1).

**Table 1. Summary of patient characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Very late diagnoses without MOs (n=87)</th>
<th>Very late diagnoses with MOs (n=40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age (SD)</strong></td>
<td>44.1 years (+12.1)</td>
<td>46.9 years (+12.6)</td>
<td>0.238</td>
</tr>
<tr>
<td><strong>Male gender</strong></td>
<td>60 (69%)</td>
<td>31 (77.5%)</td>
<td>0.367</td>
</tr>
<tr>
<td><strong>Female gender</strong></td>
<td>26 (29.9%)</td>
<td>9 (22.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Transgender</strong></td>
<td>1 (1.1%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>White ethnicity</strong></td>
<td>41 (47.1%)</td>
<td>28 (70%)</td>
<td>0.016</td>
</tr>
<tr>
<td><strong>Non-White ethnicity</strong></td>
<td>46 (52.9%)</td>
<td>12 (30%)</td>
<td></td>
</tr>
<tr>
<td><strong>Country of birth - UK</strong></td>
<td>26 (29.9%)</td>
<td>23 (57.5%)</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>Country of birth - outside the UK</strong></td>
<td>61 (70.1%)</td>
<td>17 (42.5%)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. Summary of disease characteristics at HIV diagnosis**

<table>
<thead>
<tr>
<th></th>
<th>Very late diagnoses without MOs (n=87)</th>
<th>Very late diagnoses with MOs (n=40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean CD4 count at diagnosis (SD)</strong></td>
<td>101.4 cells/µL (+78.2)</td>
<td>61 cells/µL (+64.5)</td>
<td>0.003</td>
</tr>
<tr>
<td><strong>Mean HIV viral load at diagnosis (SD)</strong></td>
<td>1 043 498 copies/mL (+1 056)</td>
<td>733 471 copies/mL (+1 473)</td>
<td>0.007</td>
</tr>
<tr>
<td><strong>AIDS-defining conditions</strong></td>
<td>28 (32.2%)</td>
<td>26 (65.0%)</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Grade 3 or worse harm</strong></td>
<td>30 (34.5%)</td>
<td>29 (72.0%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Deaths</strong></td>
<td>1 (1.1%)</td>
<td>2 (5.0%)</td>
<td>-</td>
</tr>
</tbody>
</table>

Only 1 of 11 leads who contacted external services where MOs occurred reported positive engagement with the feedback process to enable earlier testing. 73.3% of services agreed the LDRP was sustainable. One site reported three deaths linked to MOs, leading to organisational learning following safety review and creation of a task force to implement universal testing.
very similar between both hospitals: CV <50 in weeks 24 and 48 of the start of ART, changes in ART in the first year, mortality rate and percentage of patients requiring admission.
Conclusion: Although improved in the last years, the percentage of late diagnosis is still high in the included centers. An improve in the delay of ART start was also observed.
- Both centers comply with GESIDA QOC indicators of follow-up including renal function measurement, pneumococcal vaccination and cardiovascular estimation.

PE31/14
Late presentation and barriers to the early HIV diagnosis in Central part of Ukraine
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1Ukrainian Medical Stomatological Academy, Infectious Diseases and Epidemiology, Poltava, Ukraine 2Poltava Regional HIV/AIDS Prevention and Control Center, Poltava, Ukraine

Ukraine has the second-largest HIV epidemic in Eastern Europe and Central Asia with high prevalence of late presentation - to 55–59% every year.
Purpose: To explore predictors for late HIV diagnosis and barriers to the early HIV diagnosis.
Method: We conducted interviews with 325 HIV-infected patients registered in Poltava regional AIDS center in 2016–2018. Barriers to early HIV diagnosis were analyzed in 128 health workers (physicians and nurses) of regional center. Nadir CD4 count <350 cells/mL or AIDS-defining illness defined late presenters. Binary or multinomial logistic regression models were used to identify the predictors for late HIV presentation.
Results: Among 325 HIV-infected patients, 182 (56.0%) were late presenters. Main predictors of late presentation identified male sex (78%, p=0.001), drug using (55.6%, p=0.05), age ≥40 years (43.2%, p<0.05). Most late presenters visited of medical clinics with symptoms during last year preceding HIV test (76.8%, p=0.001) and obtained first HIV-test following a doctor’s recommendation (62.9%, p<0.001). The main barriers to the early HIV diagnosis in health workers were pre-test and post-test counseling (82.1%), writing consent (92.7%) and social problems with testing patients from not key groups (it’s not convenient) (71.3%).
Conclusion: This study suggests association between the male sex, age ≥40 years, drug using and late presentation of HIV. Implementation of new HIV testing strategies and enhanced HIV-testing in medical clinics are urgently needed.

PE31/15
Operational research of barriers and facilitators to harm reduction services for intravenous drug users (including female IDUs)
T Zurashvili, T Kasrashvili and M Gogia
Georgian Harm Reduction Network, Tbilisi, Georgia

Purpose: Harm Reduction programs have been operating in Georgia since 2005 with the aim to reduce the health, social and economic harms of substance use to individuals, communities and societies. The aim of the study was to evaluate barriers and facilitators to HR programs and develop recommendations for improving quality of services and overcoming those barriers.
Method: Qualitative study using in-depth interviews was conducted during September-November 2017; the study participants were providers and beneficiaries of harm reduction services. Overall 12 providers and 35 IDUs participated in the study.
Results: The study results showed that stigma and discrimination is one of the leading barriers to harm reduction services, which is even much greater against female IDUs. Anonymity and confidentiality are among the most important factors for IDUs when using harm reduction services. Existing strict drug policy considerably limits access to NSP services. The issue concerning the take away dosages was named as an important barrier for joining as well as for retaining in OST programs. The study revealed that there is a geographical accessibility barrier to all harm reduction services in regions. There is a lack of awareness of NSP while awareness of OST programs is very high among IDUs. The leading factor encouraging IDUs to get harm reduction services is a free service that was common for all programs. User-friendly environment is another facilitator to the services.
Conclusion: Results of this study shed additional light on some social, structural, individual and environmental factors hindering IDUs’ access to harm reduction services. Overcoming these barriers and addressing IDUs’ needs is an important prerequisite for effective implementation of preventive programs. The study results serve as a bases for key policy recommendations for improving measures of HIV response in Georgian.

PE31/16
A seven–month prospective review of HIV admissions to a regional infectious disease unit in Manchester, UK
HZ Farooq1,2, LC Goodwin1, JY Thompson1 and A Ustianowski1,3
1North Manchester General Hospital, Department of Infectious Diseases & Tropical Medicine, Manchester, UK 2Manchester University NHS Foundation Trust, Department of Virology, Manchester, UK 3University of Manchester, Manchester, UK

Background: North Manchester General Hospital (NMGH) is home to a tertiary Regional Infectious Diseases unit (RIDIU) in the North West of England. It is the largest HIV centre outside of London in the United Kingdom, caring for around 2500 people living with HIV (PLWH). It is also the primary HIV inpatient unit for the Greater Manchester region specialising in all aspects of HIV patient care from disease complications to opportunistic infections [01]. It additionally provides specialist advice to healthcare professionals in the region with regards to assessment, management of PLWH and their holistic care.
Method: A prospective analysis of all patients admitted to RIDU was undertaken over a 7-month period (1st Nov 2017 – 1st Jun 2018). Each patient who required inpatient admission was assessed for patient demographics, referral method (whether from primary or secondary care), presenting complaint and whether their 18 month end-diagnosis was related or independent of their HIV diagnosis
Results: Of 1053 admissions to the Regional Infectious Disease Unit in Manchester, 12% (123/1053) of all admissions were due to HIV related disease. From the patients with an HIV related admission, 50% (61/123) were due to "Complications of HIV infection", 31% (38/123) were "HIV patients with OIs and 19% (24/123) were "New HIV diagnosis" who required inpatient admission. There were multiple OIs in 20 patients, PCP in 14 patients, Mycobacterial infection in 9 patients and Respiratory infection in 26 patients. Sui generis end-diagnoses comprised of leishmaniasis, falciparum malaria, schistosomiasis, limbic encephalitis, CD8 encephalopathy and immune reconstitution inflammatory syndrome secondary to progressive multifocal leukoencephalopathy.
Conclusion: The RIDU in Manchester admits a significant number of people with HIV who require inpatient care due to the complexity of their condition. The unit manages People living with HIV due to a large diversity of reasons including a variety of opportunistic infections.

PE31/17
Annual health review for people living with HIV – an evaluation
S Edwards, T Barber and F Burns

Purpose: To better standardise our documentation and to meet national standards we introduced an annual health review form from early 2019. The annual form is in two parts, one completed by the patient and one by an HIV nurse. The purpose of this audit was to evaluate the completion of the proforma and documented outcomes of people living with HIV.
Method: We reviewed completeness and outcome of the annual review process after 6 months of implementation. We interrogated documentation of physical comorbidities such as bone health, cardiovascular risk, general physical health and frailty. The Patient health questionnaire-2 (PHQ2) and Generalised anxiety disorder2 (GAD2) scales were used to screen for anxiety and depression and AUDIT C for alcohol consumption.
Results: A total of 68 annual review forms were analysed: 18% female; 76% white or not stated, 21% black, 3% Asian ethnicity; mean age 56 years (IQR 51–63). According to BHIVA guidelines 84% (57/68) needed cardiovascular risk assessment, of which 51/57 (99%) occurred. Almost all 67/68 (99%) had a FRA20 score recorded and all patients >50 years (n=84) had frailty assessed.
The GAD2 was completed on 100% and 98% had a PHQ2 documented with 21% and 17% respectively triggering consideration of onward referral to psychology support services. Almost all had alcohol consumption assessed with 13% scoring 5 or higher. Onward referrals arising from annual review is presented in Table 1.

Conclusion: Our annual form has improved documentation and identified a significant proportion of medical comorbidities triggering further investigation and intervention. Involving the wider clinical team in this process has helped improve detection of otherwise missed comorbidity, facilitated onward referral, and better supported the delivering of holistic, person-centred HIV care.

Referrals to specific services following annual health review (N=68)

<table>
<thead>
<tr>
<th>Referral Type</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fraility Clinic</td>
<td>17 (25%)</td>
</tr>
<tr>
<td>Psychology Services</td>
<td>7 (10%)</td>
</tr>
<tr>
<td>Peer Support</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>In-house Support hub</td>
<td>9 (13%)</td>
</tr>
<tr>
<td>Community Nurse Specialist</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Cardiology Clinic</td>
<td>8 (12%)</td>
</tr>
<tr>
<td>AIN (anal) Screening</td>
<td>6 (9%)</td>
</tr>
<tr>
<td>Psychology Services</td>
<td>7 (10%)</td>
</tr>
</tbody>
</table>

Annual Health Assessment

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHQ2 Score</td>
<td></td>
</tr>
<tr>
<td>&lt;3</td>
<td>36/68 (53%)</td>
</tr>
<tr>
<td>≥3</td>
<td>20/68 (29%)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>11/68 (17%)</td>
</tr>
<tr>
<td>GAD Score</td>
<td></td>
</tr>
<tr>
<td>&lt;3</td>
<td>54/68 (79%)</td>
</tr>
<tr>
<td>≥3</td>
<td>14/68 (21%)</td>
</tr>
<tr>
<td>FRAX Score</td>
<td></td>
</tr>
<tr>
<td>≥10%</td>
<td>7/68 (11%)</td>
</tr>
<tr>
<td>&lt;10%</td>
<td>60/68 (88%)</td>
</tr>
<tr>
<td>Not recorded</td>
<td>1/68 (1%)</td>
</tr>
<tr>
<td>GRISE</td>
<td></td>
</tr>
<tr>
<td>Not recorded</td>
<td>6/68 (9%)</td>
</tr>
<tr>
<td>Performed</td>
<td>11/68 (16%)</td>
</tr>
<tr>
<td>Audit-C Score</td>
<td></td>
</tr>
<tr>
<td>≥5 or more</td>
<td>9/68 (13%)</td>
</tr>
</tbody>
</table>

1Scored ≥3, suggesting some degree of depression, prompting further discussion and/or onward referral.
2Scored ≥3, suggesting some degree of depression, prompting further discussion and/or onward referral.
3Required intervention following our local guidelines.
4Positive screening - prompting further discussion and/or onwards referrals.

Onward Referral to other services following annual health review

PE31/18

Analysis of adherence to HIV-positive quality of care indicators and their impact of service quality perceptions in patient: a Spanish cross-sectional study

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Purpose: The objective was to evaluate compliance with current quality indicators of care and analyze their influence on satisfaction with patient-perceived healthcare.

Method: All HIV patients attended in a Spanish hospital between 2011 and 2017 were included for compliance with HIV quality indicators proposed by GeSIDA (Spanish AIDS Study Group). To assess patient satisfaction, the SUCE (User Satisfaction of External Consultations) questionnaire was given between February and November 2017 to those who signed the informed consent. This questionnaire was specifically designed and validated to understand the satisfaction of patients at outpatient clinics hospital. It consists of 12 items with a response scale of 1 (worst rating) to 10 (best). Through ROC curves, 6.3 was selected as value to discriminate satisfied/unhappy patients.

Results: Compliance with 47 indicators was calculated in the 334 patients attended. The satisfaction of 163 patients was assessed: 93 were excluded for loss of follow-up, transfer or decease, 43 for illiteracy or declined to participate. Of the 198 surveys delivered, 26 were not returned, 8 were delivered unanswered and 6 were invalid. The quality indicators evaluated were met. The average satisfaction score was 9.04 out of 10 (95% CI: 8.90–9.20). 98.16% patients were satisfied. The response rate was high (86%).

The indicators whose compliance was most related were 16-Periodicity of visits [difference of averages CI 95%: 0.62 (0.13–1.11)], 21-Vaccination against Hepatitis A [difference of averages CI 95%: 0.14 (0.16–2.12)] and 23-Vaccination pneumococcal infection [difference of averages CI 95%: 0.74 (0.10–1.38)]. Those who met the indicator of 26-Assessment of alcoholic intake had a lower satisfaction [difference of averages CI: -1.20 (-1.97–0.44)].

Conclusion: In this Spanish cohort, compliance with quality indicators was high, and satisfaction with healthcare scored, favorably. Adherence to quality indicators showed little relation to patient satisfaction. Quality healthcare requires the achievement of the health objectives proposed by scientific societies but also in meeting patient expectations.
Sleep and functional characteristics of Central London Outpatient HIV Cohort

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Background: Studies conducted in people living with HIV (PLWH) report high rates of sleep disturbance, without clear explanation as to cause or effect. We designed a study to assess overall quality of sleep, daytime functioning and wellbeing in a central London outpatient cohort of PLWH.

Methods: Outpatients attending 56 Dean Street were administered 8 validated sleep and wellbeing questionnaires: PSQI, FOSQ, ESS, ISI, FSS, GAD, PHQ and Wellness Thermometer. Associations were analyzed by univariate/ multivariable analyses.

Results: Of 254 patients, >99% were men (96% MSM), 60% British, mean age 41 (SD 11.7) years, mean HIV duration 8 years (SD 36.6). 94% were on ART, 99% were on dolutegravir (supplied by 3ViiV Healthcare); 22% insulinoma (ISI ≥27), 21% daytime sleepiness (ESS ≥10), 33% fatigue (FSS ≥36), 14% moderate/severe anxiety (GAD ≥10), 19% moderate/severe depression (PHQ ≥10). Mean self-reported wellbeing score was 7 (score 0–10) SD ± 2.2. HIV duration ≥10 years, anxiety and depression were associated with poor sleep quality (OR 3.2; 95% CI 1.7–5.8), BMI ≥30 (OR 1.49, 95% CI 1.09–2.04), BMI ≥18.5 (aOR = 1.69, 95% CI 1.21–2.38), smoking (aOR = 1.42, 95% CI 1.14–1.79), history of fracture (aOR = 1.46, 95% CI 1.02–2.09) were independently associated with reduced bone mineral density.

Conclusion: Among young HIV-infected MSM, low BMI is common and also the leading factor of osteopenia or osteoporosis. Besides, smoking, non-exercise, history of fracture and ever exposure of TDF have been implicated significantly; hence, TDF sparing regimen is more suitable for patients with risk factor of osteopenia and osteoporosis, and increasing body weight and exercise were encouraged to improve reduced bone mineral density.
Purpose: Recent studies have highlighted a significant weight increase in HIV-infected patients who began antiretroviral drugs (ART), particularly dolutegravir (DTG). Aim of the present study was to evaluate predictors of weight gain in DTG-treated patients in SCOLTA (Surveillance Cohort Long-Term Toxicity Antiretroviral) cohort.

Method: We analyzed data from SCOLTA prospective database. All patients initiating DTG and for whom weight was registered were considered. We defined as gainers those patients whose weight increased by at least 7% from baseline. Ninety-one patients with weight gain ranging from 1% to <7% were excluded. Non-gainers were those whose weight increased <1% or decreased.

The multivariable analysis was performed by logistic regression, with gain y/n as the dependent variable, including baseline weight, age, sex, CDC stage, ART, years of previous ART, naive/experienced, HCV treatment and statin use.

Results: A total of 503 patients were analyzed: DTG was associated to abacavir/lamivudine (ABC/3TC) in 276 patients (54.9%), tenofovir/emtricitabine (TDF/FTC) in 128 (25.4%), darunavir/ritonavir or cobicitab in 29 (5.8%), rilpivirine in 24 (4.8%), 3TC in 34 (6.8%) and tenofovir alafenamide (TAF)/FTC in 12 (2.4%). Among them, 503 and 393 patients reached 6 and 12 months follow-up. Eighty-one subjects (16.1%) were gainers (Table 1). In the multivariate analysis, the determinants for being gainers were lower baseline weight (OR by 5 Kg more 0.82, 95% CI 0.73–0.93), male sex (OR 2.04, 95% CI 1.01–4.13), TDF/FTC as compared to 3TC/ABC (OR 2.57, 95% CI 1.42–4.65), CD4 count (OR for cell/ml>500 vs <200 0.50, 95% CI 0.25–0.99), statin use (OR 2.43, 95% CI 1.06–5.05) and successful HCV treatment (OR 6.63, 95% CI 2.08–21.13).

Conclusion: In SCOLTA the use of TDF/FTC resulted as independent factor associated with weight gain in PLWHT treated with DTG. Male patients with lower baseline weight and lower CD4 were those more prone to gain weight.

Table 1. Characteristics of patients in SCOLTA DTG cohort, according to weight gain status.

<table>
<thead>
<tr>
<th>Non Gainers</th>
<th>Gainers</th>
<th>All</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=422</td>
<td>81</td>
<td>503</td>
<td>100%</td>
</tr>
<tr>
<td>N=81</td>
<td>16.1%</td>
<td>N=503</td>
<td>100%</td>
</tr>
</tbody>
</table>

Male Sex

N=310 73.5% N=64 79.0% N=374 74.0% 0.29
Age, years (mean±SD)

47.4±11.7 46.0±12.0 47.1±11.7 0.36
Weight, Kg (mean±SD)

71.2±13.3 67.4±15.4 70.6±13.7 0.02
CD4, cells/mm³ (mean±SD)

594±360 440±370 570±365 0.0006
Naive Status

N=96 22.7% N=29 35.8% N=125 24.9% 0.013
HCV active infection (baseline)

N=32 7.6% N=13 16.0% N=45 9.0% 0.014
HCV eradication during follow-up (N=45)

N=8 25% N=7 53.8% N=15 33.3% 0.06
Statin use at baseline

N=34 8.1% N=8 9.9% N=42 8.3% 0.58

PE32/4

Effects of lamivudine plus dolutegravir 2-drug regimen on bone mineral density in a multicenter Italian cohort

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Purpose: We aimed to assess the effects on bone mineral density (BMD) of a dual therapy with lamivudine (3TC) plus dolutegravir (DTG).

Method: We analyzed a multicenter cohort of HIV-1 infected, virologically suppressed patients switching to 3TC+DTG. DXA scans were performed at baseline and at weeks 48 and 96 of follow-up; areal BMD (g/cm²) was measured at the lumbar spine and at the femoral neck. Changes were compared using non-parametric tests; we assessed predictors of changes by linear regression.

Results: Eighty-one patients were analyzed. Full patients’ characteristics are shown in tables 1 and 2. Overall, after 48 weeks, we observed a significant improvement in both spine BMD (+0.06 g/cm², p=0.048) and femoral neck BMD (+0.03 g/cm², p=0.001). At a multivariate analysis, improvement in femoral neck BMD was negatively associated with baseline femur BMD (per 1 g/cm² more, −0.29, p=0.002); meanwhile, the improvement in spine BMD was negatively predicted by peak HIV-RNA value (per 10 log10 copies/mL more, −0.11, p=0.021) and baseline spine BMD (per 1 g/cm² more, −0.08, p=0.036), after adjusting for age, sex, HCV-coinfection, BMI and cumulative time on TDF or PIs.

After 96 weeks, we registered a significant improvement in femoral neck BMD (+0.04 g/cm², p=0.014); we also registered an improvement, although not significant, in spine BMD (+0.005 g/cm², p=0.065). Changes in spine BMD at 48 weeks were significantly different between patients coming from a TDF-based regimen and those who didn’t (+0.038 and +0.002, p=0.036) and at 96 weeks (+0.038 and +0.004, p=0.020).

Conclusion: 3TC+DTG showed a favorable effect on BMD in our cohort. A greater improvement was observed in patients coming from a non INI-based strategy and those with osteoporosis.

Table 1. Patients’ characteristics at baseline (n=81).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Male</th>
<th>N (%)</th>
<th>Age (years), median (IQR)</th>
<th>Anti-HCV positive, n (%)</th>
<th>HCV eradication During follow-up, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>59 (72.8)</td>
<td>52 (49.5)</td>
<td>22 (27.8)</td>
<td>93.0 (31.0; 204.0)</td>
<td>73.0 (30.2; 109.0)</td>
</tr>
</tbody>
</table>

Table 2. Patients’ characteristics at baseline (n=81).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Nadir CD4+ cell count (cells/mm³), median (IQR)</th>
<th>Lumbar spine BMD, median (IQR)</th>
<th>Lumbar spine T-score, median (IQR)</th>
<th>Lumbar spine Z-score, median (IQR)</th>
<th>Femur neck BMD, median (IQR)</th>
<th>Femur neck T-score, median (IQR)</th>
<th>Femur neck Z-score, median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>252 (148; 348)</td>
<td>0.918 (0.810; 1.019)</td>
<td>−1.60 (−2.40; 0.43)</td>
<td>−1.00 (−1.70; 0.10)</td>
<td>0.728 (0.644; 0.818)</td>
<td>−1.40 (−2.00; −0.70)</td>
<td>−0.60 (−1.10; 0.10)</td>
</tr>
</tbody>
</table>

PE32/5

Switching from tenofovir disoproxil fumarate (TDF) to tenofovir alafenamide (TAF) lowers alanine transaminase (ALT) and aspartate transaminase (AST) in patients with HIV infection or without viral hepatitis coinfection

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Purpose: Our aim was to investigate the effect of switching TDF to TAF on liver enzymes and renal and lipid profile.

Method: Consecutive HIV patients enrolled in Surveillance Cohort Long-term Toxicity Antiretrovirals/Antivirals (SCOLTA) project switching from TDF to TAF for any reasons were included. Changes from baseline (T0) to 6-month follow-up (T1) were evaluated using paired t-test if differences were normally distributed and using signed rank test if not.

Results: 291 patients switched from TDF to TAF, 163 had at least one follow-up visit. They were mostly males (131, 80.4%) and Caucasian (151, 92.6%). Forty-three (26.4%) were in CDC stage C, 48 (29.4%) on second-line antiretroviral therapy (ART), 154 (94.5%) had HIV-RNA <50 copies/mL, 35 (21.5%) were HCV-Ab positive and 14 (8.6%) HBsAg positive. Median time on TDF was 669 days (IQR 417–911). Median aspartate aminotransferase (AST) 23 IU/L (IQR 18–30), alanine aminotransferase (ALT) 24 IU/L (IQR 17–34). See table 1 for other patients’ characteristics. Changes from switch (T0) to 6-month follow-up (T1) are shown in the Table 2. At T1, both ALT (median –2, IQR -7 to 3 IU/L, p=0.0008) and AST (median –1, IQR –5 to 2 IU/L, p=0.003) were significantly reduced. ALT and AST reduction remained significant in patients negative for HCV-Ab and HBsAg (p=0.05 for both). Among 24 pts with ALT >40 IU/L, a significant proportion reduced this parameter (median change -20, -34 to -4, p=0.0001). Total cholesterol (TC) and HDL Cholesterol increased significantly [mean change 14.8±4.3 mg/dL (p<0.0001) and 3.0±1.3 mg/dL (p=0.05), respectively] and eGFR decreased significantly (3.3±1.0 mL/min, p=0.002). Conclusion: Switching from TDF to TAF demonstrated a significant reduction of ALT and AST and was associated with an improvement in eGFR and increased TC and HDL.

Table 1. Patients switching from TDF to TAF.

<table>
<thead>
<tr>
<th>Variables</th>
<th>N=163 N (%) or mean±SD or median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>46.3±10.7</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>24.9±3.7</td>
</tr>
<tr>
<td>Risk factor IVDU</td>
<td>27 (16.6)</td>
</tr>
<tr>
<td>CD4+ (cells/mL)</td>
<td>637 (440–898)</td>
</tr>
<tr>
<td>ART duration (years)</td>
<td>5.5 (2.2–13.4)</td>
</tr>
<tr>
<td>Second-line ART</td>
<td>48 (29.4)</td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>196±40</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dL)</td>
<td>49±16</td>
</tr>
<tr>
<td>eGFR (mL/min)</td>
<td>86±19</td>
</tr>
</tbody>
</table>

Table 2. Liver enzymes changes from switch to 6-month follow-up in 163 patients enrolled in SCOLTA cohort.

<table>
<thead>
<tr>
<th>Number of patients according to HCV or HBV co-infection</th>
<th>HCV-Ab Neg (n=128)</th>
<th>HCV-Ab Pos (n=35)</th>
<th>HBsAb Neg (n=149)</th>
<th>HBsAg Pos (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver enzymes</td>
<td>Median change (IQR)</td>
<td>p</td>
<td>Median change (IQR)</td>
<td>p</td>
</tr>
<tr>
<td>AST (IU/L)</td>
<td>–1 (–5 to +3)</td>
<td>0.049</td>
<td>–2 (–9 to +1)</td>
<td>0.01</td>
</tr>
<tr>
<td>ALT (IU/L)</td>
<td>–1 (–7 to +3)</td>
<td>0.024</td>
<td>–3 (–14 to +2)</td>
<td>0.006</td>
</tr>
</tbody>
</table>

PE32/6

Weight gain in people living with HIV switched to dual therapy with dolutegravir plus rilpivirine: changes in body fat mass

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Purpose: We investigated changes in weight and body composition, and associated factors, in virologically suppressed HIV-infected adults switching to a dolutegravir-based dual therapy.

Method: Weight, fat mass and lean mass were measured in a prospective cohort of HIV-infected individuals switching to dolutegravir-based dual therapy using whole-body dual-energy X-ray absorptiometry (DXA) (NCT02491242). Data were compared with a control group of HIV-infected adults switched to boosted darunavir-based dual therapy. Individuals with lipodystrophy, or prior exposure to integrase inhibitors were excluded.

Results: Overall, 54 individuals met the inclusion criteria (mean age 53 years, male 61%), 37 (69%) switched to dolutegravir plus rilpivirine and 17 (31%) switched to darunavir plus lamivudine. At baseline, median weight was 73 Kg (standard deviation, SD 14.7) and 70 Kg (SD 13.1) in the dolutegravir and darunavir group, respectively (P=0.14). After 48 weeks, weight increased by 1.80 Kg (SD 3.8, +2.5%, P=0.03) in the dolutegravir group and 0.70 Kg (SD 3.9; +1%, P=0.28) in the darunavir group, without significant differences between groups (P=0.45). After a median of 16 months (IQR 11.1–22.6) of switching, DXA scan exhibited similar increases in median fat mass in trunk, arms and legs in both groups (Table 1). Fat mass ratio was unaltered, and there were no significant changes in lean mass or muscle-related index in any group. In adjusted multivariable linear regression analysis, total fat mass increase was associated with baseline fat mass (Beta, −0.19, 95% confidence interval, CI: −0.08, −0.30) and nadir CD4+ count (Beta, −0.006, 95% CI: −0.0001, −0.012).

Conclusion: Weight gain observed with dolutegravir plus rilpivirine dual therapy was significant and related with fat mass gain in the different body compartments, with no modifications of lean mass. Nevertheless, comparable changes were observed in individuals switching to darunavir plus lamivudine. Fat mass increase was associated with baseline fat mass and immunological status.

Table 1. Changes in body fat mass. *p<0.05, Wilcoxon rank test

<table>
<thead>
<tr>
<th>Variables</th>
<th>Dolutegravir plus rilpivirine (n=37)</th>
<th>Boosted darunavir plus lamivudine (n=17)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total fat mass [%, median (SD)]</td>
<td>31.7 (8.2)</td>
<td>25.6 (8.4)</td>
<td>0.13</td>
</tr>
<tr>
<td>– Median change in percentage (IQR)</td>
<td>+1.1* [0–2.75]</td>
<td>+1.7* [−0.5, 3.8]</td>
<td>0.09</td>
</tr>
<tr>
<td>Trunk fat mass [%, median (SD)]</td>
<td>32.8 (9.1)</td>
<td>25.6 (8.4)</td>
<td>0.07</td>
</tr>
<tr>
<td>– Median change in percentage (IQR)</td>
<td>+1.4* [−0.3, −3.8]</td>
<td>+1.85* [−0.1, 4.1]</td>
<td>0.57</td>
</tr>
<tr>
<td>Arms fat mass [%, median (SD)]</td>
<td>35.3 (12.2)</td>
<td>26.1 (12.2)</td>
<td>0.05</td>
</tr>
<tr>
<td>– Median change in percentage (IQR)</td>
<td>+1.45* [−0.9, 3.87]</td>
<td>+2.45* [0.2–5.1]</td>
<td>0.22</td>
</tr>
<tr>
<td>Legs fat mass [%, median (SD)]</td>
<td>28.2 (9.2)</td>
<td>26.5 (10)</td>
<td>0.67</td>
</tr>
<tr>
<td>– Median change in percentage (IQR)</td>
<td>+1.2* [−0.55, 2.6]</td>
<td>+0.7 [−0.4, 4.9]</td>
<td>0.72</td>
</tr>
</tbody>
</table>

PE32/7

Does switching to tenofovir alafenamide fumarate impair recovery of renal function in individuals newly diagnosed with tenofovir disoproxil fumarate induced renal tubular toxicity?

N Agrawal1, M Murphy2 and J Booth1

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Purpose: Tenofovir disoproxil fumarate (TDF) causes renal proximal tubulopathy in a minority of people living with HIV (PLHV). Tenofovir alafenamide fumarate (TAF), a second generation tenofovir prodruge associated with much lower plasma tenofovir levels, appears to lack renal toxicity, but its safety when used in PLHV with a new diagnosis of TDF-tubulopathy has not been confirmed. We sought to assess the outcomes of PLHV switching from TDF to TAF for the indication of TDF-tubulopathy, compared to those switching to non-TAF regimes.

Method: In this retrospective, single-centre observational study, we identified all PLHV switching combined antiretroviral therapy (cART) regimens for the indication of newly diagnosed TDF-tubulopathy between...
2014 and 2018. Demographic data, renal (serum creatinine, urine protein: creatinine ratio [uPCR], serum phosphate, fractional excretion of phosphate [FEPO4]), and HIV (viral load and CD4) parameters were extracted from clinical databases for each individual at diagnosis of tubulopathy and last recorded clinic visit post-switch.

Results: 16 PHLV with TDF-tubulopathy were identified; 7 converted to TAF, and 9 to non-TAF CART, with mean exposure to TDF of 8.4±3.9 years and 9.2±3.9 years respectively. Significant reductions in uPCR (67±57 to 15±8 mg/mmol; p=0.04) and serum creatinine (119±12 to 115±14 μmol/l; p=0.03) and increase in serum phosphate (0.68±0.12 to 0.89±0.08 mmol/l; p=0.02), were observed in PLHV switching to TAF, after 352±215 days follow-up. No significant difference in the magnitude of change in any renal or HIV variable was observed when comparing TAF and non-TAF switch groups (Table 1). All patients had HIV PCR RNA <200 copies/mL at last follow-up.

Conclusion: Switching to TAF-based cART in PLHV with newly diagnosed TDF-tubulopathy appears safe and effective and does not impede renal recovery.

Comparison of renal variables at last follow-up, and the proportional change observed from baseline (mean±SD). *Data available in n=12/16

<table>
<thead>
<tr>
<th>TAF cART</th>
<th>Non-TAF CART</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>uPCR (mg/mmol)</td>
<td>15±8</td>
<td>22±25</td>
</tr>
<tr>
<td>Serum creatinine (μmol/l)</td>
<td>115±14</td>
<td>126±47</td>
</tr>
<tr>
<td>Serum phosphate (mmol/l)</td>
<td>0.89±0.08</td>
<td>0.97±0.22</td>
</tr>
<tr>
<td>Urine FEPO4 (%)*</td>
<td>23±8</td>
<td>26±6</td>
</tr>
<tr>
<td>% change from baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>uPCR</td>
<td>-66±21</td>
<td>-75±28</td>
</tr>
<tr>
<td>Serum creatinine</td>
<td>-4±3</td>
<td>-18±35</td>
</tr>
<tr>
<td>Serum phosphate</td>
<td>+38±36</td>
<td>+88±132</td>
</tr>
<tr>
<td>Urine FEPO4*</td>
<td>-20±55</td>
<td>-12±50</td>
</tr>
</tbody>
</table>

PE32/8

Weight gain among HIV-positive persons treated with dolutegravir or elvitegravir

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2ULouvain, Brussels, Belgium

Objectives: Integrase inhibitors-based regimens are recommended as first line antiretroviral therapy but they could lead to weight gain. The aim of our study was to evaluate the weight gain in HIV-1 infected persons treated either by dolutegravir (DTG) or Elvitegravir (EVG).

Methods: We retrospectively compared weight changes after initiating DTG or EVG among persons living with HIV (PHLV) followed in the AIDS reference center of Cliniques universitaires Saint-Luc, Brussels. Of the 619 PHLV included in the study, 508 were treated with DTG and 111 with EVG. The weight gain over time for patients on DTG and EVG was estimated by performing univariate and multivariate linear regressions adjusted for age, sex and race.

Results: In the total cohort, we observed a significant relative increase in weight of 2.80% (SEM of ±0.23) (p<0.001) during a median time of 31 weeks (0.9–64.9). This increase was more pronounced in black people than white people (3.41%±0.39 vs 2.12%±0.31, respectively, p=0.0043) but less pronounced in elderly patients: the relative weight gain decreased by an average of 0.108% per year of age. Sex bared no significant influence.

In multivariate analyses adjusting for age, sex, race, only age remains significant (p<0.001). The average relative increase in weight in the 508 patients treated with DTG and the 111 treated with EVG was 3.80%±0.35 and 4.11%±0.63, respectively (p<0.001). The relationship between weight gain and duration of treatment was significant for EVG (r=+0.209; p=0.029) but not for DTG (r=−0.033; p=0.43) (Figure 1 and 2).

Conclusion: Significant weight gain was associated with DTG and EVG treatment. This effect was less pronounced in elderly patients. On EVG, weight gain was continuous over time, whereas on DTG, weight initially increased and then stabilized. Further studies with larger cohorts are warranted to confirm these observations.

PE32/9

NRTI backbone modification impact on weight, lipids and cardiovascular risk

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1Chelsea & Westminster Hospital NHS Foundation Trust, London, UK 2Imperial College London, London, UK 3Magna Graecia University, Catanza, Italy 4University of Liverpool, Liverpool, UK

Purpose: Switch from tenofovir disoproxil fumarate (TDF) to tenofovir alafenamide (TAF) may be associated with weight gain and worsening of lipid profile. It is unclear if this is related to loss of protective effect of TDF or an effect of TAF. The impact of these findings on cardiovascular risk (CVR) has not been specifically investigated.

Method: This is a retrospective data collection from clinical notes of people living with HIV, switched to TAF-based antiretroviral treatment at Chelsea and Westminster Hospital, London, without changing other regimen components. Body weight, lipid profile, blood pressure were measured and CVR scores (QRISK2-2017 and Framingham) calculated before and every 12–24 weeks after the switch.

Results: 274 patients were included in the analysis: 216 switched from TDF (group 1), and 58 switched from non-TDF-containing regimens to TAF (group 2). Mean (SD) age was 59±9.9 years, 88.7% were male, 75.2% Caucasian, with a BMI of 23.95±4.6 m²/Kg and CD4 count of 682±300 cells/μl at switch. Overall, weight increase one year post-switch to TAF was 1.7±6.8 Kg. Statistically significant weight and cholesterol increases from baseline were observed in group 1 (1.4±5.6 Kg p=0.02 and 0.3 mmol/l±1.0; p<0.05). One year after the switch to TAF the proportion of subjects with BMI >25 Kg/m² had risen by 10%. In a logistic regression analysis the odds of having a BMI increase >10% was associated with older age (odds ratio: 0.9; 95% CI (0.9, 1.0)) p=0.02; CD4<200 cells/μl (p=0.04) and smoking (p=0.04). QRISK2-2017 and Framingham scores remained stable (p=0.0997 and p=0.17) with no changes observed from baseline to one year post-switch.
Conclusion: Our real world analysis suggests that weight and lipid increases may relate to switching away from TDF rather than the independent effect of TAF, however, long term data in larger populations are warranted.

PE32/10

Comparative neuropsychiatric toxicity profile of dolutegravir (DTG) versus efavirenz (EFV) versus other antiretroviral third drugs used either in first-line or switch antiretroviral therapies (ART): data from Icona Foundation Study Cohort

A Mondi1, A Cozzi-Lepri2, A Cingolani3, A Taveli4, M Puoti5, Y Barocci6, A Landoni7, F Bai8, C Pinnetti9, P Cinque9, A d’Arminio Monforte9, A Antinori1 and Icona

Public Health, Ancona, Italy7Infectious Diseases Clinic, University of Udine and Diseases, Polytechnic University of Marche, Dept. of Biomedical Sciences and treatment-experienced (p < .001) population [Fig. 1a,1b]. In both populations, at multivariable analysis, DTG as third drug was associated with a risk of discontinuing treatment due to NPAEs significantly lower than EFV but higher compared to other non-DTG non-EFV drugs [Table 2]. In ART-naive patients, this result was also confirmed restricting the analysis to patients starting ART after 2011 [Table 2].

In this large cohort, both ART-naive and treatment-experienced patients on DTG-based regimens showed a risk of experiencing treatment-limiting NPAEs significantly lower than patients on EFV-based regimens but higher than people on non-EFV non-DTG ART.

Figure 2: Probability of discontinuing third drug due to NPAEs according to treatment group [2A ART-naive population, 2b Treatment-experienced population].

Purpose: The aim of this study was to compare the risk of neuropsychiatric toxicity among DTG-based, EFV-based and other different antiretroviral regimens used as either first-line or switch ART.

Method: We included all ART-naive or virologically-suppressed treatment-experienced HIV+ patients, enrolled in the Icona cohort, who started or switched to an antiretroviral regimen including DTG or EFV or other currently used third drugs (boosted darunavir, atazanavir, rilpivirine or other integrase strand transfer inhibitors [INSTIs]). Probabilities of discontinuing third drug due to neuropsychiatric adverse events (NPAEs) were estimated by Kaplan Meier analysis. Predictors of treatment discontinuation due to NPAEs were identified by Cox regression analysis. Sensitivity analysis was performed in ART-naive patients starting ART from 2011 (first year in which DTG was available in Icona database).

Results: Overall, 7,854 ART-naive patients (starting regimens based on DTG in 17%, EFV in 20% and non-EFV non-DTG in 63%) and 3,300 treatment-experienced patients (switching to regimens based on DTG in 31%, EFV in 15% and non-EFV non-DTG in 54%) were included. Main baseline characteristics are shown in Table 1. At survival analysis, patients on EFV-based ART were more likely to stop third drug due to NPAEs compared to patients on DTG-based or other ART both in ART-naive (p <.001) and in treatment-experienced (p<.001) population [Fig. 1a,1b]. In both populations, the SWORD studies demonstrated noninferiority post-switch to dolutegravir (DTG) + rilpivirine (RPV) vs. 3- or 4- drug current antiretroviral

PE32/11

SWORD 1&2: maintenance or improvement in renal function in PLWH through 148 weeks after switch to the dolutegravir + rilpivirine 2-drug regimen

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1University Hospital Germans Trias and the Fight AIDS Foundation, Barcelona, Spain 2Hospital of Infectious Diseases, St. Petersburg, Russian Federation 3HIV Unit, Department of Internal Medicine, Madrid, Spain 4Saint-Antoine Hospital, AP-H, Paris, France 5Metropolis Medical Group, San Francisco, USA 6ViiV Healthcare, Brentford, UK 7GlaxoSmithKline, Uxbridge, UK 8ViiV Healthcare, Research Triangle Park, USA 9Janssen Research & Development, Beerse, Belgium

Purpose: Our real world analysis suggests that weight and lipid increases may relate to switching away from TDF rather than the independent effect of TAF, however, long term data in larger populations are warranted. In this large cohort, both ART-naive and treatment-experienced patients on DTG-based regimens showed a risk of experiencing treatment-limiting NPAEs significantly lower than patients on EFV-based regimens but higher than people on non-EFV non-DTG ART.

Figure 2: Probability of discontinuing third drug due to NPAEs according to treatment group [2A ART-naive population, 2b Treatment-experienced population].

Table 1. Relative hazards (RH) of discontinuing third drug for neuropsychiatric toxicity from fitting Cox regression models according to treatment history:

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ART-naive population</th>
<th>ART-experienced population</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTG-based regimen</td>
<td>EFV-based regimen</td>
<td>Other regimen</td>
</tr>
<tr>
<td>RH (95% CI)</td>
<td>RH (95% CI)</td>
<td>RH (95% CI)</td>
</tr>
<tr>
<td>Adjusted</td>
<td>Adjusted*</td>
<td>Adjusted**</td>
</tr>
<tr>
<td>p-value</td>
<td>p-value</td>
<td>p-value</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td>ART-naive</td>
<td>ART-experienced</td>
<td>ART-naive</td>
</tr>
<tr>
<td>DTG</td>
<td>EFV</td>
<td>Other</td>
</tr>
<tr>
<td>Starting ART after 2011</td>
<td>Starting ART before 2011</td>
<td>Starting ART before 2011</td>
</tr>
<tr>
<td>3.03 (1.01, 9.32)</td>
<td>3.19 (1.01, 9.99)</td>
<td>3.78 (1.18, 11.51)</td>
</tr>
</tbody>
</table>

*Adjusted for: gender, age, mode of HIV transmission, nationality, calendar year of starting ART, AIDS diagnosis, BMI, STI (yes vs no), backbone, CD4 count nadir, highest level of education, employment and NPS symptoms at baseline.

**Sensitivity analysis on pts starting ART from 2011.
therapy (CAR) at Week 48 and maintained viral suppression to Week 148. The NRTI tenofovir (TDF) and certain protease inhibitors (lopinavir, atazanavir) are associated with renal toxicity. DTG+RPV may be a suitable therapy for renally impaired patients. We report pooled SWORD study data of renal parameters through Week 148.

Method: Adults with suppressed HIV-1 RNA were randomized to DTG+RPV (Early-Switch group, ES) or continue CAR. CAR participants suppressed at Week 48 switched to DTG+RPV at Week 52 (Late-Switch group, LS). Renal function post switch to DTG + RPV was evaluated using eGFR estimated by serum cystatin C (CKD-EPI Equation), retinol binding protein (RBP): creatinine ratio and beta-2-microglobulin (β2M): creatinine ratio by receipt of TDF pre-switch. Changes in eGFR for subjects with moderate renal impairment i.e. eGFR = 60 – 90 ml/min/1.73 m² were assessed.

Results: Following switch to DTG+RPV, minimal change was observed in eGFR, irrespective of pre-switch TDF exposure (Table 1). For participants with moderate renal impairment pre-switch (53 subjects in ES group, 31 in LS group), eGFR remained stable or slightly improved post-switch to DTG+RPV (median change from Baseline and LS Baseline was +13.1 and 0.0 for the ES and LS groups, respectively, at Week 148), with few participants decreasing below 60 ml/min/1.73 m² at any time. RBP and β2M: creatinine ratios had numerically greater improvements in the participants taking TDF prior to switch (Table 2).

Conclusions: Irrespective of pre-switch status, renal function was maintained for SWORD participants through 148 weeks post-switch to DTG+RPV with greater improvement in renal tubular function for those switching off TDF. The switch to DTG+RPV in suppressed patients, including those with moderate impairment, did not adversely affect renal function while maintaining suppressive HIV treatment.

Change in eGFR following switch to DTG + RPV for the Pooled SWORD-2/5 Population Estimated by Serum Cystatin C Using CKD-EPI Equation by Pre-switch TDF exposure

<table>
<thead>
<tr>
<th>Visit</th>
<th>Early Switch DTG + RPV group</th>
<th>Late Switch DTG + RPV group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Median (IQR) ml/min/1.73 m²</td>
<td>Median (IQR) ml/min/1.73 m²</td>
</tr>
<tr>
<td>Week 48</td>
<td>355.4 (330.0–375.5)</td>
<td>354.7 (330.0–402.4)</td>
</tr>
<tr>
<td>Week 148</td>
<td>353.1 (330.0–370.9)</td>
<td>352.6 (330.0–390.0)</td>
</tr>
</tbody>
</table>

Table 1

Percent Change in Retinol Binding Protein: Creatinine Ratio and Beta-2-Microglobulin: Creatinine Ratio Post Switch to Pathology Through Week 148 by Pre-switch TDF exposure

<table>
<thead>
<tr>
<th>Retinol biomarker</th>
<th>Visit</th>
<th>Early Switch DTG + RPV group</th>
<th>Late Switch DTG + RPV group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (IQR)</td>
<td>Median (IQR)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2

PE32/12

Neurotoxicity related to efavirenz does not predict neurotoxicity related to dolutegravir

S de la Fuente1, A Diaz-de Santiago1, M Vivas1, E Sanchez Chica1, C Folguera2 and A Angel-Moreno1

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Purpose: Central nervous system (CNS) disturbances, especially sleep disorders, are the main cause of interruption of dolutegravir (DTG)-based therapies. Predisposing factors are not well-known. In pretreated patients, previous efavirenz (EFV)-related neurotoxicity, also frequently consisting of sleep disorders, could be predictive of neuropsychiatric intolerance to DTG and question its use in these patients.

Method: The medical records of all HIV-infected patients who ever received DTG were retrospectively reviewed, and selected those who previously had received EFV. Any neuropsychiatric symptom temporally related to these drugs was recorded.

Results: In our hospital, a total of 481 patients have received or are currently taking DTG-based therapies since 2014. Of them 184 (38.3%) had received EFV previously. Of the 184 patients exposed to both drugs, 79 (43%) presented adverse CNS reactions in clear temporal association with EFV, considered clinically relevant (classified 3–4 by the patients or resulting in EFV interruption) and 19 (10.3%) developed CNS toxicity under DTG, as defined above. From 79 patients who presented previous CNS toxicity under EFV, only 12 (15.1%) also presented clinically relevant neuropsychiatric disorders, after their exposure to DTG.

Conclusion: The history of neuropsychiatric adverse effects related to EFV does not predict the development neuropsychiatric toxicity by DTG.

PE32/13

Human embryonic stem cells exposed to dolutegravir show decreased cellular proliferation, reduced pluriptensity, and increased mitochondrial toxicity, in a dose-dependent manner: preliminary data

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1The University of British Columbia, Pathology and Laboratory Medicine, Vancouver, Canada 2UBC Centre for Blood Research, Vancouver, Canada 3Universite Angers, Polytech Angers, Angers, France

Purpose: Approximately 80% of women living with HIV worldwide now receive cART during pregnancy, reducing their vertical transmission rates to <2%. Most ARVs can cross the placenta, but their safety has not been fully characterized in the context of pregnancy, especially for InSTIs. A recent study suggested an early signal for increased neural tube defects with dolutegravir (DTG) exposure from conception. As neural tube develops during the first four weeks of gestation, early exposure to certain ARVs may be detrimental. Previous work in our lab showed that DTG (but not raltegravir [RAL]) affect mitochondrial health, as well as pluripotency.

Method: CA15 hESCs were cultured in the presence of DTG, RAL, elvitegravir (EVG), and bictegravir (BIC) on cultured human embryonic stem cells (hESCs), with respect to cellular and mitochondrial health, as well as pluriptensity.

Results: DTG exposure at levels >0.1 Cmax decreased cellular proliferation, increased mitochondrial reactive oxygen species, and induced differentiation as indicated by the loss of the SSEA-3 pluripotency marker, in a dose-dependent manner. This was not seen with other InSTIs. However >0.5 Cmax BIC and >2 Cmax DTG induced hESC death that precluded flow cytometry.
Conclusion: These preliminary data suggest that even low dose exposure to DTG may induce mitochondrial toxicity and differentiation in hESCs. Given the widespread use of DTG and other InSTIs prior, during, and after conception, it is imperative to further elucidate their short and long-term safety in the context of pregnancy.

PE32/14
Dolutegravir but not raltegravir reduces cell proliferation and increases mitochondrial toxicities in cultured fibroblasts; effects that are not mitigated by telomerase reverse transcriptase
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1 University of British Columbia, Pathology and Laboratory Medicine, Vancouver, Canada 2 UBC Centre for Blood Research, Vancouver, Canada

Purpose: Dolutegravir (DTG) and raltegravir (RAL) have excellent clinical tolerance and increasing usage but little is known regarding their long-term toxicities. Older NRTIs inhibit mitochondrial pol γ and affect mitochondrial DNA (mtDNA), while some PIs induce reactive oxygen species (ROS). Under oxidative stress, human telomerase reverse transcriptase (hTERT) translocates to mitochondria, where it protects mtDNA. Our objective was to evaluate cellular and mitochondrial effects of exposure to InSTI-containing cART, and their modulation by hTERT.

Method: Transformed human fibroblast cells that utilize the alternate lengthening of telomeres (ALT) mechanism to maintain telomeres were transduced with either control vector, vector encoding mutant hTERT that cannot translocate to mitochondria, or WT hTERT. The three cell lines were exposed to various cART (1X Cmax) for nine days, then allowed to recover in media for six days. Cell viability and proliferation were determined every three days, while mitochondrial mass, inter-membrane potential, ROS and cellular apoptosis were quantified via flow cytometry on days 9 and 15.

Results: At day 9, cell proliferation was significantly reduced, while apoptosis, mitochondrial ROS, mass and membrane potential were increased in DTG-containing cART exposed cells compared to control cells (0.1% DMSO). Cells exposed to RAL-cART were similar to controls. Lopinavir-containing cART also induced apoptosis and ROS. A positive correlation between mitochondrial ROS and apoptosis was observed. ROS levels were highest in DTG-, and lowest in RAL- and efavirenz (EFV)-cART-exposed cells. WT hTERT (but not mutant hTERT) mitigated PI-induced effects but did not protect against DTG effects. All effects were reversed following drug removal.

Conclusion: In this cell model, DTG but not RAL induced mitochondrial and cellular toxicities. Furthermore, the mechanism behind DTG toxicity appears different from that of boosted-PIs. Additional investigations are required to determine whether these effects may be relevant to human health.

Treatment as prevention
PE33/1
HIV-1 viral load quantification using Aptima HIV-1 Quant Dx assay in Kenya: a diagnostic accuracy study
G Kangogo1, J Atsaya1, M Ombwayo1, E Kirui1, S Kipkerich2, N Bowen4 and M Umuro5

Purpose: Accurate quantitation of HIV-RNA (viral load) is critically significant for diagnosis, treatment, monitoring and assessment of HIV-1 infection. The choice of assay platform is very important in influencing treatment decisions of HIV patients. This study is important to determine the diagnostic accuracy of the new assay to be used in Kenya and other low- and middle-income countries. The objective of this study is to evaluate viral load diagnostic accuracy of Aptima HIV-1 Quant Dx assay in HIV-positive people on antiretroviral therapy.

Method: The performance of the Aptima assay was compared against the Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Version 2.0 (CAP/CTM) assay. The analytical sensitivity, specificity, diagnostic agreement with CAP/CTM, carryover contamination and precision of Aptima HIV-1 assay was analyzed using 219 HIV positive viral load remnant samples. Sensitivity of Aptima and CAP/CTM was assessed using clinical specimens from HIV-1 patients on antiretroviral therapy (ART) with quantifiable results. Aptima assay specificity was determined using individual donor 40 HIV-1 seronegative plasma specimens. Linearity and accuracy of quantitation was assessed using clinical specimens ranging in concentration from 1.0–7.0 log10 copies/mL. A method comparison was performed and Bland Altman analysis was used to analyze the level of agreement between the two assays.

Results: Analytical sensitivity of Aptima HIV-1 assay using clinical samples was 99.1% (95% CI: 95.3%–100.0%). Using the 40 HIV-1 negative plasma specimens, all results were negative (specificity of 100%: 95% CI: 99.4–100%). High pearson correlation (r=0.92) and excellent agreement was observed between Aptima HIV-1 assay and CAP/CTM. Aptima’s precision as per the coefficient of variation was less than 3%.

Conclusion: The Aptima HIV-1 Quant assay on the Panther system is a suitable platform for detecting and monitoring HIV-1 viral load in HIV-infected patients in Kenya. This will increase access of HIV viral load tests thus contributing to effective HIV treatment management.

PE33/3
Rapid ART start in primary HIV infection: time to viral suppression in a London cohort
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Chelsea & Westminster Hospital NHS Foundation Trust, London, UK

Purpose: Rapid antiretroviral therapy initiation is now recommended in primary HIV infections (PHI) as it limits HIV transmission and reduces the viral
reservoir. In the absence of baseline viral resistance test results (VRT), immediate ART is historically given as protease inhibitor-based (PI) combinations and integrase inhibitor-based (INSTI) regimens are delayed until VRT is reported, usually in 7 days. We analysed outcomes in patients according to ART regimen at 56 Dean Street, a sexual health clinic in London (UK).

**Methods:** Clinical records of all individuals consecutively diagnosed with PHI between July 2016 and June 2018 were reviewed. PHI was defined as documented plasma HIV-RNA positivity with a negative HIV enzyme immunoassay (EIA) test, or HIV-EIA test switching from negative to positive within six months. Rapid start was defined as ART initiated within 14 days of HIV diagnosis. The Mann-Whitney U test was used to measure differences between groups.

**Results:** 262 individuals (97% MSM) were diagnosed with PHI: 153 (58%) agreed to rapid ART start (full details in Table 1). Median time from HIV diagnosis to first doctor appointment was 8 days (IQR 4–14). PI-based (all Darunavir-based) regimens were the main option chosen when VRT was not available at time of rapid start and switch was encouraged once VRT was available. Raltegravir was preferred in 97% of those starting INSTI. Median time from PI start to INSTI switch was 16 days (IQR 14–23.5).

**Conclusion:** Rapid start with INSTI regimens results in quicker viral suppression than with PI-based regimens in PHI, even when Ps are subsequently switched to INSTIs. Concerns about lack of a baseline VRT result prior to rapid ART start may potentially be overcome by the use of the newer INSTIs with a high genetic barrier such as dolutegravir and bictegravir.

### Table 1

<table>
<thead>
<tr>
<th></th>
<th>Total rapid starters (n=153)</th>
<th>INSTI starters (n=28)</th>
<th>PI starters (n=77)</th>
<th>PI/INSTI switch (n=42)</th>
<th>INSTI vs. switch</th>
<th>PI vs. switch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years (IQR)</td>
<td>27 (33–40.5)</td>
<td>26 (33–43)</td>
<td>31 (26–38)</td>
<td>31 (26–41)</td>
<td>0.92</td>
<td>0.58</td>
</tr>
<tr>
<td>Median time from HIV diagnosis to ART start, days (IQR)</td>
<td>6 (3–10)</td>
<td>11 (10–14)</td>
<td>4 (2–8)</td>
<td>5 (3–7)</td>
<td>&lt;0.01</td>
<td>0.83</td>
</tr>
<tr>
<td>Baseline HIV viral load, log10 (IQR)</td>
<td>4.90 (4.21–5.83)</td>
<td>5.22 (4.53–6.45)</td>
<td>4.84 (4.08–5.75)</td>
<td>5.14 (4.28–5.83)</td>
<td>0.65</td>
<td>0.20</td>
</tr>
<tr>
<td>Baseline HIV viral load &gt;1 million cp/mL, n (%)</td>
<td>32 (20.9)</td>
<td>10 (34.5)</td>
<td>12 (15.6)</td>
<td>9 (21.4)</td>
<td>0.03</td>
<td>0.22</td>
</tr>
<tr>
<td>Baseline CD4 cell count, mm (IQR)</td>
<td>551 (431–700)</td>
<td>610 (430–750)</td>
<td>541 (418–714)</td>
<td>515 (435–666)</td>
<td>0.23</td>
<td>0.64</td>
</tr>
<tr>
<td>Time from ART start to first HIV VL &lt;200 cp/mL, days (IQR)</td>
<td>56 (31–108)</td>
<td>31 (28–56)</td>
<td>80 (39–121)</td>
<td>49 (42–63)</td>
<td>0.03</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Legend: *– Of 153 starters, 5 started with a non-nucleoside reverse transcriptase inhibitors regimen and were not reported in the sub-analyses †– patients who switched from an initial PI-based regimen to either raltegravir, n=dolutegravir, n=10 within 28 days from ART start IQR = interquartile range

### PE33/4

#### Reality check: HIV post-exposure prophylaxis (PEP) in real-life at a tertiary care centre prior to the PrEP era

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**Purpose:** Published data on the use of PEP in German-speaking countries are rare potentially impeding identification of candidates for HIV pre-exposure prophylaxis (PrEP). Here we report data of PEP-patients at the University Hospital Bonn.

**Method:** Data of 101 patients referred for advice regarding PEP after Diagnosis for HIV post-exposure prophylaxis (PEP) were consecutively collected from September 2017 to the University Hospital Bonn. The PEP regime was discussed with patients and included immediate ART in PHI patients. Results: Of 153 starters, 5 started with a non-nucleoside reverse transcriptase inhibitors regimen and were not reported in the sub-analyses. 10% within 28 days from ART start. Patients were vaccinated against hepatitis B (33.3% vs. 82.1%; p=0.003) and received PEP more often (89.8% vs. 65.1%; p=0.001) than patients presenting after OE.

**Conclusion:** The majority of PEP patients at the University Hospital Bonn were MSM. This underlines the importance of a generous roll-out of PrEP in this population at high risk for HIV infection. The subsequent engagement in regular medical check-ups should be used to improve hepatitis B vaccination rates.

## Treatment in resource-constrained settings

**PE34/1**

### Peer navigation improves linkage to HIV treatment and retention in Malawi

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**Center for the Development of People, Local Human Rights Organisation, Lilongwe, Malawi**

**Purpose:** In Malawi, LINKAGES project reaches men who have sex with men (MSM) with HIV prevention, care, and treatment through Centre for the Development of People (CEDEP). Despite the success registered in identifying HIV infected users of the peer educators, there has been low linkage to antiretroviral treatment. We present a successful story of linkage to treatment after training and using peer navigators (PNs) to support their peers.

**Method:** We trained 18 PNs from districts of Lilongwe, Mzuzu, Blantyre and Mangochi to identify and support their hard-to-reach KPLHIV peers and assist in provision of community care services to support them with treatment uptake. These PNs are HIV-positive persons trained and willing to support their MSM and Transgender (TG) peers on the community care for HIV/AIDS and its treatment, Sexually transmitted infections (STIs), self care, gender based violence (GBV), disease progression, safer sex for and income generating activities.

**Results:** In the period before the training of PNs the linkage to treatment was 97 key population (KP) members between the month February 2016 to September 2017). Following the training, the one year period (between October 2017 to September 2018) linkage to treatment moved to 493 KPs. Peer navigators also supported 57 KPs who defaulted on ART to be re-initiated on ART. Three hundred and Eighty four KPs were eligible for viral load testing after none ascertained for viral load testing the previous year. From this number, Three hundred and Seventy–Nine viral loads came out of which, 365 were virally suppressed representing (96% suppression rate)

**Conclusion:** Peer navigators are playing a significant role in increasing and improving the linkage to treatment and viral load testing. Another unique success is the identification of new HIV positive MSM and TG networks to access HIV care and treatment services including support services on gender-based violence.

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PE34/2

Optimizing clients linkage into ART using family-centered differentiated approach (FCDA) in Kebbi state, northwestern Nigeria: successes and challenges
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²Management Sciences for Health, Abuja, Nigeria

Purpose: Linking newly diagnosed HIV positive clients into ART is an important task in the pursuit of the ambitious UNAIDS 95–95–95 targets. Although there is a sustained improvement in access to HIV testing services globally, connecting newly diagnosed clients into sustainable anti-retroviral therapy has remained a challenge in HIV treatment programs. Renewed efforts and strategies are required to surmount this challenge. This evaluation shares the successes and challenges of using family-centered differentiated approach (FCDA) as a strategy to improve new clients’ linkage into ART.

Method: In Oct 2018, the CaTSS project funded by USAID and implemented by Management Sciences for Health initiated the FCDA strategy in 2 partner PMTCT-only facilities – GH Warra and GH Kaoje – to improve ART linkage of clients identified through partner notification services (PNS). Prior to the commencement of the FCDA, new HIV positive clients identified through this process in the PMTCT-only facilities were referred to the comprehensive facilities for ART services. Using the FCDA approach, newly diagnosed HIV positive children and spouses of pregnant and breastfeeding women were provided access to ART services in the same PMTCT-only facilities as the index women. Appropriate training was provided to relevant health care workers at the inception of the program.

Results: From pre-intervention rate of 67% (10/15) and 40% (4/7) in Oct 2018, ART linkage improved to 100% (12/12) and 5/5 respectively in GH Warra and GH Kaoje. About $10 required to complete a 2-way referral per client for ART initiation in the distant comprehensive facilities was eliminated. However, a reliable commodity supply chain was required to operationalize the system.

Conclusion: FCDA is a reliable way of improving client linkage into ART and reducing incidental cost of initiating ART services. This strategy could be scaled up and prioritized in facilities where PNS is adopted as targeted HTS.

PE34/3

A multi-stakeholder evaluation of the early implementation experiences of differentiated anti-retroviral therapy (ART) delivery roll-out across Uganda: a qualitative analysis
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Purpose: World Health Organization recommends Differentiated ART delivery in resource-constrained settings. There is a paucity of evidence on national roll-out of Differentiated ART models in Uganda since initial implementation in 2017. We sought to explore national stakeholders’ perceptions of the early implementation outcomes of differentiated ART delivery roll-out across Uganda.

Methods: Between April and June 2019 we conducted 76 in-depth interviews with national-level HIV program managers (n=18), district health leaders (n=24), representatives of PEPFAR implementing organizations (11), ART clinic in-charges (23) in six purposively selected Uganda districts (Kampala, Luwero, Wakiso, Mbarara, Buduburam, Gulu) with relatively high HIV burden. Six focus group discussions (48 participants) were held with patients enrolled in DSD (Differentiated Service Delivery) models in case-study districts. Data were analyzed by inductive content analysis.

Results: HIV program managers identified low patient literacy of DSD models, limited DSD competence among health workers, supply chain barriers to multi-month ART dispensing as barriers to DSD implementation. PEPFAR implications from organizations identified a lack of funding and guiding protocols for operationalising community-based DSD models as barriers to uptake at the sub-national level. Existing community health systems such as Village Health Teams (VHTs) were identified as a under-utilized resource. Patients identified stigma as a major barrier to the uptake of community-based DSD models particularly Community Drug Delivery Points (CDDP). Private pharmacy networks were proposed as an alternative to CDDP. Overall, clients expressed preference for facility-based individualized DSD models. Patients perceived current choices of DSD models to be provider-directed and not sufficiently patient-centred.

Conclusion: This is one of the first national-level stakeholder evaluations of DSD implementation in Uganda since 2017. Our study suggests that DSD models will require continuous refinement to ensure that they are truly patient-centered. Increasing patient literacy of DSD models and sustained stakeholder engagement are critical to further DSD roll-out in Uganda.

PE34/4

Why treatment does not work: findings of one year project survey about IDUs treatment in Quetta, Pakistan
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iiChief, Media, Human Rights and Community Development, Quetta, Pakistan
iiiAdvisor, Human Rights and Community Development, Quetta, Pakistan

Purpose: There are around 11 Drug treatment centers including govt; sector providing treatment to IDUs, DUs but the relapse ratio still sustaining at 87%. It is reported that there are more than 47,000/- addicts, IDUs living across Quetta city areas including women.

Method: Community Development & Entrepreneurship Foundation NGO in collaboration with local drug treatment center carried out a one year project based survey in 2016 to see the factors involved in relapse ratio. Total 700 drug users were interviewed mostly from indigenous tribes including Dari Hazaras 20%, Panjshiris 46%, Panjabi 8% and Afghan migrants 26 %. The survey allowed for a clear comparison and defines groups at risk.

Results: During the survey intervention, 700 drug users were recruited/ interviewed mostly received treatment more than once. Relapse ratio of 87% shows that it is nourishing despite treatment and detoxification services. The factors identified involved including personal frustration, domestic violence, joblessness; family disrespect, lack of sustainable economic support and social status/ownership.

Conclusion: Harm reduction services needs to be sensitized by local CBOs. More community based interventions such as sports, social, cultural, and recreational activities to be initiated and a regular awareness campaign to IDUs and general public. Drug users need sustainable health care series for knowledge building and better understanding. Government is has a central role to play.

Keywords: Care & harm reduction, IDUs, community mobilization, social protection.

PE34/5

Evaluation of the financial cost of treating people living with human immunodeficiency virus in the United Kingdom versus matched HIV-negative controls in 2004, 2010 and 2017
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The purpose of this study was to evaluate the quantum of NHS financial costs attributed to the care of people living with HIV (PLHIV), in comparison to matched HIV-negative controls. Survival rates of PLHIV have dramatically improved over the last two decades, and the changing pattern of illness in the ageing cohort of PLHIV has resulted in differing costs of care. The purpose of this study is to characterise these changes and associated costs in the UK population.

The Clinical Practice Research Datalink (CPRD) was used for this analysis as it captures approximately 10% of GP records and is representative of the UK as a whole. PLHIV were matched to HIV-negative controls and costs were calculated for hospital admissions, outpatient visits, GP attendances and pharmacy prescriptions in 2004, 2010 and 2017 (in GBP at 2018/2017 prices). Costs of anti-retroviral (ARV) drugs were excluded from analysis due to the majority of ARVs being prescribed in secondary care.
It was possible to identify and match 2,945 PLHIV to 5,890 HIV-negative controls. The mean costs of care per person year (PPY) for PLHIV were £5,013, £1,378 and £867 in 2004, 2010 and 2017, respectively. For HIV-negative controls, these values were £531, £692 and £648, respectively. Therefore, the ratio of mean total cost for PLHIV compared to HIV-negative controls was 9.4:1, 2:1 and 1:3:1 for the three annual periods, respectively.

### Table 1. Comparison of mean cost of care PPY for PLHIV to HIV-negative controls (£)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cohort</th>
<th>Primary care costs</th>
<th>Prescription costs</th>
<th>Inpatient costs</th>
<th>Outpatient costs</th>
<th>Total costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>HIV-negative</td>
<td>108</td>
<td>86</td>
<td>253</td>
<td>84</td>
<td>531</td>
</tr>
<tr>
<td></td>
<td>PLHIV</td>
<td>267</td>
<td>130</td>
<td>3,986</td>
<td>630</td>
<td>5,013</td>
</tr>
<tr>
<td>2010</td>
<td>HIV-negative</td>
<td>143</td>
<td>106</td>
<td>266</td>
<td>176</td>
<td>692</td>
</tr>
<tr>
<td></td>
<td>PLHIV</td>
<td>225</td>
<td>149</td>
<td>301</td>
<td>703</td>
<td>1,378</td>
</tr>
<tr>
<td>2017</td>
<td>HIV-negative</td>
<td>149</td>
<td>115</td>
<td>220</td>
<td>165</td>
<td>648</td>
</tr>
<tr>
<td></td>
<td>PLHIV</td>
<td>164</td>
<td>139</td>
<td>72</td>
<td>493</td>
<td>867</td>
</tr>
</tbody>
</table>

Excluding ARVs, the marginal cost of treating PLHIV has converged markedly towards that of the general population over the previous 15 years. This convergence may be positively attributed to improvements in HIV specialist care and treatment options. With decreasing cost of management, this alleviates funds for investment in innovation. Future care should focus on providing care that ensures good quality of life for people living with HIV, in addition to longevity.

**PE34/6**

Continuous quality improvement across the viral load testing spectrum at the Infectious Diseases Institute, Uganda

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**Purpose:** Viral load (VL) testing is the gold standard for monitoring patients on antiretroviral therapy. However, efficient implementation of VL monitoring (low rejection or failed samples rates and short turnaround time) for all patients poses complex technical and logistical challenges. We introduced a quality improvement (QI) initiative, to improve efficiency and coverage of routine VL testing at the Infectious Diseases Institute (IDI). We present annual VL coverage in the subsequent two years and the proportions for rejected/failed samples.

**Method:** We used retrospective clinic data from electronic records to populate a VL cascade at the clinic. It comprised patient identification, sample collection/transfer for testing at national level, management of results returned, and patient management actions based on the result. At baseline (Jan 2015), point prevalence of VL coverage was 14%. The QI team brainstormed root causes, analyzed using fishbone tool, and formulated three key areas for improvement: 1) Increase VL coverage and reduce proportion of failed/rejected samples 2) Reduce turn-around time by providing a dedicated QI VL focal person to manage VL results 3) Introduce a special clinic to ensure appropriate action for those with detectable VL.

**Results:** Viral load coverage at IDI increased substantially from 14% (2015) to 82% tests (2016) and 89% (2018). Failed samples reduced from 70% (2015) to 21% (2017). However, the rejection proportion increased to 1.054% (2016) from 0.168% (2015), this was addressed by meeting with the laboratory team and reduced to 0.78% (2017). Failed and rejected samples resulted from: insufficient/ clotted samples, improper handling/transportation and poor sample labeling. Overall 10% results (VL >75 copies/mL) were appropriately referred to the clinic. The QI team addressed VL challenges in the monthly clinic meeting.

**Conclusion:** Implementing a quality improvement system increased VL coverage. A VL monitoring cascade is key in identifying gaps for better treatment outcomes.

**PE34/7**

Pediatric HIV viral load suppression: qualitative insights of barriers and facilitators among caregivers of children on ART in high volume sites in Kisumu County, Kenya

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1Kenya Medical Research Institute/FACES Program, Center for Microbiology Research (CMR), Kisumu, Kenya 2University of California San Francisco, Department of Obstetrics, Gynecology and Reproductive Sciences, San Francisco, CA, USA 3Department of Pediatrics, University of Colorado, Department of Pediatrics, University of Colorado, Denver, USA

**Purpose:** The number of virally suppressed HIV+ children remains unacceptably low; the experiences of caregivers of children on antiretroviral treatment (ART) are critical to developing interventions to achieve maximum viral load (VL) suppression in this population.

**Method:** Eight focus group discussions (FGDs) were conducted among a purposively sampled cohort of 76 caregivers of children (<18 yrs.) on ART (≥ 6 months) at eight facilities in Kisumu County. A trained qualitative researcher used semi-structured guides to explore VL testing and suppression; translated audio transcriptions were coded using a collaboratively developed framework and Dedoose.
Results: Most caregivers were female (63%), aged 19–85 (median age 40), and biological parents (71%). Caregivers expressed a general understanding of VL; weight-based dosing and medication and appointments adherence were facilitators. VL testing schedules were challenging and ambiguous. HIV-disclosure to children was a facilitator; determining the appropriate age for disclosure, managing anticipated stigma, and disclosure beyond the immediate family were challenges. Medication-specific barriers included timing of pills, management of side effects, medication refusal, and daily pill burden. Health system barriers included long wait times, high frequency of appointments for high VLs, insufficient medications dispersion, and negative provider reactions to missed ART doses. Assisted disclosure and ART management were facilitators; caregivers requested additional disclosure support for school-age children.

Conclusion: Facilitated disclosure and support for caregivers and their children is critical. Facility-level interventions and differentiated care models are needed to improve caregiver-provider interaction. FGDs were conducted with providers and young adults on ART to triangulate findings in this study.

PE34/8

Boosting economic affordability of HIV medicines while considering safety and effectiveness within transition from donor funding. Enabling access to TAF regime with better safety profile in Ukraine through advocacy campaign of community organization

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Purpose: Drop of HIV-treatment because of side effects precludes achievement of 90-90-90 global target in Ukraine. Transition from donor to national funding requires constant review of the HIV-medicines national procurement list using economic approach. Including tenofovir alafenamide (TAF) treatment regime with lower procurement price ensures increase in HIV-treatment coverage while securing treatment with better safety profile comparing to tenofovir disoproxil fumarate (TDF) regime.

Method: In 2018, procurement price for tenofovir disoproxil fumarate/entecitabine and dolutegravir (TDF/FTC+DTG) for Ukraine constituted 10,15 USD per monthly course. According to the WHO, price for fixed-dose combination of TAF/FTC/DTG is lower. At the same time, equally effective TAF-based regime has reduced potential for kidney injury and loss of bone mineral density. In 2019, All-Ukrainian Network of PLWH (Network) facilitated inclusion of TAF/FTC/DTG into the medicines procurement list for 2020. Simultaneously, Network sent several requests to the generic producer to discuss entering Ukrainian market and possible price for Ukraine. As a result of advocacy efforts, the meeting between the generic manufacturer and state health officials was organized in Ukraine to consolidate previous agreements.

Results: In 2019, Ministry of Health of Ukraine received confirmation from the generic producer on 6,25 USD price per monthly course. Based on the Network’s expert official report, TAF/FTC/DTG was included into the procurement list of HIV-medicines for 2020. Considering 29388 patients receiving TDF/FTC + DTG in 2019, the state budget savings for annual course constitutes 978798 USD.

Conclusion: Network interventions demonstrated effectiveness of integrated approach to achieve the global target, which includes decreased price and increased safety of medicines. Saved budget funds enable procurement of additional social HIV-services for key groups essential while shifting to the national funding. Procurement of medicines with better safety profile secures sustainability of treatment that is vital for achieving the second and third 90s of the global targets.

Tuberculosis and opportunistic infections

PE35/1

Nontuberculous mycobacteria infections in Russian HIV patients: clinical features and outcomes

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Purpose: This study was conducted to investigate nontuberculous mycobacterial rates in HIV patients in Russian infectious diseases hospital for a last decade, describe clinical features and analyze outcomes on different treatment regimens.

Method: Data was collected at the Saint-Petersburg Botkin Clinical infectious diseases hospital from January 2006 to January 2019. Cases were divided by etiology, forms of process. Student’s t-test was used, survival time on different treatment regimens was evaluated with Kaplan-Meier estimator.

Results: We enrolled 104 HIV patients with different forms of NTM infections. We received a prominent increase of NTM incidence.

Incidence of nontuberculous mycobacteria at Botkin Clinical infectious diseases hospital (from January 2006 to January 2019).

In the absolute majority of cases m. avium (86; 82.7 %) acted as an etiological agent.

Distribution of etiological agents.

Disseminated infection developed in 75 (72.1 %) of cases, pulmonary NTM infection – in 29 (27.9 %). CD4 was significantly higher in patients with pulmonary than disseminated forms: 47.7±9.9 and 19.8±3.9 cells/mm3 (p<0.05). Significant difference as well was obtained in the hemoglobin level: 108.1±4.5 and 88.7±2.3 g/l (p<0.05).
Laboratory data for patients with pulmonary and disseminated forms.

<table>
<thead>
<tr>
<th></th>
<th>Form</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Standard error</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 account</td>
<td>pulmonary/disseminated</td>
<td>47.7±19.8</td>
<td>50.9±33.6</td>
<td>9.9±3.9</td>
</tr>
<tr>
<td>CD3 account</td>
<td>pulmonary/disseminated</td>
<td>470.9±331.4</td>
<td>454.2±413.8</td>
<td>94.7±53.8</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>pulmonary/disseminated</td>
<td>108.1±88.7</td>
<td>23.8±19.6</td>
<td>4.5±2.3</td>
</tr>
<tr>
<td>CD4 account on treatment</td>
<td>pulmonary/disseminated</td>
<td>125.7±55.7</td>
<td>78.8±70.8</td>
<td>20.3±10.0</td>
</tr>
<tr>
<td>Alkaline phosphatase</td>
<td>pulmonary/disseminated</td>
<td>128.1±156.1</td>
<td>140.2±217.6</td>
<td>38.9±33.1</td>
</tr>
<tr>
<td>LDH (U/l)</td>
<td>pulmonary/disseminated</td>
<td>333.5±291.0</td>
<td>177.1±138.8</td>
<td>41.7±21.6</td>
</tr>
</tbody>
</table>

A high death rate of 34.6% (36 patients) was recorded regardless of prolonged antibacterial therapy (5.0±0.9 months of treatment). Clarithromycin showed some advantage over azithromycin when analyzing survival by the method of Kaplan-Meier (p<0.05 Breslow).

Kaplan-Meier survival analysis comparing clarithromycin and azithromycin based treatment regimens.

Conclusion: Despite the widespread introduction of antiretroviral therapy, unlike other countries in Russia there is a significant increase in the number of cases of infections caused by NTM in HIV patients. Pulmonary forms are characterized by higher levels of CD4 and good immunological response. Clarithromycin is preferable when choosing a macrolide base in the treatment regimen.

PE35/3

Rifampicin pharmacokinetics and pharmacogenetics in Ugandan patients with multi-drug resistant tuberculosis

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Purpose: Suboptimal antibacterial drugs exposure may cause multi-drug resistant tuberculosis. The role of African predominant SLC01B1 variant alleles on rifampicin pharmacokinetics and subsequent effect on M. tuberculosis - rifampicin sensitivity requires to be defined. We described rifampicin population pharmacokinetics profile and investigated the relevance of SLC01B1 genotypes on rifampicin pharmacokinetics and rifampicin-TB sensitivity status.

Method: Fifty patients with tuberculosis (n=25 with Rifampicin resistant TB and n=25 with rifampicin susceptible TB) were genotyped for SLC01B1 rs4149032 (g.38664C>T), SLC01B1*1B (c.389A>G), and SLC01B1*5 (c.521T>C). Steady state plasma rifampicin levels were determined among patients infected with rifampicin sensitive TB. Data were analysed using NONMEM to estimate population rifampicin pharmacokinetics as well as the effect of SLC01B1 genotype on rifampicin-TB sensitivity status.

Results: Overall allele frequencies of SLC01B1 rs4149032, *T8 and *S were, 0.66, 0.90 and 0.01 respectively. Median (IQR) Cmax and Tmax were 10.2 (8.12–12.47) mg/l and 1.7 (1.125–2.218) hours respectively. Twenty four percent of patients exhibited Cmax below the recommended 8–24 mg/l range. SLC01B1 genotypes, sex and age did not influence rifampicin pharmacokinetics or TB-rifampicin sensitivity.

Conclusion: Although SLC01B1 genotype, age and sex influence neither rifampicin pharmacokinetics nor rifampicin-TB sensitivity status, one of every four Ugandan TB patients achieve sub-therapeutic plasma rifampicin concentrations.

PE35/2

Human immunodeficiency virus and the outcome of pulmonary tuberculosis: a retrospective study in Tehran, Iran

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Purpose: Tuberculosis (TB) is among the major clinical challenge in Iran. The risk of treatment failure and mortality among TB patients is significantly increased in patients with human immunodeficiency virus (HIV). We aimed to assess the treatment outcomes and mortality among TB patients co-infected with HIV.

Method: We analyzed the records of 224 TB patients referred to health centers of Tehran, in year 2018. Multivariate analysis using logistic regression model was used to analyze the association between treatment outcome and potential predictor variables.

Results: Among included patients with TB, the overall treatment success was significantly higher in HIV-negative than HIV-positive persons (60.6% vs 39.4%; P value<0.05) and the treatment failure was higher in TB patients with HIV. Mortality rate was significantly higher in HIV-positive than HIV-negative patients (66.7% vs 33.3%; P value<0.05). In the final multivariate logistic model, the odd of death was higher among patients older than 40 years of age, patients with extrapulmonary TB and intravenous drug users.

Conclusion: The treatment success rate of TB patients with HIV was unsatisfactorily low and a high proportion of patients died of default, which is a serious public health concern. Efforts to improve treatment for these patients, additional follow-up and social support are urgently needed.

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PE35/4
Mycobacteria-induced immune responses by mucosal-associated invariant T (MAIT) cells are impaired in patients with tuberculosis (TB) and HIV-associated TB
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2Francis Crick Institute, London, UK

Purpose: MAIT cells are non-classical T lymphocytes that recognize and rapidly respond to microbial vitamin B metabolites and have the capacity to kill bacteria-infected cells. Circulating MAIT cell numbers decrease in patients with active TB and HIV, but previous findings regarding functional changes have been conflicting. We conducted a cross-sectional study to assess the effect of HIV, TB and HIV-associated TB (HIV-TB) on MAIT cell numbers, activation, inhibitory and functional profile in a TB endemic setting in South Africa.

Methods: Blood was collected from healthy controls (HC, n=26), individuals with HIV infection only (HIV, n=30), with active TB only (aTB, n=30), and with HIV-TB (n=26). All TB participants were newly diagnosed with TB and sampled prior to treatment. Peripheral blood mononuclear cells (PBMC) were isolated and stimulated with BCG expressing GFP (BCG-GFP) or heat-killed (HK) Mycobacterium tuberculosis (Mtb) and analyzed using flow cytometry.

Results: There were lower frequencies of MAIT cells in HIV (median: 0.3%; p=0.04), and aTB (0.4%; p=0.02) compared to HC (0.7%). BCG-specific MAIT cell activation (measured by HLA-DR expression (median fluorescent intensity)) was higher in aTB (230, p=0.006) and HIV-TB (280, p=0.0008) compared to HC (114). BCG-induced MAIT cell degranulation (measured by CD107 expression) was lower in aTB (4.5%; p=0.003) and HIV-TB (4.6%; p=0.04) compared to HC (9.8%). Similarly, IFNg expression was lower in aTB and HIV-TB (3.2% and 1.0%); p=0.0005 and 0.0006, respectively) compared to HC (17.6%). Similar results to BCG were obtained with HK-Mtb stimulation. Compared to HC, MAIT cells from individuals with aTB had higher basal PD-1 expression (2.1% vs 5.2%; p=0.0001).

Conclusions: Our data show that compared to HC, HIV and aTB result in a decrease in circulating MAIT cells, while aTB and HIV-TB resulted in a significant increase in activation and inhibitory status, and an impaired mycobacteria-induced functional profile.

PE35/5
Acute onset of cerebral toxoplasmosis in patients with HIV infection
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Purpose: The analysis of clinical picture of Cerebral toxoplasmosis (CT) in patients with AIDS in Moscow.

Methods: The diagnosis of toxoplasmosis was confirmed in 207 patients (IgG to T. gondii DNA in the cerebrospinal fluid in 42.5%, and the presence of lesions of the CNS in MRI in 100%).

Results: 44 (21.3%) seemingly “healthy” patients had an acute onset of illness. The majority of patients did not know about their HIV status. CT was the first AIDS-indicator disease. 55% of patients had body temperature above 38°C, 46% of patients had headache. 32% patients were admitted to hospital in a coma and only 17% with a gradual onset of the disease.

We have identified several options for the development of acute onset of the disease. The most frequent (50%) begins as an acute cerebrovascular accident (stroke): the sudden development of hemiparesis, dysarthria or aphasia, followed by rapidly increasing brain edema. These patients often arrive to the neurological Departments. 25% of patients develop acute tonic-clonic convulsions in the absence of other focal neurological symptoms. They often arrive to the Department of neurosurgery, and after detection of lesions on MRI some patients even underwent surgery for “brain tumor”. Another 25% of patients who arrived to the intensive care unit with a diagnosis of «brain coma» and rapidly increasing depression of consciousness and swelling of the brain. Lethal outcome was in 48% of patients with acute onset of CT in contrast to 30% with the gradual development of the disease.

Conclusions: Thus it should be remembered that AIDS patients with CNS lesion often – one in 5 patients - may have acute onset of CT and it may have different developments with rapid fatal outcome.

PE35/6
Association between immunological status and TB disease development in HIV-infected individuals with LTBI
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Purpose: Limited research has addressed factors associated with TB disease development in HIV-infected patients with latent tuberculosis infection (LTBI). This study aims to examine the association between immunological status and TB disease development in HIV-infected individuals who have ever tested tuberculin skin test (TST) positive during HIV care.

Method: Retrospective anonymous baseline, clinical and LTBI testing records of HIV-infected individuals were collected from a major HIV specialist clinic in Hong Kong. Patients who were diagnosed with HIV between 2002 and 2013 and had tested TST positive, but without any history of active TB at or before HIV diagnosis, were included in the analysis. The main outcome variable was TB disease development, after exclusion of TB cases whose interval between positive TST and TB diagnosis was <1 year. Univariable and multivariable cox regression models adjusted by history of LTBI treatment were performed.

Results: A total of 508 subjects met the inclusion criteria, of whom 87% were male, 93% had initiated ART, 40% were positive at the first LTBI test, and 86% had received LTBI treatment. TB incidence from the last negative TST time point was 4.68 per 1000 person-years (95% CI: 2.72–7.55). Adjusted by history of LTBI treatment, local residency (aHR=0.18, 95% CI:0.06–0.60), ART (aHR=0.18, 95% CI:0.05–0.65), and number of negative TSTs before positive results (aHR=0.36, 95% CI:0.15–0.85) were negative predictors of TB disease development, while positive result at the first TST was a positive predictor (aHR=5.73, 95% CI:1.61–20.43). Immunologically, CD4 count (aHR=0.99, 95% CI:0.99–0.9999) and CD4/CD8 ratio (aHR=0.08, 95% CI:0.01–0.93) at the time of positive TST result, CD4 <200/L (aHR=2.84, 95% CI:1.003–8.02), concurrent CD4 <200/L and CD4/CD8 ratio<0.5 (aHR=3.11, 95% CI:1.10–8.73) after the last negative TST were significantly associated with TB disease development.

Conclusion: Poorer immunological status markers from positive TST results could be used as a surrogate for predicting TB disease in HIV-infected patients.
population, can be challenging. However, this model provides a way to enrich for *Legionella* spp. and can serve as an outline for developing similar protocols for other difficult-to-study intracellular bacteria while providing a cheaper alternative to standard cell culture. Improving diagnostic tests and better understanding bacterial pathogenesis can translate to improved outcomes for HIV-infected individuals with pneumonia.

**PE35/8**

**Causes and outcomes of hospitalizations among HIV positive persons in Georgia’s referral institution, 2012–2017**

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**Purpose:** We assessed trends in causes and outcomes of hospitalization among HIV positive patients receiving care at the Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC).

**Method:** Retrospective analysis included adult HIV patients admitted to IDACIRC for at least 24 hours. Data were abstracted through chart review. Trends in causes of hospitalizations and mortality were tested using adjusted test for trend. Factors associated with mortality were evaluated in multivariate logistic regression analysis. AIDS admissions were split in 3 groups based on mortality rates for the individual AIDS diseases: severe (>15%), moderate (5–15%) and mild (<5%).

**Results:** A total of 2085 hospitalizations among 1123 HIV patients were registered over 2012–2017. 72.3% (814/1123) of patients had CD4 count <350 at time of HIV diagnosis and 51.9% (583/1123) of patients were hospitalized within 3 months of HIV diagnosis. 931 (44.7%) hospitalizations were due to AIDS-defining conditions and 1154 (55.3%) were due to non-AIDS conditions.

Among 167 deceased patients 137 (82.0%) had CD4 count <50 and 50–500 at the time of hospitalization, including 88.8% (95/107) among AIDS admissions. In multivariate analysis, severe AIDS admission was associated with significantly higher odds of mortality compared to non-AIDS admission (OR 3.55, 95%CI:1.70–7.40). CD4 cell counts of <50 and 50–100 at hospitalization were also significantly associated with mortality compared to >200 (OR 3.34, 95%CI: 1.83–6.09 and OR 2.06, 95% CI: 1.08–3.95).

**Conclusion:** AIDS remains a significant cause of hospitalization and fatal outcome in Georgia. Earlier diagnosis of HIV is critical for decreasing AIDS hospitalizations and mortality.

**PE35/9**

**Population pharmacokinetic analysis of dolutegravir in HIV/ TB co-infected people with and without rifampicin**

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**Purpose:** Treatment of HIV/TB co-infection is complicated by drug-drug interactions, toxicities, and immune reconstitution inflammatory syndrome. The antiretroviral integrase inhibitor dolutegravir is a substrate of UGT1A1 and CYP3A4, both of which are induced by rifampicin. Our objective was to characterize the population pharmacokinetics of dolutegravir in HIV/TB co-infected patients receiving rifampicin-based treatment.

**Method:** Data from INSPIRING (NCT02178592), a Phase III randomized open label study in HIV-1 infected ART naive adults on rifampicin-based TB treatment (isoniazid, rifampin, pyrazinamide, ethambutol; <8 weeks prior to initiating HIV treatment) were used in this analysis (n=65). Participants were randomized to dolutegravir (50 mg twice-daily during and 2 weeks post- tuberculosis therapy, then 50 mg once-daily) or efavirenz (800 mg) and two nucleoside reverse transcriptase inhibitors for 52 weeks. In dolutegravir treated participants, pre-dose plasma samples were collected at Weeks 8, 24, 36, 48 and post-dose samples at Weeks 8 and 36. A nonlinear mixed-effects modeling approach was used for the population pharmacokinetic analysis, using NONMEM program version 7.3 (ICON, Eli Lilly, US).

Results: A one-compartment PK model with linear elimination and lag time in absorption was used to describe dolutegravir pharmacokinetics. The population clearance with and without rifampicin were 2.36 L/h and 1.09 L/h, respectively, resulting in ~half exposure in subjects with rifampicin following dolutegravir 50 mg dose. The apparent volume of distribution and absorption rate were 28.9 L and 2.02 hr⁻¹, respectively and Lag time was fixed to 0.263 h. Weight, albumin and age were statistically significant predictors of dolutegravir clearance and albumin and age were predictors of volume of distribution.

**Conclusion:** A 50 mg BID dose in presence of rifampicin (~2-fold induction) was adequate to achieve comparable exposure (AUC and C trough) to 50 mg QD administration without rifampicin. The effect of covariates was not considered clinically significant, therefore, no DTG dose adjustment by these covariates is necessary.
Emphasis should be placed on screening PTB patients with severe disease in the presence of other risks factors for abnormal lung function at end of PTB treatment.

PE35/11
Clinical and laboratory characterization of progressive multifocal leukoencephalopathy in HIV-infected patients in the intensive care unit
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Progressive Multifocal Leukoencephalopathy (PML) is an opportunistic infection of the CNS, which has a high mortality rate. There is no specific treatment for PML. Routine algorithms for diagnosis of PML in HIV-positive patients have not yet been developed in Russia.

Purpose: To identify the clinical and diagnostic aspects of PML in HIV patients.

Method: Retrospective medical records study of HIV patients admitted to the intensive care unit (ICU) at Infectious Clinical Hospital in Moscow, from 2015–2017.

Results: Data from 60 patients were analyzed (40% female; median age – 39.8 (27–61) years). HIV infection had been diagnosed for the 1st time during hospitalization in 13.3% cases, while 36.6% had been HIV diagnosed >5 years. 91.6% were admitted >14 days after the initial symptoms. Focal neurological signs were present in 100% cases: limb paresis (73.3%), speech disorders (63.3%), gait abnormalities (38.3%), cognitive impairment (33.3%), visual impairment (23.3%), dysphagia (3.3%). 96.7% had disturbance of cerebral function, meningeal signs and fever were present in 10% and 70% respectively. 70% patients were ART-naive before hospitalization. Patients had substantial immunodeficiency (CD4 <50 cells/µL – 61.6%, 51–200 cells/µL – 26.6%) and high HIV RNA level (>100 000 copies/mL – 46.6%). The JC polyomavirus DNA was detected in CSF in 93.3% cases. MRI was performed in 58.3% patients, 91.4% of whom had positive PML scans. Patients with PML were mainly treated with ART. ICU stay was longer than 2 weeks in 70% of cases while in total 91.6% had died.

Conclusion: PML manifests in severe immunocompromised HIV patients without ART and characterized by high mortality, triggered by a delay to seek medical aid, despite substantial manifestations. Basic neurological manifestations include focal symptoms and disturbance of cerebral function. MRI identify typical changes in the brain. Detection of JC polyomavirus DNA in the CSF is an important diagnostic tool.

PE35/13
Cryptococcal and tuberculosis coinfecion: case series identified through the implementation of an advanced HIV disease package of care linked to a TB active case finding strategy in rural Mozambique
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Background: One third of people living with HIV (PLHIV) are diagnosed with advanced HIV disease (AHD) globally. Tuberculosis (TB) and cryptococcal disease (CD) are responsible for ~50% AIDS-mortality in sub-Saharan Africa. Innovative strategies to increase detection and improving AHD-outcomes are needed.

Methods: An active TB-case finding study was implemented in the Maniça district, Mozambique. Community workers reached all household and community contacts of new TB-cases reported during the study period. Participants were tested for HIV and TB (Xpert® Ultra in induced sputum).

Results: Between June–December 2018, 589 adult TB-index cases and 2347 of their contacts were identified (Figure 1). HIV was confirmed in 688 participants, including 155 ART-naive/poorly ART-adherent who accepted AHD screening. 59.4% (92/155) had AHD, including 5.4% (5/92) with TB/CD+; Of those, 3/5 had cryptococcal meningitis (TB/CM) and 2/5 were serum CrAg-positive (TB/CM) without CM (Table 1). Patients with TB/CM received short-course amphotericin-B, high-dose fluconazole and management of intracranial pressure with repeated lumbar punctures (LP). TB/CD+ patients were treated with high-dose fluconazole. ART was started 2 and 6 weeks after diagnosis among TB/CD+ and TB/CM respectively. Mortality was 0 among TB/CD+ and 2/3 in CM patients.

Conclusion: CD and TB coinfecion remains underdiagnosed in sub-Saharan Africa. Most cryptococccemic cases go unnoticed in the absence of CrAg-screening. Several challenges exist regarding the management of TB/CD patients, including the lack of first-line antifungals and the low implementation of secondary prophylaxis, and the resulting in high mortality. The WHO package of interventions offers an opportunity to address these gaps.
Table 1. Baseline characteristics of CD/TB coinfected patients

<table>
<thead>
<tr>
<th>Case</th>
<th>Age/Sex</th>
<th>ART history</th>
<th>Xpert Ultra Stp</th>
<th>CrAg Serum/</th>
<th>Crypto. culture</th>
<th>ART timing</th>
<th>6-month Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>43 (M)</td>
<td>Naive</td>
<td>92</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
<td>2 weeks Alive</td>
</tr>
<tr>
<td>2</td>
<td>29 (F)</td>
<td>Non-adherent</td>
<td>111</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
<td>2 weeks Alive</td>
</tr>
<tr>
<td>3</td>
<td>28 (F)</td>
<td>Naive</td>
<td>1</td>
<td>+/-</td>
<td>+/-</td>
<td>6 weeks Alive</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>40 (F)</td>
<td>Naive</td>
<td>45</td>
<td>NP/-</td>
<td>+/-</td>
<td>6 weeks Death, 9 weeks after discharge</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>32 (M)</td>
<td>Non-adherent</td>
<td>18</td>
<td>NP/-</td>
<td>+/-</td>
<td>-</td>
<td>Death, 48 days after discharge</td>
</tr>
</tbody>
</table>

PE35/14
Trends in latent tuberculosis screening in a cohort of HIV-infected patients from a low tuberculosis incidence country
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Purpose: Latent tuberculosis (LTB) screening is recommended in HIV-infected patients by international guidelines. Portugal is a low tuberculosis incidence country, where national guidelines for LTB screening were implemented in 2015. Our aim was to evaluate the trends in LTB screening in a cohort of HIV-infected patients over a 9 year period.

Methods: Cross-sectional, retrospective study of HIV-infected patients with a diagnosis of HIV infection in 2008–2017. LTB was defined as having a positive tuberculin skin test, interferon-gamma release assay and/or recent contact history. Active TB (ATB) was defined as having microbiological or clinical diagnosis. ATB cases before HIV diagnosis were excluded. Logistic regression was performed to identify independent factors associated with likelihood of screening.

Results: Of 967 included patients, LTB screening was performed in 596 (61.6%). ATB was diagnosed in 91 (9.38%) patients. We found an increase in likelihood of LTB screening over 2008–2017 (from 61.5% to 77.8%, p<0.001). Factors correlated with likelihood of LTB screening were diagnosis in the outpatient setting (OR 4.34 95% CI: 3.05–6.18) and sexual acquisition of HIV infection (OR 2.40 95% CI: 1.59–3.61). Patients aged >51 years (OR 0.54 95% CI: 0.39–0.75), migrants (OR 0.58 95% CI: 0.37–0.91), those with CD4 count <50 cells/μl (OR 0.35 95% CI: 0.22–0.52) and hepatitis C and/or B (OR 0.42 95% CI: 0.27–0.65) were less likely to be screened. LTB screening increased from 2015 onwards after implementation of national guidelines (OR 2.00 95% CI: 1.59–2.36). Patients aged >51 years (OR 0.54 95% CI: 0.39–0.75) and cases of ATB decreased (4.65–5.38% vs. 7.53–17.27%; p<0.001).

Conclusion: Despite some improvement in LTB screening, adherence to recommendations remains low. Measures should be implemented to strengthen screening in identified-at-risk groups, such as migrants and older-aged patients.

PE35/15
Drug-induced hepatic injury developed in tuberculosis/HIV co-infection treatment
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Objective: The objective of the study was to evaluate the Drug-Induced Hepatic Injury (LHIM) in the treatment of tuberculosis (TB) in people living with HIV through the instruments of Naranjo and RUCAM, in a reference center in the Southeast of Brazil for infectious-contagious diseases.
Vaccines and immune based therapies

PE36/2
Development of engineered nanocarrier for controlled delivery of a protease inhibitor
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Purpose: AIDS is a chronic, progressive syndrome, characterized by intense viral replication and profound immunosuppression, resulting in the development of life threatening opportunistic infections. HIV infection leads to deterioration of immune functions. The objective of the present study was to develop, optimize and characterize engineered nanocarriers for controlled delivery of a protease inhibitor. Lopinavir was the drug of choice as it is an effective antiretroviral drug having specific and prominent anti-HIV action. In the present study, it is envisaged to develop and characterize a controlled delivery system wherein the drug lopinavir (LPV) will be entrapped in engineered nanocarrier. Engineered nanocarriers targeted towards the prespecified target tissues by coupling with mannose delivers the drug in a controlled manner to the site of action. Thus it results in increased bioavailability and avoids the adverse effects associated with the drug. Overall the approach leads to a safe, economical and effective Anti-HIV formulation.

Method: The uncoupled Solid Lipid Nanoparticles (SLN) were prepared by Solvent diffusion method and then coupled with mannose. Characterization studies were done by Scanning & Transmission Electron Microscopy (SEM & TEM). X-ray diffraction (XRD) and Differential scanning calorimetry (DSC) studies were performed along with the in-vitro studies followed by in-vivo studies on albino rats.

Results: In-vitro & in-vivo studies results shows Mannose coated SLNs (MSLN) deliver their contents to macrophage rich organs and tissues, which are the reservoir of HIV. Low elimination and better distribution profile can be achieved by MSLNs. The dose of the antiviral agent can be reduced due to the site-specific delivery from this carrier.

Conclusion: Conclusively, ligand-mediated bio-disposition and cellular interaction of MSLNs, especially at target sites, would be a focal paradigm for upcoming research in the field of anti-HIV drug delivery. MSLNs have paved the way for the bio-stable, site-specific and ligand-mediated delivery systems with desired therapeutics.

Viral hepatitis

PE37/1
Acute hepatitis C infection in HIV-infected patients who achieved viral suppression: incidence and risk factors
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Background: The cases of sexually transmitted diseases (STDs) are commonly reported among HIV-infected men who have sex with men (MSM), especially syphilis, gonorrhea, acute hepatitis A and genital wart, but acute hepatitis C (AHC) became one of rampant STDs recently, even those living with fully suppressed HIV. The study was performed to evaluate the incidence and risk factors of AHC.

Materials and methods: We used Taiwan Centers for Disease Control (TCDC)-operated National Disease Surveillance Systems (NDSS) to identify incidence of AHC in Taoyuan General Hospital during October 2016 to October 2018. Overall, a total of 43 AHC with HIV co-infection cases were documented, and each AHC case was matched to four HIV-infected controls without AHC reported in the NDSS on age (±5 years), risk factor of HIV infection, CD4 lymphocyte counts (±50 cells/mL).

Results: Forty-three HIV/AHC cases were matched to 182 controls, and all cases and controls were males and MSM. The mean age (SD) was 31.0 (±5.6) years in AHC cases, and 30.6 (±6.7) years in controls, respectively (p=0.695). Forty-two cases (97.7%) and 182 controls (100%) took ART (anti-retroviral therapy) (p=0.191), and 39 cases (90.7%) and 182 controls (100%) had recent HIV RNA <200 copies/mL (p=0.001) and CD4 lymphocyte count were 700 (±262) versus 695 (±282) (p=0.972). In multivariable conditional logistic

Table 1. Characterization of liver injury (n=160)
regression analysis, a history of chemsex with amphetamine abuse (adjusted OR=3.11, 95% CI 1.39-6.96) and syphilis infection (aOR=3.55, 95% CI 1.25-10.13) were independently associated with acute hepatitis C infection.

Conclusions: Acute HCV cases continued to increase particularly among sexually active HIV-infected MSM with a syphilis diagnosis and a history of chemsex. We recommend surveillance of associated behavioral and virologic characteristics and HCV counseling and testing for HIV-infected men in Taiwan.

PE37/2

HBV infections among HIV infected HAART receiving mothers and their exposed infants in a tertiary hospital in Kenya

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Purpose: Mother-to-child transmission (MCT) of Hepatitis B virus (HBV) is responsible for more than one third of chronic HBV infections worldwide.

Antiretroviral therapy (ART) naive HIV/HBV co-infected mothers have a high tendency of transmitting the two viruses. This study aimed to determine prevalence & predisposing factors of HBV infections among HAART-receiving HIV-infected mothers and their exposed infants.

Method: A structured questionnaire was used to capture socio-demographic data and factors associated with HBV infections. A 4 ml sample of paired whole blood obtained from HIV positive mothers & their exposed infants was analyzed for Hepatitis B surface antigen (HBsAg) using both rapid and Enzyme-linked immunosorbent assay (ELISA) tests. HBsAg positive samples were further screened for HBV envelope antigen (HBeAg) using ELISA. HBsAg positive samples with both ELISA and rapid tests were subjected to a nested Polymerase chain reaction (PCR) targeting the preS1 region.

Results: A total of 534 HIV-infected mothers - infant pairs were recruited. Mean age of mothers was 31.2 years (SD 5.4 years) and infants' median age of 6 months (IQR 3-10 months). 502 (94.4%) of the mothers were taking TDF/FTC/NVP and 32(6%) were on AZT/3TC/NVP or EFV. 19 of 534 (3.6%) mothers were HBsAg positive with all tests. History of dental surgery was associated with HBV negative with all tests. History of dental surgery was associated with not receiving DAA therapy within the Bonn University Hospital cohort.

Method: 397 HCV/HIV co-infected patients from the HIV outpatient clinic at the university hospital in Bonn were analyzed retrospectively regarding sociodemographic, laboratory, HIV and DAA therapy data. Fisher’s Exact Test, T-test and Chi-Squared Test were used for statistical analysis.

Results: The median age of the 397 patients was 49.9 years (IQR 40.5-59.3), 83.6% were male. Main HIV transmission routes were: 27.2% men who have sex with men (MSM), 28.7% hemophilia, 25.4% intravenous drug use (IVDU). 95.5% received antiretroviral therapy, 84.2% were undetectable for HIV.

Hepatitis E seroprevalence in HIV-positive patients

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Purpose: Hepatitis E virus (HEV) infection is usually an acute self-limiting disease, leading rapidly progressive cirrhosis and a chronic infection in patients
with hematological malignancies, patients with chemotherapy requirement and patients with HIV-infected. The aim of this study was to investigate the seroprevalence of HEV in HIV-positive patients.

Method: In this study, serum samples of patients who applied to the Clinical Microbiology Laboratory of Sakarya University Education and Research Hospitals between October 2017 and December 2018 were evaluated for anti-HEV IgG and IgM. The study group consisted of 126 patients with HIV infection. Sixty healthy volunteers were used as the control group. Anti-HEV IgG and IgM antibodies were investigated by ELFA (Enzyme-linked Fluorescent Assay) method and commercial kits (Biomerieux diagnostic, France) from the plasma samples of the patients. In addition, ALT, AST, CD4, CD8, HIV-1 RNA viral load, anti-HEV, HBSAg, and VDRL results of patients were evaluated.

Results: The study group consisted of 114 (90.5%) males and 12 (9.5%) females with a mean age of 38.1±13.32 (min: 18, max: 80) years. Anti-HEV IgG was positive in 5 (4.0%) HIV-positive patients. Anti-HEV IgM was not positive in any patient. In the control group, anti-HEV IgG positivity was detected in only 1 of 60 patients. None of the patients with anti-HEV IgG positivity had anti-HCV and HBSAg positivity. There was no statistically significant difference between anti-HEV IgG positive and negative patients in terms of ALT, AST, CD4 and CD8, HIV-1 RNA viral load values (p=0.05).

Conclusion: Anti-HEV IgG positivity was found to be 4% in HIV-positive individuals and HCV and HBV co-infection was not detected in any patients with HIV-HEV co-infection. HEV infections do not emerge as a priority in HIV-infected people, but HEV should also be investigated in HIV-infected individuals with uncertain etiology of liver abnormalities.

PE37/6

Success of unrestricted DAA therapy is limited by HCV reinfections and loss to follow-up in HIV-positive patients

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Purpose: In contrast to interferon (IFN)-based therapy, direct-acting antivirals (DAAs) achieve hepatitis C virus (HCV) elimination in most individuals living with HIV. We assessed temporal trends in patient characteristics, transmission risks, treatment uptake and outcome (SVR) in eras of (i) IFN, (ii) restricted DAA-access (R-DAA), and (iii) unrestricted DAA-access (UNR-DAA) in HIV/HCV.

Method: Consecutive HIV/HCV starting HCV treatment at the Medical University of Vienna between Q2/2002-Q2/2019 were enrolled.

Results: Overall, 471 HIV/HCV initiated HCV treatment: n=152(32%) in IFN, n=129(27%) in R-DAA and n=190(41%) in UNR-DAA eras (Figure). Comparing IFN vs. R-DAA vs. UNR-DAA eras, distribution of age (38.4 vs. 45.9 vs. 41.5 years), gender (76% vs. 76% vs. 80%/male) and transmission routes (intravenous drug-use: 66% vs. 60% vs. 58%) were similar, whereas more patients with advanced fibrosis were treated during R-DAA (42% vs. 20%; p<0.01). Time from HCV diagnosis to therapy was significantly shorter in the UNR-DAA and IFN eras (median years UNR-DAA: 42.3 vs. IFN: 2.83 vs. R-DAA: 8.82; p<0.01). The number of therapies for HCV reinfections increased to n=60/21% in the UNR-DAA vs. n=0/0% in the IFN and n=4/3% in the R-DAA eras (p<0.01).

SVR was achieved in 49%, 95% and 79% in the IFN, R-DAA and UNR-DAA eras, respectively. While virologic failure was mostly limited to the IFN era (34% vs. UNR-DAA:5% vs. R-DAA:4%, p<0.01), lost-to-follow up re-occurred as major reason for non-SVR in the UNR-DAA era (16% vs. IFN:18% vs. R-DAA:2%, p<0.01). Without considering lost-to-follow-up patients, SVR was 95% in the UNR-DAA era.

Conclusions: With unrestricted DAA access, SVR is now achieved in 79% of HIV/HCV since loss-to-follow-up emerged as main reason for non-SVR, while virological failure occurred only in 5%. Most HIV/HCV patients with advanced fibrosis were treated in the R-DAA era. A rising number of HCV re-treatments for reinfections are observed in the UNR-DAA-era.

HIV/HCV-CoInfection

Timeline of treatment initiations

PE37/7

Efficacy and safety of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide as maintenance treatment of patients with HIV and Hepatitis B Virus (HBV) coinfection

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1National Taiwan University Hospital, Taipei, Taiwan, Province of China 2Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan, Province of China 3Chung Shan Medical University Hospital, Taichung, Taiwan, Province of China 4Hsinchu Mackay Memorial Hospital, Hsinchu, Taiwan, Province of China 5Far Eastern Memorial Hospital, Taoyuan, Taiwan, Province of China 6Changhua Christian Hospital, Changhua, Taiwan, Province of China 7Chi Mei Medical Center, Tainan, Taiwan, Province of China 8Taichung Veterans General Hospital, Taichung, Taiwan, Province of China 9Taoyuan General Hospital, Ministry of Health and Welfare, Taoyuan, Taiwan, Province of China 10Kaohsiung Medical University Hospital, Kaohsiung, Taiwan, Province of China 11China Medical University Hospital, Taichung, Taiwan, Province of China 12National Taiwan University Hospital Hsinchu Branch, Hsinchu, Taiwan, Province of China 13Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan, Province of China

Purpose: Tenofovir alafenamide (TAF) can suppress both HIV and HBV. The efficacy and safety of switching from TDF-based antiretroviral therapy to coformulated elvitegravir/cobicistat/emtricitabine/TAF (E/C/TAF) has not been widely investigated in HIV/HBV-coinfected Asian populations.

Methods: Between January 2018 and October 2018, HIV/HBV-coinfected patients who had achieved HIV viral suppression with TDF-containing regimens were switched to E/C/TAF in this multicenter study. Assessment of plasma HBV and HIV viral load, HBV serology, renal function, metabolic profiles, and bone mineral density (BMD) were performed at Weeks 24 and 48 after initiation of E/C/TAF.

Results: A total of 275 HIV/HBV-coinfected patients were enrolled, of whom 13.5% were HBeAg-positive at baseline and 94.2% had plasma HBV DNA <20 IU/mL. 275 and 200 have completed 24 and 48 weeks of follow-up, respectively. In snapshot analysis, 92.7% and 90.0% of the participants achieved plasma HBV DNA <20 IU/mL at Weeks 24 and 48, 89.1% and 63.0% maintained HIV viral suppression, and 9.1% and 36.5% had no virological data, respectively. At Weeks 24 and 48, 89.1% and 63.0% maintained HIV viral suppression, and 9.1% and 36.5% had no virological data, respectively. At Weeks 24 and 48, 89.1% and 63.0% maintained HIV viral suppression, and 9.1% and 36.5% had no virological data, respectively. At Weeks 24 and 48, 89.1% and 63.0% maintained HIV viral suppression, and 9.1% and 36.5% had no virological data, respectively. At Weeks 24 and 48, 89.1% and 63.0% maintained HIV viral suppression, and 9.1% and 36.5% had no virological data, respectively.

Conclusions: With restricted DAA access, SVR is now achieved in 79% of HIV/HCV since loss-to-follow-up emerged as main reason for non-SVR, while virological failure occurred only in 5%. Most HIV/HCV patients with advanced fibrosis were treated in the R-DAA era. A rising number of HCV re-treatments for reinfections are observed in the UNR-DAA-era.
**Conclusions:** E/C/TAF achieved both HBV and HIV viral suppression in HIV/HBV-coinfected patients. Switch to E/C/TAF resulted in less proteinuria, improved BMD of the lumbar spine and hip, but increased lipids at Week 48.

<table>
<thead>
<tr>
<th>Table 1. Lipid profiles of the patients at baseline and 48 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>N=275</td>
</tr>
<tr>
<td>Triglyceride (mg/dL), median (IQR)</td>
</tr>
<tr>
<td>Triglyceride, median change from baseline</td>
</tr>
<tr>
<td>Total cholesterol (mg/dL), median (IQR)</td>
</tr>
<tr>
<td>Total cholesterol, median change from baseline</td>
</tr>
<tr>
<td>LDL (mg/dL), median (IQR)</td>
</tr>
<tr>
<td>LDL median change from baseline</td>
</tr>
<tr>
<td>HDL (mg/dL), median (IQR)</td>
</tr>
<tr>
<td>HDL median change from baseline</td>
</tr>
<tr>
<td>Total cholesterol: HDL ratio, median (IQR)</td>
</tr>
</tbody>
</table>

**PE37/9**

**HIV patients remain at high risk for advanced liver fibrosis after curing HCV infection**

N Bolokadze1,2, M Asatiani1, L Sharavadze1,2, P Gabunia1, A Abutidze1,2, O Chokoshvili1, N Gedenidze1, T Tsertsvadze1,4 and N Chkhartishvili1

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**Purpose:** The aim of this study was to evaluate changes in liver fibrosis among HIV/HCV co-infected persons after curing HCV infection.

**Method:** Study included adult HIV/HCV co-infected patients, who cured HCV infection during 2015–2017 and were followed at least for 6 months after achieving sustained virologic response (SVR). Primary outcome of interest was change in the advanced liver fibrosis status defined as FIB-4 score of ≥3.25 or LS ≥9.5 kPa on transient elastography, with preference given to LS when available. FIB-4 and LS measurements closest to HCV treatment initiation were considered as baseline, while measurements closest to 31 December 2018 were defined as follow-up.

**Results:** Among 343 patients included the median age was 44 (IQR: 39-49) years, 301 (87.8%) were men and 237 (69.1) were infected through injection drug use (IDU). Patients were known to be HIV positive for the median 6.2 (IQR: 3.6-9.2) years. Overall 227 (66.2%) had advanced fibrosis at baseline. Patients were followed after SVR for the median 1.9 (IQR: 1.4-2.2) years. FIB-4 was available for all patients at baseline and follow-up, LS was available for 243 (70.8%) patients at baseline and 92 (26.8%) patients at follow-up. At the end of follow-up 212 (61.8%) patients had advanced liver fibrosis. Advanced fibrosis persisted in 148 (43.1%) patients, advanced fibrosis regressed in 79 (23.0%) patients, liver fibrosis progressed to advanced stage in 64 (18.7%) patients based on combined FIB-4 and LS data. Among 92 patients with follow-up LS data, 39 (42.4%) had persisted advanced liver fibrosis, 35 (38.0%) had progression in advanced liver fibrosis and 5 (5.4%) had regression to advanced liver fibrosis based on LS data only.

**Conclusion:** Despite curing HCV infection, HIV patients remain at high risk for persisted liver damage and progression to advanced liver fibrosis as measured predominantly by FIB-4.

**PE37/10**

**Effectiveness of hepatitis A vaccination among people living with HIV in Taiwan: is one dose enough?**

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**Purpose:** Single dose of hepatitis A virus (HAV) vaccine had been proven its efficacy in short-term and over 5 years effectiveness in immunocompetent hosts, but not in immunocompromised hosts. We aim to compare the effectiveness of one dose versus 2 doses HAV vaccine among people living with HIV (PLWH) during the outbreak of acute hepatitis A in Taiwan between June 2015 and December 2017.

**Method:** We conducted a 1:1 retrospective case-control study for PLWH in a tertiary hospital in Taiwan during June 2015 and December 2017. The aim of this study was to evaluate changes in liver fibrosis among HIV/HCV co-infected persons after curing HCV infection.

**Results:** Among 423 PLWH during February 2016 and December 2017, 90 cases received single dose of HAV vaccine provided by the campaign while the other 333 age-matched cases completed second dose of HAV vaccine 6 months later based on the suggestion from current guideline.

**Conclusion:** Two doses of hepatitis A vaccine are necessary among PLWH to achieve adequate seroresponse at one year in the setting of HAV outbreak, especially for patients with HIV/HCV coinfection.

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and 10.9% MSM). Of these 578, 409 cleared HCV after anti-HCV therapy, 104 cleared HCV spontaneously, 64 were HCV-RNA-positive, and 1 had unknown HCV-RNA. The prevalence of HCV-RNA-positive was, therefore, 3.7%. As 21 of 64 patients were receiving DAAIs, and assuming treatment effectiveness of 95%, the prevalence of HCV-RNA-positive could be considered to be 2.5%. A summary of the main findings in the four national cross-sectional studies is shown in the table. Overall, HCV-related liver cirrhosis was present in 6.6% of the PLWH, 10.9% of HCV-RNA-positives, and 26.4% of those who cleared HCV after anti-HCV therapy (P<0.001).

Conclusion: Active HCV infection among PLWH in Taiwan at the end of 2018 was 3.7%, that is, 83.3% lower than in 2015. Increased exposure to DAAIs was the reason for this sharp decrease. The elimination of HCV infection among PLWH in Spain is an achievable goal shortly, but the burden of HCV-related cirrhosis will continue to be significant among these individuals.

Trends in HIV/HCV coinfection in Spain

<table>
<thead>
<tr>
<th>Year</th>
<th>Centers</th>
<th>Reference population</th>
<th>Sample size</th>
<th>Tested for HCV Ab</th>
<th>HCV Ab-positive</th>
<th>HCV-RNA-positive</th>
<th>Anti-HCV treatment uptake</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>41</td>
<td>35,791</td>
<td>1,867</td>
<td>98.7%</td>
<td>99.8%</td>
<td>99.1%</td>
<td>93.3%</td>
</tr>
<tr>
<td>2016</td>
<td>43</td>
<td>38,904</td>
<td>1,588</td>
<td>37.7%</td>
<td>34.6%</td>
<td>34.0%</td>
<td>92.4%</td>
</tr>
<tr>
<td>2017</td>
<td>43</td>
<td>40,322</td>
<td>1,690</td>
<td>22.1%</td>
<td>11.8%</td>
<td>8.0%</td>
<td>92.2%</td>
</tr>
<tr>
<td>2018</td>
<td>43</td>
<td>40,650</td>
<td>1,733</td>
<td>58.3%</td>
<td>74.7%</td>
<td>82.4%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

PE37/11
Care cascade of incident HCV infection among HIV-positive patients in Taiwan

M-H Huang1, S-Y Chang2, S-Y Ho3, L-H Su1, H-Y Sun1 and C-C Hung3

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Purpose: Direct acting antivirals (DAAs) have replaced pegylated interferon plus ribavirin (Peg/RBV) and have been reimbursed for the treatment of chronic HCV infection in Taiwan in 2017-2018. Despite the government’s commitment to elimination of HCV by 2025, little is known about the engagement and completion of HCV treatment in HIV/HCV-coinfected patients, in whom the incidence rate of HCV infection has steadily increased to 28.5 per 1000 PYFU in 2018.

Method: From January 2011 to December 2018, HIV-positive patients testing negative for anti-HCV antibody at baseline followed by subsequent HCV serocconversion were identified as having incident infections. Care cascade of HCV infection included the total case number of incident HCV infection identified by retrospectively testing all archived blood samples, HCV serocconversion detected by treating physicians, HCV RNA load determined, HCV RNA positivity, HCV treatment initiated, and sustained virologic response (SVR) achieved. We calculated the duration of HCV viremia, from the diagnosis of incident HCV infection until viral clearance by treatment or end-of-observation on 30 June 2018. The number of sexually transmitted infections were recorded.

Results: Among 3671 HCV-seronegative, HIV-positive patients, 234 (91.5%) being MSM) developed HCV serocconversion between 2011 and 2018. Of those patients, 226 (96.6%) were found to have HCV serocconversion by HIV-treating physicians, 206 (88.0%) had an HCV RNA load determined and 182 (77.8%) were viremic. Of those known to have HCV viremia, 128 (70.3%) initiated treatment and 111 (61.0%) achieved SVR. The median interval of HCV viremia period was recorded.

Conclusion: Despite improved access to treatment for HCV infection in Taiwan, HCV RNA load testing and early initiation of anti-HCV treatment need to be improved in order to prevent onward transmission among HIV-positive patients in Taiwan.

PE37/12
Current characteristics of HIV/HBV coinfected patients in a single HIV reference centre of Madrid


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Purpose: HIV epidemiology and prognosis has changed in Spain since the beginning of the epidemic. The objectives of our study were to assess if changes in epidemiologic characteristics have changed also in HIV patients with chronic hepatitis B (CHB) and to study clinical evolution of HIV/HBV-coinfected patients over the years.

Methods: Retrospective review of CHB coinfected patients in a single reference HIV clinic in Madrid, Spain. We compared incidence and baseline characteristics in different time periods (before 2000, 2000-2004, 2005-2009, 2010-2014, 2015-2018). Univariate and multivariate logistic regression analysis (including age, gender, diagnosis before 2000, intravenous drug use [PWID], CD4 cell count, HCV and HDV coinfecition and fibrosis) was done to study factors associated with mortality and advance fibrosis (AF). AF was considered when the last fibroscan was >12 Kp/mL or clinical cirrhosis was diagnosed.

Results: Out of 5453 HIV+ patients included, 163 had CHB (prevalence 3%; 95% CI 2.6-3.5). Incidence rate has not change since year 2000 (2.4/100 patients-year). Most CHB are men (85.5%) without difference among study periods. In the last period we have seen differences in origin (fewer Spanish native patients and more latin americans), fewer former PWID, coinfection with HDV and HCV. After a median follow-up of 18.9 (IQR 8.8-25.4) years since diagnosis, twenty patients had died (0.69*100 patients-year); 9 liver related, 5 cancer, 3 HIV related, 3 other.

Having a first fibroscan >12 Kp/mL was independently associated with death (Table 2).

At the end of follow up 31/122 (25.4%) had AF. AF was independently associated with diagnosis before year 2000 and coinfection with hepatitis delta.

TABLE 1: PATIENT CHARACTERISTICS REGARDING YEAR OF DIAGNOSIS

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of patients</th>
<th>Male (%)</th>
<th>Age (Median ± IQR)</th>
<th>HIV stage</th>
<th>CD4 cell count (Median ± IQR)</th>
<th>Last observation</th>
<th>Last FIBROSCAN</th>
<th>AF (%</th>
<th>Death (%)</th>
<th>Cancer (%)</th>
<th>Liver (%)</th>
<th>Other (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>500</td>
<td>496 (99.2)</td>
<td>37.5 ± 15.5</td>
<td>2</td>
<td>755 (500)</td>
<td>9</td>
<td>3.4 ± 1.0</td>
<td>16</td>
<td>4</td>
<td>11</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>2005</td>
<td>500</td>
<td>496 (99.2)</td>
<td>37.5 ± 15.5</td>
<td>2</td>
<td>755 (500)</td>
<td>9</td>
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<td>16</td>
<td>4</td>
<td>11</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>2010</td>
<td>500</td>
<td>496 (99.2)</td>
<td>37.5 ± 15.5</td>
<td>2</td>
<td>755 (500)</td>
<td>9</td>
<td>3.4 ± 1.0</td>
<td>16</td>
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<td>4</td>
<td>11</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>

* Median [IQR]: CHB: chronic hepatitis B; PWID: former intravenous drug addicts; MSM: Men sex with men.
Conclusions: The epidemiology of CHB in our cohort is changing, with less native Spanish and less coinfection with other hepatotropic virus. Liver fibrosis predicts mortality while coinfection with hepatitis delta and diagnosis before year 2000 predicts advanced fibrosis.

<table>
<thead>
<tr>
<th>TABLE 2: FACTORS ASSOCIATED WITH MORTALITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (1.03 (0.2-3.8) 0.9</td>
</tr>
<tr>
<td>Age at the end of follow-up (1.01 (0.9-1.07) 0.5</td>
</tr>
<tr>
<td>Diagnosis before year 2000 (2.9 (0.9-8.3) 0.09</td>
</tr>
<tr>
<td>PDI* (4.9 (1.0-13.2) &lt;0.01</td>
</tr>
<tr>
<td>Nadir CD4 count (0.9 (0.3-2.1) 0.1</td>
</tr>
<tr>
<td>Chronic hepatitis C (2.9 (1.4-6.7) 0.03</td>
</tr>
<tr>
<td>Hepatitis Delta (4.2 (1.3-13.6) 0.01</td>
</tr>
<tr>
<td>Baseline Fibroscan (1.4 (1.6-15.2) &lt;0.05</td>
</tr>
</tbody>
</table>

* PDI: patients infected by injection of medicines drugs. +Fr 10% of HIV coinfection increases.

PE37/13
High HCV reinfection rate in MSM living with HIV in Barcelona: the need to focus on high risk population to achieve HCV elimination

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Hospital Clinic-IDIBAPS-University of Barcelona, HIV Unit, Infectious Diseases Service, Barcelona, Spain

Purpose: The aim of this study in the characteristics and the incidence of HCV reinfection among men who have sex with men (MSM) living with HIV (LWHIV) from the Hospital Clinic HIV cohort in Barcelona, Spain.

Methods: The MSM HIV-HCV coinfected patients who have had one or more HCV reinfections in this cohort have been analysed retrospectively from January 2010 until the December 2017. Demographic, epidemiological and HIV-HCV variables have been collected at the time of the first HCV reinfection and in the following episodes. Data were analysed using Stata (StataCorp. 2017).

Results: 194 patients were diagnosed with an AHC during the period time. 174 were treated for the first episode infection and 95 achieved a SVR. During the follow-up, 35 HCV reinfection episodes were identified in 30 MSM HIV patients. Baseline characteristics are shown in Table 1. Twenty-six (87%) patients with one reinfection, three (10%) with two and one (3%) with three reinfections. Fourteen (40%) subjects had a concomitant STI at the first episode, being 75% in the second episode. Twenty-seven (77%) patients were asymptomatic. 21 patients, agreed to answer about risk factors and sexual behaviours: 9 (42%) disclosed multiple sexual partners in the last month before the reinfection; 14 (66%) had unprotected anal sex, and 13 (61%) used no intravenous drugs in sexual context. The global incidence rate for reinfection episode and 19/100 py in the second reinfection. Twenty-seven (77%) patients were asymptomatic. 21 patients, agreed to answer about risk factors and sexual behaviours: 9 (42%) disclosed multiple sexual partners in the last month before the reinfection; 14 (66%) had unprotected anal sex, and 13 (61%) used no intravenous drugs in sexual context. The global incidence rate for reinfection episode and 19/100 py in the second reinfection. Twenty-seven (77%) patients were asymptomatic. 21 patients, agreed to answer about risk factors and sexual behaviours: 9 (42%) disclosed multiple sexual partners in the last month before the reinfection; 14 (66%) had unprotected anal sex, and 13 (61%) used no intravenous drugs in sexual context. The global incidence rate for reinfection episode and 19/100 py in the second reinfection.

Conclusions: High rate of HCV reinfection has been observed in MSM LWHIV in our cohort, most of them being asymptomatic and mainly associated to other concomitant STI. HCV-RNA should be tested regularly in HIV-positive MSM already cured from an AHC and routine screening of HCV should be done when an STI is diagnosed.

PE37/14
Liver disease in HIV-infected subjects in the post-HCV DAA treatment era

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1HIV Unit. Hospital Universitario La Paz. IDiPaz, Madrid, Spain 2Hepatology Unit, Gastroenterology Service. Hospital La Paz, Madrid, Spain 3HIV unit. Internal Medicine Hospital Universitario La Paz, Madrid, Spain

Purpose: Hepatopathy in HIV-infected patients has changed after the ART era, even more so after HCV treatment and cure. The objective of our study was to analyze liver function tests and the severity of hepatopathy and hepatic fibrosis in a C/HIV-Spanish cohort in the post-HCV DAA treatment era.

Method: Cross-sectional study in a cohort of 4009 HIV-infected patients in February 2019 in a clinical unit in Madrid, Spain. We analysed the demographic, clinical and analytical records of all patients with HCV infection followed regularly in our cohort. We compared HCV-HIV coinfected and HIV monoinfected patients regarding liver function tests, metabolic parameters and liver fibrosis severity with transient elastography (FibroScan®). Advanced fibrosis was considered when the FS was >9.6 kPa.

Results: The main clinical and demographic characteristics are shown in table 1. Out of 4009 HIV patients, 1065 were HCV-coinfected (26.6%), 1028 HVC-monoinfected patients. Advanced fibrosis was identified in 272 patients (12.6%) being most prevalent in HCV coinfection (19.6% vs 6.4%; p < 0.005).

Liver function tests, lipid profiles and glycaemia were similar among HCV-HIV-coinfected and HIV-monoinfected subjects. The only differences found were in platelets, prothrombine time, albumin, FS measurements and non-invasive markers of fibrosis between both populations (table 2).

Conclusion: Nowadays HCV infection is almost eradicated in HIV-infected subjects from our cohort. Most of the HCV-HIV infected subjects who have reached SVR present normal liver function tests as well as metabolic profile are similar to those of HIV-monoinfected subjects. Patients with advanced liver fibrosis maintain analytical alterations related to portal hypertension and would require close and specific follow-up.
PE37/15
Seroprevalence of hepatitis E in a Portuguese cohort of human immunodeficiency virus infected patients
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1Centro Hospitalar São João, Infectious Diseases, Porto, Portugal 2Centro Hospitalar São João, Molecular Biology Lab, Porto, Portugal 3Centro Hospitalar São João, Immunohemotherapy Lab, Porto, Portugal

Purpose: To study the seroprevalence of HEV and prevalence of chronic HEV in a population of HIV infected patients from Porto, Portugal.

Method: We randomly selected 299 patients from the cohort of HIV infected patient followed in Centro Hospitalar Universitário São João. We performed an ELISA to search for IgG for HEV (Wanted HEV-IgG ELISA). When the absorbance/cut-off was inferior to 3.5 the test was repeated and a confirmatory test (recomLine HEV IgG/IgM) executed in the same sample. For reactive tests and for immunosuppressed patients (CD4 count less than 200/mm³), an in-house Polymerase Chain Reaction (PCR) test is being performed. We used the most suitable descriptive and inferential statistics, using a significance level of 0.05.

Results: Seventy-five patients (25.1%; 95% confidence interval: 20.1%–30.1%) had reactive IgG Hepatitis E serology. From the 299 patients included, 225 (75.3%) were men. The mean age was 48.18 (standard deviation 12.26).

Conclusion: Seroprevalence of HEV was 25.1% (95% confidence interval: 20.1%–30.1%) in HIV infected patients. Older age and higher GGT showed a relation to HEV reactive IgG test.

PE37/16
Loss of seroprotection against hepatitis B virus (HBV) was associated with lower CD4 counts among HIV-positive patients who were born in the era of nationwide neonatal HBV vaccination
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1National Taiwan University Hospital Hsinchu Branch, Hsin-Chu City, Taiwan, Province of China 2National Taiwan University Hospital, Taipei, Taiwan, Province of China 3National Taiwan University Hospital Jinn-Shan Branch, New Taipei, Taiwan, Province of China

Purpose: HBV seroprevalence has declined among Taiwanese born in the era of the universal neonatal HBV vaccination implemented in 1986. However, 40% to 50% of these individuals lose seroprotection against HBV in their adulthood. Factors associated with loss of seroprotection against HBV among people living with HIV (PLWHIV) who were born in the HBV vaccination era remains unclear.

Method: PLWHIV who were born after 1 July, 1986 and tested negative for HBsAg and anti-HBc with anti-HBs titer <10 mIU/mL were defined as being “triple-negative”. People testing negative for HBsAg and anti-HBc with anti-HBs titer ≥10 mIU/mL were considered being “seroprotective” against HBV. Clinical characteristics were analyzed, including age, sex, HIV risk group, CD4 count, plasma HIV RNA load, and presence of opportunistic infection, HCV infection, or syphilis.

Results: Between 2004 and 2015, 427 patients who were born in the neonatal HBV vaccination era were included: 8 (1.8%) were HBV carrier; 210 (49.2%) tested triple-negative; and 169 (39.6%) were seroprotective against HBV. Compared with patients testing triple-negative, those with persistent seroprotection had a higher CD4 count when HIV infection was diagnosed [372 [IQR 218–493] vs 411 [IQR 282–524] cells/mm³; p = 0.06], and were less likely to present with AIDS (20.8% vs 15.4%, p = 0.03). Persistent seroprotection against HBV was correlated with CD4 count category (adjusted odds ratio, 1.79 [95% CI 1.01–3.19], p = 0.05; and 2.06 [95% CI, 1.09–3.04], p = 0.03 for patients with baseline CD4 count of 200–499 cells/mm³ and ≥500 cell/mm³, respectively, compared with those with CD4 count <200 cells/mm³).

Conclusion: Among PLWHIV born in the nationwide neonatal HBV vaccination era, patients presenting with lower CD4 counts were more likely to lose their immunity against HBV. Strategies to improve HIV case finding and HBV revaccination for those who have lost seroprotection are needed in this country of higher endemicity of HBV infection.

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PE37/18
DAA treating Hepatitis C in HIV/HCV coinfected patients in two prisons of Rome: results and problems
S Lardo, S Rosati, G Iannicelli, P Magini and M Zaccarelli
INMI L.Spallanzani IRCCS, Roma, Italy

Purpose: The rate of hepatitis C infection in jail is estimated about 13%. Among HIV-positive prison inmates and the rate of hepatitis C co-infection is about 38%. There are few data on real-world experience of Hepatitis C treatment with DAA in prison and, in particular, of HIV/HCV coinfected patients. Thus, we present the initial results of our project of DAA treatment in two prisons of Rome.

Method: HIV/HCV coinfected patients who started DAA treatment in “Rebbibbia” and “Regina Coeli” prisons between 2016 and May 2019 were included. Primary outcome of the analysis was sustained virological response at 12 weeks after DAA completion (SVR12). Secondary outcome was assessing critical issues of treating prisoners and carrying out their follow-up to 12 weeks.

Results: Overall, 48 coinfected patients were included, 45 of them started DAA therapy (3 patients did not start for personal motivation or getting out of prison). Main characteristics: males 92.9%; median age 47 years; non-Italian 20.8%; cirrhosis 12.5%; HCV genotype 1a 53.3%, 1b 4.4%, 3 20.0%, 4 22.3%; All patients but one were on steady antiretroviral treatment.

Conclusion: Our data suggest that DAA therapy in prison is feasible with acceptable SVR rates. However, the continuing changing imprisonment situation is the main obstacle to treatment success. Key points are: i) motivation of patients, ii) close collaboration with prison operators, iii) easy accessible follow-up clinic to manage patients out of prison.

PE37/19
Progress towards eliminating mother-to-child transmission of HIV in the Macha area in Zambia from 2010–2018
M Hamahawa
Macha Te, Choma, Zambia

Purpose: To assess progress made in prevention of mother-child transmission coverage in the Macha area.

Method: We analysed data of 1, 175 mother-infant pairs from the three studies conducted at Macha hospital, of HIV-infected mothers bringing their infants for early infant diagnosis from August 2010 to August 2018.

Results: The median age of the infants at their first HIV DNA test was 6 months. The majority of the mothers (85%) and infants (75%) received ARVs to prevent mother-to-child transmission of HIV. The proportion of mothers that received cART increased from 2010 (28%) to 2018 (91%). In 2010–2018, 101 (9%) infants tested positive for HIV. The proportion of infants testing positive decreased from 12% in 2010-2013 to 4% in 2016-2018 (P<0.0001). The proportion of infants who tested positive differed significantly by maternal receipt of PMTCT. Among infants whose mothers did not receive any PMTCT, 38% tested positive compared to 2% among infants whose mothers received cART for PMTCT (P=0.0001).

Conclusion: Comparing these data collected at different time periods in the Macha area indicates that significant progress has been made from 2010 to 2018. To continue with these gains, a concerted focus will be needed to target and improve on the integration of new guidelines into clinical practice at a facility level.
significantly higher in OGE (63%) & IDU (60%) as compared with MSM (20%) (p = 0.001). Acquired HBV immunity (HBcAb+ & HBsAb+): 33% vs. 30% (p = ns); significantly higher in OGE (46%) as compared to MSM (20%) & IDU (33%) (p = 0.001). Isolated HBcAb: 12.3% vs. 11.0% (p = ns); similar to the reported Israeli rate. Vaccine induced immunity (HBsAb+): 17% vs. 29%; significantly higher at end of FU (P = 0.001), the increase was significantly higher in MSM risk group (P = 0.001). HCV carriage (HCVAb+): 7.5% vs. 9.5% (p = ns), significantly higher in IDU (68%) (p = 0.001), and significantly higher than the Israeli prevalence of 2.3% (p = 0.001).

Conclusion: We found higher HBV exposure & acquired immunity in the OGE risk group, probably due to higher prevalence in their country of origin. IDU patients had higher HBV and HCV carriage. MSM had higher vaccination rates, especially at end of FU, suggesting better vaccine compliance. This data is important to consider when planning prevention strategies in HIV infected patients.

PE37/22

Hepatitis C treatment outcomes of HIV infected people who inject drugs in a real-world cohort

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Laikon Athens General Hospital and Medical School, National and Kapodistrian University of Athens, 1st Internal Medicine Department, Athens, Greece

Purpose: Among the most marginalized populations is people living with HIV (PLWHIV) and inject drugs (PWIDs); access to HCV treatment remains problematic. The aim of this analysis was to assess efficacy and safety of direct acting antivirals (DAA) in a population of HIV-infected PWIDs in a real-world setting.

Method: Of 88 HIV-HCV co-infected PWIDs who initiated DAA treatment, 66 have already completed DAA treatment and sustained viral response data (SVR) data is available. Univariate logistic regression analysis was used to assess statistically significant predictors of achieving SVR.

Results: All patients were under highly active antiretroviral treatment (HAART) at the time of enrollment, although in 16/66 (24.2%) a change in HAART regimen was required due to drug interactions with DAs. Demographic and clinical information is presented in the tables. SVR was successful for 53/66 (80.3%). Two of our patients who failed SVR, had a different genotype when they were re-tested, implying a reinfection. A further one patient has been re-infected after achieving SVR. In univariate analysis, none of the listed parameters predicted SVR failure. However, lack of adherence was statistically significant in predicting failure (p = 0.008, OR = 7.7, 95% CI 1.7–34.7). Amongst those with good compliance, success was still only at 86% (49/57). Continuous IV drug use had a tendency for significance (p = 0.081). A decrease (end – start of treatment) in APRI score (p = 0.008, OR = 15.3, 95% CI 2.0–116.6) but not FIB4 (p = 0.393, OR = 1.68, 95% CI 0.5–5.49) would predict SVR success. There were no serious adverse events during treatment.

Conclusion: Success rates for HCV infection in HIV infected PWID are lower than expected, partially due to lack of adherence. A significant proportion of patients require monitoring for drug interactions before or during HCV DAA administration. Larger studies are needed to identify modifiable risk factors in succeeding HCV elimination to those populations at high risk of ongoing transmission.

Demographic information

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD) or Median (IQR 25th, 75th) or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>39.6 (7.2)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>60 (90.9)</td>
</tr>
<tr>
<td>Greek nationality, n (%)</td>
<td>63 (95.5)</td>
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<tr>
<td>Steady occupation, n (%)</td>
<td>17 (25.8)</td>
</tr>
<tr>
<td>Alcohol abuse, n (%)</td>
<td>8 (12.1)</td>
</tr>
<tr>
<td>Benzo diazepine use, n (%)</td>
<td>31 (47)</td>
</tr>
<tr>
<td>Active IV drug use, n (%)</td>
<td>17 (25.8)</td>
</tr>
<tr>
<td>Polypharmacy (&gt;2/4, excl. DAA), n (%)</td>
<td>20 (30.3)</td>
</tr>
<tr>
<td>Opioid Substitution program, n (%)</td>
<td>39 (59.1)</td>
</tr>
</tbody>
</table>

Clinical information pertaining to HIV and HCV infection

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD) or Median (IQR 25th, 75th) or n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetectable HIV RNA, n (%)</td>
<td>62 (93.9) (kPa, median (IQR) 6.25 (5.2, 7.72)</td>
</tr>
<tr>
<td>CD4/mm³, mean (SD)</td>
<td>520 (296) (Previous HCV treatment, n (%) 10 (15.2)</td>
</tr>
<tr>
<td>Log HCV RNA, median (IQR)</td>
<td>6.19 (5.84, 6.72) (APRI score, median (IQR) 0.42 (0.29, 0.74)</td>
</tr>
<tr>
<td>HCV Genotype</td>
<td>FIB4 score, median (IQR) 1.09 (0.91, 1.56)</td>
</tr>
<tr>
<td>1a, n (%)</td>
<td>28 (42.4) (HCV treatment regimen)</td>
</tr>
<tr>
<td>1b, n (%)</td>
<td>1 (1.5) (SOF/LDV, n (%) 22 (33.3)</td>
</tr>
<tr>
<td>3, n (%)</td>
<td>23 (34.8) (SOF/VEL, n (%) 28 (42.4)</td>
</tr>
<tr>
<td>4, n (%)</td>
<td>13 (19.7) (ELB/GRZ, n (%) 12 (18.2)</td>
</tr>
<tr>
<td>Mixed, genotype, n (%)</td>
<td>1 (1.5) (2D or 3D, n (%) 4 (6)</td>
</tr>
</tbody>
</table>

PE37/23

Treatment of acute HCV infection with direct acting antivirals (DAA) in HIV patients

C Gomez-Ayerbe1,2, R Palacios1,2, C Perez1,2, F Tellez2, C Sayago1,2, MJ Rios1,2, M Martin-Aspas5, A Camacho1, R Munioz1, J Santos1,2 and HEPAVIR Group
1Hospital Universitario Virgen de la Victoria, Malaga, Spain 2Instituto de Investigación Biomédica de Málaga (IBIMA), Malaga, Spain 3Hospital Universitario de Puerto Real, Puerto Real, Spain 4Hospital Universitario Virgen de Valme, Sevilla, Spain 5Hospital Universitario Virgen Macarena, Sevilla, Spain 6Hospital Universitario Puerta del Mar, Cádiz, Spain 7Hospital Universitario Reina Sofia, Córdoba, Spain 8Hospital Universitario San Cecilio, Granada, Spain

Purpose: The aim of this study is to describe cases of acute HCV infection treated with DAA in seven Andalusian (Spain) hospitals.

Method: Retrospective, multicentre study of HIV-infected patients treated with DAA during HCV acute infection (in the first six months after diagnosis), from Nov-15 to Dec-18. Epidemiological, clinical, analytical, therapeutic and evolution variables were analysed.

Results: 30 episodes of acute HCV infection in 27 patients (6 re-infection cases) were included; all were MSM, with a mean age of 40.9 (±8) years and a median HIV infection time of 33.6 months (IQR: 20.4–67.2). All were on ART at the time of enrollment, although in 16/66 (24.2%) a change in ART regimen was required due to drug interactions with DAs. SVR was successful for 53/66 (80.3%). Two of our patients who failed SVR, had a different genotype when they were re-tested, implying a reinfection. A further one patient has been re-infected after achieving SVR. In univariate analysis, none of the listed parameters predicted SVR failure. However, lack of adherence was statistically significant in predicting failure (p = 0.008, OR = 7.7, 95% CI 1.7–34.7). Amongst those with good compliance, success was still only at 86% (49/57). Continuous IV drug use had a tendency for significance (p = 0.081). A decrease (end – start of treatment) in APRI score (p = 0.008, OR = 15.3, 95% CI 2.0–116.6) but not FIB4 (p = 0.393, OR = 1.68, 95% CI 0.5–5.49) would predict SVR success. There were no serious adverse events during treatment.

Conclusion: Success rates for HCV infection in HIV infected PWID are lower than expected, partially due to lack of adherence. A significant proportion of patients require monitoring for drug interactions before or during HCV DAA administration. Larger studies are needed to identify modifiable risk factors in succeeding HCV elimination to those populations at high risk of ongoing transmission.

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</table>
Hepatic fibrosis progression among HIV patients in Israel
K Olshtain-Popa, A Bennachum and R Safadi
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2Hadassah University Medical Center, Jerusalem, Israel
3Hadassah University Medical Center, The Liver Unit, Jerusalem, Israel

Purpose: Liver diseases have become common causes of death in people living with HIV. The aim of this study was to define the degree of fibrosis in HIV-HBV-HCV co-infected patients in Israel.

Method: All adult patients followed at the Hadassah AIDS Center were included. Demographic data, hepatitis serology, HIV disease parameters and FIB-4 data were recorded at beginning and end of follow up (FU).

Results: A total of 391 patients were included in the study, 256 (63%) males, 191 (49%) born in Africa, all but one in Ethiopia, mean age at beginning of follow up (FU) 44 years, mean follow up period 9.3 years. The HBV carriage (HBsAg+) was identified in 3.3% of patients at start FU, with no significant differences among risk groups. This was significantly higher than the reported 1.75% prevalence in Israel (p<0.001). The HBV carriage (anti-HCV+) was identified in 7.5% at start of FU, significantly higher (p<0.001) in IDU (68%) and significantly higher than the reported 2.3% Israeli prevalence (p=0.001). Low fibrosis (Fib-4<1.3) at start vs. end of FU was 63.3% vs. 67.9%, advanced fibrosis (Fib-4>2.67) 5.4% vs. 6.3%, respectively. Fibrosis severity was not affected by origin or hepatitis status, suggesting it was the result of fatty liver (metabolic, alcoholic or drug induced). HBV carriers had increased fibrosis at end of FU (p=0.049). Patients with CD4<200 had higher rates of low fibrosis than patients with CD4<200 (73.1 ± 54.5%, p=0.05).

Conclusion: Advanced fibrosis was found in 5.4% of the population. HBV-HCV co-infected patients in Israel with HIV. The aim of this study was to define the degree of fibrosis in HIV-HBV-HCV co-infected patients in Israel.

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Virological response to elvitegravir/cobicistat/emericitabine/tenofovir alafenamide in HIV-positive patients with lamivudine-resistant hepatitis B virus co-infection
Y-S Huang, S-Y Chang, H-Y Sun, Y-C Su, W-C Liu and C-H Hung
National Taiwan University Hospital, Taipei, Taiwan, Province of China

Purpose: Tenofovir alafenamide (TAF) has potent antiviral effect on both HIV and hepatitis B virus (HBV). However, data are limited on the effect of TAF against lamivudine-resistant HBV. We aimed to assess the virological response of lamivudine-resistant HBV to TAF-containing regimens among HIV/HBV-coinfected patients.

Methods: Between January 2018 and June 2019, antiretroviral therapy-experienced HIV-positive patients coinfected with lamivudine-resistant or lamivudine-susceptible HBV who switched to coformulated elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) were enrolled. Plasma HBV and HIV viral load, HBV serologic markers, and liver functions before and 48 weeks after the initiation of E/C/F/TAF were retrospectively collected and analyzed.

Results: A total of 107 HIV/HBV-coinfected patients with a median age of 44 years were enrolled. Thirty-four patients were coinfected with lamivudine-resistant (LAM-R) HBV, and 73 lamivudine-susceptible (LAM-S) HBV. At baseline, 37.5% of patients in the LAM-R group and 9.6% in the LAM-S group were tested positive for HBeAg (p=0.001). Prior to E/C/F/TAF, the percentage of patients who achieved plasma HBV DNA <20 IU/mL were 94.1% and 98.6% in LAM-R and LAM-S group, respectively. At 48 weeks of E/C/F/TAF, all patients in both groups achieved plasma HBV DNA <20 IU/mL. The rate of HBeAg loss at 48 weeks was 9.1% (1/11) of the LAM-R group and 28.6% (2/7) of the LAM-S group (p=0.528). Compared with baseline, the median HBsAg level at 48 weeks of LAM-R group increased significantly (157 vs 440 IU/mL, p=0.017) but that of the LAM-S group decreased significantly (615 vs 439 IU/mL, p=0.044).

Conclusions: Coformulated E/C/F/TAF achieved high rate of HBV viral suppression in HIV/HBV-coinfected patient with either lamivudine-resistant or lamivudine-susceptible HBV. A significant decrease in HBsAg level and a higher rate of HBeAg loss were observed in patients with lamivudine-susceptible HBV than those with lamivudine-resistant HBV.
PE37/27
Impact of direct-acting antiviral (DAA) agents on T cell counts and liver stiffness in HIV/HCV-coinfected patients: a multicenter prospective observational cohort study
TF Aiello1, A Jaen2, M Navarro Vilasoro3, R Font4, J Martinez Lacasa1, S Calzado Ibiser5, E Van den Eynde Otero1, A Palau Dominguez4, M Cervantes Garcia1, D Dalmay6 and M Cairo1
1Hospital Universitari Mutua Terrassa, Unidad de VIH, Terrassa, Spain
2Servicio de Enfermedades Infecciosas, Sabadell, Spain
3Hospital Universitari Parc Taulí, Unidad de Enfermedades Infecciosas, Sabadell, Spain
4Hospital Universitari Parc Taulí, Servicio de Medicina Interna, Sabadell, Spain
5Hospital Universitari Parc Taulí, Servei de Dermatologia, Sabadell, Spain

Purpose: assess evolution of liver stiffness and peripheral CD4+ and CD8+ cell counts in HIV/HCV patients treated with DAA.

Method: prospective observational multicenter open cohort study of HIV/HCV-coinfected patients treated with DAA between June 2015 and June 2019 at Hospital Universitari Mutua Terrassa and Hospital Universitari Parc Taulí and followed-up until 96 weeks after the end of treatment (EOT). Sociodemographic, epidemiological, clinical, biochemical, immunological, virological, treatment-related variables and liver stiffness assessed by METAVIR score were collected at the beginning, at the EOT (W0) and 12 (W12), 24 (W24), 48 (W48) and 96 (W96) weeks after the EOT.

Results: 260 HIV/HCV-coinfected patients enrolled, 80% male, mean age 50.4 years (±6.2). Most frequent transmission group was intravenous drug users (89%). Most frequent HCV genotype was 1A (39%). At baseline, medians and IQR.P25-P75 for Child-Pugh score were 6 (5-6); 48% of patients had F3-F4 METAVIR stage and medians and IQR.P25-P75 absolute and percentage for CD4+ and CD8+ were 583 cells/mm3 (398-810), 51% (25-71) and 845 cells/mm3 (567-1201) respectively. A 22 % of patients previously received interferon-based therapy. Sustained virological response 12 weeks after the EOT was demonstrated in 96% of patients. We observed a statistically significant increase from baseline in absolute CD4+ cell count at W12 (p<0.005) maintained over the follow-up period but not in CD4+/CD8+ ratio. About fibrosis evaluation, 46.7 % of patients with F3-F4 METAVIR stage dropped significantly (p<0.005) to a F1-F2, 12 weeks after the EOT.

Conclusion: Our data provide further evidence of the efficacy of DAA-based therapy in HIV/HCV coinfection and indicate that DAAs-based regimens improve liver stiffness 12 weeks after the EOT. Data from this study do not confirm the hypothesis that DAA enhance the host’s immune response after treatment.

PE37/28
Trends of HCV infection among HCV-seronegative, HIV-positive patients in Taiwan between 2011–2018
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1National Taiwan University Hospital, Taipei, Taiwan, Province of China
2National Taiwan University Hospital, Taipei City, Taiwan, Province of China

Purpose: The trends of HCV infection among HIV-positive MSM remain less investigated in Asia–Pacific region. We aimed to examine the current status of HCV infection among HCV-seronegative, HIV-positive patients in Taiwan between 2011 and 2018.

Methods: Between 2011 and 2018, 3,495 consecutive HIV-positive patients were included. The HCV antibody screening was performed on sequentially collected archived blood samples with the use of IgG ELISA kit. For sample tested positive for HCV antibodies, HCV RNA load was further determined by Roche cobas system and HCV genotypes were determined by NS5B PCR and sequencing.

Results: During the study period, 294 cases of recent HCV infection were diagnosed, resulting in an overall incidence rate of 17.97 per 1000 PYFU, which increased from 12.96 in 2011 per 1000 PYFU to 25.38 per 1000 PYFU in 2018. The mean plasma HCV RNA load was 5.4 log10 IU/mL. In multivariate analysis, patients with HCV co-infection were more likely to have elevated ALT levels (OR, 1.03; 95% CI, 0.02-0.04) and recent syphilis (OR 7.85; 95% CI, 1.49-2.63). The most prevalent genotype was 2a (39.7%), followed by 1b (29.1%), 6a (11.2%), 1a (9.9%), 3a (6.8%), and 6n (2.4%). Genotypes 3a and 6a increased from 0% and 5.2%, respectively, in 2011-2014 to 4.1% and 17.1% in 2015-2018. In phylogenetic analysis, three clusters of HCV infection were observed due to genotypes 2a and 6a, two clusters due to 3a and one cluster due to 1b. Almost all clusters occurred among MSM except one 2a cluster of two patients with unknown sexual orientation.

Conclusion: This study revealed a significantly increasing trend of recent HCV seroconversion among HIV-positive patients in Taiwan and HCV seroconversion was significantly associated with recent syphilis. The increasing trends of genotypes 3a and 6a and clusters suggest an expanding HCV epidemic among HIV-positive MSM in Taiwan.

PE37/29
The micro-elimination approach to eliminating Hepatitis C: a Fast Track City project
F Maggiolo1, A Callegaro2, R Teocchi1, D Valenti3, E Di Filippo1, L Comi1 and M Rizzi1
1ASST Papa Giovanni XXIII, Infectious Diseases, Bergamo, Italy
2ASST Papa Giovanni XXIII, Microbiology and Virology Laboratory, Bergamo, Italy
3ASST Papa Giovanni XXIII, UOC of Informatics, Bergamo, Italy

Purpose: To eliminate HCV infection in a cohort of HIV-infected subjects within a FTI project.

Method: Through intensive HCV re-testing and universal treatment with DAA, a single-center, large cohort of HIV-infected subjects in Northern Italy is closely monitored for HCV co-infection and all HCV-RNA positive subjects undergo antiviral treatment (figure 1). The project started at the end of 2018, the first 6 months results are reported. The project was approved by the local EC and all subjects gave their informed consent.

Results: At start 2733 PLWHIV were included in the cohort, 213 of them (7.8%) were still HCV-RNA positive. They were mostly males (74.1%), of Italian origin (87.8%) with a median age of 52 years (IQR 12). Almost half (48.1%) acquired HIV through heterosexual contacts, 26.9% were previous IVDUs and 24.3% MSM. During the 6 months of FU, 74 new HIV-infected subjects were enrolled, 7 of whom (9.52%) with an active HCV infection. During the same period of time 548 subjects were tested for HCV. Thirteen subjects (2.4%) already followed and previously HCV-Ab negative tested HCV-RNA positive (undiagnosed asymptomatic infections), 5 more subjects got re-infected after a DAA treatment. They are the 0.91% of the tested subjects, the 0.89% of patients at risk (HCV positive pre-treated and with HCV-RNA negative) and the 0.18% of the whole population. Finally, 1 patient (0.2 %) relapsed after DAA therapy. On the other hand, 71 subjects (13.0%) ended DAA treatment with SVR lowering the total proportion of HCV-RNA patients to 6.1% (173 subjects) (figure 2).

Conclusion: DAA universal treatment is a potent instrument to end HCV epidemic. Micro-elimination approaches limited to well-defined sub-populations may result an effective local answer. However, the risk of previously undiagnosed asymptomatic infections and the occurrence of re-infections may tamper the effect of DAA therapy. That makes intensive HCV monitoring mandatory.
Purpose: The main objective of NoCo study is to evaluate the possibility of eliminating HCV in HIV/HCV population in Italy over 3-years. The aim of this analysis is to estimate the prevalence of active HCV infection in HIV-positive patients in care at present.

Method: Cross-sectional analysis using data from NoCo study. Subjects included are those screened for HCV from September-2017 to June-2019, independently of their HCV status. Prevalence of HCV infection (HCVAb-positive) and active HCV infection (HCV-RNA positive) was evaluated. Prevalence, incidence and predictors -using unadjusted and adjusted logistic regression- of HCV seroconversions were also assessed.

Results: 8,283 patients included. Prior to study entry 2,314 (27.9%) were HCVAb-positive, 4,800 (57.9%) HCVAb-negative and 1,169 (14.1%) had unknown HCV serology. At the 1st-NoCo screening 2,420 (29.2%) were HCVAb-positive and 5,863 (70.8%) HCVAb-negative. Demographic characteristics in Table1. 76/1,169 (6.5%) participants with unknown HCVAb status, were HCVAb-positive. 35/4,800 (0.7%) subjects previously HCVAb-negative reported an HCV seroconversion at 1st-screening. Injecting drug users had the higher probability of HCV seroconversion at 1st-screening (AOR vs heterosexual=9.44, 95% CI: 3.32-26.84) [Table 2]. 2,158/8,283 (26.0%) subjects had one subsequent HCV screening in a median follow-up of 0.7 years (IQR: 0.4-0.9). 7 participants/1446 PYFU had an HCV seroconversion after the 1st-screening ([R=4.8/1000PYFU, 95% CI: 2.3-10.1]. Table 3 shows prevalence of HCV-RNA in HCVAb-positive at different timepoints. At 1st-screening 1,086/2,420 HCVAb-positive patients (44.9%) were HCV viremic, subject tested at least 2-times were viremic in 12.6% (157/1244) and overall 513/2427 (21.1%) where HCV-RNA positive.

Conclusion: At study entry, IDUs are the group at highest risk of new HCV infection in Italy. More than 75% of HCV patients have achieved viral eradication, suggesting that the target of HCV coinfection elimination within 3 years, could be achievable.

Table 2. Predictors of HCV seroconversions using a logistic regression mode.

<table>
<thead>
<tr>
<th>Gender M (vs.F)</th>
<th>OR (95%CI)</th>
<th>p</th>
<th>AOR* (95%CI)</th>
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</thead>
<tbody>
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<td>Heterosexual</td>
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<td>1.00</td>
<td>&lt;0.001</td>
<td>1.00</td>
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<tr>
<td>IDU</td>
<td>9.67 (5.55-16.36)</td>
<td>&lt;0.001</td>
<td>3.32 (1.76-6.24)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>MDM</td>
<td>1.37 (0.60-3.14)</td>
<td>0.45</td>
<td>1.08 (0.55-2.14)</td>
<td>0.32</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>1.30 (0.94-1.89)</td>
<td>0.873</td>
<td>1.01 (0.51-1.97)</td>
<td>0.973</td>
</tr>
<tr>
<td>Age (per 10 years increase)</td>
<td>0.80 (0.59-1.07)</td>
<td>0.140</td>
<td>0.81 (0.59-1.11)</td>
<td>0.188</td>
</tr>
<tr>
<td>Italian</td>
<td>1.33 (0.62-2.45)</td>
<td>0.459</td>
<td>1.36 (0.60-2.10)</td>
<td>0.458</td>
</tr>
</tbody>
</table>

*Adjusted for all the variables shown in the table.

Table 3. HCV-RNA status in HCVAb positive subjects enrolled in NoCo: data at first screening, at second screening and overall.

<table>
<thead>
<tr>
<th>N HCVAb positive</th>
<th>HCV-RNA negative</th>
<th>HCV-RNA positive</th>
<th>HCV-RNA not tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>First screening (Subjs with at least 1 screening)</td>
<td>2420</td>
<td>1255 (51.9%)</td>
<td>1086 (44.9%)</td>
</tr>
<tr>
<td>Last screening (Subjs with at least 2 screenings)</td>
<td>1244</td>
<td>1072 (86.2%)</td>
<td>157 (12.6%)</td>
</tr>
<tr>
<td>Overall (Subs with 1 or more screenings)</td>
<td>2427</td>
<td>1832 (75.5%)</td>
<td>513 (21.1%)</td>
</tr>
</tbody>
</table>

Table1. Demographic Characteristics at first NoCo Screening according to HCVAb
PE37/31

HCV cascade of care for HIV/HCV coinfected individuals in Greece and HCV treatment considerations in clinical practice

M Psichogiou1, C Thomadakis2, V Papastamopoulos2, E Kakalou3, D Basolis1, A Antoniadou1, A Papadopoulos1, S Metallidis1, T Chrysanthidis1, V Paparizos1, S Kourtounti1, G Adams1, G Chryso1, O Katara1, M Chini1,2, N Sipasa1, C Gogos1,2, A Giakas1,2, E Sambatakou1, P Panagopoulos1, G Vourli1, G Touloumi1, M Lazanas10 and AMACS Study Group

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Purpose: HCV cascade of care for HIV/HCV coinfected individuals in Greece and HCV treatment considerations in clinical practice.

Method: Analysis was performed for individuals alive in Athens Multicenter AIDS Cohort Study (AMACS) with available anti-HCV test by 31/10/2018. CoC was initiated in 213 patients. SVR12 was achieved in 67 of 75 (89.3%) (figure). From a total of 9664 patients, 8202 (84.8%) had anti-HCV test uptake. DDI potential between ART and DAAs was evaluated and careful selection of appropriate HCV DAAs regimen due to DDIs is warranted in clinical practice. HCV micro-elimination is a viable strategy, but requires optimization in linkage/retention in care, monitoring and treatment implementation.

Conclusion: Linkage/retention in care is the main gap for HIV/HCV coinfected individuals in Greece, followed by HCV treatment uptake. Caution and careful selection of appropriate HCV DAAs regimen due to DDIs is warranted in clinical practice. HCV micro-elimination is a viable strategy, but requires optimization in linkage/retention in care, monitoring and treatment implementation.

PE37/32

Hepatitis B core-related antigen and anti-hepatitis B core antibody are not associated with liver fibrosis evolution in HIV-HBV co-infected patients during treatment with tenofovir

R Cruchet1,2, L Dezantes1, A Gabas3, S Maylin3, H Rougi4, P Mialilhs5, C Lascoaux-Comb6, J Chas6, P-M Girard6, C Delaugerre3, K Lacombe1,8 and A Boyd1,8

1Sorbonne Université, INSERM, Institut Pierre Louis d’Épidémiologie et de Santé Publique, IPLESP, F75012, Paris, France 2Hospices Civils de Lyon, Lyon, France; Université Claude Bernard Lyon 1, Faculté de Médecine Lyon Est, Lyon, France 3APHP, Hôpital Saint-Louis, Laboratoire de Virologie, Paris, France; Université de Paris, INSERM U944, Institut de Recherche Saint-Louis, F75010, Paris, France 4IMEA, Institut de Médecine et d’Épidémiologie Appliquée, Paris, France 5Hôpital de la Croix-Rousse, Hospices Civils de Lyon, Service de Maladies Infectieuses, Lyon, France 6APHP, Hôpital Saint-Louis, Service de Maladies Infectieuses, Paris, France 7APHP, Hôpital Tenon, Service de Maladies Infectieuses, Paris, France 8APHP, Hôpital Saint-Antoine, Service de Maladies Infectieuses et Tropicales, Paris, France

Purpose: To study the association between quantitative hepatitis B core-related antigen (qHBCrAg) and anti-hepatitis B core antibody (qAnti-HBc) on liver fibrosis evolution in HIV-positive patients with chronic hepatitis B virus (HBV) infection undergoing treatment with tenofovir (TDF).

Method: 154 HIV-HBV-infected patients initiating a TDF-containing antiretroviral regimen were prospectively followed. Data on qHBCrAg and qAnti-HBc obtained using immunoassays and liver fibrosis assessment using Fibrotest® were collected every 6–12 months during TDF treatment. Hazard ratios (HR) assessing the association between qHBCrAg/qAnti-HBc and liver fibrosis progression (F0-F1→ F2-F3→ F4) or regression (F3-F4→ F0-F1→ F2) were estimated using a time-homogeneous Markov model. HR were adjusted for age, gender, duration of antiretroviral therapy and protease inhibitor-containing antiretroviral therapy in multivariable analysis.

Results: At baseline, median age was 41 years (IQR=35–48) and patients were predominately male (84%). Advanced liver fibrosis or cirrhosis (F3-F4) was observed in 40 (26%) patients and was more frequently observed in males (p=0.001), at older ages (p=0.001), longer durations of HIV (p=0.02) and HBV (p=0.001) infection, with AIDS-defining illness (p=0.01), and past exposure to previous visit

Markers levels and their changes as determinants of transitioning between F0-F1→ F2 and F3-F4 liver fibrosis stages

<table>
<thead>
<tr>
<th>Marker</th>
<th>Univariable</th>
<th>Multivariable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F0-F1→ F2→ F3-F4</td>
<td>F0-F1→ F2→ F3-F4</td>
</tr>
<tr>
<td></td>
<td>F0-F1→ F2→ F3-F4</td>
<td>F0-F1→ F2→ F3-F4</td>
</tr>
<tr>
<td>qHBCrAg (log10 U/mL)</td>
<td>At baseline 1.11 (0.99-1.25)</td>
<td>1.14 (0.98-1.33)</td>
</tr>
<tr>
<td></td>
<td>During follow-up 1.08 (0.95-1.23)</td>
<td>1.23 (1.03-1.49)</td>
</tr>
<tr>
<td></td>
<td>Change from previous visit 1.05 (0.58-1.88)</td>
<td>0.89 (0.53-1.51)</td>
</tr>
<tr>
<td>qAnti-HBc (log2 PEI U/mL)</td>
<td>At baseline 0.82 (0.69-0.97)</td>
<td>0.86 (0.73-1.00)</td>
</tr>
<tr>
<td></td>
<td>During follow-up 0.81 (0.68-0.98)</td>
<td>0.93 (0.76-1.15)</td>
</tr>
<tr>
<td></td>
<td>Change from previous visit 1.48 (0.65-3.38)</td>
<td>4.56 (1.91-10.91)</td>
</tr>
</tbody>
</table>

Stages of CoC in HIV/HCV co-infected individuals
zidovudine (p=0.03) or zalcitabine (p=0.03). During a median follow-up of 48 months (IQR=31–90), 38 transitions of progression (IR=7/100 person-years) and 34 transitions of regression (IR=6/100 person-years) were observed. Baseline levels of either marker were not associated with liver fibrosis progression or regression (Table). Nevertheless, higher changes from the previous visit of qAnti-HBc levels were associated with liver fibrosis regression.

Conclusions: qHBcAg and qAnti-HBc levels are not associated with liver fibrosis evolution in TDF-treated HIV-HBV co-infected patients. The link between strong changes in qAnti-HBc levels during follow-up and low liver fibrosis regression merits further study.

PE37/33
Antiretroviral therapy: a possible role in lipid changes after HCV eradication by DAAs
A Vergori1, E Grilli2, P Lorenzini2, G Passavanti2, V Bordoni3, S Cicalini2, R Bellagamba2, A Giannetti2, R Gagliardini2, I Abbate4, MR Capobianchi4, C Agrati3 and A Antoni2
1National Institute for Infectious Diseases, IRCCS L.Spallanzani, Rome, Italy 2National Institute for Infectious Diseases ‘L. Spallanzani’ IRCCS, HIV/AIDS Unit, Rome, Italy 3National Institute for Infectious Diseases ‘L. Spallanzani’ IRCCS, Cellular Immunology and Pharmacology Unit, Rome, Italy 4National Institute for Infectious Diseases ‘L. Spallanzani’ IRCCS, Laboratory of Virology, Rome, Italy

Purpose: HCV has complex interactions with lipid metabolism and a worse lipid profile has been observed after HCV eradication by DAAs. Among HIV+ patients, dyslipidemia is highly prevalent, partially due to cART. Aim of the analysis was to examine lipid changes in HIV/HCV+ patients at SVR24 and to investigate predictive factors of these changes according to cART exposure.

Methods: This analysis included HIV/HCV+ patients treated with DAAs since 2016 who achieved SVR24 and on stable cART. Patients with laboratory data on baseline (DAA start) and SVR24, without CART modification during the observation period were selected. Mean changes of total cholesterol (TC), LDL-c, HDL-c and triglycerides were calculated as the mean difference between BL-start and SVR24, without cART modification during the observation period were selected. Mean changes of total cholesterol (TC), LDL-c, HDL-c and triglycerides were calculated as the mean difference between BL-start and SVR24. Wilcoxon test was used to compare variations between BL-SVR24 and multivariable linear regression to investigate factors associated with the variations.

<table>
<thead>
<tr>
<th>Total Cholesterol</th>
<th>Beta</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obs</td>
<td>8.56</td>
<td>-0.91</td>
<td>18.04</td>
</tr>
</tbody>
</table>

HCV Genotype

<table>
<thead>
<tr>
<th>Type 1 (reference group)</th>
<th>6.51</th>
<th>-18.07</th>
<th>31.68</th>
<th>0.122</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2</td>
<td>24.12</td>
<td>11.56</td>
<td>36.70</td>
<td>2.17</td>
</tr>
<tr>
<td>Type 3</td>
<td>13.91</td>
<td>1.35</td>
<td>26.66</td>
<td>0.50</td>
</tr>
<tr>
<td>Type 4</td>
<td>2.69</td>
<td>-28.71</td>
<td>34.08</td>
<td>0.12</td>
</tr>
</tbody>
</table>

TDF exposure

- Not exposed before and after DAAs (reference group) | -2.35 | -14.38 | 9.69 | 0.701 |
- Not exposed before but exposed during DAAs | -141.16 | -221.32 | -60.99 | 0.001 |
- Exposed before DAAs | -0.55 | -21.23 | 20.13 | 0.958 |

DRV exposure

- Not exposed before and after DAAs (reference group) | 1.46 | -9.97 | 12.88 | 0.802 |
- Exposed before and after DAAs | 47.86 | 7.15 | 88.57 | 0.011 |
- Exposed before DAAs, not exposed during DAAs | 73.81 | -20.21 | 167.82 | 0.123 |

RV exposure

- Not exposed before and after DAAs (reference group) | 1.56 | -13.10 | 16.22 | 0.384 |
- Exposed before and after DAAs | 14.22 | -31.01 | 2.57 | 0.096 |
- Exposed before DAAs, not exposed during DAAs | 60.55 | 0.52 | 160.50 | 0.049 |

Table 1. Factors associated with TC change by means of multivariable linear regression. Significant results in bold.

Results: 382 patients were included, 27% on PI/b, 26.4% on NNRTIs and 24.3% on INSTI. Characteristics: 23% female, median (IQR) age 56 (53–59) years, 69.9% acquired HIV through IVDU, 97.4% Caucasian; TC 167±189 mg/dL, LDL-c 91±123 mg/dL at baseline. HCV genotypes GT1 59%, GT3 21% and GT4 15%; TC and LDL-c significantly increased at SVR24 ([Δ = +16.7 mg/dL (SD 38.1); +19.3 (SD 32.9)], respectively); HDL-c and triglycerides remained unchanged. In patients who started DRV/b during DAAs a significant increase of both TC and LDL-c was observed compared to patients who did not change DRV exposure (p=0.02 and p=0.001, respectively); being exposed to TDF-based backbone during DAAs was associated with a significant decrease of TC and LDL-c (p=0.001 and p=0.01, respectively) (Tables 1, 2).

Conclusion: An increase of TC and LDL-c was observed in HIV/HCV coinfected patients at SVR24. DRV/b seems to contribute to this increase; conversely, TDF appears to be associated with a better lipid profile. Longer follow up beyond SVR24 and a larger cohort are needed to better explore clinical implications of these findings.

PE37/34
Treatment of cirrhotic monoinfected and HCV/HIV coinfected patients with direct acting antivirals (DAAs)
F Videira Santos, A Cipriano, S Valdoleiros, AP Tavares, A Horta, J Mendez, O Vasconcelos, J Seabra, MA Abreu, MJ Goncalves, MJ Santos and R Sarmento-Castro
Centro Hospitalar Universitário do Porto, Serviço de Doenças Infecciosas, Porto, Portugal

Background: Several clinical trials have shown similar sustained virologic response (SVR) rates in HCV mono and HCV/HIV coinfected cirrhotic patients treated for chronic hepatitis C (HCV) with DAA.

Aim: To compare the baseline characteristics, the evolution of clinical parameters and the rate of sustained virologic response in mono and coinfected cirrhotic patients in a real-life setting.

Methods: Prospective study of cirrhotic patients treated for 12 to 24 weeks, between 2014 and 2018. We compared the baseline characteristics, the evolution of several parameters (AST, ALT, platelets, albumin, fibrosis) before and 12 week after the end of treatment and global SVR12 and response by genotype. Data was analysed with SPSS version 25.0.

Results: Of the 235 cirrhotic patients included, 146 (62.9%) were HCV/HIV coinfected. Mean age was 52 years in the monoinfected and 49 years in coinfected group. Men predominate in both groups (93.3% vs 88.4%); genotype 1 was the most frequent in both groups.
At baseline we found statistical differences between IDU use, values of aminotransferases and in the prevalence of genotypes 1 and 3. Mean value of HCV-ARN was higher in coinfected patients (p=0.065). The majority of patients were treated with SOF/LDV (66.8%).

The following tables show baseline biological, biochemical and fibrosis features (Table 1), the treatment on laboratory values and fibrosis and the achieved rates of cure (Table 2) in the two groups.

Conclusion: HIV coinfection no longer appears to be a negative response factor for HCV treatment. Treatment of mono or coinfected cirrhotic patients induced a significant reduction of fibrosis and of the values of aminotransferases. The rates of SVR were very high and there were no differences between the two groups.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>HCV (n=89)</th>
<th>HIV/HCV (n=146)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>52</td>
<td>49</td>
<td>-</td>
</tr>
<tr>
<td>Males (%)</td>
<td>93.3%</td>
<td>88.9%</td>
<td>-</td>
</tr>
<tr>
<td>Intravenous Drug Use (IDU)</td>
<td>90.9%</td>
<td>96.5%</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Naive patients (%)</td>
<td>80.9%</td>
<td>70.5%</td>
<td>0.052</td>
</tr>
<tr>
<td>Baseline AST (UI/L)</td>
<td>89.9</td>
<td>67.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Baseline ALT (UI/L)</td>
<td>113</td>
<td>73.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Baseline platelets (cells/uL)</td>
<td>148,426</td>
<td>131,404</td>
<td>-</td>
</tr>
<tr>
<td>ARN HCV UI/mL</td>
<td>5,113.889</td>
<td>3,757.028</td>
<td>0.065</td>
</tr>
<tr>
<td>Mean Fibrosis (kPa)</td>
<td>24.5</td>
<td>25.8</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th></th>
<th>HCV (n=89)</th>
<th>HIV/HCV (n=146)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global SVR12</td>
<td>89.9%</td>
<td>93.8%</td>
<td>0.270</td>
</tr>
<tr>
<td>G1</td>
<td>(42/45)</td>
<td>(104/109)</td>
<td>0.69</td>
</tr>
<tr>
<td>G3</td>
<td>(28/32)</td>
<td>(18/21)</td>
<td>1.0</td>
</tr>
<tr>
<td>G4</td>
<td>9(10)</td>
<td>93.3%</td>
<td>1.0</td>
</tr>
<tr>
<td>AST (pre and post TX)</td>
<td>87.4/29.3</td>
<td>68.6/27.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ALT (pre and post TX)</td>
<td>110/26.7</td>
<td>74.8/24.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Albumin</td>
<td>4.44/4.65</td>
<td>4.73/4.59</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>INR</td>
<td>1.11/1.08</td>
<td>1.09/1.11</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Fibrosis (kPa)</td>
<td>25.0/16.7</td>
<td>26.1/19.1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

PE37/35

Predictors of vaccine efficacy after hepatitis B vaccination in people with HIV infection

G Ibara, JR Bogner and U Seybold

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Purpose: Immunization against the hepatitis B virus (HBV) is indicated in people living with HIV/AIDS (PLHA). However, HBV vaccine efficacy (VE) is lower in PLHA, an optimal vaccination strategy has not been defined. The aim of this study is to identify predictors of HBV-VE in adult PLHA.

Method: All patients with HIV infection of our HIV outpatient clinic vaccinated between January 2011 and July 2018 were included in a case-control study. For the analysis of initially antiHBs-/antiHBc-negative patients compared to those with "low and non-response" (antiHBs < 100 IU/L) were no differences found.

Results: 202 initially seronegative PLHA received ≥3 HBV vaccine doses. The majority were Caucasian (76%) and male (74%), mean age before vaccination was 43.6 years (IQR: 19–75). The median CD4+ T cell count was 566/µL, 88% received antiretroviral therapy (ART), the HIV plasma viral load (VL) was <50 cp/mL in 80%. At least 4 weeks after the third dose of HBV vaccine, 75 (37%) had an antiHBs titer of ≥100 IU/L. In univariate analysis the following were significantly associated with vaccine response (all p<0.025): female gender, non-Caucasian ethnicity, origin not from Germany, VL <50 cp/mL, and non-smoking status. Age, ART, and CD4 cell count, both nadir and at time of vaccination, were not significantly associated with vaccine response. Administration of further doses induced vaccine response in the majority of PLHA with primary non-/low-response (figure).

Conclusions: Female gender, ethnicity/country of origin, suppressed VL and non-smoking status were associated with HBV vaccine response. Following initial vaccine non-/low-response further doses are effective for eventually reaching antiHBs titer of ≥100 IU/L in the majority of PLHA. For the definition of an optimal vaccination strategy the identification of additional predictors, especially the co-administration of other vaccines, is still ongoing.

Figure: Disposition of PLHA undergoing HBV vaccination

PE37/36

Long term response to mandatory anti-HBV vaccination: risks for disease acquisition and opportunities for re-vaccination within the ICONA cohort

R Rosso1, A Saracino2, P Lorenzini3, C Alcantarini4, A Latini5, G Lapadula6, S Nozza7, L Sarmati8, E Girardi9, A Castagna7, A d’Arminio Monforte10, M Puoti1 and ICONA Foundation Cohort

1ASST Grande Ospedale Metropolitano Niguarda,Division of Infectious Diseases, Milan, Italy 2Università di Bari, Italy, Bari, Italy 3INMI ‘L. Spallanzani’ IRCCS, Rome, Italy 4Università di Turin, Department of Medical Sciences, Turin, Italy 5San Gallicano Dermatological Institute IRCCS, Rome, Italy 6Università of Milano Bicocca, Monza, Italy 7San Raffaele Scientific Institute, IRCCS, Milan, Italy 8Università di Roma ‘Tor Vergata’, Rome, Italy 9INMI ‘L. Spallanzani’ IRCCS, Rome, Italy 10Università of Milan, Infectious Diseases, San Paolo Hospital, Milan, Italy

In Italy, anti-HBV vaccination is mandatory from 1992, administered at the twelfth birthday for the cohort born in 1979–1991, and at the first year of age for the cohort born after 1992. According to the Italian Health Agency, HBV
vaccination coverage is >90%. Efficacy after 20 years from administration is 60% in the general population.

Objectives: Assess long term vaccination response in horizontally infected HIV+ subjects who received anti-HBV vaccine in their childhood; evaluate proportion and risk factors for HBV acquisition despite vaccination.

Methods: Subjects born in Italy after 1978 with full serology for HBV available at ICONA enrollment (i.e. before antiretroviral treatment start) were included. Factors associated to maintaining protective anti-HBs levels (>10 IU/mL) were analyzed. Cumulative incidence of any new infection (HBsAg+, anti-HBs+/anti-HBC-, or anti-HBs-/anti-HBC+) and factors associated with HBV acquisition were calculated. Follow up was calculated as the interval between time of vaccination completion and date of serology performance.

Results: 1,628 individuals were included: 88.7% males with a median age of 29 years (IQR 25-32) mainly belonging to the 1979-1991 cohort (Table 1). 1,145 subjects (70.3%) showed a protective anti-HBs value: 393 (24.2%) resulted eligible for re-vaccination, 90 (5.5%) acquired HBV before ICONA enrollment. Cumulative incidence over the course of 29,343 years was 3 per 1,000 patients/years of follow up (95% CI 2.5-3.7). Belonging to the 1992 cohort was the only factor associated with vaccine non-response (OR 0.47, 95% CI 0.34-0.66, p < 0.001), while no HIV-related feature played a role. Being HCV+ active smoker and alcohol daily user were factors associated with HBV acquisition before enrollment (Table 2).

Conclusion: In a large cohort of HIV+ individuals, anti-HBV vaccination response was high and similar to what observed in the general population. However, HIV+ population resulted at high risk for HBV acquisition: non-responders should undergo re-vaccination as harm reduction strategy.

Demographic, clinical and behavioral features of study population.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Total HIV/CHB co-infection, N=80</th>
<th>HBsAg positive Chronic hepatitis B, N=7</th>
<th>p value</th>
<th>HBsAg negative Chronic HBV infection, N=25</th>
<th>p value</th>
<th>HBsAg negative Chronic hepatitis B, N=48</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>35.75±0.84</td>
<td>32.0±0.69</td>
<td>&lt;0.001</td>
<td>35.68±0.91</td>
<td>0.1</td>
<td>35.29±0.79</td>
</tr>
<tr>
<td>Males, N (%)</td>
<td>52 (65%)</td>
<td>5 (71.4%)</td>
<td>0.17</td>
<td>11 (44%)</td>
<td>&lt;0.05</td>
<td>36 (75%)</td>
</tr>
<tr>
<td>Females, N (%)</td>
<td>28 (35%)</td>
<td>2 (28.6%)</td>
<td>0.22</td>
<td>14 (56%)</td>
<td>&lt;0.05</td>
<td>12 (25%)</td>
</tr>
<tr>
<td>HIV/CHB duration, years</td>
<td>4.38±0.35</td>
<td>4.6±0.37</td>
<td>0.26</td>
<td>4.12±0.28</td>
<td>&lt;0.05</td>
<td>4.8±0.41</td>
</tr>
<tr>
<td>VL HIV, copies/mL</td>
<td>91183.84±35780.61</td>
<td>38291.43±4111.88</td>
<td>&lt;0.001</td>
<td>2933±3181.12</td>
<td>&lt;0.001</td>
<td>144861.08±45342.36</td>
</tr>
<tr>
<td>CD4+ count, cells/µL</td>
<td>426.69±25.55</td>
<td>617.71±26.65</td>
<td>&lt;0.001</td>
<td>491.04±20.09</td>
<td>&lt;0.001</td>
<td>365.46±25.65</td>
</tr>
</tbody>
</table>

Factors associated with being HBV infected (i.e. HBsAg+, anti-HBs+/anti-HBC-, or anti-HBs-/anti-HBC+) at enrollment by means of logistic regression.

PE37/37
The assessment of HBsAg serum concentration during chronic hepatitis B phases' identification among HIV/HBV coinfected patients before antiviral therapy prescription

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Purpose: qHBsAg investigation in each CHB phase of HIV/CHB coinfected patients before antiviral therapy (it is supposed to differ); correlations estimation between qHBsAg and other parameters.

Method: Cross-sectional study of 80 HIV/HBV coinfected patients, observed in Vinnytsia regional AIDS Centre, Ukraine, conducted before antivirals prescribing. All HIV/HBV coinfection cases were confirmed and documented. Serum HBsAg quantification was carried out using "Abbott HbsAg Architect Kit (GC36)". Additionally HBV DNA, HBeAg, ALT, CD4, HIV VL have been done. Data were evaluated with "IBM SPSS Statistics".

Results: All coinfected people were divided into 3 subgroups accordingly with "EASL-2017": 7 (8.75%) patients were referred to "HBeAg positive Chronic hepatitis B (CHB)", 25 (31.25%) – to "HBeAg negative Chronic HBV infection (CHBV)"; 48 (60%) – "HBeAg negative Chronic Hepatitis B (CHB)". "HBeAg positive Chronic HBV infection" excluded. See tables. Significant differences by gender, coinfection duration (p<0.05) were observed in "HBeAg negative CHB" phase. QHBsAg levels among "HBeAg positive CHB" patients have qHBsAg 6.8 time bigger than "HBeAg negative CHB" patients and 177, 3 times bigger than "HBeAg negative CHBV" (p<0.001). Significant correlations of qHBsAg with ALT, CD4, HIV VL, APRI index were detected in "HBeAg negative CHBV" group whereas in "HBeAg negative CHB" group only correlation of qHBsAg with ALT (r=0.512, p<0.01) was found.

Conclusion: Significant differences of qHBsAg levels obtained through CHB phases in coinfected patients. Positive qHBsAg correlations were observed.
with ALT and HBV DNA. Thus, qHBsAg will be helpful for estimation and demarcation of CHB phases in HIV/CHB coinfected people. Further qHBsAg levels estimation is needed after starting HIV/CHB antiviral treatment.

PE37/38
Predictors of liver fibrosis improvement after HCV eradication in HIV+ patients: data from an Italian cohort
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Purpose: The aim of the analysis was to evaluate liver stiffness and serum liver fibrosis scores in HIV/CHB patients at SVR24 after DAA and to investigate predictive factors of these changes according to cART exposure.

Method: This analysis included HIV/CHB patients consecutively treated with DAA from 2016 who achieved SVR24. Patients with laboratory data at baseline (DAA start) and SVR24, without cART modification during the observation period, were selected. Mean changes of liver stiffness (kPa), Fibrosis-4 (FIB-4) and AST to Platelet Ratio Index (APRI) were calculated as the mean difference between BL-SVR24. Wilcoxon test was used to compare values at BL-SVR24 and multivariable linear regression used to investigate associations with the variations.

Results: 533 patients were included, 23% female, median (IQR) age 56 (52-59) years, 70.1% IVDUs, 97% Caucasian. HCV GT1 57%, GT3 23% and GT4 16%. 27% were on PI/b, 26.4% on NNRTI and 24.3% on INSTI. At baseline, median (IQR) liver stiffness, FIB-4 and APRI were [10.2 (6.3-18.5), 2.12 (1.44-3.41) and 0.69 (0.42-1.28), respectively.

Liver stiffness, FIB4 and APRI significantly decreased at SVR24 (A-4.49 SD 7.11; -0.89 (2.28); −0.62 (2.28); p<0.001). A pre-DAs high fibrosis score (>9 kPa Metavir F4) significantly contributed to the decrease of FIB4, APRI and liver stiffness (p<0.001). Patients exposed to DRV/b who discontinued DRV at DAsA start had a significant increase in liver stiffness [B -1.64 kPa (p<0.007)] as compared to patients who did not change DRV/b (Table 1). An increase of liver stiffness was also observed in female vs male.

Conclusion: A reduction in liver stiffness and an improvement in fibrosis scores were observed in HIV/CHC coinfected patients at SVR24 post DAsA. A worse fibrosis evolution was found in female gender. The protective role of DRV/b versus fibrosis evolution is interesting although controversial, therefore further investigations are required.

Table 2. Clinical HBV characteristics of HIV/CHB coinfected patients accordingly to chronic hepatitis B phases

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Total HIV/CHB coinfection, N=80</th>
<th>HBeAg positive Chronic hepatitis B, N=7</th>
<th>p value</th>
<th>HBeAg negative Chronic hepatitis B, N=25</th>
<th>p value</th>
<th>HBeAg negative Chronic hepatitis B, N=48</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBeAg, positive/negative</td>
<td>N/A</td>
<td>positive</td>
<td>N/A</td>
<td>negative</td>
<td>N/A</td>
<td>negative</td>
</tr>
<tr>
<td>qHBsAg, IU/mL</td>
<td>17357.17±4340.67</td>
<td>98007.94±9841.17</td>
<td>&lt;0.001</td>
<td>552.89±46.58</td>
<td>&lt;0.001</td>
<td>14347.83±2280.82</td>
</tr>
<tr>
<td>HBV DNA, IU/mL</td>
<td>3169095.31±1331469.13</td>
<td>12307612.57±1236315.77</td>
<td>&lt;0.001</td>
<td>653.56±69.06</td>
<td>&lt;0.001</td>
<td>3486624.96±160372.96</td>
</tr>
<tr>
<td>ALT, IU/mL</td>
<td>49.15±6.58</td>
<td>55.91±1.11</td>
<td>&lt;0.001</td>
<td>21.39±1.05</td>
<td>&lt;0.001</td>
<td>62.43±7.98</td>
</tr>
<tr>
<td>Index APRI</td>
<td>0.76±0.08</td>
<td>0.57±0.02</td>
<td>&lt;0.001</td>
<td>0.28±0.01</td>
<td>&lt;0.001</td>
<td>1.03±0.09</td>
</tr>
<tr>
<td>Fibrosis F0-F1, N</td>
<td>25</td>
<td>-</td>
<td>N/A</td>
<td>25 (100%)</td>
<td>N/A</td>
<td>34 (70.8%)</td>
</tr>
<tr>
<td>Fibrosis F2-F3, N</td>
<td>40</td>
<td>6 (85.7%)</td>
<td>N/A</td>
<td>-</td>
<td>N/A</td>
<td>-</td>
</tr>
<tr>
<td>Fibrosis F4, N</td>
<td>15</td>
<td>1 (14.4%)</td>
<td>N/A</td>
<td>-</td>
<td>N/A</td>
<td>14 (29.2%)</td>
</tr>
</tbody>
</table>

Table 1. Factors associated with Liver Stiffness change by means of multivariable linear regression. Significant results in bold.

PE37/39
Long-term follow-up of people who use drugs (PWUD) following HCV infection therapy: drug use patterns among HIV co-infected versus mono-infected patients
A Thiam, P Sian, L Yamamoto, D Rhee, T Magel, K Wuerth and B Conway
VIDC, Vancouver, Canada

Purpose: People who use drugs (PWUD) constitute the majority of Hepatitis C infection cases in developed countries. Co-infected patients with HIV may engage in high-risk drug use behavior even after successful HCV therapy. We sought to evaluate drug use behavior and to determine the health outcomes of HCV mono-infected and HIV co-infected individuals after HCV therapy.

Method: We undertook a prospective study of HCV-infected PWUD who received oral HCV treatment from 03/14–12/17 at our centre and who were followed up from the end of treatment to 06/19. The primary outcome of this analysis was the occurrence of an adverse event (recurrent viremia, death or loss to follow up). Drug use was evaluated by using urine drug screens. Statistical analyses were conducted using Chi square test, Cox proportional hazard models and Kaplan Meier survival analysis with SPSS IBM V24.

Results: There were 215 patients, 32 co-infected with HIV, (74 % male (n=160), 39 % active/recent drug users (n=83), 20% poly-drug users; 21% (46/215) consumed amphetamines, 17% cocaine (37/215) and 15% fentanyl (32/215). During the 267 patient-years of follow-up we observed three confirmed reinfection cases (1.12/100 person-years), 5 lost to follow-up and 8 deaths, all among mono-infected individuals. These outcomes occurred despite the fact that active drug users were more common among HIV co-infected individuals (56.3%; 18/32 vs. 30.6%; 56/183); p=0.005, including more frequent polysubstance use (p=0.007). Only mono-infected drug users had a higher prevalence of adverse events (HR: 2.85; CI: 95 % (1.20–6.75) p=0.017).

Conclusion: No significant difference between mono-infected and HIV co-infected individuals. In our analysis, co-infected patients used significantly more illicit drugs, but within the context of engagement in our care program, this did not affect long-term health outcomes. HIV co-infection should not be a factor to limit access to HCV treatment.
PE37/40

Treatment outcome of HCV single vs multi tablet regimen in mono and HIV co-infected patients who use drugs (PWUD): a long-term follow-up analysis

A Thiam, L Yamamoto, P Sian, D Rhee, B Conway, T Magel and K Wuethr

VIDO, Vancouver, Canada

People who use drugs (PWUD) have been identified as a priority population to receive HCV therapy. Adverse treatment outcomes such as treatment failure or reinfections remains a concern for this population. We sought out to determine the impact of the number of DAA tablets on HCV treatment outcomes among HCV mono-infected and HCV/HIV co-infected PWUD.

Method: We conducted a prospective study of HCV-infected PWUD who received oral HCV treatment from 03/14–12/17 at our centre and who were followed up from the end of treatment to 06/19. The primary outcome of this analysis was the occurrence of an adverse event (recurrent viremia, death or loss to follow up).

Statistical analysis was conducted using Chi square test, Cox proportional hazard models and Kaplan Meier survival analysis with SPSS IBM V24.

Results: A total of 215 patients (mean age 55 years, 74% male, 20% cirrhotic, 32 co-infected with HIV, 39% active/recent drug users (n=83)). HCV cure (SVR12) was achieved in 92.9% [170/183] mono-infected versus 84.4% [27/32] co-infected patients; (p=0.156). During the 267 patient-years of follow-up, 99 subjects received multiple tablets (46%) versus 116 subjects who had single tablet (54%). The number of adverse events rates noted were 13.1% [13/99] versus 17.2% [20/116] respectively (p=0.405). We noted 34 % ([11/32]) HIV/HCV infected patients who took multiple pills, among them, four had adverse outcomes vs (9/88) 10.2% HCV only infected patients (p=0.036).

The number of tablets and HIV co-infection were not associated with adverse outcomes.

Conclusion: There were no significant differences with respect to treatment outcome between single and multiple DAA tablets. However HIV co-infected patients who took multiple tablets had significantly more adverse outcomes, single tablet regimens may be preferred among HIV co-infected individuals, given the fact they are often receiving multiple concomitant medications, including those taken as antiretroviral therapy.

Virology

PE38/1 Identification of an HIV-1 BC intersubtype recombinant form, which is circulating in Spain

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1Health Institute Carlos III, Biology and Variability of HIV-1 Unit, Madrid, Spain 2Tragorrinix Hospital, Vitoria, Spain 3Donostia Hospital, San Sebastian, Spain 4Basurto Hospital, Bilbao, Spain 5University Hospital Miguel Servet, Zaragoza, Spain

Introduction and Purpose: Human immunodeficiency virus (HIV-1) group M shows a great genetic diversity and rapid evolution, having led to the emergence of 9 subtypes, 94 circulating recombinant forms (CRFs) and numerous unique recombinant forms (URFs). 11 CRFs derived from subtypes B and C have been described in China, Brazil and Italy. Here we identify one additional CRF_BC, which circulates in Spain.

Method: Samples were collected from HIV-1-infected patients diagnosed in Spain from 2006 to 2018. Partial genome sequences (PR-RT) were analyzed and clustering was determined with phylogenetic trees constructed with FastTree and PhyML. Near full length genome (NFLG) sequences were obtained and recombination was determined by bootscanning. The time and clustering was determined with phylogenetic trees constructed with Bayesian coalescent method using BEAST v1.10.4, summarizing the set of breakpoints. The cluster was associated with heterosexual transmission and 7 copies/million CD4+ T cells. VRb and VRr were observed at W0. At W48, all but one patient in the control group have undetectable VL in plasma. In the cases group CD4 cells increased to 821/ mm³, VRb decreased to 71.8 and 10 copies/million CD4+ T cells for total (p=0.02) and integrated DNA (p=0.06), respectively, and VR to 54.7 and 14 copies/million CD4+ T cells for total (p=0.04) and integrated DNA (p=0.01), respectively. In the control group CD4 increase and VR decrease were less pronounced (p>0.05).

NFLG were obtained for 10 viruses collected in 3 cities, which showed identical mosaic structures, with a predominantly subtype C genome and 8 breakpoints delimiting 4 subtype B fragments, 2 in pol, 1 in vpr and 1 in nef. Phylogenetic analysis of NFLG revealed monophyletic clustering supported by a 100% bootstrap value. The subtype C fragments grouped with viruses from Brazil and the MRCA of the cluster was estimated around 2002 in the city of Vitoria (Basque Country) with a strongly supported ancestry in Brazil.

Conclusion: The analysis of NFLG from epidemiologically-linked viruses clustering in phylogenetic trees and with coincident mosaic structures allow to define a new HIV-1 CRF_BC.

PE38/2 Viral reservoir dynamics in very early primary HIV infection (PHI) patients receiving an intensified antiretroviral regimen (ART): a pilot clinical trial

J Ambrosioni1, S Sánchez-Palomino1, N Climent1, D Nicolás1, JA Ramirez-Corra1, C Liger1, C Rovira1, M Subirana1, T Gonzalez1, C Rodriguez de Miguel1, J Llach1, M Meulbroek2, M Plana1, JM Miro3 and Hospital Clinic PHI Investigators

1Hospital Clinic-IDIBAPS, Barcelona, Spain 2Projecte dels NOMS-Hispanosida, BCN Checkpoint, Barcelona, Spain

Purpose: ART during PHI has been associated with decreased transmission, better immunological recovery and limitation of viral reservoir (VR) seeding. The aim of the study was to characterize VR dynamics in blood and rectal tissue and immunological recovery after initiating an intensified–5-drug ART regimen during very early PHI.

Method: We compared two groups: cases (Fiebig stages I–II) and controls (Fiebig stages III–V). Patients started an intensified ART consisting on abacavir/lamivudine/dolutegravir regimen during 48 weeks plus darunavir–r and maraviroc the first 12 weeks. Rectoscopies were performed at W0 and W48. Immunological recovery and viral reservoir in blood (VBR) and rectal tissue (VRr) were compared between W0 and W48. Clinical Trials NCT02588820.

Results: Seventeen patients were included, 6 were Fiebig stage II (cases), and 11 were Fiebig stages III–V (controls).

Main characteristics of included patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>All patients</th>
<th>Cases (Fiebig I–II)</th>
<th>Controls (Fiebig III–V)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiebig stage</td>
<td>17 (100)</td>
<td>6 (35.3)**</td>
<td>11 (64.70)**</td>
<td>N/A</td>
</tr>
<tr>
<td>Gender and risk</td>
<td>Trasgender woman</td>
<td>1 (5.88)</td>
<td>0 (0.0)</td>
<td>1 (9.09)</td>
</tr>
<tr>
<td>factor</td>
<td>16 (94.11)</td>
<td>6 (100)</td>
<td>10 (90.9)</td>
<td>1</td>
</tr>
<tr>
<td>Age</td>
<td>36 (28.44)</td>
<td>35 (32.44)</td>
<td>36 (24.48)</td>
<td>0.76</td>
</tr>
<tr>
<td>Ethnicity/origin</td>
<td>European</td>
<td>6 (35.26)</td>
<td>0 (0.0)</td>
<td>3 (27.27)</td>
</tr>
<tr>
<td>Hispanic-american</td>
<td>8 (47.05)</td>
<td>2 (33.33)</td>
<td>5 (65.48)</td>
<td>0.77</td>
</tr>
<tr>
<td>Other</td>
<td>3 (17.64)</td>
<td>0 (0.0)</td>
<td>1 (9.09)</td>
<td>1 (9.09)</td>
</tr>
<tr>
<td>HIV subtype B</td>
<td>11 (64.7)</td>
<td>3 (50)</td>
<td>8 (72)</td>
<td>0.32</td>
</tr>
</tbody>
</table>

*All variables expressed as N (%) or median (IQR)

**All cases were Fiebig II

***Including 2 Fiebig III, 4 Fiebig IV and 5 Fiebig V

Tolerance of the intensified ART was good and no serious AE were reported. At W0 in cases group, median CD4 cells were 250/mm³, VL: 3,128,000 copies/mL, VBR was 772.9 total and 55.9 integrated DNA copies/million CD4+ T cells. VRb was 7126.4 total and 1054.9 integrated DNA copies/million CD4+ T cells. In the control group, a trend to lower VL (1,086,350 copies/mL) and to higher CD4 cells (447/mm3), VBR and VRr were observed at W0.At W48, all but one patient in the control group have undetectable VL in plasma. In the cases group CD4 cells increased to 821/ mm³, VRb decreased to 71.8 and 10 copies/million CD4+ T cells for total (p=0.02) and integrated DNA (p=0.06), respectively, and VR to 54.7 and 14 copies/million CD4+ T cells for total (p=0.04) and integrated DNA (p=0.01), respectively. In the control group CD4 increase and VR decrease were less pronounced (p>0.05).
Viral Reservoir dynamics in blood and rectal tissue at week 0 and week 48

<table>
<thead>
<tr>
<th>Viral Reservoir in Blood (b) and rectal tissue (r)</th>
<th>All patients (N=17)</th>
<th>Cases (N=6)</th>
<th>Controls (N=11)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRb* W0 (Total)</td>
<td>1475.2 (830.7; 7784.8)</td>
<td>772.9 (370.0; 2242.2)</td>
<td>2250.4 (1243.2; 8610.9)</td>
<td>0.47</td>
</tr>
<tr>
<td>VRb* W0 (Integrated)</td>
<td>94.6 (31.4; 612.2)</td>
<td>55.9 (27.5; 314.3)</td>
<td>244.3 (31.4; 920.3)</td>
<td>0.31</td>
</tr>
<tr>
<td>VRb* W48 (Total)</td>
<td>111.6 (85.3; 1026.1)</td>
<td>71.8 (31.8; 749.8)</td>
<td>242.4 (97.2; 1026.1)</td>
<td>0.96</td>
</tr>
<tr>
<td>VRb* W48 (Integrated)</td>
<td>30.7 (11.2; 197.6)</td>
<td>10.0 (6.5; 104.4)</td>
<td>36.4 (25.5; 251.0)</td>
<td>0.90</td>
</tr>
<tr>
<td>VRb** W0 (Total)</td>
<td>9912.0 (3885.9; 22675.7)</td>
<td>7126.4 (2435.3; 8393.9)</td>
<td>12620.2 (4193.3; 29580.0)</td>
<td>0.19</td>
</tr>
<tr>
<td>VRb** W0 (Integrated)</td>
<td>1351.7 (3872.3; 3406.1)</td>
<td>1054.9 (225.4; 1793.5)</td>
<td>13737.3 (697.7; 3843.4)</td>
<td>0.14</td>
</tr>
<tr>
<td>VRb** W48 (Total)</td>
<td>59.8 (51.2; 133.4)</td>
<td>54.7 (53.9; 178.0)</td>
<td>70.6 (48.7; 119.0)</td>
<td>0.99</td>
</tr>
<tr>
<td>VRb** W48 (Integrated)</td>
<td>14.9 (7.1; 21.0)</td>
<td>14.0 (3.6; 81.1)</td>
<td>17.1 (10.1; 20.6)</td>
<td>0.96</td>
</tr>
</tbody>
</table>

All variables expressed as median (IQR)

\*DNA copies/million CD4+ T cells

\**DNA copies/million CD4+ T cells

<table>
<thead>
<tr>
<th>CD4 T cell absolute count evolution in cases (Fiebig II) and controls (Fiebig III–V)</th>
</tr>
</thead>
</table>

**Conclusion:** Starting intensified ART in very early PHI (Fiebig II) is associated with better immunological reconstitution and higher reservoir reduction in blood and tissues.

**PE38/3**

Lamivudine-based two-drug regimens are not associated with an increased risk of detectable rectal HIV-RNA

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2Università Cattolica del Sacro Cuore, Istituto Clinica Malattie Infettive, ROMA CAPITALE, Italy
3Università Cattolica del Sacro Cuore, Istituto di Microbiologia, ROMA CAPITALE, Italy
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5Università Cattolica del Sacro Cuore, Dipartimento di Clinica Chirurgica, ROMA CAPITALE, Italy
6Università Cattolica del Sacro Cuore, Roma, Italia, Istituto Clinica Malattie Infettive, ROMA CAPITALE, Italy
7Università di Siena, Department of Medical Biotechnology, Siena, Italy

**Purpose:** We aimed to assess whether lamivudine-based dual therapies (DT) are associated with a larger rectal HIV-RNA reservoir compared with standard triple therapy (TT) strategies.

**Method:** During routine proctological examination, consecutively-enrolled, HIV-positive MSM underwent anal swab for detection of mucosal HIV-RNA load. A cross-sectional analysis was conducted to test the association between detectable rectal HIV-RNA and the use of lamivudine plus either a boosted protease inhibitor or dolutegravir compared with TT through multivariable logistic regression.

**Results:** From 60 patients were analysed. Eighteen patients (30.0%) were on a lamivudine-based DT and forty-two (70.0%) on TT (2 NRTIs plus an InSTI or a NNRTI). Median age was 50 years, with 12 years since HIV diagnosis and 9 of cumulative exposure to antiretrovirals. The study groups differed for current CD4 count, treatment line and months since last plasma HIV-RNA<50 copies/mL (see table 1). All patients except two (3.3%) had a plasma HIV-RNA< 50 copies/mL, but in fourteen cases (23.3%) residual viremia was detectable; nine patients (15.0%) had a detectable rectal HIV-RNA with a median of 84 copies/swab (IQR 50–120 copies/swab). No patients had concomitant sexually-transmitted diseases nor high-grade anal dysplasia. The agreement between plasma and rectal detectable HIV-RNA was minimal (Cohen's kappa: 0.26) even if statistically significant (p=0.034). After adjusting for current CD4 count and months since last HIV-RNA<50 copies/mL, the use of DT had no effect on the risk of detectable rectal HIV-RNA (aOR: 1.79, 95% CI 0.28–25.40; p=0.389), whereas a larger number of treatment lines was associated with the outcome (per each line more, aOR 1.22, 95% CI 1.03–1.44, p=0.022). A stepwise forward model also including variables associated with the outcome at univariate analysis (plasma HIV-RNA, CDC stage and ethnicity) confirmed no effect of DT on rectal HIV-RNA.

**Conclusion:** Lamivudine-based DT, compared with TT, was not associated with increased detection of rectal HIV-RNA.

Table 1. Characteristics of study population according to antiretroviral therapy (N=60)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Two-drug regimens (N=18)</th>
<th>Other regimens (N=42)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>53 (44–58)</td>
<td>47 (39–53)</td>
<td>0.076</td>
</tr>
<tr>
<td>Non Caucasian ethnicity</td>
<td>1 (5.6)</td>
<td>7 (16.7)</td>
<td>0.246</td>
</tr>
<tr>
<td>CDC stage C</td>
<td>6 (33.3)</td>
<td>11 (26.2)</td>
<td>0.574</td>
</tr>
<tr>
<td>Years since HIV diagnosis</td>
<td>14 (9–22)</td>
<td>10 (4–22)</td>
<td>0.093</td>
</tr>
<tr>
<td>CD4 count (cells/μL): 1 Nadir 2</td>
<td>1) 263 (25–313)</td>
<td>1) 286 (52–452)</td>
<td>2) 1.0 0.477</td>
</tr>
<tr>
<td>Current</td>
<td>2) 630 (514–769)</td>
<td>774 (525–956)</td>
<td>2) 0.048</td>
</tr>
<tr>
<td>Zenith HIV-RNA (log10 copies/mL)</td>
<td>4.69 (4.00–5.52)</td>
<td>4.77 (4.21–5.34)</td>
<td>0.974</td>
</tr>
<tr>
<td>Treatment line</td>
<td>7 (5–10)</td>
<td>5 (3–8)</td>
<td>0.047</td>
</tr>
<tr>
<td>Antiretroviral therapy: 1</td>
<td>1) 7 (39) 2) 11</td>
<td>1) 0 (0) 2) 0 (0) 3) NA</td>
<td></td>
</tr>
<tr>
<td>Lamivudine + boosted protease inhibitor 2</td>
<td>(61.1) 3) 0 (0) 4) 0 (0)</td>
<td>26 (61.9)</td>
<td>(38.1)</td>
</tr>
<tr>
<td>Lamivudine + dolutegravir 3</td>
<td>2NRTIs + integrase inhibitor 4</td>
<td>2NRTIs + NNRTI</td>
<td></td>
</tr>
<tr>
<td>Months since last HIV-RNA ≥50 copies/mL</td>
<td>120 (84–149)</td>
<td>41 (12–113)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

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HIV Medicine © 2019 British HIV Association, HIV Medicine, 20 (Suppl. 9), 3–316
Comparison of HIV-1 viral load and drug resistance mutations between cerebrospinal fluid and plasma in patients with HIV and Cryptococcal meningitis co-infection in Botswana

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Purpose: To compare HIV-1 viral load (VL) and drug resistance mutations (DRMs) between cerebrospinal fluid (CSF) and plasma amongst individuals co-infected with HIV-1C and Cryptococcal meningitis in Botswana.

Method: This was a retrospective cross-sectional study utilising paired CSF and plasma samples from 60 participants enrolled in Ambition phase II Study conducted between 2014 and 2016. HIV-1 protease and reverse transcriptase fragments were sequenced using Big dye sequencing chemistry. Sequences were analysed for DRMs using Stanford HIV drug resistance database. Viral escape was defined CSF VL 0.5 log10 higher than plasma VL.

Results: HIV-1 VL was measured in 38/60 (63%) CSF and plasma paired samples. A total of 24/38 participants (68.4%) had detectable VL in both CSF and plasma with medians of 4.7 (IQR:3.6–5.0) and 5.2 (IQR:4.8–5.7) log10 copies/mL, respectively (p<0.001). There was a statistically significant correlation between plasma and CSF VL (spearman r=0.49, p=0.003). The estimated prevalence of CSF viral escape was 2.9% [95% CI: 0.07–15.3%]. A total of 30/45 (67%) paired samples were successfully sequenced and an overall of 9 and 11 different DRM was observed in the plasma and CSF samples respectively. The most predominant DRM in the plasma samples was K101E with a frequency of 2 whilst mutations in the CSF occurred at equal frequencies of 1. DRM discordance was present in 3/30 (10%) paired samples, of these, I84T and 11 different DRM was observed in the plasma and CSF samples

Conclusion: Despite the elevated VL in these participants, CSF viral escape was not commonly observed. However, there were cases of DRM found in the CSF compartment only; this could be explained by compartmentalisation of HIV viral strains as a consequence of varying penetration effectiveness of some antiretroviral drugs through the blood-brain barrier or present in plasma at low frequency. Studies measuring the levels of antiretroviral drugs in both compartments are warranted.

PE38/5

HTLV-II antisense protein Aph-2 negatively regulates HIV-1 transcription

R Londhe1, A Patil1, V Arankalle2 and S Kulkarni1

1National AIDS Research Institute, Pune, India 2Interactive Research School For Health Affairs (IRSHA), Bharati Vidyapeeth University (Deemed to be), Pune, India

Purpose: Slower HIV-1 disease progression among HTLV-II/HIV-1 co-infected patients is well known. HTLV-II Aph-2 negatively regulates HTLV-II transcription. Given the common cellular factors orchestrating transcription of HTLV-II and HIV-1, we explored if HTLV-II Aph-2 coiled regulate HIV-1 transcription as well.

Method: HIV-1 molecular clone pNL4.3 and HA- tagged HTLV-II Aph-2 were co-transfected in 293T cells. Virus release in the culture supernatants and cell lysates was confirmed by HIV-1 p24 western blot. Expression of HA-Aph-2 was detected using anti-HA antibody. Simultaneously, effect of Aph-2 on Tat mediated HIV-1 transcription was analyzed by co-transfecting, HA-Tat, HA-Aph-2 WT/mutants and HIV-1 LTR Luc plasmid in to 293T cells. The relative expression was measured using luciferase reporter assay.

Results: HIV-1 release was severely impaired with increasing concentrations of HA-Aph-2 [Fig. 1A]. Moreover, concentrations of HA-Aph-2 inhibiting HIV-1 release also impaired HIV-1 gag mRNA expression leading to reduced cellular gag protein [Fig. 1B]. Further, Aph-2 over expression hampered ability of HIV-1 tat to transactivate expression of luciferase from HIV-1 promoter. Introduction of mutations in the IXXL motif at the N-terminal domain of Aph2 reverted the inhibitory effect imposed by Aph2 [Fig. 1C].

Conclusion: HTLV-II Aph-2 protein may negatively regulate early events of HIV-1 life cycle, especially, transcription fromLTR and the critical determinants required for this negative effect plausibly lie in its N-terminal domain. Deepr insights in this area necessary to may help in combating HIV-1 infection.
PE38/7
Determinants of neurocognitive impairments in a Romanian cohort of young adults with chronic HIV infection
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1Stefan S Nicolau Institute of Virology, Bucharest, Romania 2Carol Davila University of Medicine and Pharmacy, Bucharest, Romania

Purpose: The Romanian cohort of young adults, parenterally infected with HIV subtype F1 in early childhood, offers a unique opportunity to explore the effect of chronic HIV-infection on the developing brain. The association between neurocognitive impairment (NCI), host and viral risk factors was evaluated in this cohort.

Method: 250 HIV+ subjects (median age: 24 years, females: 52%, median duration of HIV infection: 23 years; median length of cART: 12 years) underwent neurocognitive testing using a comprehensive neuropsychological test battery. Pol and env gene sequencing was performed on plasma and available paired CSF samples with a viral load >1,000 copies HIV RNA/mL. Inflammatory biomarkers (IL-1β, IL-6, IL-8, TNF-α, CXCL10/IP-10, MCF-1, IL-8) were measured using multiplex assays (Meso Scale Diagnostics, Gaithersburg, MD).

Results: Viral suppression was achieved in 63% of the cases, severe immunosuppression was present in only 16% of the cases. 36% of the patients had mild cognitive impairment, without any association with age, CD4 cell count (actual or nadir), plasma and CSF viral load, AIDS-diagnosis, duration of HIV infection and cART exposure. A trend toward a higher impairment rate was identified in the group of subjects carrying resistant viruses, but did not reach statistical significance. No signs of virologic compartmentalization were observed based on CSF vs plasma viral load and on the profile of pol sequences. Multivariable logistic regression analyses showed that in plasma, higher levels of IL6 (OR=2.85) and TNF-α (OR=1.9), were associated with NCI (p < 0.05), after controlling for HIV RNA level. Low plasma CXCL10 levels were positively correlated with CSF CXCL10 levels and with the degree of NCI (df=1,44, p=0.01).

Conclusion: Chronic, sustained immune activation in the CNS might explain the relatively high level of neurocognitive impairment present in young adults with long term HIV infection, despite successful antiretroviral therapy.

PE38/8
Reconstruction of phylogeography for Indian HIV-1 sub-subtype A1
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Purpose: Subtype A is second only to the infections caused by HIV-1 subtype C around the globe. Though Indian HIV-1 subtype A was shown to be monophyletic, there is no study addressing its ancestral roots with respect to its phylogeography. In this regard this study aims to estimate the spatio-temporal spread of HIV-1 sub-subtype A1 in India.

Method: Data-set included 28 Indian HIV-1 A1 and 186 HIV-1 A1 partial reverse transcriptase sequences from other countries retrieved from HIV sequence database. Root to tip analysis for molecular clock was performed by TempEst. Bayesian Evolutionary Analysis Sampling Trees (BEAST) analysis was performed to estimate the time to most recent common ancestor (tMRCA) for Indian HIV-1 A1. Maximum clade credibility (MCC) tree was generated using Tree Annotator and tree was visualized using FigTree v1.4.2. Phylogeographic reconstruction was performed with asymmetrical discrete trait using Bayesian stochastic search variable selection (BSSVS). Phylogeographic reconstruction was visualized with Spread D3 Bayes factor (BF) test used as a measure of statistical support for locations.

Results: Root to tip analysis of Indian HIV-1 A1 sequences demonstrated positive correlation between genetic distance and divergence time (correlation coefficient=0.41; slope rate=1.065 x 10^-7). BEAST analysis estimated the mean tMRCA for Indian HIV-1 A1 to be 1967.71 (95% HPD: 1956.47–1976.35). Time scaled MCC tree shows the monophyletic nature of Indian HIV-1 A1 and their possible evolution from Kenyan HIV-1 A1 sequences around 1967. Further, phylogeographic reconstruction of HIV-1 A1 migration to India inferred using BEAST locations annotated MCC tree indicated the migration of HIV-1 A1 to India from Kenya between 1967–1970, with strong statistical support of BF >10 (12.34).

Conclusion: Phylogeographic reconstruction indicates that HIV-1 A1 was introduced to India from Kenya between 1967 to 1970.

PE38/9
Broad and potent neutralizing antibody responses in HIV-1 infected Angolan patients: implications for vaccine design and efficacy
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Characterizing the neutralizing antibody response and virus evolution in Central and West African countries with old HIV epidemics driven by highly divergent viruses may provide useful insights for vaccine design. Herein, we make the first detailed characterization of the neutralizing antibody responses and identify its determinants in Angolan patients infected with HIV-1. A total of 204 plasma samples from Angolan patients were analysed against a reference cross-clade Env-pseudotyped tier 2 indicator virus panel (n=12). Binding antibody activity to polypeptides comprising the C2, V3 and C3 envelope regions from different HIV-1 clades was evaluated in ELISA assays. The envelope C2V3C3 region was sequenced in order to assess subtype, co-receptor use and virus evolution.

Neutralizing antibody responses were positively associated with subtype C infection and patients’ age, and negatively associated with CD4 counts. Patients infected with isolates more closely related to the viruses in the indicator panel had stronger neutralizing responses neutralization. However, few patients developed broad neutralizing antibody (bnAb) responses despite the high genetic distance to the pseudoviruses in the indicator panel. There was a strong and positive correlation between neutralizing responses and titer of antibodies binding to C2V3C3-pseudopolypeptides of all clades. Viruses from patients with bnAb responses had far less variability in C2V3C3 region as measured by entropy analysis and number of positively selected sites, relative to patients without bnAb responses. Important V3 bnAb recognition sites and sites associated with resistance to neutralization in the C2V3C3 region were under positive selection in patients with elite neutralizing capacity.

In conclusion, binding antibody titer against the envelope C2V3C3 region was a good indicator of neutralization responses in HIV-1 infected individuals from Angola. Taking into consideration the neutralizing responses of certain HIV-1 infected Angolan patients the design of a pan-HIV vaccine might not be an utopic concept.
Performance of 'Xpert® HIV-1 Qual assay' for diagnosis of HIV-1 infection using Dried Blood Spot specimens

S Gadhe1, N Mourya2, N Goel3 and S Kurle4
1ICMR-National AIDS Research Institute, HIV Drug Resistance Laboratory, Pune, India 2ICMR-National AIDS Research Institute, Pune, India 3National AIDS Control Organisation, New Delhi, India

Purpose: Point Of Care (POC) assays are important for timely diagnosis and effective HIV management. In this study 'Xpert® HIV-1 Qual assay' was evaluated for accuracy, specimen stability and limit of detection (LOD) using Dried Blood Spot (DBS) specimens from HIV exposed infants and adults.

Method: The study was conducted between May 2018–March 2019 at ICMR-National AIDS Research Institute, Pune, India on 100 DBS specimens (HIV-1 infected and HIV-1 uninfected, 50 each) collected from HIV infected adults and HIV exposed infants less than 18 month of age. Diagnostic accuracy of the assay was assessed using Abbott Real Time HIV-1 Qualitative test prior to test on Xpert® HIV-1 Qual platform. The specimen stability was assessed by testing each specimen at three time points; 2 weeks, 6 weeks and 12 weeks when stored at 25–30°C. The LOD was assessed using frozen plasma specimens (N=3) collected from HIV infected individual which were serially diluted using negative plasma and mixed with negative whole blood. Viral load of diluted samples was assessed using Xpert® HIV-1 Viral Load test and prepared DBS samples was tested on Xpert® HIV-1 Qual platform.

Results: The observed accuracy of the results of Xpert® HIV-1 Qual assay and Abbott Real Time assay was 100% for HIV uninfected specimens and 98% for HIV infected DBS specimens. DBS stored at 25–30°C could be used for testing up to 12 weeks with 100% concordance confirming the stability of DBS at ambient temperature and its utility for diagnosis using Xpert® HIV-1 Qual assay. The lowest viral load detected using this platform was observed to be 983cp/ml (range: 983–3330 copies/ml).

Conclusion: The “Xpert® HIV-1 Qual assay” can be utilized as POC for diagnosing HIV infection using DBS specimens. This can be useful for early initiation of treatment leading to achieve the second 90 of 90-90-90 goal.
the time of contracting the infection. This aims to investigate the average time between testing positive for screening and time of initial infection based on rate of decay in CD4 count among seropositive MSM and to analyse its social implications.

Method: Total of 2491 MSMs who tested HIV positive were enrolled. The mean CD4 values were determined by age-groups. The mean interval between between infection and seropositivity was estimated based on the average annual CD4 decay rate. Data analysis was performed using SPSS.

Results: Upon diagnosis, the mean CD4 values were 372 cells/μL for those among those aged 20 and below, which was found to be significantly higher than 323 cells/μL for 21–30 group (p=0.007), 284 cells/μL for 31–40 group (p=0.00008), 279 cells/μL for 41–50 group (p=0.015). Thus, the significant difference among age groups and WHO CD4 staging (p=0.00).

Average of age of diagnosis, time interval of infection, and estimated age at diagnosis

<table>
<thead>
<tr>
<th>Sample</th>
<th>Age at Diagnosis</th>
<th>Time Interval of Infection</th>
<th>Estimated Age at Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 and below</td>
<td>204</td>
<td>19</td>
<td>5.8</td>
</tr>
<tr>
<td>21–30</td>
<td>1988</td>
<td>26</td>
<td>6.5</td>
</tr>
<tr>
<td>31–40</td>
<td>717</td>
<td>34</td>
<td>6.8</td>
</tr>
<tr>
<td>41–50</td>
<td>66</td>
<td>44</td>
<td>6.9</td>
</tr>
<tr>
<td>Above 50</td>
<td>5</td>
<td>56</td>
<td>5.8</td>
</tr>
</tbody>
</table>

The average time between infection and testing is 5.81 years among ages 20 and below and 6.49 among 21–30 age group, estimating an average infection age of 13.2 and 19.5, respectively, implying that 73.5% of the sample likely had been infected 20 years and below.

Conclusion: Being diagnosed with a CD4 count of 200–499 cells/μL is common among all age group. It is consistent with the estimated count calculated from the average time of infection among all age groups. Three-quarters of the patients were likely to have been infected below the age of 20. It is consistent with the 8.1 person-years incidence density among 21 years and below in the 2012–2016 data from the same facility. This emphasises the need to empower the youth’s and healthcare providers’ positivity towards sexual health through legislation, education, and awareness.

PE39/2

Evaluating factors increasing the vulnerability of adolescent girls and young women to HIV/AIDS infection in selected communities, Akwa Ibom State

J Iyang
National AIDS Control Program, Uyo, Nigeria

Purpose: Adolescent girls and young women are particularly vulnerable to HIV/AIDS infection because of the risky sexual behaviour, the lack of access to accurate and personalized HIV information and prevention, and for a host of other social and economic reasons. Hence, this study identiﬁes factors increasing vulnerability of adolescent girls and young women to HIV/AIDS infection.

Methods: A qualitative household survey was conducted through a random sampling with a computer-assisted personal interviewing to select adolescent girls and young women aged 13–18 and 19–24 years, respectively, an HIV testing service in 3 rural communities in Akwa Ibom State, Nigeria. 350 households in the communities participated. Data were collected with a questionnaire that asked information about the sources of HIV/AIDS, and sexual behaviour, self-efficacy to refuse sex, and peer inﬂuence.

Results: The evaluating factors revealed that adolescent girls (especially half of the poorest girls) in Etuk, Oron and Ik community of Akwa Ibom state, report that their first sexual encounter was coerced. Some of them are student, slum and street youth. This target group of adolescent and young women ages 15–24 is highly vulnerable to HIV/AIDS infections and related sexual diseases as they have limited access to services such as HIV testing, prevention and treatment.

Conclusions: Adolescent girls and young women between the ages 15–24 are prone to the vulnerability of HIV/AIDS infection judged by the following life situations: out of school, especially very young adolescent (ages 10–14); those newly migrated to cities and in domestic service, girls acting as heads of households and pressured to earn income. Considerable data gap exist in our knowledge among adolescent and young women, particularly because of the challenges in getting parent approval for their involvement in surveys. In parts, because of these gaps adolescent are often missing from National HIV Strategic plans.

PE39/3

Men’s perspectives on HIV self-testing in sub-Saharan Africa: a systematic review and meta-synthesis

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Purpose: To synthesize evidence on men’s perspectives on HIV Self-Testing in sub-Saharan Africa.

Method: The databases we searched include PubMed/MEDLINE; American Doctoral Dissertations via EBSCO host; Union Catalogue of Theses and Dissertations; SA ePublications via SABINET Online; World Cat Dissertations; Theses via OCLC; ERIC; CINAH; PsychInfo; Embase, Sociological Abstract, Scopus and Google Scholar. We search World Health Organization and The Joint United Nations Programme on HIV and AIDS. We extracted only qualitative information from the included studies, despite the research method used (qualitative or mixed methods). We used the Preferred Reporting Items for Systematic Reviews and Meta-Analysis. The Mixed Method Appraisal Tool version 2018 was used to determine the methodological quality of the included studies. NVivo version 11 was used for thematic analysis.

Results: A total of 2053 articles were identiﬁed by our initial search criteria. Only 12 articles were included to data extraction and quality assessment stage. The following key themes emerged: knowledge of HIVST; acceptability of HIVST; need for HIVST counselling; confiﬁdentiality of HIVST; convenience of HIVST; and accuracy of HIVST. The study shows that while HIVST provides men with an alternative confidential and convenient testing model, the potential for psychological and physical harm remain a challenge.

Conclusion: The introduction of HIVST strategy has a potential of improving men’s uptake to HIV testing services, thereby contributing towards addressing the first cascade of the 90–90–90 strategy. While HIVST is aimed at addressing many men’s barriers to attending clinic settings, such as, conﬁdentiality and convenience, it hardly addresses the HIVST counselling and accuracy concerns. Empirical evidence on the risk-benefit analysis associated with HIVST testing strategy is still required, especially among men in Africa.

PE39/4

Molecular-biological methods of diagnostics in the investigation of the case of transmission of HIV-infection

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Purpose: Analysis of phylogenetic relationships of HIV isolates.

Method: The HIV infected blood plasma samples of 8 patients (5 women and 3 men) from Velikiy Novgorod were used. The studied material is presented in two groups: clinical material from the intended source of infection (4 people, including 3 women and 2 men), comparison samples. In the study we used genotyping by direct sequencing of the site of the polymerase gene (pol) length of 1285 nt., The gene encoding the protease (PR) length of 465 nt. and a portion of the reverse transcriptase (RT) gene length of 820 nt.

Conclusion: The study allows identifying HIV in clinical specimens, as well as in establishing phylogenetic relationships between virus isolates. During the epidemiological investigation of a case of HIV-1 group infection, it was determined that infection of women in the target group occurred from a single source. The results of phylogenetic analysis indicate the presence of an epidemiological link within the survey group. The unconditional commonality of HIV-1 isolates of patients of the target group and patients of the reg. № 14 f, previously not involved in the target group in this case. Nucleotide identity within the group was 97.25% Conclusion. Molecular phylogenetic analysis using routine methods for determining the resistance of HIV to antiretroviral drugs allows to investigate cases of HIV infection, identifying the source of infection.
PE39/5

Implementation of demedicalized and decentralized HIV testing project in Brussels: action test, project for vulnerable populations at high HIV risk in Brussels, including Subsaharan African Migrants (SAM)

T Kouadio¹, T Martin¹, C Pezeril², S Detandt³ and M Louhenapessy¹

¹Plate-Forme Prevention Sida Asbl, Brussels, Belgium ²Saint Louis University, Sexuality and AIDS Observatory, Brussels, Belgium

Purpose: Facilitate access to rapid HIV testing for vulnerable populations.

Method: *Data collected from 01/2017 to 12/2018 with an anonymous electronic questionnaire during counseling.

*2 strategies used for screening: (1) inside community association office; (2) outreach bus prevention which proposes additional services like HTA and diabetes screening.

*TROD INSTI VIH1/2 was used and tests were offered by trained lay-providers.

*Descriptive analysis performed with Epi-info version 7.2.2.2

Results: 835 people received HIV testing and 12% of them were MSM. Overall, 73% are male, 50% are SAM and the median age is 32 years. 24% don't have insurance coverage, among which 27% of them are undocumented and 58% refused to give their administrative status. 9 including 5 men and 4 women, had a reactive screening result. Only two men received a confirmatory laboratory testing and three women were already known to be HIV positive. 62% had never been tested for HIV and 51% have done the test because they found a near opportunity for testing. Among reasons evoked for testing, there is a significant difference between places of testing with more risks taken (24%) when it was at the office (24%) and more opportunity based in the bus (88%) 87% had unprotected sex with casual partner in the last years. PEP and PrEP knowledge was low (15% and 11.6%).

Conclusion: Findings from this project indicate that offering rapid HIV testing in community settings, in particular through outreach activities, is an effective approach to increase access to testing and to reach previously untested vulnerable populations. To increase the acceptance of HIV testing, it is important to offer HIV testing along screening for other chronic diseases such as HTA, diabetes, etc.

A combination of testing on site and outreach activities should be promoted as both strategies reach different risk profiles of people.

Sociodemographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>1. Association</th>
<th>2. Bus</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>median age (min–max)</td>
<td>32 (17–71)</td>
<td>32 (16–70)</td>
<td>32 (16–71)</td>
</tr>
<tr>
<td>no health insurance</td>
<td>433 29%</td>
<td>259 17%</td>
<td>692 24%</td>
</tr>
<tr>
<td>origin SAM</td>
<td>465 51%</td>
<td>361 48%</td>
<td>826 50%</td>
</tr>
<tr>
<td>gender (male)</td>
<td>467 76%</td>
<td>364 70%</td>
<td>831 73%</td>
</tr>
</tbody>
</table>

Risk profile and awareness

<table>
<thead>
<tr>
<th></th>
<th>1. Association</th>
<th>2. Bus</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>never testing for HIV before</td>
<td>453 63%</td>
<td>288 61%</td>
<td>741 62%</td>
</tr>
<tr>
<td>had unprotected sex with casual partner</td>
<td>207 86%</td>
<td>96 89%</td>
<td>303 87%</td>
</tr>
<tr>
<td>MSM reason for testing</td>
<td>349 11%</td>
<td>249 13%</td>
<td>598 12%</td>
</tr>
<tr>
<td>risk taken</td>
<td>465 10%</td>
<td>247 19%</td>
<td>712</td>
</tr>
<tr>
<td>opportunity</td>
<td>35%</td>
<td>22%</td>
<td>30%</td>
</tr>
<tr>
<td>other reason</td>
<td>41%</td>
<td>68%</td>
<td>51%</td>
</tr>
<tr>
<td>know what PrEP is</td>
<td>254 11%</td>
<td>91 14%</td>
<td>345 12%</td>
</tr>
</tbody>
</table>

PE39/6

HIV prevalence, risk–taking behavior and self-testing potential among men who have sex with men and transgender people

E Pisemskiy

NGO Phoenix PLUS, Orel, Russian Federation

Purpose: Acceptability of oral self-testing among MSM and TG in five Russian cities.

Method: Quantitative and qualitative data collection was conducted from December 2016 to February 2018 as part of a campaign for free of charge HIV self-testing among MSM and TG in five Russian cities. As part of the project, all the MSM and TG who wanted had a chance to receive OraQuick express testing kits for HIV on condition of anonymity. The study presents an analysis of quantitative data collected as part of the project on HIV self-testing among MSM and TG in Russia.

Results: In the three years of the project, almost 24,000 people in five cities received self-testing kits, which indicates a high demand for alternative HIV testing methods in these groups. Out of 3,003 people who informed us of the self-test results, 14% received a reactive result, which corresponds to the percentages given in similar studies in the Russian conditions.

Conclusion: Self-testing for HIV has already proven itself as an accurate and reliable tool with high acceptability among MSM and TG, and its potential to encourage first-time and repeated testing even in highly stigmatized settings is underlined by multiple research. In our research, we asked MSM and TG about their previous testing. As it turned out, self-testing was the first ever HIV test for 13% of the research participants and one out of five had not tested for over a year before the project’s self-test. These facts, combined with general demand for self-testing we saw in the project, show high efficiency of the self-testing approach that can help to expand coverage and increase the frequency of HIV testing among MSM/TG in Russia.

PE39/7

Political commitment matters in the elimination of the threat of HIV and HCV and TB among people who use drugs

G Fulane

UNITE – The Global Parliamentarians Network to End HIV/AIDS, Viral Hepatitis and Other Infectious Diseases, Lisbon, Portugal

Purpose: Eleven years to reach the 2030 SDGs, infectious diseases are still serious health threat, with 71.1 million people living with chronic hepatitis C (1) and 36.9 million people living with HIV/AIDS (2). Higher mortalities and transmission rates are concentrated among key subpopulations such as drug users who, in many geographical settings, lack basic rights to health care (3–6). Despite the efforts, many people around the world continue to use drugs. Harm reduction strategies prove to be cost effective at reducing negative consequences associated with the use of drugs in people unable or unwilling to stop (7). Notwithstanding, harm reduction exists in only half of total countries in the world, whereas prevalence of HCV and HIV are still high among drug users if compared with general populations (3).

Method: Considering the role of parliamentarians to eliminate infectious diseases within this population, UNITE has taken action and organized the Joint Action Policy Day 2019 entitled Road to 2030: Concrete Actions to Scale up Human Rights-based approaches to Harm Reduction, attended by 184 participants coming from 30 countries, across 5 continents: 15 parliamentarians, 37 community organizations, 12 donors, 22 government and law firms, and 8 scientists. Case-examples from Portugal, China, West Africa, France, Brazil and the US were discussed.

Results: Participants agreed that: good policies that are effectively implemented are needed to assure human rights-grounded services for people using drugs. Proved to be cost-effective, accessible harm reduction services that are human-centered, without causing financial hardship, have the potential to reduce the burden of Hepatitis C, HIV/AIDS and TB among people using drugs.

Conclusion: Recommendations include the following: drug use decriminalization, human rights-based approaches, community grounded outreach and peer support, prison health as public health, quality evidence and MSHA, Universal Health Coverage, sustainable financing, new partnerships, and political will and leadership.
**PE39/8**

**Challenges in health and social care for migrant HIV patients in the Czech Republic**

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**Purpose:** In the Czech Republic, about 30% of all HIV-positive persons are citizens of other EU and non-EU countries. However, needs of this group are not reflected in any governmental strategy or program. Our purpose was to identify challenges in health and social care for HIV-positive migrants and EU mobile citizens in the Czech Republic from the providers’ perspective.

**Method:** A web-based questionnaire has been distributed among health care (hospitals, relevant outpatient facilities) and social service providers (NGOs assisting migrants, HIV positive persons or working with other vulnerable groups with higher HIV risk – drug users, sex workers). The survey included questions regarding barriers on different levels which providers of health or social services face while working with patients with HIV or other STIs who are not Czech citizens.

**Results:** At present, we received 48 responses (60.4% healthcare workers, 27.1% social workers). Based on our data, 51.2% of respondents have clients with HIV/STIs who are nationals of other countries and more than half of respondents (53.8%) find that services currently available for these clients are insufficient. The main barriers are: lack of information, discrimination in access to treatment, poor availability of free anonymous testing, language barrier, low adherence to treatment. As a key reason, 65.4% of respondents see the lack of coherence of the health and social care, 61.5% – the lack of attention from the state (no prevention and treatment programs) and 53.8% mentions the lack of finances. From other perspective, 53.8% of respondents claim that migrants underutilize existing (especially social) services.

**Conclusion:** According to this, first in our country, survey among providers of health and social services, there is a number of legal, institutional and individual barriers in access of migrants and EU mobile citizens living in the Czech Republic to HIV testing and treatment.

**PE39/9**

**Integration of hepatitis C cure in housing facility Soleil Levant: health cost implications**

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**Purpose:** The Soleil Levant is a psycho-social-medical housing foundation providing healthcare services to multimorbid and vulnerable adults with infectious diseases (HIV, viral hepatitis) as well as other chronic conditions associated with psychosocial disorders and/or addiction problems. http://www.levant.ch/soleil-levant.

Nurses and social workers are core care givers with weekly psychiatric, medical and physiotherapy interventions. A tight collaboration with the local pharmacy team allows treatment updates as needed. From 2017 treatment classes and cost monitoring are part of the annual quality care assessment.

**Methods:** Analysis of treatment classes and their cost due to medical management of residents from Soleil Levant between 2017 and 2018 based on annual pharmacists’ reports.

**Results:** Overall, main health problems included HIV infection or AIDS defining criteria, chronic hepatitis C, social precariousness and chronic illness (cirrhosis, diabetes, renal failure, cancer, physical handicap, etc.) and recovery from addiction and/or psychiatric comorbidity. In summary 15 residents were followed during the 2 years period with an average age of 53 years. The main five treatment classes according to cost impact were DAAs/HIV antiretroviral (55%), opioid pain relievers (6%), opioid substitution (3%), antiepileptic drugs (~2%) and neuroleptics (~2%).

**Conclusion:** Chronic hepatitis C treatment with SVR-6 and HIV co-infection therapy represented half of the total pharmacy expenses for all residents during 2017–2018 and concerned one third of patients. DAA treatment was easily integrated in Soleil Levant housing facility and achieved hepatitis C cure in multimorbid patients.

**PE39/10**

**The role of sexual partners of people who inject drugs in better uptake of retention in HIV services**

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**Background:** PWIDs remain most vulnerable population in Georgia. Heterosexual transmission rate of HIV is increasing continuously during recent years and became the dominant 63% among new HIV registered cases, while IDU associated transmission decreased from 43% (2012) till 15% in 2017. 14 Harm reduction sites have been providing comprehensive services to 30,000 PWIDs annually within the GFATM-program since 2006. From 2016 the program covers sex partners of PWIDs with HIV prevention services to support safer behavior. Majority of sex partners of PWIDs (90–92%) are women.

**Methods:** The qualitative research methods were applied to identify attitudes, motivations and needs, barriers and facilitators and services needed for sex partners. The convenience sampling method was used to recruit PWIDs, sex partners and harm reduction service providers. The study was provided in 5 cities of Georgia.

**Results:** The following barriers were revealed for sex partners of PWIDs: fear of HIV testing and associated stigma; Low awareness of HIV transmission risks and importance of testing; PWIDs don’t allow their sex partners to be tested on HIV; Low awareness about anonymous free HIV testing services; Feeling of shame to do HIV-testing, especially in small cities; Lack of women oriented services; High risk from harm reduction sites; Negative approach towards PWIDs from society and criminalization of drug consumption. The needed services were free HIV and HCV testing; medical consultations and referral to free treatment (HIV, HCV, Syphilis, TB, reproductive healthcare) programs.

**Conclusions:** More efforts are needed to address the barriers revealed by this study. Harm reduction program personnel should increase motivation of sex partners to do HIV testing. Risk counseling of couples should be enhanced for decreasing HIV associated risks and better utilization of harm reduction services; Besides, women oriented services should be developed and adjusted to needs of sex partners for better uptake of HIV Services of PWIDs.

**PE39/11**

**Male sex workers and ICT: anthropological approach of male sex workers and the different practices online: bareback, PrEP and chemsex**

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**Purpose:** PrEP, bareback, chemsex, are now firmly part of strategies gay and MSM men use in their sexual interactions/socialization in much of Europe. This was an exploratory study to assess the impact on working practices that bareback, chemsex, PrEP, have had on MSM sex workers, utilizing websites (such Hunqz, Rent.men, etc.) and mobile applications (Grindr, Scruff, etc.) to contact and interact with clients.

**Method:** Between February 2017/March 2019 these issues were discussed with 600 plus sex workers. This involved four face to face interviews with 10 different persons, 2 sex worker facebook groups [one of 536 and one of 71 people] created and for sex workers. Issues explored were sex workers perception and using of PrEP, the frequency of requests for bareback services, and chemsex, as well as more generally how sex workers viewed. The use of mobile and internet platforms as good ways to offer services.

**Results:** Almost all of the sex workers participating in the research had experienced impacts upon their ability to successfully negotiate, maintain, and control the services they provided to clients. Oftentimes clients knowledge of PrEP and its availability was used to pressure the workers into barebacking when they were not comfortable with this. The availability and offerings of ‘chemsex’ being provided by clients was also used to pressure workers into sessions were it was difficult for workers to maintain the boundaries they felt were appropriate.

**Conclusion:** Specific interventions need to be in place for those using mobile and internet based platforms for sex work – to improve negotiation skills for sex workers, as well as to educate (as is always necessary) clients about the rights of sex workers in deciding upon the services they offer free from coercion.
PE39/12
Portuguese League Against AIDS – mobile screening unit
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Purpose: The Mobile Screening Unit aims to facilitate access to testing, counseling, diagnosis, care and treatment of HIV and other Sexually Transmitted Infections (STI). The use of a MSU allows greater accessibility of screening services throughout Lisbon, Loures and Odivelas closely linked to users, primarily vulnerable and most at risk populations [sex workers and their clients, Men who have Sex with Men (MSM), intravenous drug users, migrants and homeless people]. The MSU offers free, voluntary, confidential STI screening services throughout Lisbon, Loures and Odivelas closely linked to local structures and health care services.

Method: The MSU has two mediators, a clinical psychologist, a doctor and a nurse. The mediators approach vulnerable populations, the psychologist conducts a survey to each patient collecting demographic information, sexual behavior data and to advise on healthier behaviours, the nurse performs the screenings and the doctor is responsible for STI appointments. The sample for this analysis was collected from October 2014 to June 2019, in a total of 5334 screenings.

Results:

Graph 1 shows the amount of screenings by population tested (2272 screenings were made to General Population, 2282 to Immigrants, 159 to Sex Workers, 156 to Drug Users, 220 to Homeless People and 253 MSM).

Graph 2 shows that the highest percentage of reactive/positive results are from Drug Users, followed by Homeless, both often diagnosed with HVC. The highest percentage of new cases of HIV is diagnosed on Drug Users and MSM. The MSU has two mediators, a clinical psychologist, a doctor and a nurse. The mediators approach vulnerable populations, the psychologist conducts a survey to each patient collecting demographic information, sexual behavior data and to advise on healthier behaviours, the nurse performs the screenings and the doctor is responsible for STI appointments. The sample for this analysis was collected from October 2014 to June 2019, in a total of 5334 screenings.

PE39/13
Detectable viraemia in the era of successful antiretroviral therapy; engagement with multi-disciplinary services
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Objectives: People living with HIV (PLWH) not willing to start and those on antiretroviral therapy (ART) who fail to suppress their viral load may require additional support. The aim of this study is to determine current utilisation of in-house support structures to facilitate uptake and adherence to ART.

Methods: Individuals attending a large urban HIV clinic June 2018–May 2019, diagnosed >1 year with at least one viral load >200 copies/mL regardless of ART status were included. Characteristics at time of detectable viral load were summarised. A notes review of a random subset of 30 individuals was conducted to assess need for additional support services; whether referral to services was offered, and patient uptake.

Results: Of 3184 people seen between June 2018–May 2019, 124 (3.9%) ever had a viral load >200 copies/mL (median VL 5189 copies/mL; 47 (38%) male, 75 (60%) gay/sexual men; median age 49 years. The majority (103/124, 83.1%) were receiving ART and 45 (21%) ever had an AIDS-defining illness. One or more in-house support services had been accessed by 89 (70%); 59 (48%) engaged with psychology/psychiatry services. The needs and usage of support services are shown in the Table 1.

Conclusions: Our findings indicate a requirement for support needs to be better identified and use of support services promoted to facilitate engagement if viral suppression is to be achieved for all.

PE39/14
Optimal HIV self-testing, potential strategies to increase HIV diagnosis in Tanzania
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Background: In Tanzania the testing gaps still remain large. An implementation science for HIVST was conducted since May 2018 targeting KVP in 10 regions out of 26 regions in Tanzania. The objective was to understand uptake, acceptability of HIVST and linkage to other HIV services.

Methodology: HIVST is implemented by the Ministry of Health as demonstration project in collaboration with PEPFAR/T community partners. Oraquick kits were used and distributed to study participants in three modalities, assisted, unassisted. Three kits were provided to clients, one for him/herself, a sexual partner and their peers. A training package was
developed, sensitization package and training of health care workers and peers from identified communities. By end of June 2019 a total of 17,692 kits were distributed.

Results: Two third of the clients opted unassisted approach of using the kits. The uptake was higher among female than males. The target population groups received kits are FSWs, PWID, MSM and AGYW. FSWs followed by PWID are the leading groups. In both cases the unassisted approach of using kits is more preferred by clients, except for PWID which shows that most opted the directly assisted approach. The proportion of primary and secondary distribution of kits is almost the same.

Proportion of the kits’ results returned is 64% with a positivity rate of 3% and 66% linkage to care. Among the FSW, ¾ of the clients opted to use HIVST kits for their own testing. Assisted approach was opted by 2/3 of clients in primary/direct distributed category. Among population types, 51% of kits were distributed to FSWs. 51% of all kits were taken up by FSWs.

Conclusion: Generally, we see higher yield among unassisted compared to directly assisted method. It is very possible that the higher yield among unassisted method reflects higher self-risk self-perception among these clients.