Presenter Disclosure Information

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Lene Ryom

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Employee: Never
Other: Never
EACS Treatment Guidelines V9.0
An introduction To The 2017 Revisions

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Aims of the EACS Guidelines

The scope of the EACS guidelines is to

• Provide easy accessible recommendations to clinicians centrally involved with the care of HIV-positive individuals

• Cover a large and geographically diverse area

• Not to be considered as a full overview of all aspects of HIV-infection, but rather as a continuously updated overview of the most relevant clinical issues in HIV
### New Summary of Changes in v9.0

#### Summary of Changes from v8.2 to v9.0

**ART section**
- What to start with: Older ARVs (LPW11) have been removed. The order of the listed regimens was changed to reflect the preference of use based on the data available. The structure of the Table was changed to facilitate the reading of essential information. Footnotes were added: a note on when to start TAF over TDF, a note on the potential CVD toxicity of DRV, a note on AVT and nevirapine toxicity, page 11.
- Primary HIV Infection: Recommendation that all HIV-positive women of reproductive age should have a pregnancy test was added, page 12.
- Switch strategies: Indications for switch were added (HIV treatment, nevirapine toxicity). DTG-RPV regimen was added as switch option. DTG monotherapy was added in the strategies not recommended. The wording and structure of “class-switching strategies” was changed to improve clarity, page 13.
- Virological failure: Changes in the definition were made to differentiate “incomplete suppression” from “virological rebound.” A note on the importance of taking into consideration all the available resistance tests when choosing a new regimen in patients with virological failure was added, page 14.
- ARV in pregnancy: A recommendation on use of INSTI in pregnant women who start ARVs in the late second or third trimester was added. A warning note on EFV in pregnancy was removed. EFV, RAL, RPV or DRV can be continued during pregnancy. Women on ETVG include to be informed that more monitoring of HIV- VL and drug levels may be necessary during pregnancy. A recommendation against the initial use of TAF and dolutegravir was added. A recommendation against breastfeeding was added, page 15.
- Post-exposure prophylaxis (PEP): A note on providing emergency contraception counseling for sexual exposure was added, page 17.

**Co-infections section**
- HIV core-antigen testing has been added, page 79.
- HCC screening recommendations have been updated, pages 56 and 90.
- HIV treatment figure has been removed. Footnotes have been converted into full text with new recommendations for individuals with HVM who face immunosuppression.
- Evaluation of concurrent causes of liver disease has been added to the diagnostic procedures table, page 81.
- The text on HCV treatment has been shortened with emphasis on DAA table.
- Recommendations for individuals with failure on DAA treatment have been updated, page 82.
- Recommendations for individuals with acute HCV have been updated.
- HCV management figure was removed.
- DDI tables have been updated and now includes Glecaprevir and Sofosbuvir. VX1, Boceprevir and Telaprevir have been deleted, page 84.
- Figure on management of acute HCV has been amended, page 95.
- All tables and figures dealing with IFN-containing HCV therapy have been removed. We refer to an older online version of the Guidelines for details on IFN-treatment, page 92.

** Opportunistic infections section**
- A comment on TMR-SBM as preferred therapy for cerebral toxoplasmosis when the oral route is not available was added, page 59.
- The preliminary results of the REALITY trial in the cryptococcal disease section were added, page 99.
- An enhanced infection prophylaxis in severely immunosuppressed individuals (CD4 < 50 cells/µl), including IINH 12 weeks, fluconazole 100 mg daily 12 weeks, azithromycin 500 mg daily for 5 days and albendazole 400 mg single dose may decrease overall opportunistic infections (including cryptococcal meningitis) and mortality.
- A comment on the possibility to add fluconazole to liposomal amphotericin B during the induction phase for cryptococcal meningitis treatment in countries where fluconazole is not available was added, page 99.
- Intermittent TB regimens (2 or 3 times per week) are contraindicated in HIV-positive persons, page 96.
- A comment on the possibility to add steroid therapy to avoid IRIS in individuals with TB was added, page 99.
- The preliminary results of the NoVa-TB trial in the section of treatment for resistant TB (MDR- and XDR-TB) were added, page 99.
- A duration of 6-months for latent TB treatment, particularly in countries with high TB prevalence, was emphasized, page 97.
- A comment explaining that other preventive regimens are needed for treating latent infection with MDR-XDR-TB in countries with high resistant TB rates was added, page 97.

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# New Topics in v9.0

## Drug-drug Interactions between Bronchodilators (for COPD) and ARVs

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**Legend**
- →: potential elevated exposure of the bronchodilator
- ←: potential decreased exposure of the bronchodilator
- ↑: no significant effect
- D: potential decreased exposure of ARV drug
- E: potential elevated exposure of ARV drug
- ATV/c: ATV co-formulated with Cobicistat (300/150 mg bid);
- DRV/r: DRV co-formulated with Cobicistat (600/150 mg bid);
- a: caution as both drugs can induce QT interval prolongation

**Colour legend**
- no clinically significant interaction expected
- these drugs should not be co-administered
- potential clinically significant interaction that is likely to require additional monitoring, alteration of drug dosage or timing of administration
- potential interaction likely to be of weak intensity. Additional action/monitoring or dosage adjustment is unlikely to be required.
New Topics in v9.0
New Topics in v9.0

Non-Alcoholic Fatty Liver Disease (NAFLD)

The prevalence of NAFLD is higher in individuals with HIV infection (30-40%) than in the general population [2]. Nearly half of the HIV-positive patients that undergo evaluation for unexplained liver test abnormalities are found to have NAFLD. The diagnosis of NAFLD requires the exclusion of both secondary causes and of a daily alcohol consumption ≥30 g for men and ≥20 g for women.

Spectrum of NAFLD

Often associated with components of the metabolic syndrome:

- Non-Alcoholic Fatty Liver (NAFL)
- Non-alcoholic fatty liver disease (NAFLD)
- Non-alcoholic steatohepatitis (NASH)
- Early NASH: no or mild (F0-F1) fibrosis
- Fibrotic NASH (F2) or advanced (F3-F4) fibrosis
- NASH-cirrhosis (F4)
- NASH (can occur in the absence of cirrhosis and histological evidence of NASH)

Most common concurrent diseases:

- AFLD: alcoholic fatty liver disease
- Drug-induced fatty liver disease

Consideration on ARV drugs:

- 3-drug (ddI, ddC, d4T) are contraindicated in individuals at risk of or with NAFLD
- Consider use of lipid neutral regimen in individuals at risk of or with NAFLD

Diagnostic flowchart to assess and monitor disease severity in case of suspected NAFLD and metabolic risk factors

- Metabolic syndrome
  - Liver ultrasound
  - Steatosis present
    - Normal liver enzymes
      - Serum fibrosis marker
        - Low risk
          - Follow-up 0-2 years
        - Medium/High risk
          - Specialist referral
          - Liver enzymes, fibrosis biomarkers
    - Abnormal liver enzymes
      - Identify other chronic liver diseases
      - In-depth assessment of disease severity
      - Decision to perform liver biopsy
      - Initiate monitoring/therapy
  - Steatosis absent
    - Normal liver enzymes
      - Follow-up 0-3-5 years
    - Abnormal liver enzymes
      - Ultrasound liver enzymes

1. Serum fibrosis markers: NAFLD-Fibrosis Score, FibroTest, FibroMeter, ELF.

These recommendations are largely inspired by the EASL-EASD-EASO Clinical Practice Guidelines for the Management of Non-Alcoholic Fatty Liver Disease: European Association for the Study of the Liver (EASL), European Association for the Study of Diabetes (EASD) and European Association for the Study of Obesity (EASO).
New Topics in v9.0

Solid Organ Transplantation (SOT) in HIV-Positive Persons

General features
- HIV infection is not a contraindication for transplantation consideration.
- Experts in HIV medicine should preferably be members of the multidisciplinary team, responsible for the pre-transplant evaluation, and take primary responsibility for the management of the HIV infection and the prevention and treatment of OIs.

Organ criteria for SOT
- HIV-positive persons should be considered for organ transplantation using the same indications as used in HIV-negative persons. HIV-positive persons with HCC can be evaluated for liver transplantation if they fulfill the Milan criteria.

HIV-infection criteria for SOT
- According to most international guidelines, HIV-positive individuals should fulfill the following criteria to be considered for SOT:
  1. Clinical criteria: No active OIs or HIV-related cancers. Individuals with PML, chronic cryptosporidiosis, multi-drug resistant fungal or mycobacterial infections, NHL and visceral KS should be excluded. For non-HIV-related cancers same criteria apply as in the general HIV-negative population.
  2. Immunological criteria: CD4 > 200 cells/μL for all SOT except for liver transplantation where CD4 > 100 cells/μL. Persons with previous opportunistic infections should have a CD4 > 200 cells/μL.
  3. Virological criteria: Full control of HIV replication prior to and after transplantation should be confirmed/predicted in all cases.
  4. Drug abuse: Abstinence period: alcohol 6 months; heroin/cocaine 2 years. Former IV/IDUs can be in methadone programme.

Preparing HIV-positive persons for transplantation
- Antiretroviral therapy:
  - Choice of ART components should avoid drugs known to cause organ dysfunction or drugs with a high potential for drug-drug interactions if at all possible, see Drug-drug interactions between Immunosuppressants (for SOT) and ARVs.
  - Using a pharmacological booster (RTV or COBI) and some of the NNRTIs are best avoided, see Drug-drug interactions between Immunosuppressants (for SOT) and ARVs.
  - For individuals nearing indication for transplantation, ART should be modified to ensure this if at all possible.
  - RAL (and probably OTG) plus 2 NNRTIs is the preferred regimen.
  - If the individual has not yet started ART and transplantation is considered, ART should be commenced as soon as possible and preferably before the transplantation is started.

Viral hepatitis co-infection
- In liver transplant candidates, every effort should be made to treat the underlying viral hepatitis, see pages 80 and 82-84. Use of DAAs in persons with HCV co-infection may improve their liver function, and possibly lead to them being removed from the transplant waiting list.

Follow-up after transplantation
- Antiretroviral therapy:
  - Same recommendations in individuals under preparation for transplantation.
  - Additionally, ARVs may exacerbate immunosuppressive agents' adverse drug effects (kidney impairment, bone marrow suppression, drug-induced liver injury, etc.). Therefore, careful consideration of which drugs to use is essential see Adverse Effects of ARVs & Drug Classes.
  - Before starting or restarting abacavir containing ART the HLA-B*5701 status of the donor should be assessed.

Primary and secondary disease-specific chemoprophylaxis
- HIV-positive transplant recipients should receive the same surveillance, prophylaxis and immunisation regimens for OIs as HIV-negative SOT recipients.
- Screening and treatment for latent TB is a priority, see page 97.

Viral hepatitis co-infection
- The efficacy and safety of DAAs in liver transplant HIV-positive recipients with HCV recurrence is the same as in HIV-negative recipients.

Immunosuppressive regimens
- Same as in HIV-negative transplant recipients. The risk of acute rejection is however double of that of HIV-negative SOT recipients and, therefore, requires close monitoring.
- Special attention to interaction with ART, see Drug-drug interactions between Immunosuppressants (for SOT) and ART.

Milan criteria: solitary tumor smaller than 5 cm or 2–3 tumors of < 3 cm in the absence of macrovascular tumor invasion and extrahepatic metastases.
# Video Links

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<tr>
<th>EACS Guidelines</th>
<th>Video Lectures</th>
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<td>HIV and CVD, CKD, Endocrinology</td>
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<tr>
<td>Kidney Disease: Definition, Diagnosis and Management</td>
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<tr>
<td>Lipodystrophy: Prevention and Management</td>
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<tr>
<td>Algorithm for Diagnosis and Management of HIV-Associated</td>
<td>CNS and HIV Part 1</td>
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<td>Neurocognitive Impairment (NCI) in Persons without Obvious</td>
<td>CNS and HIV Part 2</td>
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<td>Confounding Conditions</td>
<td>Hepatitis C and HIV Co-infection Part 1</td>
<td><a href="https://vimeo.com/197259934/b5c5aad91d">https://vimeo.com/197259934/b5c5aad91d</a></td>
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<td>Introduction to OIs</td>
<td>Pulmonary Infections Part 1</td>
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<td>Pulmonary Infections Part 2</td>
<td><a href="https://vimeo.com/197388870/7e266b8551">https://vimeo.com/197388870/7e266b8551</a></td>
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<td>Pulmonary Infections Part 3</td>
<td><a href="https://vimeo.com/197392161/f09002a0ae21">https://vimeo.com/197392161/f09002a0ae21</a></td>
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<td>CNS and HIV-related Opportunistic Infections Part 2</td>
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<td>Diagnosis and Treatment of TB in HIV-positive Persons</td>
<td>Tuberculosis and HIV Co-infection Part 1</td>
<td><a href="https://vimeo.com/197161188/4e881a687c">https://vimeo.com/197161188/4e881a687c</a></td>
</tr>
</tbody>
</table>
The guidelines V9.0 consist of:

- Summary of changes from v8.0 to 9.0
- Part I: Visit Assessment
- Part II: ART
- Part III: Co-morbidities
- Part IV: Co-infections
- Part V: Opportunistic Infections
- References
- Videolinks
EACS Guidelines Management

Each individual part of the guidelines is

Managed by
• A Panel of experienced European HIV experts
• External experts (e.g. in the co-morbidity part)
• And Reviewed by community representatives and Wave

Governed by
• A 3-person leadership group
  – Panel Chair, Co-chair and Young Scientist

The guidelines content is managed by
• The EACS Medical Secretariat; guideline coordination chair and assistant working closely with the EACS Secretariat
EACS Guidelines Availabilities

- In print as a booklet
- Since 2015 as a free App for IOS and Android systems by the Sanford Guide
- Online on the EACS website

http://www.eacssociety.org/guidelines/eacs-guidelines/eacs-guidelines.html
EACS Guidelines Revisions

• Formal reviews are made annually for the electronic versions, and biennially for the printed version, but updates are also made continuously
  • New important data immerge
  • Feedback from the users

• We warmly welcome feedback on content and translations, can be submitted via guidelines@eacsociety.org
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The EACS Medical Secretariat is responsible for the coordination and update of the EACS Guidelines based on the recommendations from the four EACS panels.

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Assistant Coordinator: Lene Ryom  
Copenhagen, Denmark

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  - Simon Collins  
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  - Christoph A. Fux  
  - Giovanni Guaraldi  
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  - Renaud du Pasquier  
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  - Alan Winston  
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  - Athens, Greece  
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  - Paris, France  
  - Copenhagen, Denmark  
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  - Nantes, France  
  - Amsterdam, The Netherlands  
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We hope you will enjoy the 2017 EACS Guidelines!
ART section updates

- Recommended regimens for naïve patients
- Alternative regimens
- Primary HIV infection
- Switch strategies
- Virological failure
- ARVs in pregnancy
- Post-exposure prophylaxis
### Recommended regimens

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Dosing</th>
<th>Caution</th>
<th>Food requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2 NRTIs + INSTI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC/3TC/DTG&lt;sup&gt;(ii, iv)&lt;/sup&gt;</td>
<td>ABC/3TC/DG 600/300/50 mg, 1 tablet qd</td>
<td>Ali/Ca/Mg-containing antacids or multivitamins should be taken well separated in time (minimum 2h after or 6h before)</td>
<td>None</td>
</tr>
<tr>
<td>TAF/FTC&lt;sup&gt;(iii)&lt;/sup&gt; or TDF/FTC&lt;sup&gt;(iii)&lt;/sup&gt; + DTG</td>
<td>TAF/FTC 25/200 mg, 1 tablet qd or TDF/FTC 300/200 mg, 1 tablet qd + DTG 50 mg, 1 tablet qd</td>
<td>DTG 50 mg bid with rifampicin</td>
<td>None</td>
</tr>
<tr>
<td>TAF/FTC/EVG/c&lt;sup&gt;(iii)&lt;/sup&gt; or TDF/FTC/EVG/c&lt;sup&gt;(iii)&lt;/sup&gt;</td>
<td>TAF/FTC/EVG/c 10/200/150/150 mg, 1 tablet qd or TDF/FTC/EVG/c 300/200/150/150 mg, 1 tablet qd</td>
<td>Ali/Ca/Mg-containing antacids or multivitamins should be taken well separated in time (minimum 2h after or 6h before)</td>
<td>With food</td>
</tr>
<tr>
<td>TAF/FTC&lt;sup&gt;(iii)&lt;/sup&gt; or TDF/FTC&lt;sup&gt;(iii)&lt;/sup&gt; + RAL</td>
<td>TAF/FTC 25/200 mg, 1 tablet qd or TDF/FTC 300/200 mg, 1 tablet qd + RAL 400 mg, 1 tablet bid</td>
<td>Co-administration of antacids containing Al or Mg not recommended RAL 400 or 800 mg bid with rifampicin</td>
<td>None</td>
</tr>
<tr>
<td><strong>2 NRTIs + NNRTI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAF/FTC/RPV&lt;sup&gt;(iii)&lt;/sup&gt; or TDF/FTC/RPV&lt;sup&gt;(iii)&lt;/sup&gt;</td>
<td>TAF/FTC/RPV 25/200/25 mg, 1 tablet qd or TDF/FTC/RPV 300/200/25 mg, 1 tablet qd</td>
<td>Only if CD4 count &gt; 200 cells/µL and HIV-VL &lt; 100,000 copies/mL PPI contra-indicated; H2 antagonists to be taken 12h before or 4h after DRV</td>
<td>With food</td>
</tr>
<tr>
<td><strong>2 NRTIs + PI/r or PI/c</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAF/FTC&lt;sup&gt;(iii)&lt;/sup&gt; or TDF/FTC&lt;sup&gt;(iii)&lt;/sup&gt; + DRV/c&lt;sup&gt;(iv)&lt;/sup&gt; or + DRV/r&lt;sup&gt;(iv)&lt;/sup&gt;</td>
<td>TAF/FTC 10/200 mg, 1 tablet qd or TDF/FTC 300/200 mg, 1 tablet qd + DRV/c 800/150 mg, 1 tablet qd or + DRV 800 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**New**

- For recommended regimens order = alphabetical
- For alternative regimen order = preference of use
- When to prefer TAF over TDF
- ATV and renal toxicity
- Potential DRV CV toxicity
**Alternative regimens**

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Dosing</th>
<th>Caution</th>
<th>Food requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2 NRTIs + INSTI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC/3TC + RAL</td>
<td>ABC/3TC 600/300 mg, 1 tablet qd + RAL 400 mg, 1 tablet bid</td>
<td>Co-administration of antacids containing Al or Mg not recommended. RAL 400 or 800 mg bid with rifampin</td>
<td>None</td>
</tr>
<tr>
<td><strong>2 NRTIs + NNRTI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC/3TC + EFV</td>
<td>ABC/3TC 600/300 mg, 1 tablet qd + EFV 600 mg, 1 tablet qd</td>
<td>Only if HIV-VL &lt; 100,000 copies/mL</td>
<td>At bed time or 2 hours before dinner</td>
</tr>
<tr>
<td>TDF/FTC/EFV</td>
<td>TDF/FTC/EFV 300/200/600 mg, 1 tablet qd</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>2 NRTIs + PI/r or PI/c</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAF/FTC or TDF/FTC + ATV/c</td>
<td>TAF/FTC 10/200 mg 1 tablet qd or TDF/FTC 300/200 mg, 1 tablet qd + ATV/c 300/150 mg, 1 tablet qd or ATV 300 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd</td>
<td>With food</td>
<td></td>
</tr>
<tr>
<td>+ ATV/r</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC/3TC + ATV/c or ATV/r</td>
<td>ABC/3TC 600/300 mg, 1 tablet qd + ATV/c 300/150 mg, 1 tablet qd or ATV 300 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd</td>
<td>Only if HIV-VL &lt; 100,000 copies/mL</td>
<td>With food</td>
</tr>
<tr>
<td>ABC/3TC + DRV/c or DRV/r</td>
<td>ABC/3TC 600/300 mg, 1 tablet qd + DRV/c 800/150 mg, 1 tablet qd or DRV 800 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd</td>
<td>Monitor in patient with allergy</td>
<td></td>
</tr>
<tr>
<td><strong>Other combinations</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAL + DRV/c or DRV/r</td>
<td>RAL 400 mg, 1 tablet bid + DRV/c 800/150 mg, 1 tablet qd or DRV 800 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd</td>
<td>Only if CD4 &gt; 100,000 copies/mL</td>
<td></td>
</tr>
</tbody>
</table>

**New**

- Older ARVs (LPV/r) removed
- Order = preference of use
Primary HIV Infection

**Acute infection:** HIV detection (p24 Ag and/or HIV-RNA) in the absence of HIV antibody.

**Recent infection:** HIV antibody detection; up to 6 months after infection.

**Circumstances where immediate treatment initiation should be advised**
- Acute infection
- Severe or prolonged symptoms
- Neurological disease
- Age ≥ 50 years
- CD4 count < 350 cells/µL

**Treatment selection**
- Clinical trials (HIV curative strategies)
- Resistance test
- If therapy starts before resistance test available:
  - Start a PI/r or PI/c or an INSTI + TDF or TAF/FTC
  - Regimen can be adjusted once the resistance test is available and viral load is suppressed

**New**
All HIV-positive women of reproductive age should have a pregnancy test.
Switch strategies

**Indications**
- Documented toxicity
- Prevention of long-term toxicity.
- Avoid serious DDIs
- Planned pregnancy
- Ageing and/or co-morbidity
- Simplification
- Starting of HCV treatment (DDIs)

**Dual therapy**
- DTG + RPV
- 3TC + (DRV/r or DRV/c)
- 3TC + (ATV/r or ATV/c)

**Monotherapy with DRV/r**
- only if
  - a) no resistance to the PI
  - b) suppression of HIV-VL <50 cp for 6 months
  - c) absence of chronic HBV co-infection

---

Pt with VL<50 cp

New
- **Indications for switch** (HCV rx, renal/bone toxicity)
- **DTG+RPV included**

**DTG monotherapy not recommended**
Virological failure

**New Definition of Virological Failure**

**INCOMPLETE SUPPRESSION:** HIV-VL > 200 copies/mL at 6 months after starting therapy

**VIROLOGICAL REBOUND:** confirmed HIV VL > 50 copies/mL in patients with previous undetectable viral loads

If HIV-VL > 50 and < 500:
- Check adherence
- Check HIV-VL 1 to 2 months later
- If genotype na, consider changing regimen based on past rx and resistance hx

If HIV-VL confirmed > 500:
- Change regimen as soon as possible based on the resistance testing results
- If no resistance mutations found: re-check for adherence, perform TDM
1. Women planning to be pregnant/becoming pregnant while already on ART: Maintain ART
   [Contra-indicated during pregnancy: ddI + d4T, triple NRTI]

2. Women becoming pregnant, treatment-naïve: Start ART ASAP

4. Women whose follow-up starts late in II/III trimester: Start ART ASAP / INSTI as the preferred choice rapid HIV-VL decline

5. Women whose HIV-VL is not <50 cp in III trimester: VRT / consider INSTI if not already on it
ARV in pregnancy

Antiretroviral regimens:

If on RAL, DTG, RPV or DRV/r: could be continued (Among PI/r, prefer ATV/r)

- EFV is a suitable alternative NEW!
- NVP not to be initiated but can be continued
- TAF and Cobicistat in pregnancy: not recommended in initial regimen (limited experience) NEW!
- Caution with EVG/cobi: monitoring of VL and drug levels may be needed (low exposure demonstrated in third trimester) NEW!

Breastfeeding

- We advise against breastfeeding. In case a woman insists on breastfeeding we recommend follow-up with increased clinical and virological monitoring of both the mother and the infant NEW!
Post-Exposure Prophylaxis (PEP)

Rapid testing of the source person for HCV/HIV (if HIV-status unknown):
if Source person HIV-positive on ART, order resistance testing if HIV-VL detectable
For sexual exposure, if HIV-positive source has documented undetectable HIV-VL, PEP is no longer recommended.

- Individualise PEP according to the source’s treatment history and previous resistance tests
- PEP to be started ideally < 4 hours after the exposure, and no later than 48/72 hours
- Duration of PEP: 4 weeks (unless discontinued due to lack of indication)

PEP regimen: TDF/FTC + RAL bid
Alternatives: TDF/FTC + DRV/r qd or
+ LPV/r bid or
+ DTG qd

- Full sexual health screen in case of sexual exposure
- Emergency contraception counselling for sexual exposure
In compliance with the Conflict of Interest Policies, the European AIDS Clinical Society (EACS) requires the following disclosure from the presenters:

Georg Behrens

Research Support: Gilead, to the department: Gilead, BMS, ViiV, Abbvie, MSD
Speaker’s Bureau: Gilead, ViiV, Janssen, Abbvie, MSD, Hexal, Sandoz
Board Member/Advisory Panel: Gilead, BMS, Janssen, ViiV, MSD
Stock/Shareholder: Never
Consultant: Never
Employee: Never
Other: Never
Part III Prevention and Management of Co-morbidities in HIV-positive Persons

Professor Georg Behrens
Department for Clinical Immunology and Rheumatology
Hannover Medical School, Hannover, Germany
Part III Prevention and Management of Co-morbidities in HIV-positive Persons

Young scientist: Lene Ryom
Copenhagen, Denmark 🤗

Catia Marzolini
Basel, Switzerland 🤗
Part III Prevention and Management of Co-morbidities in HIV-positive Persons

We recommend multi-disciplinary care for aging HIV patients with multiple co-morbidities and chronic immune activation to maintain good quality of life and to prevent frailty.
Prevention of CVD

Principles: The intensity of efforts to prevent CVD depends on the underlying risk of CVD, which can be estimated\(^{(1)}\). The preventive efforts are diverse in nature and require involvement of a relevant specialist, in particular if the risk of CVD is high and always in persons with a history of CVD.

Assess CVD risk in next 10 years\(^{(1)}\)

- Advise on diet and lifestyle in all persons
- Consider ART modification if 10-year CVD risk ≥ 20\(^{(1)}\)

Identify key modifiable risk factors\(^{(3)}\)

- Smoking (see page 39)
- Blood pressure
  - Drug treatment if: SBP ≥ 140 or DBP ≥ 90 mmHg (especially if 10-year CVD risk ≥ 20\(^{20}\))
  - Target\(^{(3)}\)
    - SBP < 140 mmHg
    - DBP < 90 mmHg
    - Treatment (see page 41-43)

- Coagulation
  - Drug treatment if: established CVD or age ≥ 50 and 10-year CVD risk ≥ 20\(^{(20)}\)
  - Target - N/A
    - Consider treating with acetylsalicylic acid 75-150 mg\(^{(3)}\)

- Glucose
  - Confirm DM and treat with drugs
  - Target
    - HbA1C: 6.5-7.0\(^{(20)}\)
    - Treatment (see page 45)

- Lipids
  - Drug treatment\(^{(4)}\) if: established CVD or type 2 diabetes or 10-year CVD risk ≥ 10\(^{(20)}\)
    - Target\(^{(4)}\)
      - Optimal
      - Standard
      - TC: ≤ 4 (155) ≤ 5 (100)
      - LDL: ≤ 2 (80) ≤ 3 (115)
    - Treatment (see page 46)

- For higher risk individuals (e.g. diabetes) where resources allow target SBP < 130 and DBP < 80 mmHg.
Type 1 diabetes should be treated according to national guidelines. Metformin may worsen lipoatrophy.

No data for any oral antidiabetic agents in terms of CVD prevention in HIV-positive persons. Incretins (DDP-4 inhibitors [e.g. linagliptin, saxagliptin (reduce dose when given with a booster), sitagliptin and vildagliptin], GLP-1 agonists [liraglutide, exenatide], and SGLT-2 inhibitors [e.g. dapagliflozin, canagliflozin, empagliflozin] have not been evaluated in HIV-positive persons, but some (e.g empagliflozin, liraglutide) have shown to reduce mortality from CVD; choice of drugs dependent on a variety of individual- & disease-specific factors; no clinically significant drug-drug-interaction or adverse effects on CD4 counts expected; clinical use of pioglitazone questioned by its side effects; HbA1c targets up to 7.5% can be considered for older persons with long-standing type 2 diabetes and evidence of CVD.
Kidney Disease: Definition, Diagnosis and Management

Diagnosis of kidney disease

<table>
<thead>
<tr>
<th>eGFR (mL/min/1.73 m²)</th>
<th>&gt; 90 mL/min</th>
<th>&gt; 60 mL/min, but accelerated decline of eGFR</th>
<th>&gt; 30 - &lt; 60 mL/min</th>
<th>&lt; 30 mL/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>UP/C (mg/mmol)</td>
<td>&lt; 50</td>
<td>Recommend follow-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UP/C (mg/mmol)</td>
<td>50-100</td>
<td>Check risk factors for CKD and nephrotoxic medications including ART**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UP/C (mg/mmol)</td>
<td>&gt; 100</td>
<td>Discontinue or adjust drug dosages where appropriate**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proteinuria</td>
<td>&lt; 500</td>
<td>Perform renal ultrasound, check random blood glucose, refer to nephrologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proteinuria</td>
<td>500-1000</td>
<td>If uremic symptoms present or any level of proteinuria refer to nephrologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proteinuria</td>
<td>&gt; 1000</td>
<td>Check creatinine levels, refer to nephrologist</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Defined as decrease in eGFR of 5 ml/min per year for ≥3 consecutive years or confirmed 25% eGFR decline from baseline.

Management of HIV-associated kidney disease

<table>
<thead>
<tr>
<th>Prevention of progressive renal disease</th>
<th>Comment</th>
</tr>
</thead>
</table>
| 1. ART                                 | Start ART immediately, where HIV-associated nephropathy (HIVAN) and/or HIV-related complex disease strongly suspected. Immunosuppressive therapy may have a role in patients with complex diseases. Renal biopsy to confirm histological diagnosis.
| Consider replacing TDF** by non-tenofovir drug or TAF*** if: |
| • UP/C < 50 mg/mmol |
| • eGFR < 50 mL/min, but decrease in eGFR by 5 mL/min per year for at least 3 consecutive years or confirmed 25% eGFR decline from baseline |
| • co-morbidities with a high risk of CKD (i.e. diabetes and hypertension) |
| • body weight < 60 kg |
| • use of a PI/r as a third agent |
| Replace TDF** by non-tenofovir drug or TAF*** if: |
| • eGFR < 30 mL/min |
| • UP/C > 50 mg/mmol |
| • nephrotoxic comedication |
| • previous TDF toxicity (proximal renal tubulopathy) |
| • Expert opinion pending clinical data |

** There are limited data on use of TAF with eGFR ≤ 30 mL/min, and longer term outcomes are unknown.

Consider replacing TDF** by non-tenofovir drug or TAF*** if:

• UP/C 20-50 mg/mmol
• eGFR > 60 mL/min, but decrease in eGFR by 5 mL/min per year for at least 3 consecutive years or confirmed 25% eGFR decline from baseline
• co-morbidities with a high risk of CKD (i.e. diabetes and hypertension)
• body weight < 60 kg
• use of a PI/r as a third agent

Replace TDF** by non-tenofovir drug or TAF*** if:

• eGFR ≤ 60 mL/min
• UP/C > 50 mg/mmol
• nephrotoxic comedication
• previous TDF toxicity (proximal renal tubulopathy)

** Expert opinion pending clinical data

*** There are limited data on use of TAF with eGFR ≤ 30 mL/min, and longer term outcomes are unknown.
The prevalence of NAFLD is higher in individuals with HIV infection (30-40% in the US) than in the general population [9]. Nearly half of the HIV-positive persons that undergo evaluation for unexplained liver test abnormalities are found to have NAFLD. The diagnosis of NAFLD requires the exclusion of both secondary causes and of a daily alcohol consumption ≥ 30 g for men and ≥ 20 g for women.
# Vaccination

<table>
<thead>
<tr>
<th>Infection</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza Virus</td>
<td>Yearly</td>
</tr>
<tr>
<td>Human Papilloma Virus (HPV)</td>
<td>Vaccinate with 3 doses for all HIV-positive persons up to age 26 / age 40 if MSM (health insurance coverage differs by country according to age, sex, sexual orientation). Use 9-valent vaccine if available. If HPV infection is established, efficacy of vaccine is questionable.</td>
</tr>
<tr>
<td>Hepatitis B Virus (HBV)</td>
<td>Vaccinate if seronegative. Repeat doses until anti-HBs antibodies ≥ 10 IU/L / ≥ 100 IU/L according to national guidelines. In order to reach ≥ 100 IU/L in non-responders repeat 3 doses if anti-HBs &lt; 10 IU/L, 1 dose if anti-HBs &lt; 100 IU/L; consider double dose (40 μg) in particular with low CD4 count and high HIV-VL. See page 79</td>
</tr>
<tr>
<td>Hepatitis A Virus (HAV)</td>
<td>Vaccinate if seronegative. Consider checking antibody titres in individuals with high risk. Weaker immune response expected with HAV/ HBV co-vaccine. See page 79</td>
</tr>
<tr>
<td>Neisseria meningitidis</td>
<td>Use conjugated⁶ vaccine (2 doses 1-2 months apart) if available. Booster every five years if exposure continues. Polysaccharide vaccine not recommended anymore.</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>One dose of conjugated⁶ 13-valent vaccine (CPV-13) for all individuals, also if pre-vaccinated with PPV-23 polysaccharide vaccine. No general recommendation for any booster dose. Some national guidelines consider one dose of PPV-23 at least 2 months after CPV-13 for all individuals.</td>
</tr>
<tr>
<td>Varicella Zoster Virus (VZV)</td>
<td>Perform serology if exposure history negative. Vaccinate if seronegative. For contraindications, see*.</td>
</tr>
<tr>
<td>Yellow Fever Virus</td>
<td>Contraindicated if past or current haematological neoplasia or thymus affection (thymoma, resection/radiation) For other contraindications, see*. Booster q 10 years.</td>
</tr>
</tbody>
</table>
Algorithm for Diagnosis and Management of HIV-Associated Neurocognitive Impairment (NCI) in Persons without Obvious Confounding Conditions

**Abbreviations**
- CSF: cerebrospinal fluid
- GDR: genotypic drug resistance test
- HAD: HIV-associated dementia
- NMD: mild neurocognitive disorder
- MRI: brain magnetic resonance imaging
- NP: neuropsychological
- OIs: opportunistic infections
- HIV-positive person(s) or their relatives complaining of, or caregiver noting cognitive problems—without obvious confounding conditions
  - Initial assessments
  - Problems suspected
  - Evaluation for depression and possible treatability
  - Problems persisting but depression excluded or optimally managed
  - NP examination
  - Neurological examination (brain MRI)

**Obvious confounding conditions:**
1. Severe psychiatric conditions
2. Abuse of psychotropic drugs
3. Alcohol abuse
4. Sequelae from previous CNS-OIs or other neurological diseases
5. Current CNS-OIs or other neurological diseases

The following questions may be used to guide doctor assessment:
1. Do you experience frequent memory loss (e.g., do you forget the occurrence of special events even more often than your family, friends, etc.)?
2. Do you feel that you are slower when reasoning, planning activities, or solving problems?
3. Do you have difficulties paying attention (e.g., to a conversation, book or movie)?
Answering “yes” to one or more of these questions may suggest the presence of cognitive disorders, although not necessarily linked to HIV.

**See Depression: Screening and Diagnosis**

NP examination will have to include tests exploring the following cognitive domains: fluency, executive functions, speed of information processing, attention/working memory, verbal and visual learning, verbal and visual memory, motor skills plus assessment of daily functioning.

NCI is defined by impairment in cognitive function on the above neuropsychological test where performance is compared to age- and education-matched appropriate controls and is considered clinically significant.

NCI is defined by impairment in cognitive function on the above neuropsychological test where performance is compared to age- and education-matched appropriate controls and is considered clinically significant.

HI-positive populations (concentration above the IC50 in > 50% examined persons):
1. proven short-term (3-6 months) efficacy on cognitive function or CSF HIV-IVL decay when evaluated as single agents or in controlled studies in peer-reviewed papers.
2. Drugs with demonstrated clear CSF penetration:
   - NRTIs: ZDV, ABC
   - NNRTIs: EFV, NVP
   - PIs: LPV/r, DRV/r
   - INSTI: DTG
   - Other classes: MVC
3. Drugs with proven clinical efficacy:
   - NRTIs: ZDV, ABC
   - PIs: LPV/r

When administered bid. Once-daily administration of these drugs, although common in clinical practice, has not been studied extensively with regard to CNS effects/CSF penetration and may have different CNS activity. RTV is preferred as PI booster.

Avoid EFV because of its detrimental effects on neurocognitive function in a RCT and potentially confounding CNS effects due to neuropsychiatric effects.

See online video lectures CNS and HIV-Part 1 and CNS and HIV-Part 2 from the EACS online course Clinical Management of HIV.
Chronic Lung Disease in HIV

Screen for chronic lung disease:
- Are you 40 years or older?
- Have you smoked more than 10 pack years?
- Do you have ANY of the following symptoms: 1) shortness of breath on flat ground; 2) cough and/or sputum; 3) wheezing?

Drug-drug Interactions between Bronchodilators (for COPD) and ARVs

There are 3 life saving interventions:
1. Smoking cessation
2. Chronic oxygen when stable (non-exacerbated) resting $SpO_2 \leq 88\%$ (or $PaO_2 \leq 55$ mmHg)
3. Non-invasive ventilation (NIV) in individuals with acute hypercapnic respiratory failure

EACS European AIDS Clinical Society
### Prescribing in the Elderly

<table>
<thead>
<tr>
<th>Age related co-morbidities ➔ polypharmacy</th>
<th>Age related physiological changes ➔ impact pharmacokinetic (PK)/ pharmacodynamic (PD) effects of drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug-drug interactions (DDI)</td>
<td>Inappropriate drug/dosage use</td>
</tr>
<tr>
<td>↑ risk of adverse drug reactions; nonadherence; cognitive impairment; impaired balance and falls; morbidity and hospitalisation</td>
<td></td>
</tr>
</tbody>
</table>

**Perform periodic medicines reviews\(^{(i)}\)

Questions to consider when reviewing a prescription:
- Is there an indication for the medicine?
- Is this medicine appropriate for elderly people?
- Is the dose correct (e.g., adjusted for the renal function)?
- Is there a significant drug-drug interaction?
- Is there a significant drug-disease interaction (e.g., delirium)?
- Is the duration of treatment acceptable?
- Is there any missing medicine?
- Is the person able to manage his/her own medicines or does he/she need assistance?

Check for DDI with HIV drugs: [http://www.hiv-druginteractions.org](http://www.hiv-druginteractions.org)

Check for inappropriate drugs use: Beers\(^{(ii)}\) and STOPP/START\(^{(iii)}\) criteria

---

Adapted from [10], [11], [12]

\(^{(i)}\) The Beers and STOPP criteria are tools established by experts in geriatric pharmacotherapy to detect and reduce the burden of inappropriate prescribing in elderly. Inappropriate medicines include, for instance, those which in elderly persons with certain diseases can lead to drug-disease interactions, are associated with a higher risk of adverse drug reactions in the elderly, medicines that predictably increase the risk of falls in the elderly or those to be avoided in case of organ dysfunction. The START criteria consist of evidence-based indicators of potential prescribing omission in elderly with specific medical conditions.
### Organ criteria for SOT

- HIV-positive persons should be considered for organ transplantation using the same indications as used in HIV-negative persons, with the exception that persons with HCC can be evaluated for liver transplantation using the Milan criteria.\(^1\)

### HIV-infection criteria for SOT

According to the guidelines for liver transplantation, a candidate must fulfill the following criteria:  

1. **Immunosuppression:** The patient must be taking effective antiretroviral therapy (ART) and have a CD4 count above 200 cells/µL for all SOT except for liver transplantation.

2. **Virology:** The patient must have full control of HIV replication prior to and after transplantation. HIV RNA levels should be confirmed/predicted in all cases.

3. **Drug use:** Abstinence period: alcohol 6 months; heroin/cocaine 2 years. Former IVDUs can be in methadone programme.
Clinical Management and Treatment of HBV and HCV Co-infection in HIV-positive Persons

Massimo Puoti for the coinfections EACS guidelines panel
In compliance with the Conflict of Interest Policies, the European AIDS Clinical Society (EACS) requires the following disclosure from the presenters:

Massimo Puoti

Research Support: To the Division by Gilead, ViiV, Pfizer
Speaker’s Bureau: Abbvie, BMS, Beckman Coulter, Gilead sciences, MSD, Pfizer, Roch
Temporary Board Member/Temporary Advisory Panel: MSD, Abbvie, Gilead Sciences, BMS
Stock/Shareholder: Never
Consultant: No
Employee: Never
Other: Never
Panel Members

Co-infections

Chair: Massimo Puoti  Milan, Italy
Vice-Chair: Andri Rauch  Bern, Switzerland
Young scientist: Christoph Boesecke  Bonn, Germany
Juan Berenguer  Madrid, Spain
Sanjay Bhagani  London, United Kingdom
Raffaele Bruno  Pavia, Italy
Svilen Konov  London, United Kingdom
Karine Lacombe  Paris, France
Stefan Mauss  Düsseldorf, Germany
Luís Mendão  Lisbon, Portugal
Lars Peters  Copenhagen, Denmark
Jürgen K. Rockstroh  Bonn, Germany
Summary: HBV

• All persons with HBV/HIV co-infection should receive ART including TDF or TAF, unless history of tenofovir intolerance.

• Life-long therapy is recommended if anti-HBV nucleos(t)ides are given as part of ART.

• In case of non-response to HBV vaccinations, ART should contain TDF or TAF.

• Anti HBV treatment should be considered in selected pts undergoing immune suppression and immunosuppressive chemotherapy.
## Anti HBV treatment and Immune suppressive Tx or Chemotherapy (CTX)

<table>
<thead>
<tr>
<th>HBsAg</th>
<th>Add TDF/TAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti HBc+/anti HBs+</td>
<td>Add TDF/TAF</td>
</tr>
<tr>
<td>Monitoring with HBVDNA or HBsAg; if not possible add TDF/TAF</td>
<td></td>
</tr>
<tr>
<td>Anti HBs isolated not vaccinated</td>
<td>Monitoring for HBV reactivation</td>
</tr>
</tbody>
</table>

Severe immunosuppressive (CTX for Haem. Malignancy or SOT)  
Other immunosuppressive Tx (eg Rituximab, anti-TNF)
Summary: HCV

• Alternatively to HCV RNA HCV Ag could be performed in anti HCV+ to confirm chronic infection

• Evaluation of concurrent causes of liver disease and/or extra-hepatic HCV disease is mandatory in HCV infected patients

• Every person with HCV/HIV co-infection should be considered for interferon-free DAA therapy to eradicate HCV

• In HCV/HIV treatment indication and regimens are the same as in HCV mono-infected

• Immediate treatment of persons with acute or chronic hepatitis at high risk of transmission could be considered at diagnosis. IFN-free treatment with DAAs is recommended as in non-cirrhotic chronic HCV/HIV co-infection
### HCV Treatment Options in HCV/HIV Co-infected Persons

<table>
<thead>
<tr>
<th>HCV GT</th>
<th>Treatment regimen</th>
<th>Treatment duration &amp; RBV usage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Non-cirrhotic</td>
</tr>
<tr>
<td>1 &amp; 4</td>
<td>SOF + SMP +/- RBV</td>
<td>GT 4 only: 12 weeks with RBV or 24 weeks without RBV</td>
</tr>
<tr>
<td></td>
<td>SOF/LDV +/- RBV</td>
<td>8 weeks without RBV or 12 weeks +/- RBV</td>
</tr>
<tr>
<td></td>
<td>SOF + DCV +/- RBV</td>
<td>12 weeks +/- RBV</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL/VOX</td>
<td>8 weeks</td>
</tr>
<tr>
<td></td>
<td>OBV/PTV/r + DSV</td>
<td>8 weeks in GT 1b</td>
</tr>
<tr>
<td></td>
<td>OBV/PTV/r + DSV + RBV</td>
<td>12 weeks in GT 1a</td>
</tr>
<tr>
<td></td>
<td>OBV/PTV/r + RBV</td>
<td>12 weeks in GT 4</td>
</tr>
<tr>
<td></td>
<td>EBR/GZR</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>GLR/PIB</td>
<td>8 weeks</td>
</tr>
<tr>
<td>2</td>
<td>SOF + DCV</td>
<td>8 weeks</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL/VOX</td>
<td>8 weeks</td>
</tr>
<tr>
<td></td>
<td>GLR/PIB</td>
<td>8 weeks</td>
</tr>
<tr>
<td>3</td>
<td>SOF + DCV +/- RBV</td>
<td>12 weeks +/- RBV or 24 weeks without RBV</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL +/- RBV</td>
<td>12 weeks +/- RBV or 24 weeks without RBV</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL/VOX</td>
<td>8 weeks</td>
</tr>
<tr>
<td></td>
<td>GLR/PIB</td>
<td>8 weeks</td>
</tr>
<tr>
<td>5 &amp; 6</td>
<td>SOF/LDV +/- RBV</td>
<td>12 weeks +/- RBV or 24 weeks without RBV</td>
</tr>
<tr>
<td></td>
<td>SOF + DCV +/- RBV</td>
<td>12 weeks +/- RBV or 24 weeks without RBV</td>
</tr>
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<td></td>
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<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL/VOX</td>
<td>8 weeks</td>
</tr>
<tr>
<td></td>
<td>GLR/PIB</td>
<td>8 weeks</td>
</tr>
</tbody>
</table>
Re-treatment of DAAs failures

• At least 2 drugs active according to RASs testing

• New options
• SOF/VEL/VOX 12 weeks in NS5Ai and/or NS3i failures
• SOF + G/P 12 weeks in NS5Ai and/or NS3i failures
• G/P in SOF based Tx failures HCV G1,2,4-6 8 weeks in Non Cirrhotics 12 weeks in Cirrhotics and 16 weeks in HCV G3
Algorithm for Management of Acute HCV in Persons with HCV/HIV Co-infection

1. **Confirmed diagnosis of acute HCV**
   - Repeat HCV RNA Week 4
     - HCV RNA +ve < 2*log₁₀ reduction in VL
       - a) Treat with short duration DAAs
       - b) Enrol in clinical trial for AHC treatment
     - HCV RNA +ve
       - Repeat HCV RNA Week 12
       - HCV RNA -ve
         - Repeat HCV RNA at 24 weeks and 48 weeks to confirm spontaneous clearance
   - HCV RNA +ve > 2*log₁₀ reduction in VL
     - Early treatment of concomitant STI, see page 65

2. **Risk reduction programme**

EACS European AIDS Clinical Society
Part V: Opportunistic Infections Update

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Juan Ambrosioni, Young Scientist
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Hospital Clínic – IDIBAPS
University of Barcelona
Barcelona, Spain

E-mail address: jmmiro@ub.edu
Part V – Opportunistic Infections Panel

<table>
<thead>
<tr>
<th>Opportunistic Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chair:</strong> José M. Miro</td>
</tr>
<tr>
<td><strong>Vice-Chair:</strong> Ole Kirk</td>
</tr>
<tr>
<td><strong>Young scientist:</strong> Juan Ambrosioni</td>
</tr>
<tr>
<td>Paola Cinque</td>
</tr>
<tr>
<td>Gerd Fätkenheuer</td>
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<tr>
<td>Hansjakob Furrer</td>
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<tr>
<td>Amanda Mocroft</td>
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<td>Philippe Morlat</td>
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<tr>
<td>Anton Pozniak</td>
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<tr>
<td>Alain Volny-Anne</td>
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<tr>
<td><strong>Barcelona, Spain</strong></td>
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<td><strong>Copenhagen, Denmark</strong></td>
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<td><strong>Barcelona, Spain</strong></td>
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<tr>
<td><strong>Milan, Italy</strong></td>
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<td><strong>Bern, Switzerland</strong></td>
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<td><strong>London, United Kingdom</strong></td>
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<td><strong>Bordeaux, France</strong></td>
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<tr>
<td><strong>London, United Kingdom</strong></td>
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<tr>
<td><strong>Paris, France</strong></td>
</tr>
</tbody>
</table>

Special thanks to Tschabi and Valentin Gisler (Bern, Switzerland)
Presenter Disclosure Information

In compliance with the Conflict of Interest Policies, the European AIDS Clinical Society (EACS) requires the following disclosure from the presenters:

Jose M. Miro MD PhD

Research Support: Angelini, Abbvie, BMS, Cubist, Gilead, MSD, Novartis, Pfizer, Theravance, ViiV Healthcare
Speaker’s Bureau: None
Board Member/Advisory Panel: Genentech, Medtronic
Stock/Shareholder: Never
Consultant: None
Employee: Never
Other: Never
Part V – Opportunistic Infections

**Toxoplasma gondii Encephalitis**

A comment was added for TMP-SMX as preferred therapy for *T. gondii* encephalitis when the oral route is not available.
Part V – Opportunistic Infections

Cryptococcal meningitis

In severely immunosuppressed patients (<50 CD4 cells/µL) primary prophylaxis including INH 12 weeks, fluconazole 100mg/d 12 weeks, azithromycin 500mg/d 5 days and albendazole 400mg single dose (in addition to TMP-SMX) may decrease overall opportunistic infections (including cryptococcal meningitis) and mortality.

Add fluconazole to liposomal amphotericin B during the induction phase for cryptococcal meningitis treatment, in countries were fluycytosine is not available.

Reality Trial Team. NEJM. 2017;377:233-245
### Part V – Opportunistic Infections

**Treatment of TB in HIV-positive Persons**

**Preventing TB-IRIS on ART**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Drug</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susceptible <em>Mycobacterium tuberculosis</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>rifampicin</td>
<td>Weight based</td>
<td>Initial phase for 2 months, then Continuation phase (rifampicin + isoniazid) according to TB type (see below) Possibility to omit ethambutol, if <em>M. tuberculosis</em> is known to be fully drug sensitive</td>
</tr>
<tr>
<td></td>
<td>+ isoniazid</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>+ pyrazinamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>+ ethambutol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Alternative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>rifabutin</td>
<td>Weight based</td>
<td>Continuation phase according to TB type (see below) Possibility to omit ethambutol, if <em>M. tuberculosis</em> is known to be fully drug sensitive</td>
</tr>
<tr>
<td></td>
<td>+ isoniazid</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>+ pyrazinamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>+ ethambutol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Continuation phase</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>rifampicin/rifabutin</td>
<td></td>
<td>Total duration of therapy: 1. Pulmonary, drug susceptible TB: 5 months 2. Pulmonary TB &amp; positive culture at 8 weeks of TB treatment: 9 months 3. Extra-pulmonary TB with CNS involvement or disseminated TB: 9-12 months 4. Extra-pulmonary TB with bone/joint in-</td>
</tr>
<tr>
<td></td>
<td>+ isoniazid</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Intermittent regimens (2 or 3 times per week) are contraindicated in HIV-positive persons.*

A comment on the possibility to add steroid therapy to avoid IRIS in patients with TB on ART was added.

Part V – Opportunistic Infections

Treatment of MDR/XDR TB in HIV-positive Persons

INH-resistant TB

- RIF or RFB + Z+ E for 2 months and RIF or RFB + E for 10 months

Some experts recommend to add a FQ in the intensive phase and replace E by the FQ in the maintenance phase.

Each dose of MDR/XDR-TB regimen should be given as DOT throughout the whole treatment.

- In persons with rifampicin-resistant or MDR-TB, a regimen with at least five effective TB medicines during the intensive phase is recommended, including pyrazinamide and four core second-line TB medicines - one chosen from group A, one from group B, and at least two from group C.
- If the minimum of effective TB medicines cannot be composed as above, an agent from group D2 and other agents from D3 may be added to bring the total to five.
- In persons with rifampicin-resistant or MDR-TB, it is recommended that the regimen be further strengthened with high-dose isoniazid and/or ethambutol.

Preliminary results of a recent RCT (Nix-TB trial) suggest that a 3-drug combination of pretomanid 200 mg/cay, becaquiline 200 mg tiw after a 3-week load, and linezolid 1200 mg/day during 6 months (3 additional months if culture positive at 4th month) may be at least as effective as the 5-drug regimens suggested above. Majority of cases included were pulmonary TB.

Duration of MDR/XDR treatment

- 8 months of intensive phase using 5 or more drugs, followed by 12 months of 3 drugs depending on response.
- E.g. 8 months of Z, MFX, Km, OFX, PTO and CS, followed by 12 months of MFX, PTO and CS.
- In persons with rifampicin-resistant or MDR-TB who have not been previously treated with second-line drugs and in whom resistance to fluoroquinolones and second-line injectable agents has been excluded or is considered highly unlikely, a shorter MDR-TB regimen of 9-12 months may be used instead of a conventional regimen.

Drug interactions with ART and MDR/XDR regimens

Unless RFB is being used, use normal doses but with caution as few data are available on potential drug interactions, see ART in TB/HIV Co-infection

The preliminary results of the Nix-TB trial were added in the section of treatment for resistant TB (MDR/XRD-TB)

Conradie F et al. Nix TB Trial. CROI; 2017. Abstract #80LB
Part V – Opportunistic Infections

Treatment of LTBI in HIV-positive Persons

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid 5 mg/kg/day (max 300 mg) po</td>
<td>6-9 months for latent TB treatment</td>
</tr>
<tr>
<td>+ Pyridoxine (Vit B6) 25 mg/day po</td>
<td>Consider high-prevalence settings</td>
</tr>
<tr>
<td>Rifampicin 600 mg/day po or rifabutin po (dose according to current cART)</td>
<td>4 months, check interactions with ARVs, see Drug-drug Interactions between ARVs and Non-ARVs</td>
</tr>
<tr>
<td>+ Isoniazid 5 mg/kg/day (max 300 mg) po</td>
<td>3 months, check interactions with ARVs, see Drug-drug Interactions between ARVs and Non-ARVs</td>
</tr>
<tr>
<td>+ Pyridoxine (Vit B6) 25 mg/day po</td>
<td></td>
</tr>
<tr>
<td>Rifampicin 600 mg 2 x/week po + Isoniazid 900 mg 2 x/week po + Pyridoxine (Vit B6) 300 mg 1 x/week po</td>
<td>3 months, check interactions with ARVs, see Drug-drug Interactions between ARVs and Non-ARVs</td>
</tr>
</tbody>
</table>

A duration of 9-months for latent TB treatment was stressed, particularly in countries with high TB prevalence.

A comment was added explaining that other preventive regimens are needed for treating latent infection with MDR/XDR-TB in countries with high resistant TB rates.

*Other preventive regimens may be considered if high risk of latent infection with MDR/XDR-TB.
Part V – Opportunistic Infections

Thank you!
Drug-drug interactions
Disclosure Information

Research Support: Janssen
Educational support: Janssen, Gilead, AbbVie, Merck
Speaker’s Bureau: Never
Board Member/Advisory Panel: Janssen, Gilead
Stock/Shareholder: Never
Consultant: Never
Employee: Never
Organization of the information on DDIs

DDIs for commonly prescribed co-medications and of particular clinical relevance

- Drug-drug interactions between ARVs and Non-ARVs

DDIs within a given therapeutic area

- Drug-drug interactions between **Antidepressants** and ARVs
- Drug-drug interactions between **Antihypertensives** and ARVs
- Drug-drug interactions between **Analgesics** and ARVs
- Drug-drug interactions between **Anticoagulants/antiplatelets agents** and ARVs
- Drug-drug interactions between **Bronchodilatators (for COPD)** and ARVs  
  New
- Drug-drug interactions between **Contraceptives** and ARVs
- Drug-drug interactions between **Corticosteroids** and ARVs
- Drug-drug interactions between **Antimalarial drugs** and ARVs  
  New
- Drug-drug interactions between **Pulmonary Antihypertensives** and ARVs  
  New
- Drug-drug interactions between **Immunosuppressants (for SOT)** and ARVs  
  New
- Drug-drug interactions between **DAAs** and ARVs
Format of DDIs tables

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**Legend**
- potential elevated exposure of the bronchodilator
- potential decreased exposure of the bronchodilator
- no significant effect
- potential decreased exposure of ARV drug
- potential elevated exposure of ARV drug

**Colour legend**
- no clinically significant interaction expected
- these drugs should not be co-administered
- potential clinically significant interaction that is likely to require additional monitoring, alteration of drug dosage or timing of administration
- potential interaction likely to be of weak intensity. Additional action/monitoring or dosage adjustment is unlikely to be required
Assessment of DDI potential and clinical relevance

### Step 1: evaluation of likelihood of having DDI
- PK/PD characteristics of coadministered drugs
- clinical DDI studies
- case reports

Evidence that DDI may occur

### Step 2: evaluation of clinical relevance
- magnitude of PK change
- therapeutic index
- possibility to monitor the drug effect
- recommendation on dose adjustment
- length of treatment required

+ recommendations of product label

No DDI
- different elimination pathways
- no significant PK change
- no safety concern
Highlights on DDIs in the revised version

DDIs with anticoagulants

- **cobicistat** has no inducing properties but **ritonavir** does
  - dosage adjustments of co-medications might be needed when switching PK booster

www.hiv-druginteractions.org, Marzolini C et al. JAC 2016
## Highlights on DDIs in the revised version

### Drug interactions between hormonal contraceptives and antiretrovirals

**Kavita Nanda³, Gretchen S. Stuart⁴, Jennifer Robinson⁵, Andrew L. Gray⁶, Naomi K. Tepper⁷ and Mary E. Gaffield⁸**

**AIDS 2017**

#### DDI with contraceptives

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**Contraceptive methods:**
- COC combined oral contraceptive
- IP implant
- IUD intrauterine device
- POI progestin only injectable
- POP progestin only pill
- TS transdermal patch
- VR vaginal ring
- EC emergency contraception

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*Interaction likely to be of weak intensity or unlikely to impair contraceptive efficacy*
Tables are linked to DDIs websites

www.hiv-druginteractions.org
www.hep-druginteractions.org

1 selection of drugs

2 detailed information on DDI

+ DDI documents related to specific topics (DDI with PrEP; DDI and PK boosters; DDI with hormones for gender transitioning, DDI with non-oral corticosteroids and management of suspected DDI, …)
Prescribing in the elderly

- **Age related co-morbidities** ➔ *polypharmacy*
- **Age related physiological changes** ➔ *impact pharmacokinetic (PK)/pharmacodynamic (PD) effects of drugs*

**Drug-drug interactions (DDI)**
- **Inappropriate drug/dosage use**

- ↑ risk of adverse drug reactions; nonadherence; cognitive impairment; impaired balance and falls; morbidity and hospitalisation

---

Perform periodic medicines reviews

**Questions to consider when reviewing a prescription**

- Is there an indication for the medicine?
- Is this medicine appropriate for elderly people?
- Is the dose correct (e.g. adjusted for the renal function)?
- Is there a significant drug-drug interaction?
- Is there a significant drug-disease interaction (e.g. delirium)?
- Is the duration of treatment acceptable?
- Is there any missing medicine?
- Is the person able to manage his/her own medicines or does he/she need assistance?

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Check for DDI with HIV drugs: [http://www.hiv-druginteractions.org](http://www.hiv-druginteractions.org)

Check for inappropriate drugs use: Beers and STOPP/START criteria

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The Beers and STOPP criteria are tools established by experts in geriatric pharmacotherapy to detect and reduce the burden of inappropriate prescribing in elderly. Inappropriate medicines include, for instance, those which in elderly persons with certain diseases can lead to drug-disease interactions, are associated with a higher risk of adverse drug reactions in the elderly, medicines that predictably increase the risk of falls in the elderly or those to be avoided in case of organ dysfunction. The START criteria consist of evidence-based indicators of potential prescribing omission in elderly with specific medical conditions.
## Acknowledgements

### EACS panel members

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<tr>
<th>Co-morbidities</th>
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### Liverpool HIV/HEP Drug Interactions websites team

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