PrEP strategies

Moderator: Fiona Mulcahy, Ireland

Christoph Spinner, Germany
Laura Waters, UK

HIV PrEP: State of the ART
The Next Generation in HIV Prevention

Christoph D. Spinner

Munich - Germany

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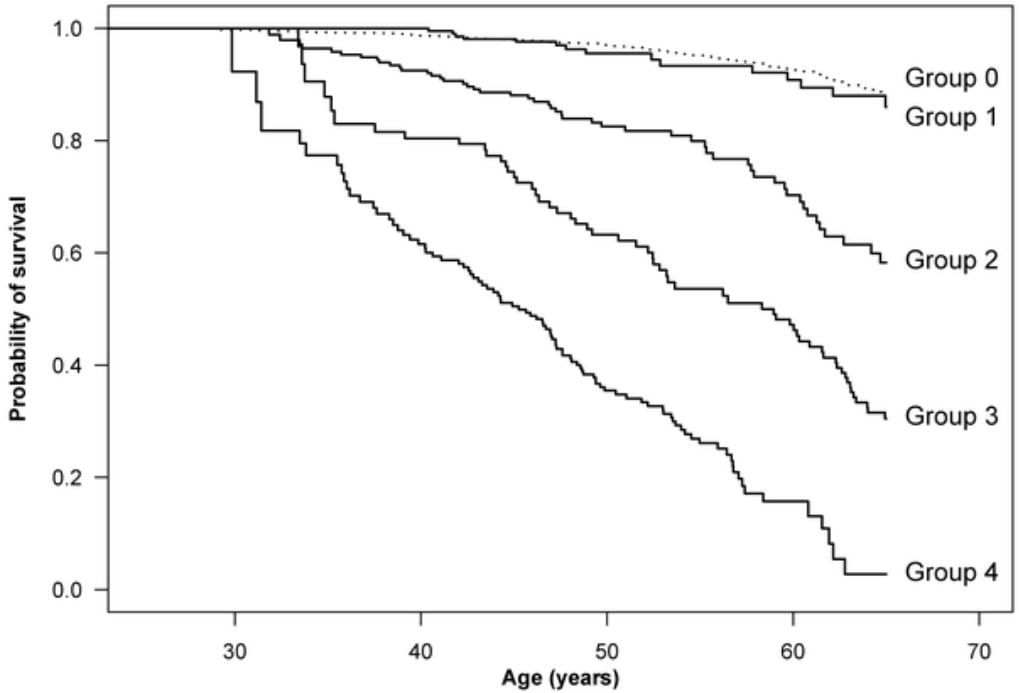
Normalization in HIV Life expectancy due to ART



Population Control

(-VL < 49, CD4 > 200) –Comorb. No alcohol/drug consumption

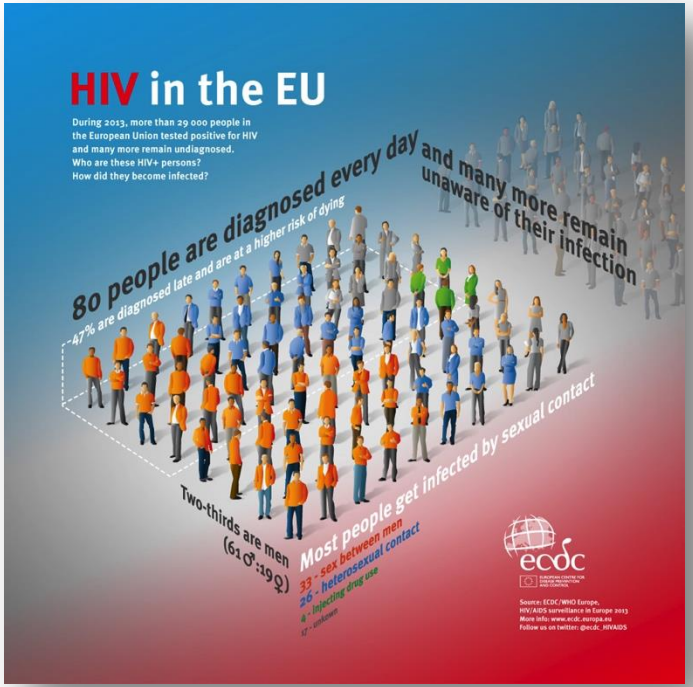
(-VL > 49, CD4 > 200) –Comorb. No alcohol/drug consumption

(-VL > 49, CD4 < 200) +Comorb. No alcohol/drug consumption

(-VL > 49, CD4 < 200) +Comorb. alcohol/drug consumption

Obel L *et al. PLoS One.* 2011;6(7):e22698

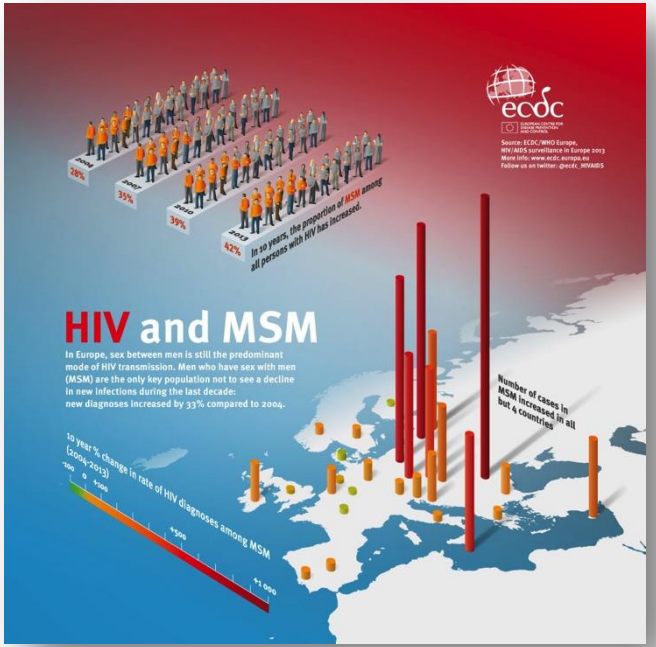
EU surveillance data



http://ecdc.europa.eu/en/healthtopics/aids/Pages/infographics.aspx

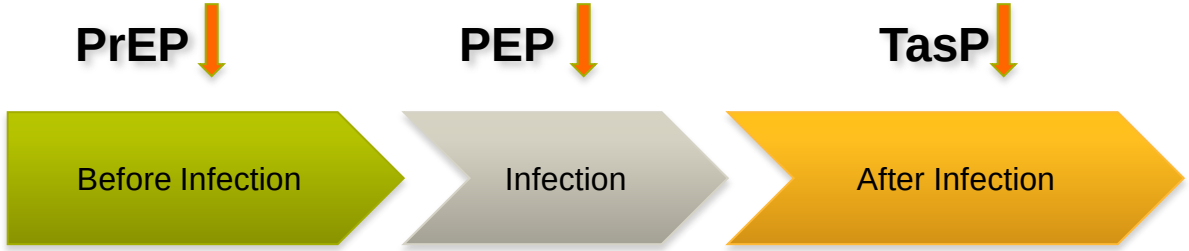
EU surveillance data

- MSM predominant transmission



http://ecdc.europa.eu/en/healthtopics/aids/Pages/infographics.aspx

HIV prevention: current perspectives



Advantage
- Efficacy

Challenges
- Adherence
- Care
- Costs
- Evolution of resistance

Advantage
- Short duration

Challenges
- Lack of data
- Risk assessment
- Short window of opportunity
- Adherence

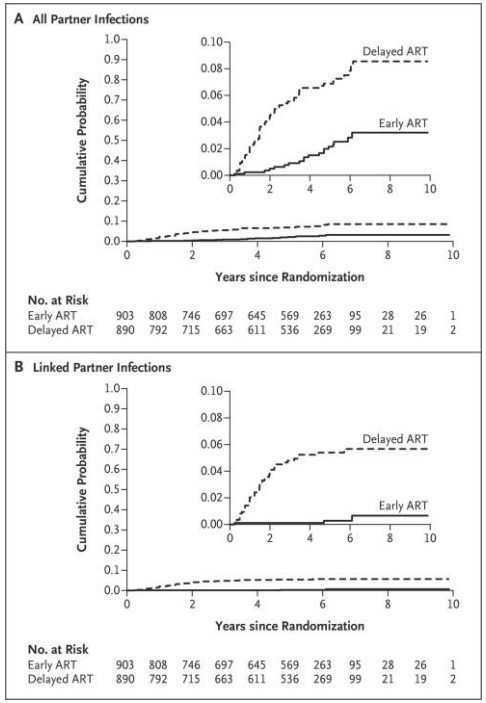
Advantages
- Reduction in mortality and morbidity
- Reduced infectious

Challenges
- Distribution of ART
- Long-term adherence
- Long-term toxicity
- Evolution of resistance

HPTN052: Treatment as prevention works

Table 2. Characteristics of Eight Linked Partner Infections Diagnosed after the Index Participant Initiated ART.*

Case	Age at ART Initiation		Index Viral Suppression 6 Mo after ART Initiation†	No. of Days before or after ART Initiation‡				No. of Days between Last Measure of Index Viral Load and Estimated Infection Date	Last Index Viral Load before Estimated Infection Date
	Index Participant	Partner		ART Failure§	Partner's Last Negative HIV-1 Test	Partner's First Positive HIV-1 Test	Estimated Infection Date (95% CI)¶		
	yr								copies/ml
A	43	52	Yes	NA	−35	35	−5 (−18 to 10)	34	278,398
B	24	24	Yes	NA	−1	84	0 (−32 to 19)	1	87,202
C	50	54	Yes	NA	0	59	5 (−4 to 22)	5	48,316
D	34	34	No	261	−42	49	4	4	>750,000
E	25	29	No	208	1019	1106	1062	43	65,128
F	30	22	Yes	441	1617	1716	1667	50	617
G	46	26	No	362	2095	2228	2162	67	43,486
H	28	19	No	891	860	1419	1140	ND‖	ND‖



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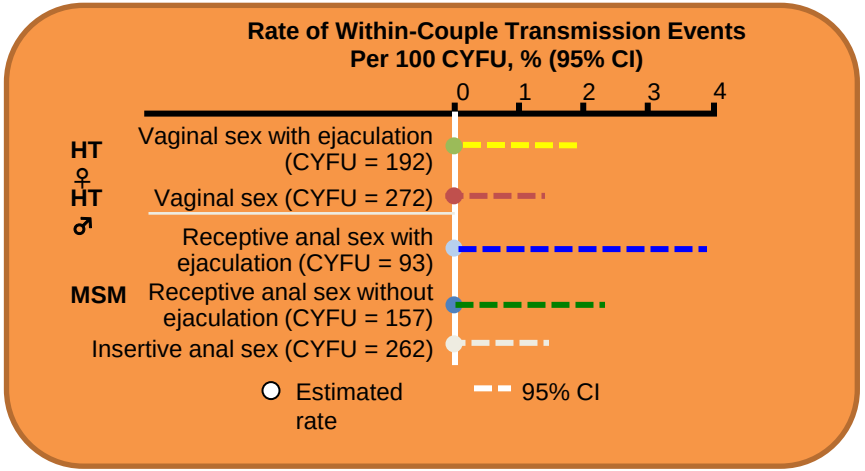
Cohen, *et al, N Engl J Med*. 2016 Sep 1;375(9):830-9.

HIV PARTNERS STUDY: “TasP works”

- Observational study of HIV transmission with serodiscordant couples (N = 767 couples)
  - HIV+ Partner with supp. ART
  - No condom use
- Analysis: 6-monthly risk questionnaire, HIV-1 RNA (HIV+ subjects), HIV-Test (HIV-negative subjects)

Result: No phylogenetic confirmed HIV transmission



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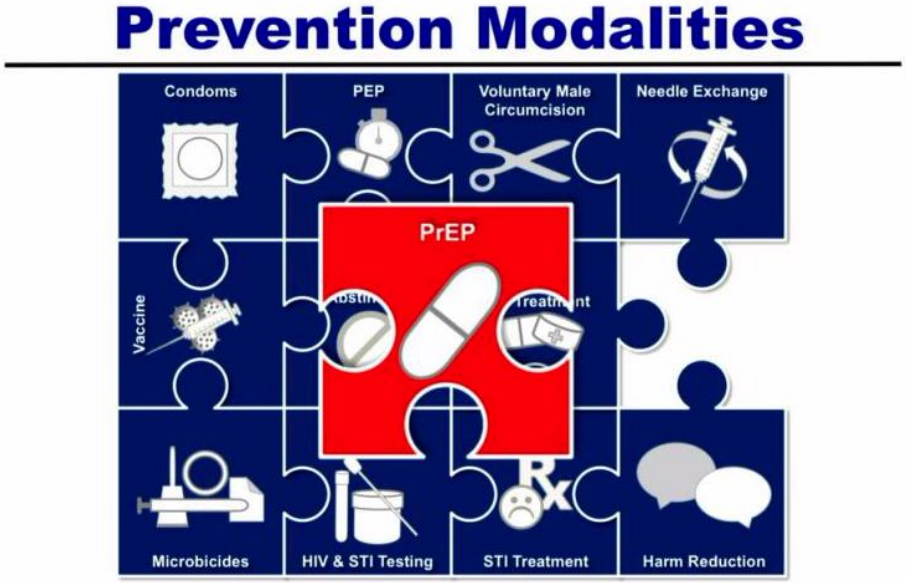
Rodger A *et al. CROI* 2014. Abstract 153LB

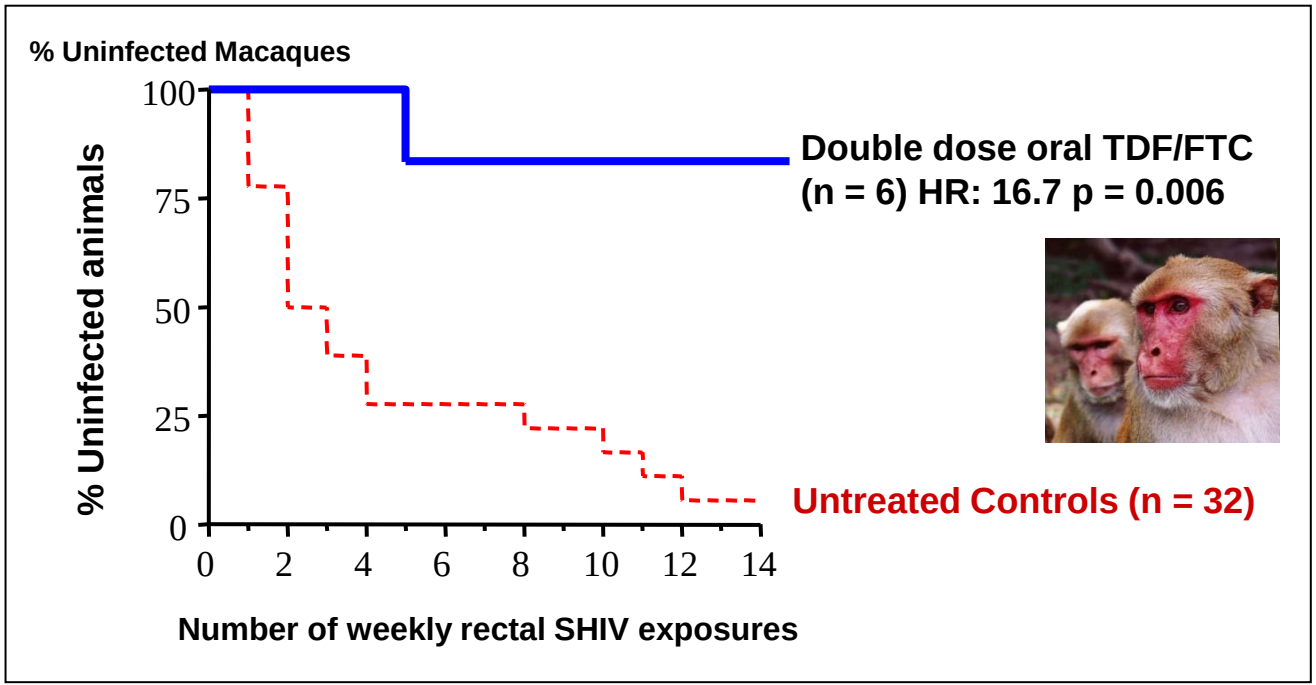
HIV prevention

PrEP as a raising option



Landowitz R *et al. CROI* 2015

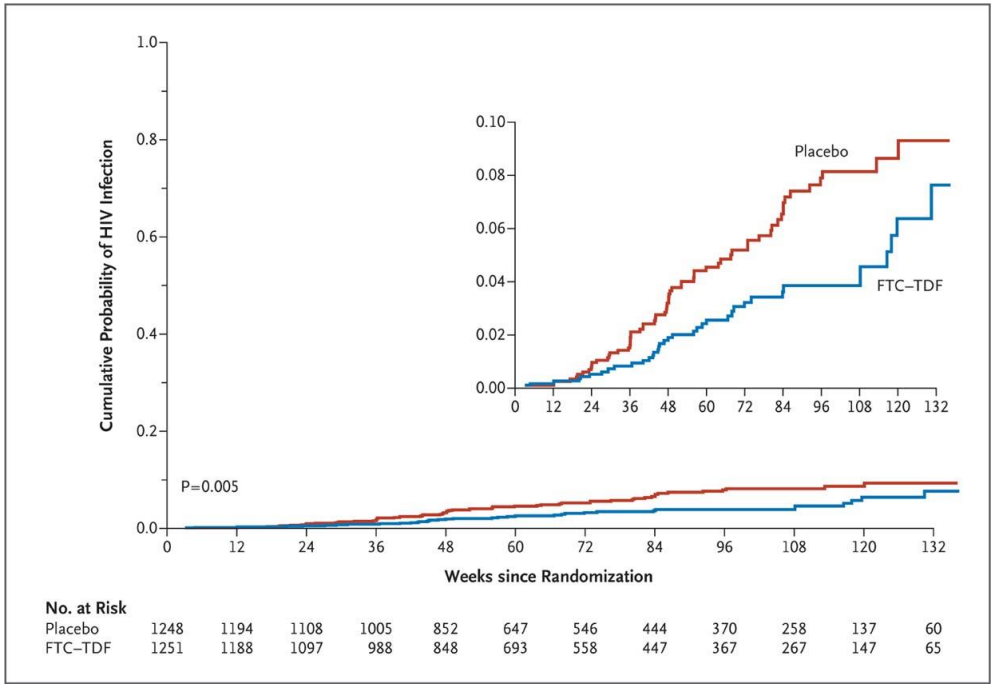
Effective TDF/FTC-PrEP in animal models



Garcia-Lerma JG *et al. Sci Transl Med.* 2010 Jan 13;2(14):14ra4

iPrEx Study

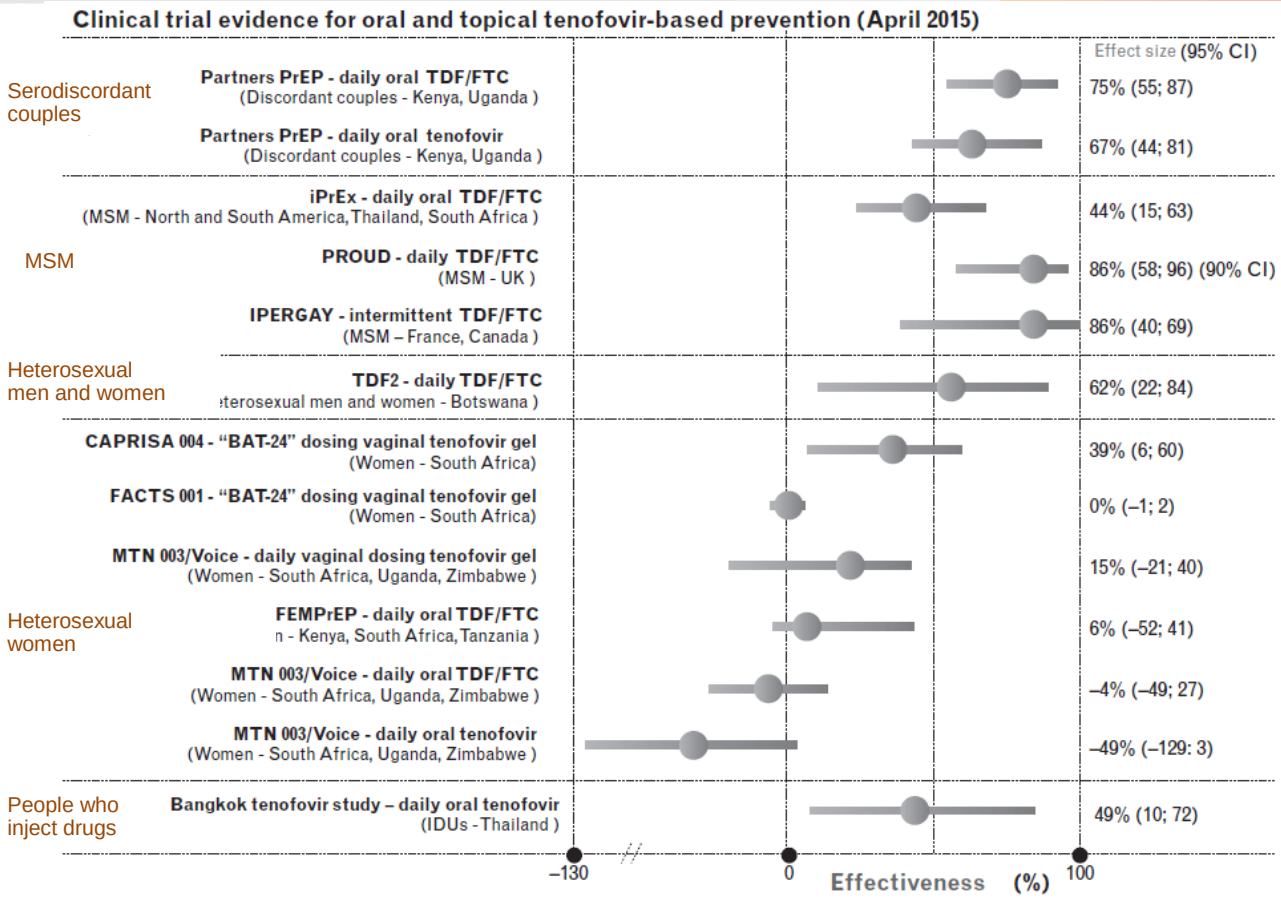
HIV prevention with continuously F/TDF PrEP



42% Risk reduction

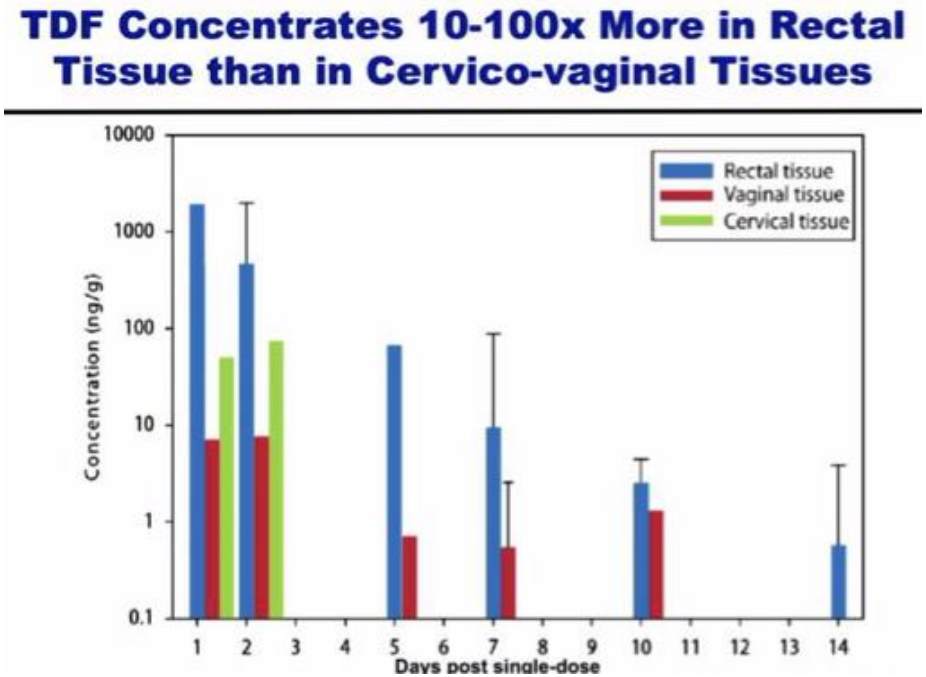
Grant RM *et al. N Engl J Med* 2010;363:2587-2599

PrEP efficacy in different studies



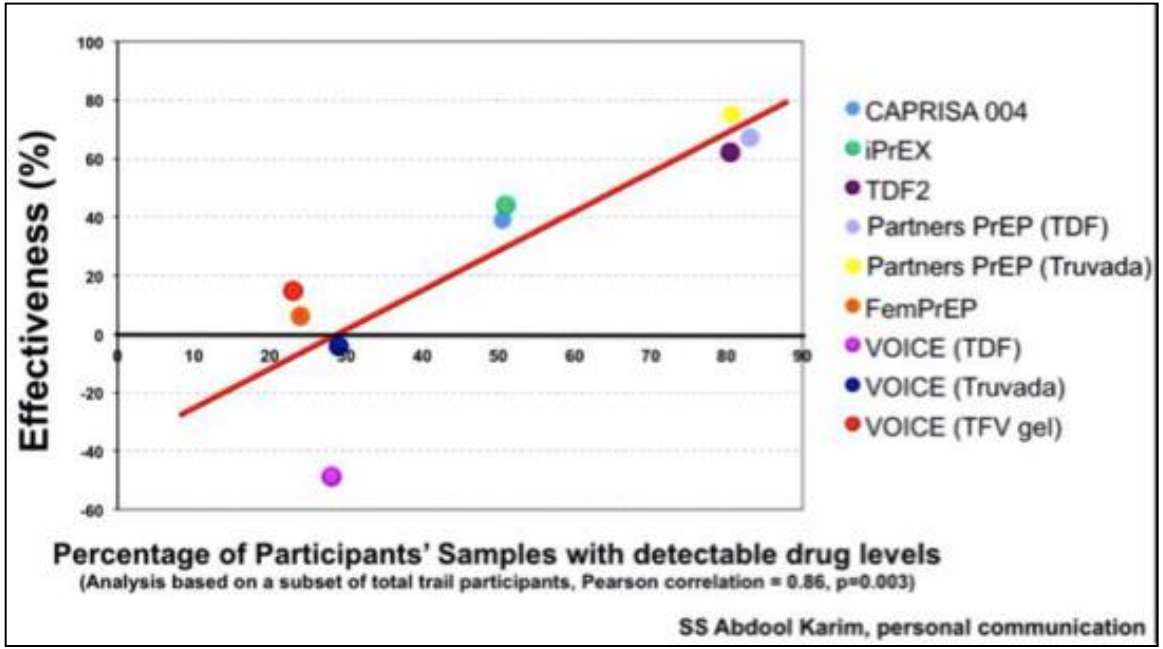
Mayer, KH, *et al. Curr Opin HIV AIDS*. 2015;10:226-232. Modified from AVAC Report. 2013.

PrEP efficacy and tissue penetration



Landowitz R *et al. CROI* 2015

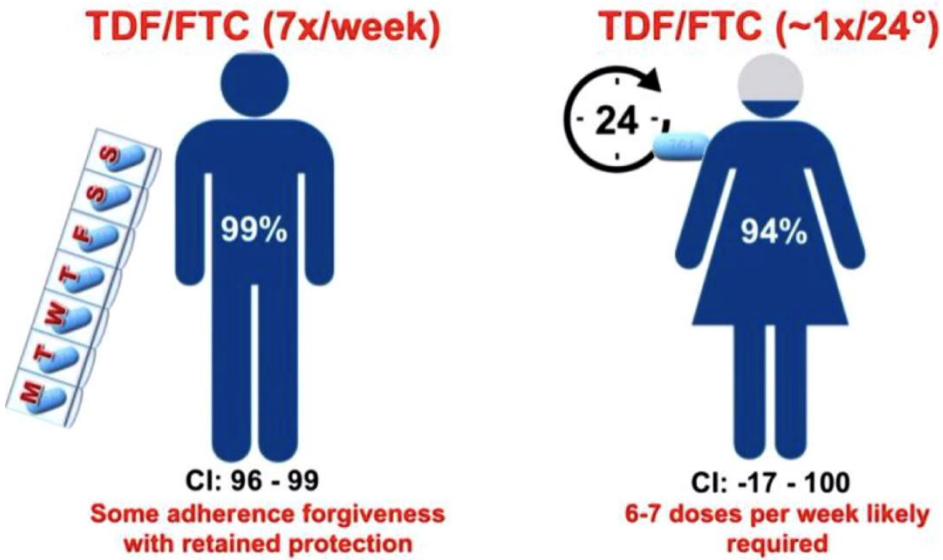
PrEP efficacy and dosing / adherence



Landowitz R *et al. CROI* 2015

PrEP efficacy

Increased efficacy with optimized adherence



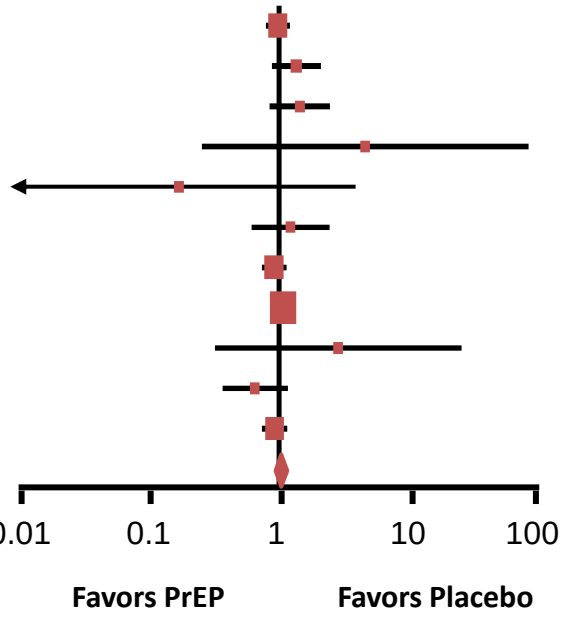
Landowitz R *et al. CROI* 2015

PrEP is well tolerated: Low discontinuations due to AE

Study Name	Subgroup Within Study	Comparison	Risk Ratio	Lower Limit	Upper Limit	Z-Value	*P* Value
BKK TDF Study	Men and women	Daily PrEP vs PBO	0.979	0.797	1.203	-0.202	.840
CDC Safety Study	MSM	Daily PrEP vs PBO	1.357	0.890	2.069	1.420	.155
FEM-PrEP	Women	Daily PrEP vs PBO	1.446	0.855	2.445	1.376	.169
IAVI Kenya Study	MSM and FSW	Multiple PrEP dosing	4.592	0.257	81.944	1.037	.300
IAVI Uganda Study	Men and women	Multiple PrEP	0.170	0.007	4.025	-1.097	.272
Ipergay	MSM	Intermittent PrEP	1.226	0.622	2.420	0.589	.556
iPrEx	MSM and TG	Daily PrEP vs PBO	0.919	0.747	1.129	-0.806	.420
Partners PrEP-Main	Men and women	Daily PrEP vs PBO	1.077	0.954	1.215	1.194	.233
Project PrEPare	MSM	Daily PrEP vs PBO	2.850	0.324	25.069	0.944	.345
TDF2	Men and women	Daily PrEP vs PBO	0.652	0.370	1.150	-1.477	.140
VOICE	Women-all PrEP	Daily PrEP vs PBO	0.925	0.746	1.147	-0.713	.476
			1.016	0.916	1.127	0.305	.760

Statistics for each study

Risk Ratio and 95% CI



- No difference in proportion of participants reporting any AE (RR: 1.01; 95% CI: 0.99-1.03, *P* = .27) or any grade 3/4 AE in PrEP vs placebo arms
- Several studies noted subclinical declines in renal functioning and BMD among PrEP users

WHO. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV

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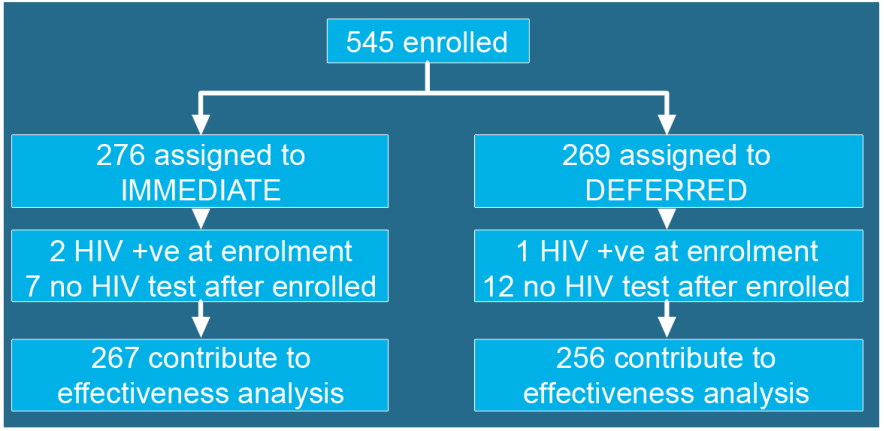
UK: PROUD study

PROUD

European PrEP pilot study

- 545 MSM at 13 “sexual health clinics“ in UK
- Key inclusion criteria: unprotected anal intercourse w/ last 90 days and no F/TDF contraindication
- Randomized immediate PrEP *vs* delayed PrEP after 12 months
- PrEP arm: F/TDF daily



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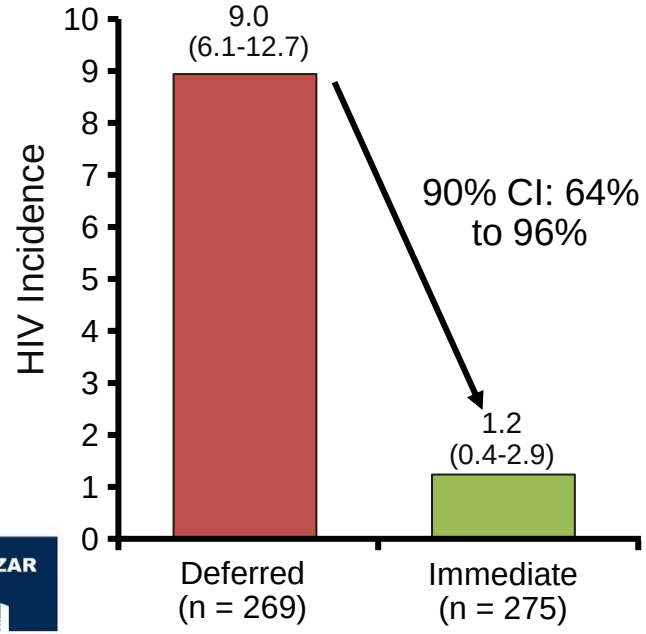
McCormack S *et al. CROI* 2015 #22LB

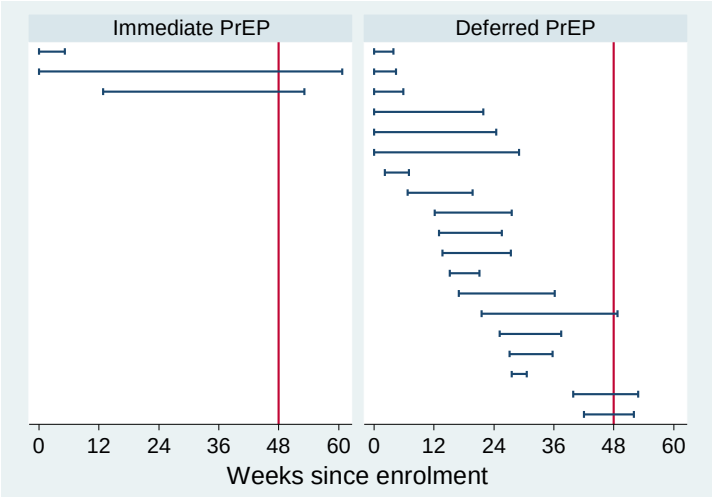
UK: PROUD study

PROUD

Significant more HIV new infections in the delayed arm



- Total HIV incidence: 4.9/100 pt-years
- 86% Risk reduction; p=0.0002
- 13 MSM need PrEP for 1 year to avoid 1 new infection; (NNT=13)



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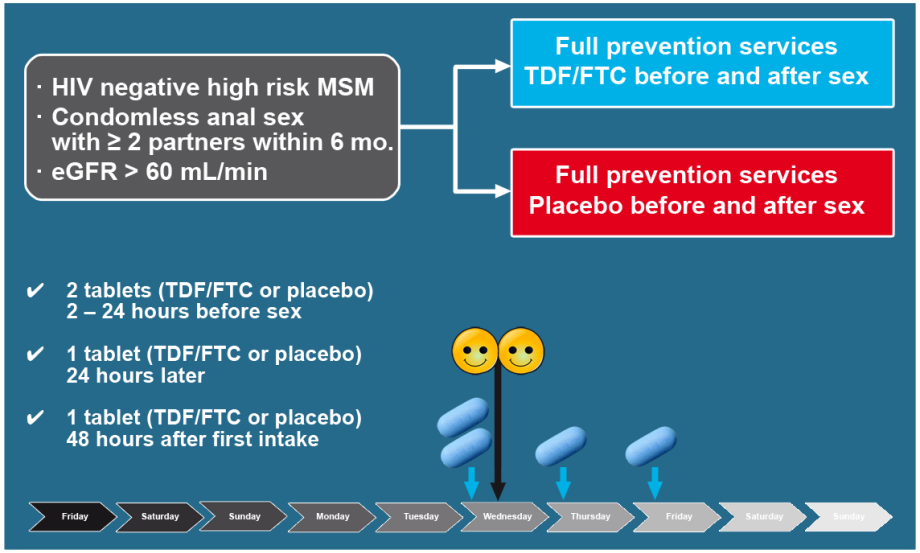
McCormack S *et al. CROI* 2015 #22LB

IPERGAY – Event-driven PrEP

Optimized adherence with event-driven PrEP?

- "Event driven PrEP" with 414 high-risk MSM in France and Canada
- Intervention: "on demand" PrEP F/TDF *vs* placebo, double-blind

ipergay
ANRS
Intervention Préventive de l'Exposition aux Risques avec et pour les Gays



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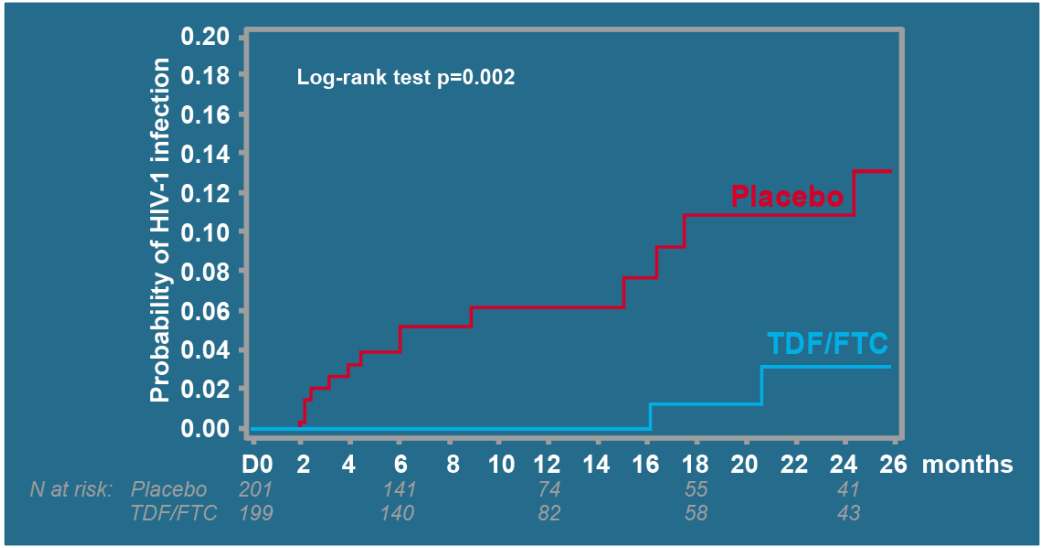
Molina JM *et al. CROI* 2015 #23LB

IPERGAY: 86% risk reduction with event-driven PrEP



ipergay ANRS Intervention Préventive de l'Exposition aux Risques avec et pour les Gays

- Interruption after DSMB decision after median follow-up of 13 months
- 16 HIV infections: 14 HIV+ im placebo arm *vs* 2 HIV+ in PrEP arm
- 18 MSM need to be "PrEPed" for 1 year to avoid one infection (NNT=18)

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Molina JM *et al. CROI* 2015 #23LB

PrEP cost effective model in the Netherlands

THE LANCET Infectious Diseases

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Articles

Cost-effectiveness analysis of pre-exposure prophylaxis for HIV-1 prevention in the Netherlands: a mathematical modelling study

Dr Brooke E Nichols, PhD, Prof Charles A B Boucher, PhD, Marc van der Valk, PhD, Bart J A Rijnders, PhD, David A M C van de Vijver, PhD

Published: 22 September 2016

Model calculation for the Netherlands

- PrEP targeted to 10% sexually highly active MSM over 40 years
- 80% effectiveness and current PrEP pricing

Results

- PrEP can cost as 11,000 Euro per QALY (daily)
- PrEP can cost as little as 2,000 Euro per QALY (intermittant)

Conclusion

- 70% reduction for daily and 30% reduction for intermittant price of F/TDF PrEP required

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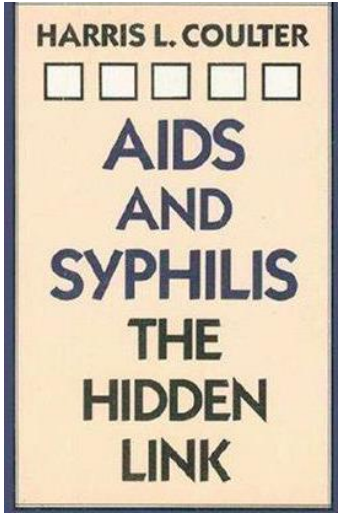
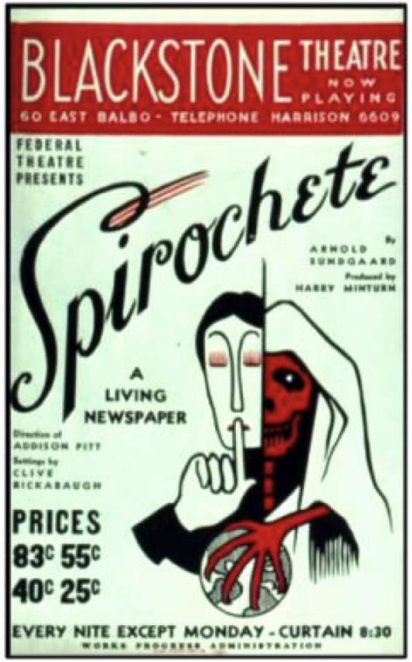
Nichols, Brooke *E et al. The Lancet Infectious Diseases*

PrEP perspectives

Raising STI rates?

- Gonorrhea
- Syphilis
- Chlamydia trachomatis
- Mycoplasma spp.
- Condyloma spp.





Resistance evolution?

Prep

- 43-yr-old MSM acquired multiclass resistant HIV-1 infection following 24 mos of oral once-daily TDF/FTC PrEP
- Pharmacy records, blood concentration analyses, and clinical history support recent and long-term adherence to PrEP
- PrEP failure likely result of exposure to PrEP-resistant, multiclass resistant HIV-1 strain

Drug Class	Mutations Detected on Day 7 Following p24-Positive Test	Estimated Fold-Change in IC_{50} or Change in Response (Drug)
NRTI	41L, 67G, 69D, 70R, 184V, 215E	1.9x (ABC), 61x (3TC), 38x (FTC), 1.3x (TDF)
NNRTI	181C	43x (NVP)
PI	10I	No relevant change
INSTI	51Y, 92Q	Reduced (RAL), resistant (EVG), reduced (DTG)

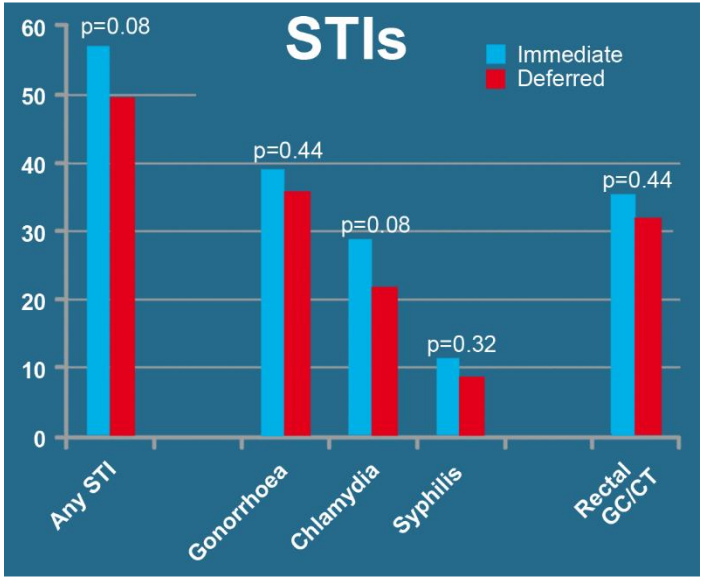
Knox DC, *et al. CROI* 2016. Abstract 169aLB.

PROUD study: High rates of STIs

PROUD

Adherence, STIs and PEP

- 5% “immediate Arm” never started PrEP
- 31% PEP use in “deferred arm”
- No change in sexual risk behavior during the entire study period



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McCormack S *et al. CROI* 2015 #22LB

IPERGAY study: High STI rates

ipergay ANRS Intervention Préventive de l'Exposition aux Risques avec et pour les Gays

STIs during Follow-up

	TDF/FTC n=199		Placebo n=201		P value
	Nb Pt (%)	Nb Events	Nb Pt (%)	Nb Events	
Chlamydia	43 (22)	61	34 (17)	48	0.23
Gonorrhoea	38 (19)	50	45 (22)	67	0.42
Syphilis	19 (10)	19	19 (10)	25	0.98
HCV	3 (<2)	3	3 (>2)	3	1.00
Any STI	76 (38)	133	65 (32)	143	0.22

- Baseline parameter
  - 35 years, >90% Caucasians, 40% intake of psychoactive drugs, 30% PrEP experience
- High-risk MSM
  - 8 sexual partners within the last 2 months
  - 10x sexual intercourse within last month, 70% w/o use condom

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Molina JM *et al. CROI* 2015 #23LB

PrEP – National German Data

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Dagnae study: www.prep-befragung.de

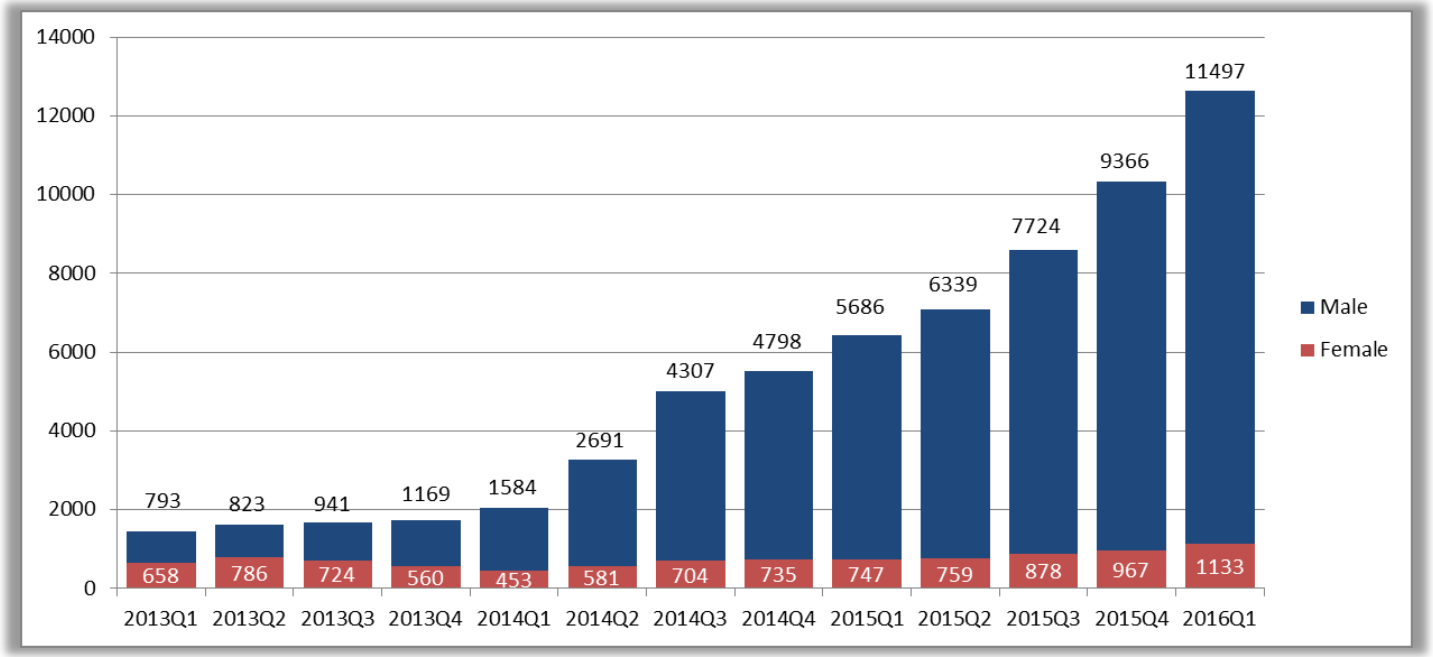
PrEP survey Germany

Online survey 01-06/2016:

- N=1.200 total; n=948 for analysis
- Overall PrEP acceptance 63% and 78% in HIV-negative MSM 25-39 years and last negative HIV-testing < 6 months and STI history
- 54% reported sexual risk situation < 6 months with recreational drug abuse and 2 or more partners
- 69% would use intermittent PrEP
- Almost 2/3 of all patients reimport and use PrEP outside regular medical prescribing

Dagnae study: www.prep-befragung.de

Unique Individuals Starting F/TDF for PrEP in US by Gender (1Q2013-1Q2016)



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Bush,S. *et al. HIV Drug Therapy* 2016; Glasgow, Scotland

PrEP licensed and reimbursed in Norway

PinkNews

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Norway to provide free HIV-preventing PrEP drugs to at-risk gay men

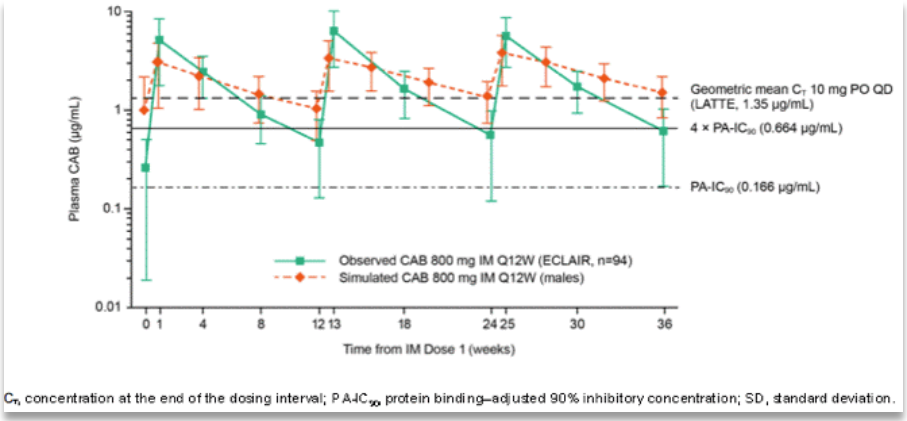
Nick Duffy

20th October 2016, 11:40 AM

Cabotegravir: 12-weekly i.m. injection?

Dosing schema in discussion

- ECLAIR study Cabotegravir LA (long acting Nano-suspension)
- 127 men with low-risk HIV 4:1 randomized (Phase IIa)
- 4 weeks oral lead-in (7 stops)
- IM phase: Tolerable (4 stops due to side-effects at injection side)
- Sub-therapeutic levels in up to 31% of all visits
- 2 Seroconversions, 1x in each arm with low CBT levels



C_T, concentration at the end of the dosing interval; PA-IC_{90}, protein binding–adjusted 90% inhibitory concentration; SD, standard deviation.

Markowitz M *et al. CROI* 2016 #106

Interdisziplinary HIV center at Klinikum rechts der Isar (IZAR), Munich, Germany

Klinikum rechts der Isar (MRI) der
Technischen Universität München (TUM)

- **IZAR-Team**
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  - Dr. Marcel Lee*
  - Prof. Dr. Claudia Traidl-Hoffmann
  - Dr. Antontia Todorova
  - Dr. Joram Ronel
  - Christiane Schwerdtfeger
  - Dr. Alexander Zink*

Ärztliches Team des **IZAR**

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*Not shown in the picture

PreP in Europe: experiences and availabilities

Laura Waters
Consultant in HIV and GU Medicine
Mortimer Market Centre, London - UK

Content

- Setting the scene
- European roll-out
- Country-level experience
- Uncertainties & limitations
- Guidelines & resources

SETTING THE SCENE

#PrEPWORKS

#TasPWORKS

Potential of TasP

- **Depends on the nature of the epidemic**
  - **UK MSM:** 82% of new infections from **undiagnosed** individuals[1]
  - **USA:** Almost 70% of new infections from **diagnosed** individuals not accessing ART[2]

1. Phillips AN *et al. PLoS One*. 2013;8(2):e55312
2. Fauci. HIV Drug Therapy, Glasgow 2016

#TasPWORKS*

*On an individual level ✓

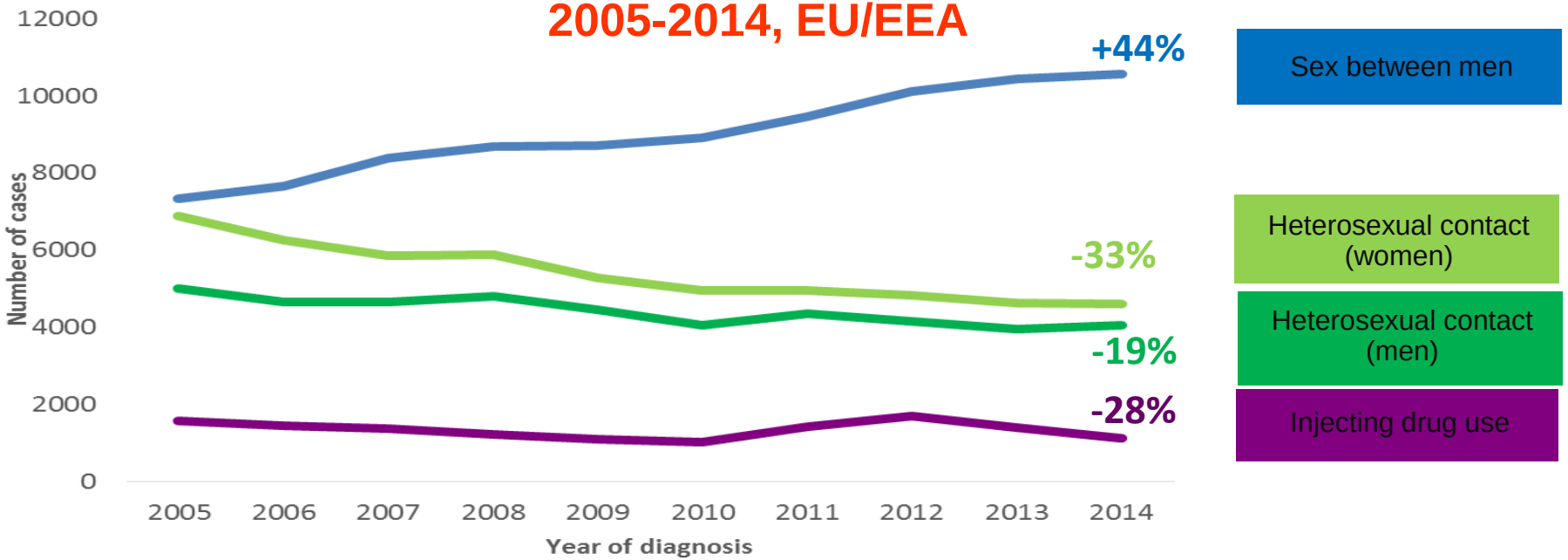
*Population level if most new infections from diagnosed ✓

*Population level if most new infections from diagnosed ✗

#CondomsWORK

HIV diagnoses, by mode of transmission

2005-2014, EU/EEA

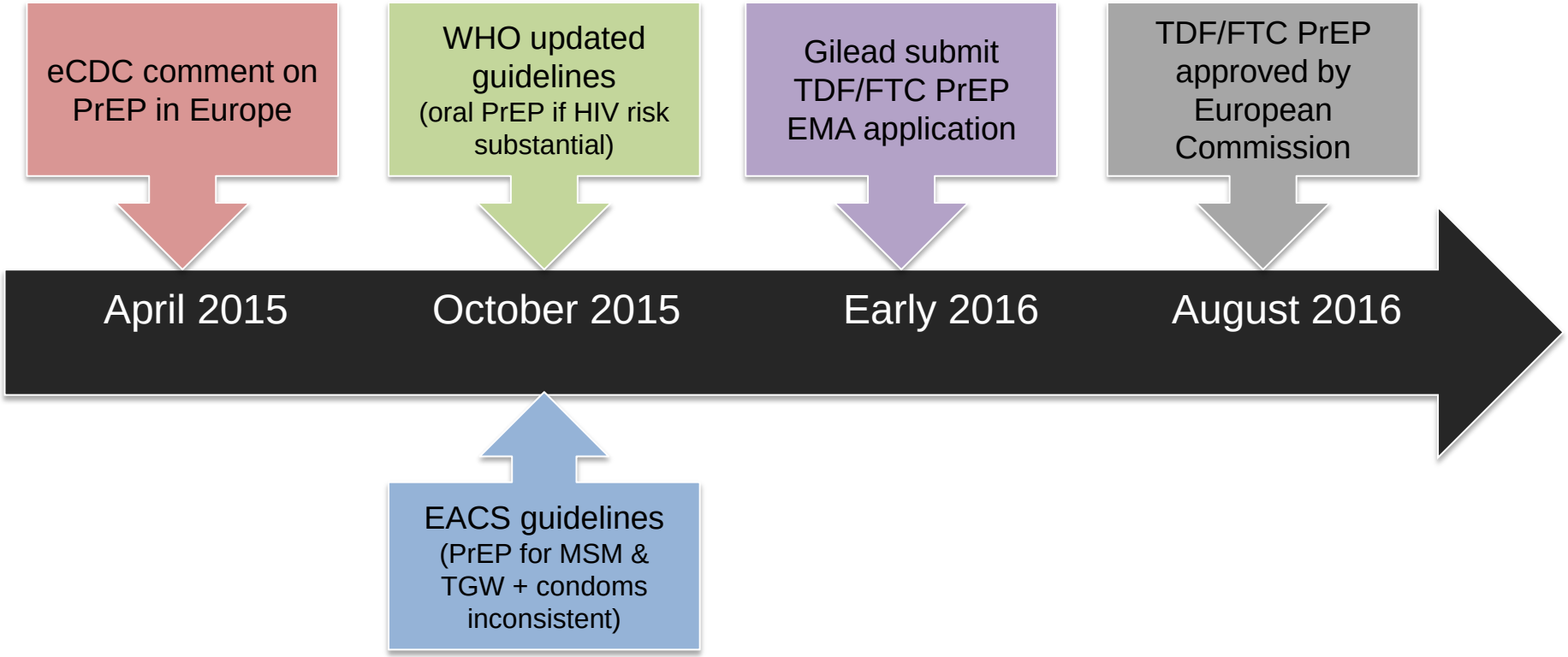


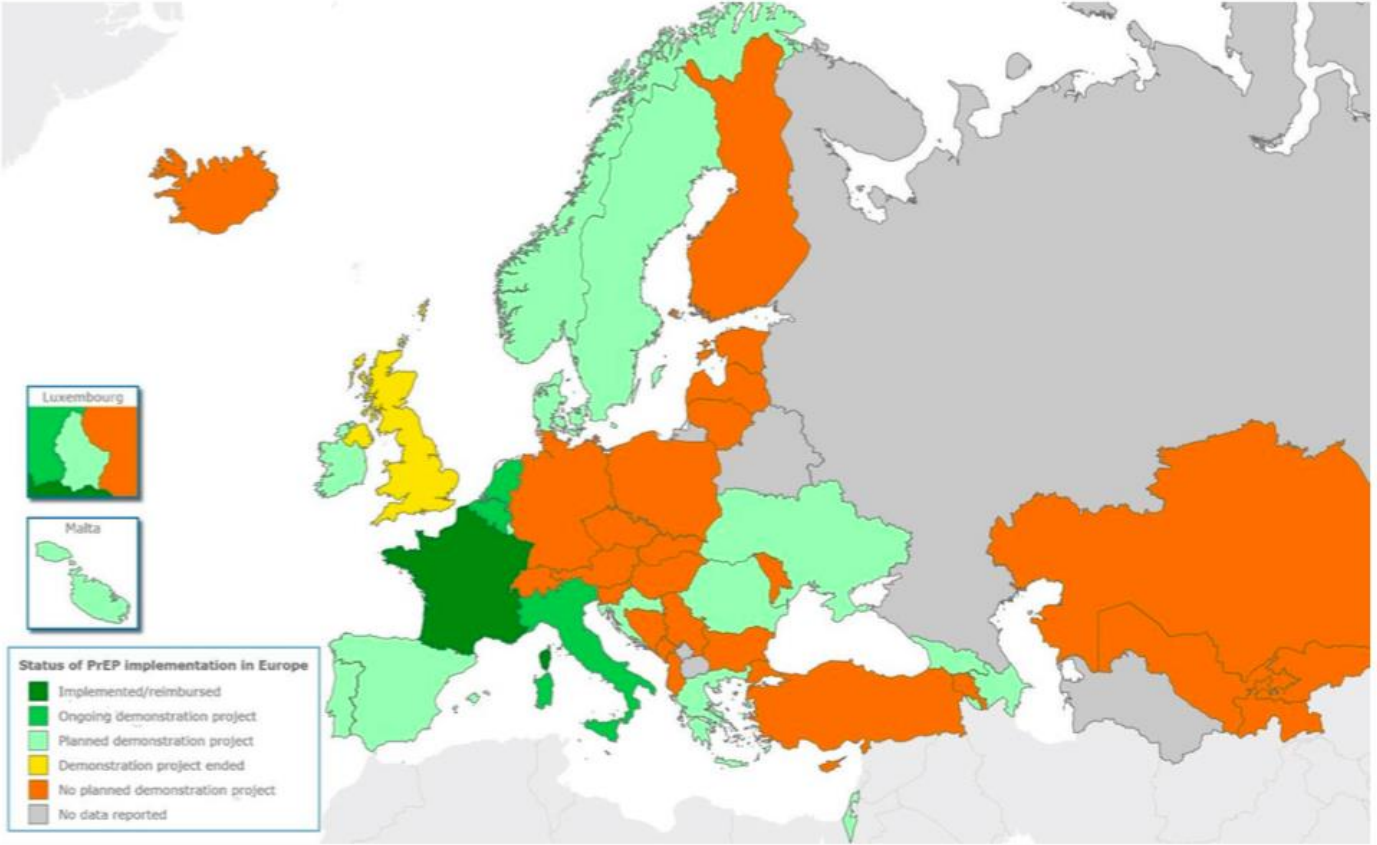
Data is adjusted for reporting delay. Cases from Estonia and Poland excluded due to incomplete reporting on transmission mode during the period; cases from Italy and Spain excluded due to increasing national coverage over the period.

ECDC/WHO (2015). HIV/AIDS Surveillance in Europe, 2014; presented by Teymur Noori, HIV Drug Therapy, Glasgow 2016

EUROPEAN ROLL-OUT

The European PrEP timeline



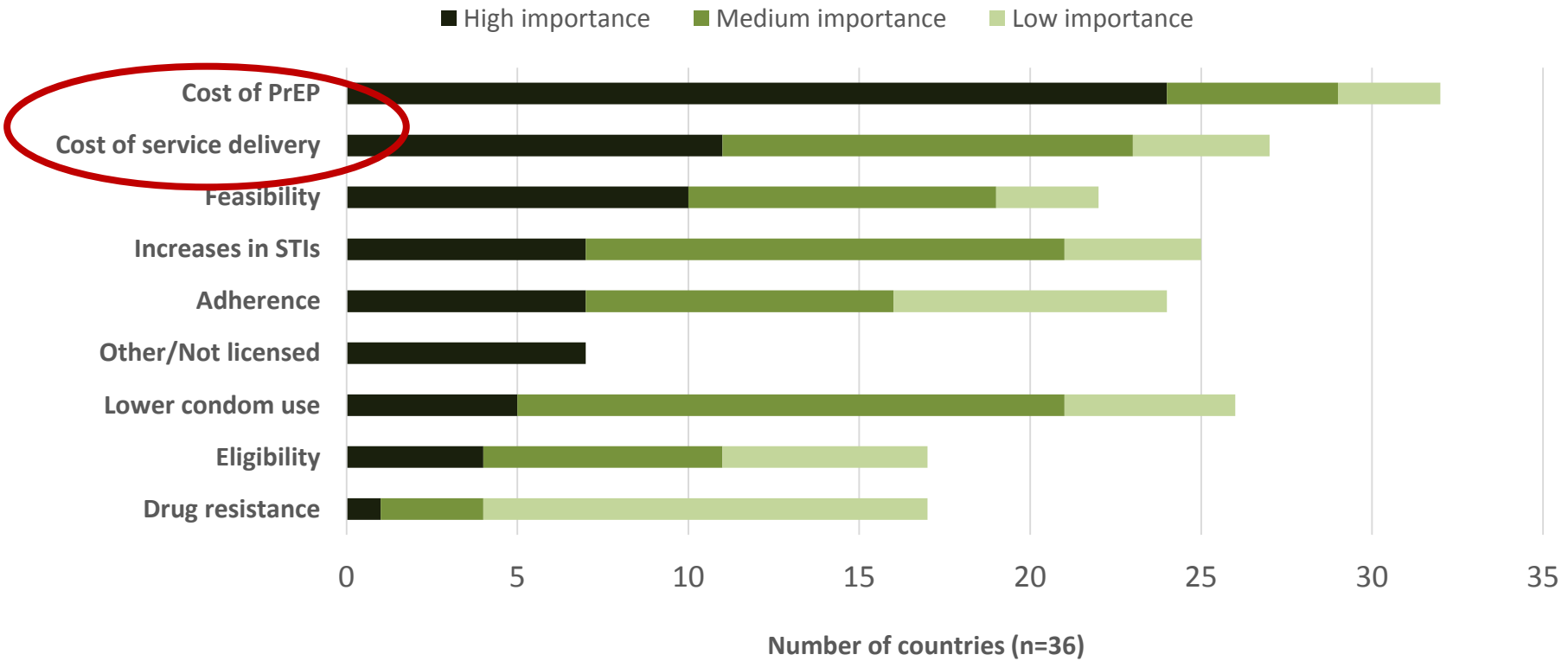


ECDC. Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe. Stockholm: ECDC; 2016. (updated)

COUNTRY	STATUS OF PrEP	TIMEFRAME	SETTING
FRANCE	Implemented/reimbursed	2016	Health care setting
NORWAY	Implemented/reimbursed	2016	Health care setting
BELGIUM	Ongoing demonstration project	(2015-2018)	Health care setting
NETHERLANDS	Ongoing demonstration project	(2015-2018)	Health care setting
ITALY	Ongoing demonstration project		Health care setting
UNITED KINGDOM	Completed demonstration project	(2012-2016)	Health care setting
CROATIA	Planned demonstration project	(2016-?)	Health care setting
DENMARK	Planned demonstration project	(2017-2018)	Community-based setting
GREECE	Planned demonstration project	(2016-2017)	Health care setting
IRELAND	Planned demonstration project	(2016-2017)	Health care & community setting
LUXEMBOURG	Planned demonstration project	(2016-2017)	Health care setting
MALTA	Planned demonstration project	--	TBD
PORTUGAL	Planned demonstration project	(2016-2017)	Community-based setting
ROMANIA	Planned demonstration project	--	TBD
SPAIN	Planned demonstration project	(2016-2017)	Community-based setting/STI clinic
SWEDEN	Planned demonstration project	(2016-2017)	Health care setting
AZERBAIJAN	Planned demonstration project	(TBD)	TBD
GEORGIA	Planned demonstration project	(2017-2018)	TBD
ISRAEL	Planned demonstration project	(2017-2018)	Health care setting
UKRAINE	Planned demonstration project	(2017-2018)	Community-based setting

ECDC. Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe. Stockholm: ECDC; 2016.

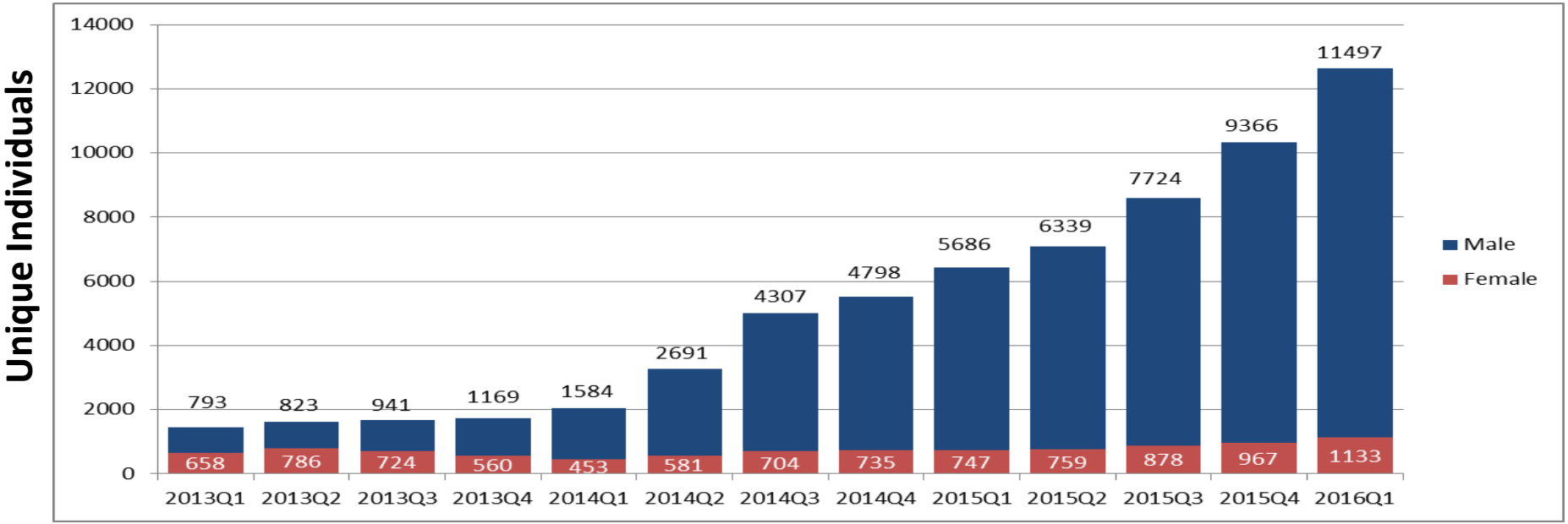
What limits/prevents PrEP implementation in your country?



ECDC. Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe. Stockholm: ECDC; 2016.

COUNTRY-LEVEL EXPERIENCE

Individuals Starting FTC/TDF PrEP in US by Gender

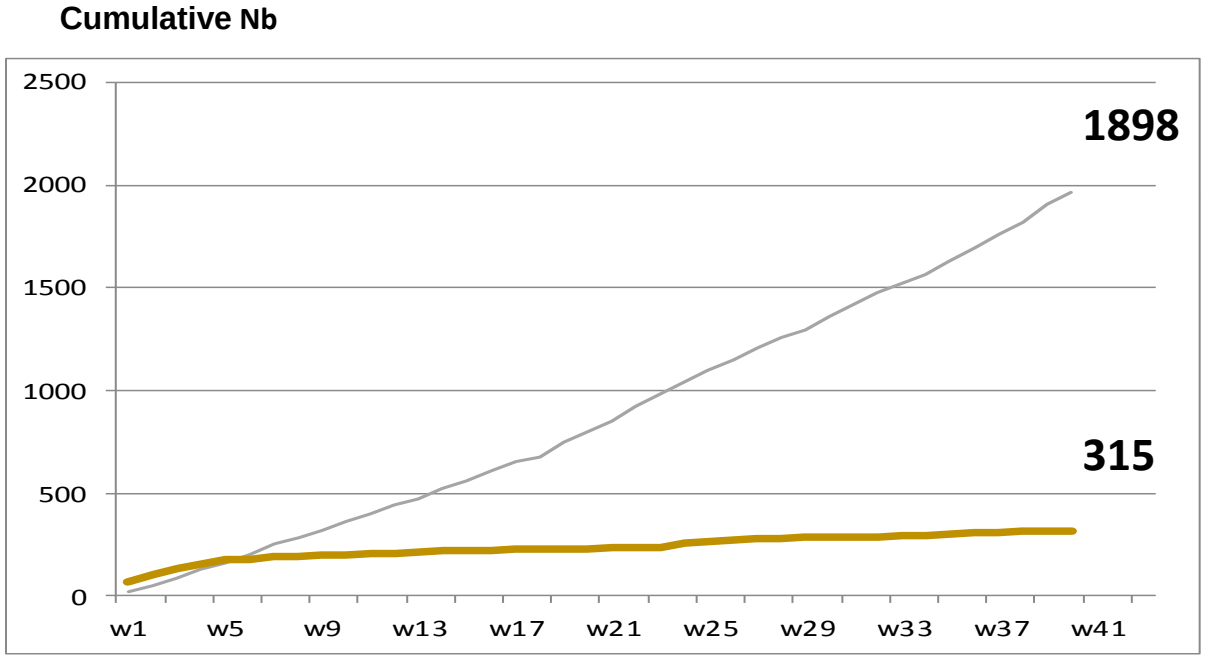


Between 1Q2013 and 1Q2016 quarter-over-quarter utilization grew 870%; 172% for women and 1,450% for men.

Bush S. et al. HIV Drug Therapy 2016; Glasgow, Scotland

PrEP Implementation in France in 2016

- > 120 PrEP clinics have opened, initially in ANRS Ipergay sites (Paris, Lyon, Nice, Lille, Nantes)
- AIDES Website: http://www.aides.org/info-sante/prep
- TDF/FTC can be obtained at private and hospital pharmacies



Molina J-M; personal communication

ENGLAND

- **2015** PrEP subgroup policy
- **01/2016** 1st consultation
- **05/2016** NHSE decide they're not responsible
- **08/2016** successful legal challenge by Nat AIDS Trust
- **Currently**
  - Task & Finish group (£2m)
  - PrEP policy working group
  - NHSE appeal ("prohibited from public health activity")

SCOTLAND

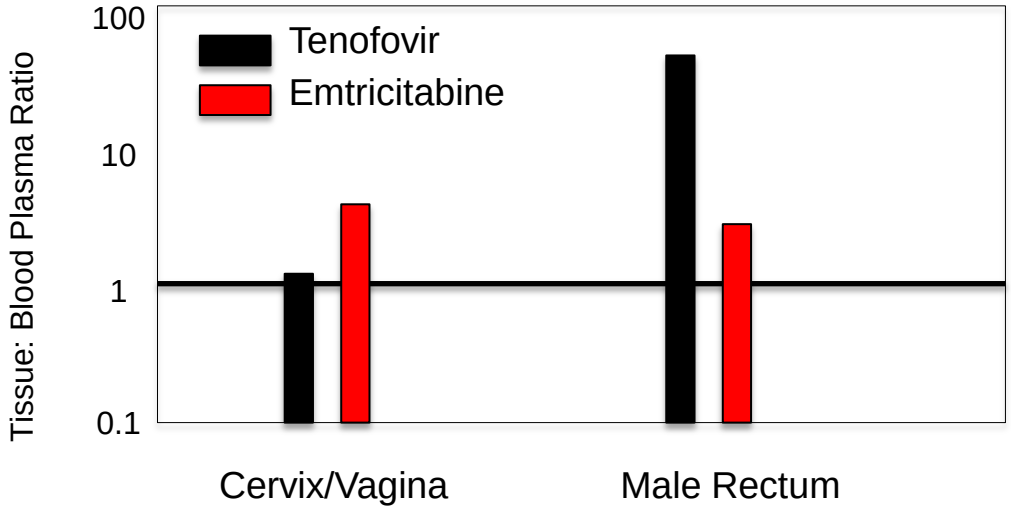
- **10/2016** working group published report, nationally endorsed
- Scottish Medicines Consortium have asked Gilead to submit price
- After that 18 weeks for SMC to review cost-effectiveness * make recommendations
- **Unlike NHS England, NHS Scotland have never questioned or challenged their responsibility**

UNCERTAINTIES (WHICH FRIGHTEN POLICY MAKERS & FUNDERS)

‘Intermittent-intermittent PrEP’ quotes

- **2015 IAS**
  - **Molina:** “Clearly the effectiveness of the IPERGAY dosing strategy in people having frequent sex cannot yet be extrapolated to people who have less frequent sex”
- **2016 17th International Workshop on Clinical Pharmacology of HIV & Hepatitis**
  - “Consistent marker of PrEP efficacy not determined”
- **2016 random conversation**
  - **Molina:** we have more data now….IAS Paris 2017

Males *versus* females:
GENDER OR COMPARTMENT?



Different concentrations of membrane transporters explain a lot of the difference in genital tract tenofovir concentrations

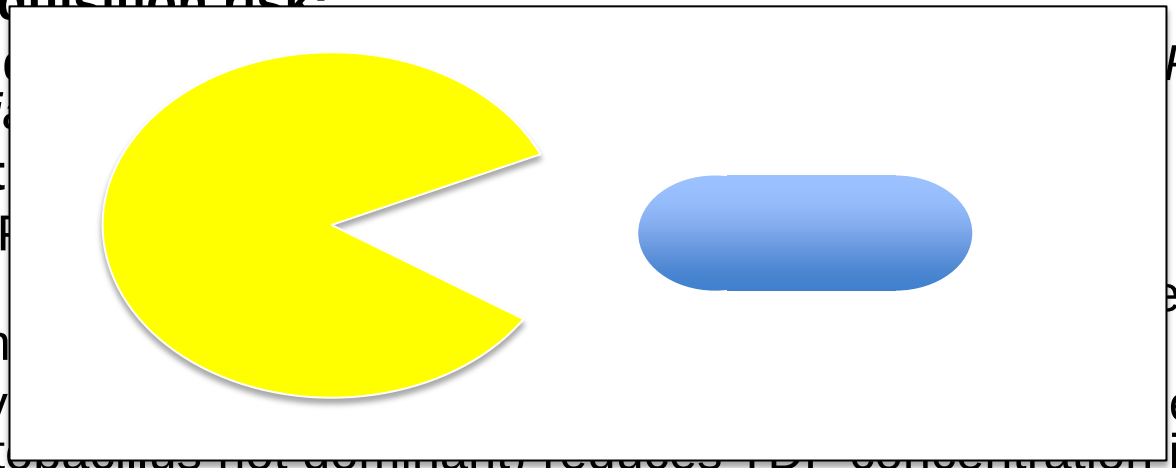
Different tissue drug concentrations = different dose-response in males *versus* females

Need for: Different adherence patterns? Different drugs/drug combinations? Different dosing schedules?

Patterson KB *et al. Sci Transl Med*. 2011 Dec 7;3(112):112re4; Nicol MR *et al. J Clin Pharmacol*. 2014 May;54(5):574-83

Vaginal flora

- **HIV acquisition risk:**
  - Stu… *Prevotella bivia…*
- **Impact…**
  - CA… 688 women
  - 3/5 …eria ben…
  - In v… …en lact… …in supernatant by 70% over 24 hours compared with lactobacilli
  - Mechanism under investigation



Burgener A *et al. Curr Opin Immunol.* 2015 Oct;36:22-30

IPERGAY: HIV Incidence (mITT Analysis)

Treatment	Follow-Up Pts-years	HIV Incidence per 100 Pts-years (95% CI)
Placebo	212	**6.60** (3.60-11.1)
TDF/FTC (double-blind)	219	**0.91** (0.11-3.30)
TDF/FTC (open-label)	515	**0.19** (0.01-1.08)

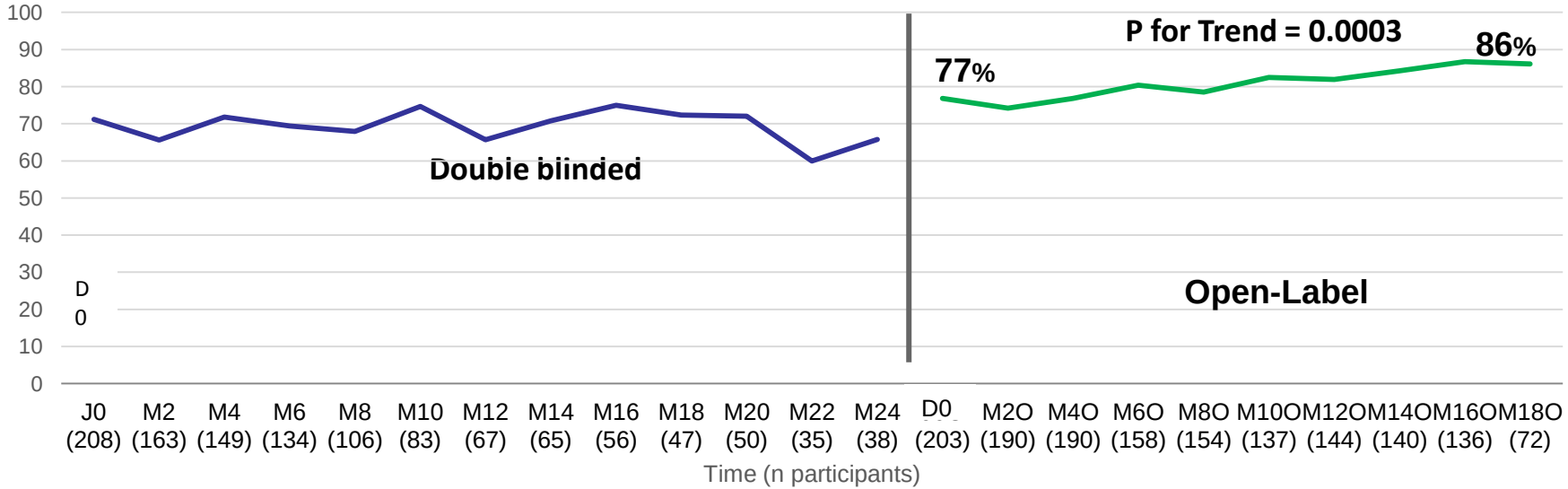
Median Follow-up in Open-Label Phase 18.4 months (17.5-19.1)

97% relative reduction *vs*. placebo

Molina JM, Charreau I, Spire B, *et al. 21st IAC* 2016. Abstract WEAC0102

IPERGAY open-label extension: 97% efficacy after median 18.4 months!

Proportion Pts with Condomless Sex for Last Receptive Anal Intercourse



No significant change in median Nb of partners or sexual acts during the open-label phase (P= 0.42 and P= 0.12)

Molina JM, Charreau I, Spire B, *et al. 21st IAC* 2016. Abstract WEAC0102.

ipergay ANRS Intervention Préventive de l'Exposition aux Risques avec et pour les Gays

anrs France REcherche Nord & sud Sida-hiv Hépatites
Agence autonome de l'Inserm

IPERGAY: open-label extension

	Double-Blind Median FU: 9.3 months n=400		Open-Label Median FU: 18.4 months n=362	
	Nb Pt (%)	Nb Cases	Nb Pt (%)	Nb Cases
Chlamydiae	81 (20)	114	122 (34)	158
Gonorrheae	88 (22)	123	117 (32)	175
Syphilis	39 (10)	45	68 (19)	77
HCV	5 (1)	5	5 (1)	5
All STIs	147 (37)	287	210 (58)	415

Incidence rate of first STI: 35.2 *vs* 40.6/100 PY in the double-blinded and OLE phases

Molina JM, Charreau I, Spire B, et al. 21st IAC 2016. Abstract WEAC0102

ipergay ANRS Intervention Préventive de l'Exposition aux Risques avec et pour les Gays

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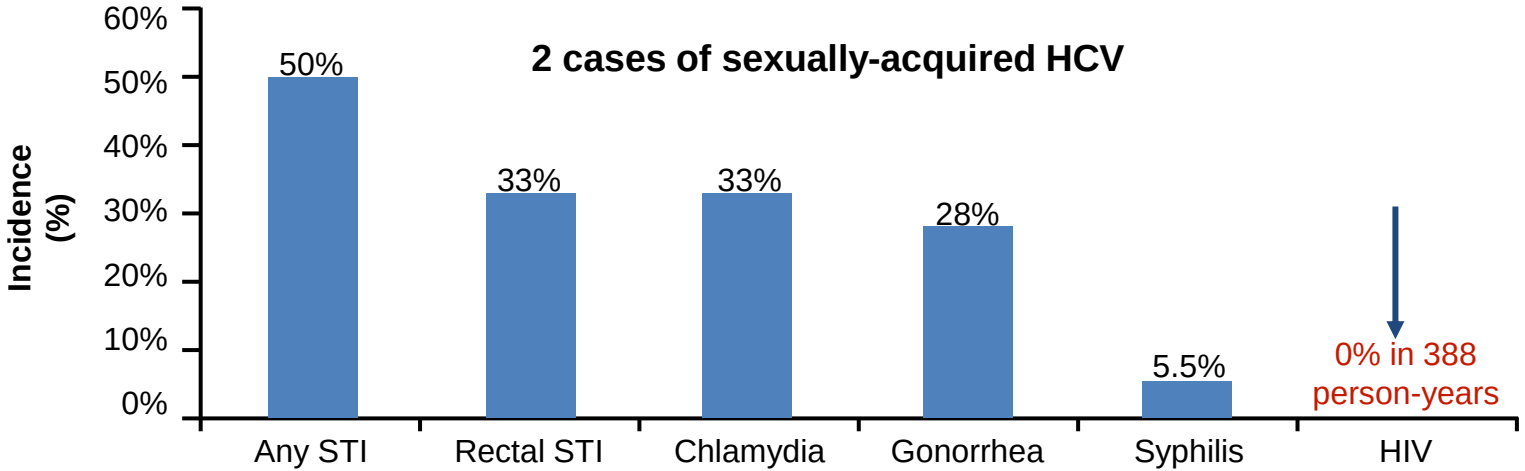
Kaiser Permanente cohort

A study of 657 PrEP users (mostly MSM) from 2012–2015 within the Kaiser Permanente integrated healthcare system, San Francisco

STI incidence after 12 months of PrEP use



Of those taking part in the study, 187 were diagnosed with at least 1 STI during follow-up, and 78 individuals were diagnosed with multiple STIs

Volk JE *et al. Clin Infect Dis*. 2015 Nov 15;61(10):1601-3

STIs and behaviour

- We are already seeing HUGE rises in STIs in MSM
  - Including acute HCV in HIV-negative MSM
- Impact of “undetectable = uninfectious”
- Will PrEP make rising STI rates worse?
- **How much ‘worse’ than 9 per 100 person years HIV incidence (deferred arm in PROUD) can you get??**

Thoughts

- **A quote from Deborah Gould (NAT)**
  - *"We cannot use fear of HIV to prevent STIs, we need another solution"*
- **The opportunities of increased STI screening**
  - STI diagnosed sooner which may REDUCE STI in the longer term due to shorter periods of transmissibility
  - Risk reduction advice
  - Combined health promotion

RESOURCES

	WHO?	HOW?
EACS[1]	**Recommended**: HIV- MSM & TGW/TGM not using condoms consistently with casual partners HIV+ partners not on ART **Consider**: HIV- heterosexuals, inconsistent condoms with multiple partners some of whom are likely to be HIV+ not on ART	**Baseline**: 4th generation HIV test, HBV, renal, STD **3 monthly**: 4th generation HIV "**Regularly**": STD screening **Renal**: as per SPC

CDC[2]	HIV- & at **substantial risk** of HIV infection:
	1. HIV+ partner
	2. MSM **not** in mutually monogamous relationship with HIV- partner AND
	  1. MSM + CLAI or STD in the past 6M;
	  2. Heterosexual not using condoms regularly with ?HIV status partners at substantial risk (e.g., PWID, bisexual male partners)
	3. PWID sharing equipment in last 6M
		Baseline: HIV, renal, HBV status documented, DDI review
		3 monthly: review adherence, risk reduction, HIV test, STI symptoms assessment
		Renal: baseline, at 3M then 6-monthly thereafter

1. http://www.eacsociety.org/files/guidelines_8.1-english.pdf accessed 31st October 2016
2. http://www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf accessed 31st October 2016

French definition: "High Risk of Sexual HIV Acquisition"

- **MSM or transgende individuals** with
  - Condomless anal sex with at least two different partners over the last M
  - Episodes of STIs (syphilis, chlamydiae, gonorrhea, HBV, HCV) over last 12M
  - Multiple PEP treatments in the last 12M
  - Use of drugs during sexual intercourse (cocaine, GHB, MDMA, etc.)
- **Other persons at high risk** of HIV acquisition **case by case**
  - Sex workers exposed to condomless sex
  - Vulnerable persons exposed to condomless sex with people from a group with a high prevalence of HIV
    - Person from areas/countries of high HIV prevalence
    - Person with multiple sexual partners
    - IVDU

ECDC

ECDC MEETING REPORT

Pre-Exposure Prophylaxis in the EU/EEA: Challenges and Opportunies

Stockholm 27-28 April 2016

https://www.researchgate.net/publication/303438065_Pre-Exposure_Prophylaxis_in_the_EUEEA_Challenges_and_Opportunities accessed 31st October 2016

NICE

NICE National Institute for Health and Care Excellence

NICE advice

Pre-exposure prophylaxis of HIV in adults at high risk: Truvada (emtricitabine/tenofovir disoproxil)

Evidence summary: new medicine

Published: 5 October 2016

nice.org.uk/guidance/esnm78

NICE: patents

- In relation to Truvada®, the relevant compound patents relate to tenofovir disoproxil and salts, which expires in July 2017 and tenofovir disoproxil fumarate, which expires in July 2018
- A supplementary protection certificate has also been granted in relation to Truvada® which expires in February 2020 (a challenge of this is pending before the UK Court; personal communication, Gilead, September 2016)

https://www.nice.org.uk/advice/esnm78/chapter/key-points-from-the-evidence accessed 31st October 2016

Other resources

- **User information leaflet**
  - Developed based on local guidelines + PROUD, developed by clinicians and reviewed by community representatives & BASHH
  - http://i-base.info/guides/prep

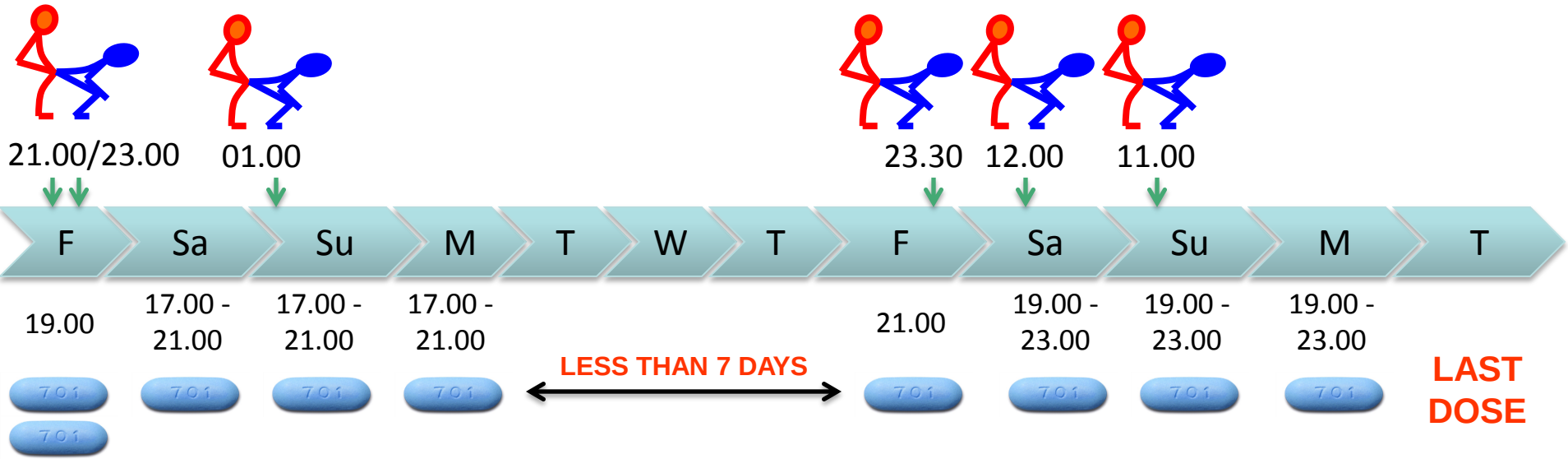
Sex several times, then more sex within 7 days of last dose

BEFORE SEX

2 Truvada® tablets at least 2 hours & not more than 24 hours before sex

AFTER SEX

Truvada® every 24 hours 'til 2 doses after your last sex; if next sex within 7 days of last dose take ONE, not two, tablets



Acknowledgements

- Teymur Noori ECDC
- Jean-Michel Molina
- Sheen McCormack

Final thoughts

If we do not have the capacity to screen high-risk groups at recommended intervals and if we cannot find a way to implement the provision of an HIV prevention strategy as effective as PrEP…

…then what are we doing?!

Thank you!

?

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Discussion