

Update on PrEP

BREACH SYMPOSIUM
ANDERLECHT, 24 NOVEMBER 2017

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Outline

PrEP update on:

- Be-PrEP-ared study
- Implementation in Belgium
- Situation in Europe
- New developments

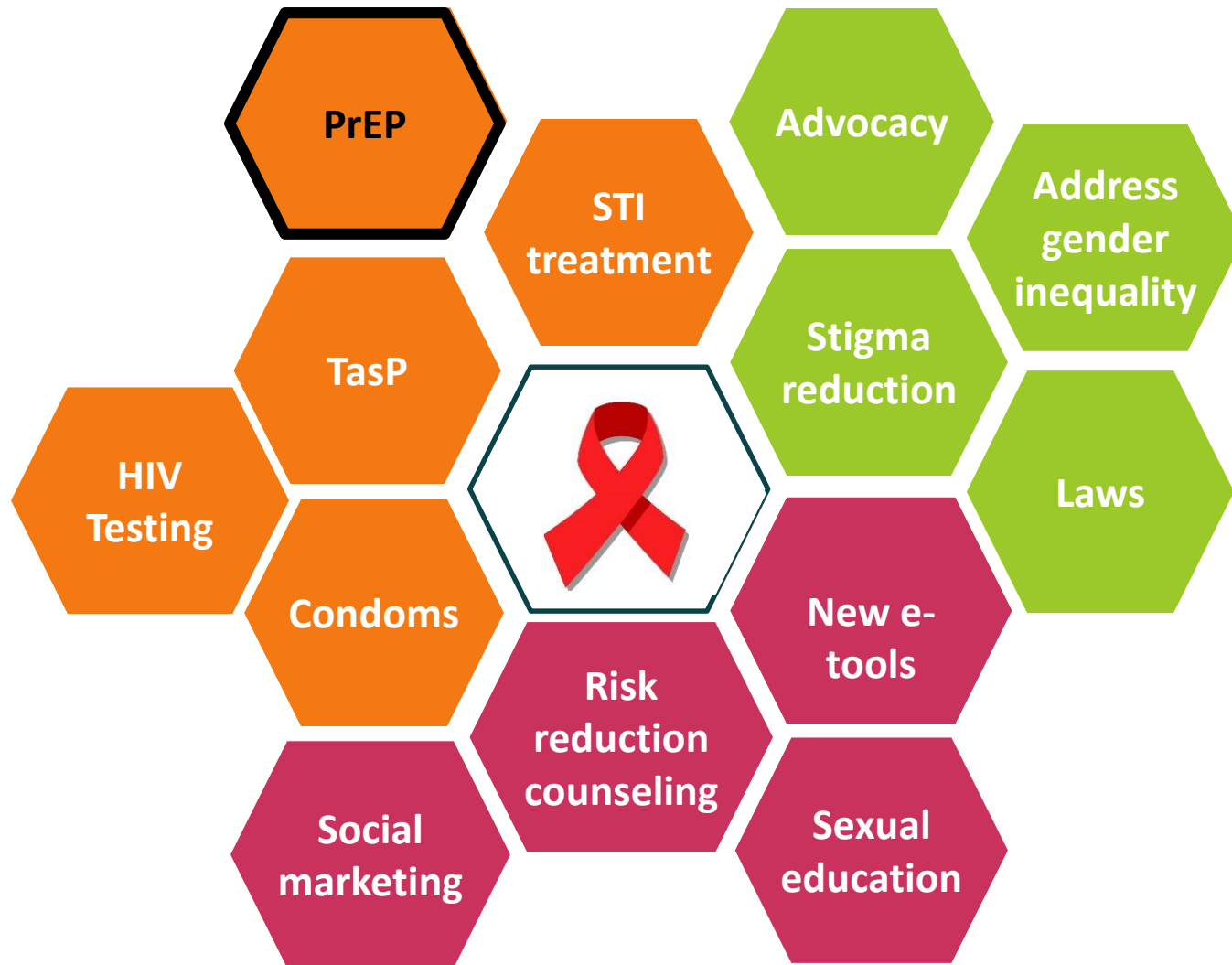
Disclosure information:

BV is principal investigator of the Be-PrEP-ared study.

Gilead is providing Truvada for this study.



HIV combination prevention



Adapted from: Intl HIV/AIDS Alliance/UNAIDS 2016



Be-PrEP-ared study

PrEP among high risk MSM in Belgium:

Uptake

Acceptability

Feasibility



Be-PrEP-ared: update



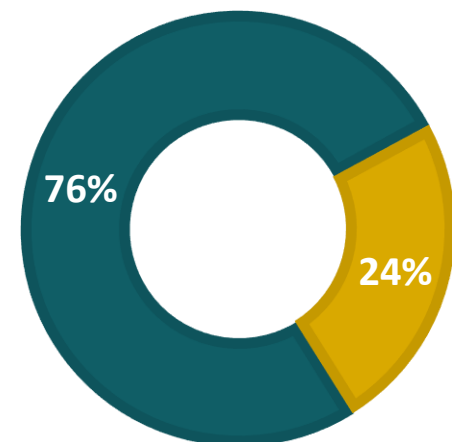
Be-PrEP-ared

- Start: Sept 2015
- End enrolment: Dec 2016
- Study population: 197 high risk MSM and 3 transgender women
- Status on 24 November 2017: 141 in active follow-up, 42 completed, 11 discontinued, 6 LTFU
- End of the study: June 2018

Study regimen: participants self-select in 2 groups (*):

- 1) Daily PrEP
- 2) Event-driven PrEP

* Switch-over between groups is possible

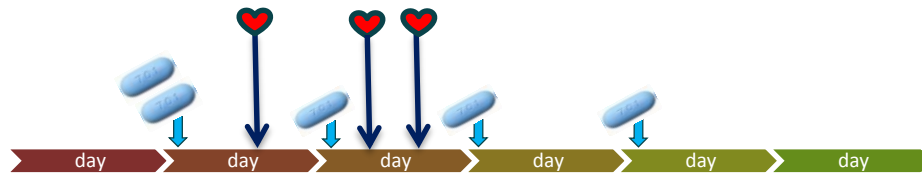


■ Daily ■ Event-driven

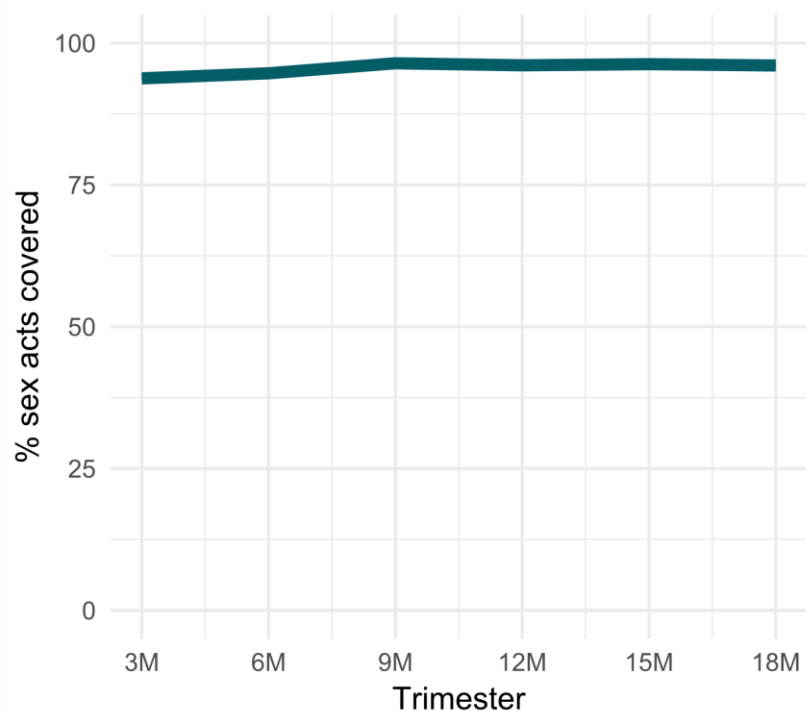
Adherence (preliminary results)



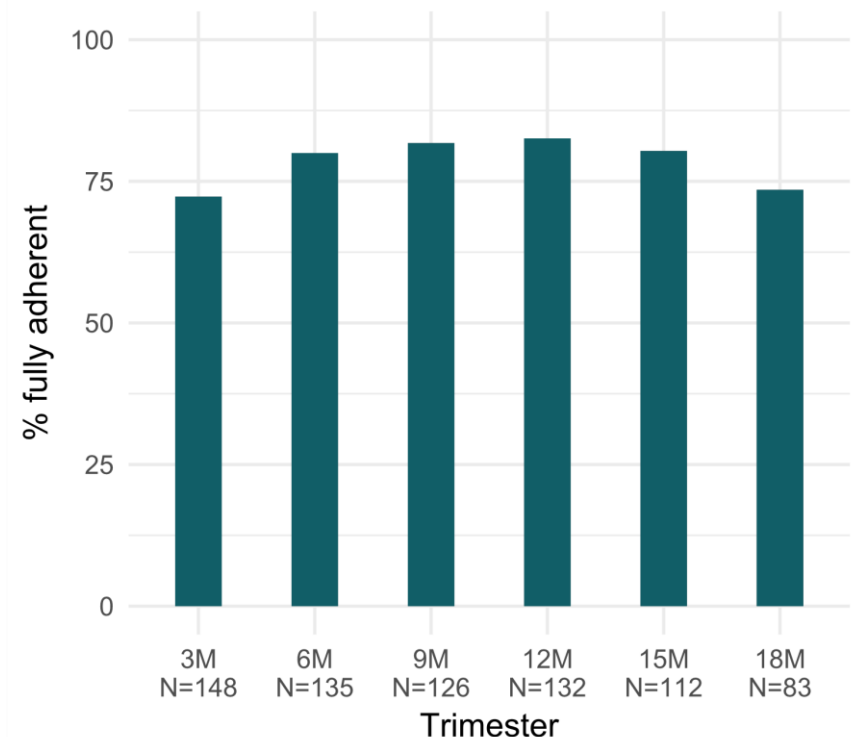
“Covered sex acts”:



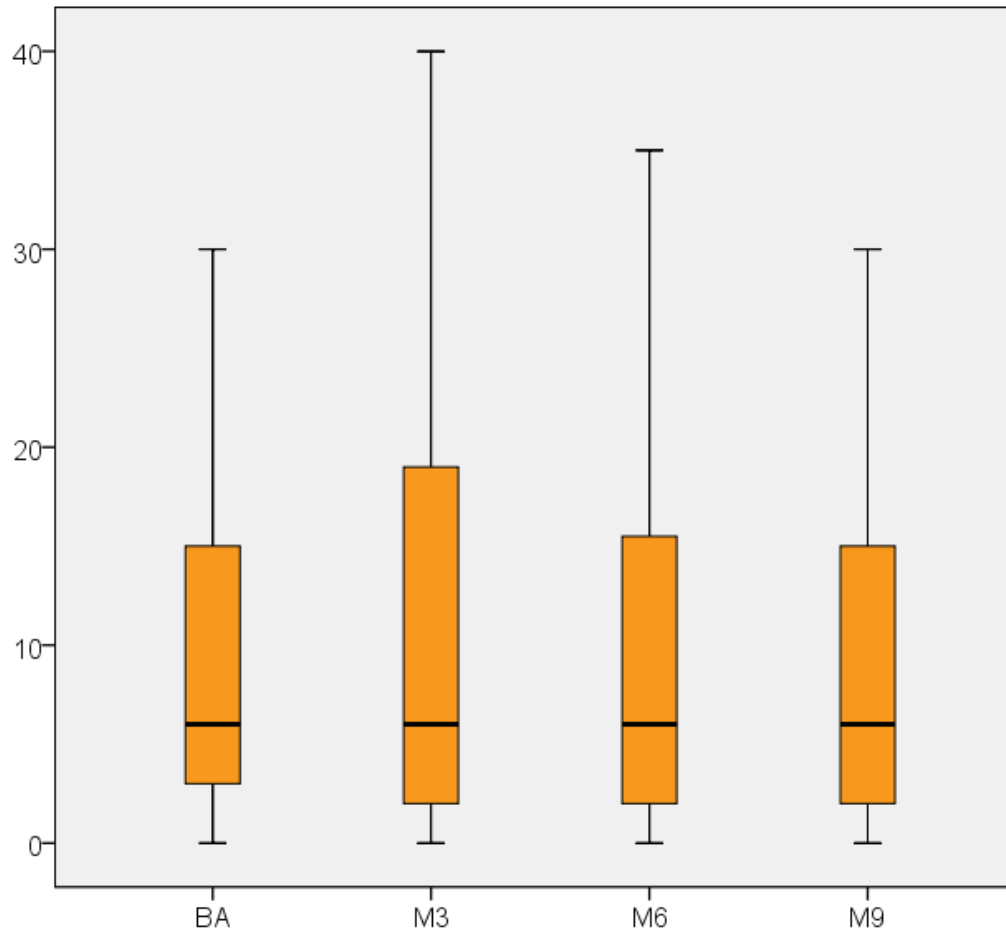
Proportion of all high risk **sex acts** covered



Proportion of **persons** with 100% covered high risk sex



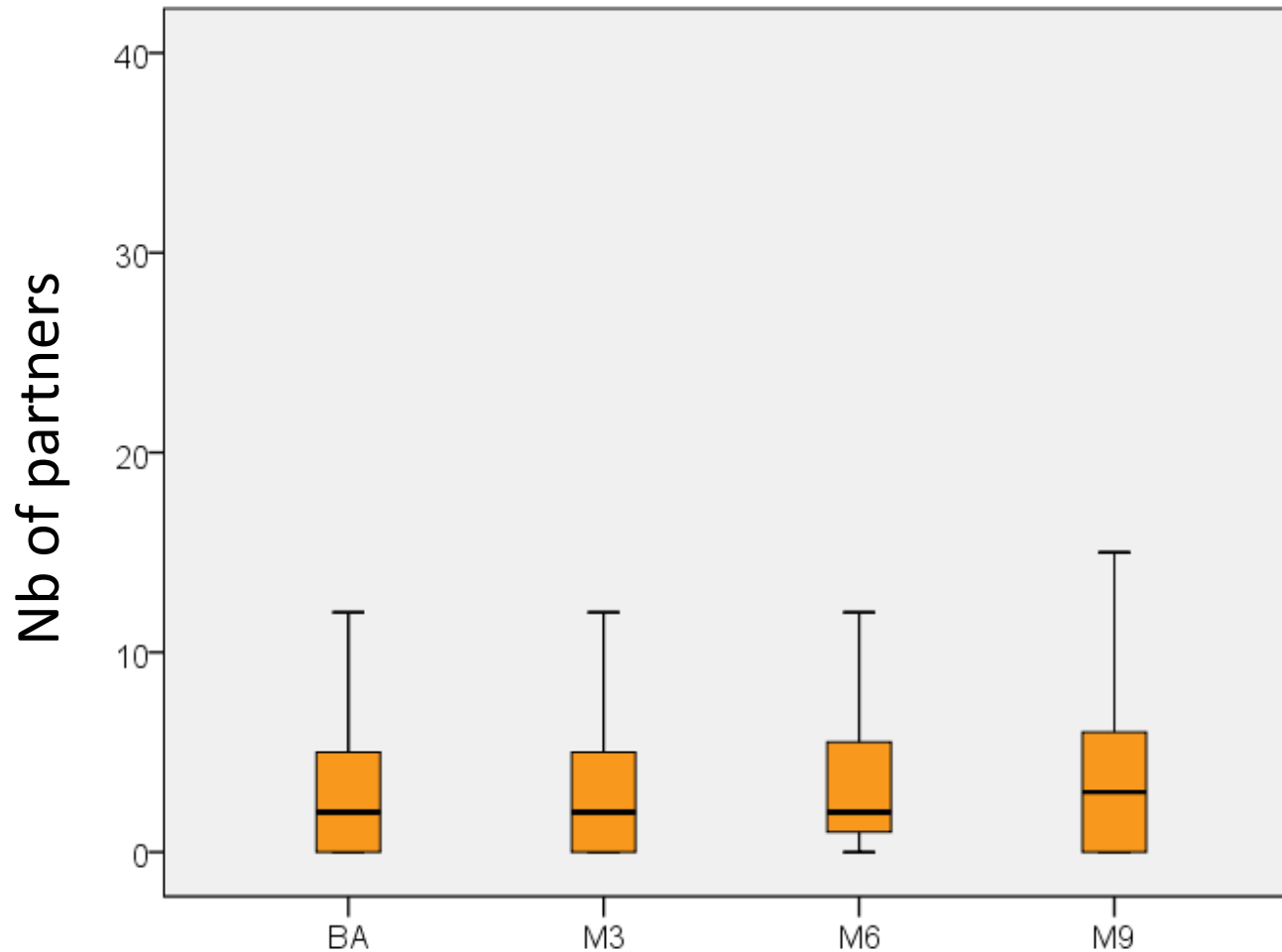
Number of anonymous sex partners in the last 3 months (preliminary results)



Outliers excluded



Receptive sex without a condom in the last 3 months (preliminary results)



Outliers excluded

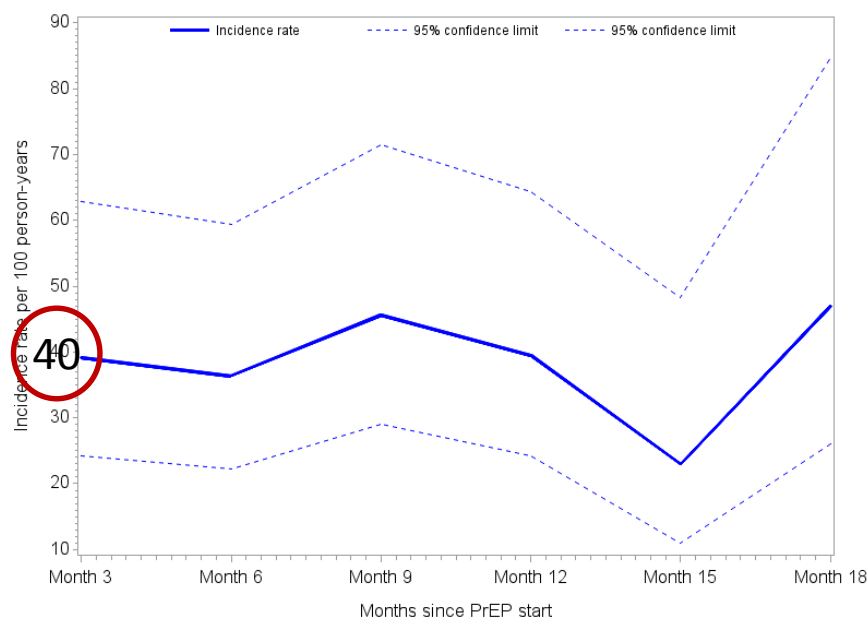




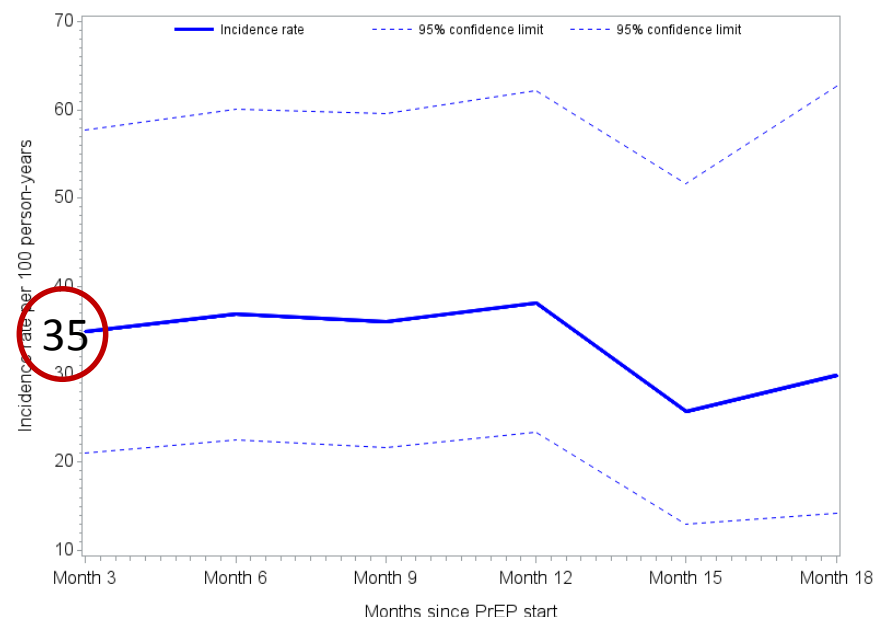
Be-PrEP-ared

Incidence of STI (preliminary results)

Gonorrhoea (% PY)



Chlamydia (%PY)



Incidence of:

Syphilis: 12,4%PY (95% CI: 8,6 – 17,9)

HCV: 2,9%PY (95% CI: 1,4 -6,1)



Results qualitative study



“But the original reason [for taking PrEP] was not because I wanted to have unsafe sex. [...] Despite knowing that I had done everything by the book to not have had any risk, afterwards I was always thinking ‘damn I should not have done that or I should not have done this’. [...] For me that was always very difficult to... stress about something you should normally enjoy.”



HIV seroconversions



No HIV seroconversions (update 24 November 2017)





Acquisition of wild-type HIV-1 infection in a patient on pre-exposure prophylaxis with high intracellular concentrations of tenofovir diphosphate: a case report

Elske Hoornenborg, Maria Prins, Roel C A Achterbergh, Lycke R Woittiez, Marion Cornelissen, Suzanne Jurriaans, Neeltje A Kootstra, Peter L Anderson, Peter Reiss, Henry J C de Vries, Jan M Prins, Godelieve J de Bree, on behalf of the Amsterdam PrEP Project team in the HIV Transmission Elimination AMsterdam Consortium (H-TEAM)



H-TEAM

Amsterdam PrEP project (AMPrEP)

- 50 yr old MSM
- On daily PrEP since 8 months
- Reported good adherence
- Tenofovir diphosphate concentrations stable & high
- No drug-resistant mutations

www.thelancet.com/hiv Vol 4 November 2017



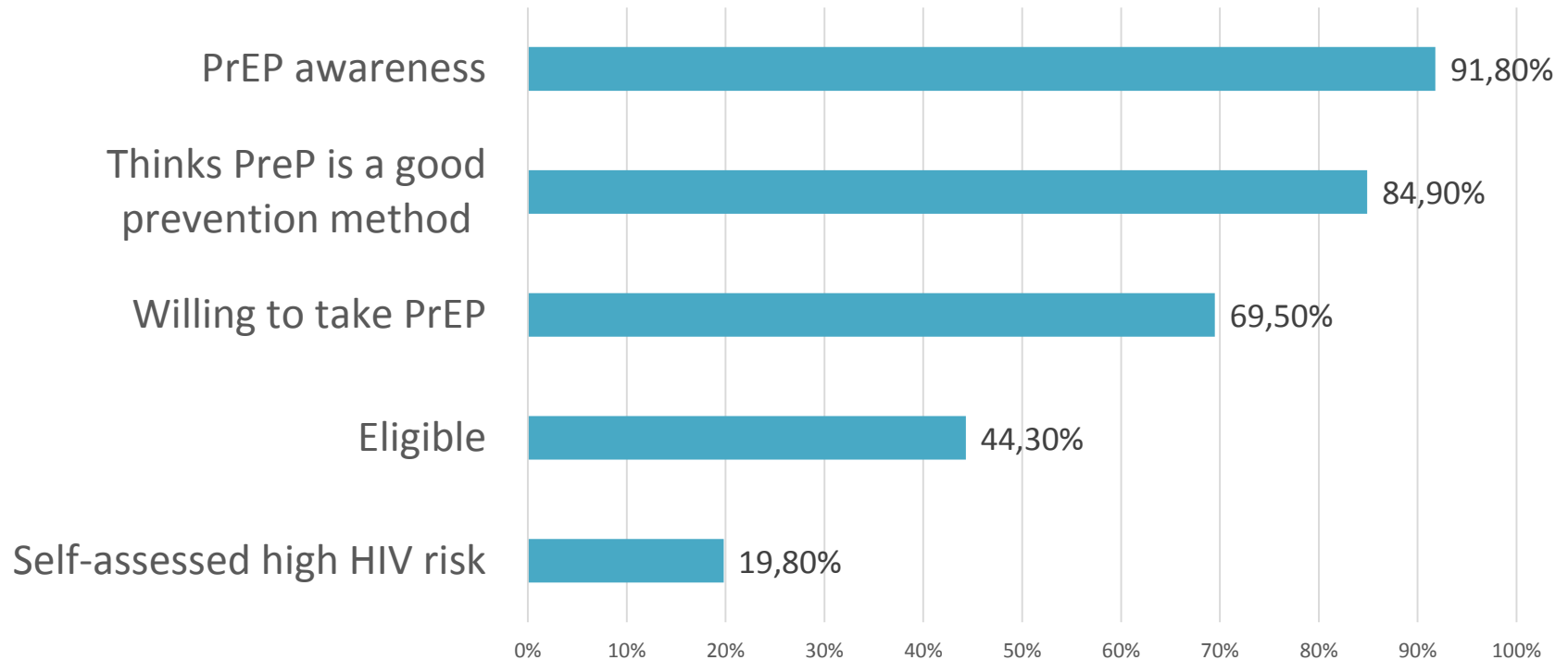
Community on-line survey



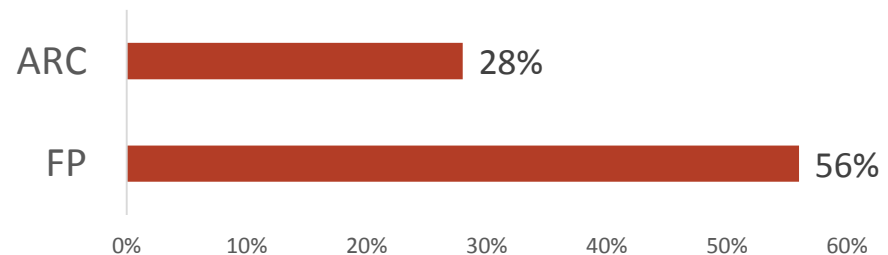
PrEP in Belgium?
Participate in our survey!



On-line survey among MSM in Belgium (Nov 16-March 2017, N=1444 HIV-)



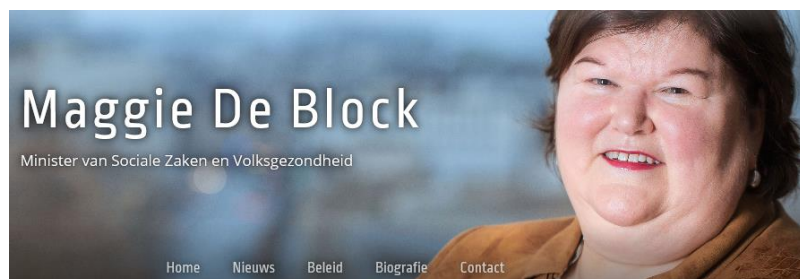
Where would you prefer to go for PrEP?



PrEP implementation in Belgium



Re-imbbursement PrEP in Belgium: from 1 June 2017



Persbericht 19 mei 2017

Terugbetaling van preventief gebruik hiv-remmers bij risicogroepen

BRUSSEL, 19/05/2017.- Mensen die een hoog risico lopen op een besmetting met hiv hebben vanaf 1 juni 2017 recht op de terugbetaling van hiv-remmers voor preventief gebruik. Dat heeft minister van Sociale Zaken en Volksgezondheid Maggie De Block beslist. De twee grootste risicogroepen zijn mannen die seks hebben met mannen en mensen afkomstig uit Sub-Saharaans Afrika.

Critères pour le remboursement:

MSM:

- Pratiques sexuelles anales non protégées avec >1 partenaire (derniers 6 mois)
- Plusieurs MST(derniers 12 mois)
- Recours à la PEP
- Utilisation des substances psycho-actives lors des activités sexuelles

Haut risque individuel:

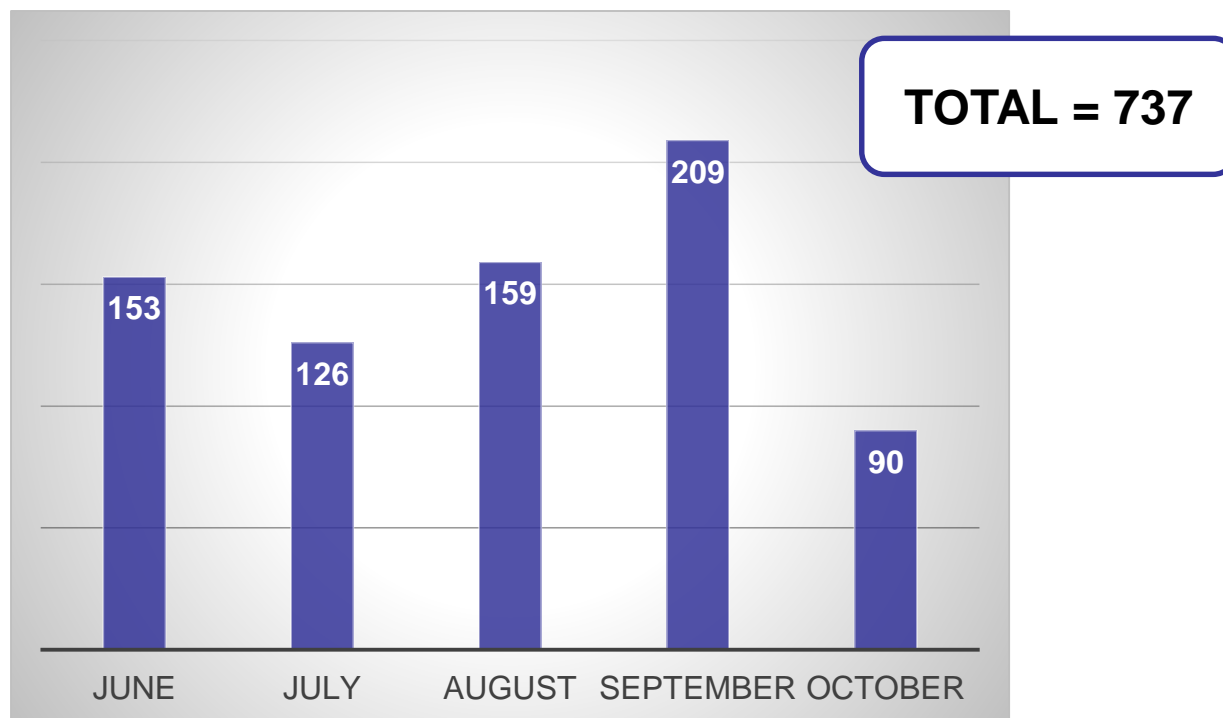
- Injection de drogue
- Travail dans la prostitution
- Exposition à des pratiques sexuelles non protégées
- Partenaire d'un patient VIH positif sans suppression virale

Extracted from: <http://www.inami.fgov.be>



INAMI-RIZIV

Number of applications for PrEP reimbursement approved in Belgium since 1 June 2017



Risk profile of new PrEP users in ARC – Antwerp (ITM)

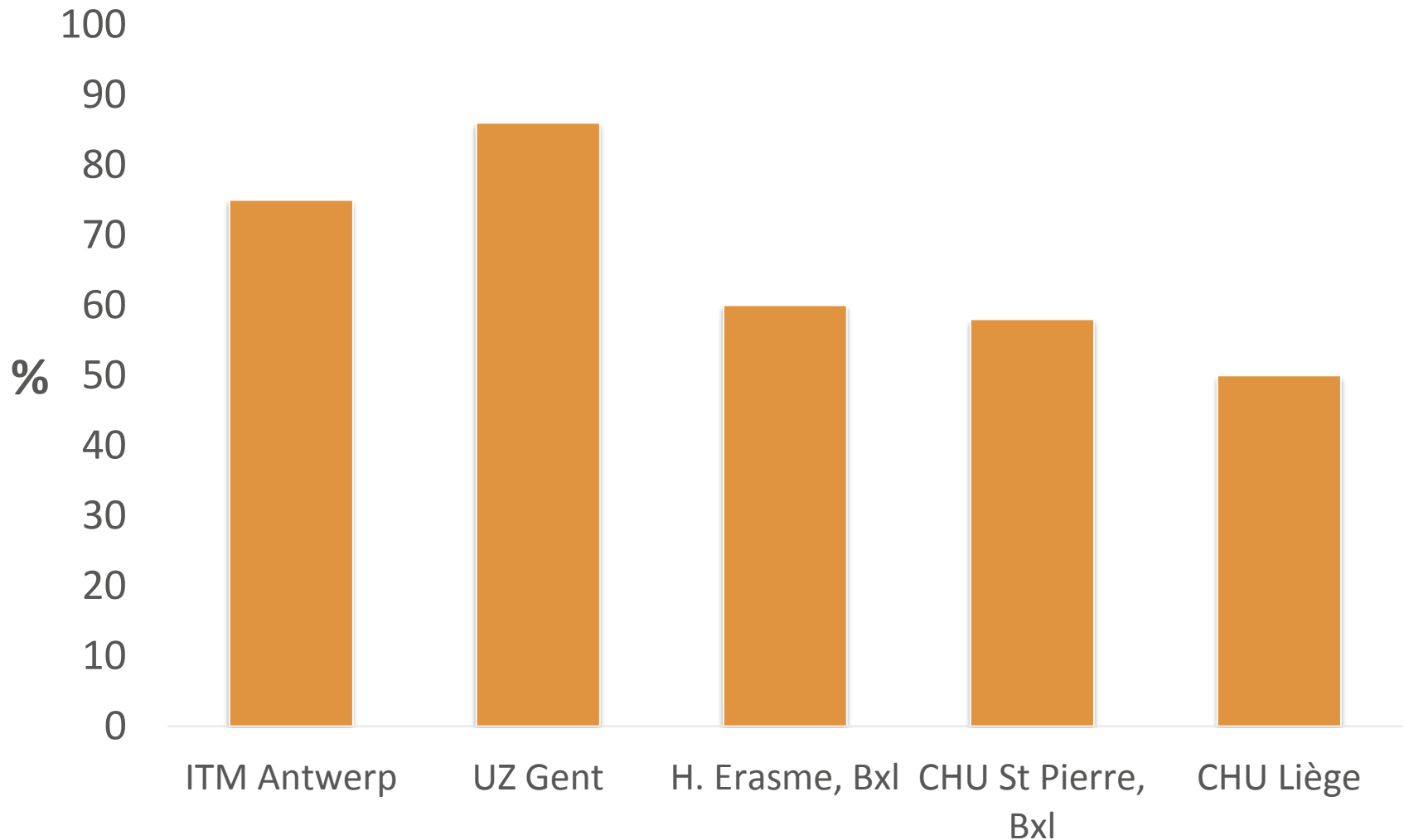
- MSM: 98,5%
- Unprotected anal intercourse with > 1 partner in the last 6 months: 80,4%
- STI in the last 12 months: 42,1%
- PEP use in the last 12 months: 5,1%
- Drug use when having sex: 36,4%
- Sex work: 4,2%

**8 recent
seroconversions
among PrEP
applicants**

*Based on 214
questionnaires*



Proportion of daily users in different ARCs



Conclusions

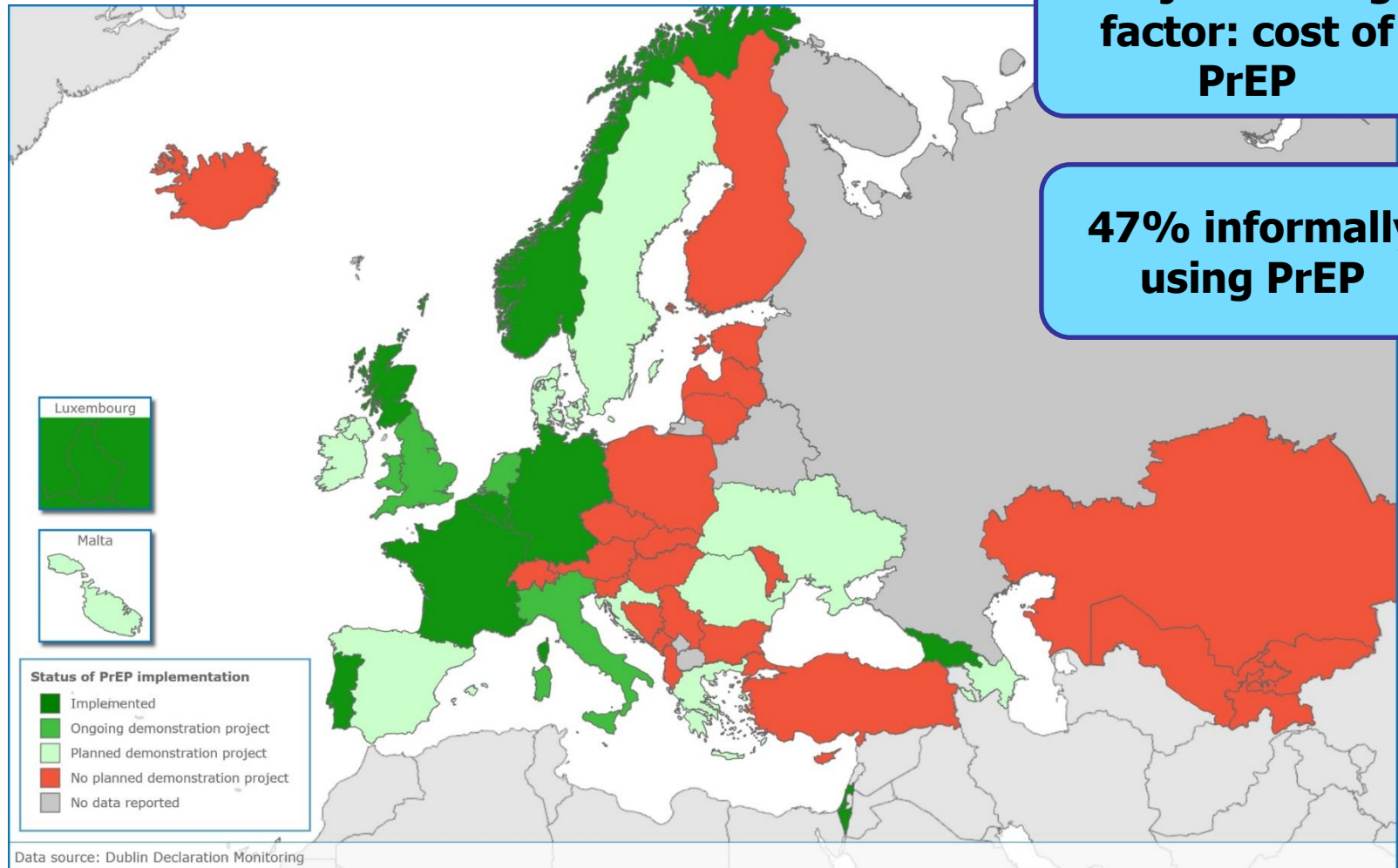
- Encouraging preliminary results of Be-PrEP-ared
 - High adherence
 - High STI rates but no increasing trends
 - No HIV seroconversion
- Implementation of PrEP in Belgium
 - High uptake among MSM
 - Health system challenges
 - Need for national monitoring and evaluation system



PrEP in Europe

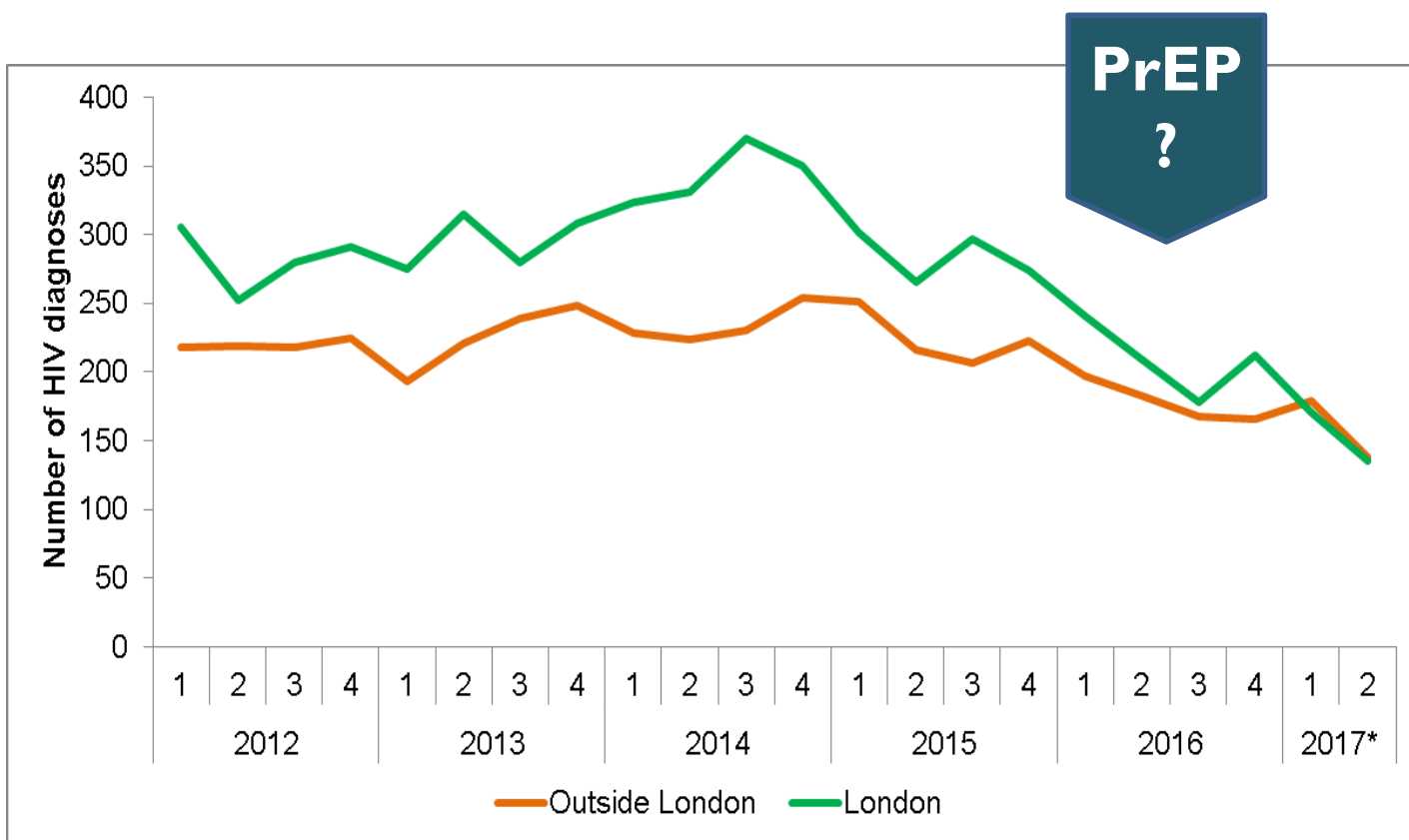
Status of formal PrEP implementation in Europe

(as of 26 October 2017)



Trend in new MSM HIV diagnoses at STI clinics

London & Outside London



New developments

New regimens

New route of administration

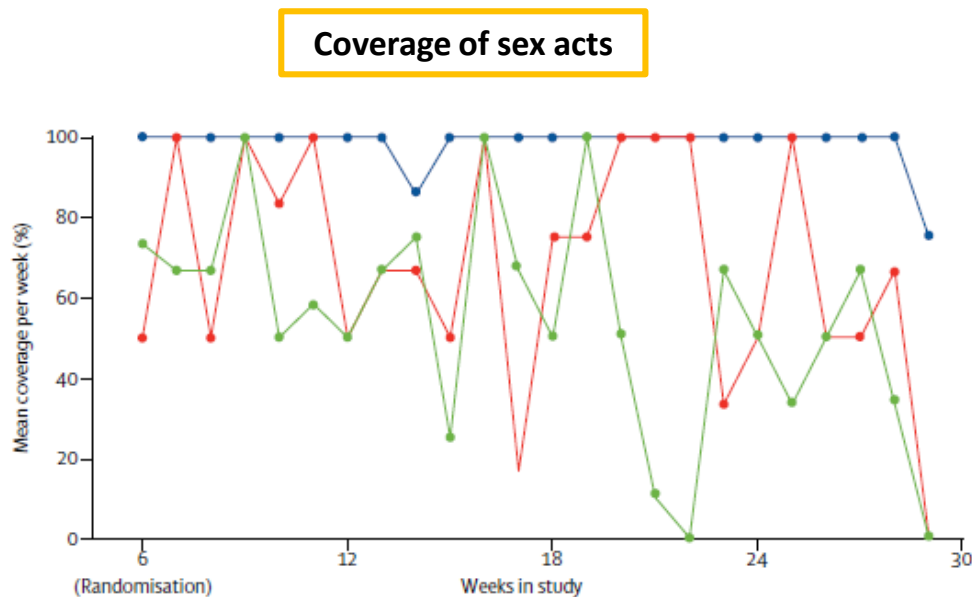
New products

Combination product development



New regimens

Daily and non-daily FTC/TDF in African women (HPTN 067/ADAPT Cape Town Trial)



- Daily
- Event-driven: 1 tablet both before and after sex
- Time-driven: twice a week + a post-sex dose

Daily PrEP resulted in:

- higher coverage of sex acts
- Increased adherence to the regimen
- Augmented drug concentration

4 seroconversions after randomisation:

- 2 in event-driven group
- 2 in time-driven regimen

New routes of administration



“Long-Acting Injectable Cabotegravir for PrEP well tolerated in HPTN 077”

New products

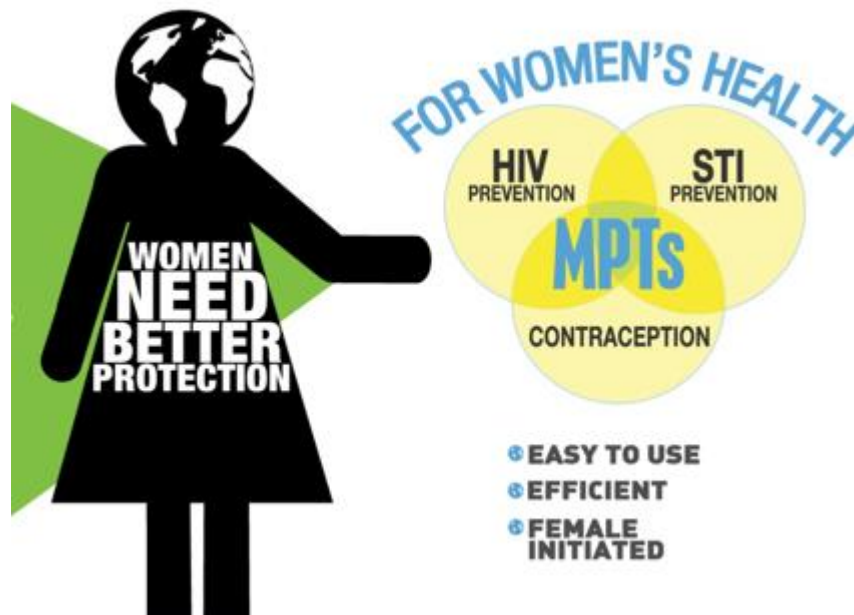


DISCOVER trial: 5 400 participants

Started in September 2016

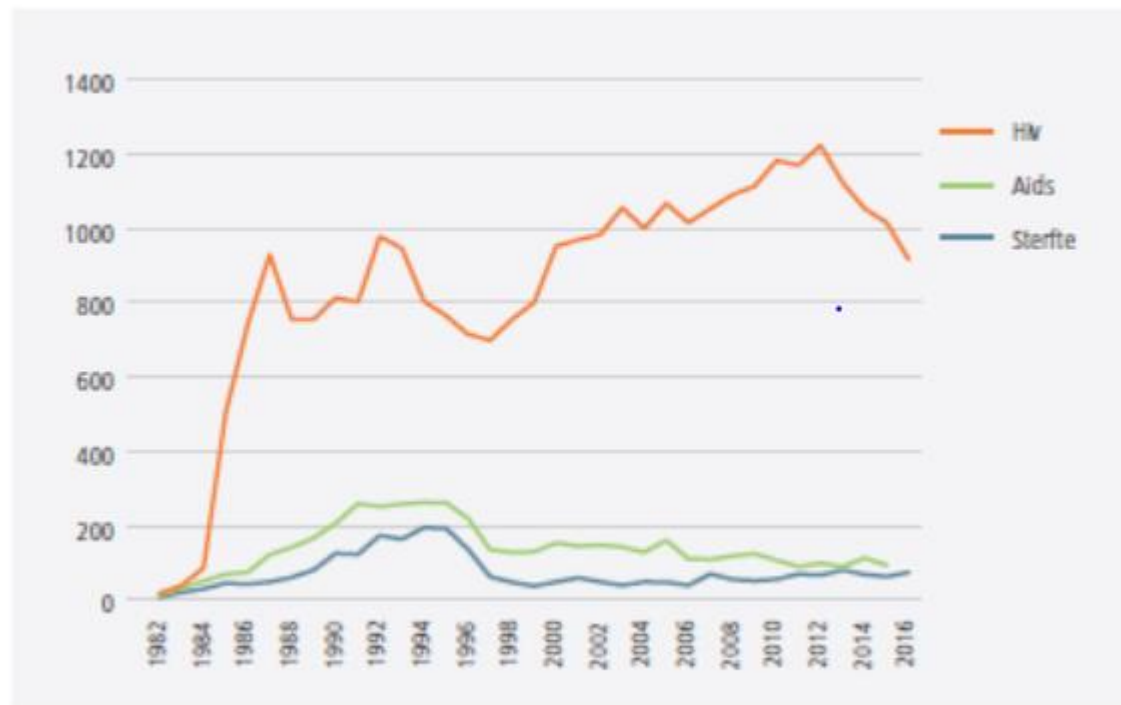
Objective: Safety and effectiveness of F/TAF

Combination product development



Are we starting to see the end of AIDS in Belgium ?

Figuur 1 | Jaarlijks aantal nieuwe hiv en aids-diagnoses* en gerapporteerde sterfte, België 1982-2016



*Aantal aids-diagnoses niet beschikbaar voor 2016

Many thanks to

ARCs:

- Joelle Defourny, CHU Liège
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- Charlotte Vandebulcke, UZ Gent

INAMI/RIZIV:

- Catherine Lucet

ECDC:

- Teymur Noori

Be-PrEPared:

- Study participants
- Study team

Institute of Tropical Medicine:

- Hanne Apers
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