



BREACH 2016

PrEP update

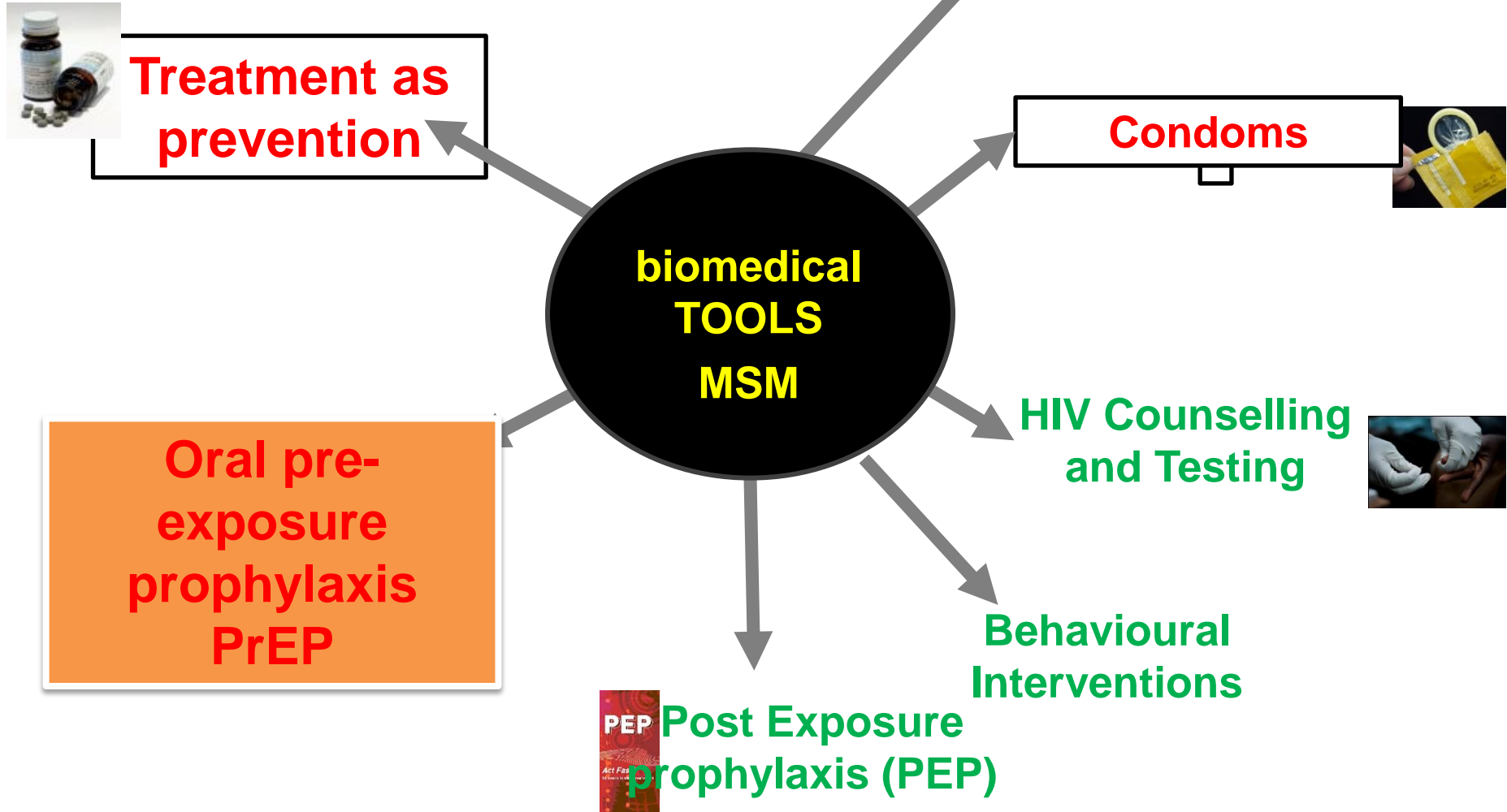
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focused on reducing sexual transmission



PrEP Science summary

- ✓ **TDF containing PrEP protective** against HIV acquisition across populations
- ✓ Analysis of subgroups of “**high adherers**” showed level of **protection >90%**, especially among MSM- both daily and event driven dosing
- ✓ **No serious toxicity** observed so far; some evidence of reduction of bone density effects and small , non-progressive reversible decline in glomerular filtration rate
- ✓ **Selection of drug resistant virus rare**
 - Initiation on PrEP during acute phase infection
 - Breakthrough infections

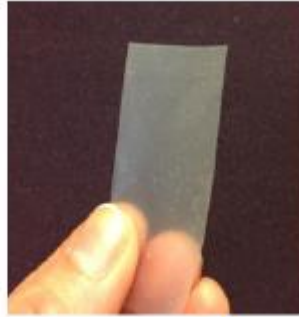
New drugs and delivery modes



Vaginal ring



Oral PrEP



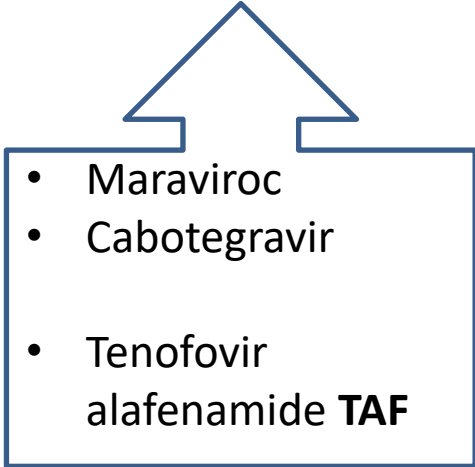
Vaginal film




Vaginal gel



Injectable

- 
- Maraviroc
 - Cabotegravir
 - Tenofovir
alafenamide **TAF**



Cabotegravir
Ripilvirine
...



Understanding the epidemic

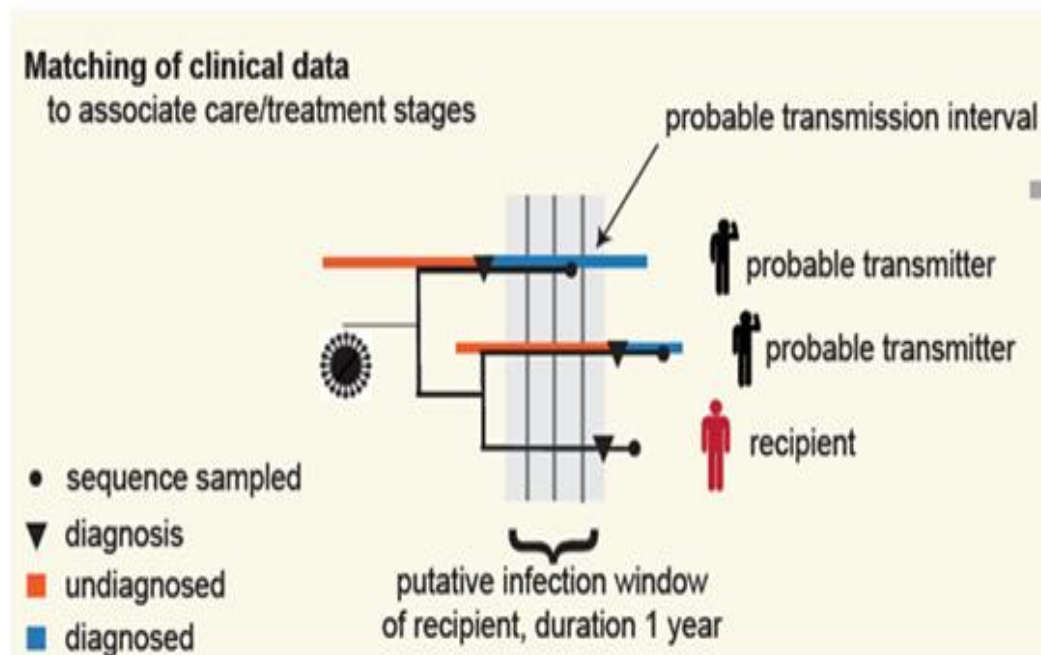
Quantifying sources of HIV transmission The Netherlands

- ❑ 71% from undiagnosed men
- ❑ 6 % from men on ART

➤ 43% from men who were diagnosed with HIV < 1 year

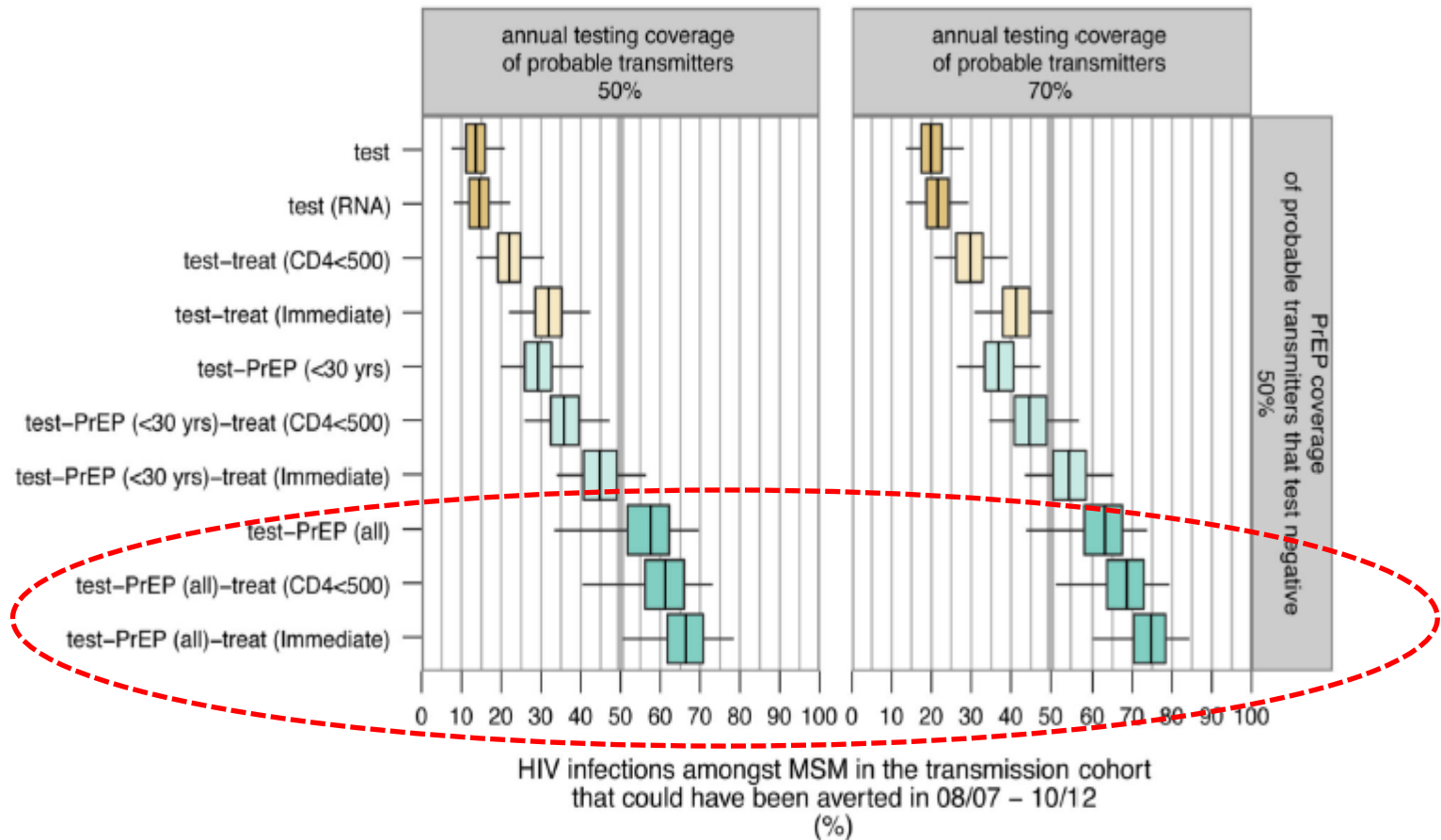
« Lack of substantial reduction in HIV incidence among MSM not a result of ineffective ART provision ... »

MSM transmission events



Ratmann et al, Sci Transl Med 2016

Implications for potential impact of Prevention strategies



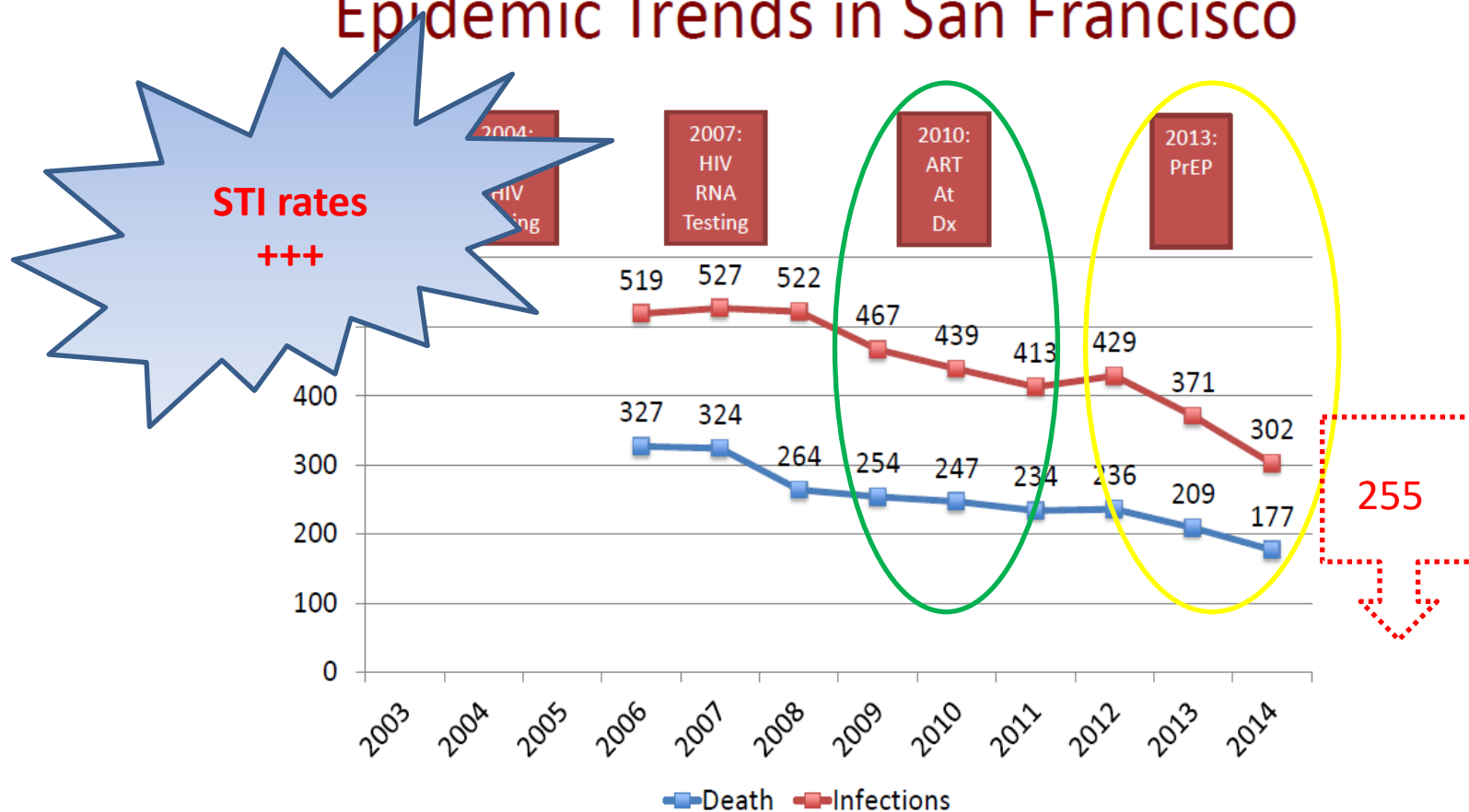
Test and Treat combined with PrEP could prevent 60-80 % of new infections



Population Impact of TasP and PrEP

30-63% of “high risk MSM” report PrEP use

Epidemic Trends in San Francisco



Adapted from SF DPH, HIV Epidemiology Annual Report, Published September 2014

From Grant , IAPAC 2015; Epid Report SF DPH 2016



PrEP effectiveness in real life

**San Francisco
CID 2015**

No New HIV Infections With
Increasing Use of HIV Preexposure
Prophylaxis in a Clinical Practice
Setting

Jonathan E. Volk,¹ Julia L. Marcus,² Tony Phengrasamy,¹
Derek Blechinger,¹ Dong Phuong Nguyen,¹ Stephen Follansbee,¹ and
C. Bradley Hare¹

Breakthrough HIV infections reported

- Majority PrEP interruptions or poor adherence /low drug levels (Fonnell 2016; Grant 2016; Lehman 2015)
- 2 cases infected with a drug resistant virus (Grant CROI 2016; R4P 2016))
- 1 case good adherence (AmPrEP nieuwsbrief Oktober 2016)



Open label phase of French trial event driven PrEP



HIV Incidence (mITT Analysis)

<u>Treatment</u>	<u>Follow-Up Pts-years</u>	<u>HIV Incidence per 100 Pts-years (95% CI)</u>
Placebo (double-blind)	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)

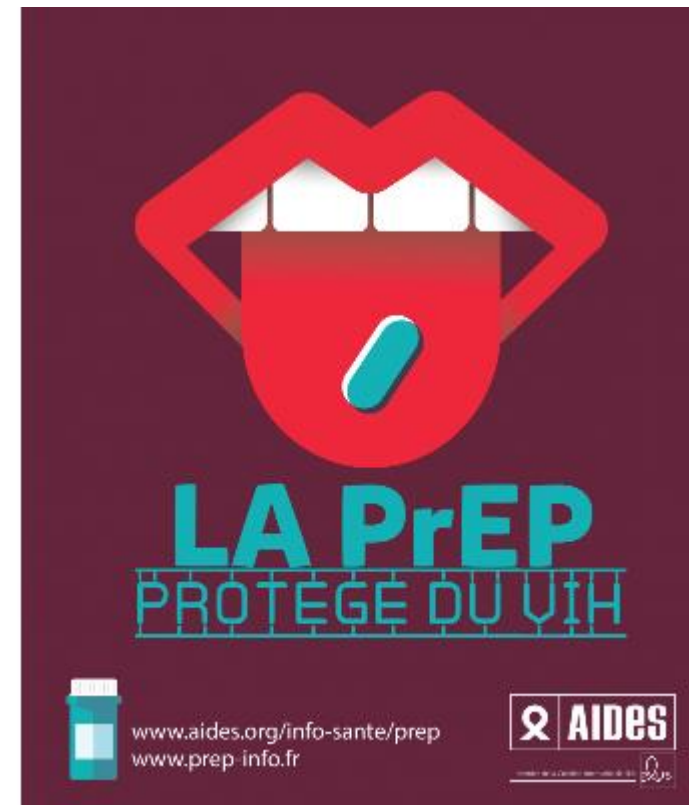
Median Follow-up in Open-Label Phase 18.4 months (IQR:17.5-19.1)

97% relative reduction vs. placebo





France Implementing PrEP





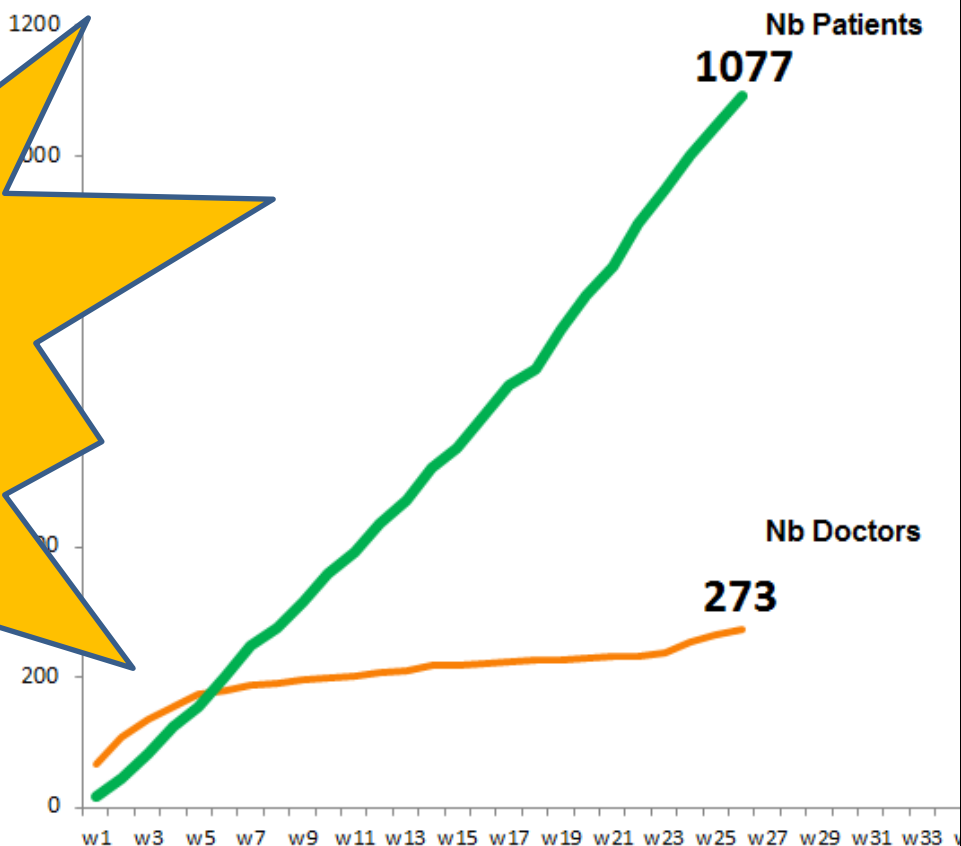
Status Implementation PrEP France January –July 2016

- > 90 PrEP clinics have opened initially in ANRS IUT sites (Paris, Lyon, Nice)
- AIDE (Association pour l'Initiative de Développement de l'Éducation)

<http://www.aide-association.org/>

Remaining Skepticism
Low PrEP awareness
Adapt Prevention messages
Comprehensive sexual health services
New delivery models
Show impact

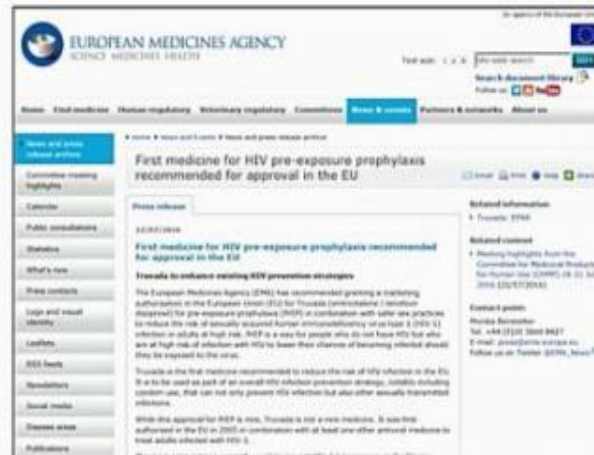
Cumulative Nb





Pre-Exposure Prophylaxis (PrEP) in Europe

July 2016:
European Medicines Agency (EMA) published its position on PrEP



22 August 2016:

European Commission granted marketing authorisation in all 28 Member States for *Truvada* for pre-exposure prophylaxis

Belgian Demonstration project

- *Design:* open-label cohort study
- *Outcomes:* **uptake, acceptability** and **feasibility** of PrEP
- *Study drug:* **Truvada**
- *Study population:* 200 HIV (-) MSM “at risk”
- *Study site:* Institute of Tropical Medicine (ITM), Antwerp
- *Follow-up:* 18 months (start Oct 2015)
- **Choice between daily and event-driven PrEP**

Funding : IWT-TBM

Study drugs donated by Gilead

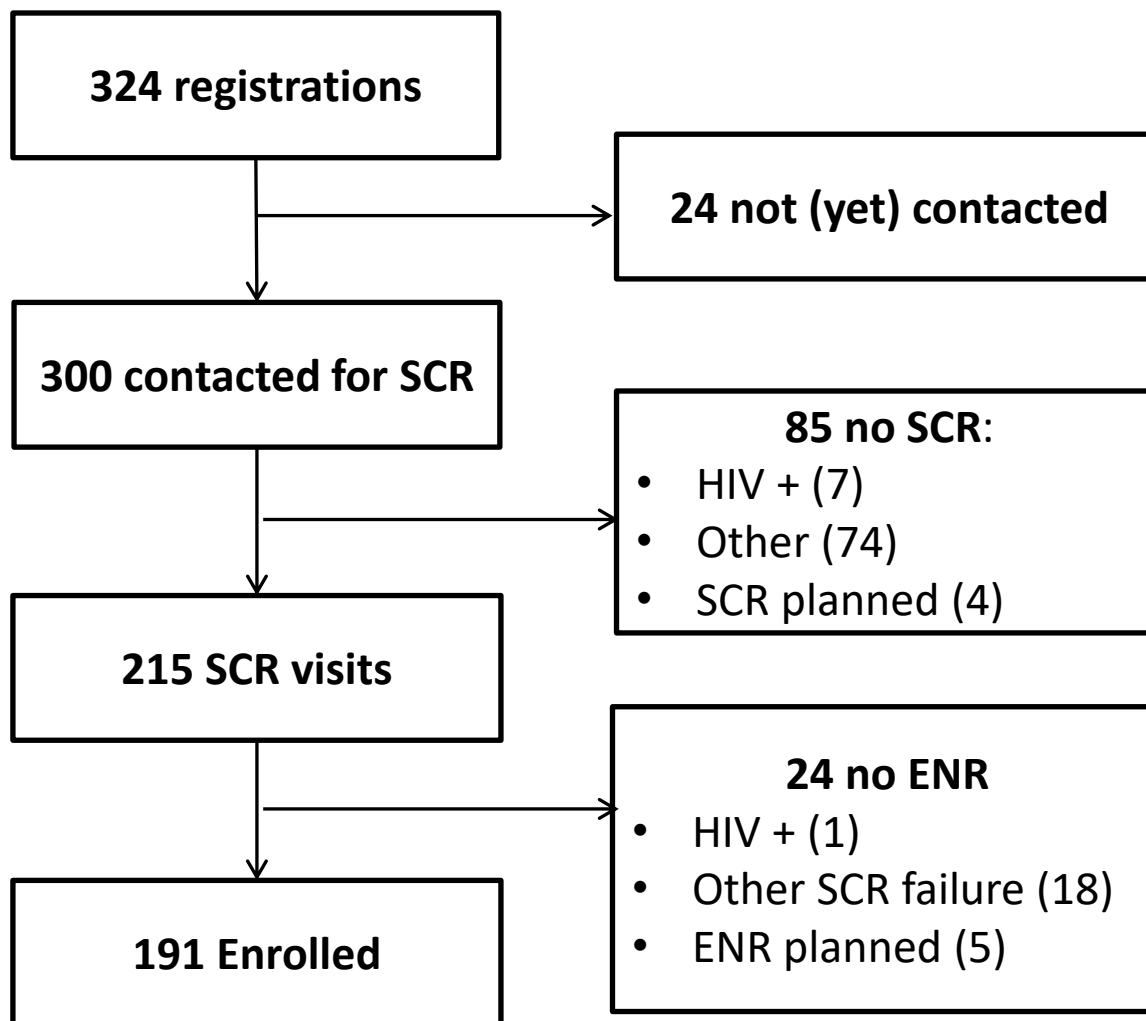


Be-PrEP-ared



Flow chart study

October 2015-November 2016





Baseline Characteristics

Study population (n= 191)



Sociodemographic factors	%
<i>Age</i>	
18-24y	4%
25-34y	29%
35-44y	44%
45-54y	20%
55+	2%
<i>Gender</i>	
Male	98%
Transwoman	2%
<i>Belgian Nationality</i>	79%
<i>Residence</i>	
Flanders	65%
Brussels	29%
Wallonia	6%



Sexual behaviour and Risk



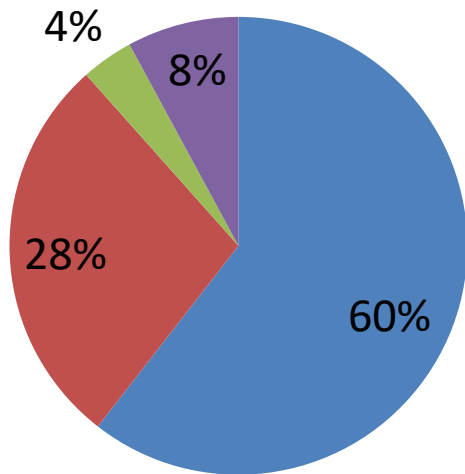
Sexual behavior and risk factors (in the last 3M)	%
Number of anonymous sex partners (anal sex):	
None	13%
1-5	34%
6-15	30%
>15	23%
Condomless Anal Intercourse [CAI] with at least one anonymous partner	70%
Any CAI receptive	64%
Had sex after using recreational drugs	61%
Participated in group sex	63%

Preventive behaviour

Preventive behavior	%
How do you generally manage your risk for HIV:	
I don't use any risk reduction strategy	29%
I frequently ask my partner to use a condom for anal sex	80%
I frequently use a condom	33%
Talked to a new sex partner about his HIV status before sex (in the last 3 months)	70%
Used PEP in the last 12 months	21%
Used PrEP in the last 12 months	6%
HIV test in the last 12 months	96%
STI test in the last 12 months	94%

Syphilis and HSV-2

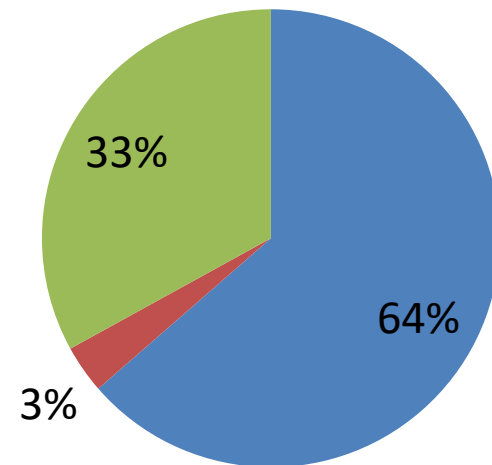
Syphilis serology



- Neg
- TPHA+/RPR-
- TPHA+/RPR+ < 1/4
- TPHA+/RPR ≥ 1/4

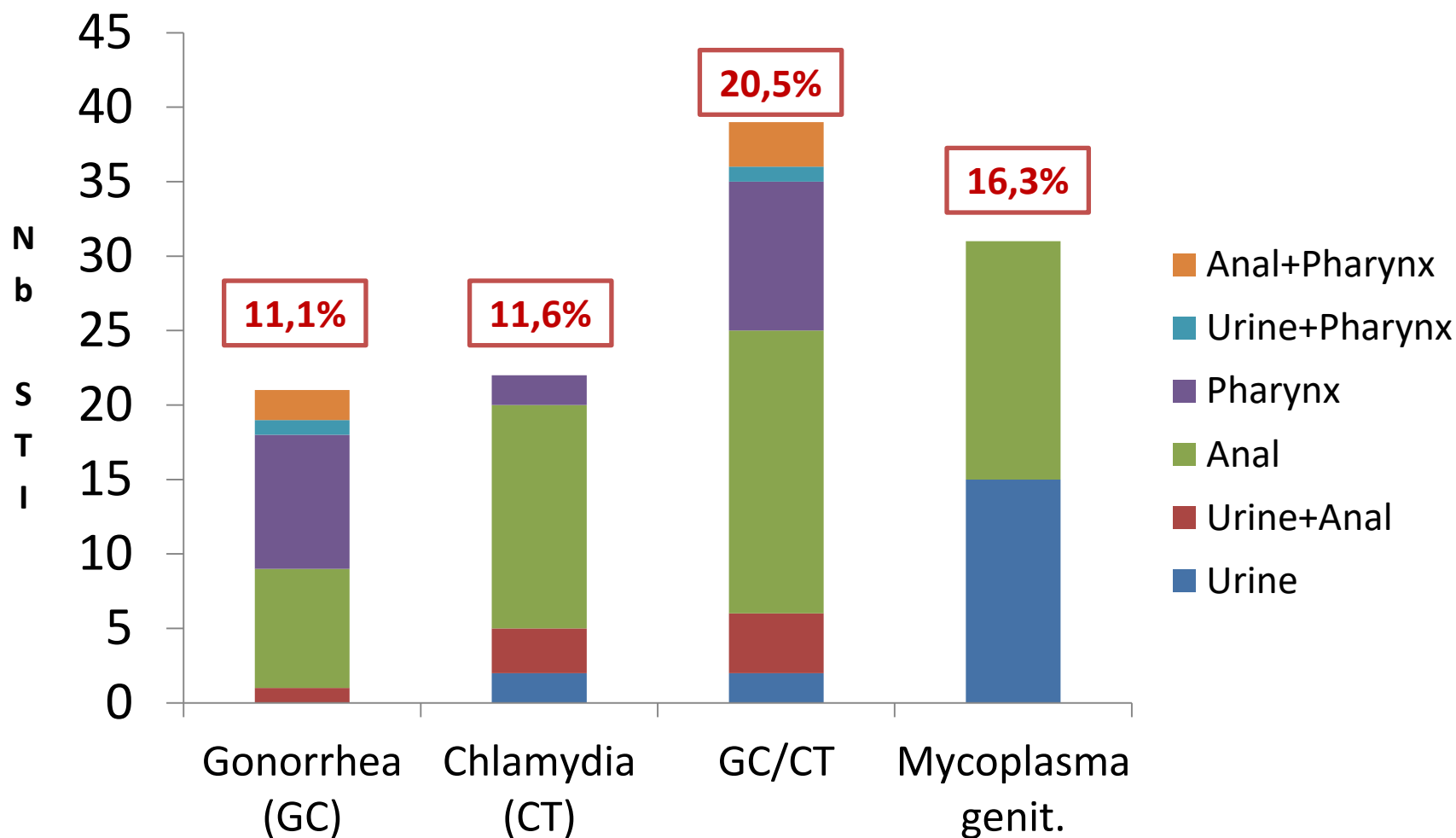
Total TPHA +: 42,2%

HSV-2 serology



- Neg
- Grey zone
- Pos

Sexually transmitted infections



Regimens and reasons for choosing

Daily use 76%

- *Daily seems to be safer*
- *I think it is easier to take one pill a day*
- *I find it difficult to anticipate when I will be at risk*

Event-driven use 24%

- *I can anticipate well when I will be at risk*
- *Event driven PrEP will be less burdensome for my body*
- *I am afraid of side effects*

Preliminary conclusions

- Study Population « at high risk of acquiring HIV » based on sexual & preventive behaviour and STI rates
- « Daily use » regimen most popular as first choice, but one quarter « event driven »
- 192 enrolled (10/2015-now) ; first roll out expected in March 2017
- 8 HIV infections **prior** to study; no new HIV infections **during** study so far



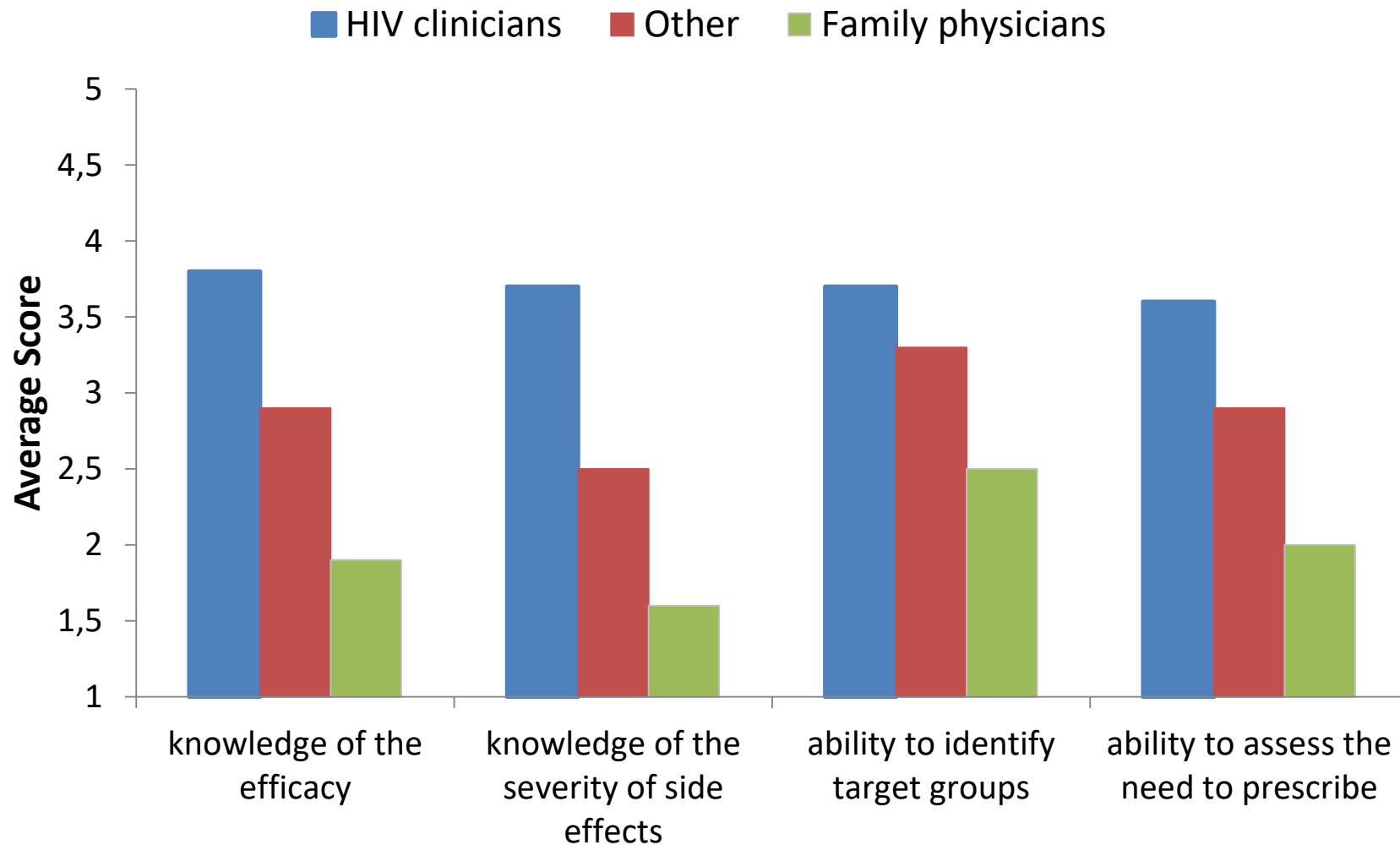
PrEP among healthcare providers



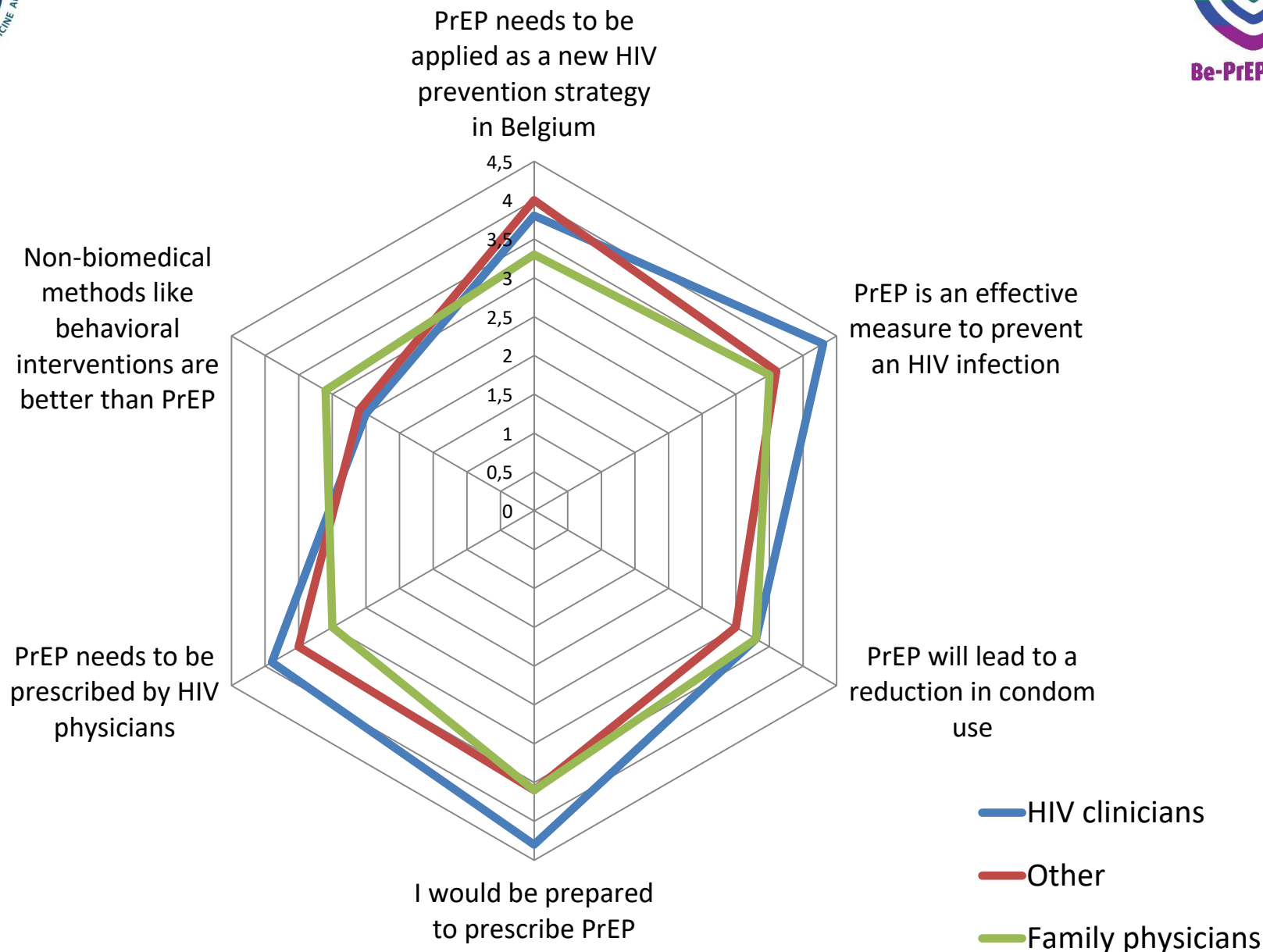
- Online survey among healthcare providers to assess their attitudes towards, knowledge of and experience with providing PrEP
- Main routes of dissemination:
 - BREACH
 - CAB
 - Family physician (FP) circles
 - E-mail lists

Healthcare providers	N (%)
Family physicians (incl. HAIO's, and physicians in low-threshold organizations, Planning Familiale)	269 (70.6)
HIV clinicians (in-hospital HIV specialists, ARC physicians & infectiologists)	39 (10.2)
Other (nurses, psychologists, other physicians & other)	73 (19.2)
TOTAL	381

Self-assessed knowledge of PrEP



Attitudes towards PrEP provision





Consultations Communautaires

Faibles
Connaissances

Besoins d'info
très large

risque de
surmédicalisation

Délai pour
l'accès !

Risque
d'explosion
des IST

PrEPers
« sauvages »



PrEP survey among MSM



PrEP in Belgium?
Participate in our survey!



www.soscisurvey.de/PrEPBE/

Please share...



Other populations

PrEP for African migrants in Europe? A research agenda

Oral pre-exposure prophylaxis (PrEP) is the most recent addition to the toolbox of evidence-based HIV-combination prevention. WHO guidelines recommend that people at substantial risk of HIV infection should be offered PrEP as an additional choice.¹ On Aug 22, the European Medicines Agency (EMA) granted marketing authorisation for once-daily tenofovir with emtricitabine for prevention,² paving the way for PrEP

www.thelancet.com/hiv Vol 3 November 2016

Loos J et al, Lancet HIV 2016

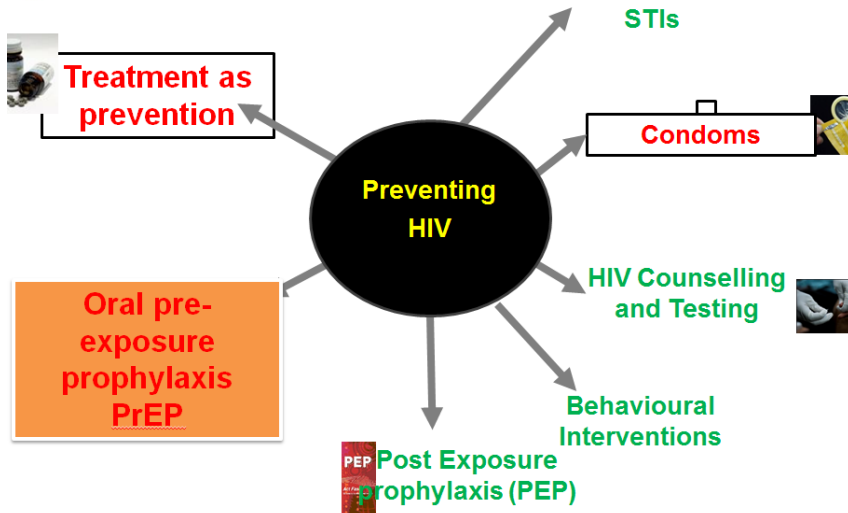


Next steps PrEP implementation Belgium

- **Market authorization by EMA** August 2016
- **PrEP task force** stake holders to coordinate , communicate and advocate
- Opening of « **PrEP clinics** » in Brussels, Liège,..
- Gilead submitted **file for reimbursement** of Truvada for PrEP in October 2016
- Positive advice Monitoring committee HIV plan
- PrEP available / reimbursed some time in 2017 ??



Towards ending the HIV epidemic in Belgium...



Figuur A | MSM: Schatting van de hiv-incidentie, per jaar

