



Southern African HIV Clinicians Society 3rd Biennial Conference

13 - 16 April 2016
Sandton Convention Centre
Johannesburg

**Our Issues, Our Drugs,
Our Patients**

www.sahivsoc.org
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Pre-Exposure Prophylaxis:

The SA PrEP Demo for MSM

Kevin Rebe

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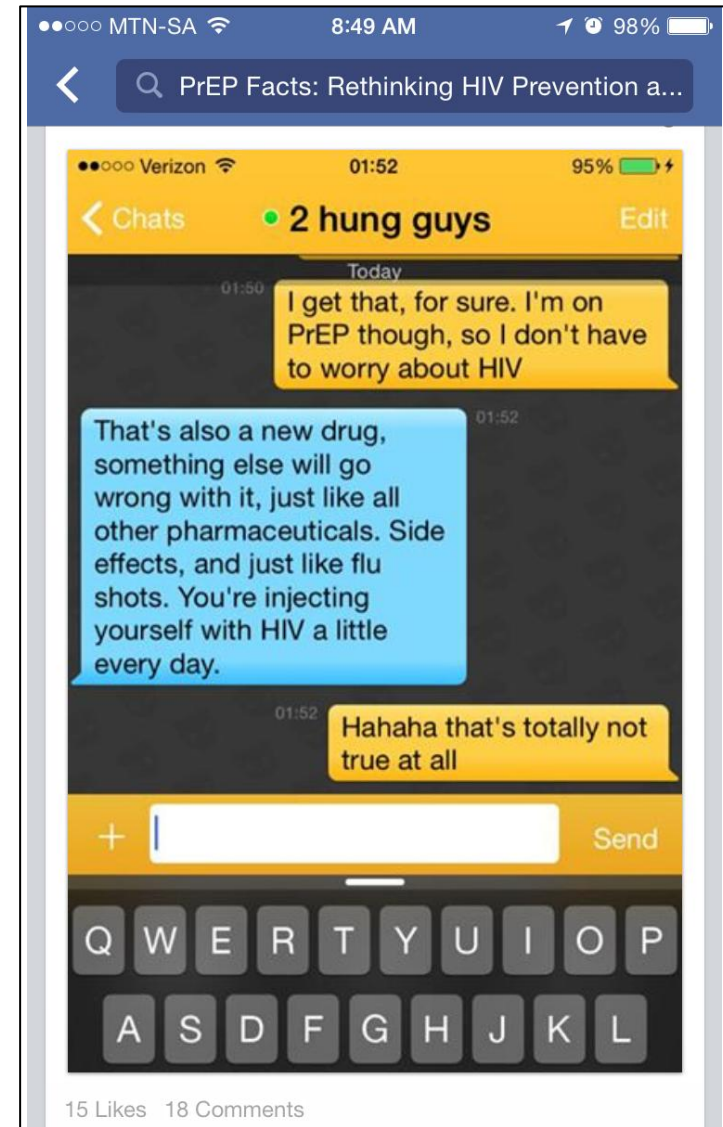
PrEP Works For High-risk People

Subgroup analyses of PrEP trials show that PrEP is effective for those at greatest HIV risk:

- **Heterosexuals (Partners PrEP)** Murnane et al. AIDS 2013
 - *Reporting sex without condoms*
 - *With an STI*
 - *With an HIV+ partner who has a high plasma HIV viral load*
 - *Women <30 years of age*
- **MSM (iPrEx)** Buchbinder et al. Lancet ID 2014; Solomon et al. Clin Infect Dis 2014
 - *Used cocaine*
 - *Had syphilis*
 - *Had anal sex with an HIV+ partner*
- HIV protection estimates for these subgroups were often higher than for the trial population as a whole, because adherence was often greater for persons taking greater risks

Concerns About PrEP

- ARV resistance
- Risk compensation
- Adherence
- Toxicity
- Roll out / Scale up



PrEP and ARV Resistance

Resistance from PrEP was very rare, with only a small number who had acute infection at the time they were started on PrEP.

Gay Man Becomes First Reported Daily PrEP User to Contract HIV

by **Sean Mandell**

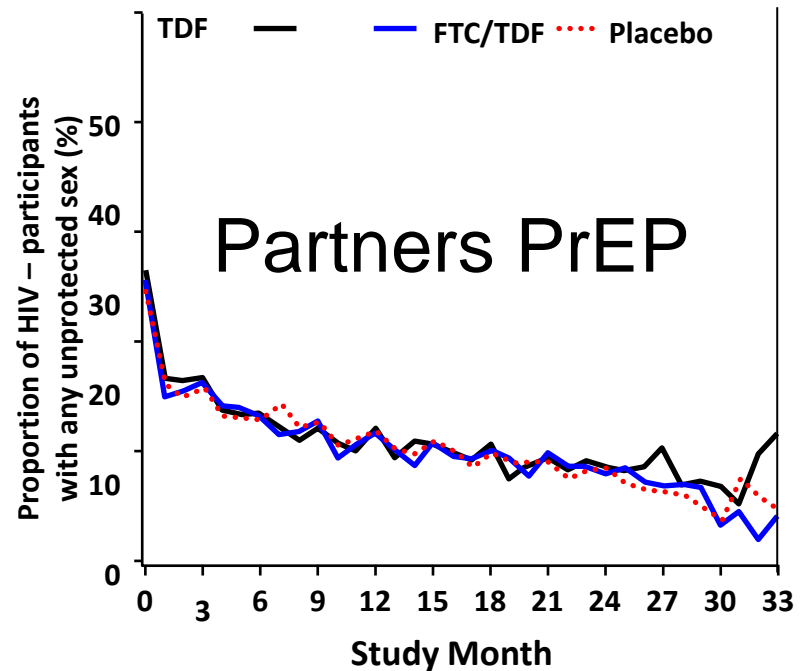
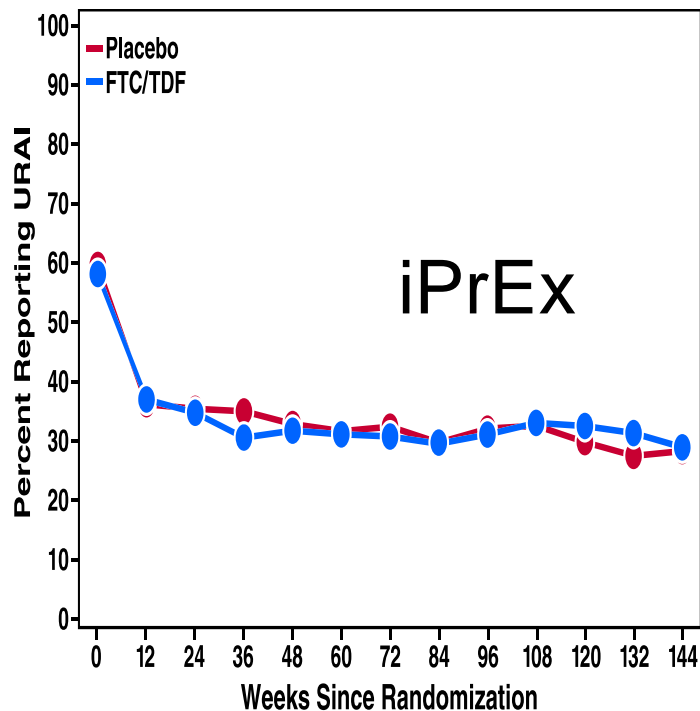
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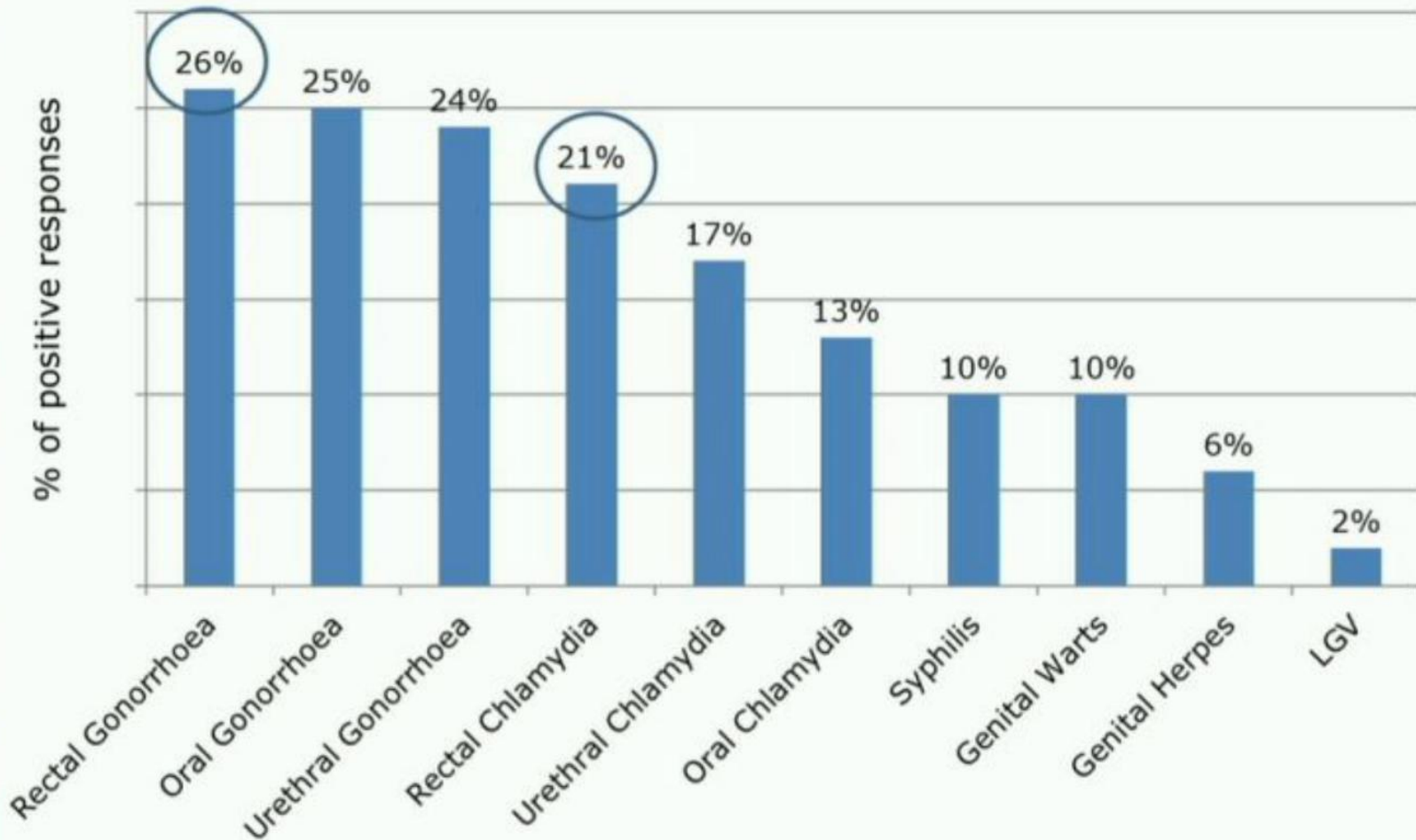
Resistance = K65R (TDF) or M184V/I (FTC) mutations

Risk compensation in PrEP clinical trials

In both iPrEx and Partners PrEP, unprotected sex and STIs were less common over time – suggesting synergy of ongoing risk-reduction counseling along with PrEP.



Self-reported STIs in the year before enrolment



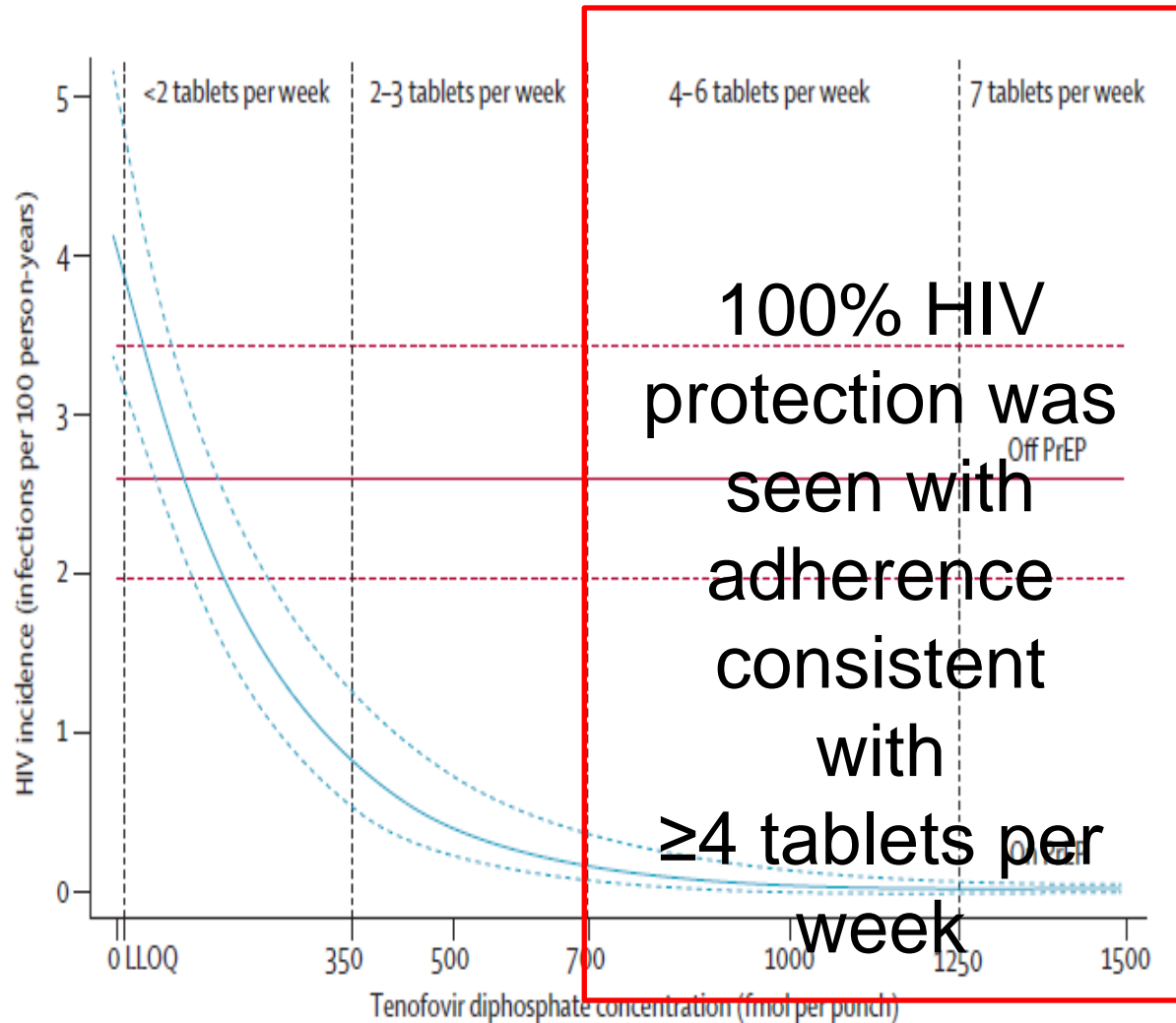
Baseline Characteristics

Characteristics (Median, IQR) or (n, %)	TDF/FTC n = 199	Placebo n = 201
Age (years)	35 (29-43)	34 (29-42)
White	190 (95)	184 (92)
Completed secondary education	178 (91)	177 (89)
Employed	167 (85)	167 (84)
Single	144 (77)	149 (81)
History of PEP use	56 (28)	73 (37)
Use of psychoactive drugs*	85 (44)	92 (48)
Circumcised	38 (19)	41 (20)
Infection with NG, CT or TP**	43 (22)	59 (29)
Nb sexual acts in prior 4 weeks	10 (6-18)	10 (5-15)
Nb sexual partners in prior 2 months	8 (5-17)	8 (5-16)

* in last 12 months: ecstasy, crack, cocaine, crystal, speed, GHB/GBL

** NG: Neisseria gonorrhoeae, CT: Chlamydia trachomatis, TP: Treponema pallidum

Perfect Adherence is Not Required: iPrEx OLE



PrEP Demonstration Projects

- US: Multisite demonstration project in San Francisco, Miami and Washington DC.
- South America: PrEP Brasil
- South Africa: TAPS project for SW in Jhb and EJAF PrEP for MSM in CT and Jhb

US PrEP Demonstration Project

- Launched Sep 2012, fully enrolled Mar 2014
- Eligible: At risk, HIV and HBV negative

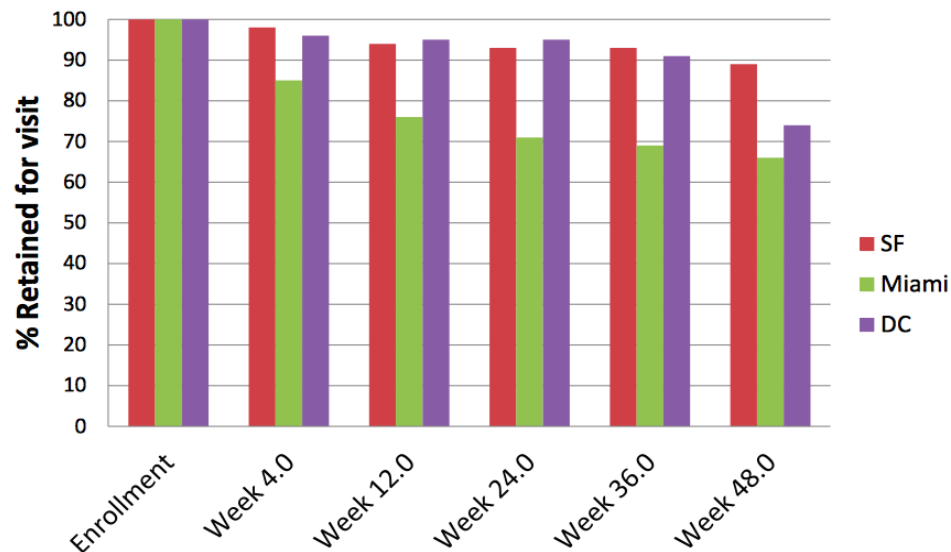
PrEP eligibility and uptake, by site

	SF	Miami	DC	Total
Approached for pre-screening	581	312	176	1069
Declined	233	76	55	364
Ineligible (behavioral or medical)	48	79	21	148
Enrolled	300	157	100	557
Uptake among potentially eligible	56%	67%	65%	60%

Fuchs, J et al. Lessons learned from the US PrEP Demonstration Project: Moving from the “real world” to the “real, real world”.

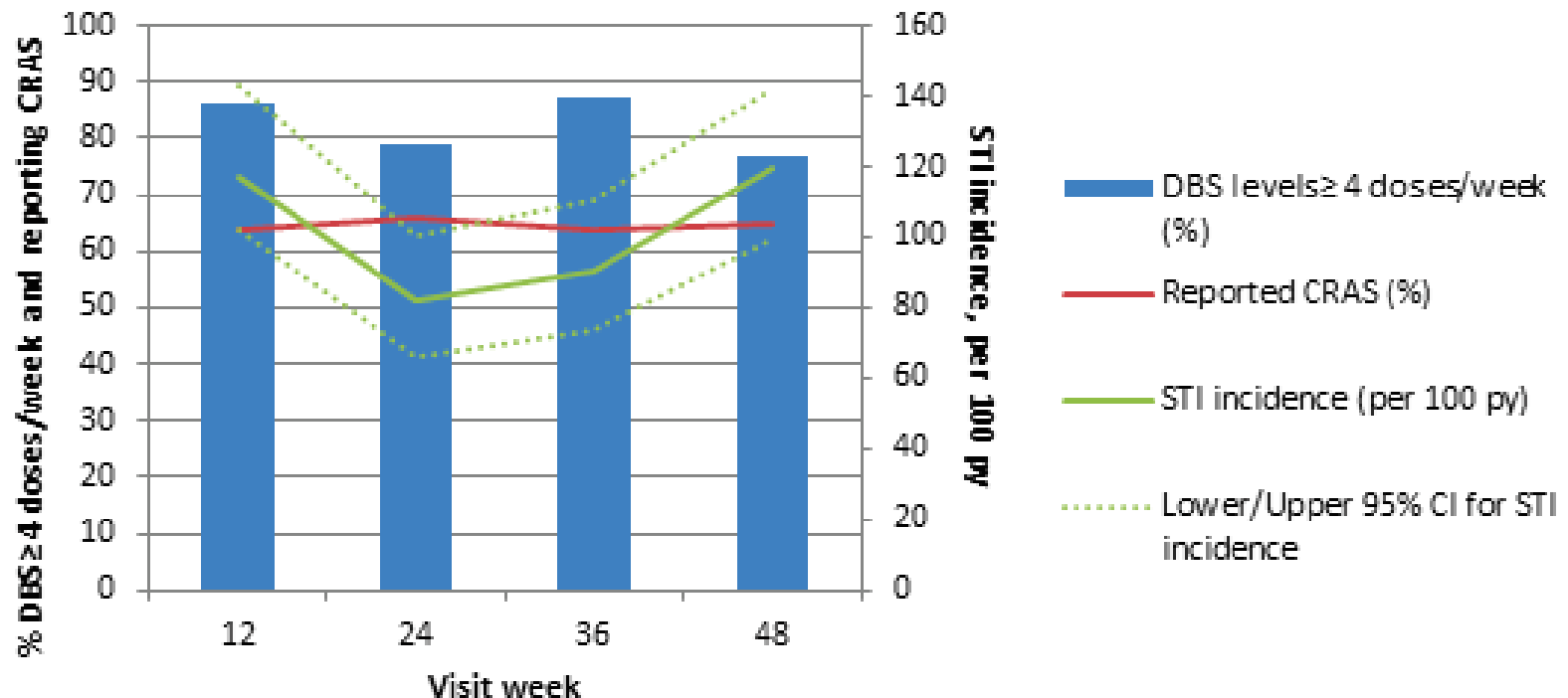
<http://federalaidspolicy.org/wp-content/uploads/2015/04/Fuchs-FAPP-15-April-15.pdf>

Retention in the Demo Project



US PrEP Demonstration Project

Adherence, Risk Behavior, and STI incidence Over Time in the Demo Project



Lui A et al. Adherence, sexual behavior and HIV/STI incidence among MSM and TGW in the US PrEP Demonstration Project. Abstract IAS 2015. Vancouver, Canada.

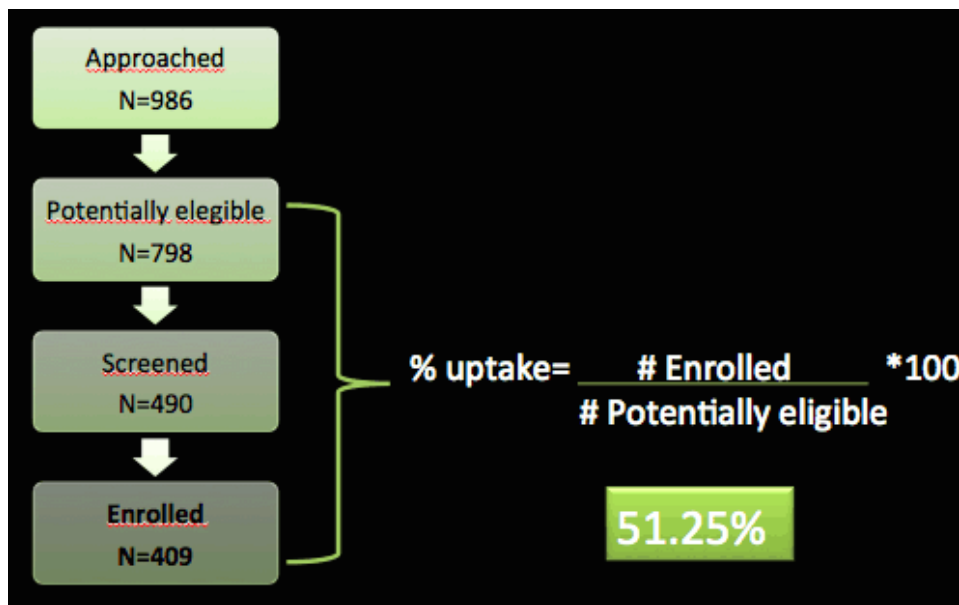
US PrEP Demo Project – HIV Rates

- 3 acute infections at enrollment
 - All had negative rapid and 4th gen HIV tests
 - 2 had positive pooled RNA, 1 positive individual RNA
 - FTC resistance (M184V) developed in one ppt 1 week after enrollment: suppressed on combination ART
- Only 2 infections during follow-up
 - PPT #1: 19 weeks after enrollment:
Reported last dose >1 month prior, TFV-DP levels < 2 doses/wk
 - PPT #2: 4 weeks after 48 week visit:
TFV-DP levels < 2 doses/wk or undetectable after week 4.
 - No evidence of HIV resistance

Fuchs, J et al. Lessons learned from the US PrEP Demonstration Project: Moving from the “real world” to the “real, real world”. <http://federalaidspolicy.org/wp-content/uploads/2015/04/Fuchs-FAPP-15-April-15.pdf>

PrEP

PROFILAXIA PRÉ EXPOSIÇÃO *Brasil*



- First Demo in LMIC
- PrEP uptake associated with:
 - City / site of delivery
 - TG versus male
 - High perceived HIV risk
 - Previous HIV testing
 - Previous PrEP awareness
 - >2 Condomless RAI partners
 - Sex with HIV pos partners

Grinsztejn, B et al. PrEP Uptake and associated factors among MSM and TGW in the PrEP Brazil demonstration project. Abstract. IAS 2015 Vancouver, Canada.

Exactly Zero Men on PrEP Contract HIV in 2.5-Year Study

The findings confirm PrEP to be a powerful tool against contracting the virus.



29.6K



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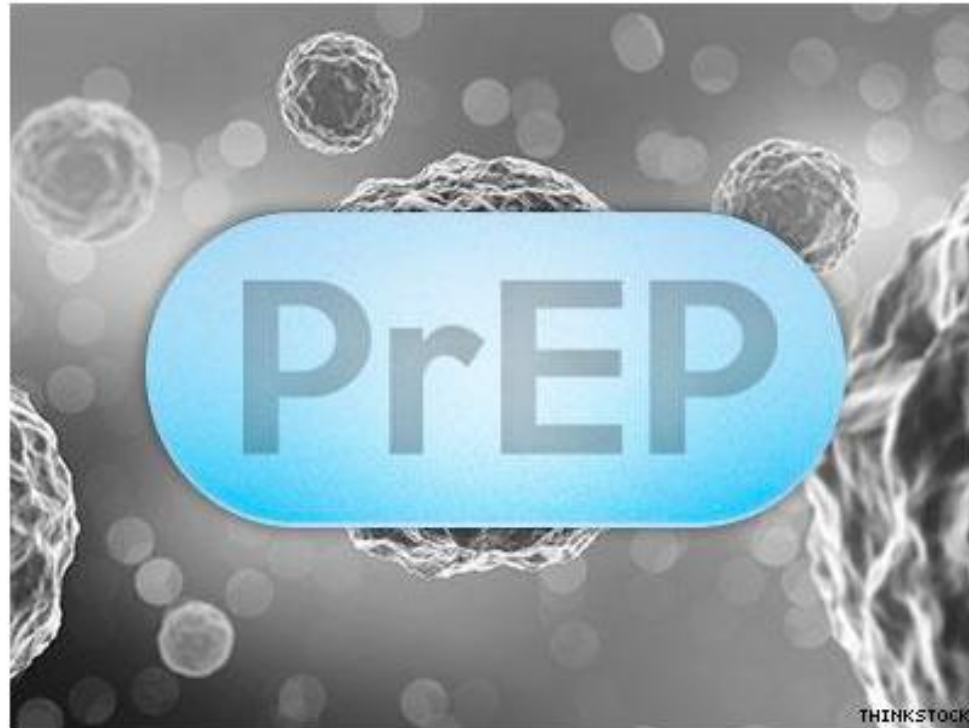
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PRINT



EMAIL



After two and a half years of trials, a new study has found no new HIV infections among a group of people on pre-exposure prophylaxis (PrEP).

For 32 months, researchers at the Kaiser Permanente Medical Center in San Francisco tracked the health of over 600 people as they used Truvada daily to prevent the virus in a real-world setting.

The average age of the study participants was 37, and 99 percent were men who have sex with men. The average length of

individual usage was 7.2 months. Members of this group also reported a higher likelihood of having multiple sex partners than those not using PrEP.

No one in the study contracted HIV.

PrEP FOR YOUR DARKROOM DANCE, WITH 1 PILL A DAY.

If you see yourself dabbling in the dark, then you should consider taking PrEP.

PrEP (Pre-exposure prophylaxis) is a revolutionary HIV prevention strategy ideal for Men who have Sex with Men.

This pill, when taken daily, reduces your risk of becoming infected with HIV. With minimal side-effects, PrEP is a convenient way to protect yourself and your health. While PrEP drastically decreases your chances of contracting HIV, it doesn't protect you from STIs so it's best to use a condom.

Available from selected Health4Men clinics.
To find out more visit www.health4men.co.za, or speak to your doctor.

PrEP₄life

THE DAILY PILL FOR HIV PREVENTION



PrEP FOR YOUR WILD TIME WITH A BEAR, WITH 1 PILL A DAY.

If you're on the hunt for a wild time with a burly bear, then you should consider taking PrEP.

PrEP (Pre-exposure prophylaxis) is a revolutionary HIV prevention strategy for Men who have Sex with Men.

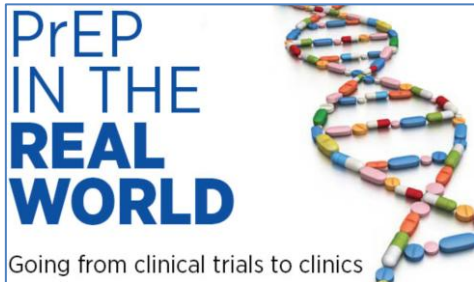
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PrEP₄life

THE DAILY PILL FOR HIV PREVENTION





The EJAF PreP Demonstration Project for MSM

- The South African PrEP Demonstration Project
- Demonstration project not a clinical study
- Running within Health4Men COE's
- Aims:
 - Assess feasibility of delivering nurse-driven PrEP at a primary health care level as part of combination HIV prevention

Recruit 300 MSM at two sites (CT and Jhb) and maintain on PrEP over two years

>115 recruited to date
1 lost to follow up at month 2.

PrEP4life
THE DAILY PILL FOR HIV PREVENTION

The EJAF PreP Demonstration Project for MSM

PrEP4life

THE DAILY PILL FOR HIV PREVENTION

Secondary Aims:

- Assess the knowledge, **acceptability** and **uptake** of PrEP and other HIV prevention interventions among HIV-negative MSM
- Characterize the population of MSM who accept PrEP
- Assess **retention** in the study at 3, 6, 9 and 12 months.
- Monitor **patterns of use** of PrEP.
- Assess prevention method preferences and acceptability.
- Monitor **side effects** and safety of PrEP.
- Monitor the HIV status of MSM using PrEP and the **emergence of drug resistance** among those who acquire HIV.
- Monitor **changes in self-reported sexual behaviour** in MSM (including reduction or increase of risky sexual behaviour).
- Assess **adherence** to PrEP medications using therapeutic drug level monitoring

Implementation Lessons

Level of monitoring

- PrEP Demo Project Monitoring:
 - Two HIV neg tests two weeks apart
 - Baseline creatinine and baseline HBV screen
 - Creatinine at month 1, 2 and 3 monthly
 - HCT at month 1,2 and 3 monthly
 - TDF blood levels at month 1,2 and 3 monthly

→ Not feasible or necessary

- No late creatinine elevation identified to date in demo project
- Not all had positive TDF blood level at month 1

→ SA Clinician Society Guidelines more than sufficient

PrEP4life

THE DAILY PILL FOR HIV PREVENTION



Implementation Lessons

- Nurses are able to provide PrEP*
- Able to educate and provide correct information
- Adherence assessment and support challenging
 - Designing an adherence support package that can be implemented by nurses in <15 minutes...
 - Adapt existing tools and using “next step counselling”
 - Train current lay counsellors
 - Leverage virtual support

***A lot of nurse mentoring was required in the first month**

Implementation Lessons

- Demand Creation
 - Political will
 - Civil society support (SANAC)
 - Education and knowledge translation
 - Outreach and peer programs
 - Marketing

**Demand has been higher
than our planned
recruitment rate**



Country MSM Sample Size

Target population for PrEP

750-1,5 million (UCSF Data Triangulation)

200 000 (DOH)

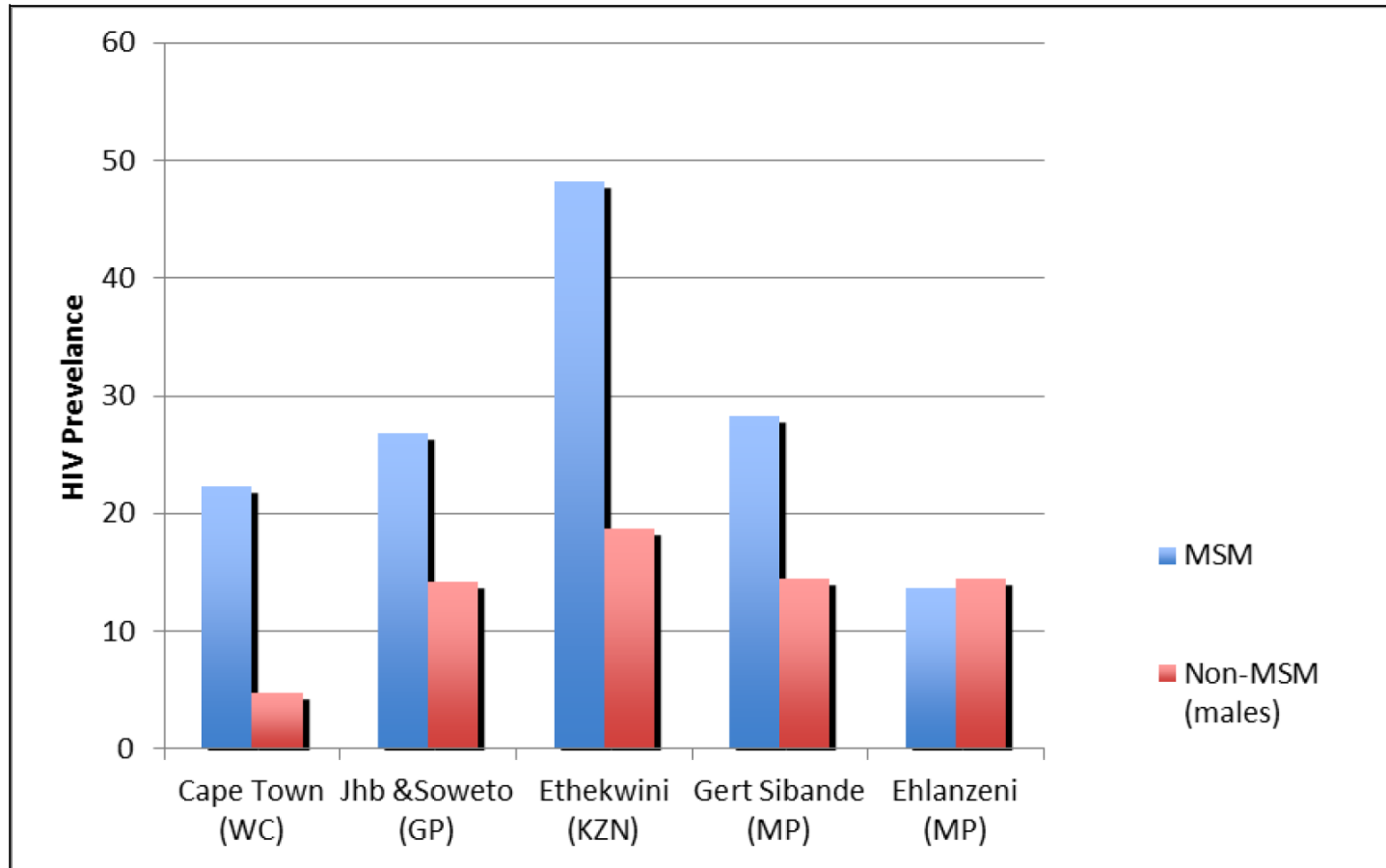
30% HIV positive → link to ART

140 000 HIV negative MSM

Assume 30% at risk & need PrEP = 42 000 MSM

Geographic Variation

Figure 3 HIV prevalence among MSM, compared to HIV prevalence among males in the general population (aged 15 years and older), 2013



How to Sell PrEP?



Thank You

SA Clinicians Society

PEPFAR / USAID

Elton John Foundation

Anova Health Institute

Cipla

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