

How will we market licensed products?



Kenneth Mayer, MD

Fenway Health

Beth Israel Deaconess Medical Center

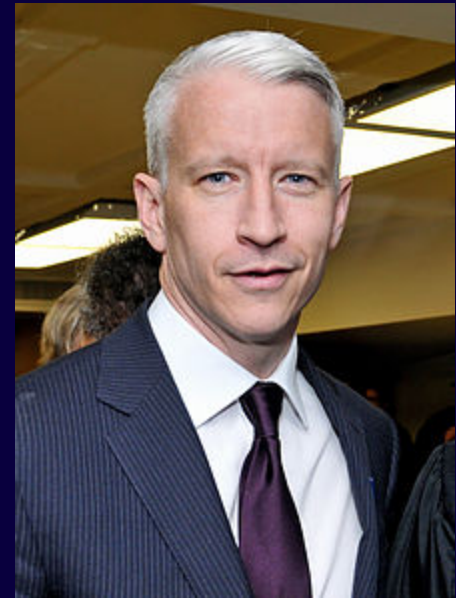
Harvard Medical School and School of Public Health

Creating Desire for Microbicides Workshop

Crystal City, May 14th, 2014

Models and Key Opinion Leaders

- Sexual lubricants? Sex toys?
- Contraceptive Technology?
- Vaginal microbicides?
- Other consumer products?
- Reaching prescribers
- Reaching consumers
- Reaching insurers
- Creating community demand



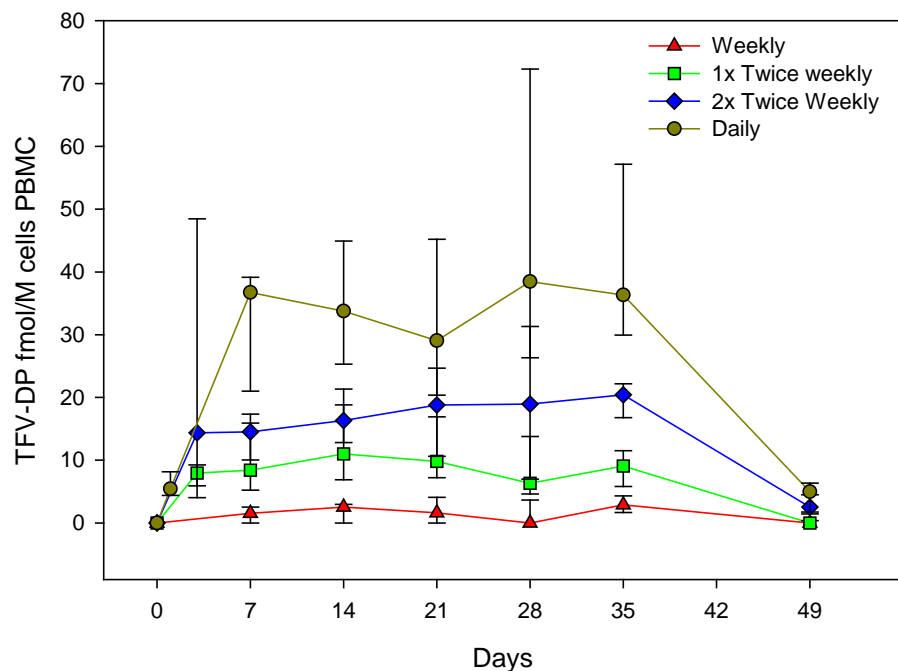
Context and Pharmacology Matter

- What is the efficacy of topical agent compared to oral (and injectable) PrEP?
- Is a single dose just before sex sufficient for protection, or is there a need for a post-exposure dose, or are loading doses needed?
- If person has anal sex sufficiently often can loading doses be skipped?
- If person has less frequent sex, is oral priming at a certain frequency optimal for protection?

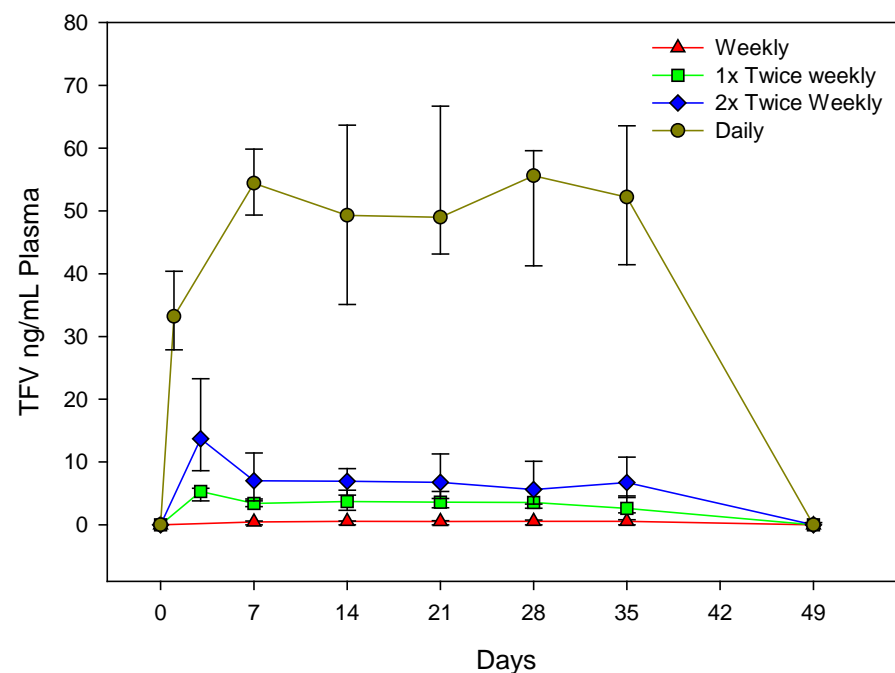
Tenofovir PBMC v. Plasma (HPTN 066)

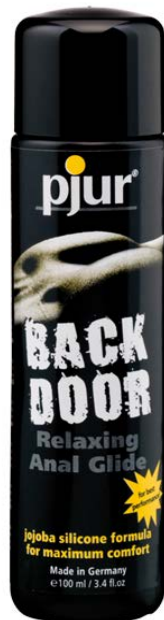
(Hendrix C et al, CROI, 2014)

PBMC Tenofovir diphosphate



Plasma Tenofovir





Crazy Girl Anal Desensitizing Gel

- A Diva's Secret for Ease of Anal Intimacy! **Formulated with Benzocaine**...A safe & effective desensitizer to assist in relaxing the anal sphincter. Also contains Aloe Vera leaf juice skin soothing/moisturizing agent. Take Sexuality to Bold, New Levels. Allows for a more pleasurable penetration during intimacy. Place a small amount of product to anal area. Gel formula absorbs faster than creams...less chance of product transfer to partner. Intended for use with a personal lubricant if used during intimacy
- Paraben-Free
- Sugar-Free
- Sulfate-Free
- Water-Soluble
- Greaseless
- Non-Staining
- Adult Toy & Latex Friendly
- pH Balanced for the Feminine Well-Being
- Made in USA
- No Animal Testing



A Pill for HIV Prevention: Déjà Vu All Over Again?

Julie E. Myers^{1,2} and Kent A. Sepkowitz³

¹Bureau of HIV/AIDS Prevention and Control, New York City Department of Health and Mental Hygiene, ²Division of Infectious Diseases, Department of Medicine, Columbia University Medical Center, and ³Infectious Disease Service, Memorial Sloan Kettering Cancer Center, New York, New York

- OCP FDA approved: 1960
- 3.8 million users by 1965
- Private and federal subsidies → ↓ disparities
- Pharma: “detail men” for provider
- Media campaign → informed consumers
- Changed social norms, topic of discussion
- 82% of US women have, or will, use hormonal contraception at some time

Hormonal contraception and anti-HIV chemoprophylaxis

- Cost (OCP <\$80/mo)
- Concerns about selection for resistance
- Less than 100% efficacy
- Toxicity concerns may be moderated by new knowledge, e.g. lower dose, different delivery system (i.e. topical)
- Risk compensation concerns raised for both
- Homophobia, HIV stigma vs. misogyny

Marketing Approaches

It's Medicine, but for intimacy

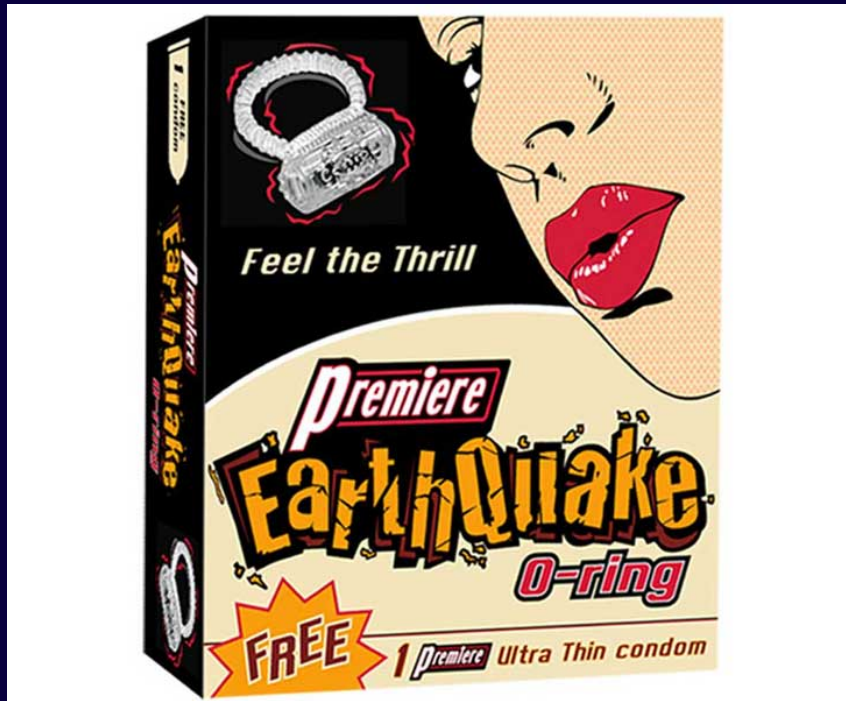
It's relational, but also about personal control



Marketing Approaches

Symbolic: The earth moves

Get to the point: It's about sex



gay.com

ENCOUNTER. EXPERIENCE. ENJOY.

10466 Members Online Now

CHAT FIND MEMBERS MY PROFILE MY LISTS VIEW



AT&T presents the HTC One™ X

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username password

online status: Online

LOGIN

Not A Member?

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I am gay.com



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English (English) v

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Forgot Password?

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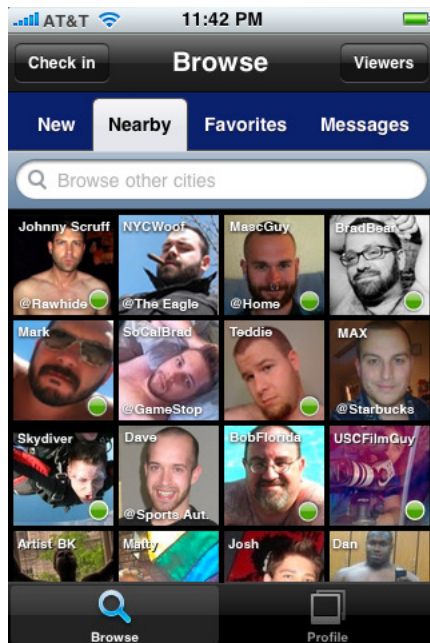
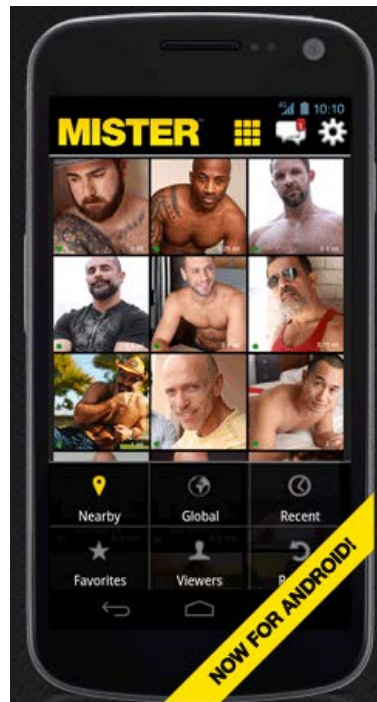
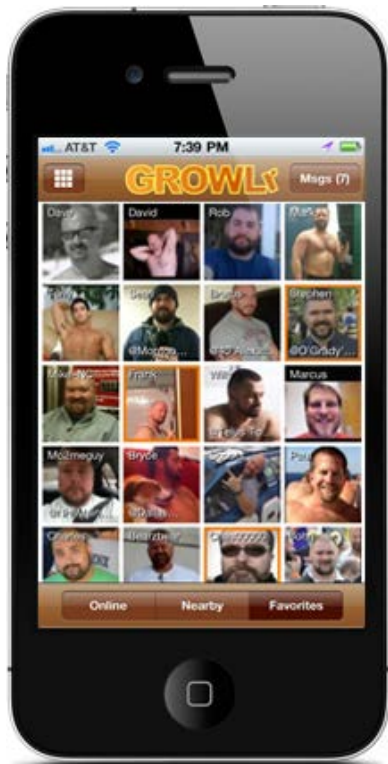


iPhone/iPad Android

Many MSM websites host Health Ed content

The screenshot displays the Manhunt Cares website interface. On the left is a dark blue sidebar with the 'MANHUNT CARES' logo and navigation links for Facebook, Twitter, and various content categories. The main content area features a header with the slogan 'Health partnerships that make a difference™'. Below this, there are three article previews:

- HRC Blog: Mitt Romney Rejected Birth Certificates for Massachusetts Children Born to Same-Sex Couples** (October 27, 0 Comments). The article includes a photo of Mitt Romney and a 'HUMAN RIGHTS CAMPAIGN' logo. The text states: 'According to a report in the Boston Globe, Romney rejected a request from the state's Registry of Vital Records and Statistics to revise birth certificate forms to apply to same-sex parents.' A 'Continue reading' link is provided.
- US Community Report: The Coolest Sex Survey Results You'll Ever See (And Play With!)** (October 25, 0 Comments). This article features an infographic titled 'Aw, Cum On!' with statistics: '61.3% like the taste of cum in their mouth' and '93.5% of dildo users have inserted a dildo into their own anus'. The text notes: 'The results, which are based on a recently published study in The Journal of Sexual Medicine, are presented on an interactive site that's as fun to play with as it is informative.' A 'Continue reading' link is provided.
- Huffington Post: Romney May End Hospital Visitation Rights for Many Gay Couples** (October 23, 0 Comments). The article is accompanied by a blue graphic of two stylized figures.
- Featured Campaign: Sero Disco 2 – Why let HIV get in the way of a good relationship?** (October 21, 5 Comments). This article includes a photo of two men and text that reads: 'LOOKING AFTER EACH OTHER IN POS-NEG RELATIONSHIPS INCLUDES EVERYTHING FROM COMMUNICATION TO CONDOMS'.

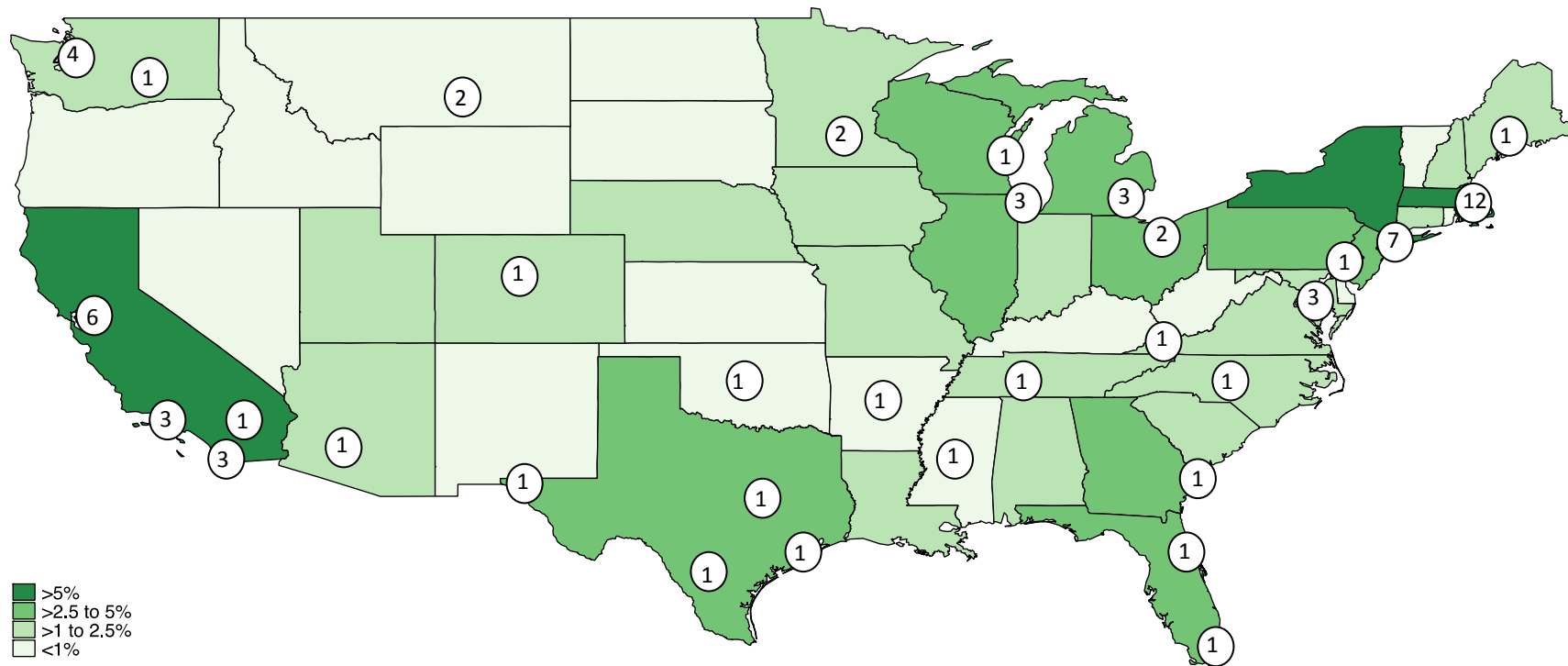


PrEP Attitudes and Uptake

- **Manhunt survey pre/post iPrEX**
 - 4,825 MSM:46 states and 5 Canadian provinces
 - Less than 20% heard of PrEP
 - Less than 1% had used PrEP
 - Majority were interested, depending.....
- **Massachusetts MD survey post-CAPRISA**
 - Most had heard of CAPRISA 004
 - Some knew that PrEP studies were underway
 - Many concerns about risk compensation, resistance, cost

Proportion of PrEP Users by State of Residence

(MH PrEP Survey, Mayer et al, CROI 2014)



Proportion of reponders; darker shades of green indicate a higher proportion of participants. Not pictured: Alaska (0.2%) and Hawaii (0.6%)

N=9,179 1.2% had used PrEP

Circles indicate locations where PrEP use was reported and number of participants reporting PrEP use in that location

Factors Associated with PrEP Use among US MSM

Multivariable Model, Manhunt Survey, CROI, 2014

Characteristic	Multivariable OR (95% CI)
College graduate or above (vs. less than college education)	5.33 (1.25 to 22.7)
Ever diagnosed with an STI	2.74 (1.36 to 5.52)
Used PEP	16.0 (8.24 to 31.2)
Comfortable talking with provider about MSM sex	4.19 (1.51 to 11.6)

To implement PrEP successfully, it will be essential to engage practicing clinicians



REVIEW

Annals of Internal Medicine

What Primary Care Providers Need to Know About Preexposure Prophylaxis for HIV Prevention

A Narrative Review

Douglas Krakower, MD, and Kenneth H. Mayer, MD

As HIV prevalence climbs globally, including more than 50 000 new infections per year in the United States, we need more effective HIV prevention strategies. The use of antiretrovirals for preexposure prophylaxis (PrEP) among high-risk persons without HIV is emerging as one such strategy. Randomized, controlled trials have demonstrated that once-daily oral PrEP decreased HIV incidence among at-risk men who have sex with men and African heterosexuals, including serodiscordant couples. An additional randomized, controlled trial of a topical pericoital antiretroviral microbicide gel decreased HIV incidence among at-risk heterosexual South African women. Two other studies in African women did not demonstrate the efficacy of oral or topical PrEP, raising concerns about adherence patterns and efficacy in this population.

The U.S. Food and Drug Administration (FDA) Antiviral Drugs Advisory Committee reviewed these studies and additional data in May 2012 and voted to advise the approval of oral tenofovir–emtricitabine for PrEP in high-risk populations. On 16 July 2012,

the FDA recommended that this combination medication be approved for use as PrEP in high-risk persons without HIV. Patients may seek PrEP from their primary care providers, and those receiving PrEP require monitoring. Thus, primary care providers should become familiar with PrEP. This review outlines current knowledge about PrEP as it pertains to primary care, including identifying persons likely to benefit from PrEP; counseling to maximize adherence and reduce potential increases in risky behavior; and monitoring for potential drug toxicities, HIV acquisition, and antiretroviral drug resistance. Issues related to cost and insurance coverage are also discussed. Recent data suggest that PrEP, combined with other prevention strategies, holds promise in helping to curtail the HIV epidemic.

Ann Intern Med. 2012;157:490–497.

For author affiliations, see end of text.

This article was published on www.annals.org on 22 July 2012.

www.annals.org

Purview paradox

Krakower et al, Boston physician focus groups

Practical issue number one is that the people who are going to be prescribing these drugs in theory, who are going to be in the best position, are going to be primary care providers with little or no HIV experience.

–Male, Hospital-based

I think that the idea of adding to what I just did this morning and adding a discussion with my patients about what is their likelihood of having sexual encounters with patients who are HIV-infected, and then on top of that trying to prescribe and get approved medication like Truvada or some other pre-exposure prophylaxis... I just can't imagine it working in the hands of a primary care doctor.

–Female, Hospital-based

A tool for risk-stratifying MSM: CDC risk index (“HIRI-MSM”)

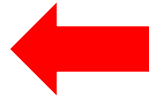
“In the past (year) have you had sex?”



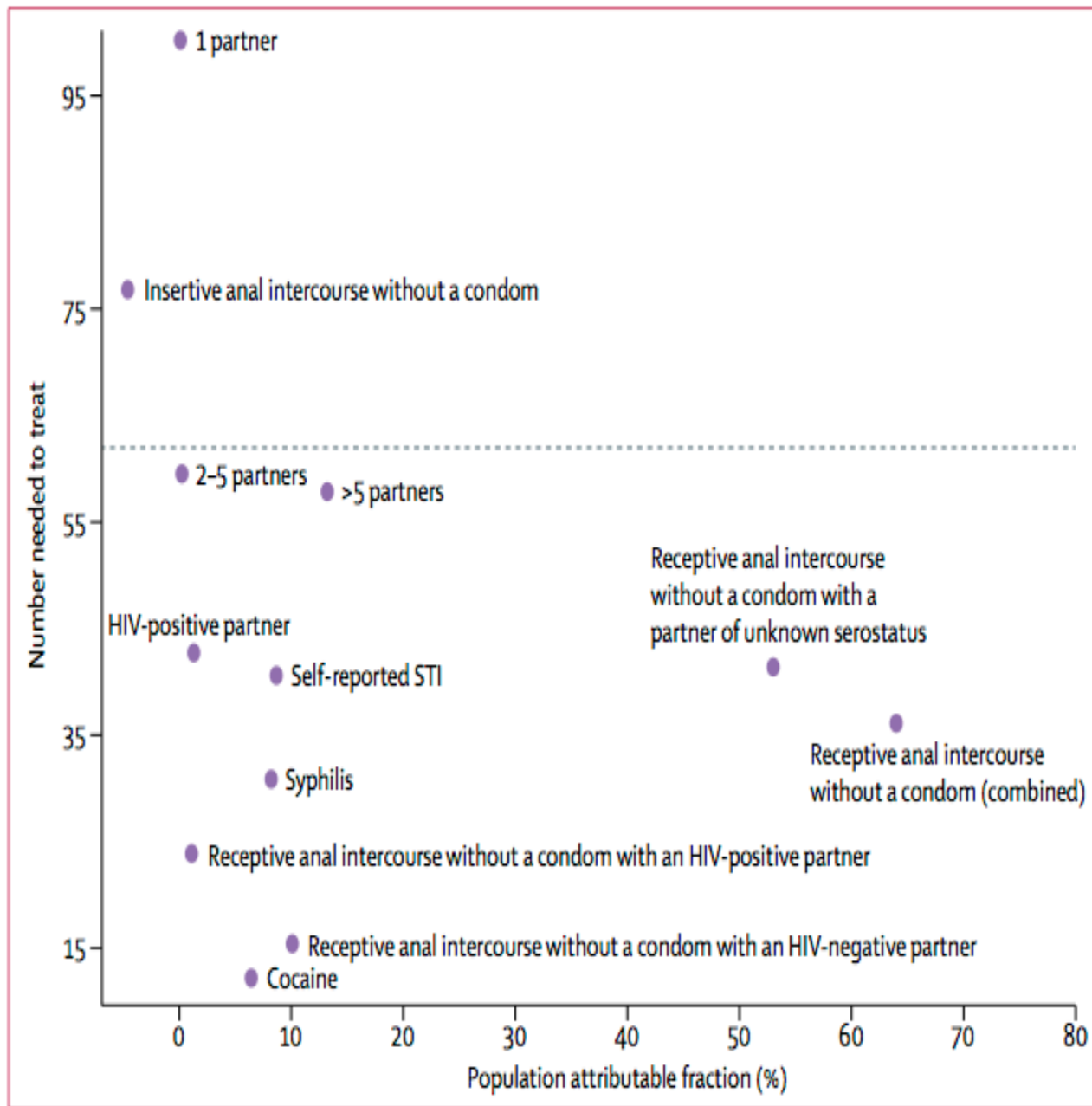
“With men, women, or both?”



Score < 9: standard prevention
Score ≥ 10: consider PrEP



HIRI-MSM Risk Index*			
1	How old are you today (yrs)?	<18 years	score 0
		18–28 years	score 8
		29–40 years	score 5
		41–48 years	score 2
		≥49 years	score 0
2	How many men have you had sex with in the last 6 months?	>10 male partners	score 7
		6–10 male partners	score 4
		0–5 male partners	score 0
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man?	1 or more times	score 10
		0 times	score 0
4	How many of your male sex partners were HIV positive?	>1 positive partner	score 8
		1 positive partner	score 4
		<1 positive partner	score 0
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?	5 or more times	score 6
		0 times	score 0
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes	score 5
		No	score 0
7	In the last 6 months, have you used poppers (amyl nitrate)?	Yes	score 3
		No	score 0
Add down entries in right column to calculate total score			Total score†



Buchbinder, et al., Lancet ID, 2014

Thank You

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