GLADSTONE INSTITUTES

A Sex-informed Framework for HIV Prevention

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SAN FRANCISCO AIDS FOUNDATION

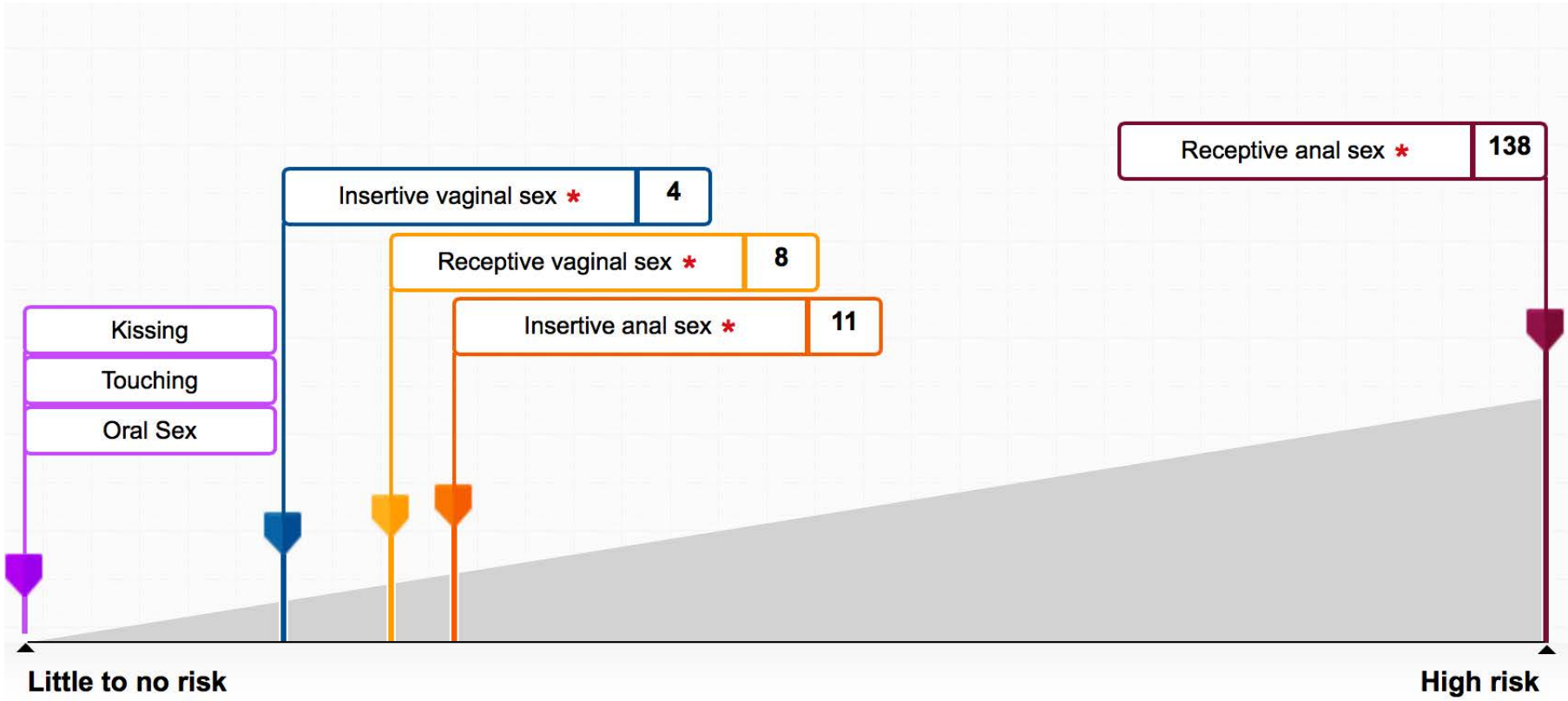
UCSF

Disclosures

- Gilead Sciences donated study medication to US NIH for trials that I have led, including iPrEx, iPrEx OLE, and HPTN 067.
- Gilead Sciences contracted with San Francisco AIDS Foundation for phase 3 research on F/TAF PrEP.
- VIIV contracted with Gladstone to support phase II research on long-acting injectable PrEP.

Risk of HIV Transmission:

if no condoms, no PrEP, and no treatment, transmission per 10,000 sex acts



https://wwwn.cdc.gov/hivrisk/estimator.html#-~sb

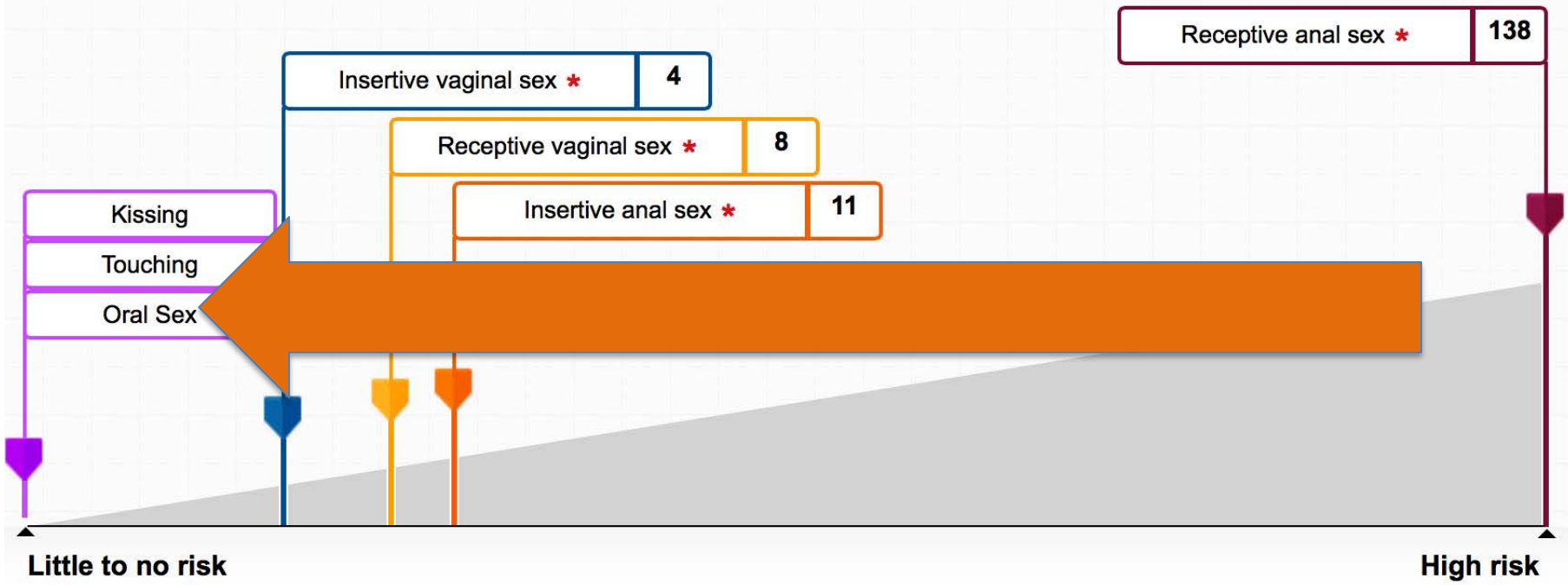
Patel *et al* (2014). Estimating per-act HIV transmission risk: a systematic review. AIDS, 28(10), 1509-1519

CDC Estimates of Efficacy

Treatment >96%

PrEP for MSM >92%, heterosexuals 90%

Condoms 63% to 80%



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Established in 1871

Swiss Medical Weekly

Formerly: Schweizerische Medizinische Wochenschrift

An open access, online journal • www.smw.ch

Editorial | Published 29 January 2016, doi:10.4414/smw.2016.14246

Cite this as: Swiss Med Wkly. 2016;146:w14246

HIV is not transmitted under fully suppressive therapy: The Swiss Statement – eight years later

Pietro L. Vernazza[a], *Edwin J. Bernard*[b]

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[b] Brighton, United Kingdom

What has changed since 2008?

- HPTN 052
- Partners
- Opposites Attract
- PrEP clinical trials
- PrEP demo & real world studies

HPTN 052 (Final Analysis)

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‖

Cohen et al, NEJM 375(9):830 2016

Original Investigation

Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy

Alison J. Rodger, MD; Valentina Cambiano, PhD; Tina Bruun, RN; Pietro Vernazza, MD; Simon Collins; Jan van Lunzen, PhD; Giulio Maria Corbelli; Vicente Estrada, MD; Anna Maria Geretti, MD; Apostolos Beloukas, PhD; David Asboe, FRCP; Pompeyo Viciana, MD; Félix Gutiérrez, MD; Bonaventura Clotet, PhD; Christian Pradier, MD; Jan Gerstoft, MD; Rainer Weber, MD; Katarina Westling, MD; Gilles Wandeler, MD; Jan M. Prins, PhD; Armin Rieger, MD; Marcel Stoeckle, MD; Tim Kümmerle, PhD; Teresa Bini, MD; Adriana Ammassari, MD; Richard Gilson, MD; Ivanka Krznaric, PhD; Matti Ristola, PhD; Robert Zangerle, MD; Pia Handberg, RN; Antonio Antela, PhD; Sris Allan, FRCP; Andrew N. Phillips, PhD; Jens Lundgren, MD; for the PARTNER Study Group

CONCLUSIONS AND RELEVANCE Among serodifferent heterosexual and MSM couples in which the HIV-positive partner was using suppressive ART and who reported condomless sex, during median follow-up of 1.3 years per couple, there were no documented cases of within-couple HIV transmission (upper 95% confidence limit, 0.30/100 couple-years of follow-up). Additional longer-term follow-up is necessary to provide more precise estimates of risk.

JAMA. 2016;316(2):171-181. doi:10.1001/jama.2016.5148

Opposites Attract Study
HIV treatment prevents HIV transmission in male serodiscordant couples in Australia, Thailand and Brazil

B. Bavinton, B. Grinsztejn, N. Phanuphak, F. Jin, I. Zablotska, G. Prestage,
A. Kelleher, A. Pinto, D. Cooper, A. Grulich. IAS Paris 2017

	Linked trans-missions (n)	Couple-years of follow up (CYFU)	CLAI acts (n)	Incidence per 100 CYFU (95% CI)
Overall	0	591.2	16,889	0 (0-0.62)
Any CLAI	0	318.0	16,889	0 (0-1.16)
Any CLAI, no daily PrEP	0	241.3	12,928	0 (0-1.53)
Insertive CLAI	0	210.0	8,389	0 (0-1.76)
Receptive CLAI	0	132.1	4,569	0 (0-2.79)
UVL (VL <200)	0	236.2	12,638	0 (0-1.56)
VL >200	0	5.17	290	0 (0-71.4)
STI diagnosed	0	23.2	1,007	0 (0-15.9)
First 6 months ART	0	10.0	341	0 (0-36.9)

[HIV incidence by category of CLAI]

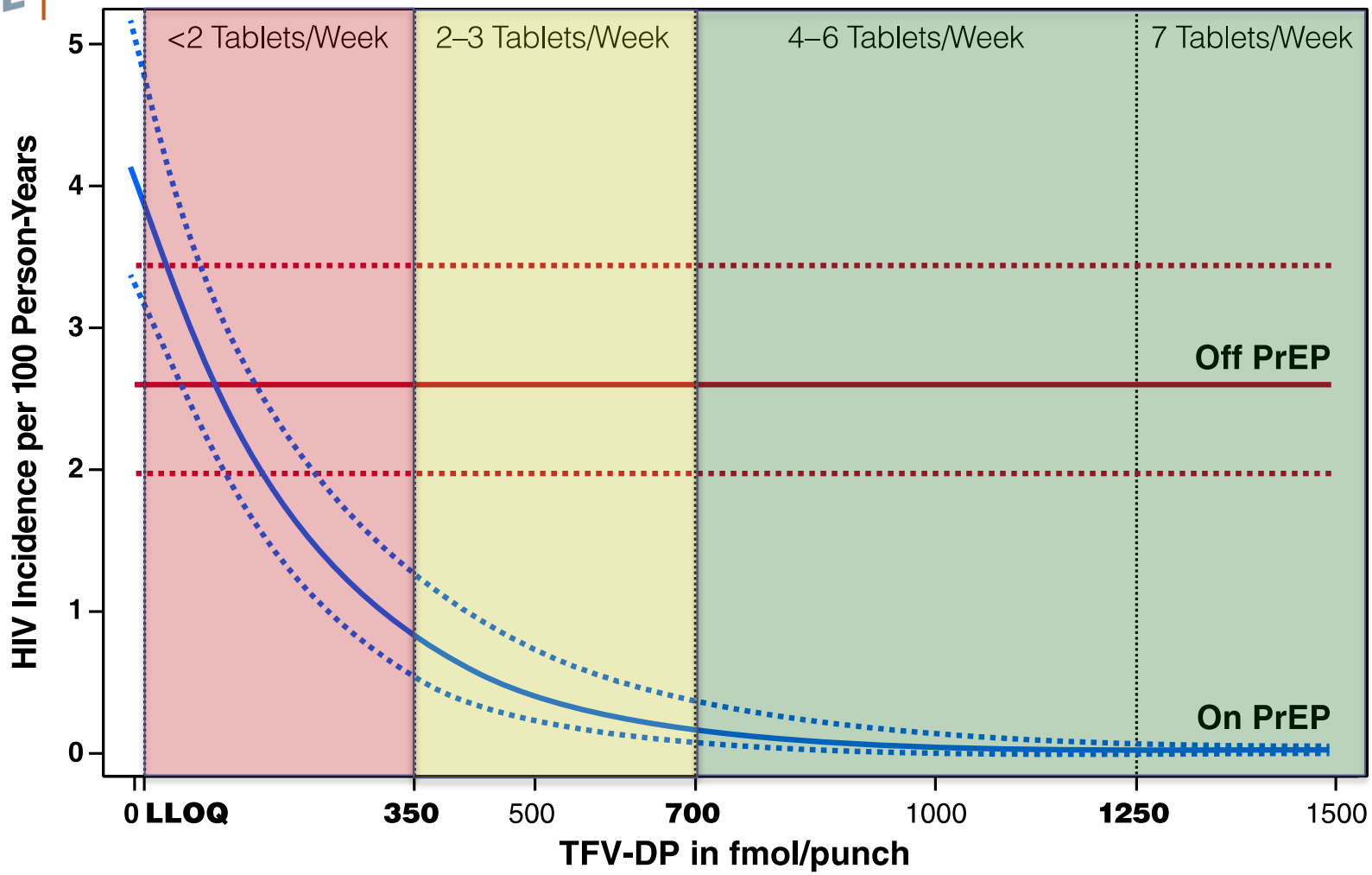
Dear Colleague: September 27, 2017

INFORMATION FROM CDC'S DIVISION OF HIV/AIDS PREVENTION

When ART results in viral suppression, defined as less than 200 copies/ml or undetectable levels, it prevents sexual HIV transmission. Across three different studies, including thousands of couples and many thousand acts of sex without a condom or pre-exposure prophylaxis (PrEP), no HIV transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed. ***This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitted the virus to an HIV-negative partner.***

Emphasis Added

HIV Incidence and Drug Concentrations

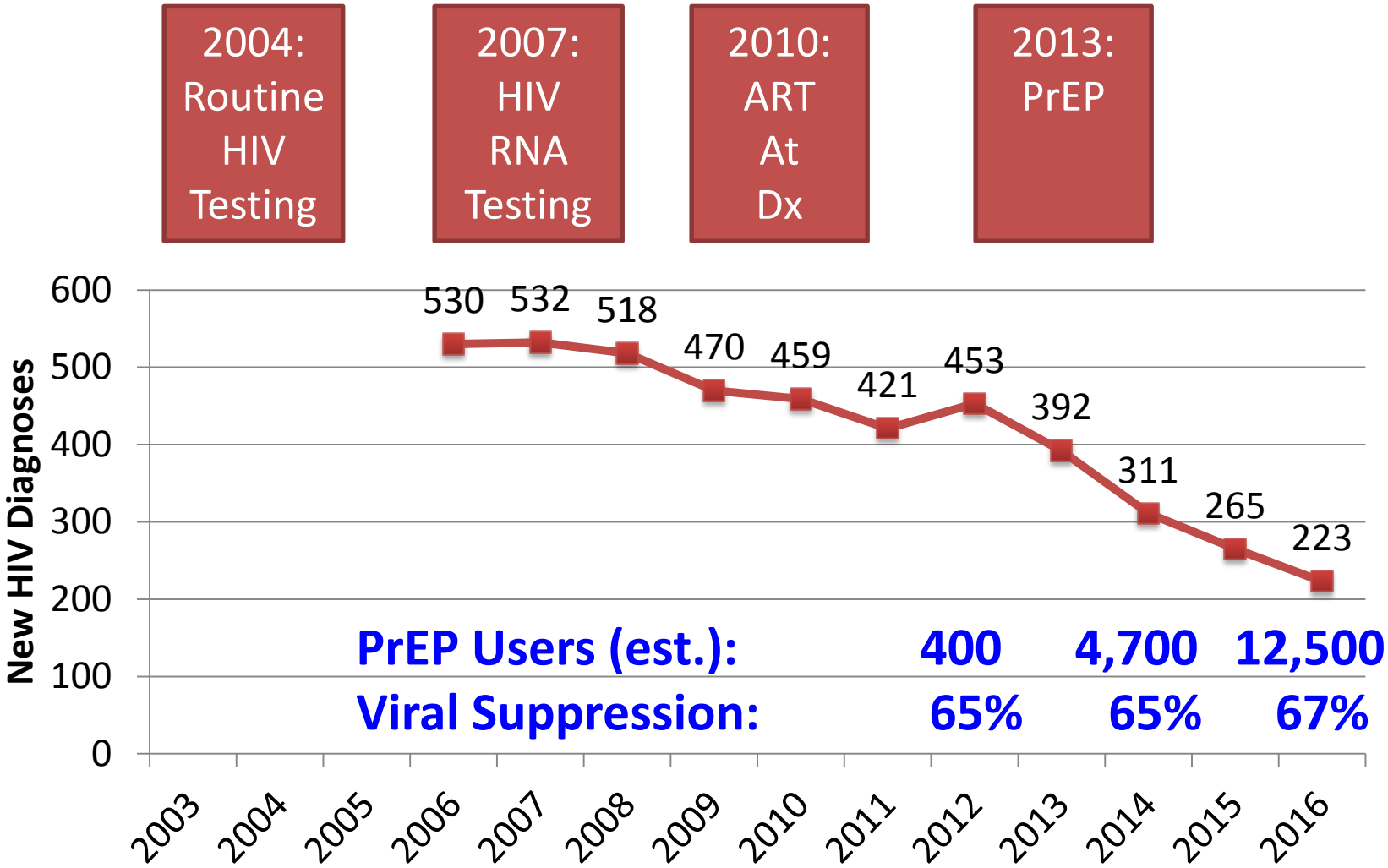


Follow-up %	**26%**	**12%**	**21%**	**12%**
Risk Reduction	**44%**	**84%**	**100%**	**100%**
95% CI	**-31 to 77%**	**21 to 99%**	**86 to 100% (combined)**	

Grant WAC Melbourne 2014;
Grant et al, *Lancet Infectious Diseases*, published online July 22, 2014

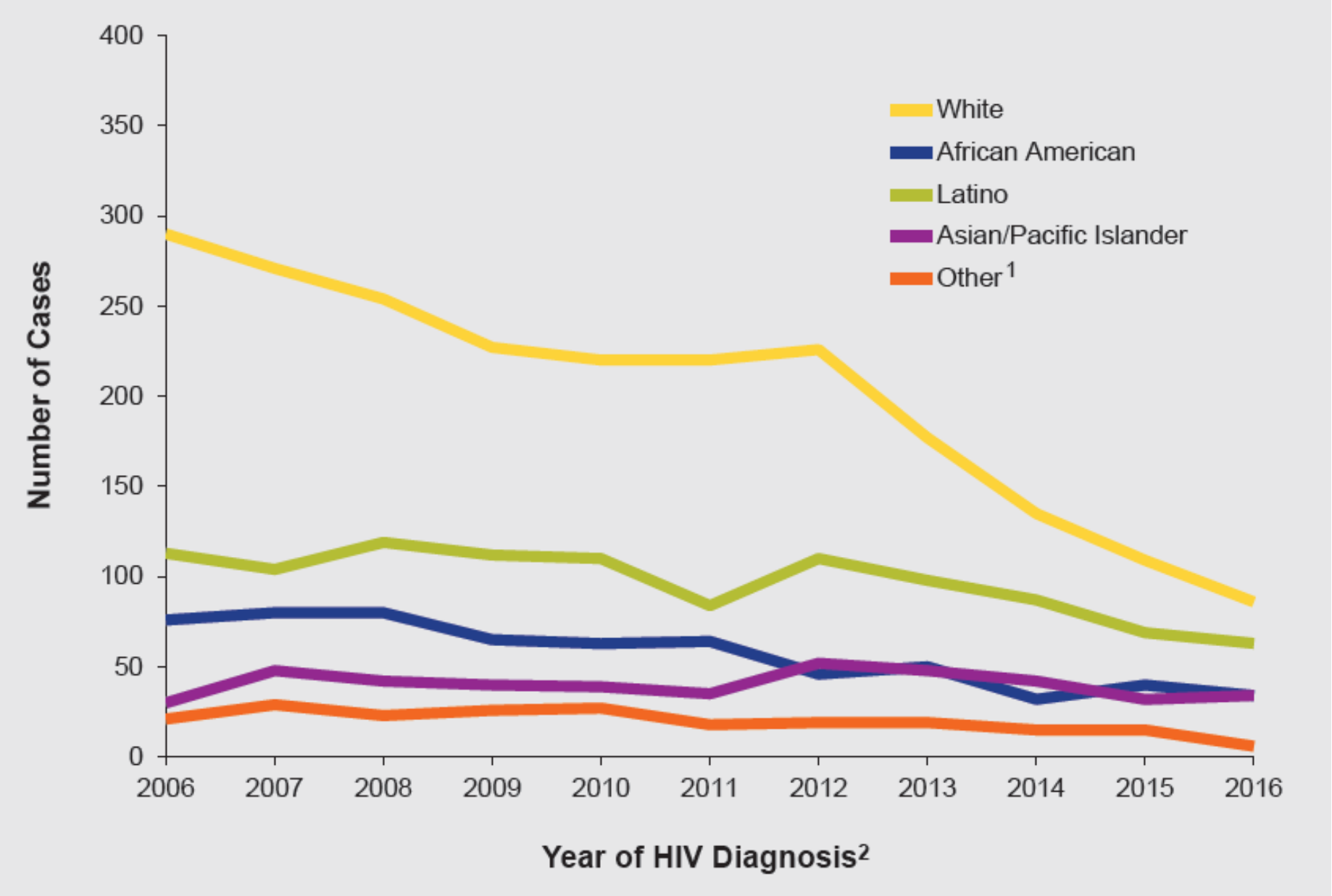
New HIV Diagnoses in San Francisco

No change since 2012 in the proportion of PLWH virally suppressed at 65%



Adapted from SF DPH, HIV Epidemiology Annual Report, Published September 2017.

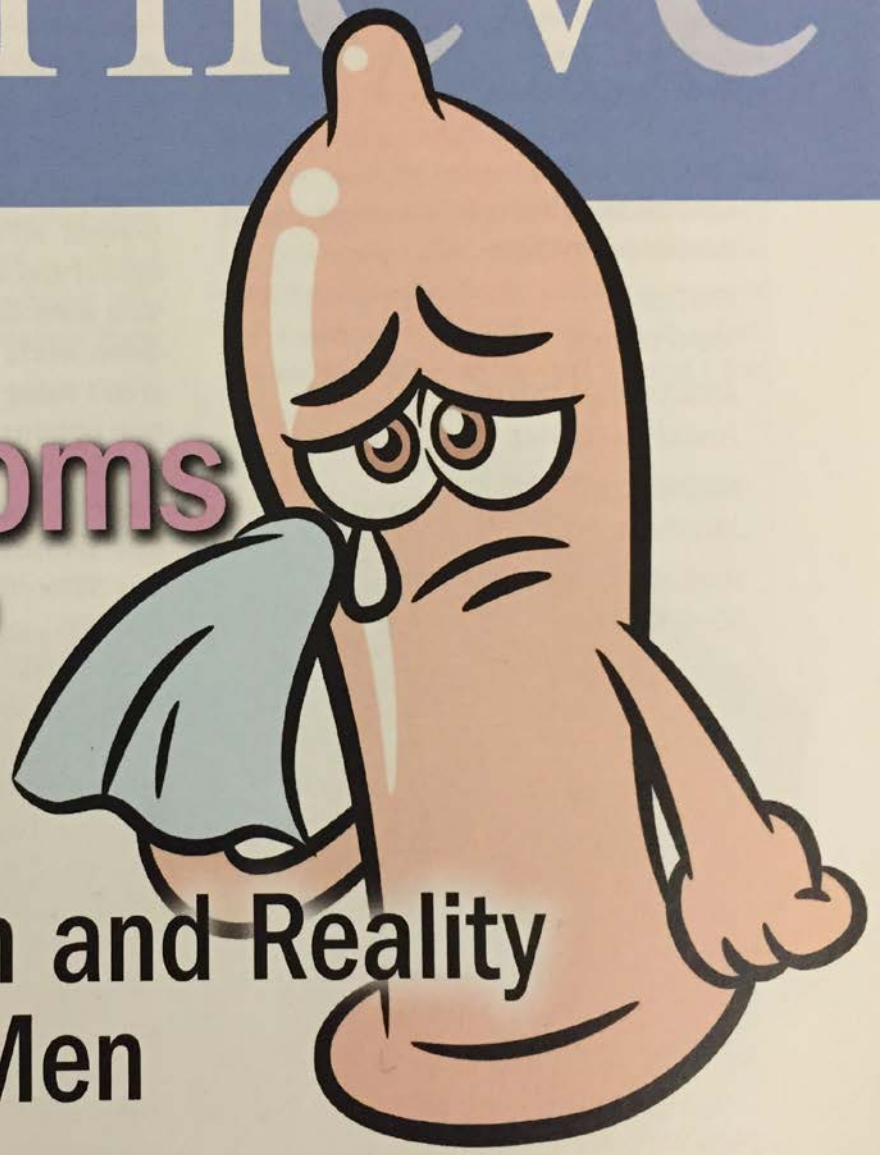
Unequal Progress



Adapted from SF DPH, HIV Epidemiology Annual Report, Published September 2017.

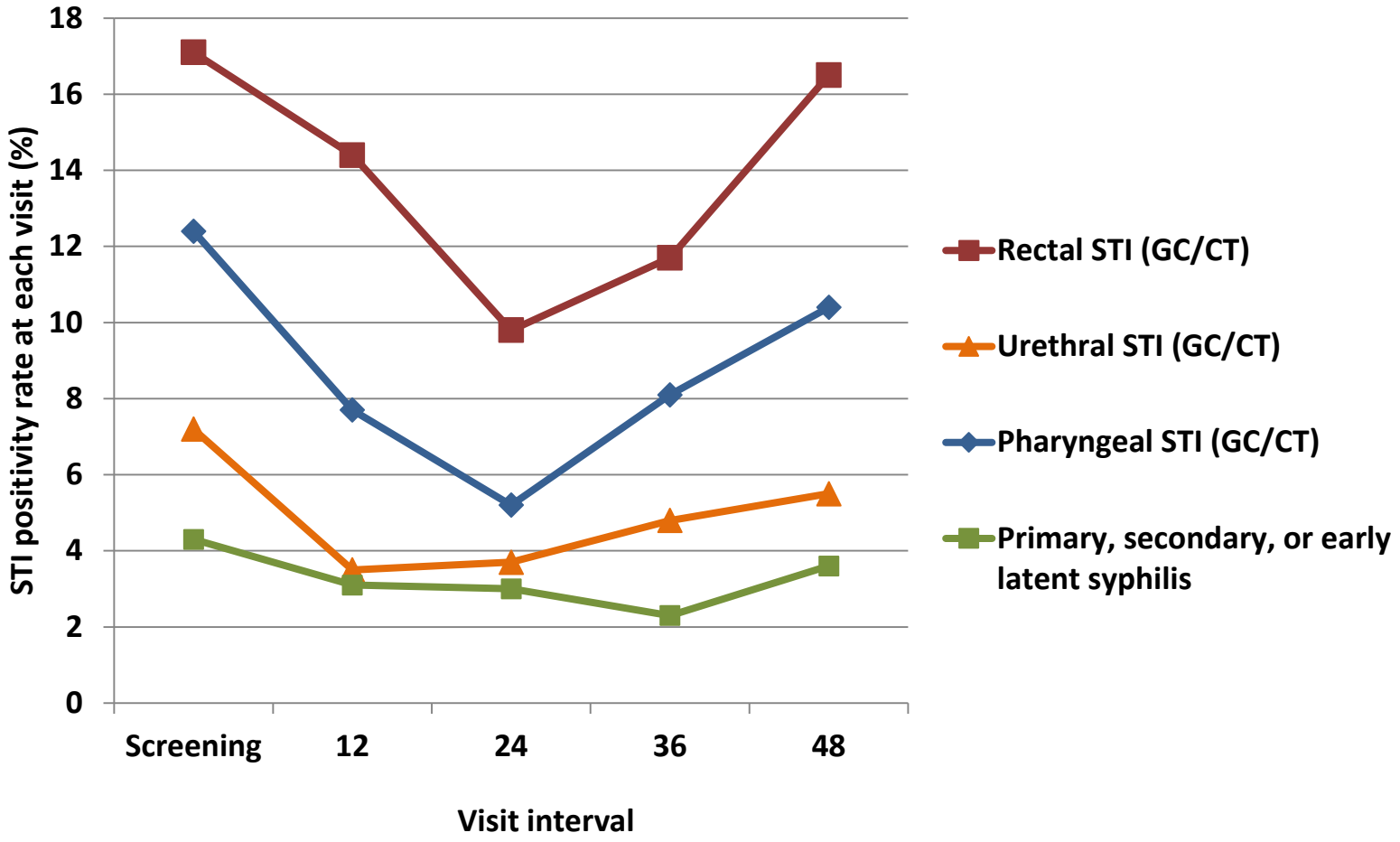
achieve

Are Condoms Over?



Research and Reality for Gay Men

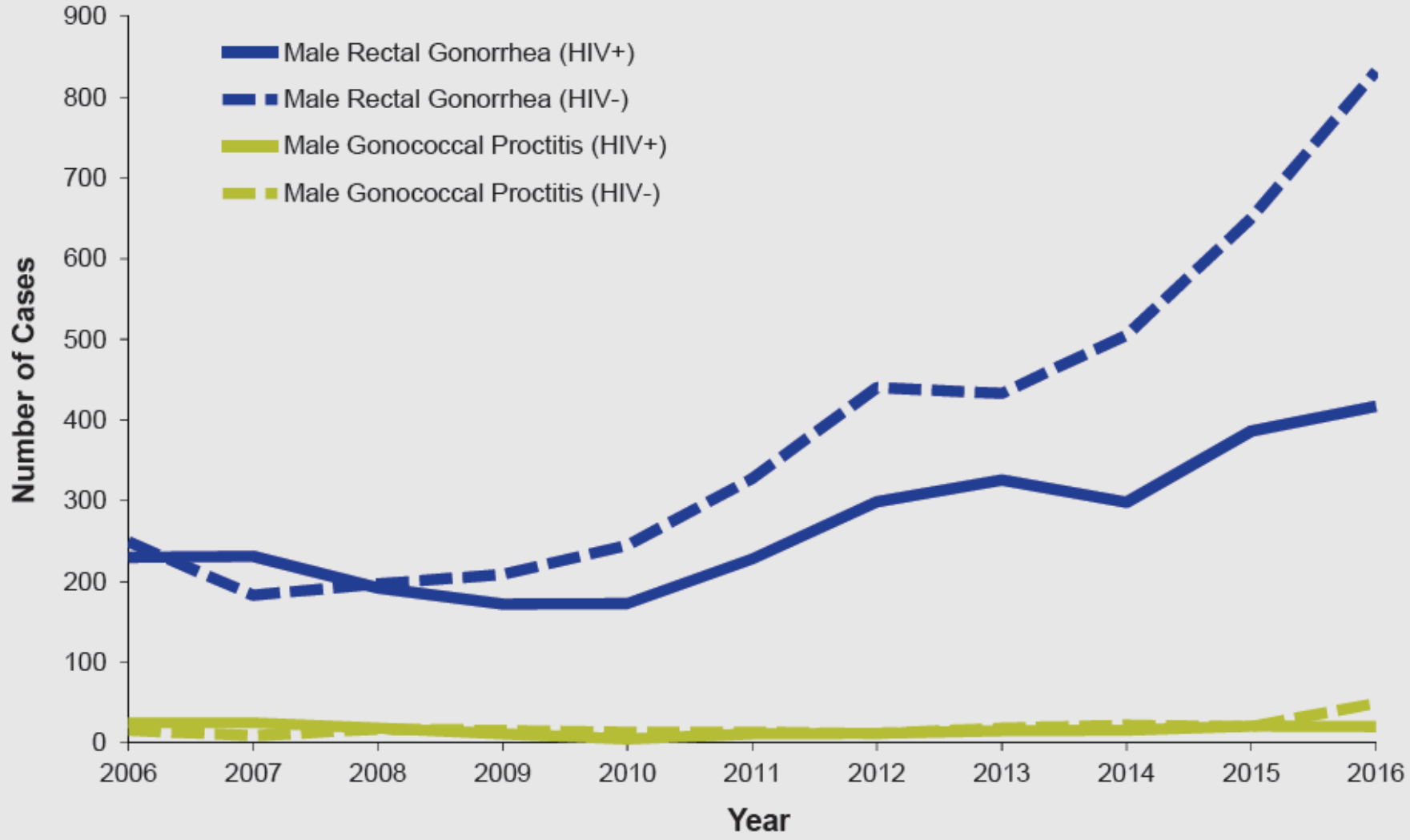
Results: STI positivity



Overall STI incidence (90/100 person years) remained stable during follow-up (P>0.1)

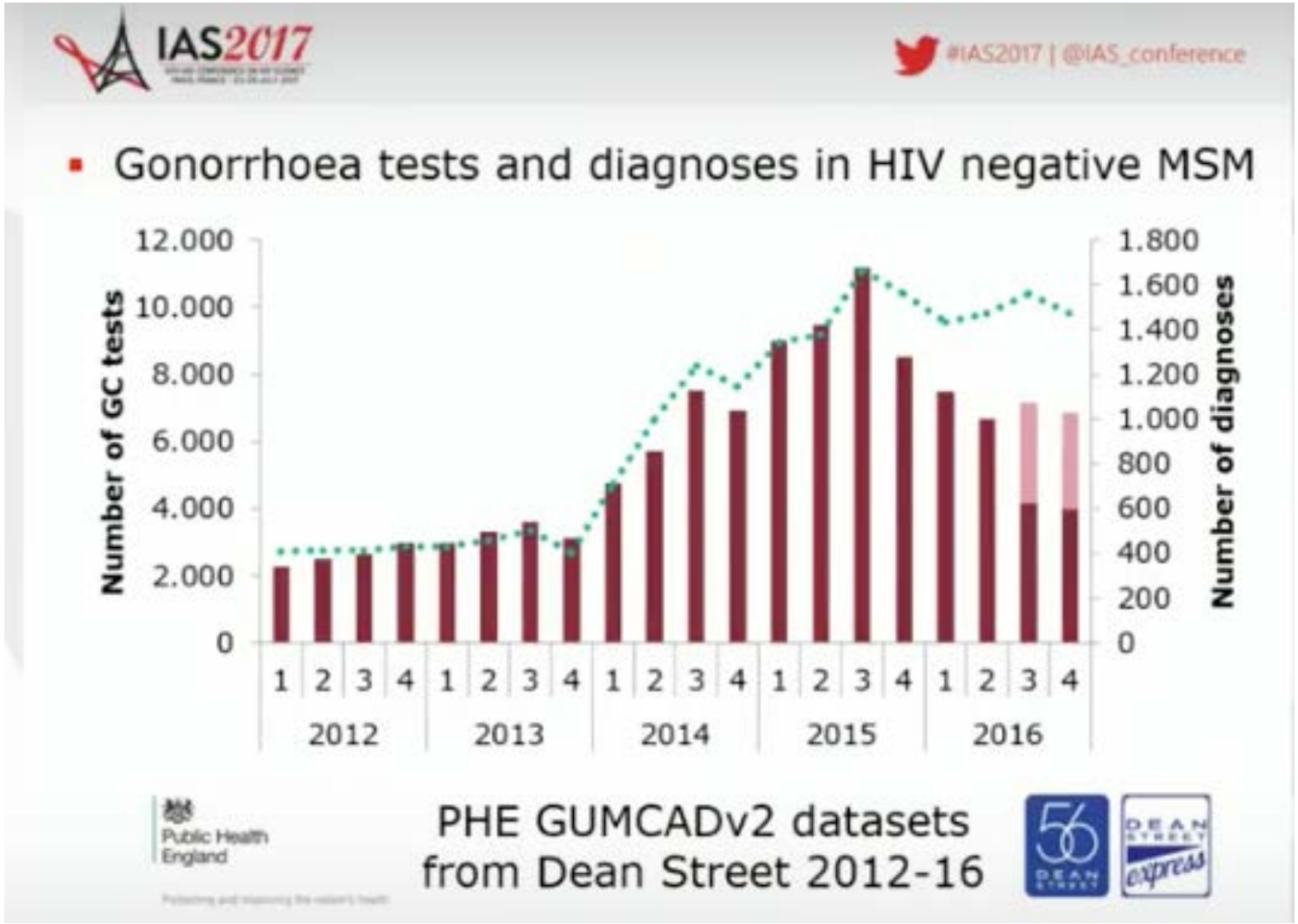
Liu et al, JAMA Int Med, Nov 16, 2015

Figure 7.3 Male rectal gonorrhea and male gonococcal proctitis among MSM by HIV serostatus, 2006-2016, San Francisco



Adapted from SF DPH, HIV Epidemiology Annual Report, Published September 2017.

Increased Testing and GC Diagnoses in London 2012 to 2016



McCormack IAS MOPLO1 Paris 2017

PrEP and Sex Without Fear

Cal Stroud, 23
Quoted by Chris Godfrey,
The Independent,
August 4, 2015.

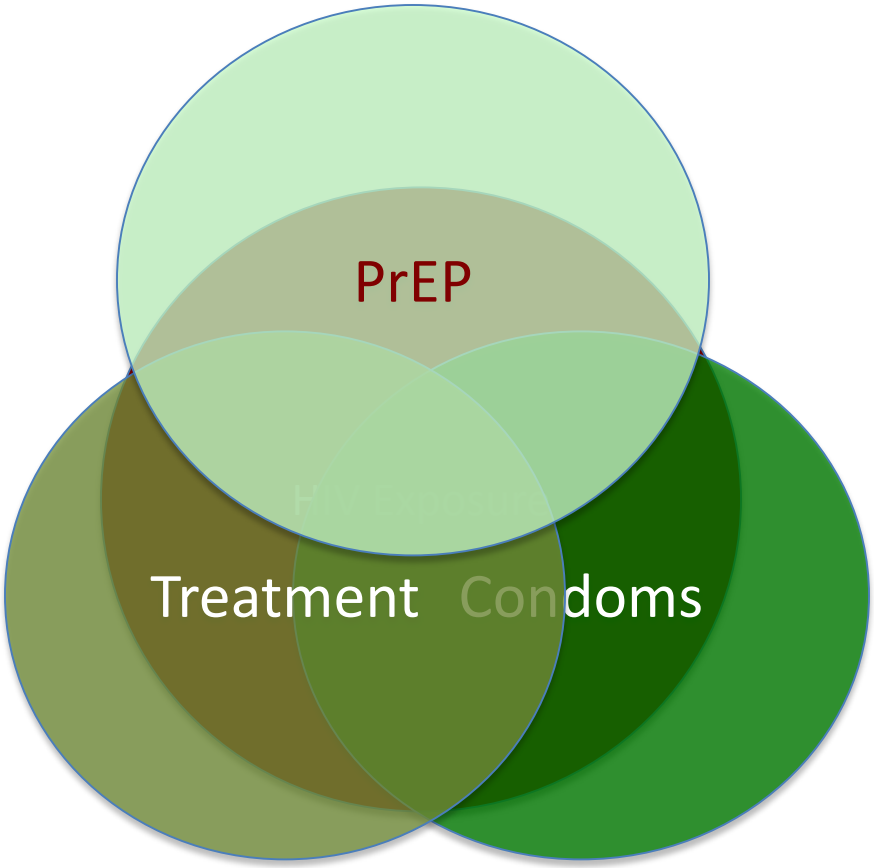
PrEP would allow me to have sex without fear for the first time in my life. It would … remove that month long hangover of psychological anguish after sex, worrying about whether or not I might have put myself at risk of HIV and looking for the slightest sign….. The entire gay community is affected by this kind of anguish and it only fuels the epidemic because when people feel anxious they don't talk about it.

Belief in Future Value Fosters Safer Behavior and the Social Benefits of PrEP

Future Value	Roles for PrEP and ART
Future time orientation	Belief that one can stay free of HIV.
Future Planning	Fosters planning for sex events.
Present time pressure	Increased control over risk.
Present focus	Feeling safe, pleasure.

T Björgvinsson and GJS Wilde *Safety Science* 1996;22(1-3):27-33; Grant NHPC Atlanta 2015.

Cumulative Power of Choice



[Video link to the community talking about U=U]