



PrEP 2016: What will it take to generate demand, increase access, and accelerate uptake?

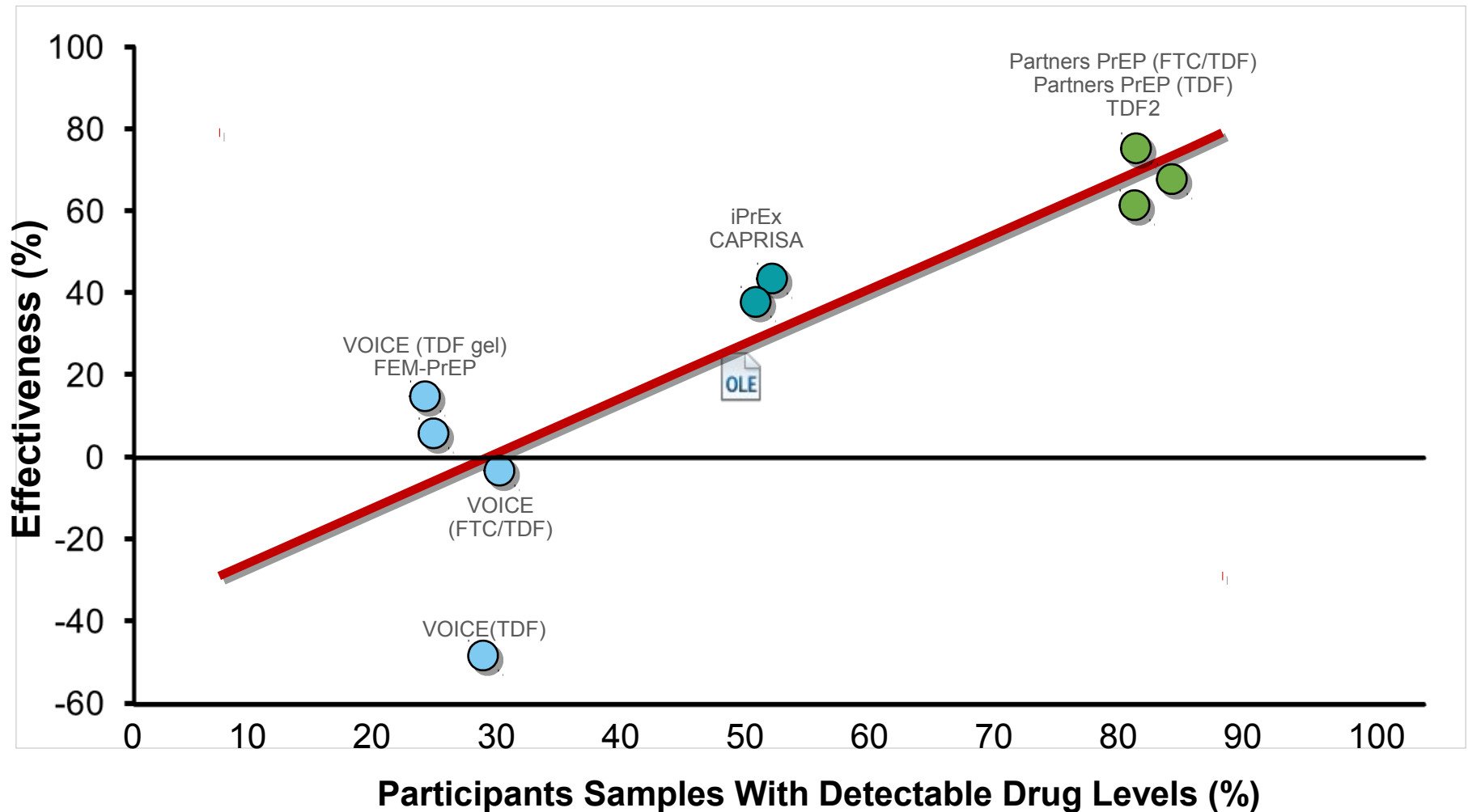
Kenneth H. Mayer, M.D.
Fenway Health
Beth Israel Deaconess Medical Center
Harvard Medical School

Disclosures: Research grants from Gilead Sciences and ViiV Healthcare

Crystal Ball, or Through A Glass Darkly.....



PrEP Is Effective: Adherence Is Critical



Pearson correlation: 0.86 ($P=0.003$).

PrEP Use and HIV/STI Incidence in a Clinical Practice Setting

- Analysis of PrEP use and HIV/STI incidence in PrEP users in large healthcare system (Kaiser Permanente San Francisco) from 2012 to 2015
- 1045 referrals for PrEP; 801 individuals with ≥ 1 intake visit
- 657 initiated PrEP (82%*); mean duration of use 7.2 mos
- Key results (PrEP initiators):
 - After 12 months, 50% diagnosed with any STI
 - 33% rectal STI; 33% chlamydia; 28% gonorrhea
 - **No HIV diagnoses (388 PY follow-up)**
 - After 6 mos PrEP, self-reported condom use was decreased in 41% of individuals

*Of persons with ≥ 1 intake visit.



If PrEP works why is it not SOP?

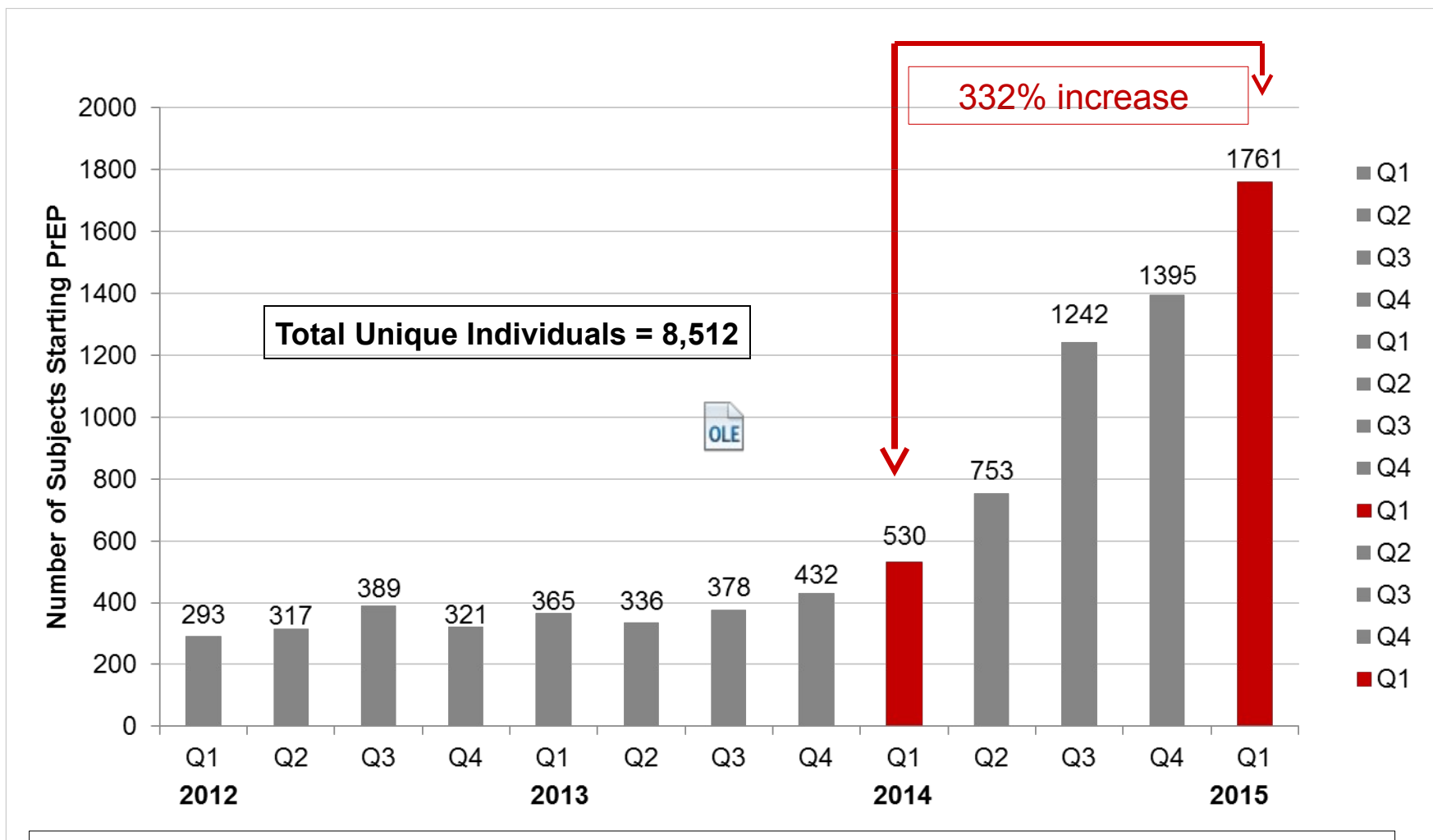
- Dis- and mis-information
- Phobias: sex, gender, substance use
- Clinicians and patients are not comfortable talking about sex and drug risks
- Institutional inertia: system disrupter
- PrEP may not be a stand-alone, needs to be part of “one stop shopping” package for some
- Regulatory hurdles globally, desire for locally-specific data
- **But, the times they are a’changing**

Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition — United States, 2015

Dawn K. Smith, MD¹; Michelle Van Handel, MPH¹; Richard J. Wolitski, PhD¹; Jo Ellen Stryker, PhD¹; H. Irene Hall, PhD¹; Joseph Prejean, PhD¹; Linda J. Koenig, PhD¹; Linda A. Valleroy, PhD¹

- 24.7% sexually active MSM=492,000
- 18.5% of PWID=115,000
- 0.4% of heterosexual adults=624,000
- Data derived from national probability surveys

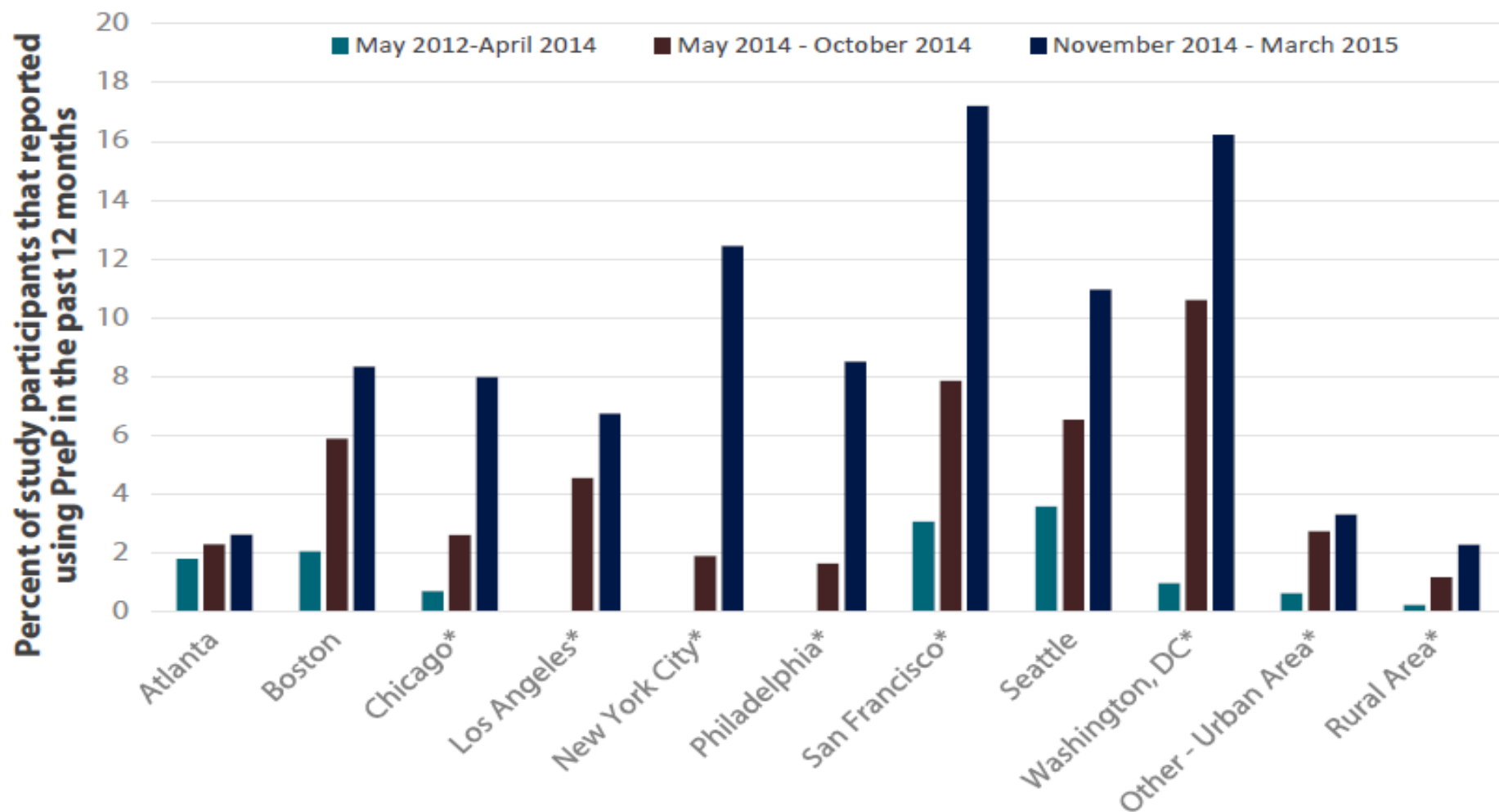
New PrEP Starts per Quarter



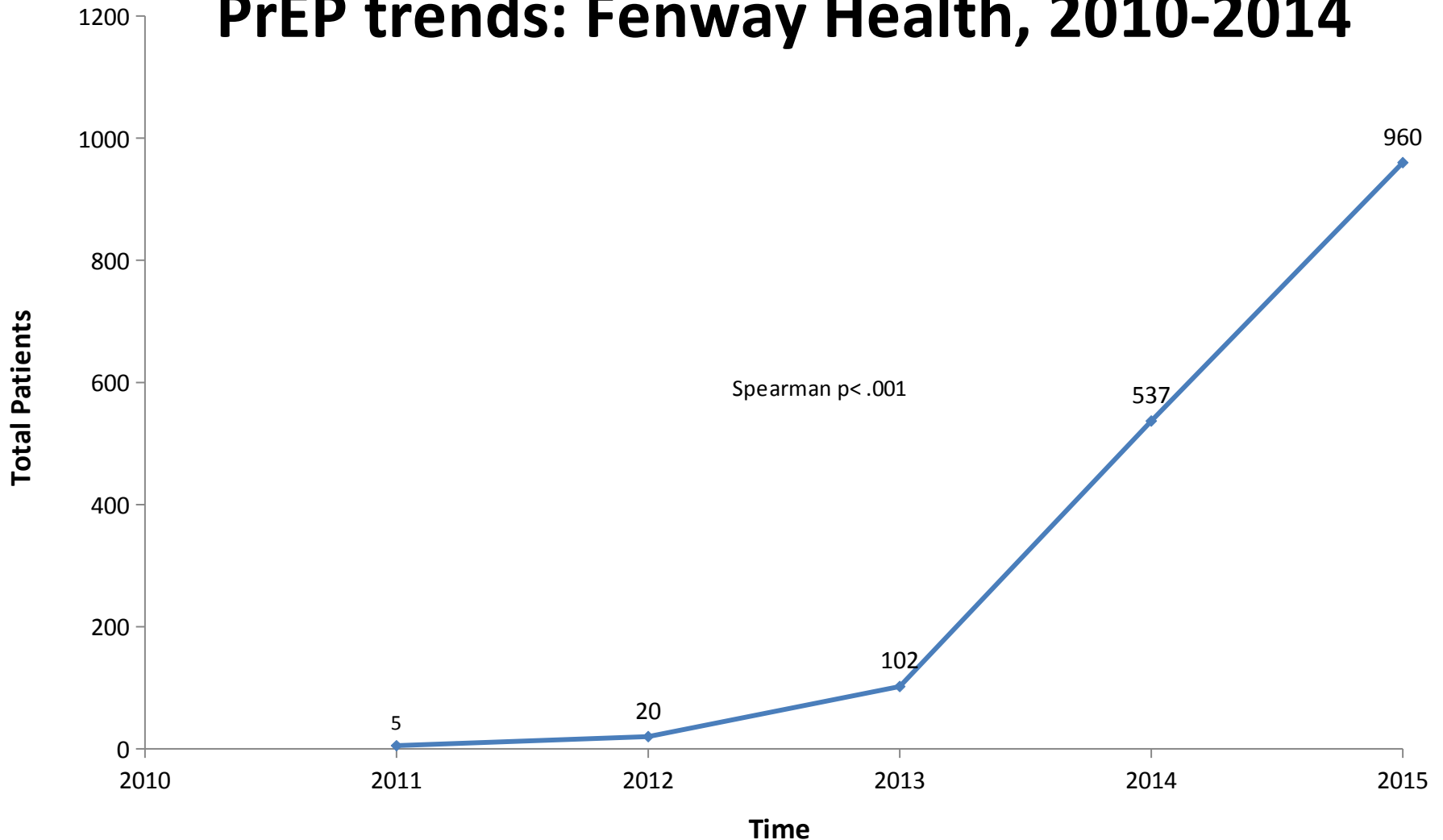
IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

Changes in PrEP Use Among U.S. MSM

(3 web surveys, N=10,097)
Delaney et al, CROI, 2016

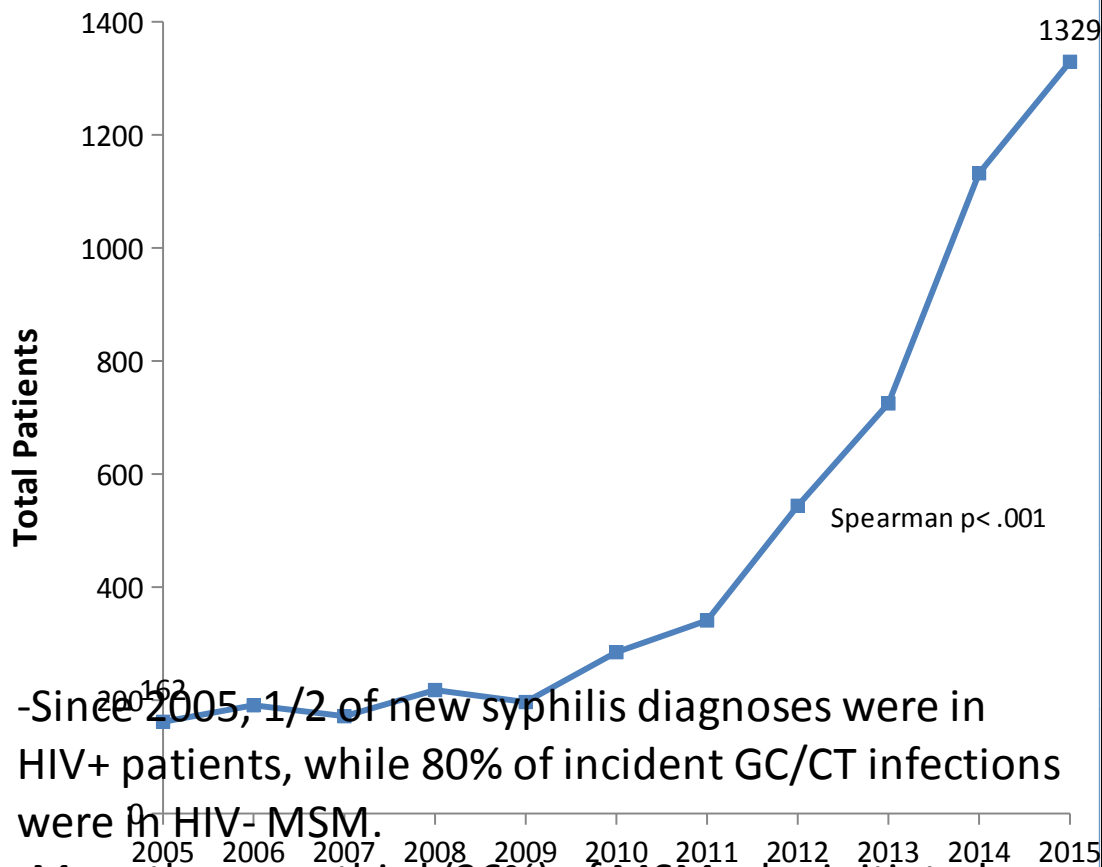


PrEP trends: Fenway Health, 2010-2014



- PrEP was first used by 5 pts outside of a clinical trial in 2011
- More than 83% of PrEP initiators still using PrEP.

Incident STDs



-Since 2005, 1/2 of new syphilis diagnoses were in HIV+ patients, while 80% of incident GC/CT infections were in HIV- MSM.

-More than one third (36%) of MSM who initiated PrEP in 2014 had a recent bacterial STD.

PrEP Use and HIV Seroconversion (2011-2015)

	PrEP	No PrEP
Seroconversion	5	93
No HIV diagnosis	659	4154
Total	664	4247*
Risk**	0.8%	>2.2%

*Patients who indicated they were MSM when registered for care, i.e. overestimate of those at risk

** p<0.001

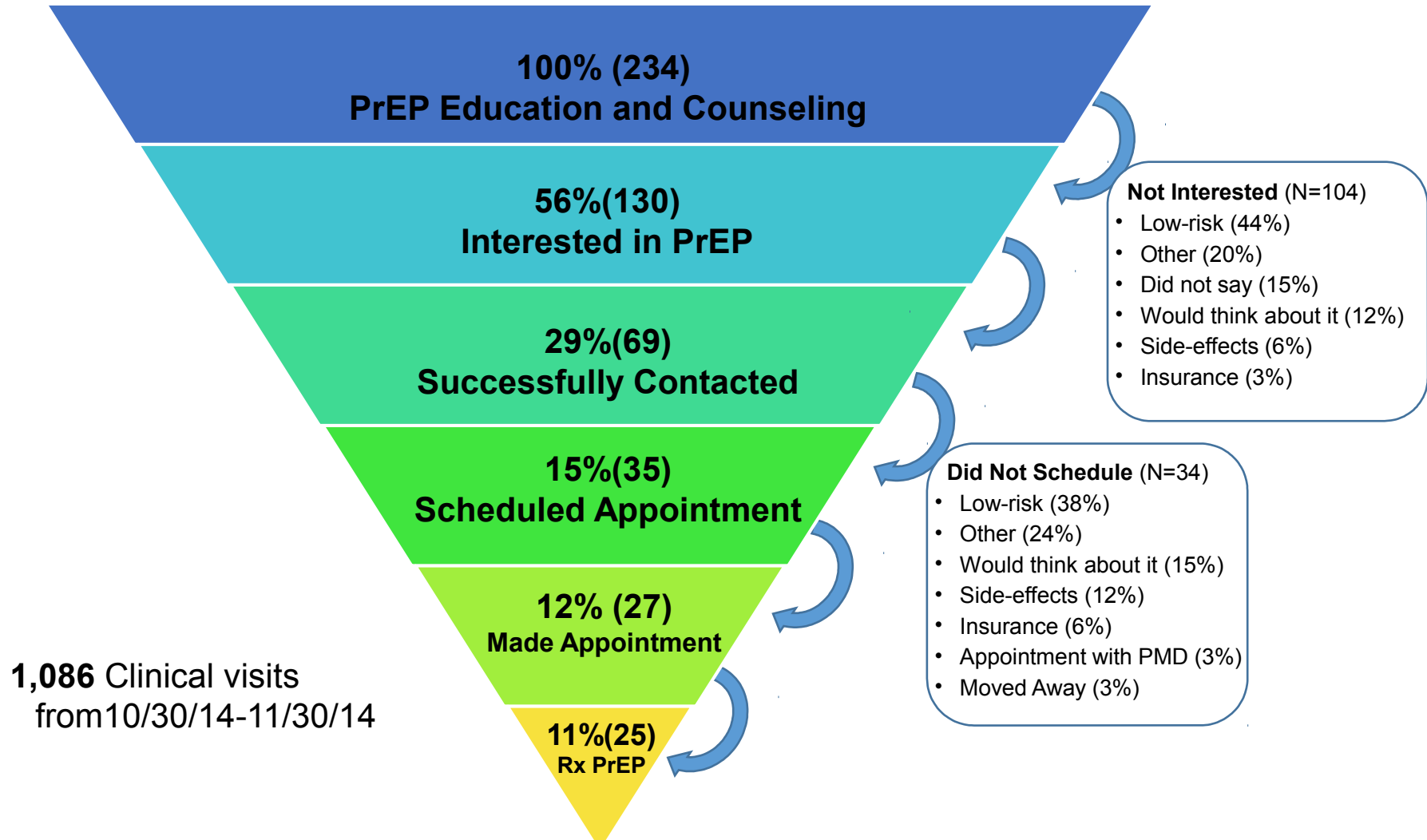


Pre-exposure Prophylaxis Implementation Program

The Miriam Hospital Immunology Center



The Miriam Hospital
A Lifespan Partner



Reporting period: **10/30/2013-11/30/2014**



“Postcards from the (cutting) edge

- Work in progress
- Some countries which hosted successful efficacy trials, are moving forward, others are dragging their heels
- Some communities are more engaged than others
- Regulatory vacuum in resource rich environments may create informal markets



From Research to Rollout

Post-trial access

- Intervention provided to trial participants and, sometimes, their communities, after trial & before product is available for widespread use

Open label extensions

- Intervention made available in follow-on protocol in which participants from previous RCT know they are receiving active intervention
- Gather information about how product use in people who are now aware of potential benefit

Open label/ Implementation studies

- Research protocols similar to above but enrolling new participants

Demonstration projects

- “Road test” use of new option in real-world settings – not in trial site
- Address both infrastructure needs to deliver intervention and ways individuals integrate it into daily activities and decision making.
- Help answer core questions about for whom and how

Product introduction

- Complex process of formally making new options widely available. Can include meeting regulatory requirements, WHO prequal, various country-specific requirement, logistical challenges

Scale-up

- Ramping up access to new options for all who need them – mobilization of resources for procurement, distribution, delivery, worker training and other costs associated with rollout; quick ID and resolution of bottlenecks

PrEP Demonstration Projects: Planned, ongoing and completed project locations

36

OLE, demo, feasibility,
implementation studies planned,
ongoing, completed globally

1

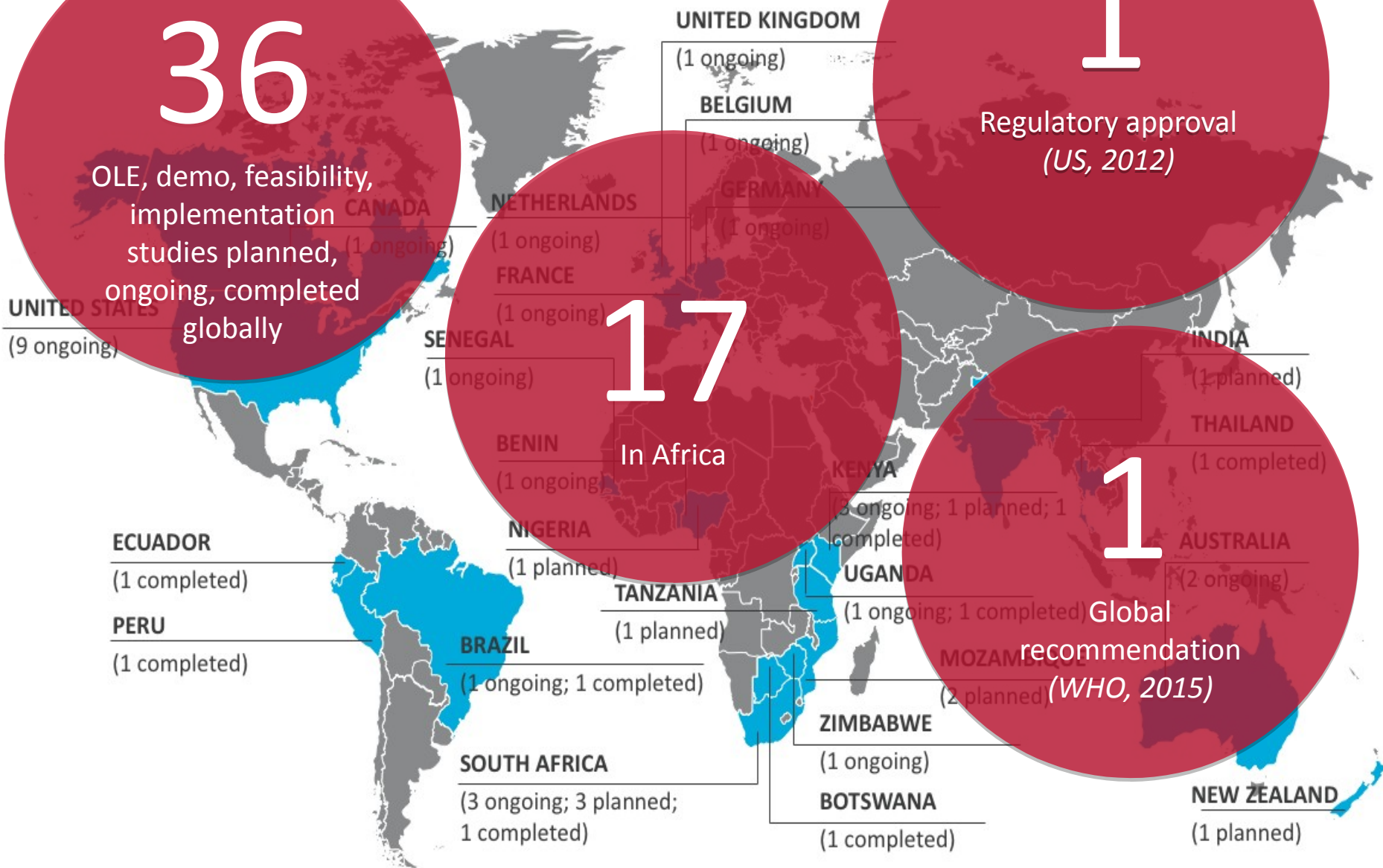
Regulatory approval
(US, 2012)

17

In Africa

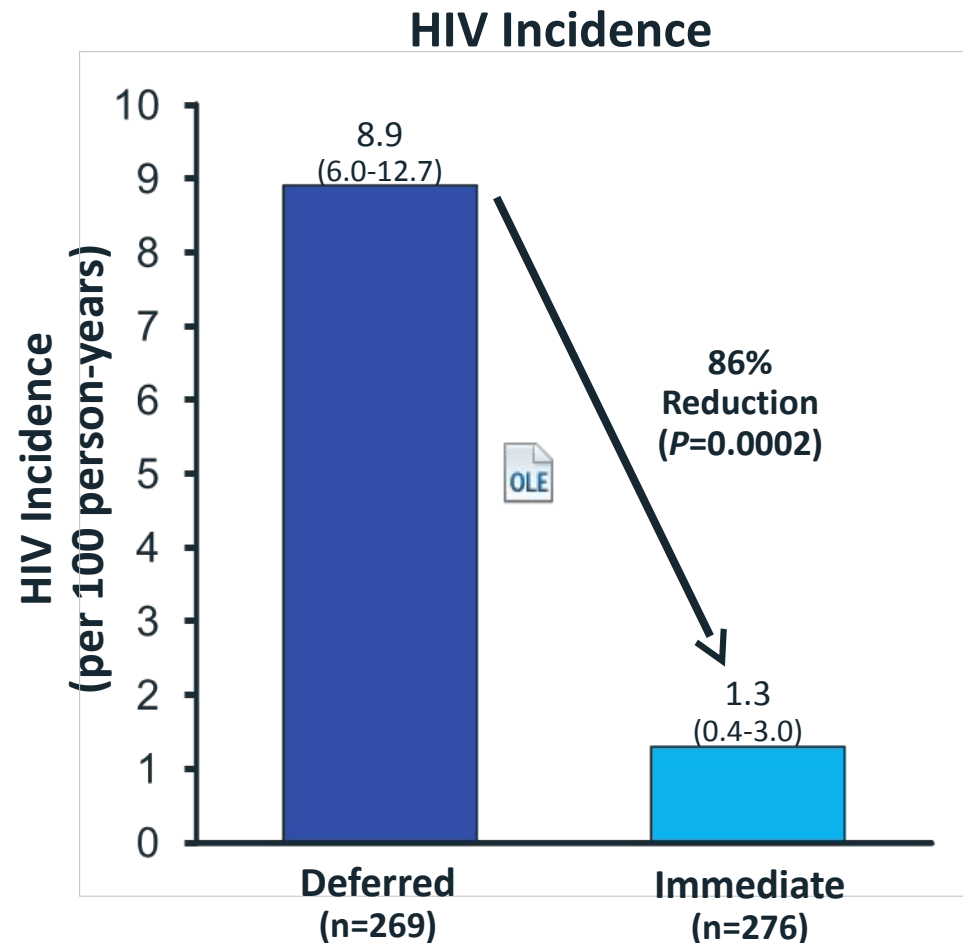
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Global
recommendation
(WHO, 2015)



PROUD Study: Results

- Significantly fewer new HIV infections with immediate versus deferred PrEP (3 versus 20 cases)
 - 86% reduction ($P=0.0002$)
- Incident HIV infection in the immediate group
 - HIV infection predated start of ART ($n=1$)
 - No drug/not adherent ($n=2$)
- Number needed to treat to prevent 1 HIV infection: 13



Shocked HIV Charities Blast NHS For “U-Turn” On Drug That Prevents HIV

The NHS has scrapped plans to make Truvada available, prompting fury from HIV organisations.

posted on Mar. 21, 2016, at 7:28 p.m.



Patrick Strudwick

BuzzFeed LGBT Editor, UK

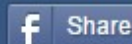




Pissed off HIV activists storm
London's NHS HQ



I Want PrEP Now

[Home](#)[About PrEP](#)[How To Get PrEP](#)[Buy PrEP Now](#)[PrEP Abroad](#)[News](#)[About Us / Donate](#)

Buy PrEP Now

Where to buy PrEP online, now, in the UK

So far we have independently verified 4 different companies who reliably sell PrEP that you can trust. For full details on our independent verification process, [click here](#).

[United Pharmacies UK](#) (£44 per month)

Buy Now



United Pharmacies UK is our personally recommended supplier of PrEP, you do not need to upload a prescription after purchasing and they have some of the cheapest prices on the internet. In addition to independently verifying their product, we also use United Pharmacies to buy PrEP ourselves. The only minor issue is that due to running out of stock, orders occasionally have a delay of around 1 - 2 weeks.

1 months supply = £45.79 per month.

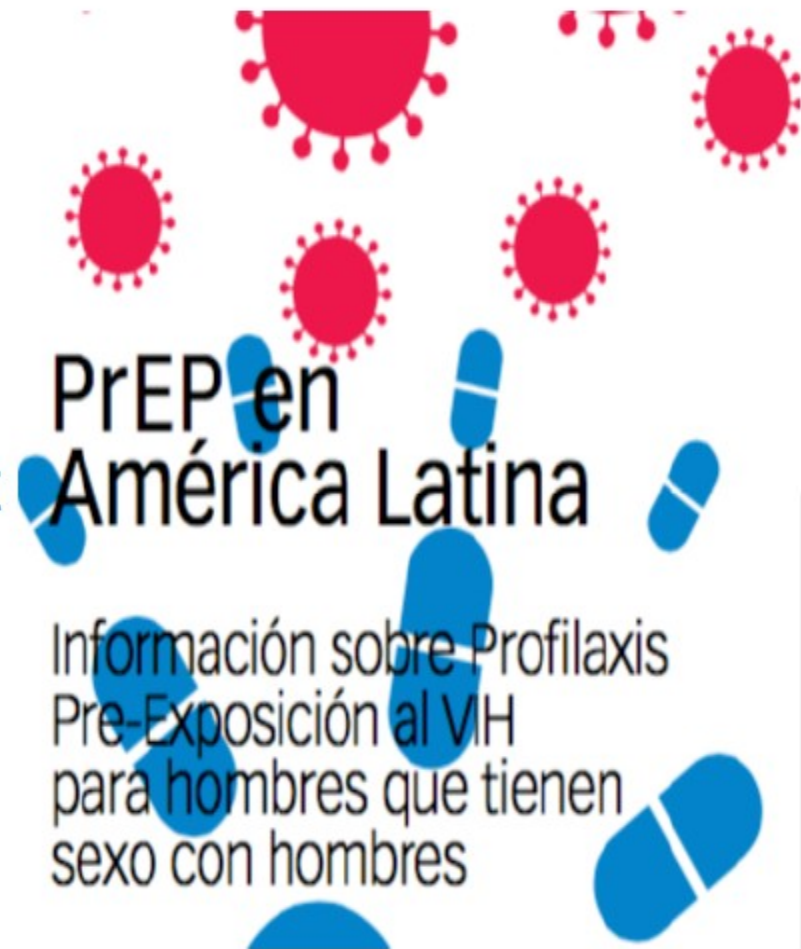
3 months supply = £41.69 per month, (£125.07 in total).

Delivery to the UK costs £6.75 and takes 7 - 14 business days.



Latin America: Steady Progress

- A project funded by UNITAID will support the implementation of demonstrative research on for MSM in Mexico, Peru and Brazil.
- Information and awareness about PrEP in Spanish is needed
- An article prepared by Ravasi G, Grinsztejn B, Baruch R, Guanira JV, Luque R, Caceres C and Ghidinelli M will discuss more of the challenges.



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Regional Consultation on PrEP for MSM in Asia

PREPARING ASIA

Attendance included 135 representatives from the region, including Community, Civil Society, Government, Policy Makers, Clinical and Health Service Providers and Development Partners*.

The three day programme discussed the current barriers to implementing PrEP for MSM in different countries throughout Asia. With a focus on developing country advocacy plans that could be used for follow up country discussions.



Organized by APCOM and supported by UNAIDS, WHO, UNICEF, the USAID LINKAGES Project managed by FHI 360, and UNDP and the Multi-Country South Asia Global Fund HIV Programme,

apcom.org

Perceptions on PrEP?

PREPARING ASIA



Currently there is little information about PrEP available in local languages. Meaning there is poor knowledge about PrEP in the region.

There is a low knowledge about the existence of PrEP.

There is a low belief in efficacy of PrEP and concern about moving away from condom-based messages and prevention.



South African PrEP Review

- Patient/Clients -MSM
 - self perspective, see as at risk and vowed to protect oneself through the use of PrEP
 - published in local e-news online
[HTTP://WWW.HEALTH24.COM/MEDICAL/HIV-AIDS/THE-SOUTH-AFRICAN-CULTURE/TO-PREP-OR-NOT-TO-PREP-20160215](http://www.health24.com/MEDICAL/HIV-AIDS/THE-SOUTH-AFRICAN-CULTURE/TO-PREP-OR-NOT-TO-PREP-20160215)
- Provider- Human Resources and Task Shifting
 - Demo projects (MSM, Sex Workers, Young women)
 - Acceptability outside strict clinical trials settings
 - Tailor methods to attract the right populations through targeted designed advertisement
 - Nurses initiated projects (Anova Health Clinics, Joz i& Cape town)
 - Demo projects so far not so populations representative in terms of race – a need to build social acceptability of PrEP





How to improve outcomes in the “PrEP Cascade”?

- Paying for PrEP-related services: PrEP-DAP
- Academic detailing
- Intensive PrEP Ed: on line and off
- PrEP navigators
- Local PrEP champions
- PrEP apps: Healthminder, SexPro and Nurx
- Other PrEP resources on line
- Providers remain a challenge
- Tailoring for key populations is needed

Paying for PrEP: CDC

Resources

To apply for health insurance on the federal exchange: www.healthcare.gov

Community Health Center Locator:
<http://findahealthcenter.hrsa.gov/>

Washington state (residents):

PrEP drug assistance program (PrEP-DAP)
<http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP>

New York state (residents):

PrEP assistance program (PrEP-AP)
Call 1-800-542-2437

Gilead Sciences:

Medication Assistance Program and Co-Pay Assistance
<https://start.truvada.com/individual/truvadaprep-copay>

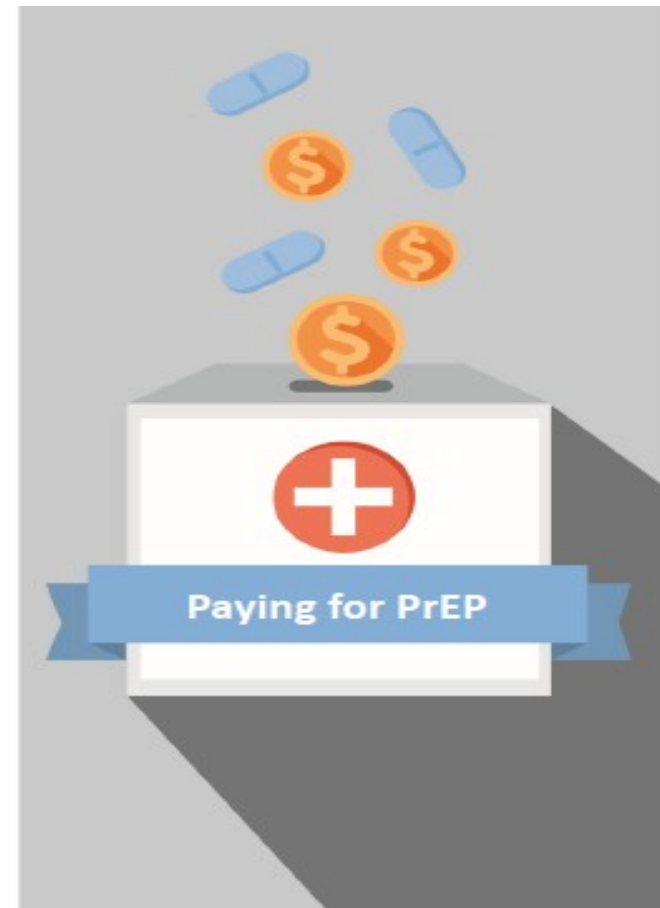
Patient Advocate (PAF) Foundation:

Co-Pay Relief Program
<https://www.copays.org/diseases/hiv-aids-and-prevention>

Division of HIV/AIDS Prevention,
National Center for HIV/AIDS,
Viral Hepatitis, STD, and TB Prevention

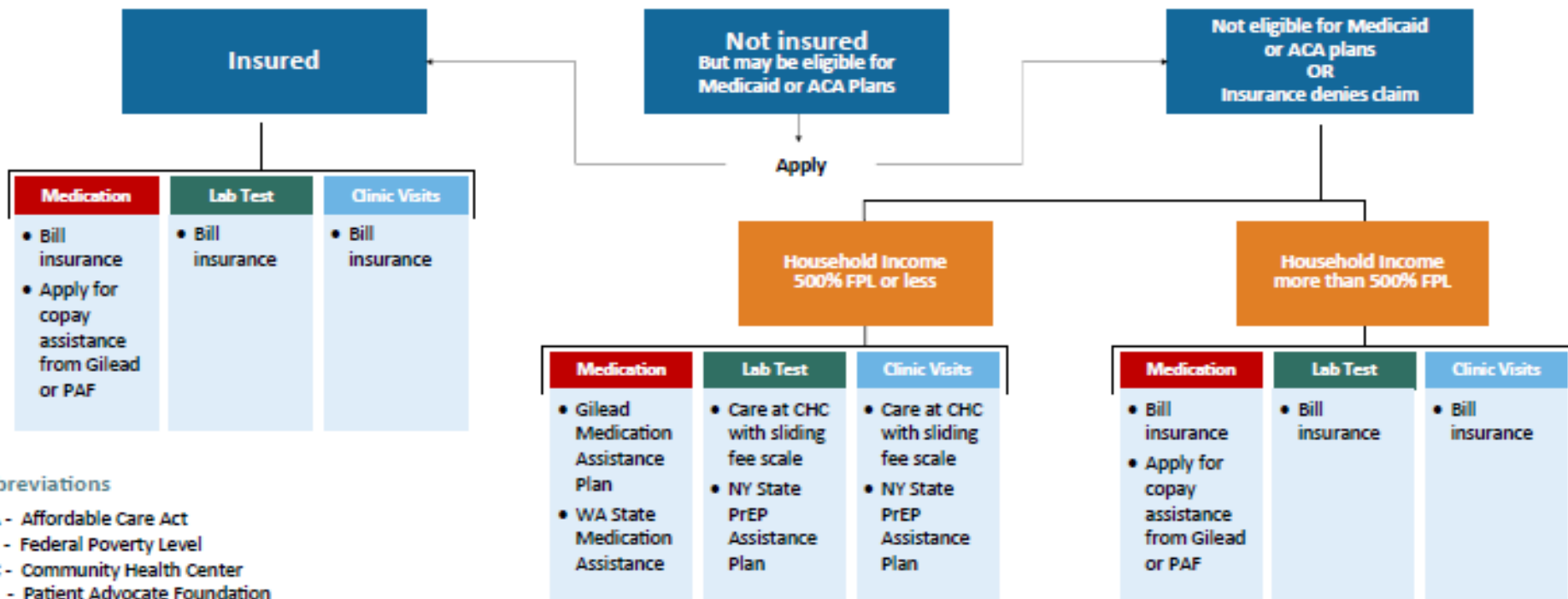
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027 USA
Phone: 800-232-4636

December 2015



Centers for Disease
Control and Prevention
National Center for HIV/AIDS,
Viral Hepatitis, STD, and
TB Prevention

Covering the Cost of PrEP Care



Abbreviations

ACA - Affordable Care Act
 FPL - Federal Poverty Level
 CHC - Community Health Center
 PAF - Patient Advocate Foundation

Definitions:

PrEP	Daily pill to prevent HIV infection (pre-exposure prophylaxis)
Co-pay	Fixed amount to be paid by insured person per prescription
Co-insurance	Fixed percentage of prescription cost to be paid by insured person
Deductible	Amount of health care cost (including prescriptions) that must be paid by the insured person before insurance begins to cover costs

PrEP Medication Assistance Program

(Gilead Sciences)

People eligible for this program must:

- Be 18 years of age or older
- Be without insurance or have payment declined by their insurance carrier
- Be resident in the US (social security number not required)
- Have family income \leq 500% of the federal poverty level

Once enrolled in this program:

- Medication will be sent to the provider, a pharmacy, or the patient's home
- Patients can get their medication at no charge from their provider or pharmacy for as long as they are eligible
- Eligibility must be confirmed every 6 months by the provider

PrEP Medication Assistance Program

Family Size 500% Federal Poverty Level Household Annual Income must be less than:

1	\$58,850
2	\$79,650
3	\$100,450
4	\$121,250
5	\$142,050
6	\$162,850

*Source: <https://www.healthcare.gov/glossary/federal-poverty-level-fpl/>

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Public Health Detailing Action Kits

Detailing Action Kits - contain clinical tools, resources for providers and patient education materials, which promote evidence-based best practices and chronic disease management.. These materials are available for health care providers and their practices to help improve patient care related to key public health challenges Clinical topics have been chosen largely because of their anticipated impact on morbidity and mortality. Click on the images below to view the contents of the Public Health Detailing Action Kits.

PrEP and PEP Action Kit

The PrEP and PEP Action Kit includes provider and patient resources. It is structured around these core HIV prevention practices:

- *Take a thorough sexual history*
- *Screen sexually active patients*
- *Talk about PrEP & PEP*
- *Prescribe PrEP & PEP*

[Download the PrEP & PEP Action Kit](#)



Events Calendar

Free Webinar: Preventing HIV with PrEP: A Clinical Update

HIV/STI Treatment and Prevention

April 25, 2016 | Webinar

Pre-exposure prophylaxis, or PrEP, is a pill taken once daily to help prevent HIV infection in uninfected people. In this webinar, Kevin Ard, MD, MPH will share clinical approaches to managing patients on PrEP based on cutting-edge research data, including recent findings reported at CROI. Through clinical case scenarios, Dr. Ard will help providers understand how to apply research findings to their own clinical practice. This webinar will also include a discussion of the status of new innovations in PrEP, such as injectable medications, rectal microbicides, and vaginal rings.

Faculty

Kevin Ard, MD, MPH, Medical Director, National LGBT Health Education Center; Massachusetts General Hospital

Date/Time

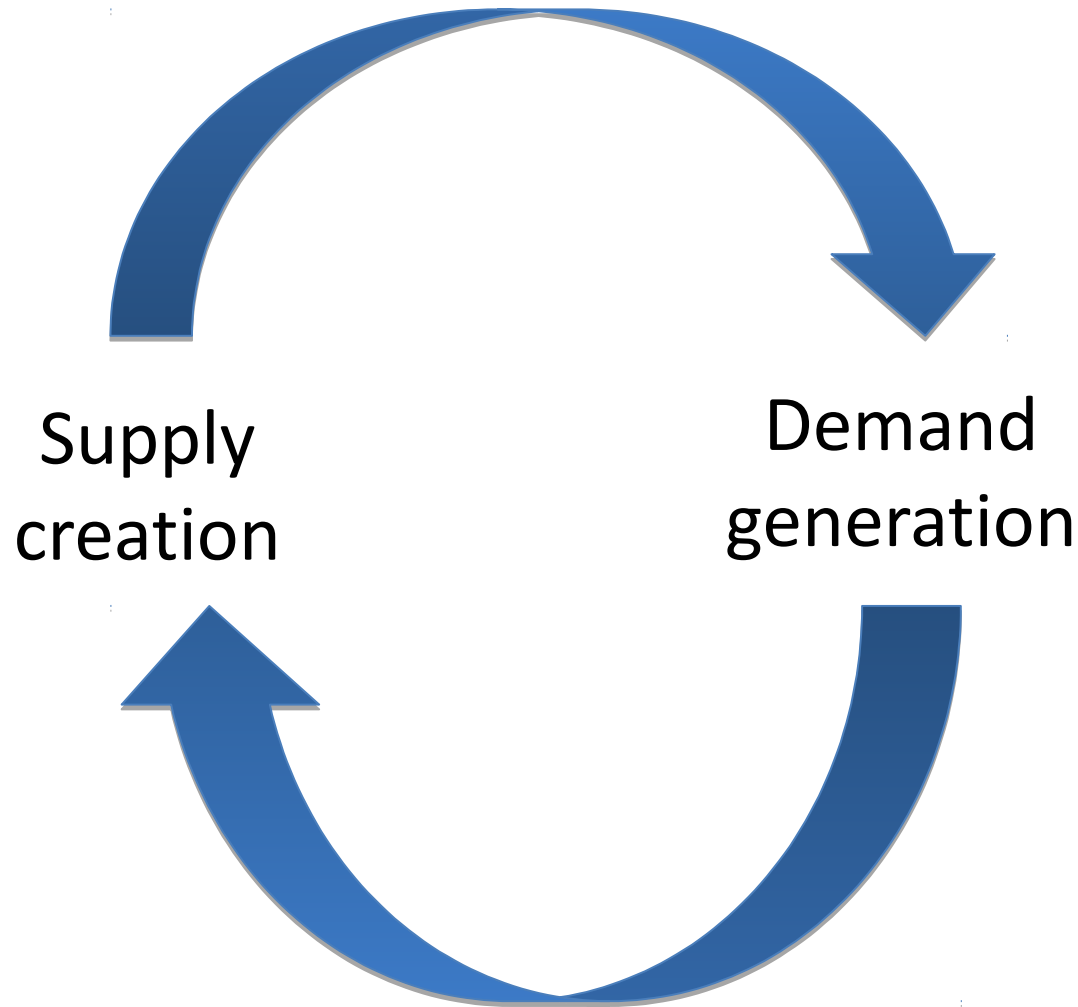
Monday, April 25, 2016, 2:00-3:00pm ET

Register

New York State Department of Health AIDS Institute
Peer Worker Course Catalogue
April, 2016



St Louis Case Study



To have successful implementation of PrEP it is a delicate balance between demand generation and supply creation and then it is a reiterative process

1. Qualitative needs assessment among community members and organizations
2. Form a PrEP info team
3. Link the team to a number
4. Then create a list of known PrEP providers where PrEP seekers can be linked to care
 - a. Part of this developed the PrEP-to-PCP implementation continuum

Multidisciplinary PrEP Team-St. Louis



HIV Physician

WUSTL PrEP Program

Insurance Navigator/Health
Literacy Counselor

St. Louis Effort for AIDS



HIV Pharmacist
Gateway Apothecary

HIV Prevention Specialist

St. Louis Effort for AIDS



PrEP Advocate

Recruited from the
WUSTL PrEP Program

HIV Activist

Recruited from the
community;
national recognition



Ready for PrEP?

Get started.

What if there were a pill
that could help prevent HIV?

There is.

Ask your doctor if PrEP is right for you.

Pre-exposure prophylaxis: A daily pill to reduce risk of HIV infection
www.cdc.gov/hiv/basics/prep.html

Washington University Infectious Diseases Clinic
now offers care for persons who are interested
in taking **PrEP** to prevent HIV infection.

When taken every day, **PrEP** provides a high level of protection
against HIV, especially when combined with condoms.

PrEP is just one pill a day.

Call to schedule a PrEP appointment
@ WU Infectious Diseases Clinic
314-362-9098

To be eligible, you must:

- be 18 years or older
- be committed to seeing a doctor and getting bloodwork every 3 months
- have health insurance or be able to make other payment arrangements

Limited financial help may be available to support access to
PrEP appointments and medications for uninsured persons.

HealthMindr Pilot Study

P Sullivan et al

Participants

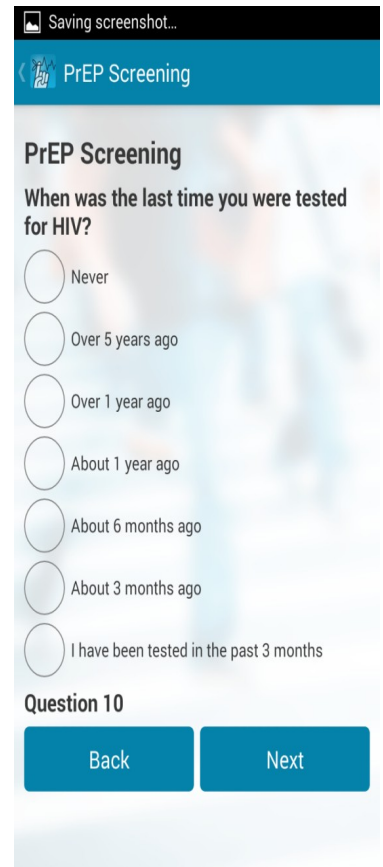
- 121 MSM enrolled
 - 72 in Atlanta, GA
 - 49 in Seattle, WA
- 18+ years
- Never tested HIV positive
- Only available to Android users

Recruitment Strategy

- Facebook banner ads
- Grindr mass text messages & banner ads
- 4 month study
 - Recruited from May-Aug
 - Finish in December
- 99 have completed Final Evaluation

Preliminary Results (n=99)

- 78% of those reported dissatisfied with current condoms ordered new condoms
- 87% report using the ordered condoms
- 2/3 of test kit orders were not planning on being tested soon
- 50% of users who did not have a testing schedule now do
- 10% of PrEP-eligible men started PrEP



Saving screenshot...

PrEP Screening

PrEP Screening

When was the last time you were tested for HIV?

☐ Never

☐ Over 5 years ago

☐ Over 1 year ago

☐ About 1 year ago

☐ About 6 months ago

☐ About 3 months ago

☐ I have been tested in the past 3 months

Question 10

Back Next

PrEP delivered to your home <http://app.nurx.co/prep>

nurx

Login |



The Fastest way to PrEP

Get on PrEP with Nurx!



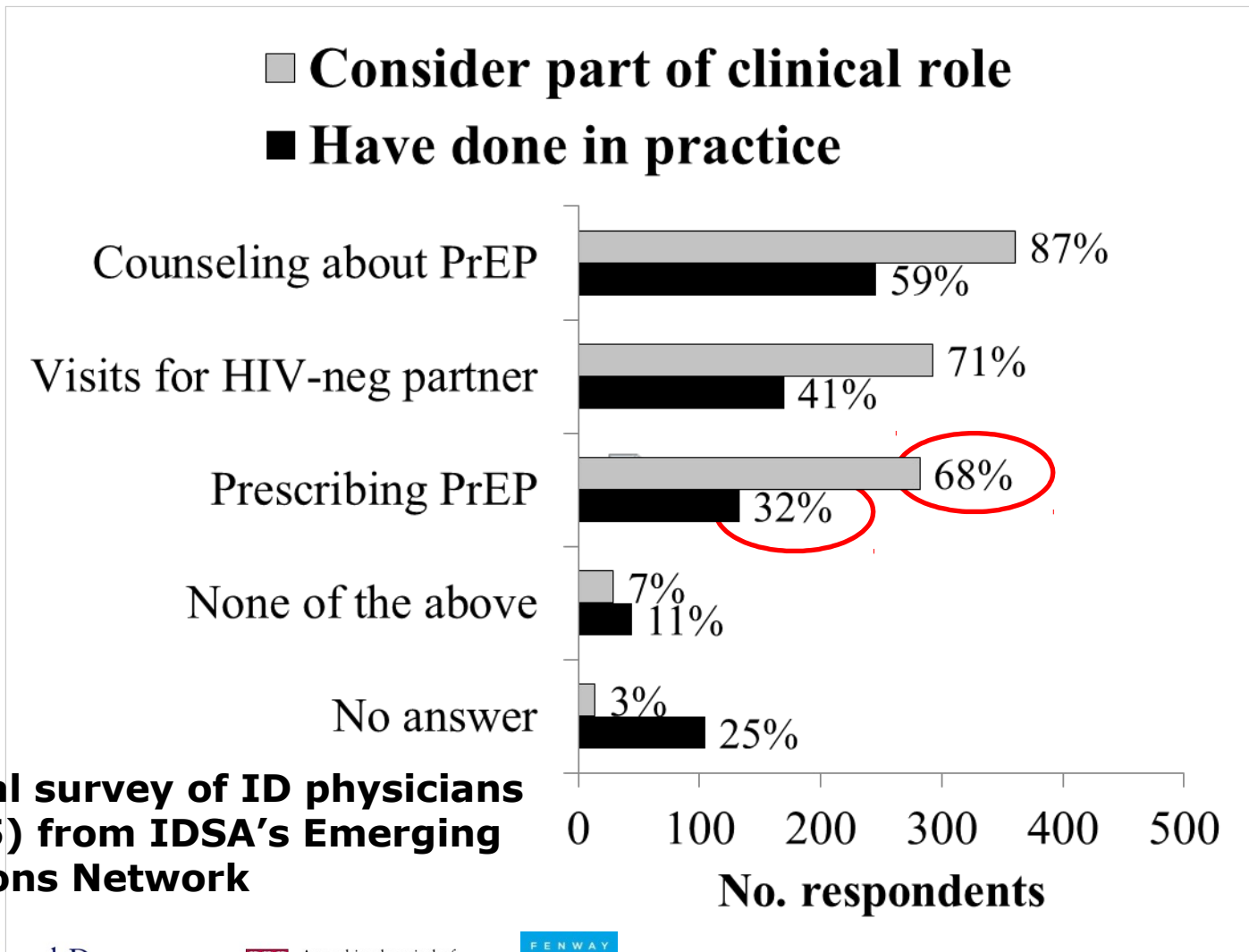
What is PrEP?

Chat Securely with NURX

PrEP Web Resources

- AIDS Foundation of Chicago
(www.myprepexperience.blogspot.com/)
- Project Inform (www.projectinform.org/prep/)
- San Francisco AIDS Foundation (www.prepfacts.org)
- The Fenway Institute
(www.thefenwayinstitute.org/prepinfo/)
- The US Centers for Disease Control and Prevention
(www.cdc.gov/hiv/prevention/research/prep/)
- The AIDS Vaccine Advocacy Coalition (www.avac.org)

A majority of HIV specialists would prescribe PrEP; only 1 in 3 has done so



Beth Israel Deaconess
Medical Center

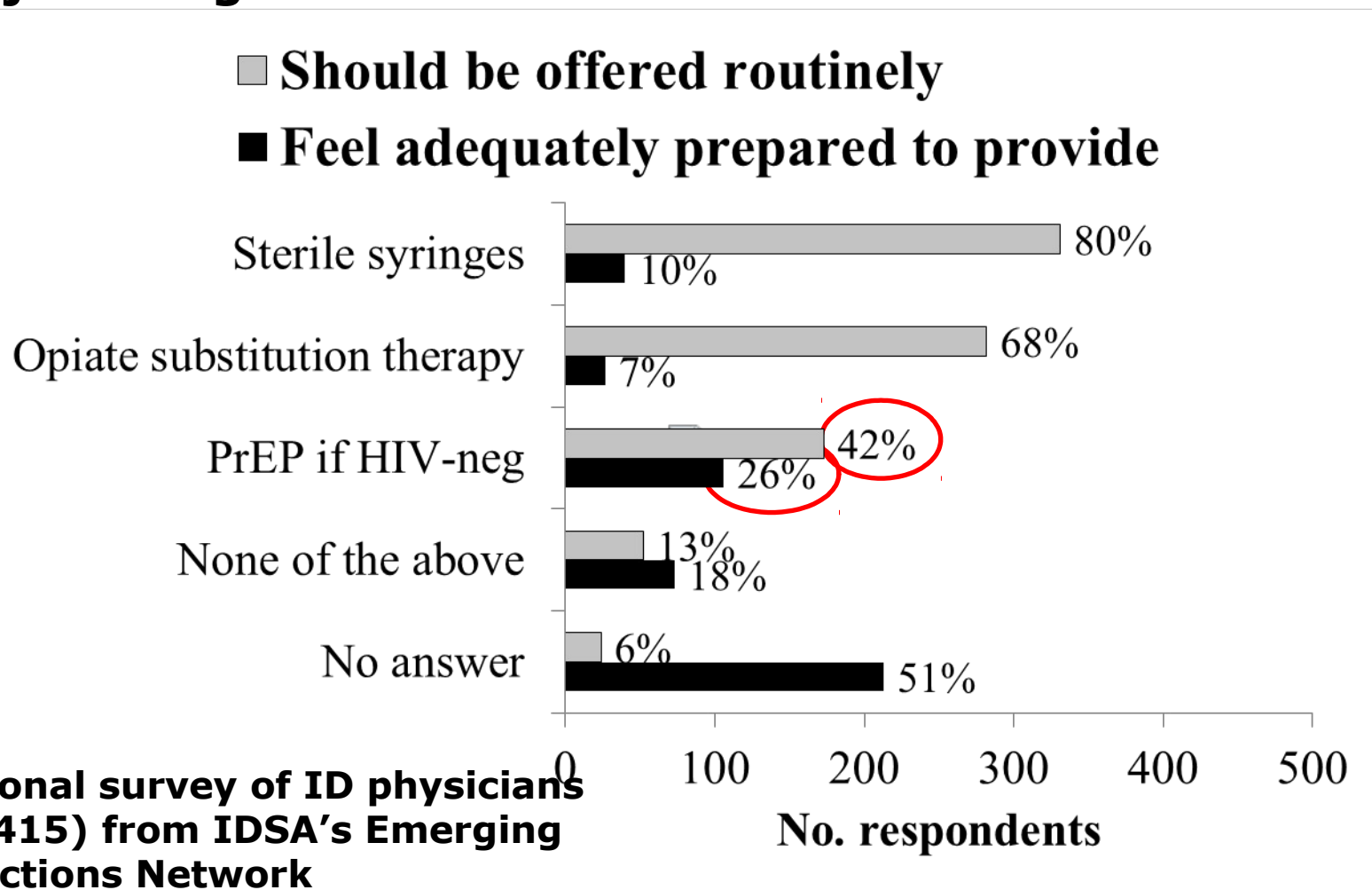


A teaching hospital of
Harvard Medical School



Krakower et al. Clin Inf Dis 2015

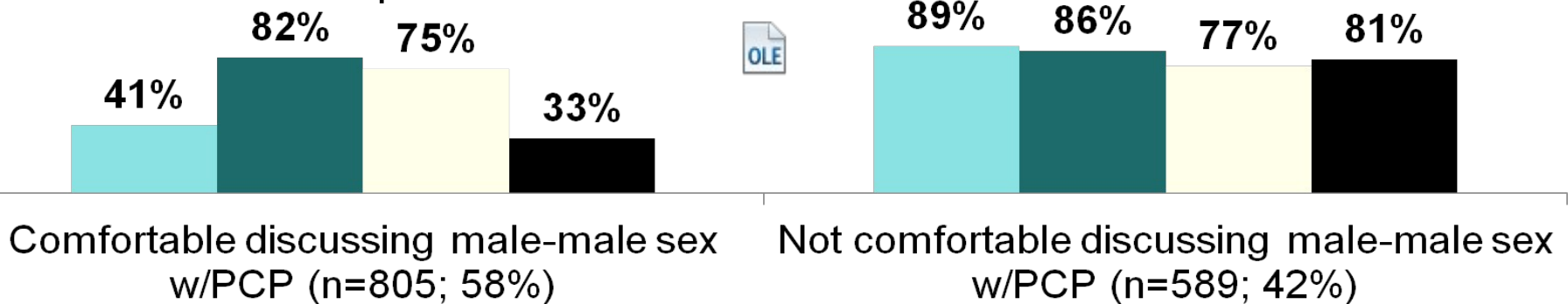
Many HIV specialists do not feel prepared to provide PrEP or other preventive interventions to persons who inject drugs



Need to improve communication about sexual risk behaviors and PrEP in primary care

- ❑ Survey of 1,394 MSM using partner-seeking website
- ❑ 42% were uncomfortable discussing male-male sex with their PCP
- ❑ Even when comfortable, few MSM had discussed PrEP with their PCP
- ❑ Most MSM perceived that PCPs would be unwilling to prescribe PrEP

■ Have not discussed CAS w/PCP
■ Have not discussed PrEP w/PCP
■ Perceive that PCP would not be willing to prescribe PrEP
■ Would prefer to obtain PrEP from source other than PCP**



**Versus other healthcare provider, the Internet, or other source



Beth Israel Deaconess
Medical Center



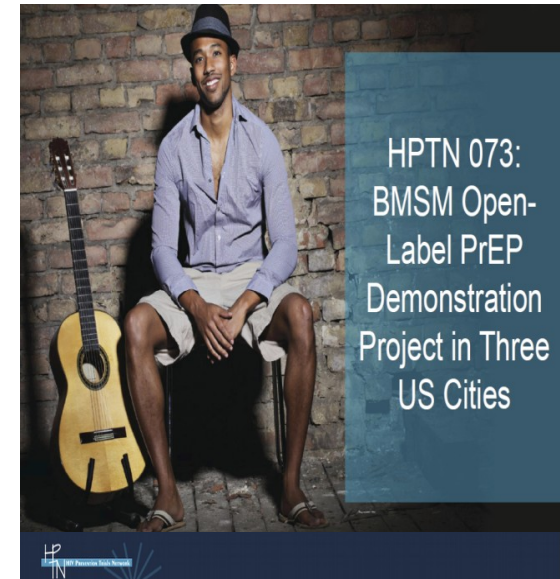
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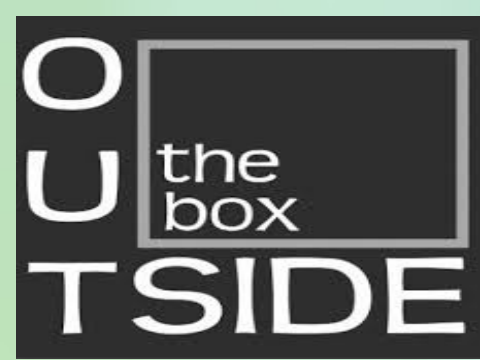


Krakower et al. IAS 2015

Tailoring PrEP for Key Populations

- ATN 110 (Hosek)
 - Young MSM, mainly of color, 18 to 22 y.o.
 - PrEP plus individual versus group behavioral risk reduction interventions
 - HIV incidence 3.3% (better than HPTN 061, but suboptimal)
- HPTN 073: (Wheeler and Fields)
 - Client-centered care coordination (C4)
 - HIV incidence lower in those who used more C4 (NS, but small sample)
- At risk Women in the U.S.
 - Needs more attention, 30% new infections





Other musings...

- “Planned PrEP” programs, building on Planned Parenthood model (specialized sexual health)
- PrEP home monitoring/self-screening (P Sullivan)
- **ONE SIZE WILL NOT FIT ALL**
- Mandatory PrEP CME/CEU (generalist training), i.e. lobby ABIM, AAFP, ANA, etc.
- PrEP Ambassadors: your favorite star(s)
- More integration in media-e.g. Sanjay Gupta, & more than “How to get away with murder”
- Generic PrEP (e.g. TDF/3TC) in richer countries?

Remember, PrEP today is PrEP 1.0

New oral PrEP drugs and dosing strategies



TAF/FTC



Novel adherence strategies

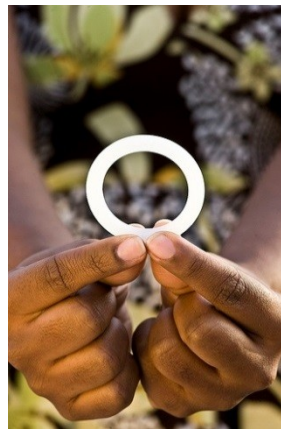


Hard-to-reach populations; PWUD

Alternative delivery systems and formulations



Vaginal & Rectal Microbicides
(e.g. Tenofovir rectal gel)



Intravaginal rings
(Dapivirine, Tenofovir +/-



Injectables:
ARVs and mAbs
(Cabotegravir, VRC01)

Conclusions

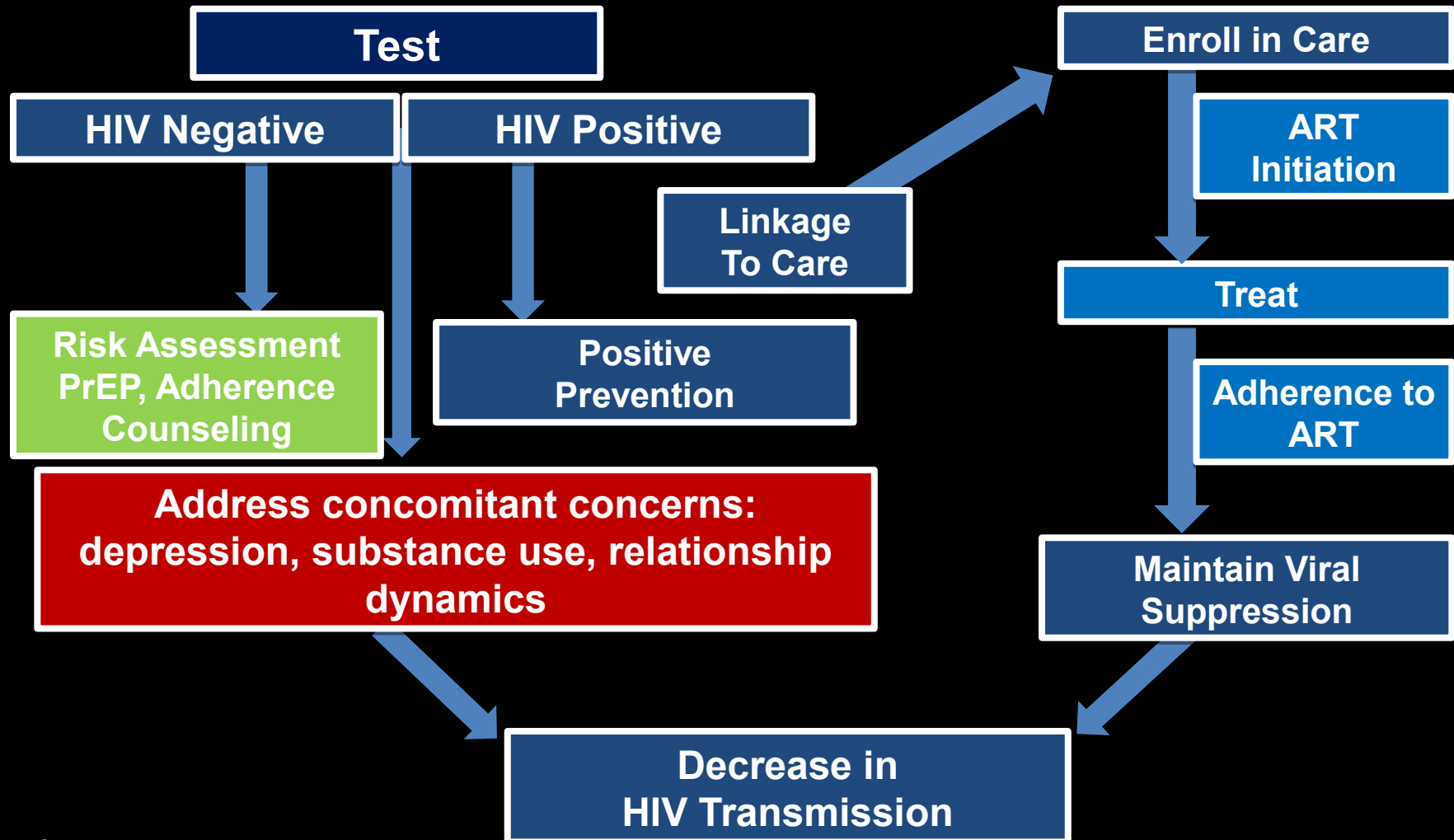
#ADHERENCE2016



- PrEP use continues to increase globally
- Many institutional impediments remain, including regulators, providers and costs
- Best practices are emerging from all over
- New models are needed, e.g. use of home monitoring, peer navigation, referral clinics
- Local champions can play a key role
- Web resources can ↑ knowledge and uptake
- Delays in PrEP access could lead to ↑ informal use or non-use, and missed opportunities to improve global sexual health

Antiretrovirals alone are not sufficient

Interventions to Increase Testing



Thank You

#ADHERENCE2016



Ricardo Baruch
Staci Bush
Sarah Calabrese
Phil Chan
Demetre Daskalaskis
Sheldon Fields
Charlene Flash
Marcy Gelman
Robert Grant
Chris Grasso
Henia Handler
Sybil Hosek
Brian Kanyemba
Douglas Krakower
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Steven A. Safren
Patrick Sullivan
Rodney Vanderwarker
Darrell Wheeler
Mitchell Warren
**NIAID, NIMH, NICHD,
MDPH, Gilead**