

CONTROLLING THE HIV EPIDEMIC WITH
ANTIRETROVIRALS



Avoiding the Cost
of Inaction

18-19 September 2014 • Royal Garden Hotel, London

Antiretroviral Chemoprophylaxis: State of the Evidence

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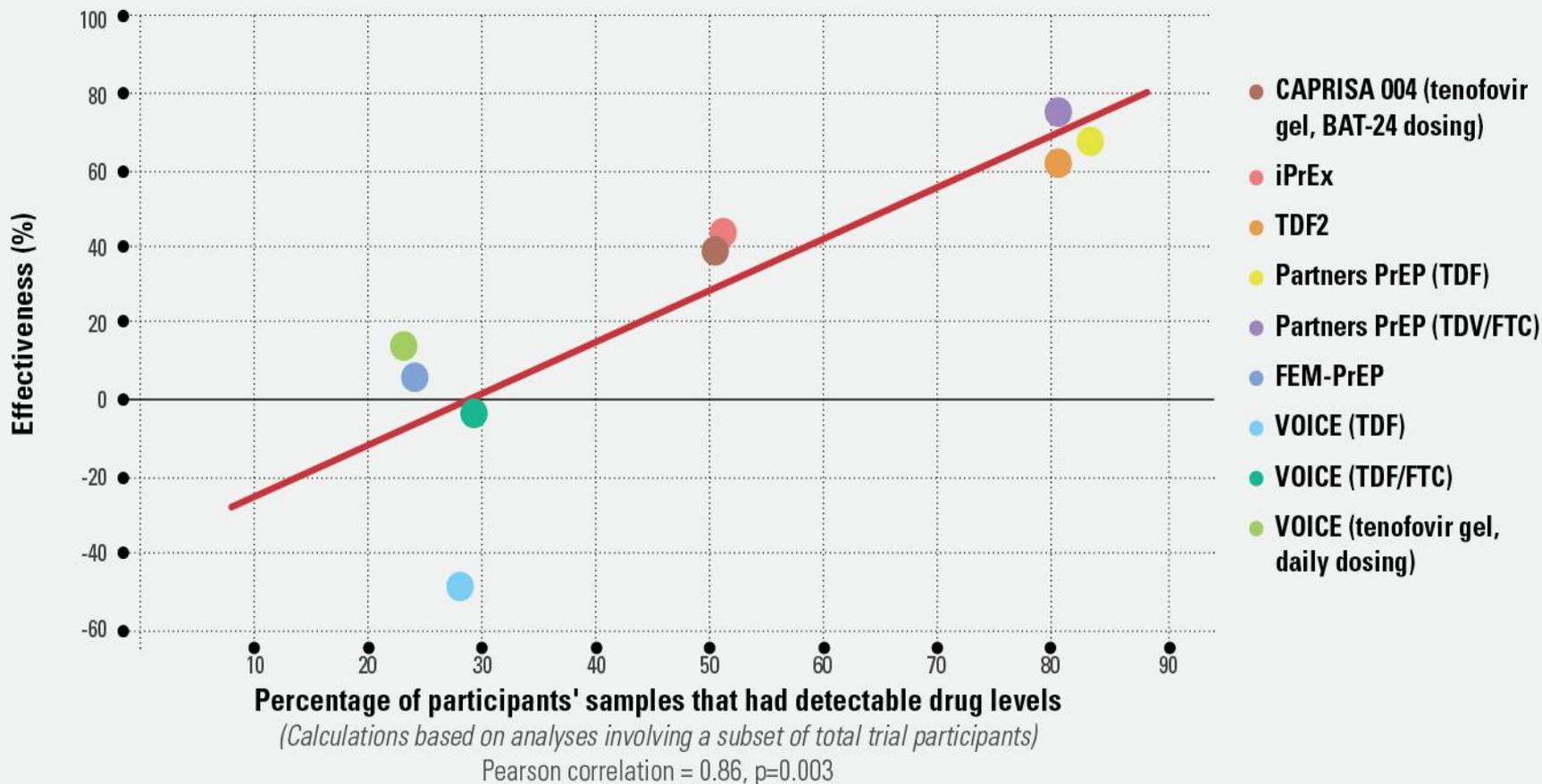
Beth Israel Deaconess Medical Center



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Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention



Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Source: Salim S. Abdool Karim, CAPRISA

PrEP clinical questions

Symptoms: Start-up, GI, uncommon

Renal: uncommon with monitoring

Bone: focus on youth ATN 110/113

Selection for resistance: rare, almost all 184V

Risk compensation vs. reaching those at risk

Other STI: need for frequent monitoring; HSV-2?

Other approaches: Two ring studies; FACTS 001

Ongoing and Planned Phase 3/4 Research, Including Demonstration Projects

- ◆ Phase 3 studies are continuing to evaluate PrEP in various demographic groups
- ◆ Gilead is committed to post-marketing demonstration studies in the U.S. and globally
- ◆ Collaborators: ANRS, CDC, FHI, MRC, NIAID (DAIDS), NICHD (ATN), SFDPH, U. Washington, and Gilead Sciences

Population	Studies	Participants
MSM	17	14,100
Heterosexual Men & Women Serodiscordant Couples	8	10,201
Total	25	24,301

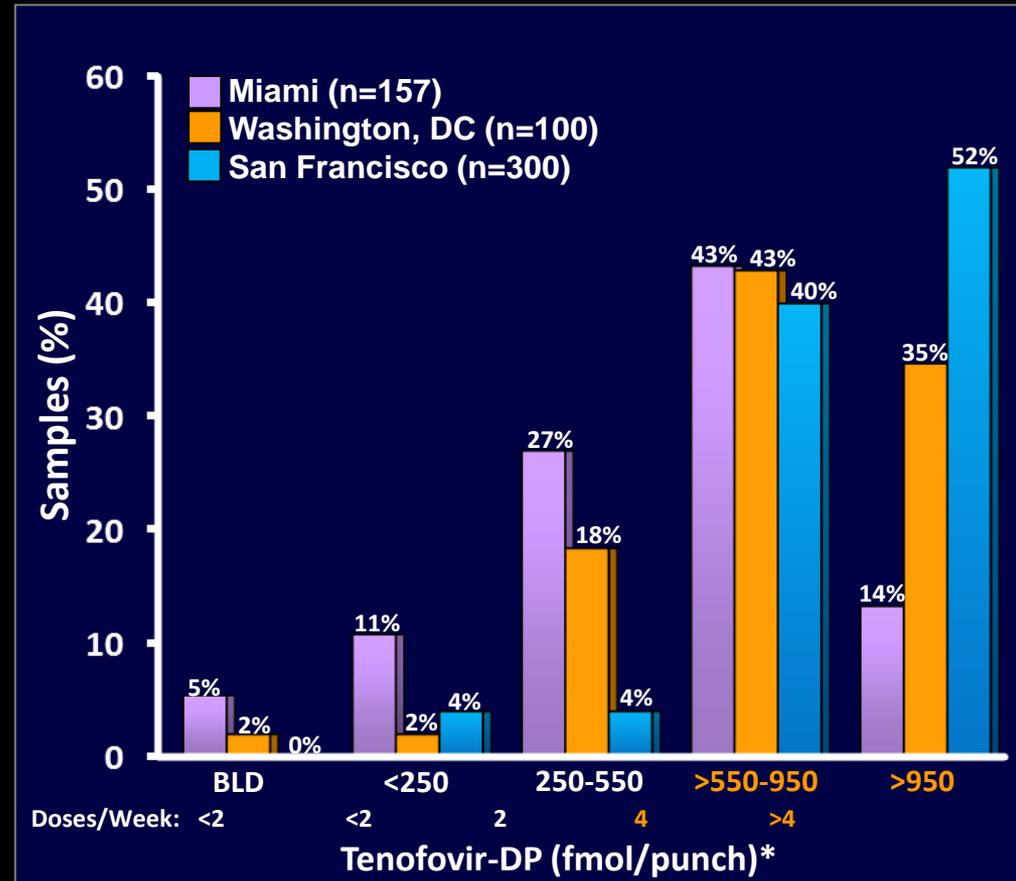
High Levels of Adherence are Feasible: US PrEP Demonstration Project: (2012-2014)

- STD clinics in San Francisco, Miami, Washington, DC (n=831)
 - MSM, transgender women (1.4%)
 - Clinic referrals (63%)
 - Self-referrals (37%): more likely to be white, higher education level, higher sexual risk behaviors and risk perception versus clinic referrals
- Offered up to 48 weeks of open-label emtricitabine/tenofovir DF
 - Accepted PrEP: 60.4%
 - 77% had TDF-DP levels consistent with taking ≥ 4 doses/week
- PrEP uptake associated with
 - Self-referral, prior PrEP awareness, higher-risk sexual behaviors

BLD: below limit of detection.

Cohen SE, et al. 21st CROI. Boston, 2014. Abstract 954.

Tenofovir-DP Levels (Week 4)



*femtomole/punch: measure of flux density.

iPrEx Open-Label Extension (OLE): HIV Incidence and Predictors of Detectable Drug

- **HIV incidence in iPrEx OLE**
 - **PrEP versus no PrEP**
 - 1.8 versus 2.6 infections/100 person-years (adjusted HR: 0.51, 95% CI: 0.26-1.01)
 - **PrEP, but no drug detected**
 - 4.7 infections/100 person-years
- **HIV incidence in original iPrEx: placebo recipients**
 - 3.9 infections/100 person-years

Predictors of Detectable Drug	
	Adjusted Odds Ratio
Non-condom intercourse (reference: none)	
Receptive, anal	1.66 ($P<0.0001$)
Male sexual partners (reference: 0-1)	
2-4	1.33 ($P=0.005$)
≥ 5	1.82 ($P<0.0001$)
Age (reference: 18-24 years)	
30-39	1.64 ($P=0.0002$)
≥ 40	3.29 ($P<0.0001$)
Education (reference: <secondary)	
Secondary	1.99 ($P<0.0001$)
Post-secondary	1.93 ($P<0.0001$)

Grant RM, et al. 20th IAC. Melbourne, 2014. Abstract TUAC0105LB.

Grant RM, et al. *Lancet Infect Dis.* 2014;July 22, 2014. [Epub ahead of print].

Lively Discussion and Debate in the Blogosphere

Project Inform launches new educational video series on PrEP!



Making decisions to take PrEP with your doctor.



Using PrEP in relationships with HIV-positive men.



Figuring out how PrEP fits into your life.

- Brief video testimonials developed regarding PrEP users' decisions and motivations to take PrEP and experiences taking PrEP
- Also: www.myprepxperience.blogspot.com AIDS Foundation of Chicago



**My PrEP
experience**



**INTRODUCING THE
"PrEP PACKAGE" FOR
ENHANCED HIV PREVENTION:**

A Practical Guide for Clinicians

October 2017

 THE FENWAY INSTITUTE



**PROTECTING
YOURSELF FROM HIV
THROUGH PRE-EXPOSURE
PROPHYLAXIS (PrEP):**

What You Need to Know

October 2017

 THE FENWAY INSTITUTE

www.thefenwayinstitute.org/prepinfo

WHAT IS
PrEP?

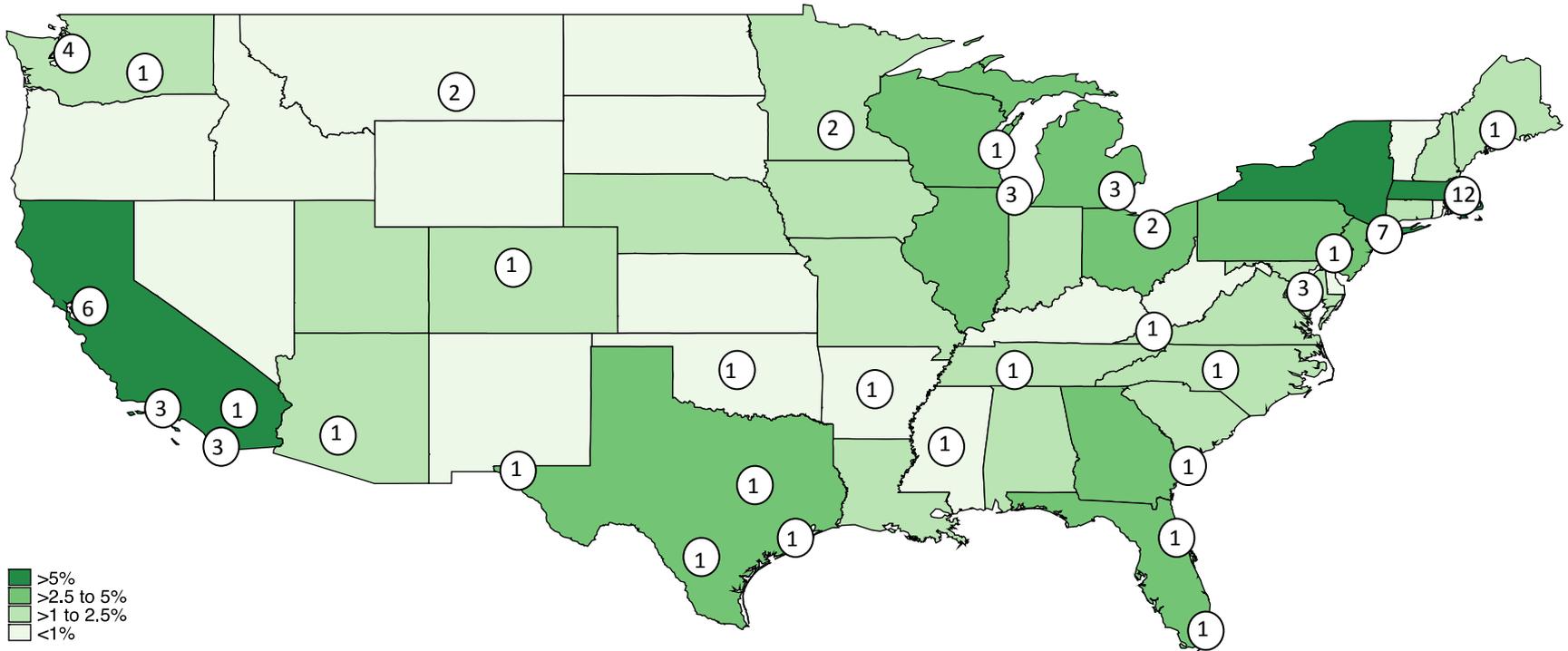


WHAT IS
PrEP?



Proportion of PrEP Users by State of Residence

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



Proportion of responders; 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)

Project PrEPare (NIMH R34, Fenway)

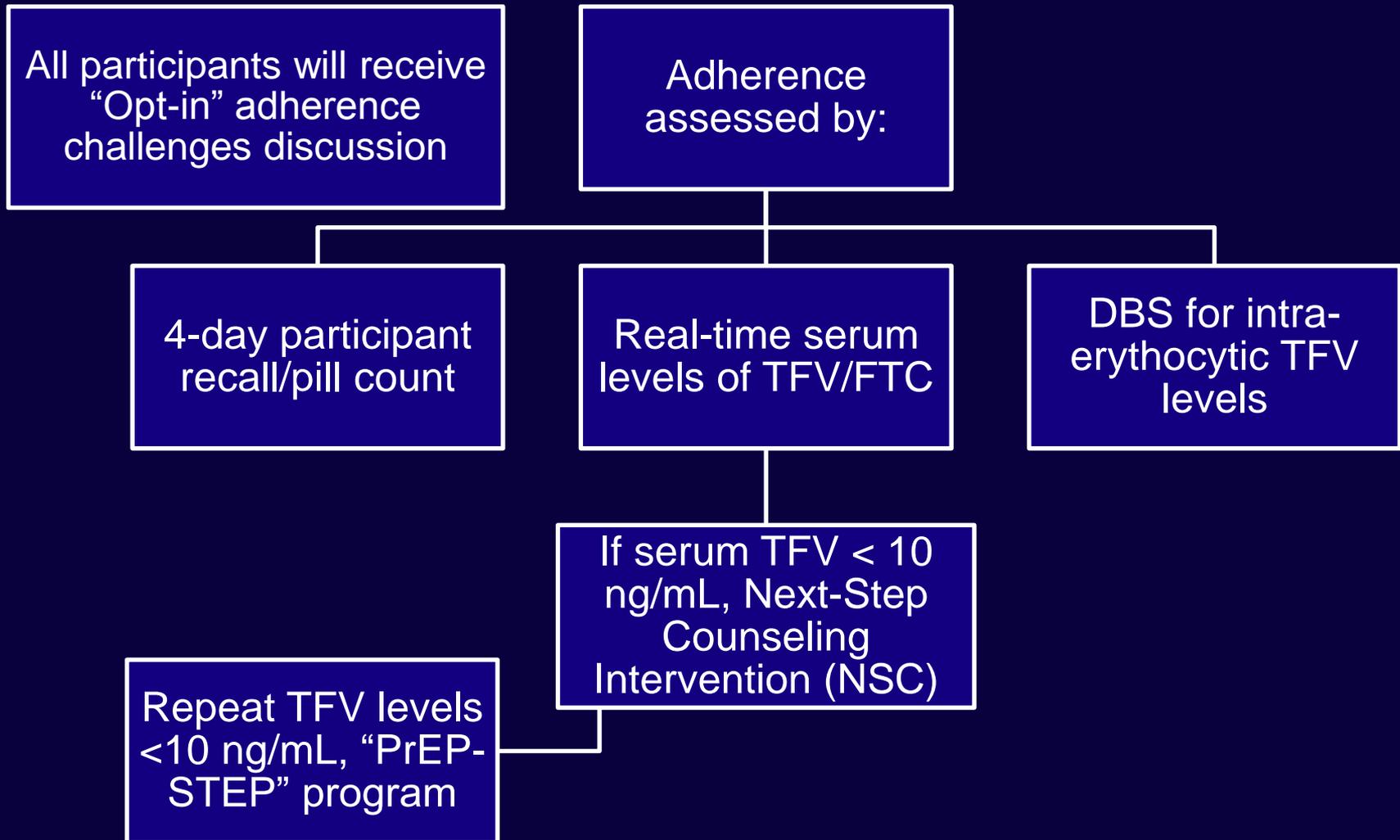
- Modeled after “Life-Steps,” (Safren et al) ART adherence intervention
- Modular intervention: 4 weekly visits and 2 booster sessions (nurse-delivered).
- Intervention content:
 - CBT-oriented adherence problem-solving
 - Brief motivational interviewing
 - Identification of barriers and solutions
 - Sexual risk-reduction strategies

Optional modules:

- Mental health and substance use concerns
- Adherence to PrEP was measured daily via Wisepill
- Sexual risk taking was assessed by text messages (Lester, 2010)



Southern California: Path-PrEP: Staged Adherence (R Landovitz)



U.S. Black MSM and PrEP: Lessons from HPTN 061

Annual HIV incidence 3%; for 18-29 y.o. 5.9%

-Koblin B et al PLoS ONE, 2013

High rates of STIs, associated with HIV

-Mayer KH et al PLoS ONE, 2014

Many men with advanced HIV were identified

-Mannheimer S et al, AIDS 2012, MS under review

Many unmet social needs, poverty, incarceration

-Brewer, R et al, AJPH, 2013; JAIDS, 2013



We've launched a new PrEP demonstration project for Black men who have sex with men.

Participate in the live Twitter chat on

#HPTN073 **Wednesday, August 14** **#PrEPChat**
at **10 am PT / 1 pm ET**

With our guests: @JonPaulLucas and @cchauncey

Be sure to follow @HIVptn

Join the HPTN 073 Webinar:

"Introducing HPTN 073: A BSM PrEP Demonstration Study"
at **11 am PT / 2 pm ET**

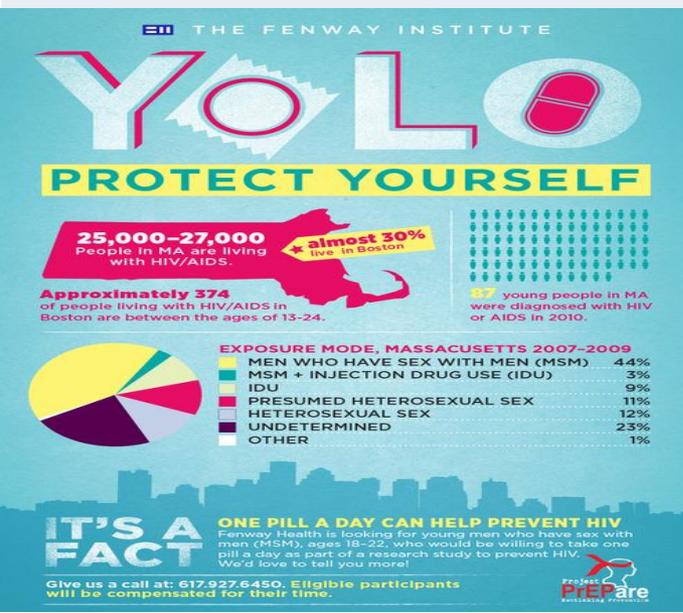
by registering at

<http://bit.ly/073Webinar>

Find out more about HPTN 073 at
www.HPTN.org and at **Facebook/HIVptn**

PrEP Uptake Among Young MSM

- Chicago cohort of young, primarily Black MSM
- 2/3 of those in earlier ATN trial enrolled in iPeEX Ole with choice of PrEP use or not
- 70% of those YMSM elected to take PrEP
- Drug detection ↑ from 45% to 58% and 70% expressed interest in ongoing PrEP use



Effective Interventions
HIV PREVENTION THAT WORKS

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Top 4

- 1 Medication Adherence
- 2 ARTAS
- 3 Diffusion of Effective Behavioral Interventions (DEBI)
- 4 Condom Distribution

Biomedical Interventions

Public Health Strategies

Behavioral Interventions

- CLEAR (Clarify, Understand, Connect)
- Asp (Defend Yourself)
- FOP: Focus on the Future
- FO: The Future is Ours
- Focus on Youth + IMPACT
- Healthy Love
- Healthy Relationships
- Holistic Health Recovery Program
- Many Men, Many Voices
- IMP
- Movement
- No

Structural Interventions

Social Marketing

What's New

PROJECT UPDATES

Video

Partnership for Health - Safer Sex

Personalized Cognitive Counseling (PCC)

Popular Opinion Leader

Project ABM

Project START

MSM Overview Fact Sheet

11/14/2013

Hosek, CROI, 2014

Purview paradox: contradictory beliefs about which providers will prescribe PrEP

(Krakower, AIDS and Behavior, 2014)



HIV providers:

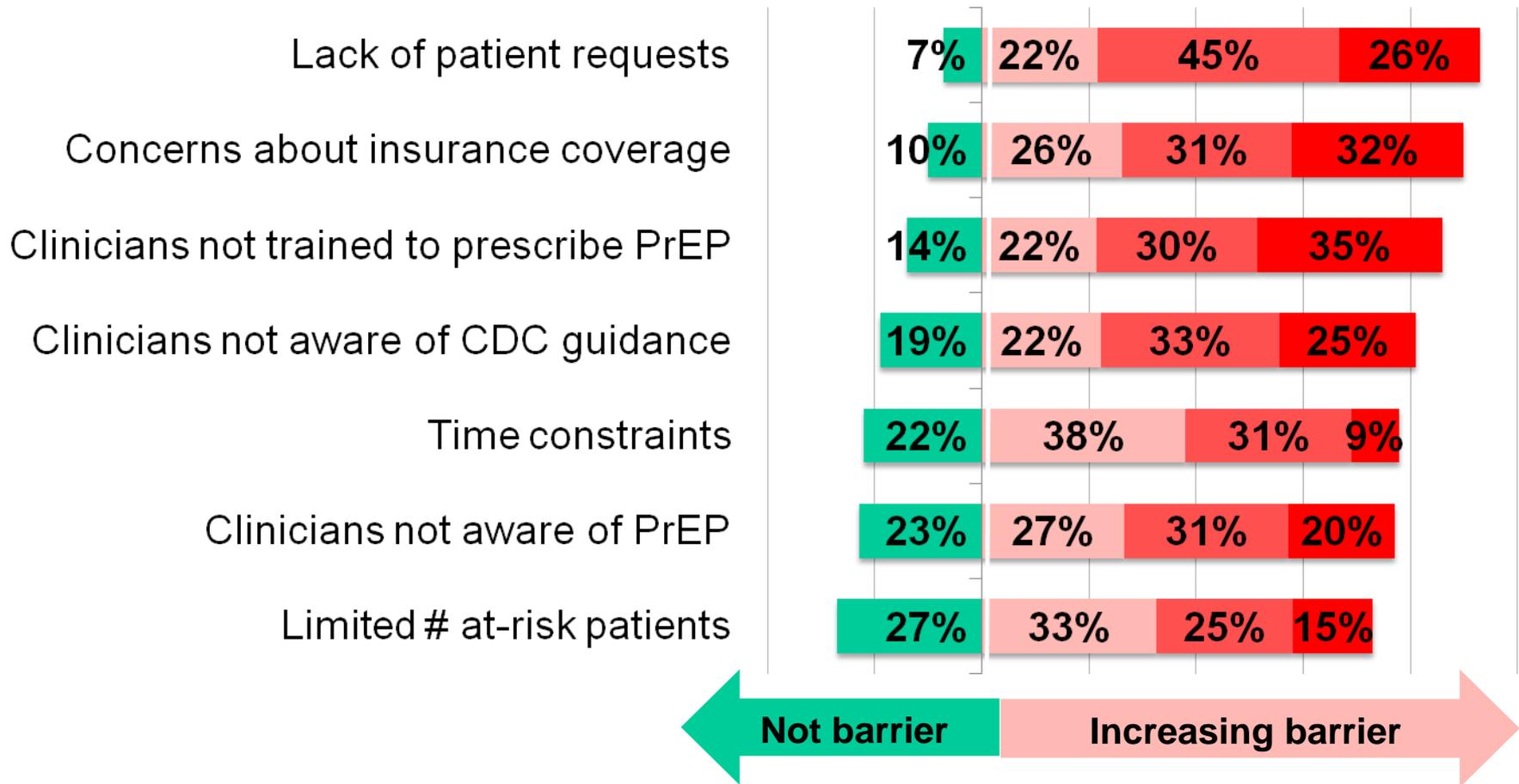
Primary care providers
are in the best position
to prescribe PrEP

Primary care providers:

It would not be feasible
to prescribe PrEP



New England providers perceived numerous barriers to prescribing PrEP (Krakower, Adherence 2014)



New Technologies may provide tools for more efficient risk screening

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†

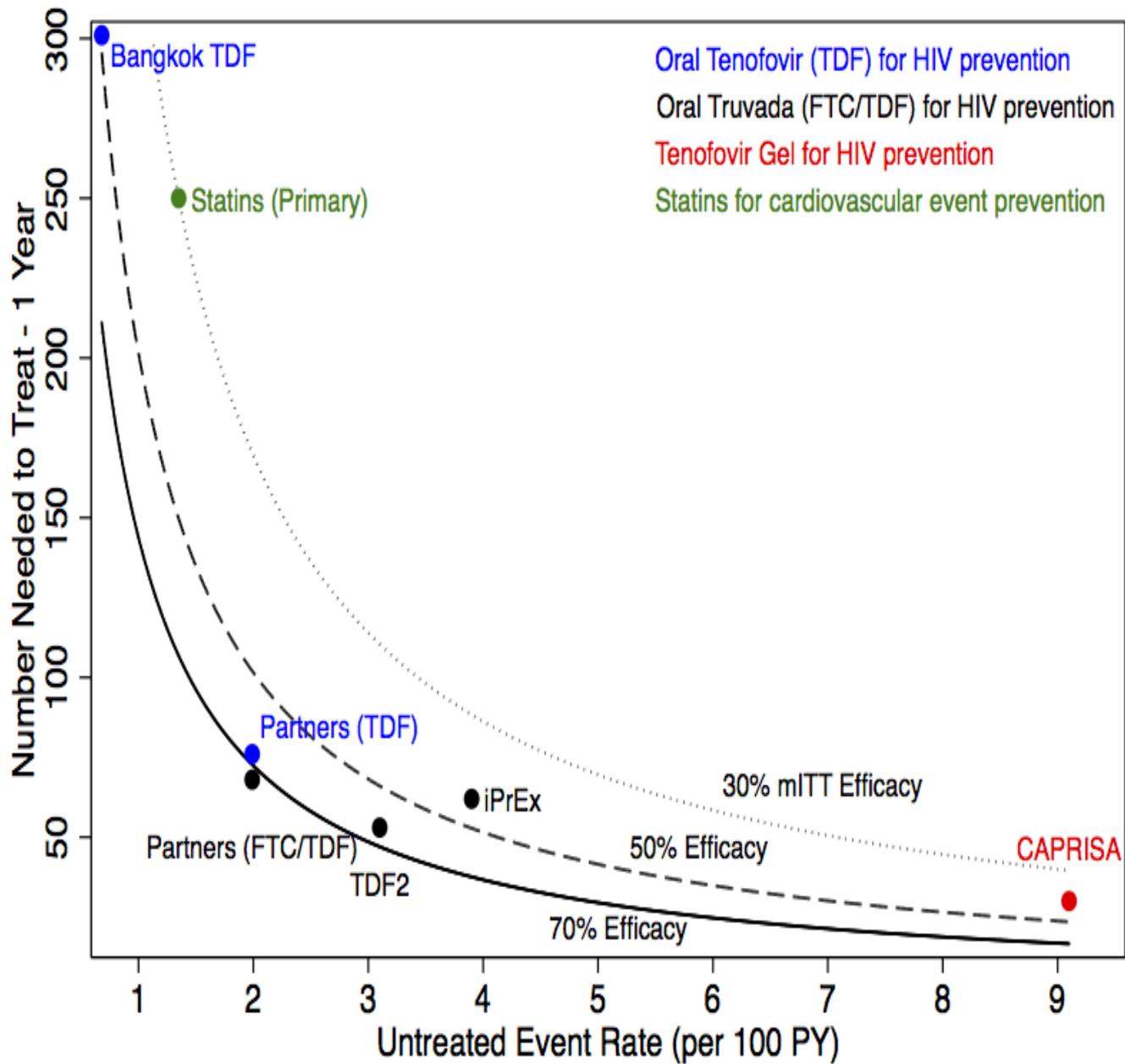
FENWAY HEALTH

In the past 6 months, how often have you had anal sex with someone whose HIV status you did not know?

- Never
- A few times or less
- A few times each month
- A few times each week

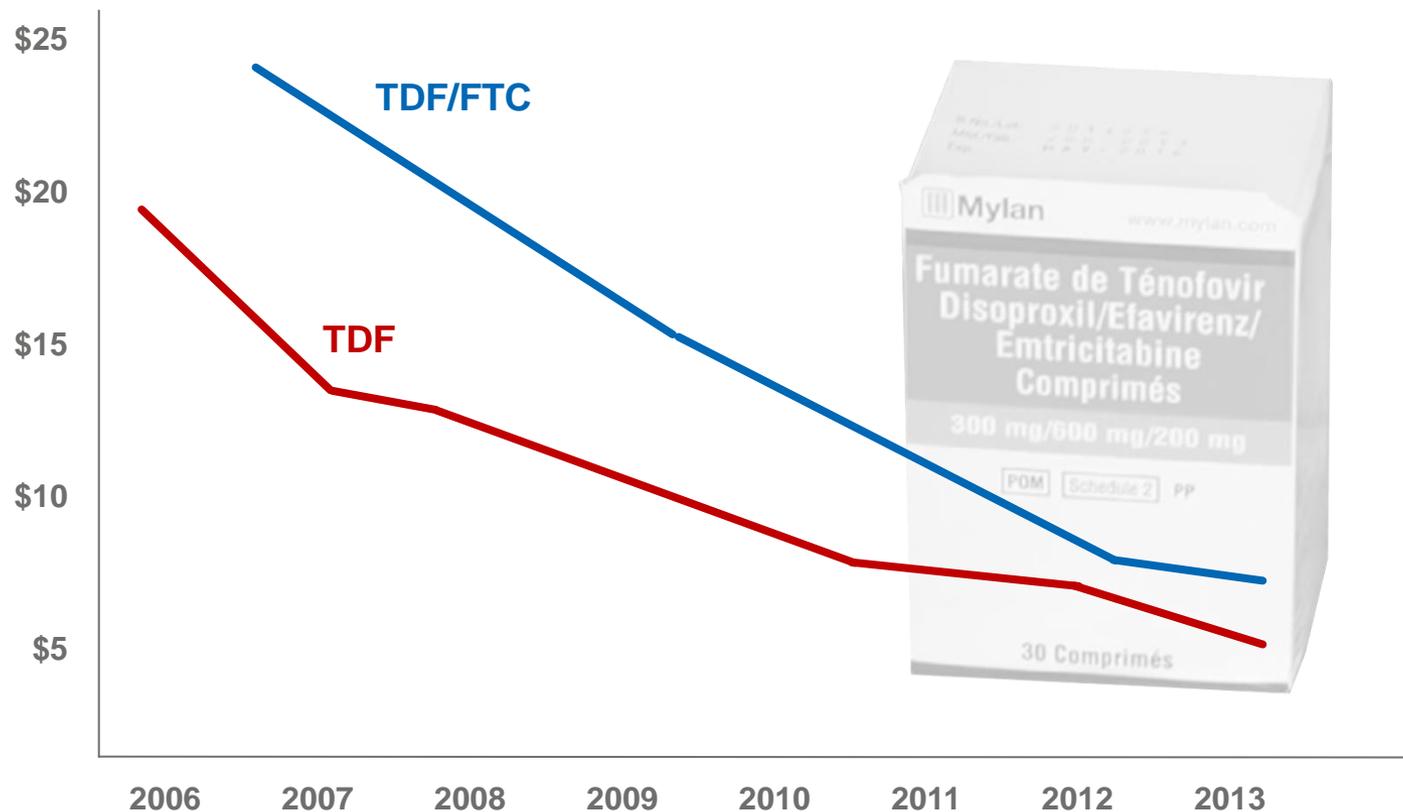
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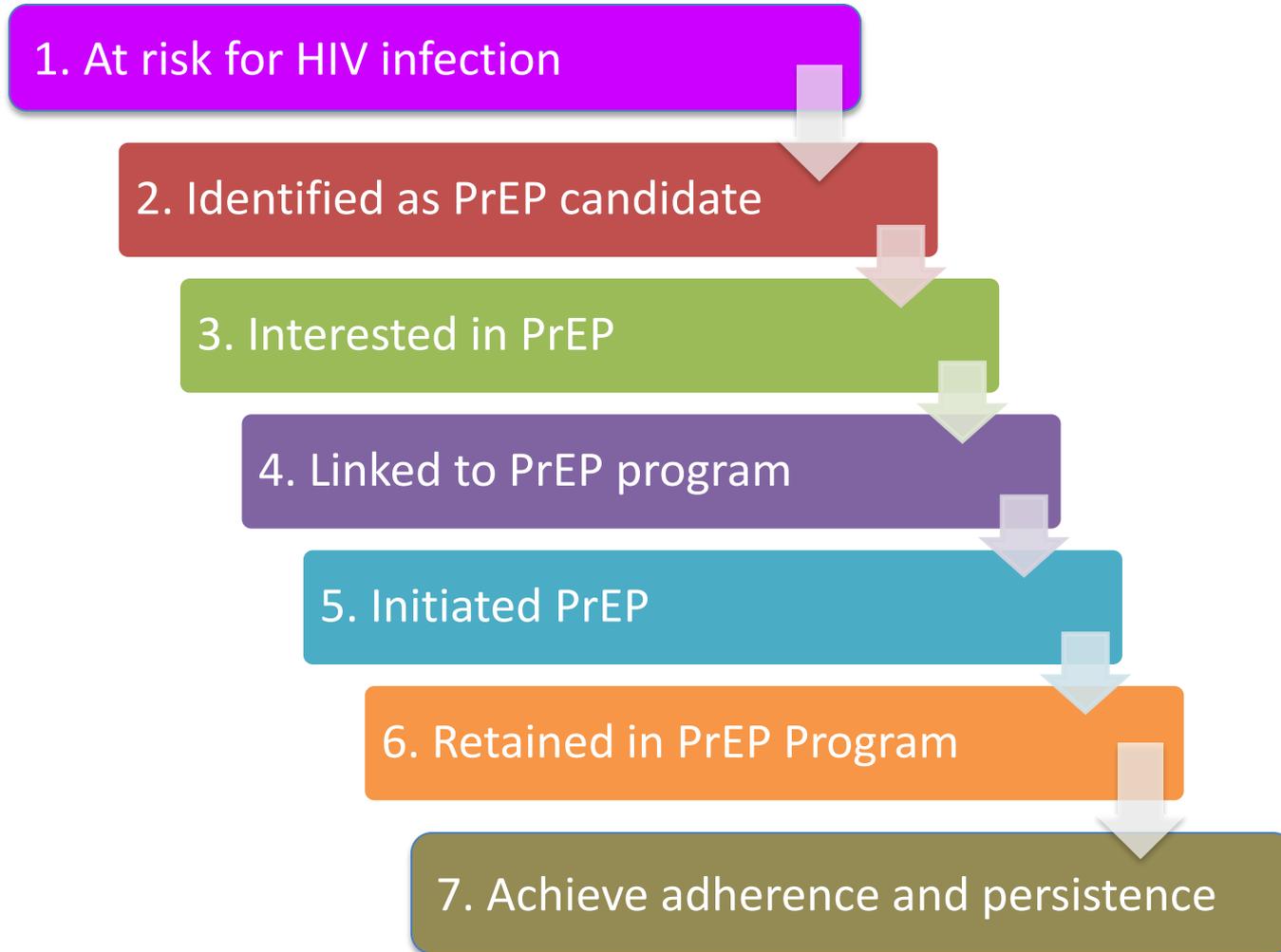


Cost of PrEP is going down globally

17 generic partners are licensed to manufacture and sell Gilead therapies; market competition has helped **reduce the cost of TDF by 80% since 2006**

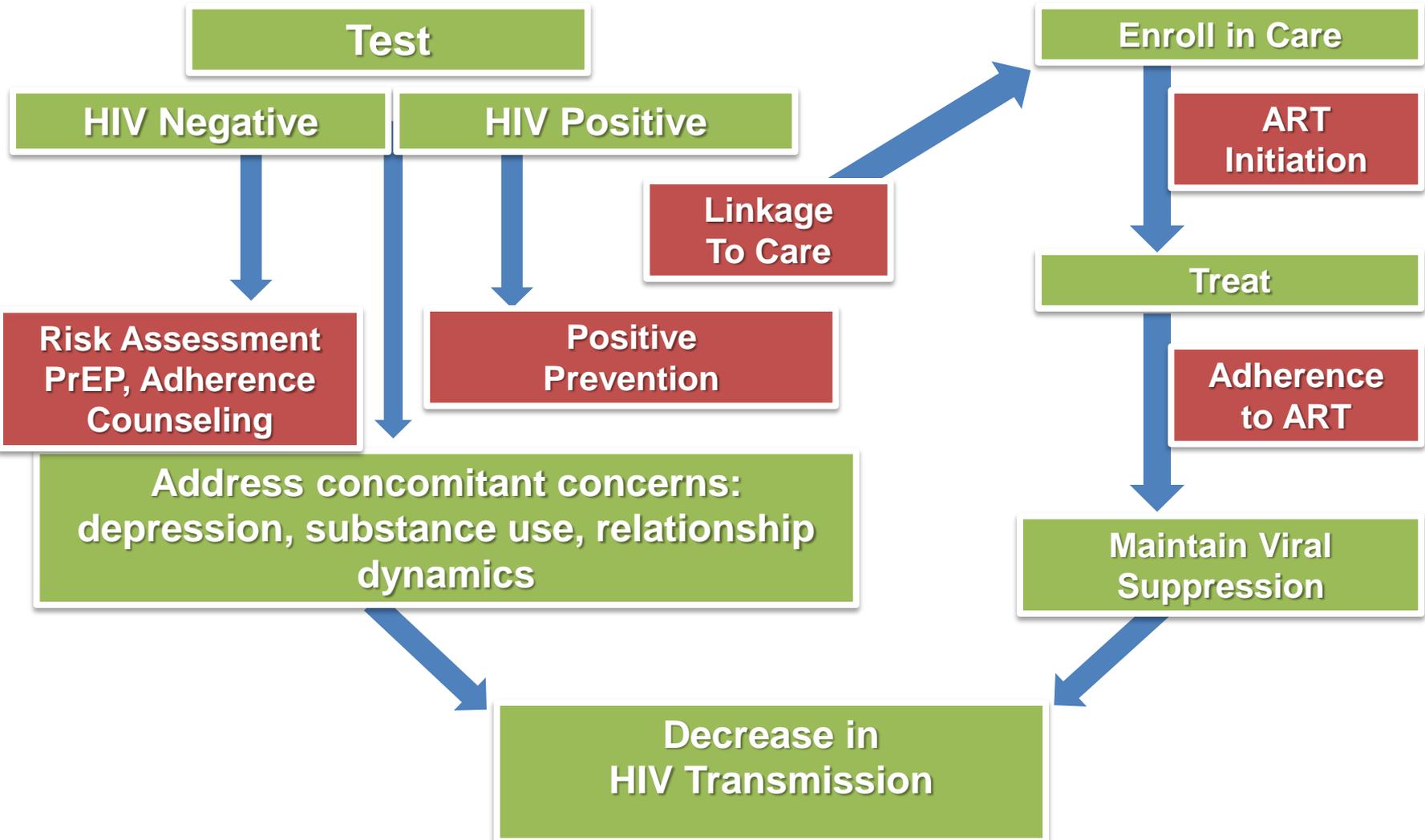


The PrEP cascade (A Liu et al)



Combination Antiretroviral Prevention

Interventions to Increase Testing



PrEP in 2014

- PrEP works when used consistently
- No new safety signals; Bone health under study
- Demo projects underway in many parts of the world
- Early demonstration projects suggest that those who present for PrEP may be motivated to adhere
- Optimizing social media may facilitate safer sex and med adherence counseling
- Providers need more education about PrEP
- Use of generics and focusing on highest risk will ↓cost
- New PrEP meds/modalities may ↑ uptake, ↓cost



Many thanks

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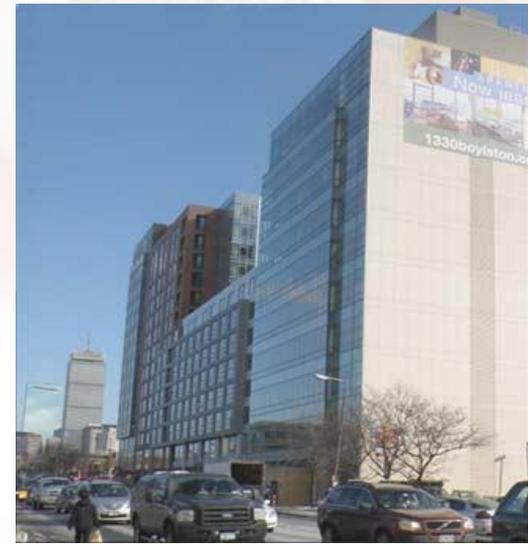
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