

# Using Modeling to Set Programmatic Goals for HIV Prevention in MSM

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**April 10, 2018**



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**Center for  
AIDS Research**

# THE LANCET

HIV in men who have sex with men · July, 2012

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"In much of the world, [men who have sex with men] remain hidden, stigmatised, susceptible to blackmail if they disclose their sexual lives, and criminalised, even in health-care facilities....To address HIV in [these men] will take continued research, political will, structural reform, community engagement, and strategic planning and programming, but it can and must be done."

HIV in men who have sex with men

Series



## HIV in men who have sex with men 3

### Successes and challenges of HIV prevention in men who have sex with men

Patrick S Sullivan, Alex Carballo-Díez, Thomas Coates, Steven M Goodreau, Ian McGowan, Edward J Sanders, Adrian Smith, Prabhudhagopal Goswami, Jorge Sanchez

Lancet 2012; 380: 388–99

Published Online

July 20, 2012

[http://dx.doi.org/10.1016/S0140-6736\(12\)60955-6](http://dx.doi.org/10.1016/S0140-6736(12)60955-6)

This publication has been

corrected. The corrected

version first appeared at

[thelancet.com](http://thelancet.com) on July 27, 2012

This is the third in a Series of

papers about HIV in men who

have sex with men

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See Online for appendix

Men who have sex with men (MSM) have been substantially affected by HIV epidemics worldwide. Epidemics in MSM are re-emerging in many high-income countries and gaining greater recognition in many low-income and middle-income countries. Better HIV prevention strategies are urgently needed. Our review of HIV prevention strategies for MSM identified several important themes. At the beginning of the epidemic, stand-alone behavioural interventions mostly aimed to reduce unprotected anal intercourse, which, although somewhat efficacious, did not reduce HIV transmission. Biomedical prevention strategies reduce the incidence of HIV infection. Delivery of barrier and biomedical interventions with coordinated behavioural and structural strategies could optimise the effectiveness of prevention. Modelling suggests that, with sufficient coverage, available interventions are sufficient to avert at least a quarter of new HIV infections in MSM in diverse countries. Scale-up of HIV prevention programmes for MSM is difficult because of homophobia and bias, suboptimum access to HIV testing and care, and financial constraints.

#### Introduction

Men who have sex with men (MSM) have always had a key role in the global HIV epidemic.<sup>1</sup> HIV epidemics in MSM are re-emerging in high-income countries<sup>2</sup> and have been noted in many low-income and middle-income countries.<sup>3,4</sup> We review HIV prevention interventions for MSM, emphasise the importance of the development and assessment of combination prevention packages, and address challenges. The World Bank used the highest attainable standard of evidence (HASTE) system (which also includes data for implementation science) in its 2011 review<sup>5</sup> of published work, whereas WHO used the grading of recommendations assessment, development and evaluation (GRADE) system.<sup>6</sup> We combine these reviews and our own comprehensive review of work and suggest a conceptual framework for packaging of interventions and modelling of the potential effect of scale-up of HIV prevention interventions for MSM.

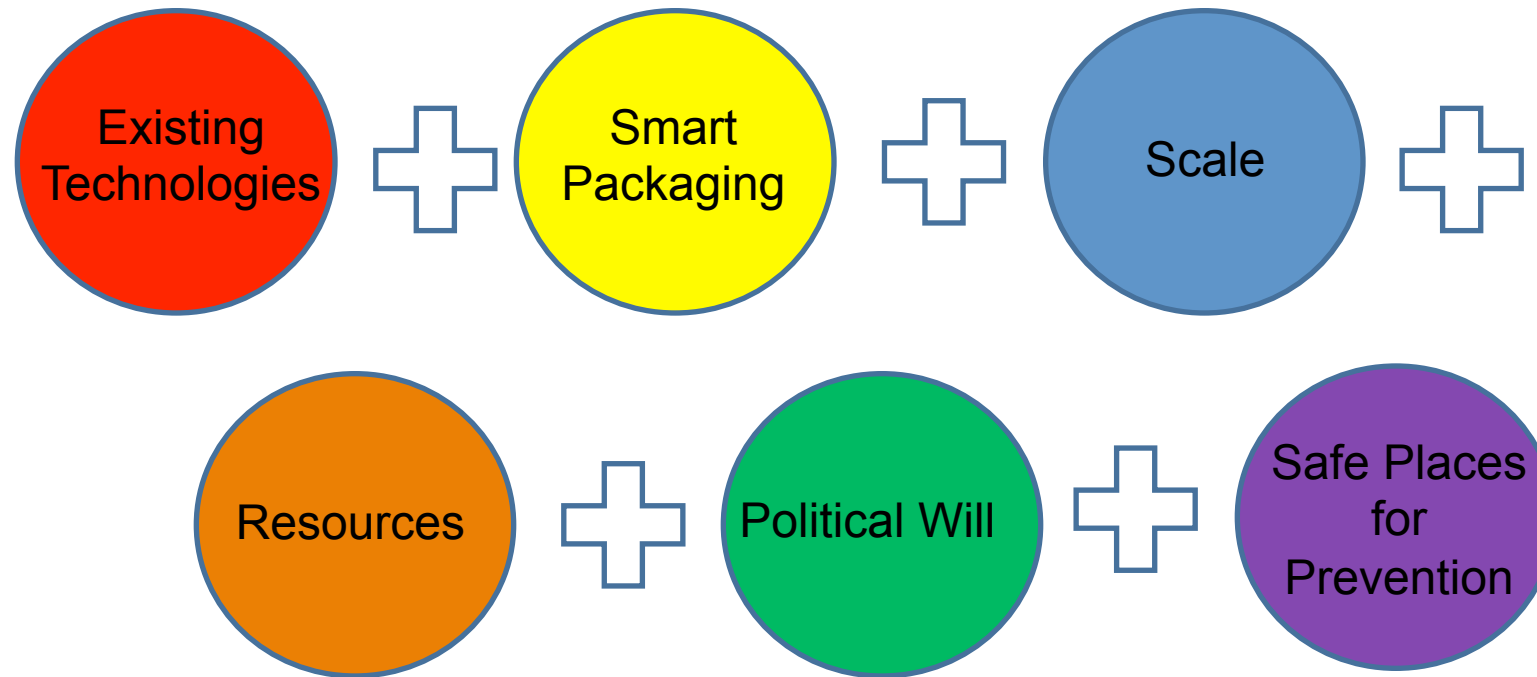
#### Search strategy and selection criteria

Between Oct 11, 2011, and Jan 9, 2012, we reviewed HIV prevention interventions for MSM published in English on PubMed, Embase, Scopus, PsycINFO, Social Sciences Citation Index, Science Citation Index Expanded, Conference Proceedings Citation Index-Science, and the Cumulative Index to Nursing and Allied Health Literature, and focused whenever possible on systematic reviews and meta-analyses (appendix). We also inventoried the results of meta-analyses of HIV prevention in MSM. We compiled 1871 non-duplicated citations and refined our results to identify 60 articles with putative HIV prevention interventions tested in MSM. Further details of our search strategy and bibliographies for all included articles, systematic reviews, and meta-analyses are in the appendix.

#### Key messages

- Governmental, academic, and community strategies have been insufficient to curb the HIV epidemic in men who have sex with men (MSM).
- HIV prevention is difficult for MSM because of the high biological risk associated with anal intercourse, high frequency and variety of sexual activity, little acknowledgment of male-male sex by governments and health-care providers, discrimination, few specific services for MSM, and syndemic challenges (eg, substance misuse).
- In most parts of the world, restricted resources and legal barriers complicate the effective provision of HIV prevention services for MSM.
- Resources are scarce for HIV prevention services in MSM and scale-up is problematic. Available interventions are insufficient, largely untested in most developing countries, and not sufficiently tailored to MSM.
- Several behavioural interventions are somewhat efficacious in reduction of the frequency of unprotected anal intercourse in MSM, but none effectively decreases the incidence of new HIV infections. However, behavioural interventions have not been fully assessed in some environments, and they have a crucial role in combination with barrier and biomedical interventions.
- Coordinated behavioural, biomedical, and structural interventions that incorporate efficacious strategies could substantially reduce the incidence of HIV infection in MSM.
- Prevention efforts reach only a small proportion of MSM, and scalability should be considered when new interventions and packaging approaches are developed.

**Using HIV prevention technologies we have today, we could prevent a quarter of new infections among MSM in the next decade.**

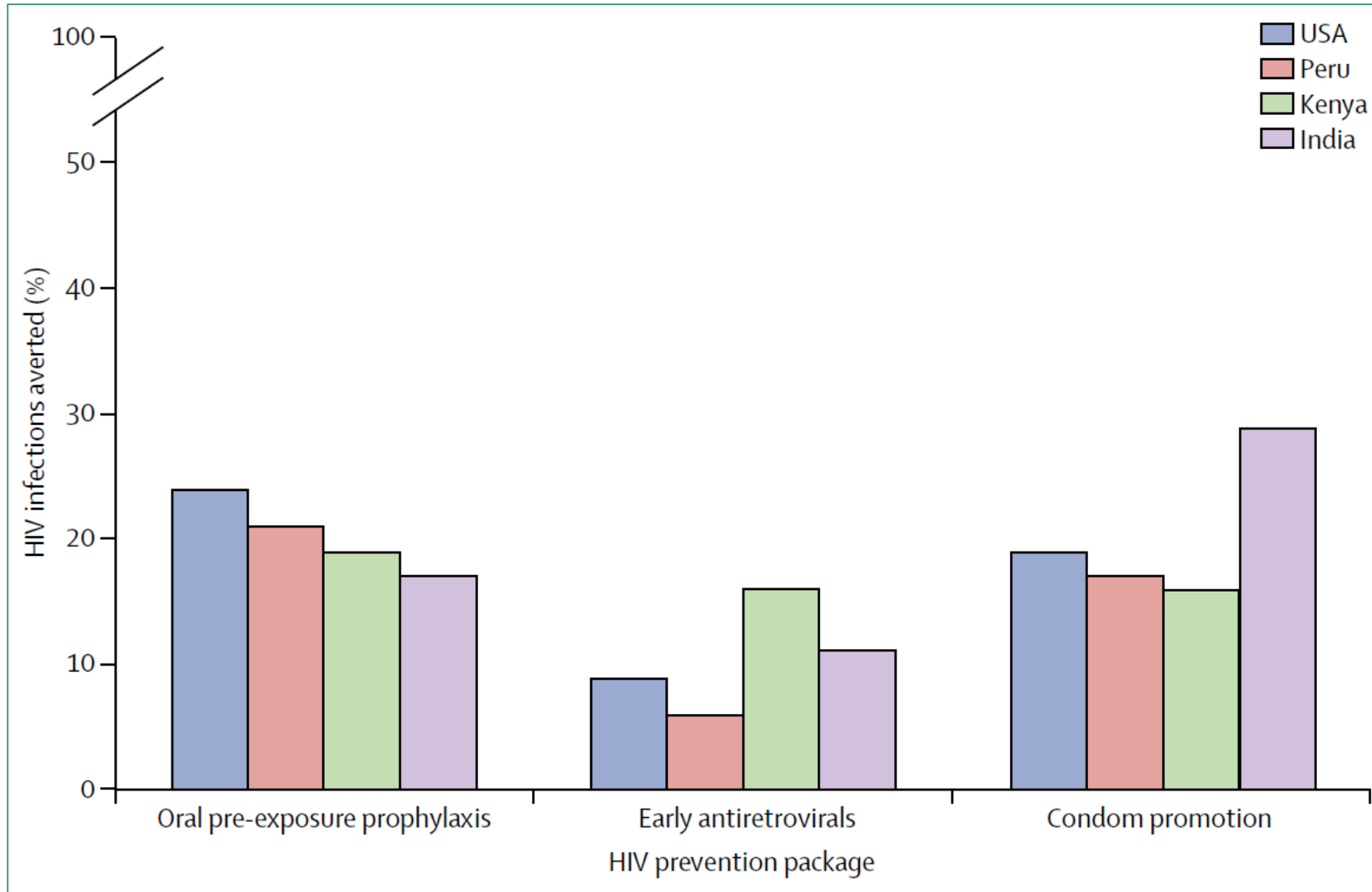


**25% reduction**

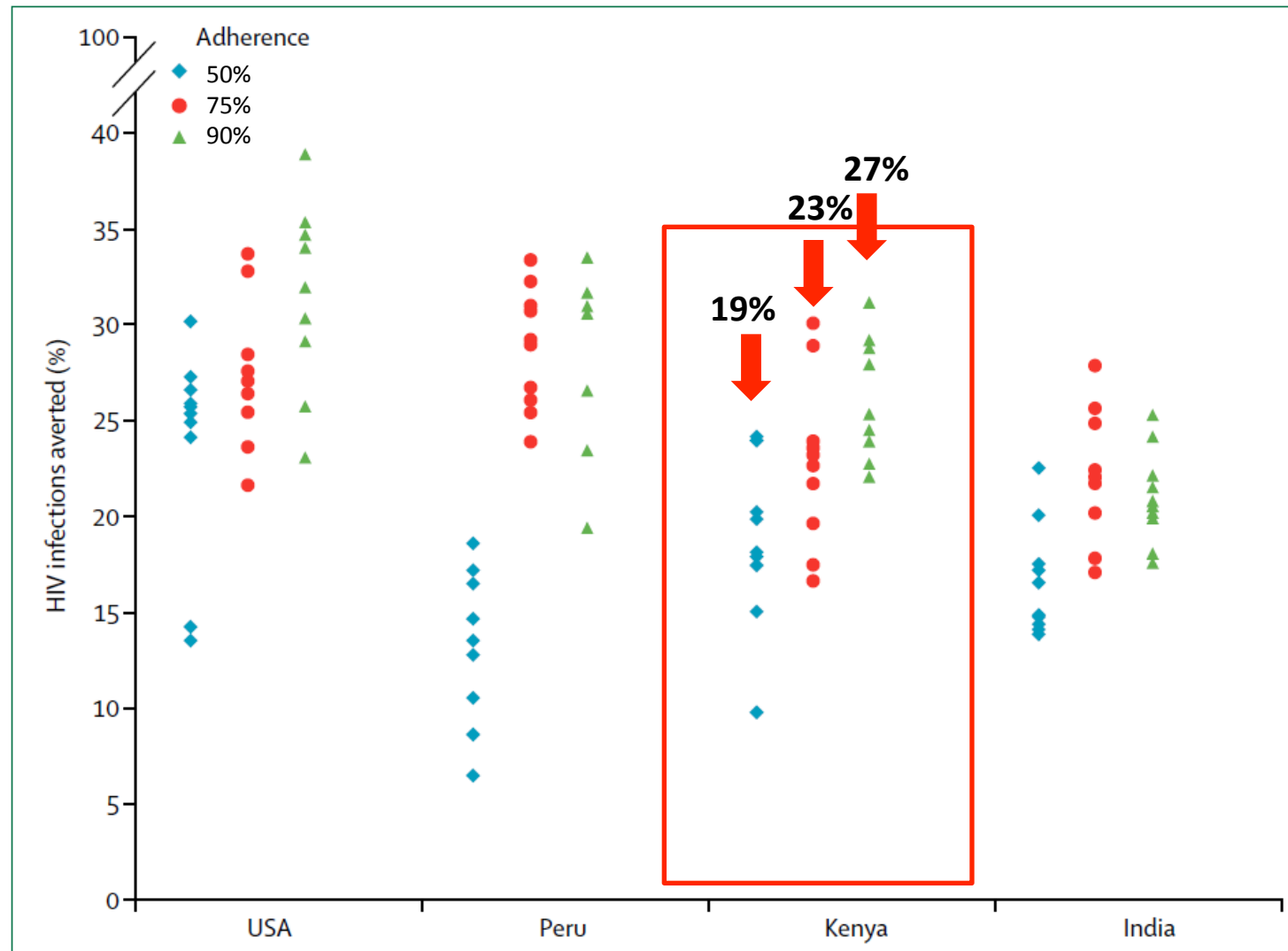
# Modeling of Prevention Impact

- Agent-based, stochastic model
- Kenya, USA, Peru, India
- Country-specific parameterization and calibration
- Three prevention approaches/packages:
  - PrEP
  - Treatment of positives
  - Increased condom use
- Outcome: Proportion of infections averted after 10 years

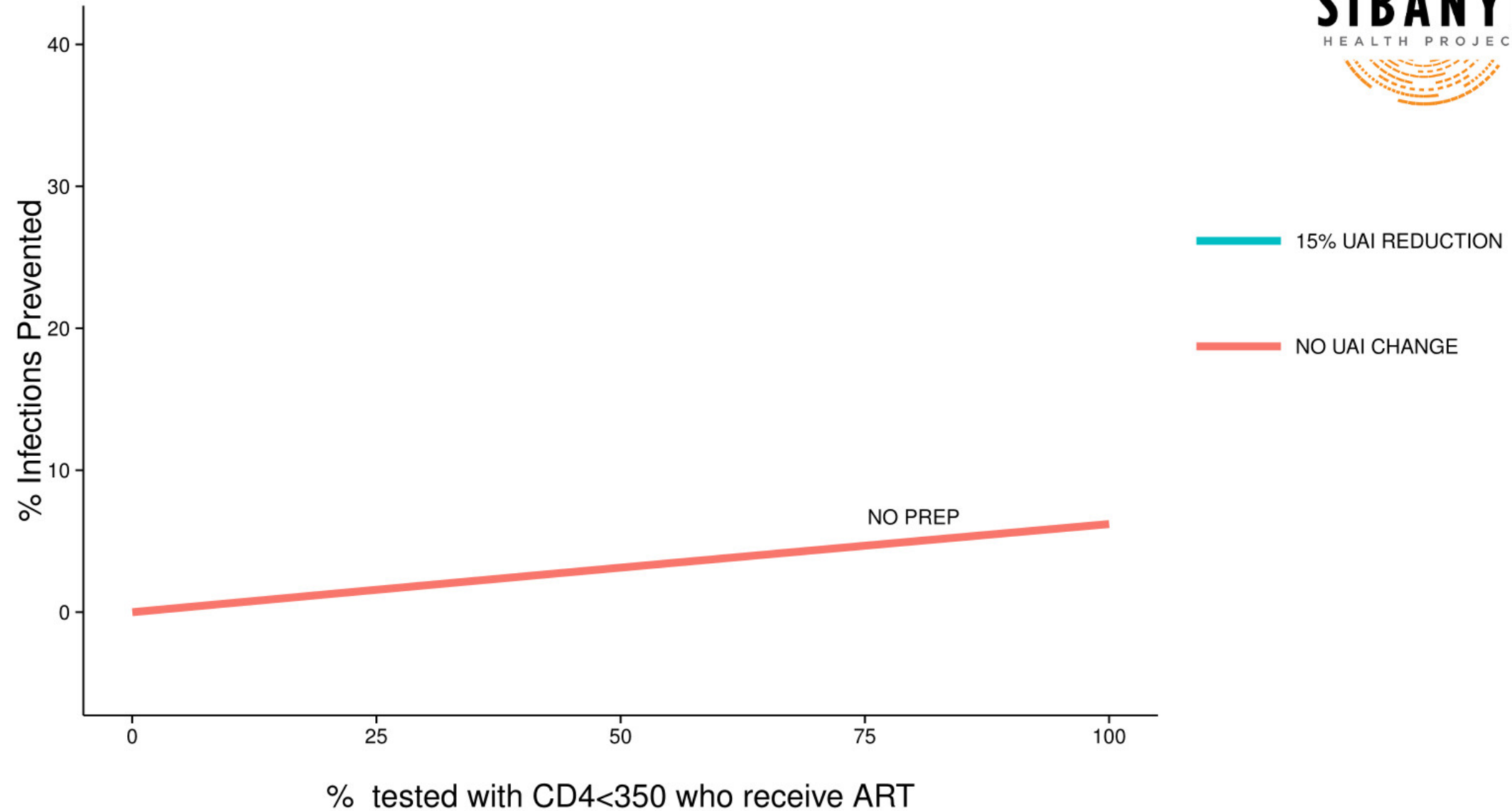
# Estimated percent of new HIV infections among MSM prevented by three prevention approaches, four countries



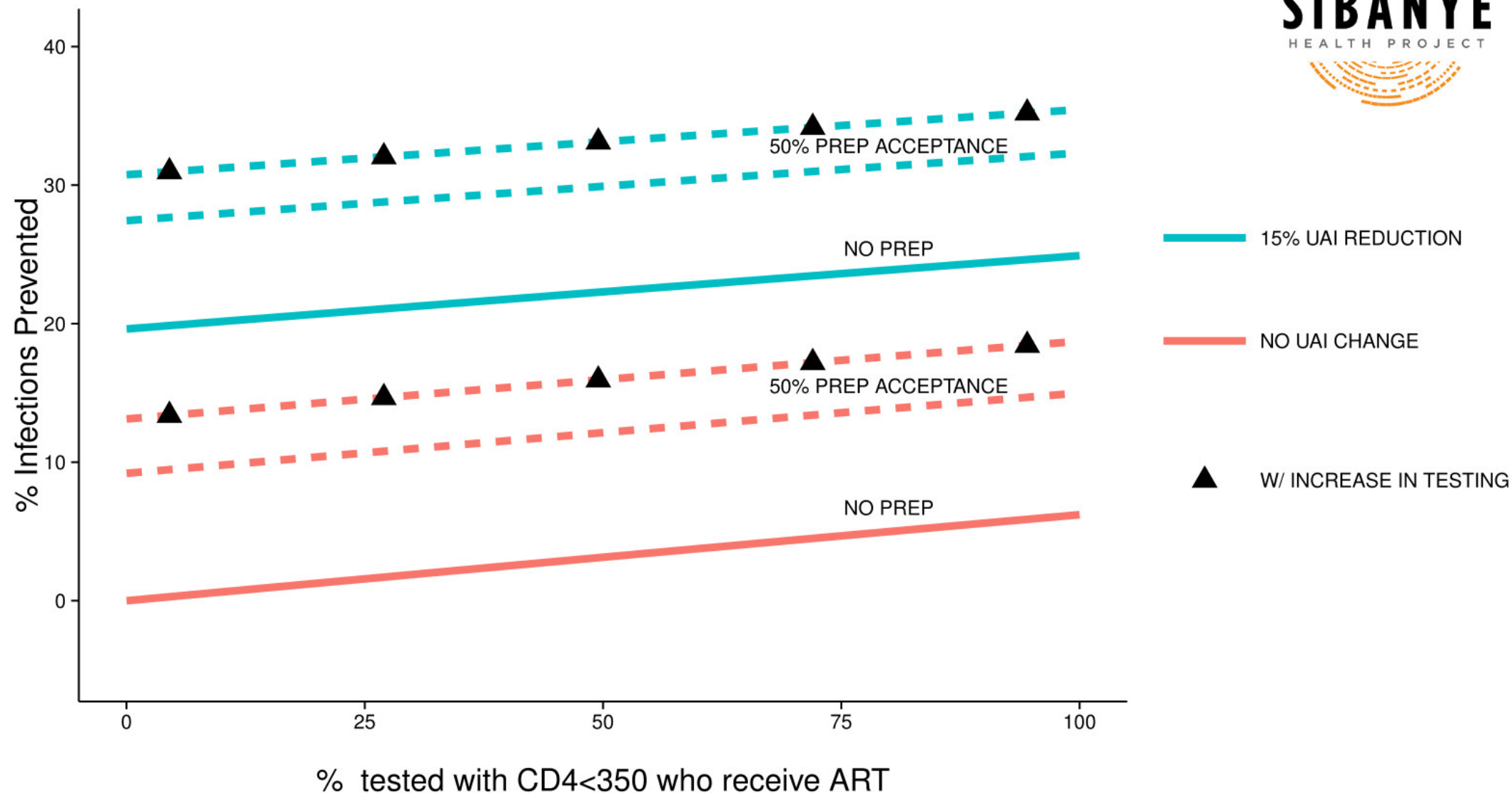
## Estimated percent of new HIV infections among MSM prevented by oral PrEP at varying levels of adherence, four countries



HIV infections estimated to be averted by PrEP, reduction in UAI, and early ARV treatment in a stochastic simulation model of HIV transmissions among MSM in Africa

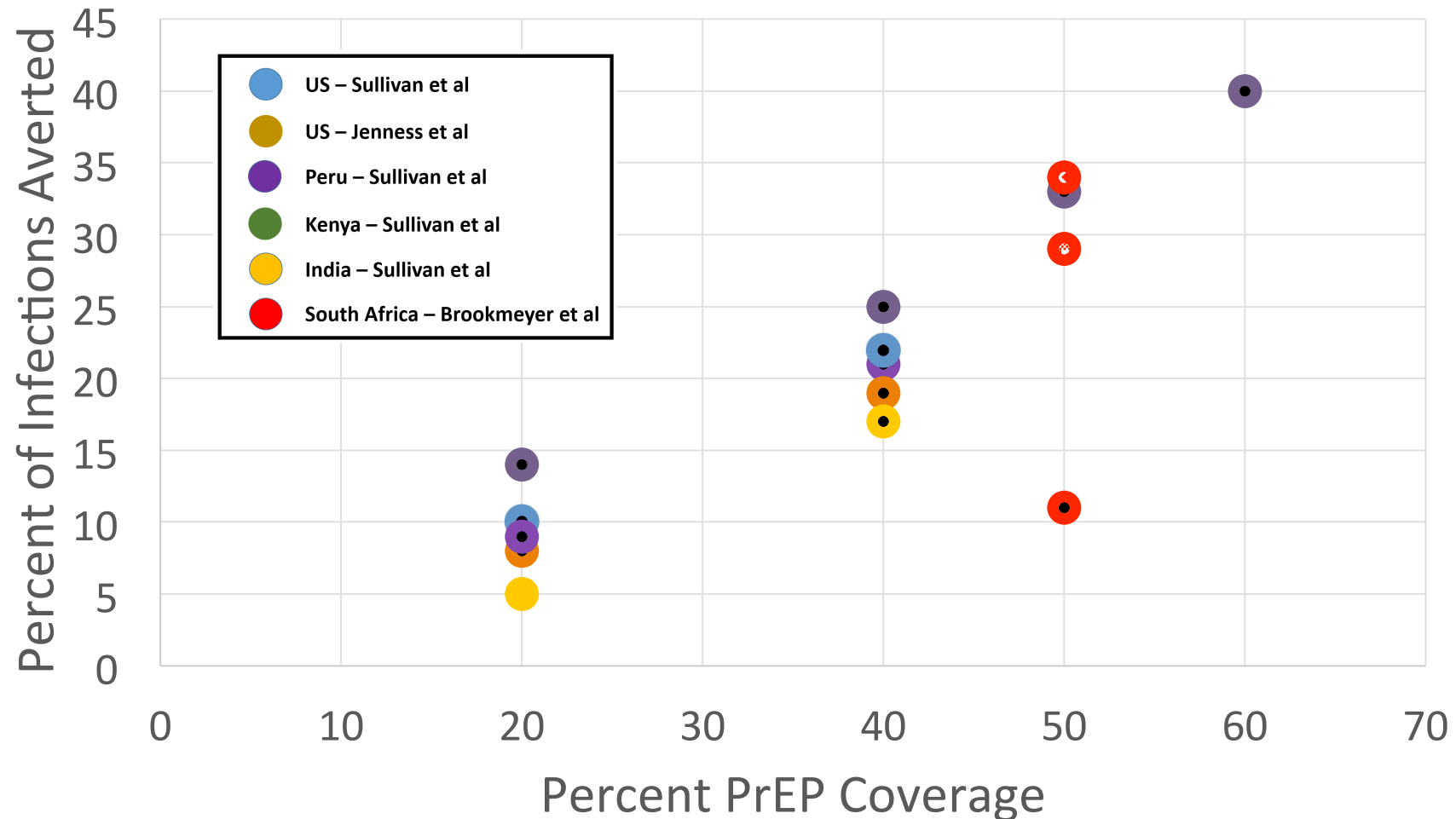


HIV infections estimated to be averted by PrEP, reduction in UAI, increased HIV testing, and early ARV treatment in a stochastic simulation model of HIV transmissions among MSM in Africa





# Proportion of HIV infections among MSM averted by PrEP, by level of coverage, US, Peru, Kenya, India, and South Africa



Sources: Sullivan et al., Lancet 2012; Brookmeyer et al PLoS ONE 2014; Jenness et al JID 2016

# Impact of HIV Pre-Exposure Prophylaxis among MSM in the United States

## A Web-Based Modeling Tool for Public Health Practice

This software tool provides additional opportunities to explore the mathematical models of the paper:

Jenness SM, Goodreau SM, Rosenberg E, Beylerian EN, Hoover KW, Smith DK, Sullivan P. Impact of CDC's HIV Preexposure Prophylaxis Guidelines among MSM in the United States. *In Press, Journal of Infectious Diseases*. 2016. Advance access online ahead of print: DOI: 10.1093/infdis/jiw223 [Paper Link]

This webtool provides tools to explore the simulation results from the main CDC guidelines modeling scenario (J2) that served as the basis of the main analysis results and sensitivity analyses.

To get started, enter a desired number of years in the simulation. One model alone or a two-model comparison set may be shown together based on different coverage and adherence parameters. The parameters are defined as follows:

- **PrEP Coverage:** the proportion of MSM indicated for PrEP under the CDC guidelines who initiate PrEP. The default value is 40% coverage.
- **PrEP Adherence:** the proportion of MSM who are highly adherent to PrEP, defined as taking 4+ pills per week, which is associated with a 95% reduction in the per-act probability of infection. The default value is 60%, following adherence data from an open-label demonstration project.

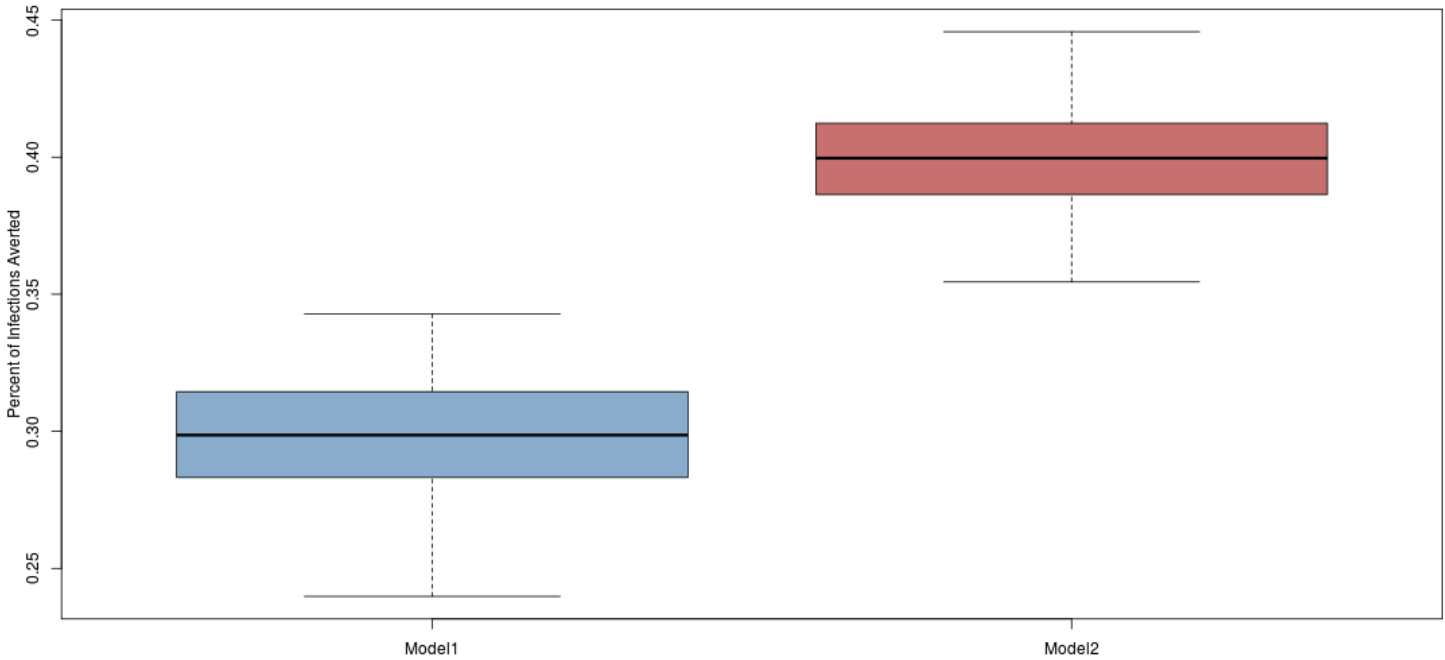
After selecting the parameters set in each model, the model will automatically update the plots and summary data tables.

In addition to these model parameters, select a starting HIV prevalence that corresponds to the local value of interest and the number of years for the PrEP intervention simulation. Note that the model in the paper corresponds to a starting prevalence of 26% that corresponds to observed values in a cohort of Atlanta-area MSM. Bayesian calibration methods were used to arrive at the other starting prevalences by adjusting the frequency of anal intercourse within partnerships; since other factors may also contribute to variation in local HIV prevalence, this model assumption should be considered when evaluating the results.

*We acknowledge support from the CDC/NCHHSTP Epidemiological and Economic Modeling Agreement (5U38PS004646). The findings and conclusions used to build this tool are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.*

<https://prism.shinyapps.io/cdc-prep-guidelines/>

Model Plots



Summary Statistic

Percent Infections Averted

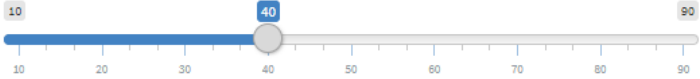
Summary Statistics

Epidemiological outcomes after years of simulations. Reported values are simulation means with a 95% credible interval. Editing inputs in the left panel and/or plot options will update the table values.

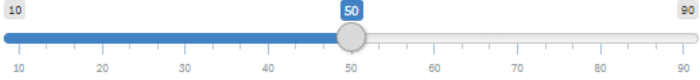
Prevalence	Incidence	NIA	PIA	NNT
0.198 (0.189, 0.207)	2.22 (0.59, 4.81)	1050 (886, 1183)	0.298 (0.252, 0.336)	27 (24, 33)
0.178 (0.169, 0.187)	1.80 (0.00, 4.12)	1410 (1284, 1551)	0.400 (0.364, 0.440)	24 (21, 26)

Model 1 Parameters

PrEP Coverage (%)

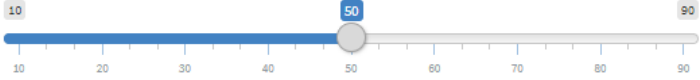


Proportion Highly Adherent

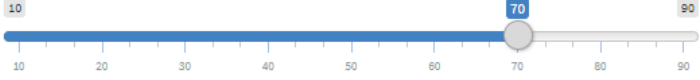


Model 2 Parameters

PrEP Coverage (%)



Proportion Highly Adherent

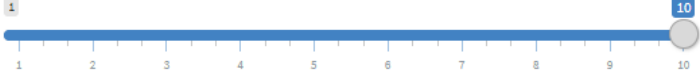


Model Settings

Starting HIV Prevalence

26% (Paper Model)

Simulation Years



Credible Interval

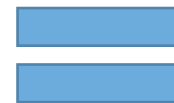


# THE LANCET



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HIV in men who have sex with men



# Action!



## Observational Designs

- Implementation in clinic settings
- Less controlled setting
- Prospective cohorts

KNOW  at HOME

## RCT Design of self-testing

- Implementation by mailout of kits
- Usual care control arm
- Results: 5.5 vs 1.5 HIV tests per year for MSM

## Stepped-wedge cluster RCT

- Immediate ARV initiation after HIV+ test
- 6 South African Communities
- Outcome: Time to viral suppression



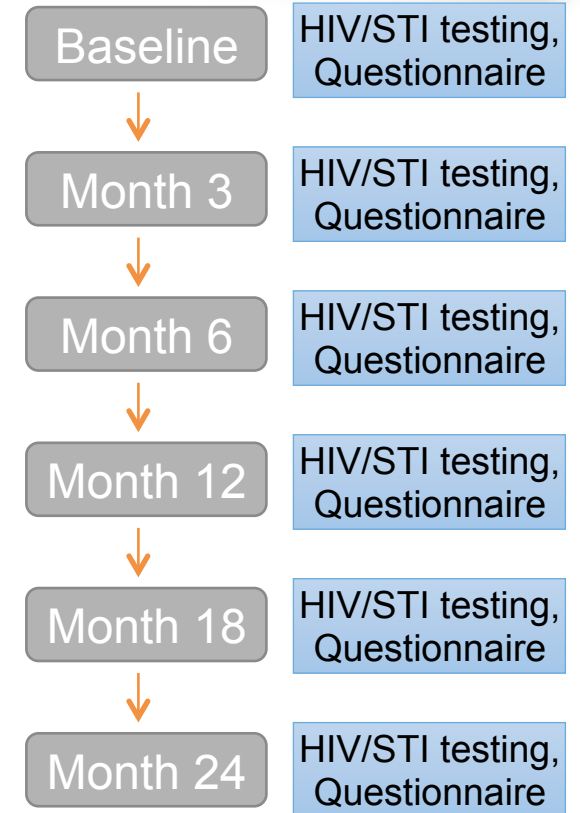
## Hybrid Design

- Primary goal: Test implementation with alternative recruitment and support strategies
- Secondary: Linkage to appropriate followup care

# KHANYISA

# Study Design

- Prospective HIV/STI incidence cohort study: 2010-2014
  - Sexually active black and white MSM in Atlanta
  - Ages 18 - 39
- Recruitment
  - MSM community venues, Facebook
- Procedures
  - Testing: HIV, Chlamydia, Gonorrhea, Syphilis
  - Behavioral questionnaire
- Enrollment
  - 803 men enrolled
  - 30% HIV-positive (BMSM: 44%, WMSM: 13%)
  - 562 HIV-negative MSM observed for 24 months
  - 79% retained in study at 24-months



# HIV Incidence

	Black MSM	White MSM
<b>Overall</b>		
Incidence rate	6.6% / year	1.7% / year
New HIV infections	24	8
% HIV-positive at end of study	11.3%	3.6%
<b>Age 18 – 24</b>		
Incidence rate	12.1% / year	1.0 % / year
New HIV infections	16	1
% HIV-positive at end of study	16.6%	1.6%
<b>Age 25+</b>		
Incidence rate	3.5% / year	1.9% / year
New HIV infections	8	7
% HIV-positive at end of study	6.0%	4.5%

# The PrEP Continuum

HIV/AIDS

VIEWPOINTS

## Applying a PrEP Continuum of Care for Men Who Have Sex With Men in Atlanta, Georgia

Colleen F. Kelley,<sup>1,2</sup> Erin Kahle,<sup>2</sup> Aaron Siegler,<sup>2</sup> Travis Sanchez,<sup>2</sup> Carlos del Rio,<sup>1,3</sup> Patrick S. Sullivan,<sup>2</sup> and Eli S. Rosenberg<sup>2</sup>

<sup>1</sup>Division of Infectious Diseases, Department of Medicine, Emory University School of Medicine, <sup>2</sup>Department of Epidemiology, and <sup>3</sup>Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, Georgia

(See the Editorial Commentary by Mayer and Krakower on pages 1598–600.)

Reductions in human immunodeficiency virus (HIV) incidence with pre-exposure prophylaxis (PrEP) for men who have sex with men (MSM) will require significant coverage of those at risk. We propose a simplified frame-



## Theoretical model of the PrEP care continuum, factors relevant to uptake, and areas for intervention.

	Factors Relevant to PrEP Uptake	Interventions to Enhance PrEP Uptake
Awareness/ willingness	<ul style="list-style-type: none"> <li>• Awareness of PrEP</li> <li>• Risk/benefit perceptions</li> <li>• Barriers to seeking PrEP                             <ul style="list-style-type: none"> <li>• PrEP cost</li> <li>• PrEP side-effects</li> <li>• Perceived PrEP stigma</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Mass media campaigns</li> <li>• Community mobilization</li> <li>• Alternative PrEP formulations</li> <li>• Community-based efforts to destigmatize PrEP</li> </ul>
Access to Healthcare	<ul style="list-style-type: none"> <li>• Individual                             <ul style="list-style-type: none"> <li>• Has public or private health insurance</li> <li>• Regularly sees primary care doctor</li> <li>• Can afford medication</li> <li>• Transportation</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Medication and/or co-payment waivers</li> <li>• Free service provision</li> <li>• Enhanced access                             <ul style="list-style-type: none"> <li>• Centralized provision</li> <li>• Enhanced referral systems</li> </ul> </li> </ul>
Likely to Receive Rx	<ul style="list-style-type: none"> <li>• Healthcare provider                             <ul style="list-style-type: none"> <li>• Aware of PrEP</li> <li>• Willing to prescribe PrEP</li> <li>• Screens for risk and determines patient eligible</li> </ul> </li> <li>• Patient                             <ul style="list-style-type: none"> <li>• Adequately report behavior eligible for PrEP</li> <li>• PrEP not contraindicated</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Provider education/training</li> <li>• Electronic tools to assess sexual risk and indicate PrEP</li> <li>• Automated systems to minimize provider burden</li> </ul>
Adherence and Efficacy	<ul style="list-style-type: none"> <li>• Side-effects/medication tolerance</li> <li>• Risk compensation</li> <li>• Dosing schedules</li> <li>• Long-term adherence and PrEP continuation</li> </ul>	<ul style="list-style-type: none"> <li>• Counseling                             <ul style="list-style-type: none"> <li>• Medication adherence</li> <li>• Sexual risk reduction</li> </ul> </li> <li>• Home support systems to minimize patient testing burden</li> <li>• Electronic adherence reminders/support</li> </ul>

Colleen F. Kelley et al. Clin Infect Dis. 2015;61:1590-1597





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### IR Outcomes:

- Sustainability
- Implementation
- Process
- Scalability

Colleen F. Kelley et al. Clin Infect Dis. 2015;61:1590-1597



# Challenges in Translating PrEP Interest Into Uptake in an Observational Study of Young Black MSM

Charlotte-Paige Ballo, MD, MPH,\* Ed S. Roenigberg, PhD† Aaron J. Sgale, PhD‡  
 Travis R. Sanders, DPM, MPH‡ Nicole Laine, MD, MPH‡ Kevin Wynn, MPH‡ Scott Cunn, MD‡  
 Garbis del Rio, MD,\*† Patrick J. Sullivan, DPM, PhD,§ and Colleen F. Kelley, MD, MPH\*†

**Background:** HIV incidence among US young, Black men who have sex with men (YBMSM) is high and structural barriers (e.g., lack of health insurance) may limit access to PrEP services (pre-exposure prophylaxis). Research studies conducted with YBMSM must account for the best available HIV prevention methods, including PrEP.

**Methods:** We implemented an optional, noncommercial PrEP program in addition to the standard HIV prevention services in a prospective, observational cohort of 800-suspect YBMSM in Atlanta, GA. Provider visits and laboratory work were covered; participant insurance plans, under the standard insurance program, were used to obtain drugs. Factors associated with PrEP initiation were assessed with propensity scores and time to first initiation with Kaplan-Meier methods.

**Results:** Of 800 suspect YBMSM, 40% were taking PrEP at study entry (interviewing rate, 40%). Median initiation (including PrEP, n=40) occurred at 10.5 months, and 30% initiated at baseline. PrEP uptake in a 12-month study (44% of 100 suspected men, 40% have not initiated a PrEP initiation appointment). Drop-outs from 800 YBMSM, 34% initiated PrEP, 1140/2 PrEP subsequently discontinued PrEP. The only factor associated with PrEP initiation was reported sexually transmitted infection in the previous year (propensity ratio 1.46, 95% confidence interval 1.00 to 2.12). Among intentional non-initiators, time to PrEP initiation was 18 months (95% confidence interval 1 to 36).

**Conclusions:** Despite high levels of interest, PrEP uptake may be suboptimal among YBMSM in an observational study environment.

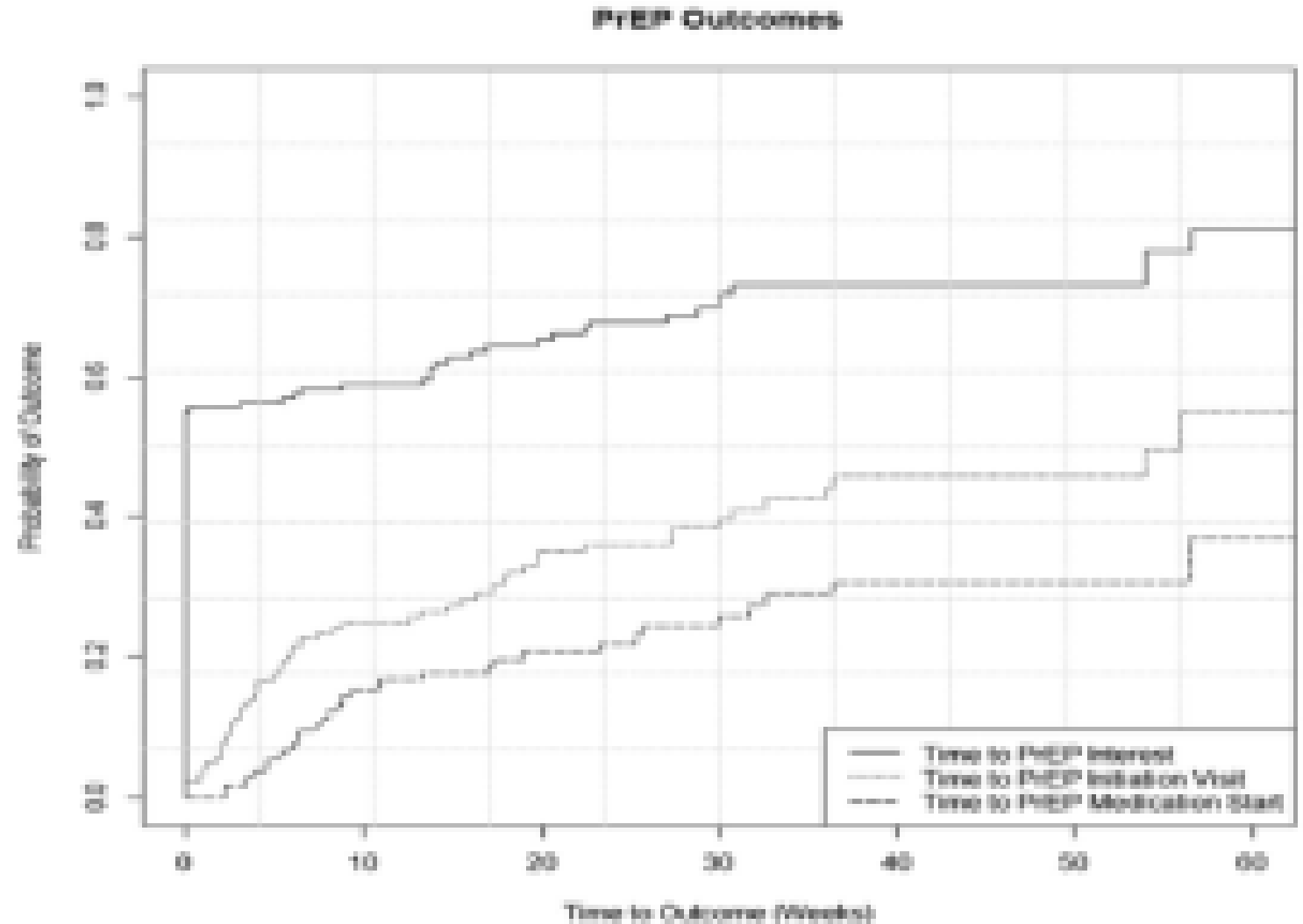
Received for publication March 10, 2017; accepted June 21, 2017.  
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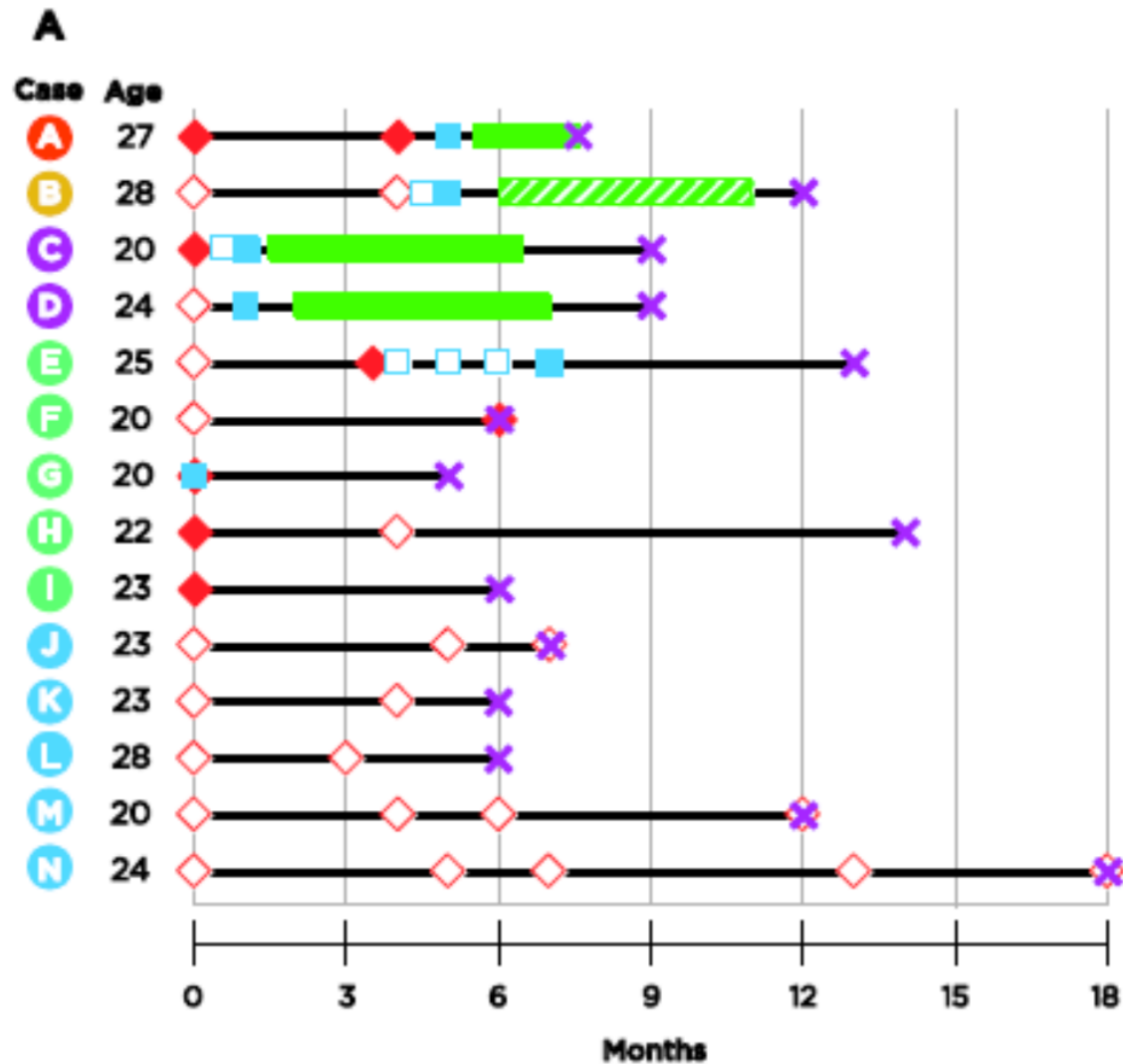
Supporting this research: National Institutes of Health (NIH) (R01AG043333, R01AG043334, R01AG043335, R01AG043336, R01AG043337, R01AG043338, R01AG043339, R01AG043340, R01AG043341, R01AG043342, R01AG043343, R01AG043344, R01AG043345, R01AG043346, R01AG043347, R01AG043348, R01AG043349, R01AG043350, R01AG043351, R01AG043352, R01AG043353, R01AG043354, R01AG043355, R01AG043356, R01AG043357, R01AG043358, R01AG043359, R01AG043360, R01AG043361, R01AG043362, R01AG043363, R01AG043364, R01AG043365, R01AG043366, R01AG043367, R01AG043368, R01AG043369, R01AG043370, R01AG043371, R01AG043372, R01AG043373, R01AG043374, R01AG043375, R01AG043376, R01AG043377, R01AG043378, R01AG043379, R01AG043380, R01AG043381, R01AG043382, R01AG043383, R01AG043384, R01AG043385, R01AG043386, R01AG043387, R01AG043388, R01AG043389, R01AG043390, R01AG043391, R01AG043392, R01AG043393, R01AG043394, R01AG043395, R01AG043396, R01AG043397, R01AG043398, R01AG043399, R01AG043400, R01AG043401, R01AG043402, R01AG043403, R01AG043404, 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IR Outcomes:

- Sustainability
- Implementation
- Speed
- Scalability

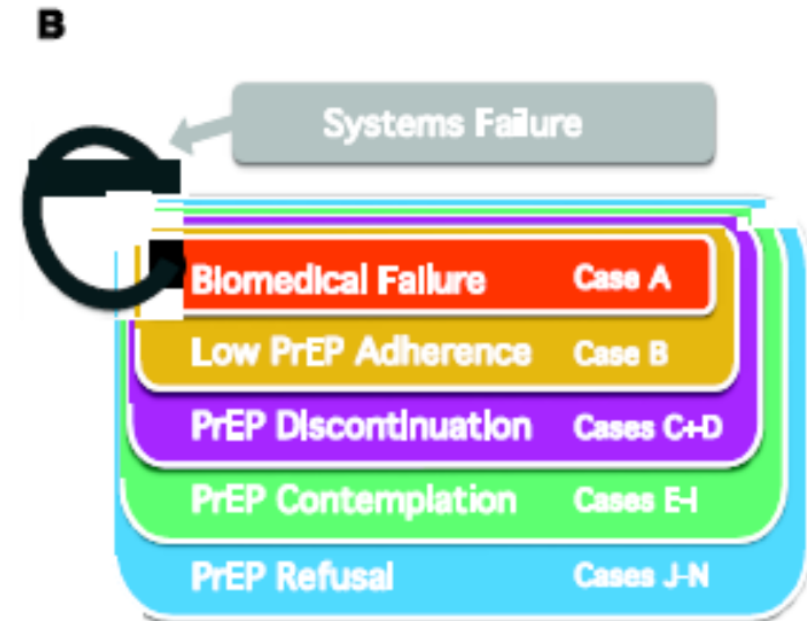
**FIGURE 3.** Time to PrEP interest, initiation, and medication start among men eligible for PrEP in the ELEMENT program (N = 184). PrEP initiation, attendance at an initiation visit; PrEP medication start, confirmed prescription fill. Solid line: Time to PrEP interest for the entire cohort, Dotted Line: Time to PrEP initiation for the entire cohort, Dashed Line: Time to PrEP medication start for the entire cohort.





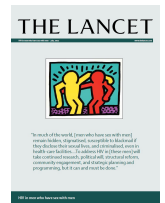
IR Outcomes:

- Barriers
- Implementation
- Process
- System effects



# Do Models work?

- Involve[men]t: cohort of HIV-negative Black, white MSM in Atlanta, 2010-2014
  - HIV incidence in Black MSM aged 18-29: 8.1/100 PY
- Lancet model prediction: 22%
- Emory CAMP/Jenness web tool prediction:
  - Instantaneous 50%: 34% reduction
  - Weighted coverage (30%): 24% reduction
- Ele[men]t: cohort of HIV-negative, Black MSM in Atlanta, 2016-present
  - 53% of men had attended PrEP initiation visit
  - HIV incidence in Black MSM aged 18-29: 6.2/100 PY
  - 23% reduction in incidence



# Evaluation of **Self-Testing Among Men** who have sex with men **Project (eSTAMP)**

## GOAL

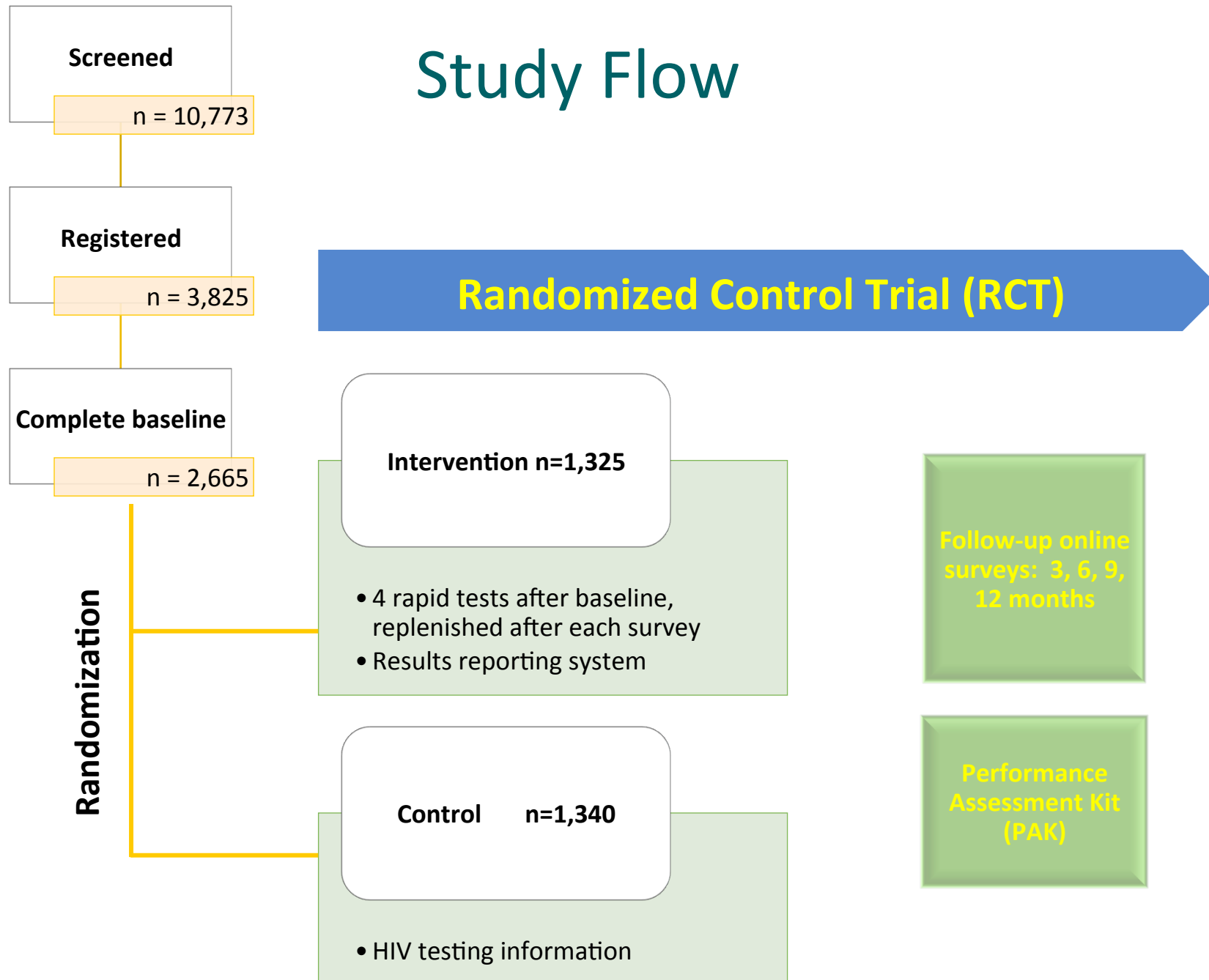
To evaluate the public health benefits of providing free HIV Rapid Diagnostic Tests (RDTs) to internet recruited MSM.

## PRIMARY OUTCOMES

- Frequency of HIV testing
- Diagnoses of HIV infection
- Differences in HIV sexual risk behaviors

**PIs: Robin Macgowan (CDC) and Patrick Sullivan (Emory)**

# Study Flow



# HIV testing outcomes among MSM who completed $\geq 1$ follow-up surveys, eSTAMP, 2015-2016

	Intervention	Control	p-value
<b>No HIV test reported</b>	29/966 (3%)	343/958 (36%)	<0.01
<b>Tested <math>\geq 3</math> times*</b>	761/965 (79%)	214/958 (22%)	<0.01
<b>Tested <math>\geq 3</math> times among never testers at enrollment</b>	110/157 (70%)	10/136 (7%)	<0.01
<b>No. of tests, mean (SD)</b>	5.5 (3.6)	1.5 (1.8)	<0.01
<b>No. facility-based tests, mean (SD)</b>	0.9 (1.5)	1.5 (1.8)	<0.01
<b>Facility-based HIV testing</b>	395/966 (41%)	614/958 (64%)	<0.01

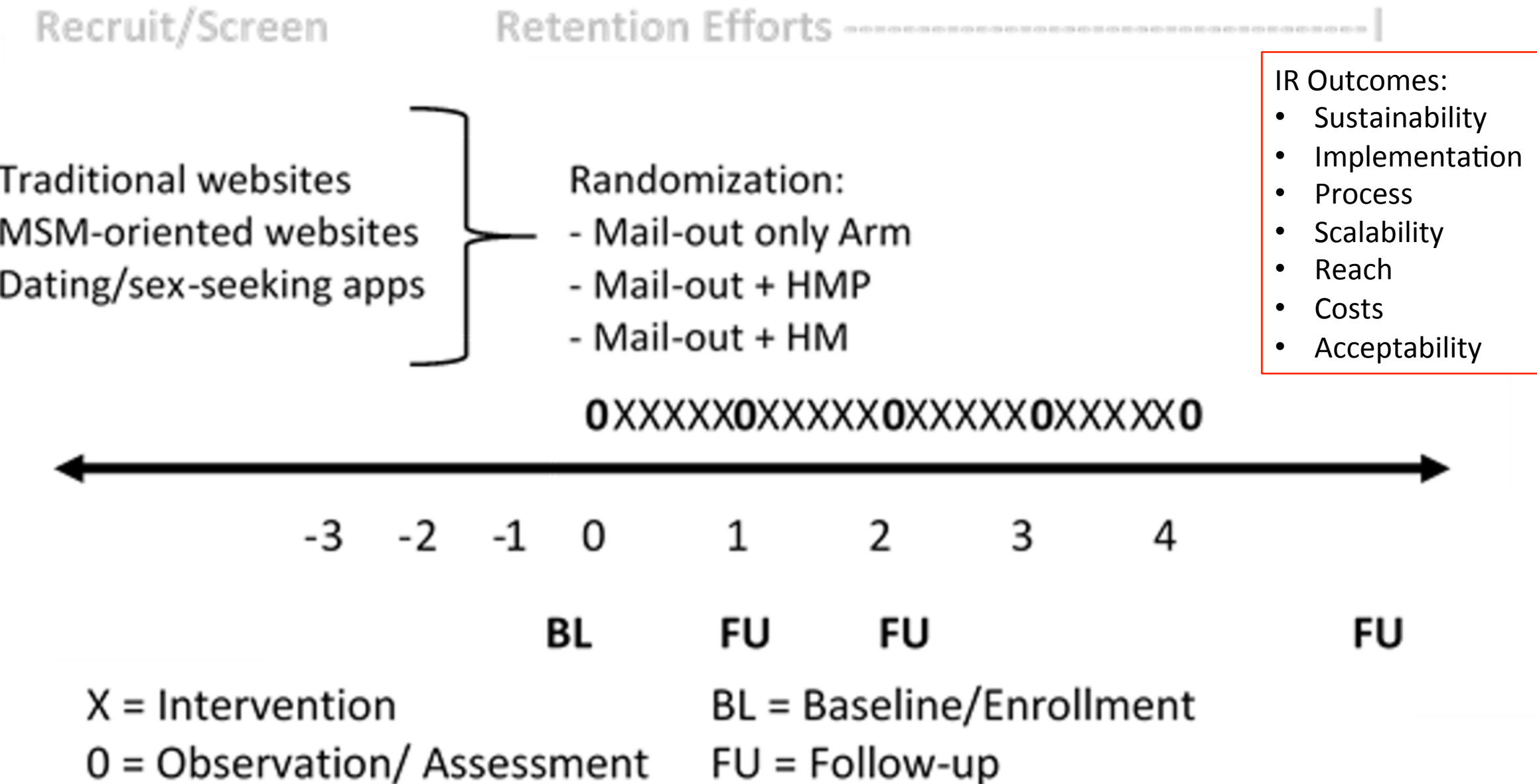
\* Excludes missing data



# Questions!!!!

- Who should distribute test kits?
- Are there better or worse online venues to recruit men to testing?
- How can we improve post-testing outcomes in terms of linkage to care?
- How often do kits need to be sent?
- How do we address needs for prevention counseling?

**Figure 1: Participant Flow**



# Summary

- Modelling helps us to understand the targets for implementation
- Even if all models are wrong, the order of magnitude is likely right
- If you're doing efficacy research or observational epidemiology from a public health perspective, you will come across important questions about implementation, and they can be answered systematically
- The methods used to answer questions about key IS questions range from familiar to exotic.
- You're likely already doing some form of implementation science, formally or informally, with or without measured IR outcomes. If not, you probably have some great implementation questions that could be answered by IS, with friends (and hopefully IR outcomes).

# Acknowledgements

- Eli Rosenberg
- Travis Sanchez
- Aaron Siegler
- David Serota
- Colleen Kelley
- Linda-Gail Bekker
- Nancy Phaswanamafuya
- Stefan Baral
- Sam Jenness
- Research Participants

## Supported by

NIAID  
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NIDA  
CDC  
Emory CFAR  
The MAC AIDS Fund  
Gilead Sciences