Improving the PrEP Care Continuum for Sexual and Gender Minorities:

Diverse Strategies for Diverse at-risk Groups

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NIH SGM Research

Investigator Awards Program

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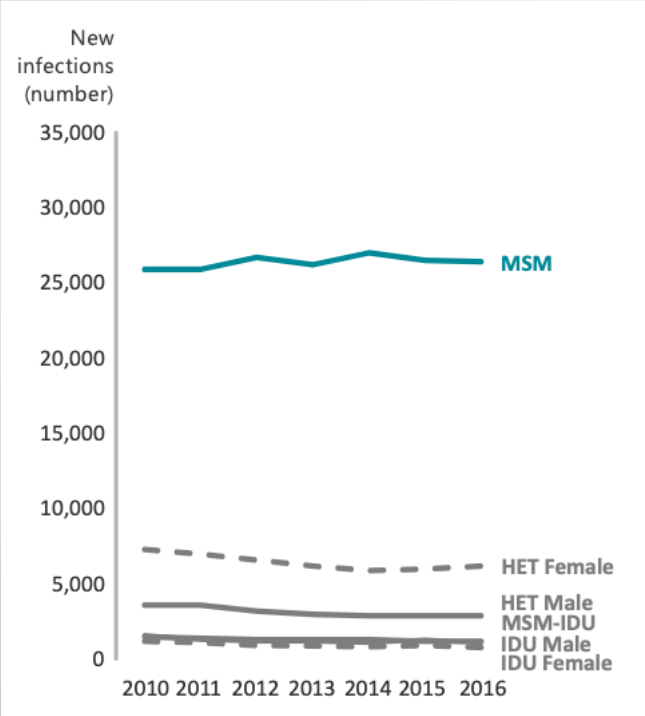
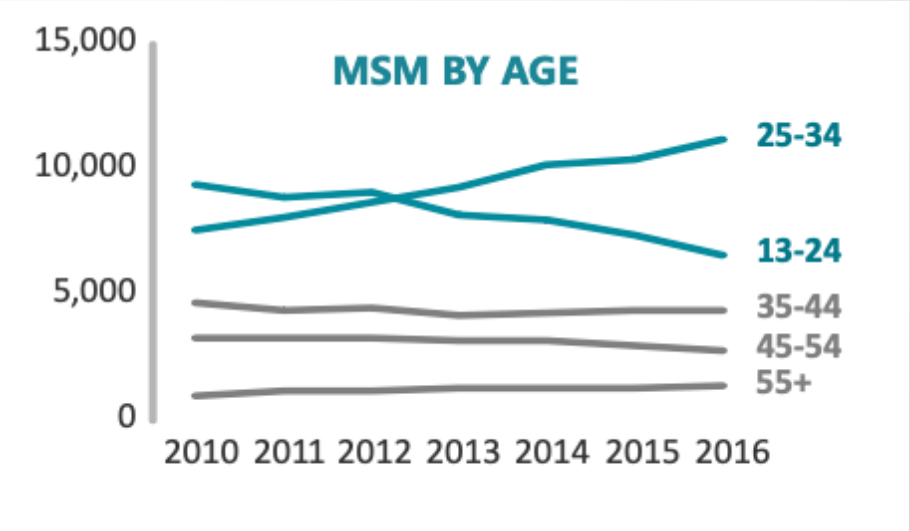
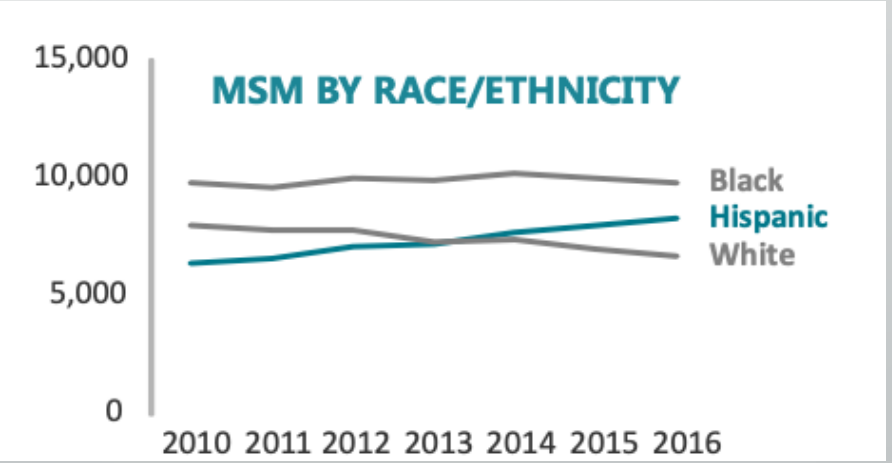
VERY Brief Overview

- Trends in HIV incidence in the United States differ across risk groups







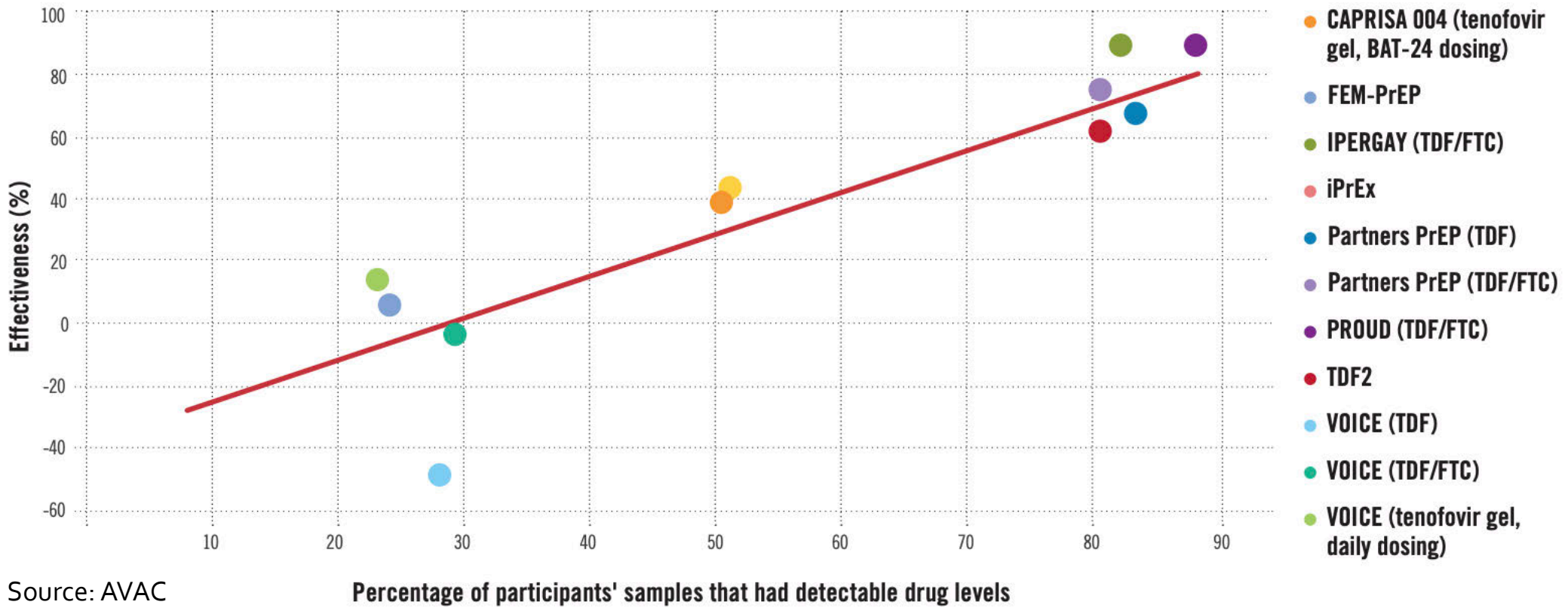
Source: Centers for Disease Control and Prevention. CDC HIV Prevention Progress Report, 2019.

HIV Prevention Works!

Source: London HIV Prevention Programme

PrEP for HIV Prevention

- Daily oral PrEP works—with near perfect efficacy—when taken as prescribed



Source: AVAC

- PrEP is underutilized and, among those who take PrEP, adherence is suboptimal

Barriers to Optimal PrEP Use

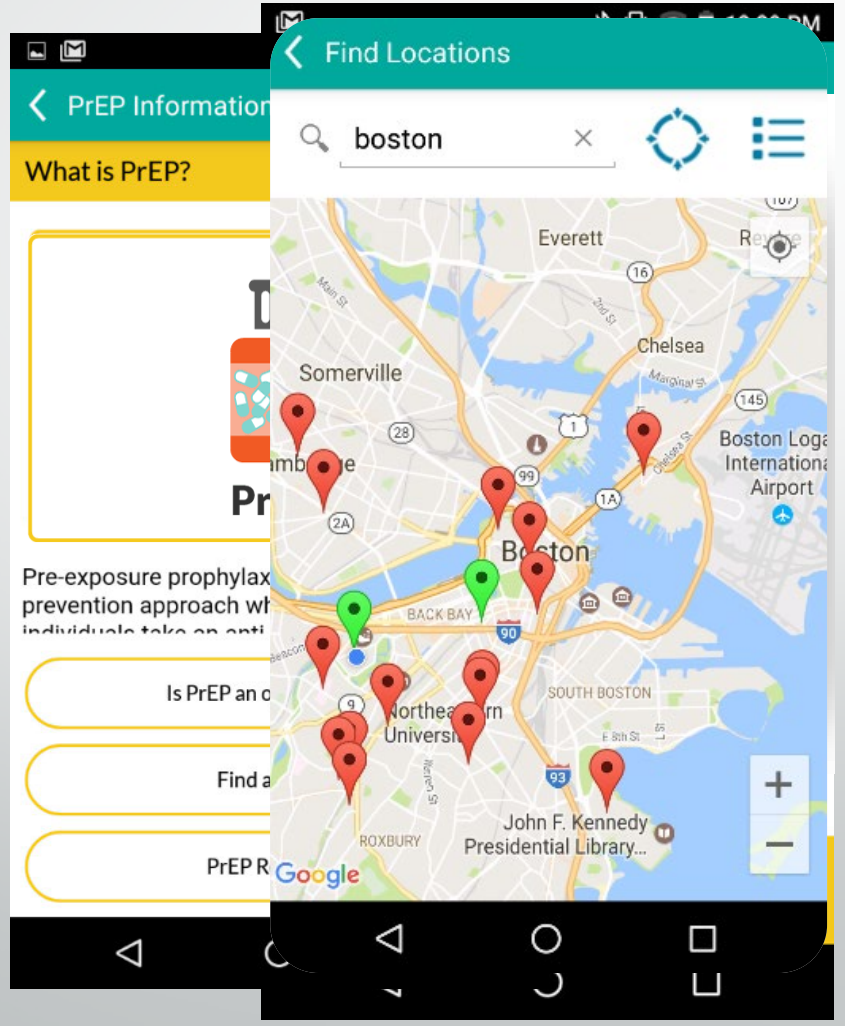
How do we support individuals—often with complex barriers—to use PrEP consistently and correctly?

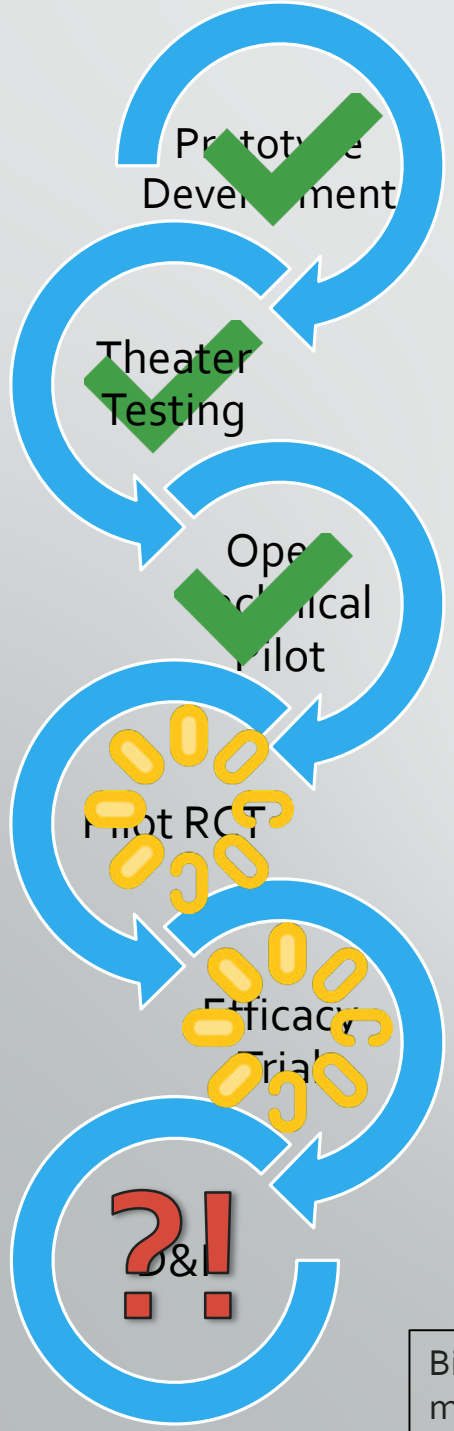
1. Cohen et al. JAIDS, 2015;68(4):439. 2. Eaton et al. AIDS Pt Care STD, 2015;29(8):423–429. 3. Golub et al. AIDS Pt Care STD, 2013;27(4):248-254. 4. Pérez-Figueroa et al. AIDS Educ Prev, 2015;27(2):112-125. 5. Biello et al. Arch Sex Behav, 2017;19:1-7. 6. Biello et al. AIDS Behav, 2017;21(1) :300-306. 7. Biello et al. AIDS Behav, 2018;22(4):1158-1164. 8. Biello et al. Arch Sex Behav, 2019;48(4):1185-1190.

PrEP for Young MSM

MyChoices

Mobile app designed to **increase HIV testing and support PrEP uptake among YMSM**





Development, Refinement, Testing

Prototype Development - complete

- 6 focus groups with 33 YMSM in Boston, Chicago and Los Angeles that led to prototype
- Led to major changes in UI, functionalities

Theater Testing - complete

- 4 groups with 28 YMSM in Boston, MA and Bronx, NY
- Led to adjustments to format and language

Open Technical Pilot - complete

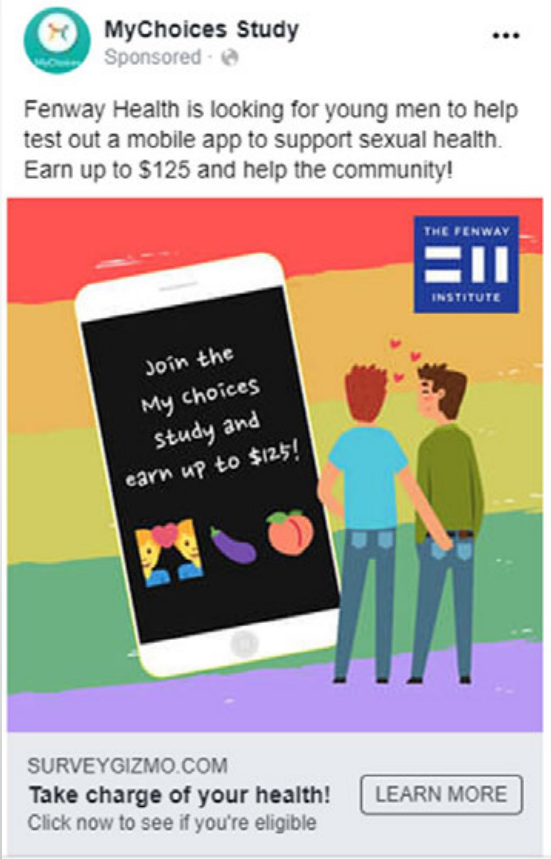
- 11 YMSM across in Boston, MA and Bronx, NY
- Led to improvements in internal processes

Pilot RCT – in final follow up

- 60 YMSM in Boston, MA and Bronx, NY
- Ensure feasibility and acceptability

3-Arm RCT Efficacy Trial – start date: TBD

- Must meet go/no-go criteria in pilot RCT
- 450 YMSM in 7 cities across the US
- Will assess efficacy to improve HIV testing and PrEP uptake compared to another app and SOC (i.e., referrals)



Biello, Katie B., et al. "A mobile-based app (MyChoices) to increase uptake of HIV testing and pre-exposure prophylaxis by young men who have sex with men: protocol for a pilot randomized controlled trial." *JMIR research protocols* 8.1 (2019): e10694.

MyChoices Pilot RCT – Preliminary Results

Age

- Age Range: **16-24 years**
- Average: **21 years**

Race

- **5%** Black, Non-Hispanic
- **15%** Hispanic
- **58%** White, Non-Hispanic

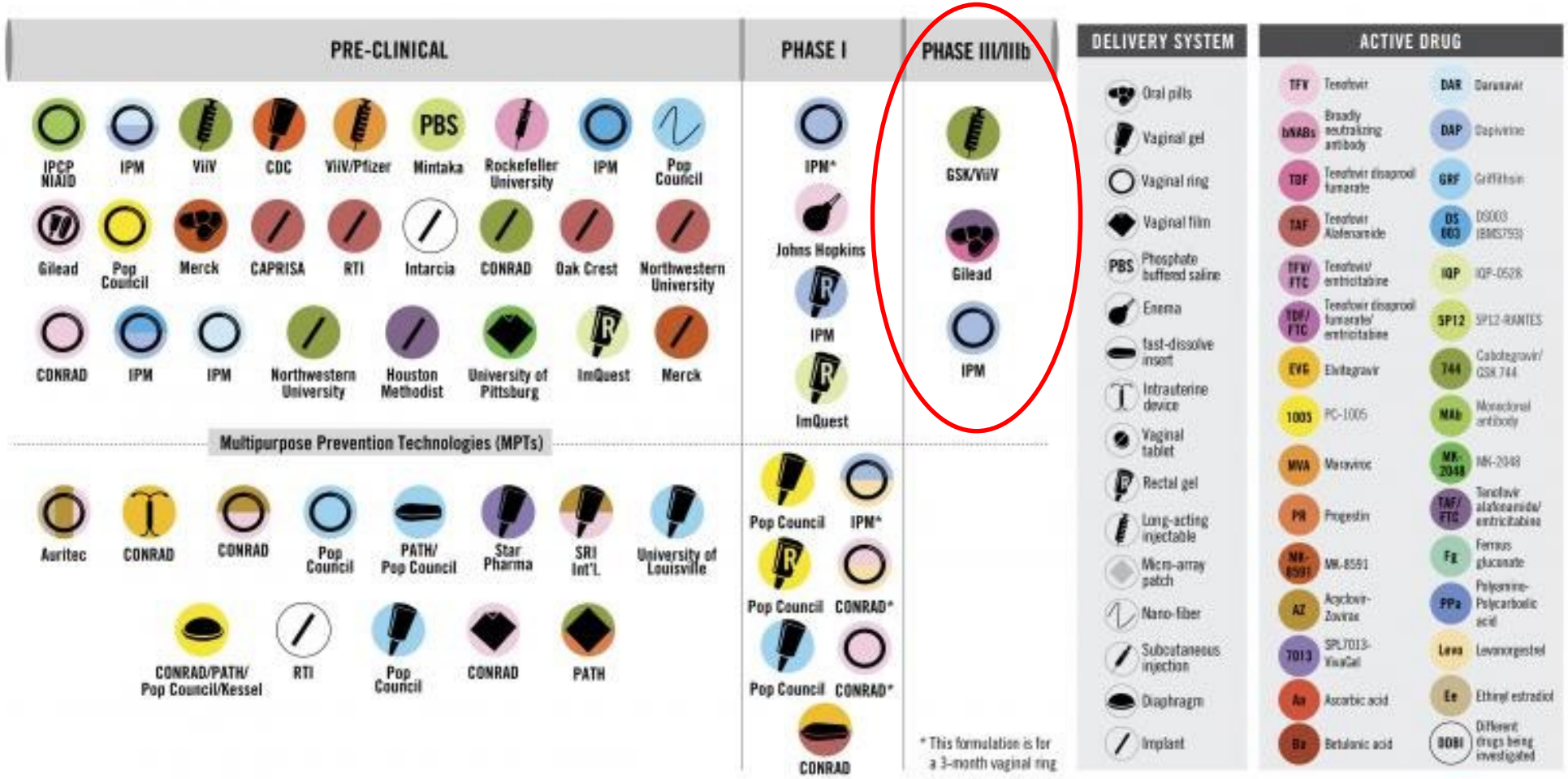
- Average app usage: **5 times** (range:1-11) over 3 months
- Average duration: **4.1 minutes** per session (range:0-33) over 3 months

- Mean System Usability Scale (0-100) score: **75** (i.e., above-average)
- **86%** reported MyChoices was **useful**
- **84%** would **recommend** MyChoices to a friend

AVAC
Global Advocacy for HIV Prevention

The Future of ARV-Based Prevention and More (February 2019)

The pipeline of non-vaccine HIV prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable antiretrovirals and more. Also pictured are the range of multipurpose prevention technologies in development that aim to reduce the risk of HIV and STIs and/or provide effective contraception for women. (Visit *www.avac.org/hvad* for vaccine and broadly neutralizing antibody pipelines.)

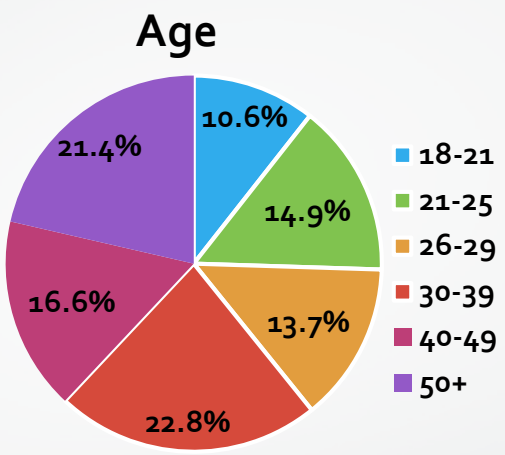


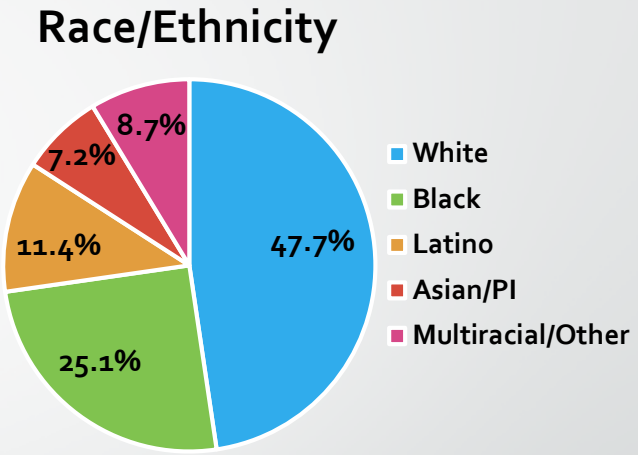
Next Generation PrEP

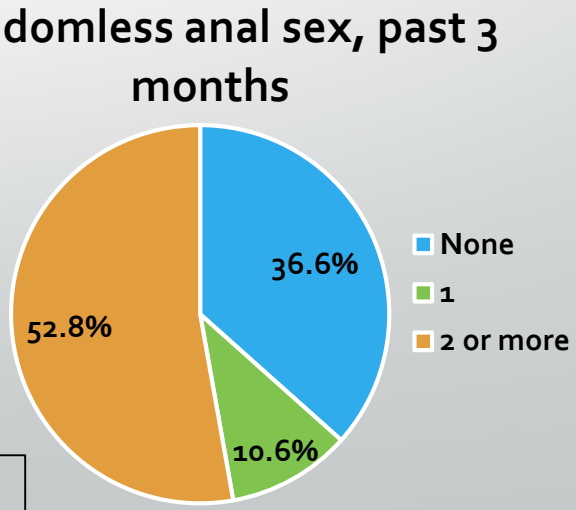
- YMSM's recruitment in these next generation PrEP trials has been limited, particularly youth under 18 years
- Limited research has examined the perceived acceptability of emerging modalities among YMSM
- Even if found to be efficacious, the absence of YMSM's perspectives on product characteristics could lead to low acceptability, slow uptake and suboptimal adherence

PrEP Product Preferences – a National Online Survey

- Led by Biello and Mayer, funded by Viiv
- Brief (~10 min) online assessment
- 4600+ MSM/TGMSM/TGWSM in US via 2 hookup apps
  - 18+ y/o; HIV(-); assigned male sex and/or identified as male; reported ever having anal sex with a man
  - Push notifications asking for their participation were sent daily (for 10 days) to all active users of each app in March 2016 (n=>1 million)

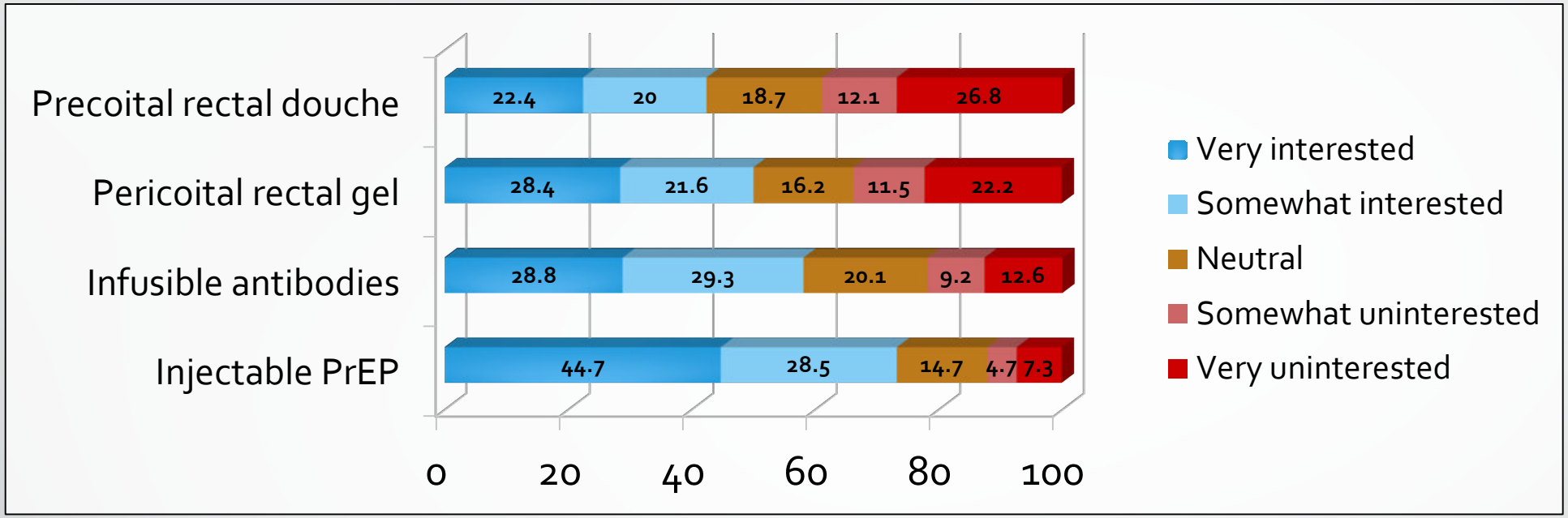


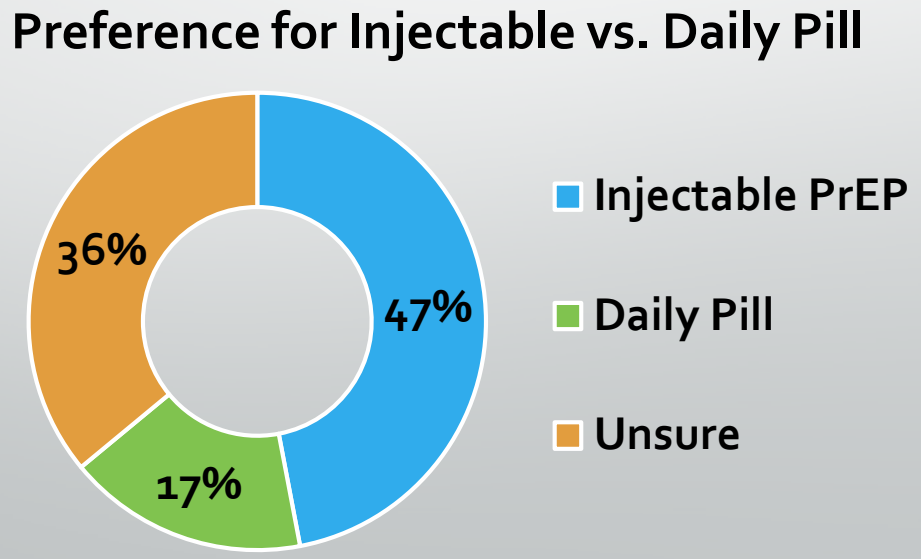




Biello et al. (2018). MSM at highest risk for HIV acquisition express greatest interest and preference for injectable antiretroviral PrEP compared to daily, oral medication. *AIDS and Behavior*, 22(4), 1158-1164.

Product Interest and Preference





Preference for injectable PrEP (vs. daily pill)

Measure		aOR (95% CI)	p
Age	18-21	1.71 (1.05, 2.79)	0.031
	22-25	1.71 (1.14, 2.55)	0.010
	26-29	1.97 (1.33, 2.93)	0.001
	30-39	1.94 (1.41, 2.68)	<0.001
	40-49	1.11 (0.81, 1.51)	0.528
	50+	1.0	
Race/ethnicity	White	1.0	
	Black	1.58 (1.17, 2.12)	0.003
	Latino	1.45 (1.00, 2.12)	0.053
	Asian/PI	1.18 (0.71, 1.96)	0.513
	Multiracial	1.03 (0.67, 1.57)	0.906
	Other	1.12 (0.46, 2.73)	0.801
Condomless anal sex acts, past 3 mos.	0	1.0	
	1	1.11 (0.78, 1.57)	0.559
	2+	1.52 (1.21, 1.91)	<0.001
Oral PrEP experienced	Yes	1.39 (1.02, 1.89)	0.038

Qualitative Examination of New Product Preferences

- 6 focus groups with 36 YMSM/TGMSM/TGWSM in Boston (n=8), Chicago (n=20) and Los Angeles (n=8)
  - 15-29 y/o; HIV(-); assigned male sex and/or identified as male; reported CAS with a man in the 3 mos. prior
  - PrEP experienced and PrEP naïve groups
- FG domains: perceived barriers, advantages/ disadvantages to oral and injectable PrEP

Biello KB, et al. Preferences for Injectable PrEP Among Young US Cisgender Men and Transgender Women and Men Who Have Sex with Men. Archives of Sexual Behavior. 2017 Sep 19:1-7.

Focus Group Results

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Lati

Black, n -Latino

Latino

We [Black MSM] have too many stories and reasons not to trust vaccines.
(Boston participant, PrEP experienced group)

If you miss you appointment more days would you

I am very forgetful and sometimes even forget to take my pills. Having an injection every 3 nths…would be so sier to keep just put it ndar. PrEP

Not everyone is sexually active every single day so not everyone wants to take a pill everyday if they don't need it. It would be tter if you could just take the know

I would stay with the pill. I don't know exactly how much of a dose the 3 month shot would be and I'm concerned about side effects.
(Chicago participant, PrEP experienced group)

All the advertisements for PrEP seem to be targeted only at gay men and I never see them for trans women or even just women…it's not advertised enough for us to be like 'Oh, we can do it, too' (LA participant, PrEP naïve group)

NextChoices

- ATN/iTech protocol seeks to ensure the inclusion of YMSM's perspectives (age 15-24 years) as next generation biomedical prevention products are being developed
  - SA1: Use natural language processing techniques to analyze social media content in order to improve our ability to inform message framing and communicate with youth about next generation biomedical prevention
  - SA2: Conduct up to 20 cognitive interviews to improve measures and methods to assess preferences for diverse HIV prevention products in acceptability surveys
  - SA3: Examine via a national web-survey (N≈1500) acceptability of next generation biomedical prevention

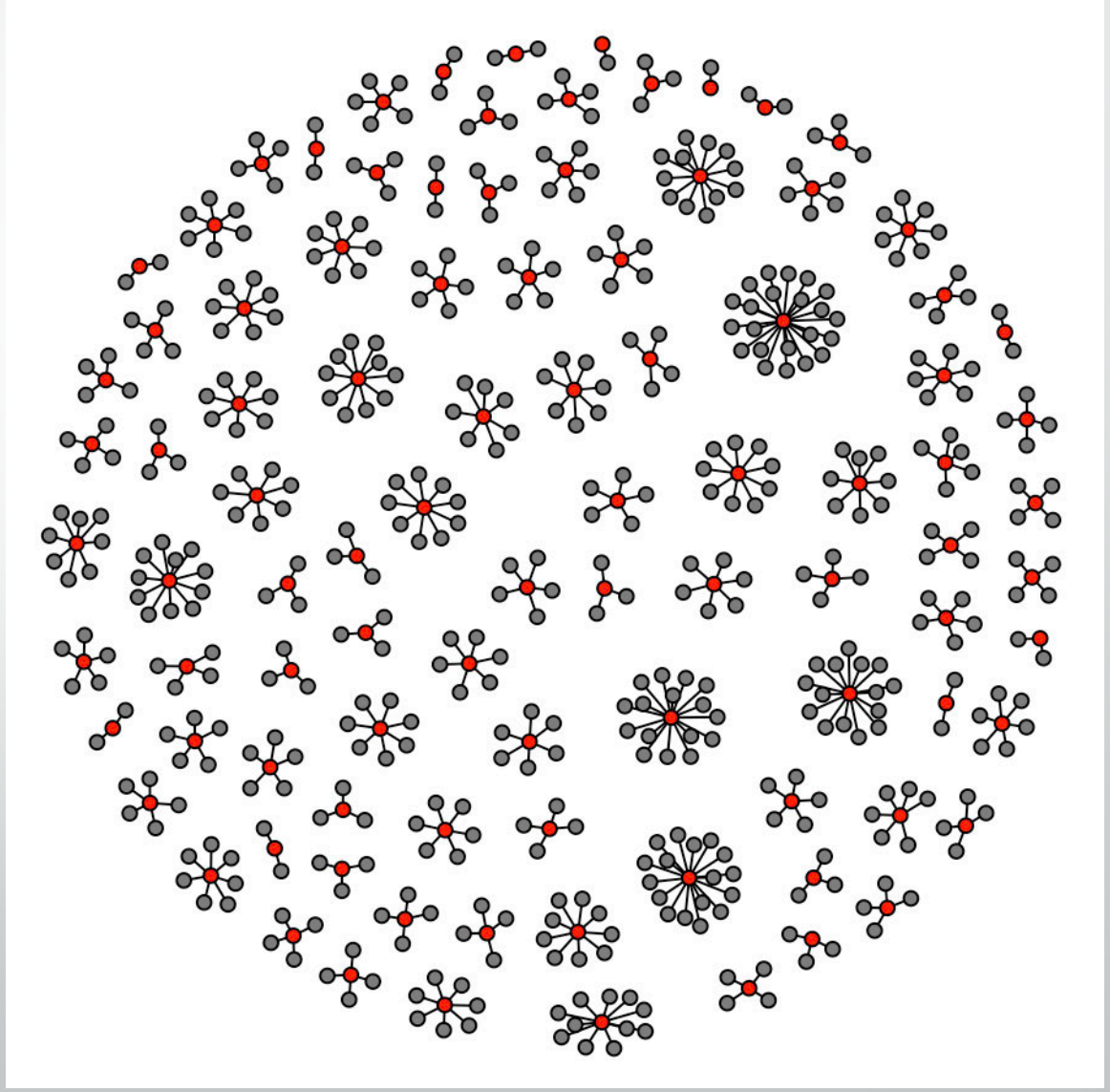
PrEP for Male Sex Workers

Male Sex Workers are at high risk for HIV

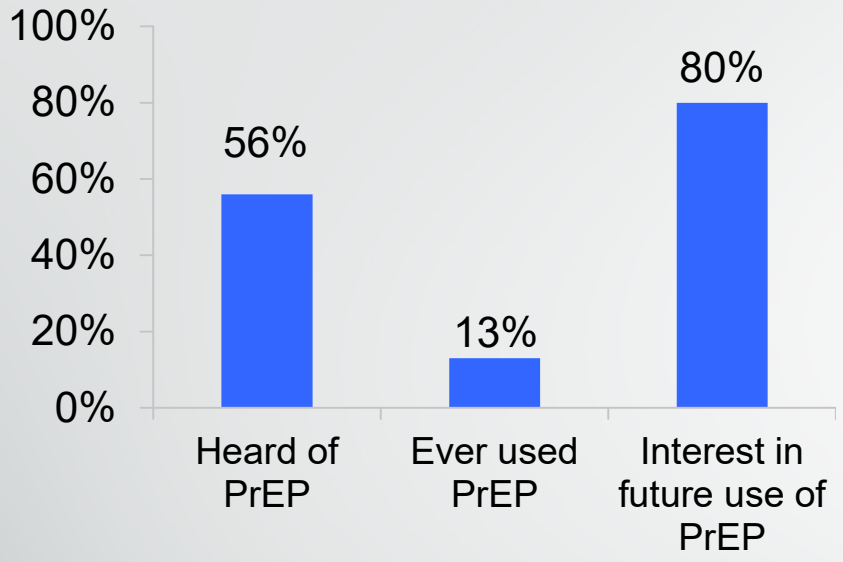
- Men who engage in transactional sex with other men in the US have nearly **25 times** the risk of HIV compared to other men
- Sex work is associated with:
  - more sexual partners
  - more frequent anal sex
  - higher burden of psychosocial problems, including substance use
- Street-based MSM sex workers have the highest rates of HIV risk behavior with clients and non-transactional partners

The NEXUS Study

- Longitudinally evaluate and describe the social, sexual, and drug abuse networks of high-risk MSM sex workers in Boston and Providence
- Enrolled 100 men who engage in frequent transactional CAS
- NIDA-funded R21 (MPIs: K. Biello, M. Mimiaga)

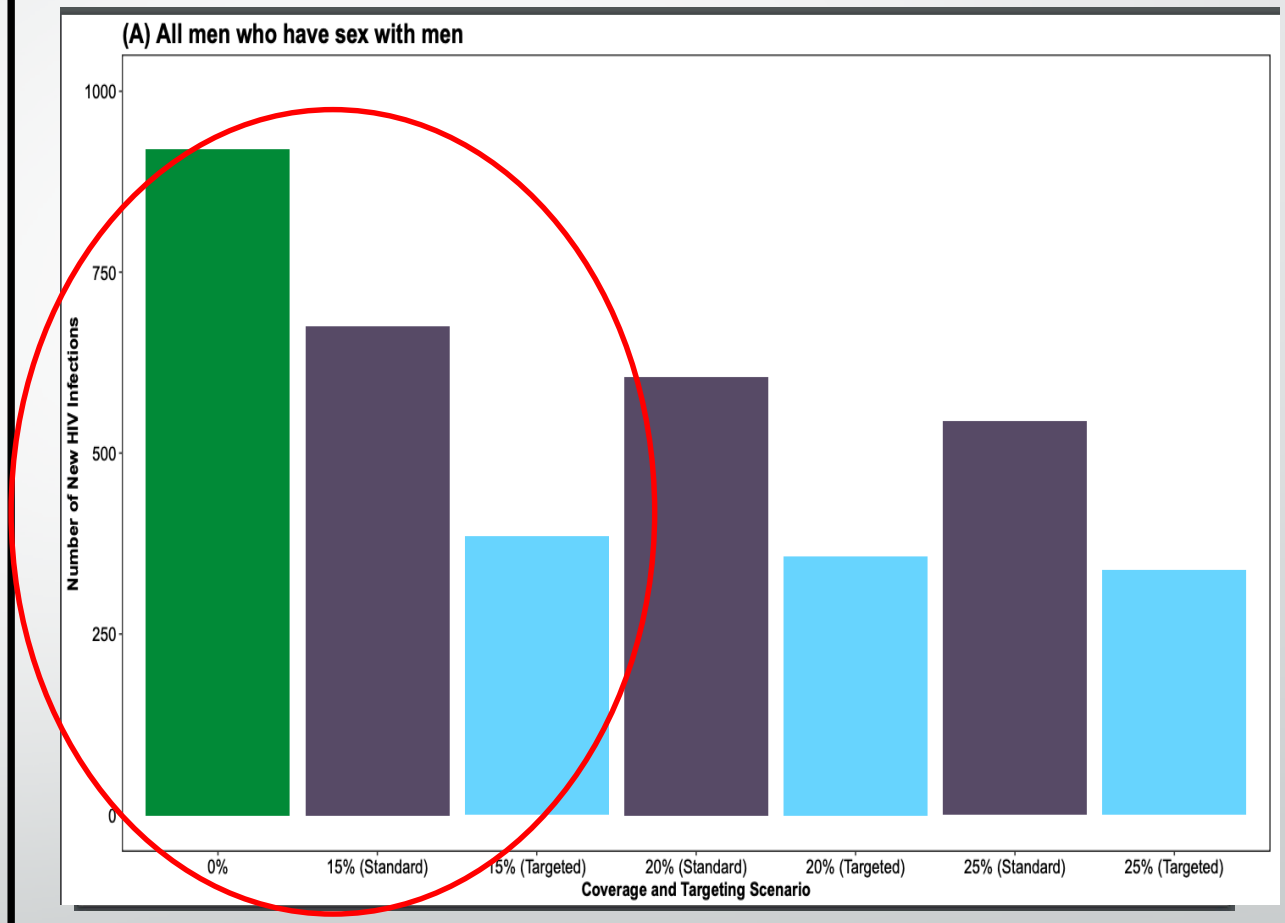


PrEP for MSWs



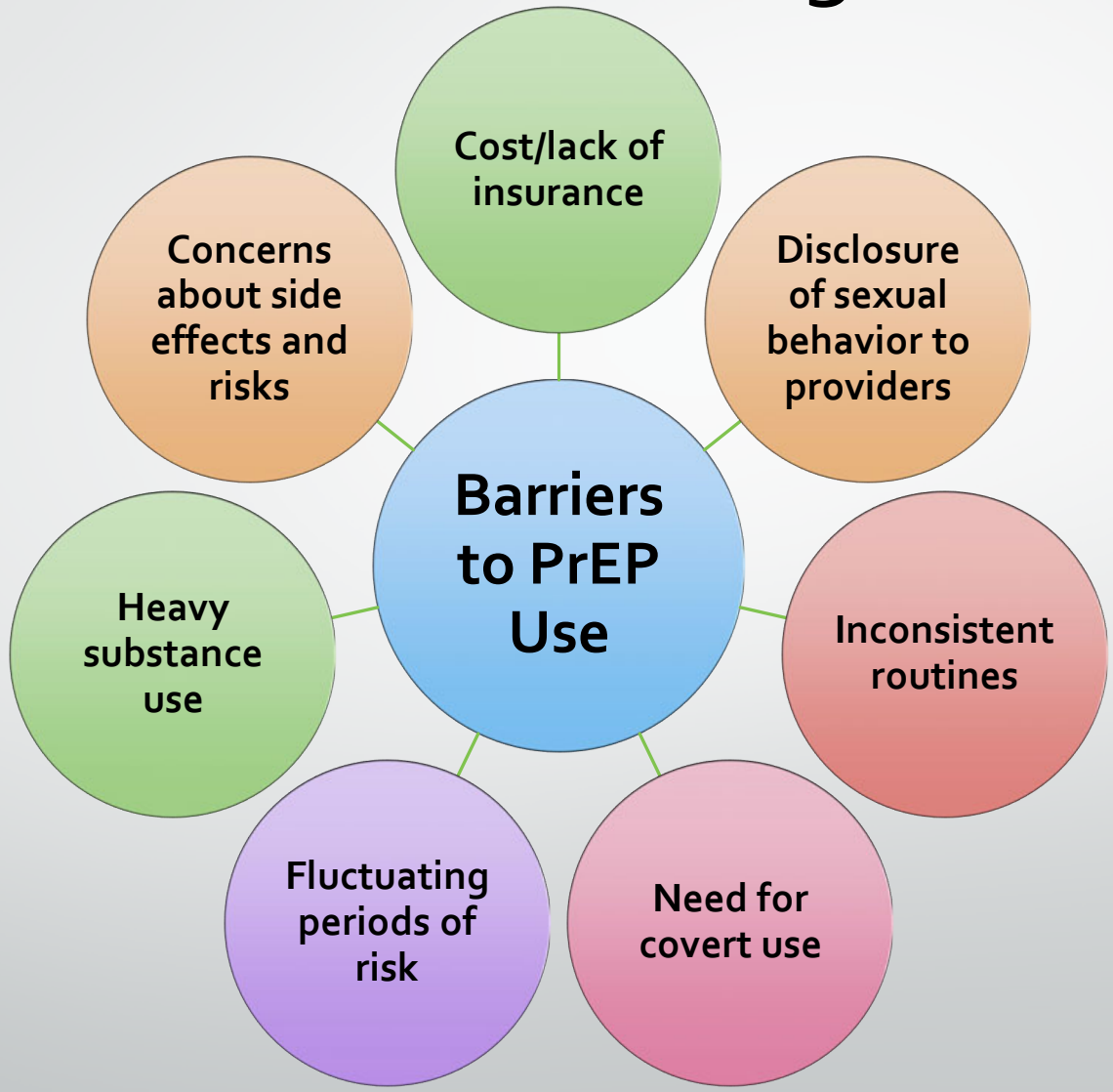
- MSWs who identified as gay were **3 times** as likely to have heard of PrEP compared to those who did not identify as gay

Biello et al. Low Awareness and uptake of HIV PrEP among MSWs in the Northeastern US. IAS 2017.



- Targeted expansion of PrEP to MSWs, new HIV infections would be reduced by 58% and cost-effectiveness of PrEP would improve by 60%

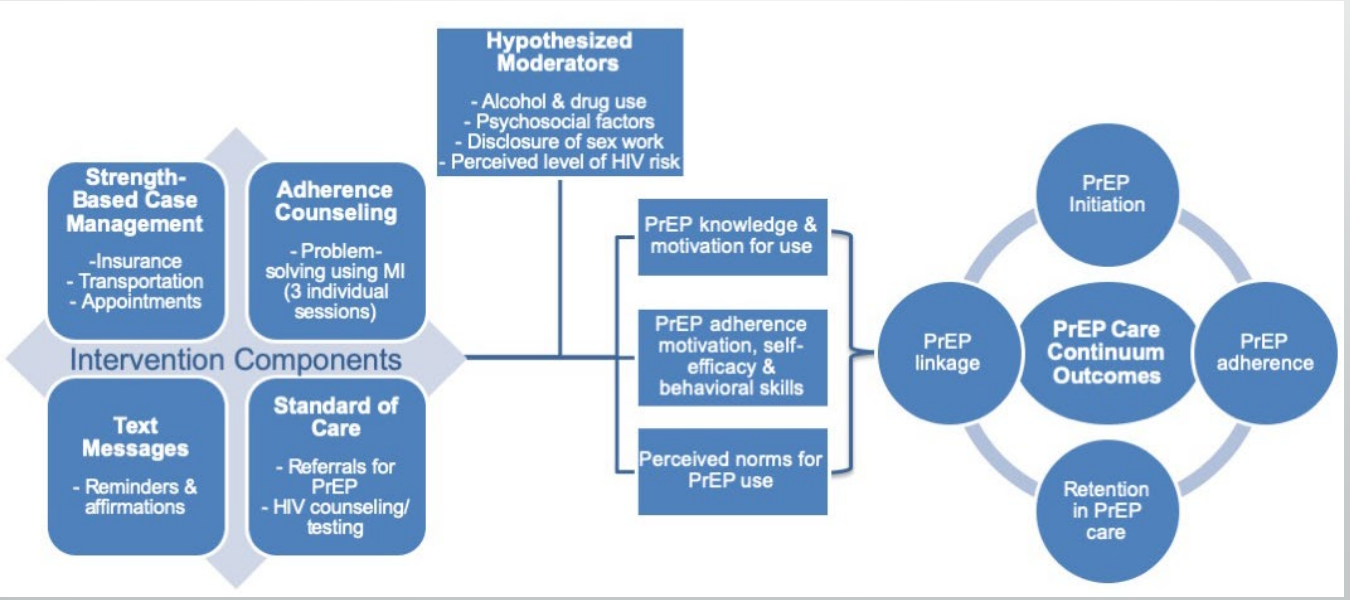
PrEP Barriers among MSWs



Underhill K, et al. Access to healthcare, HIV/STI testing, and preferred pre-exposure prophylaxis providers among men who have sex with men and men who engage in street-based sex work in the US. PLoS One. 2014:e112425.

PrEPare for Work Intervention

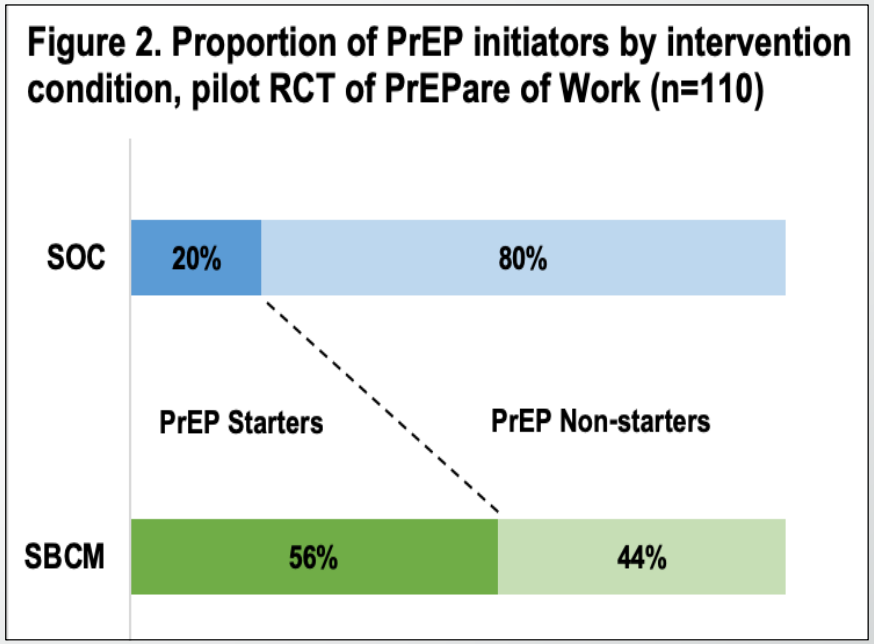
- NIMH R34 (MPIs: Biello, Mimiaga, Chan)
- "PrEPare for Work" addresses uptake of PrEP, and provides skills training to optimize adherence
  - Based on the Social Cognitive Theory and uses principles of motivational interviewing and cognitive behavioral therapy
- A pilot RCT of 110 MSWs in Rhode Island, using a two-stage randomization
  - Stage 1: Strength-based Case Management for PrEP uptake
  - Stage 2: CBT-based PrEP adherence counseling by a trained, masters-level counselor with daily text messaging



P4W Preliminary Results

- Participants randomized to SBCM were nearly **3 times** as likely (95% CI=1.46-5.27, p=.001) to initiate PrEP compared to those in SOC

- In Stage 2, participants randomized to the CBT-based adherence counseling were **1.6 times** as likely to be adherent to PrEP compared to those in SOC



Straightforward, simple, fast, efficient

All the resources were there, it was perfect!

I had a great experience

Discrete yet welcoming

Biello et al., PrEPare for Work: An Intervention to Increase PrEP Uptake Among Male Sex Workers. IAS 2019.

Looking ahead…

- Continue developing and testing technology-enhanced interventions
- Integrating new prevention modalities as they come to market
- Focusing on highest risk, and most marginalized, groups – SGM youth, sex workers, transgender women and PWID
- Responding to U=U by developing and testing interventions to improve adherence and viral suppression among PLWH
- Local, regional, national and international
  - MA, RI, Northeast, US, India, Vietnam, Brazil

Thanks and Acknowledgements

Thanks for my nomination!

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- Matthew Mimiaga (Brown)
- Lisa Hightow-Weidman (UNC)

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- Viiv

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