

Session I – Capacity Building Assistance for High Impact HIV Prevention

PrEP Awareness in Special Populations of Women and People who Use Drugs

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Yale AIDS Program

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10:00 AM – 11:30 AM EST



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Disclosures

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- No conflicts of interest to declare



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Who's out there?

What is your professional degree/role?

1. Physician (MD, DO)
2. Nurse Practitioner or Nurse
3. Clinic administrator
4. Researcher
5. Other/Interested citizen



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Who's out there (II)?

What is your primary area of specialty?

1. Primary care
2. Infectious diseases
3. Women's health
4. Not a clinician
5. Other



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How much experience do you have providing PrEP services?

1. Extensive experience or a dedicated PrEP clinic
2. Some experience
3. Minimal experience



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Goals and Objectives

- Discuss the **need and potential for PrEP** as HIV prevention among special populations of women and people who use drugs;
- Evaluate potential **barriers to PrEP uptake** and retention among special populations of women and people who use drugs, including **lack of awareness**;
- Identify **strategies to increase PrEP awareness** among special populations of women and people who use drugs, including the use of patient-centered decision aids.



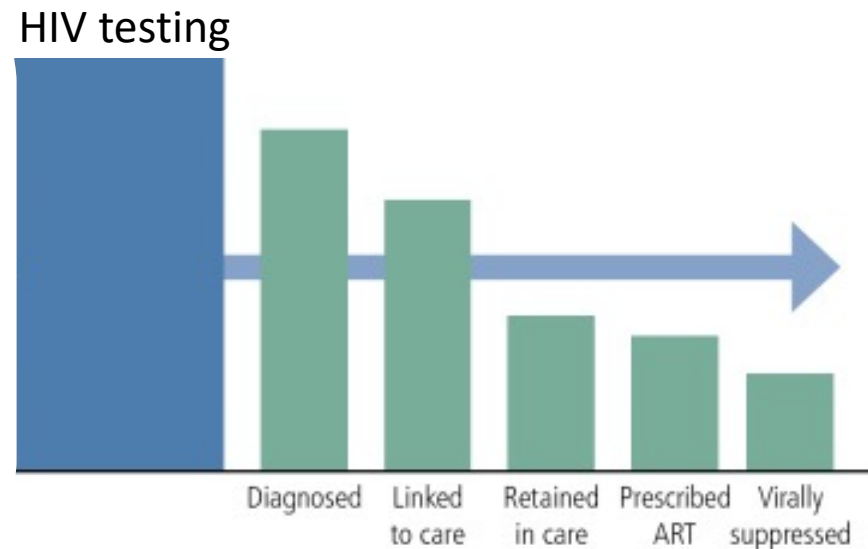
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THE POWER AND PROMISE OF PrEP



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The Status Neutral Continuum



[Buchbinder S. Top Antivir Med. 2018 Apr; 26\(1\): 1–16.](#) (Adapted from CROI 2018 Abstract 61, www.nastad.org)



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HIV Prevention

- U.S. National HIV/AIDS Strategy 2020
 - Priority #1: Reducing new HIV infections
- Combination of prevention strategies
- HIV PrEP Framework: scale-up PrEP by **500% by 2020**

Available at: hiv.gov

Key Target Populations for High Impact HIV Prevention

- Men who have sex with men
- Communities of color
- Women
- People who inject drugs
- Transgender women and men
- Youth

National HIV/AIDS Strategy; CDC HIV Strategy



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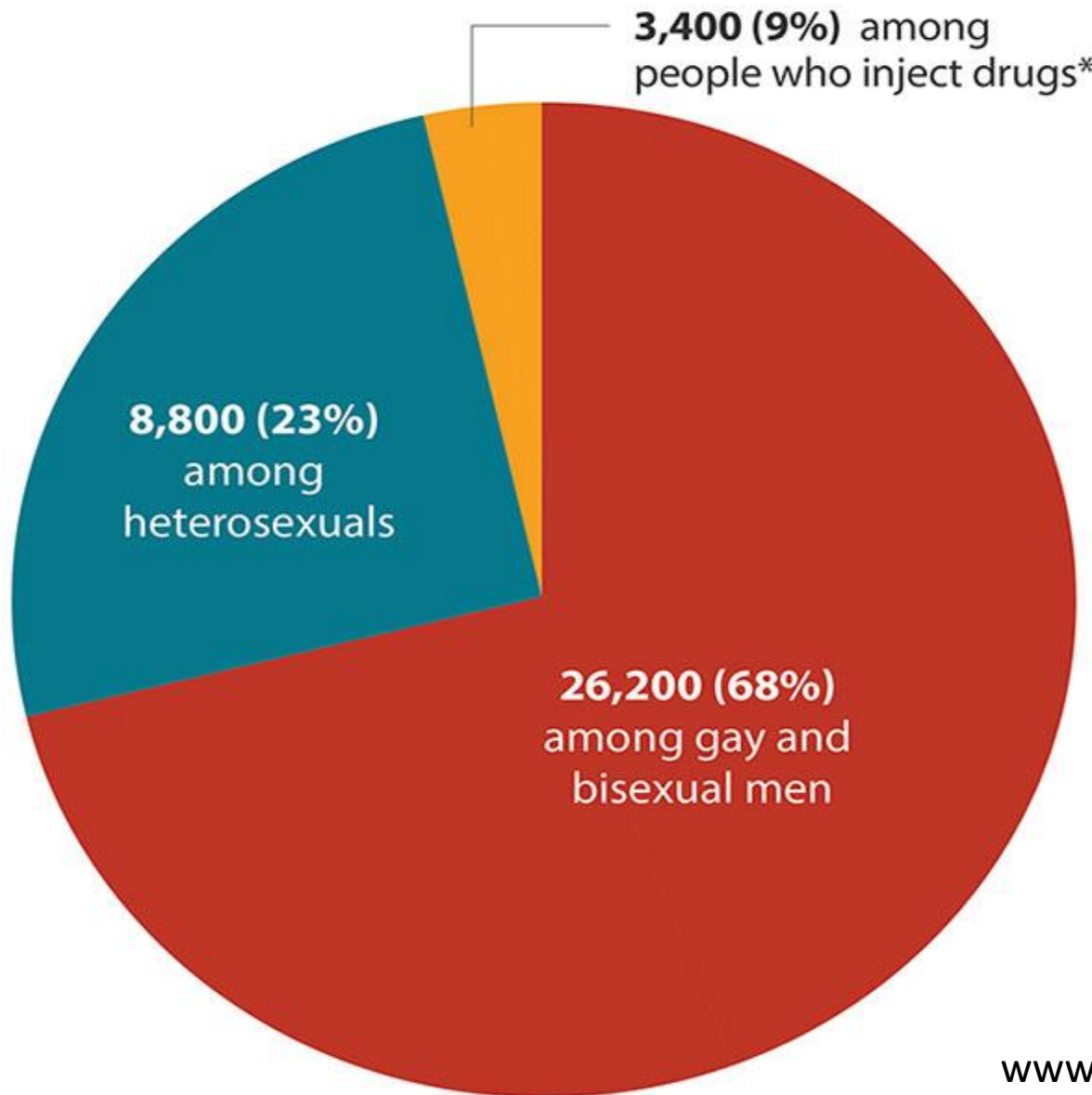
Some basic definitions

- Women
 - Cis-gendered
 - Not pregnant
- People who use drugs (PWUD)
 - People who inject drugs (PWID)



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Estimated New HIV Infections in the United States by Transmission Category, 2015



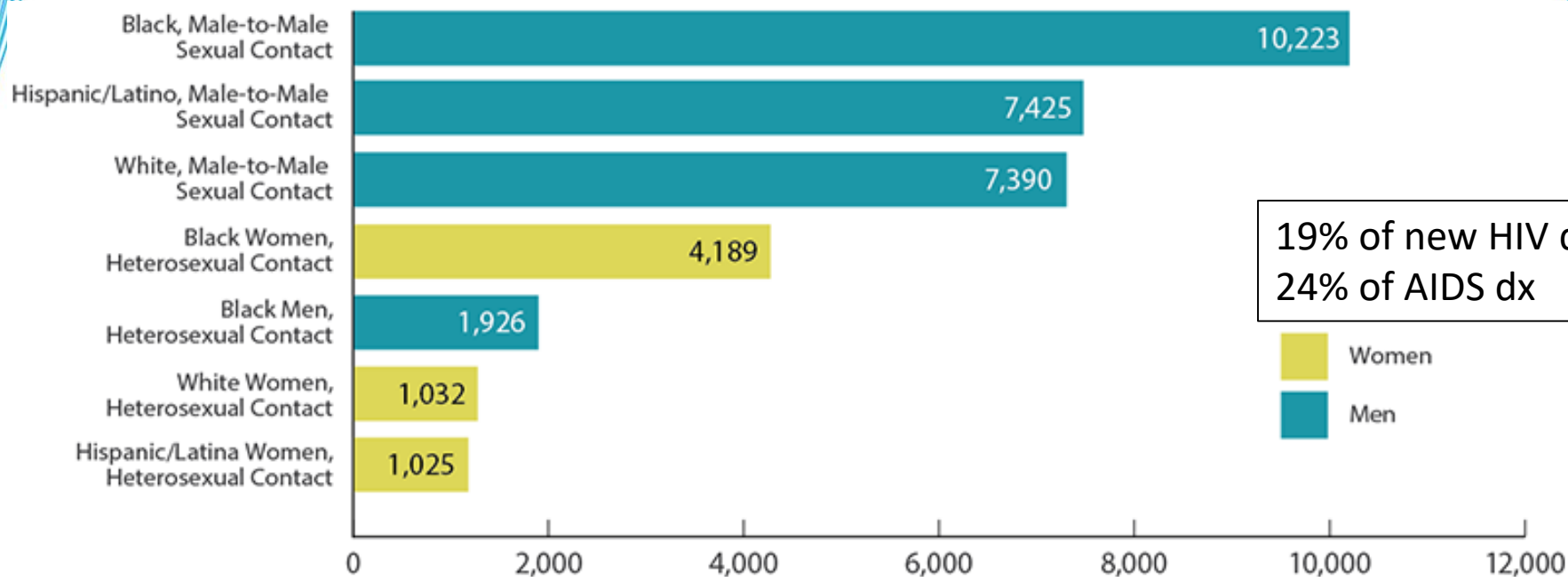
www.CDC.gov



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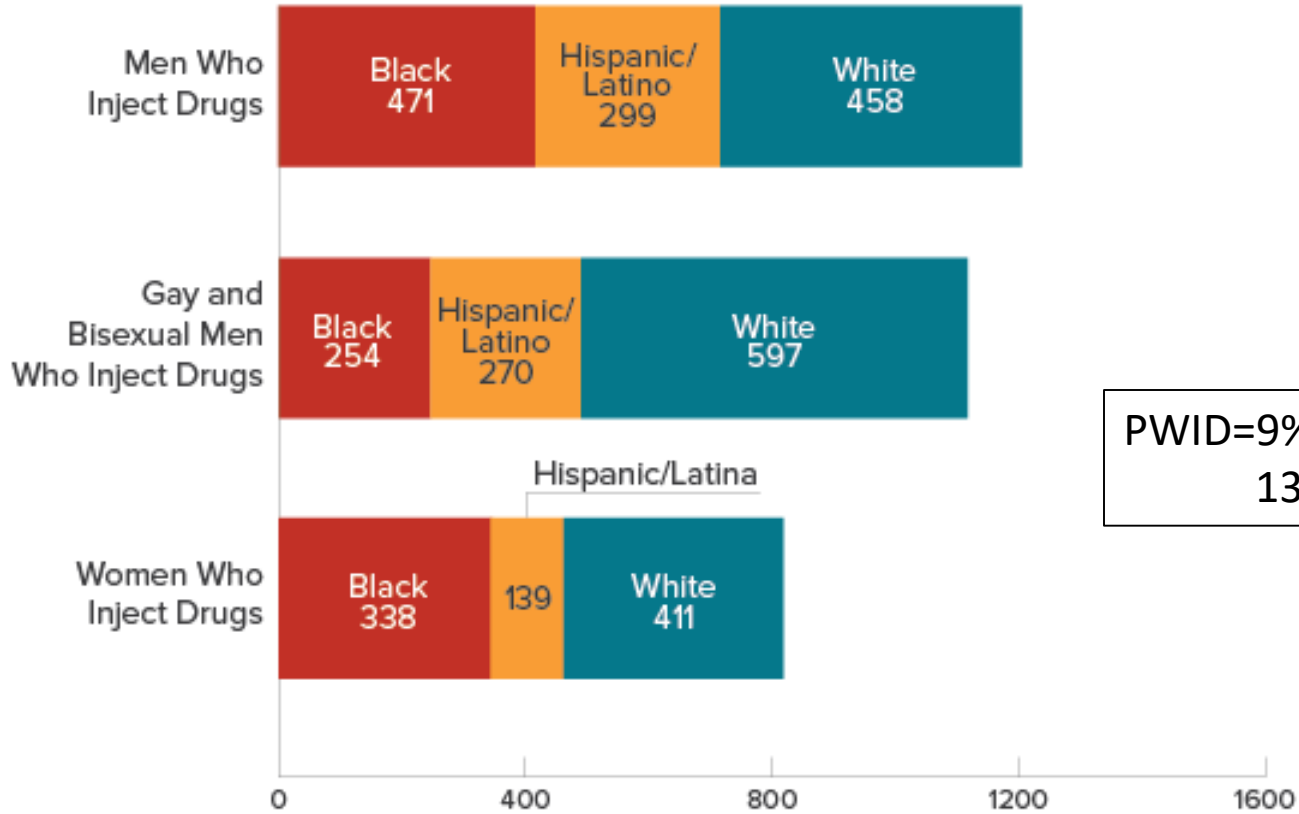
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HIV Diagnoses in the United States for the Most-Affected Subpopulations (by Gender and Risk), 2016



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HIV Diagnoses Among People Who Inject Drugs, by Transmission Category, Race/Ethnicity, and Sex, 2016—United States



PWID=9% new HIV dx
13% AIDS dx



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Jennifer is a 26yo woman who presents to a new primary care physician to establish care. She is currently homeless and uninsured.

She smokes crack 2-3 times per week and occasionally exchanges sex for drugs or money to acquire drugs. Most of her sex partners are acquaintances but she does not know their HIV status.



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What will you do to address her HIV prevention needs?

1. Start PrEP if HIV testing negative
2. Defer PrEP until she engages with treatment for her substance use disorder
3. Defer PrEP until she obtains insurance or housing.
4. Defer PrEP for now. Encourage her to use condoms with male partners.



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KNOW YOUR (and your partner's) STATUS

IDENTIFY AND TREAT SUDS

Vaccines

Male and female condoms

PrEP

Microbicides

Welcome to the preexposure prophylaxis revolution

Jared Baeten^{a,b,c} and Sheena McCormack^d

CURRENT OPINION

AND TREAT STIS

Clean injecting equipment

Voluntary counselling and testing

Male circumcision

CBA CENTER

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Power of PrEP

- Highly effective at preventing HIV
 - Optimal coverage in heterosexual epidemic could ↓ new infections by 39% in 10 years!
- Fully user-controlled

Supervie Sci Rep 2011



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Clinical trial evidence for oral and topical tenofovir-based prevention (April 2015)

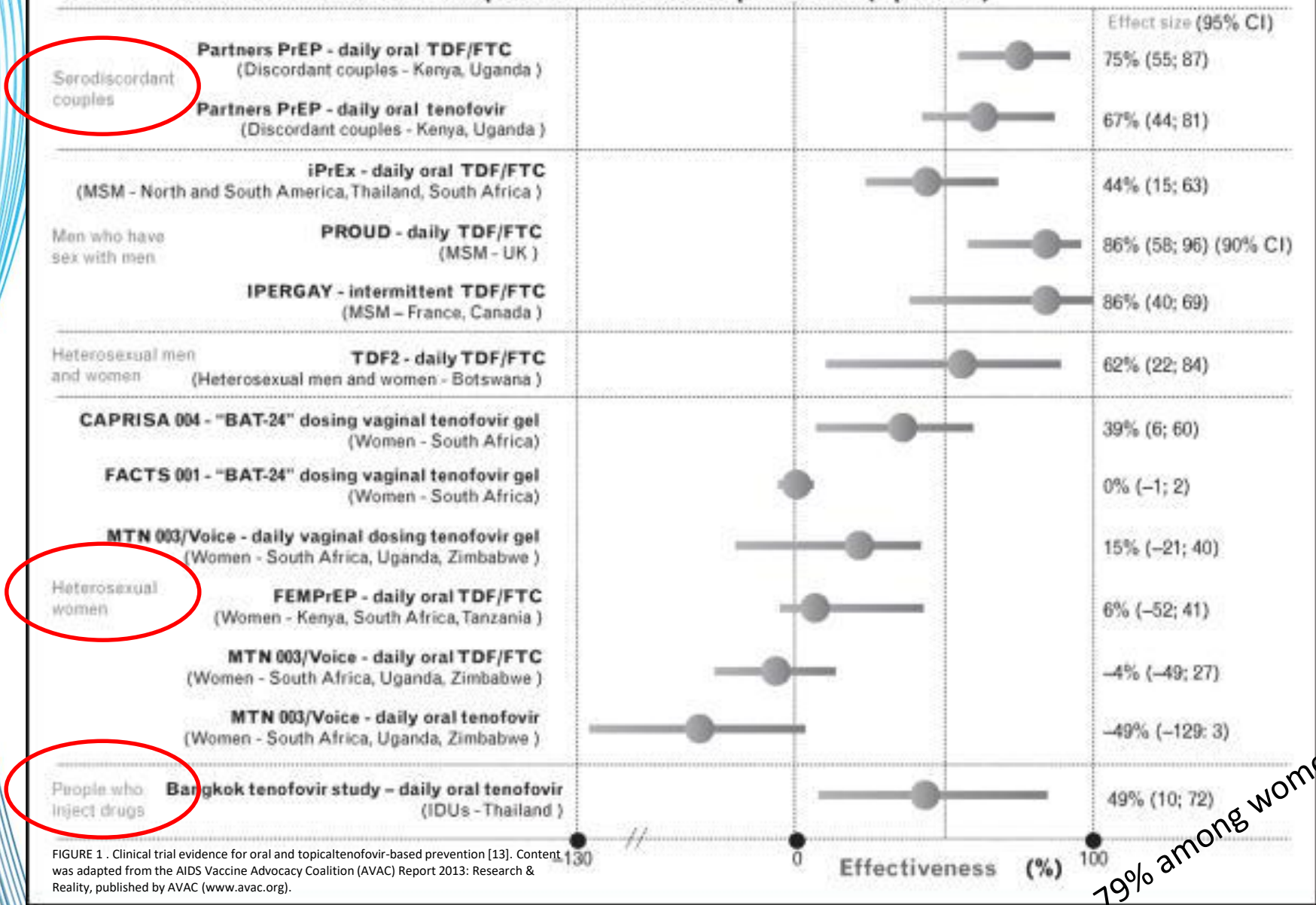


FIGURE 1. Clinical trial evidence for oral and topical tenofovir-based prevention [13]. Content was adapted from the AIDS Vaccine Advocacy Coalition (AVAC) Report 2013: Research & Reality, published by AVAC (www.avac.org).



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The current status of the use of oral medication to prevent HIV transmission.
Mayer, Kenneth; Ramjee, Gita
Current Opinion in HIV & AIDS. 10(4):226-232, July 2015.



PrEP Formulations



- TDF/FTC oral pill
 - Once daily dosing
 - On-demand (event-driven) dosing (MSM)
- 1% TFV topical gel
- In research and development:
 - Cabotegravir injectable (Phase III)
 - Dapivirine vaginal ring (Phase IIIb)
 - TAF/FTC (Phase III)
 - Maraviroc oral (Phase II) and topical (Phase I)
 - TFV implants (Phase I)



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BOX B2: RECOMMENDED INDICATIONS FOR PREP USE BY HETEROSEXUALLY ACTIVE MEN AND WOMEN

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months



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CDC PrEP Guidelines 2017

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BOX B3: RECOMMENDED INDICATIONS FOR PrEP USE BY PERSONS WHO INJECT DRUGS

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

CDC PrEP Guidelines 2017



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Table: Estimated numbers of adults with indications for PrEP, by transmission risk group and race/ethnicity, United States, 2015

	Transmission Risk Group			Total # (% of total with indications)
	MSM # (% of total MSM)	HET # (% of total HET)	PWID # (% of total PWID)	
Black/African American, non-Hispanic	309,190 (38.0)	164,660 (63.8)	26,490 (36.5)	500,340 (43.7)
Hispanic/Latino	220,760 (27.1)	46,580 (18.0)	14,920 (20.6)	282,260 (24.7)
White, non-Hispanic	238,670 (29.3)	36,540 (14.2)	28,020 (38.6)	303,230 (26.5)
Total	813,970 (71.1)	258,080 (22.5)	72,510 (6.3)	1,144,550 (100)

176,670-468,000
women

72,510-115,000
PWID

Smith CROI 2018 Abstract 86 & Ann Epidem 2018; MMWR Nov 27, 2015



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Efficacy-Effectiveness Gap

Had indications for PrEP (2014-15)

- 1.1 million adults
- 176,670-468,000 U.S. women
- 72,510-115,000 PWID

Smith CROI 2018 Abstract 86; MMWR
Nov 27, 2015



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Received PrEP (2012-16)

- Overall: 11,000 new initiations every quarter 2016
 - 75% non Hispanic White
- 15,060 U.S. women
- ?PWID (low)

Mera Giler IAS 2017; Kuo CROI 2018
Abstract 1030

KEY BARRIERS TO PREP ACCESS AND SCALE-UP



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Challenges for PrEP for Women



- Wide range of efficacy in clinical trials
 - Adherence
 - Vaginal microbiome (dysbiosis)
 - CAPRISA-004: 1% TFV gel efficacious only for women with *Lactobacillus* dominant microbiota
 - Partners PrEP: oral TDF/FTC or TFV efficacy did not differ by bacterial vaginosis status

Klatt et al. Science 2017; Heffron et al. CROI 2017; Velloza and Heffron Curr HIV/AIDS Rep 2017



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Challenges for PrEP for PWID

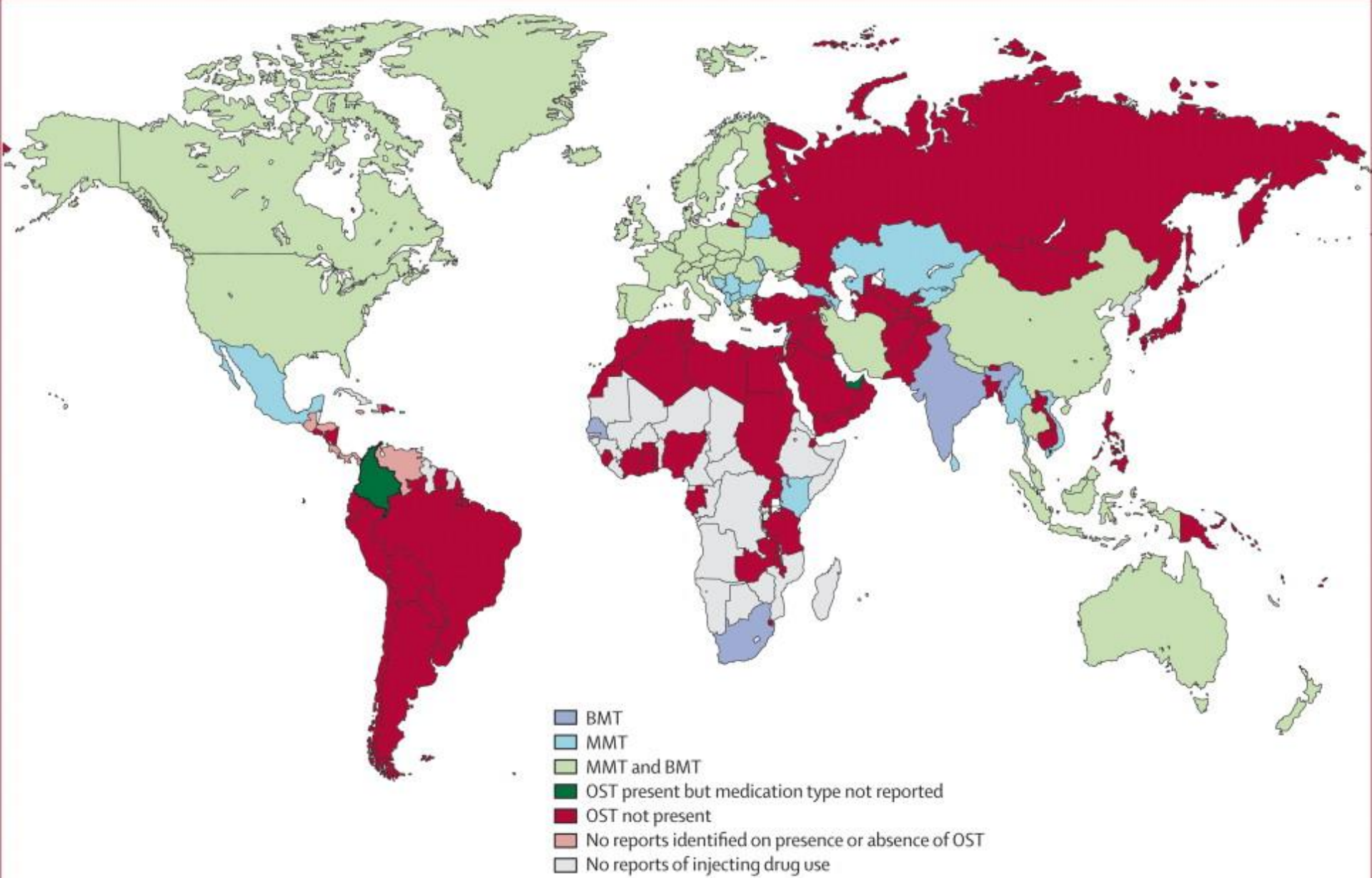


- Minimal data: single RCT
- Overlapping sex and drug use networks
- Acceptability?
- Cost-effectiveness?
- Ethics of “promoting” PrEP over harm reduction services?

Eisengerich PLoS One 2012; Alistar PLoS Med 2011; Mayer JAIDS 2018



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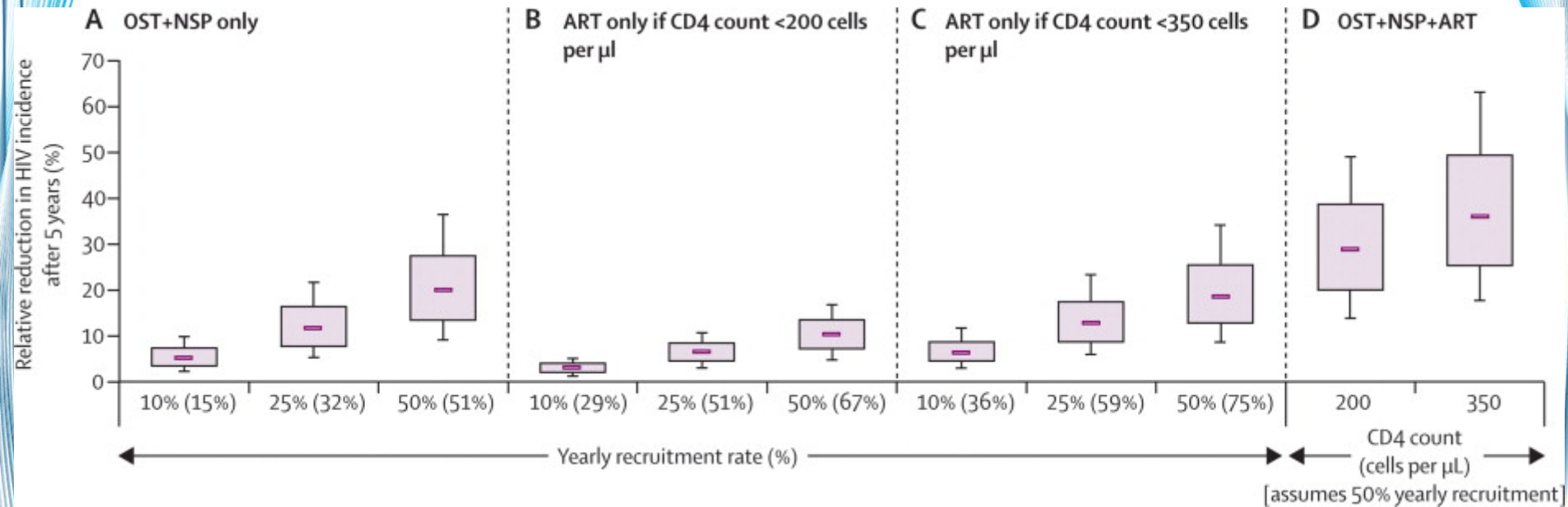


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Mathers Lancet 2010

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Effect of different intervention combinations and yearly recruitment rates on HIV incidence after 5 years



Degenhardt Lancet 2010



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Interpersonal/Social Barriers

- Stigma and discrimination
- Distrust in providers, healthcare systems
- Health literacy



Auerbach AIDS Pt Care STDs 2015



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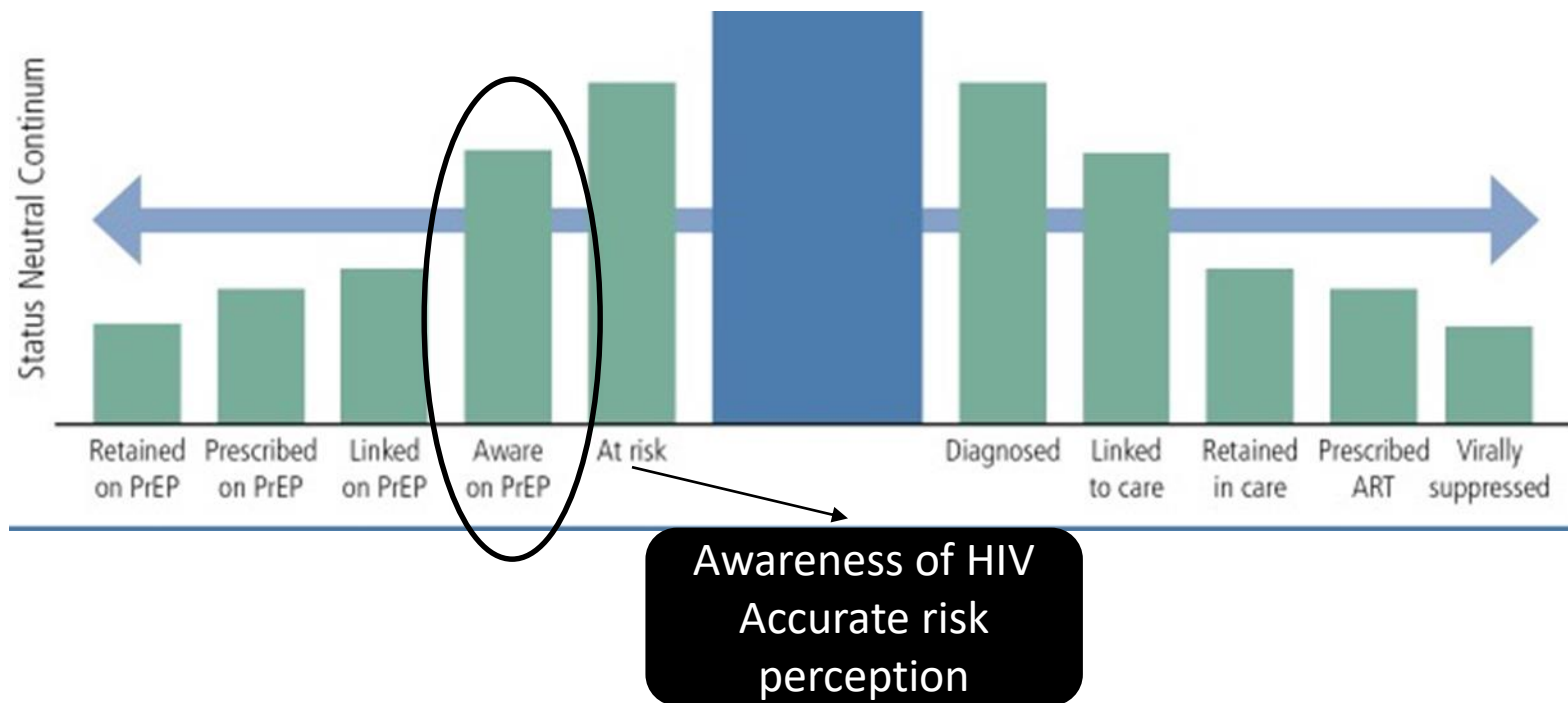
Structural Barriers

- Insurance
 - Medicaid expansion
- Cost
 - Patient drug assistance programs
 - Generic TDF/FTC?
- Providers
 - Who? Where? How?



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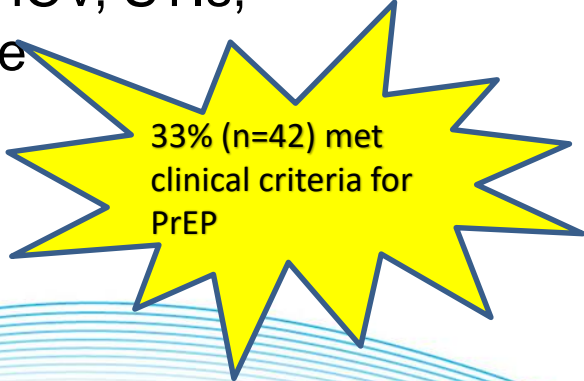
Individual Barriers



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PrEP for women on probation

- Cross-sectional survey of 125 HIV- CJ-involved women in Connecticut
- Extensive CJ-involvement (mean 4.4 lifetime incarcerations)
- High social comorbidity: unstably housed, unemployed, impoverished
- High medical & psychiatric comorbidity: HCV, STIs, depression, IPV-exposure, substance use
- High risk behaviors:
 - Recent transactional sex (22.4%)
 - Unsafe injecting (14.4%)

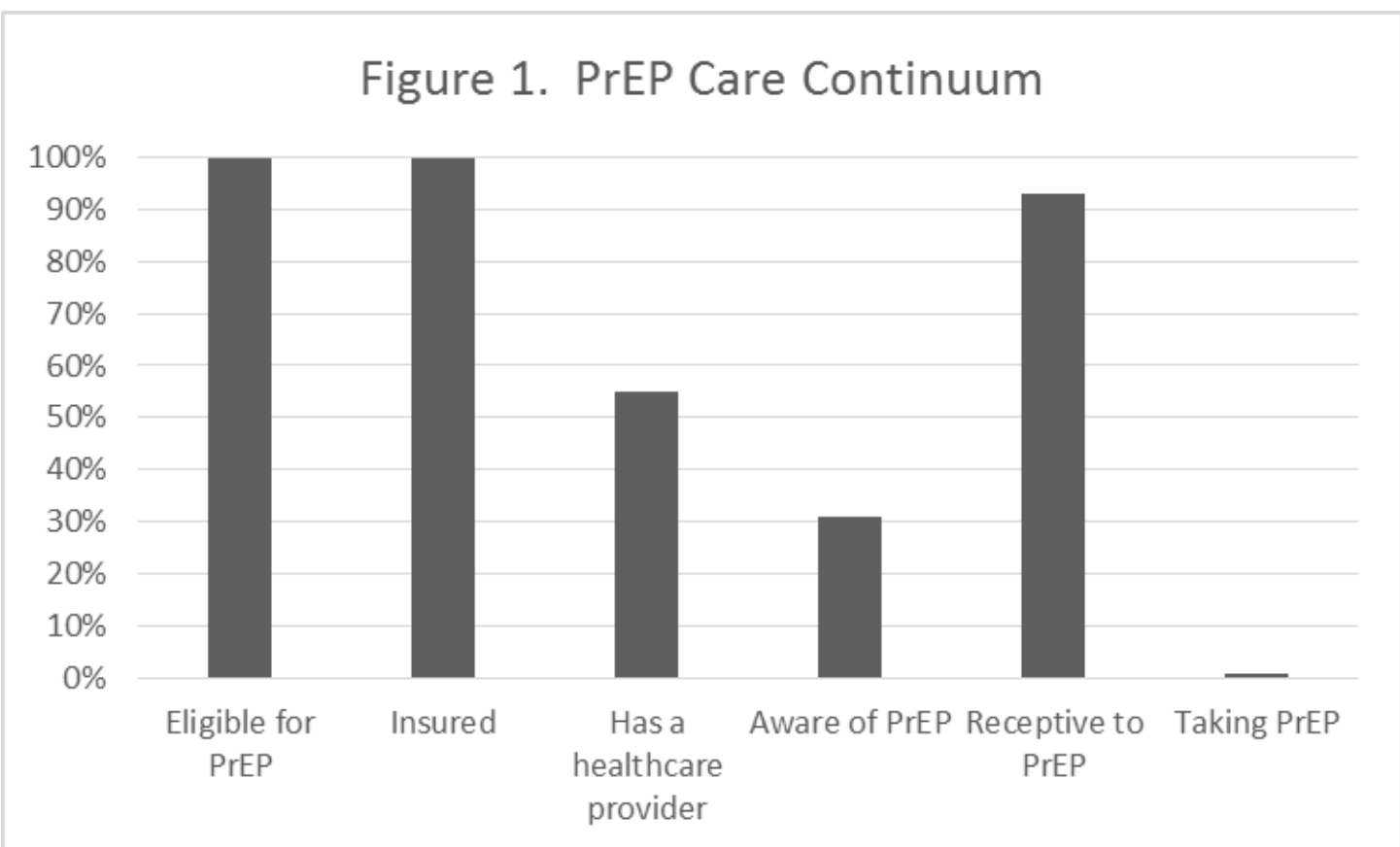


33% (n=42) met clinical criteria for PrEP



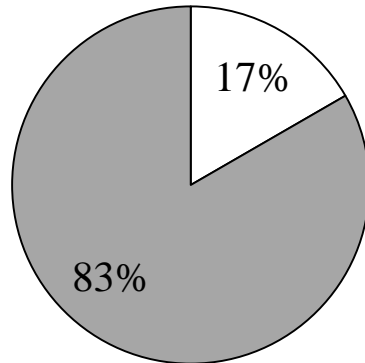
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Figure 1. PrEP Care Continuum



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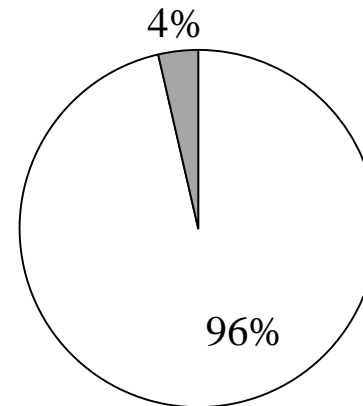
PrEP Eligible N = 42



Less likely to:
Be stably housed
Have a PCP

More likely to have:
IPV-exposure
Drug possession
charge
Lifetime substance
use
HCV

PrEP Ineligible N = 83



- Participants who correctly perceived their HIV risk
- Participants who incorrectly perceived their HIV risk



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↓ PrEP Awareness among Women

- 32% of 2406 women enrolled in WIHS PrEP-eligible
 - 6% had ever heard of PrEP
 - 1 had ever used PrEP
 - 86% interested in PrEP
- Among 716 HIV- participants, willingness to use PrEP associated with:
 - Younger age
 - Belief that PrEP will prevent HIV
 - Willingness to recommend PrEP to others

Patel CROI 2018 Abstract 1048; Kasaye CROI 2018 Abstract 1050



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...but ↑PrEP Acceptability

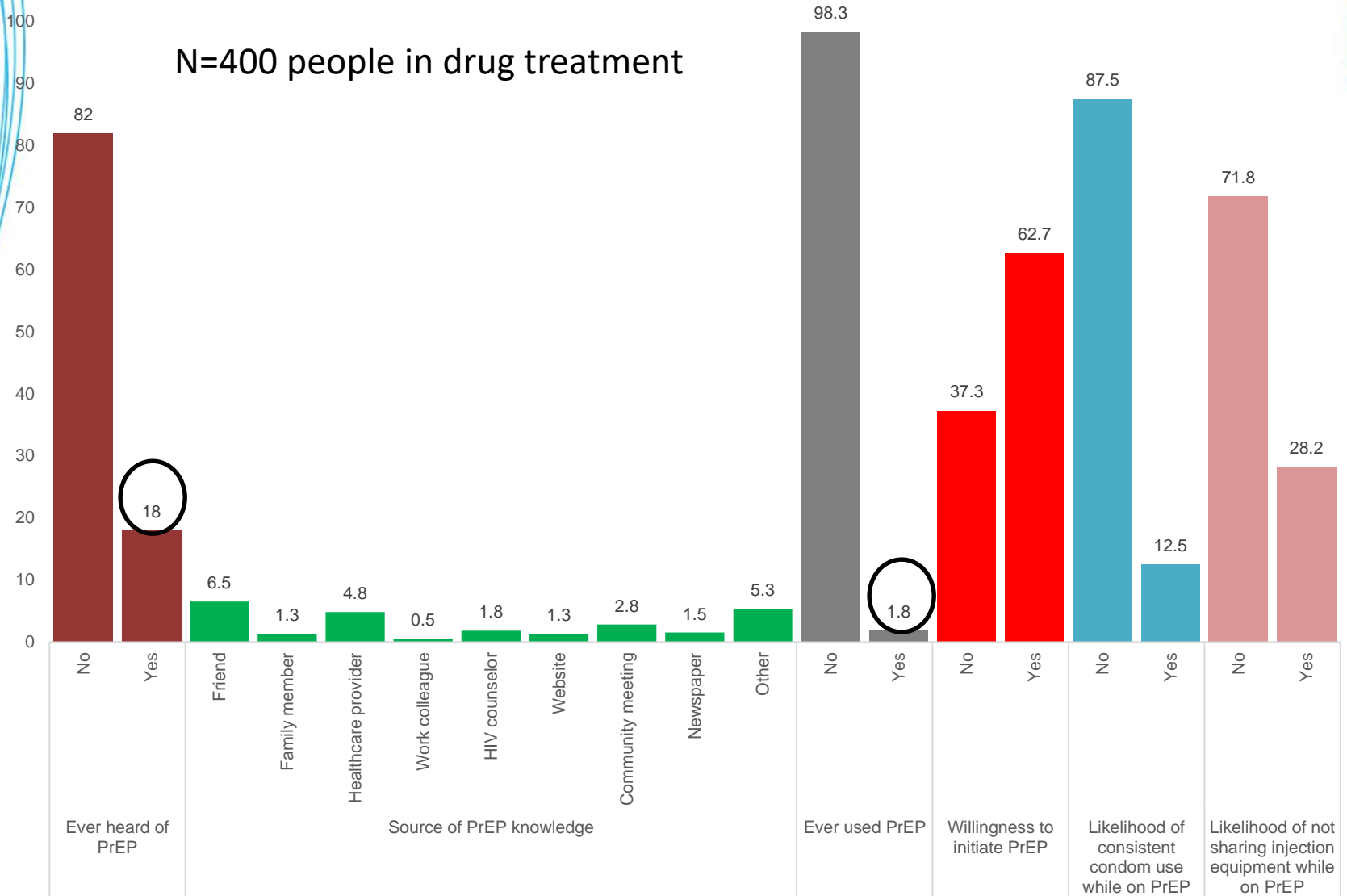
- Nationally representative random sample (1500 women)
- Correlates of potential PrEP uptake:
 - less educational status
 - more sex partners
 - provider recommendations and
 - peer norms supportive of PrEP

Wingood JAIDS 2013



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N=400 people in drug treatment



Shrestha DAD 2017
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↓ PrEP Awareness among PWID

- 2015 National HIV Behavioral Surveillance System
- Among PWID with PrEP indication (n=181/516):
 - 7.4% ever heard of PrEP
 - <1% had received a PrEP prescription
 - None were taking PrEP

Kuo CROI 2018 Abstract 1030



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Why is PrEP Awareness Limited among Women and PWID?



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#Social media messaging




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CDC PrEP Consumer Info

PrEP is an HIV prevention option that takes **one pill every day**.



In several studies, HIV infection was much less likely for those who took PrEP than for those who did not.



ARE YOU READY FOR PrEP?

If you and your health care provider agree that PrEP might reduce your risk of getting HIV, he or she will test you for HIV and other sexually transmitted diseases.

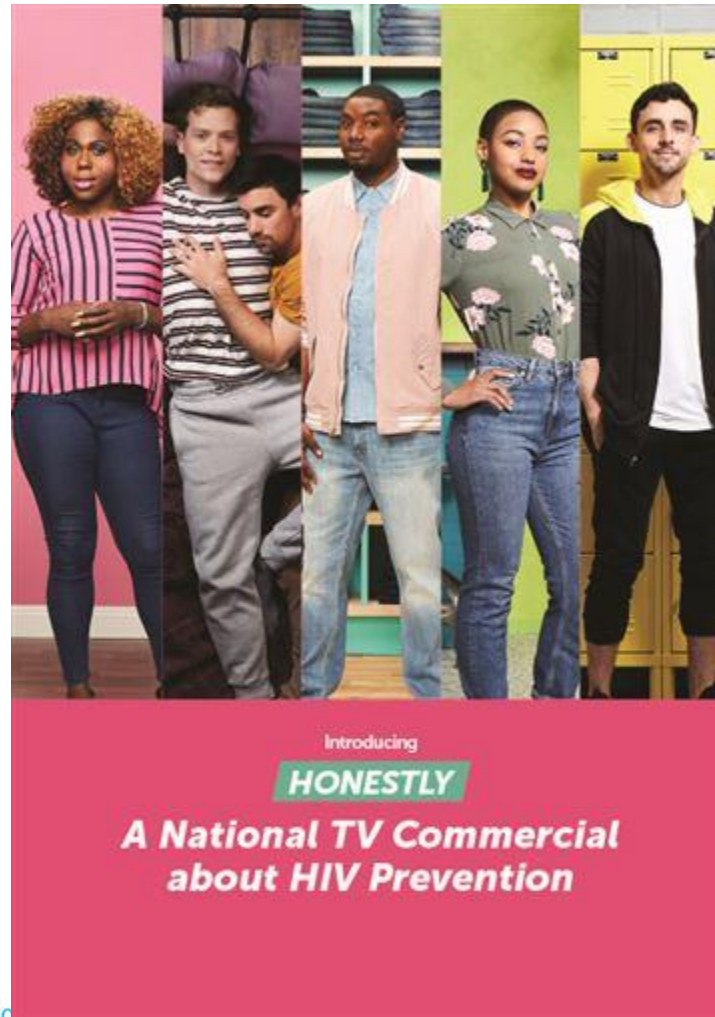


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Limited Direct-to-Consumer Marketing

2012: TDF/FTC approved
for PrEP

May 2018



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STRATEGIES TO OVERCOME THE “AWARENESS GAP”



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Inclusive messaging



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In-reach

- Integrate HIV testing/PrEP into non-traditional settings
 - Drug treatment programs
 - Needle syringe programs
 - Criminal justice settings
 - Health fairs



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Harnessing Technology (mHealth)

- Seeking high risk populations for HIV prevention (testing, PrEP)
 - Using social networking sites
- Reduce substance use
 - Motivational interviewing techniques
- Reduce risk, increase knowledge
 - Messaging content from peer health navigators
 - Video game for teens (role playing):
www.play2prevent.org



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Peer-led interventions

Peer Health Advocates, peer change agents

PrEP champions (including through social media)

Latkin Health Psychol 2003; Weeks Subst Use Misuse 2009; Patel JMIR Res Protoc 2018; Young Clin Trials 2018



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Asking the right questions

Question	Assesses	Potential solution
Have you heard about PrEP?	Awareness	Increase awareness
Now that we've told you about PrEP, do you want to take it?	Acceptability	Cultural adaptation of intervention delivery
Are you at risk for HIV?	Risk perception	Re-align perceptions
Is PrEP right for you?	Personal preferences	Individualized content



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Patient-centered decision aids

- Support informed and shared decision making
- Recommended by the IOM, supported by >115 RCTs
- Core elements:
 - Information delivery
 - Deliberation
 - Implementation
- Internationally standardized criteria: IPDAS
- <https://decisionaid.ohri.ca/index.html>

Stacey Cochrane Rev 2014; Elwyn BMJ 2006; Elwyn BMJ 2010

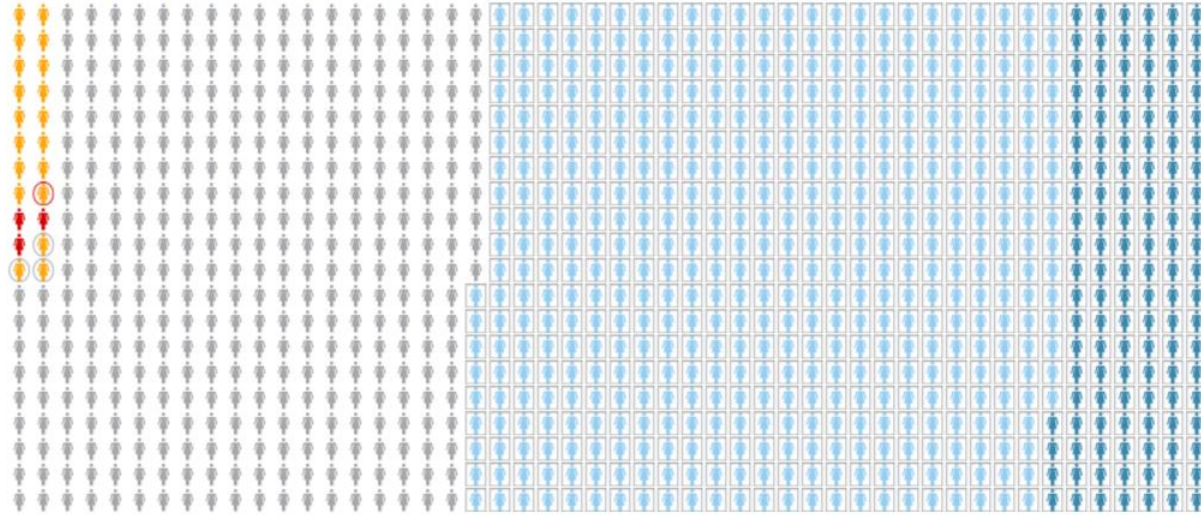


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Decision: Get mammograms & how often?

No Biennial **Annual**

For 1000 women age 40 over 10 years







Population




Icon

years

22 are diagnosed with breast cancer.

- >  15 survive breast cancer with or without screening.
- >  1 saved from a breast cancer death.
- >  3 die from breast cancer.
- >  3 extra are over-diagnosed by screening.

978 are not diagnosed with breast cancer.

- >  369 no breast cancer, recalls or biopsies.
- >  609 recalled for one or more false alarms.
- >  124 undergo a biopsy that is normal.

[Continue](#)



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Project OPTIONS

- AIM 1: To create a patient-centered HIV prevention decision aid for women with substance use disorders (SUD) entering treatment.
 - Interviewed 20 HIV- women in drug treatment and 20 “stakeholders”
 - Qualitative analysis: How do women think about (or not) and make decisions about HIV prevention?
- AIM 2: Building on findings from Aim 1, to pilot test the effect of the informed decision aid intervention on PrEP uptake among women with substance use disorders entering treatment.

Doris Duke Charitable Foundation Scholars



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**What's in
your HIV
prevention
toolbox?**



**If you're a
woman in care at
APT, a new study
could help you
find out!**

What potential PrEP users want to know

Will my insurance cover it?

Does my partner need to know?

Do I still need condoms?

What is involved?

How does PrEP work?

Are there side effects?

Where do I get it?

Will it affect my other medications (methadone)?

How well does PrEP work?

Will PrEP prevent...
Hep C?
Pregnancy?
STIs?

How much does it cost?



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Jennifer is a 26yo woman who presents to a new primary care physician to establish care. She is currently homeless and uninsured.

She smokes crack 2-3 times per week and occasionally exchanges sex for drugs or money to acquire drugs. Most of her sex partners are acquaintances but she does not know their HIV status.



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What will you do next to address her HIV prevention needs?

1. Offer HIV testing
2. Offer HIV and STI testing
3. Review her risk for HIV + Offer HIV/STI testing
4. Review her risk for HIV + Offer HIV/STI testing + Discuss pros/cons of PrEP



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Take-home messages

- Women and PWID are key target populations for HIV prevention...
- ...but experience a number of barriers to PrEP uptake, including lack of awareness.
- Tools for addressing awareness are: inclusive messaging, decision aids, peer-led interventions, and mHealth.



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QUESTIONS?



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Thank you!

- Any questions?
- Please feel free to email me:
jaimie.meyer@yale.edu



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Learning Collaborative Discussion:

1. How well does your PrEP program reach women and people who inject drugs?
2. What are the major barriers you see to delivering PrEP services to women and people who inject drugs?
3. What types of resources or messaging is needed to broaden the reach of PrEP?
4. What other tools are needed for HIV prevention among women and people who inject drugs?



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Session 2 – December 2018 (TBA)



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