



DORIS DUKE  
CHARITABLE FOUNDATION

# PREP FOR WOMEN WITH SUBSTANCE USE DISORDERS

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Yale AIDS Program

# DISCLOSURES

- I have received research support from a Gilead Sciences Investigator Sponsored Award.
- I have no conflicts of interest to disclose.


medicine.yale.edu/lab/jmeyer/

J. Meyer Lab

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Principal Investigator



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Assistant Professor of Medicine (AIDS) and Assistant Clinical Professor of Nursing

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## Overview - Welcome!

Our research centers on HIV and women's health. We inform, develop and test HIV prevention and treatment interventions specific to women who are involved in criminal justice systems, women with substance use disorders, and women experiencing intimate partner violence. In doing so, we aim to develop interventions that address social determinants of health and are gender-responsive and trauma-informed.

We apply principles of implementation science to adapt these interventions to key contexts, including criminal justice settings (prison, jail, probation, parole), drug treatment centers, and domestic violence service providers. Our work includes using patient-centered decision aids on HIV pre-exposure prophylaxis (PrEP) to help women make informed choices about HIV prevention, scaling up PrEP among key populations of women, and integrating housing and health services for people who are justice-involved.

We strive to build programs for social justice, empowerment, and access to services to alleviate the burden of infectious diseases among key populations.

Yale SCHOOL OF MEDICINE

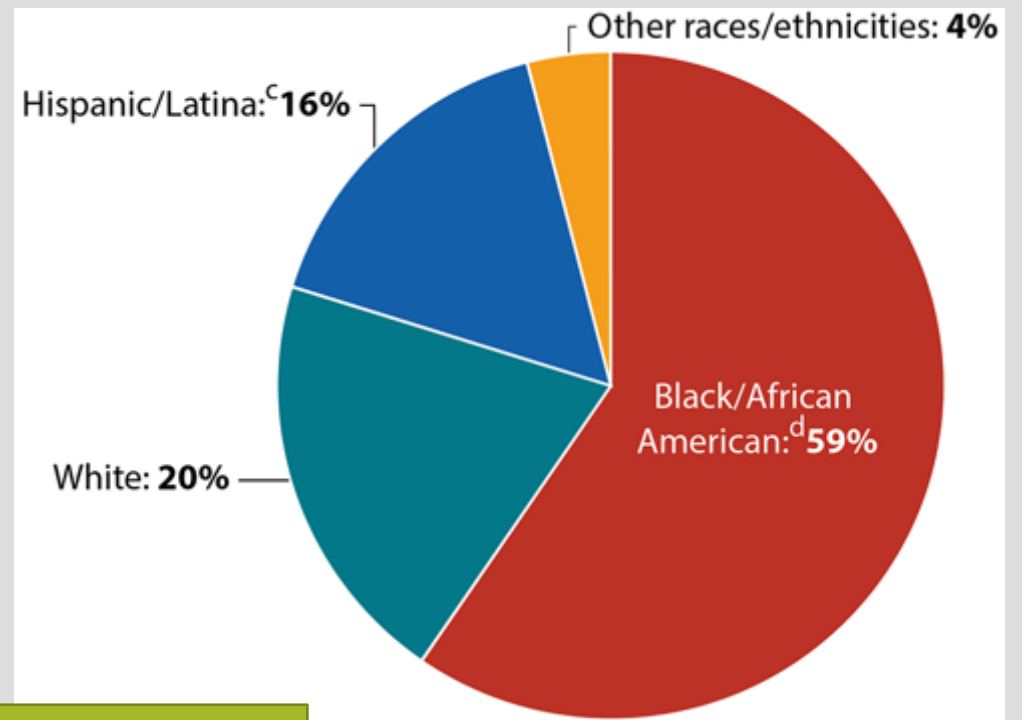
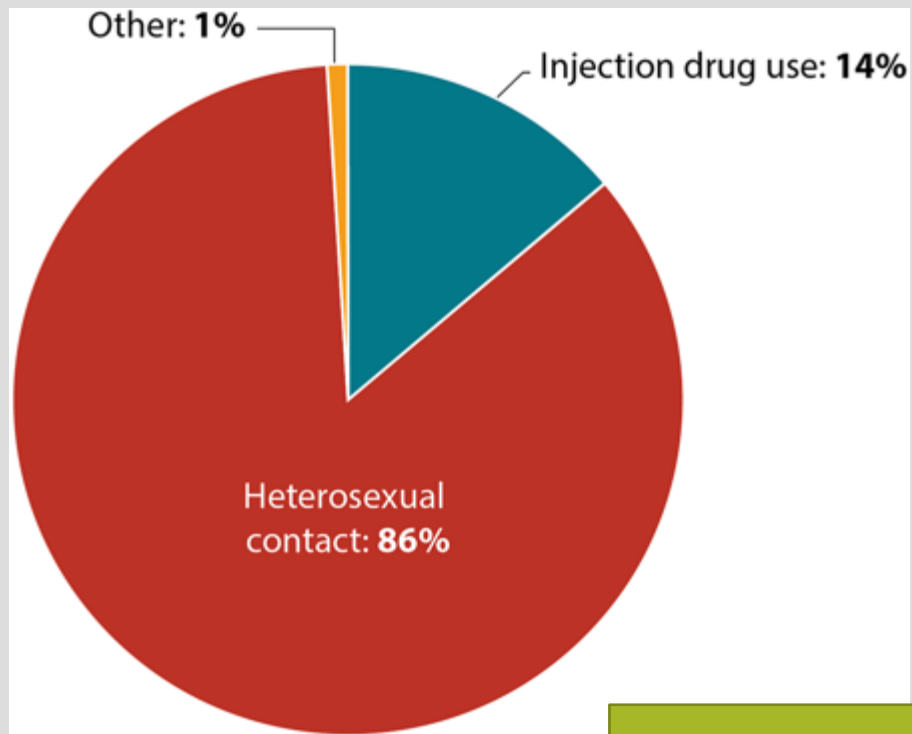
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# GOALS AND OBJECTIVES

- To describe the power, promise, and pitfalls of PrEP for HIV prevention in women with substance use disorders;
- To introduce Project OPTIONS and provide preliminary efficacy data;
- To discuss challenges and strategies to integrate PrEP with treatment for substance use disorders.

# HIV AMONG U.S. WOMEN



7,401 new HIV diagnoses in 2017

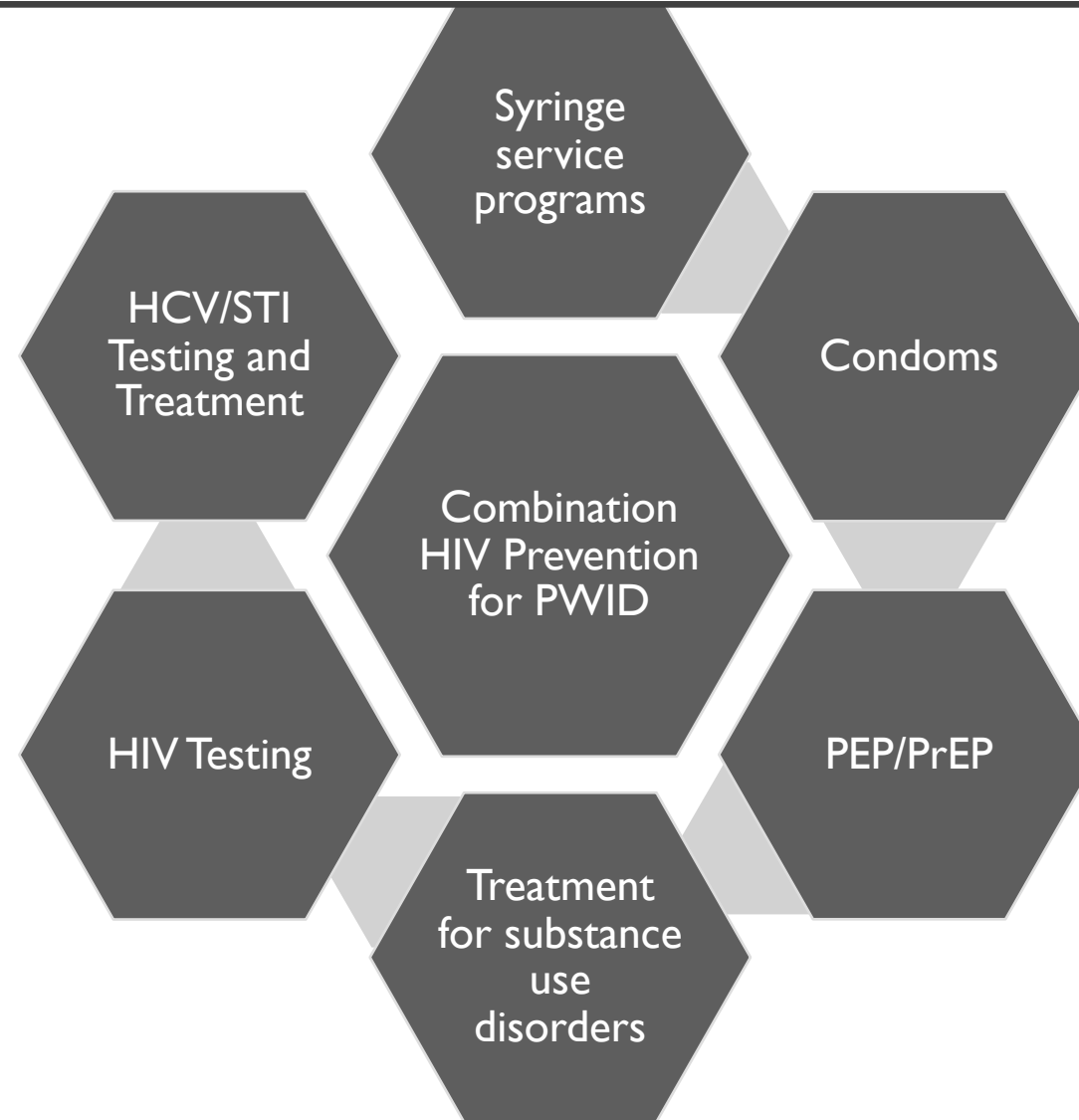
# HIV Prevention

The background of the slide is a photograph of the White House at night. The building is illuminated with vibrant, multi-colored lights in shades of red, orange, yellow, green, and blue, creating a rainbow effect. The sky is a deep twilight blue. The American flag is visible on a tall pole in front of the building's portico.

- 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](http://hiv.gov)

# COMBINATION HIV PREVENTION



Shrestha R, McCoy-Redd B, Meyer J. Pre-Exposure Prophylaxis (PrEP) for People Who Inject Drugs (PWID). Brianna Norton, Ed. The Opioid Epidemic and Infectious Diseases. Elsevier 2019. MacArthur G, et al. *BMJ*. 2012;345:e5945. Vickerman P, et al. *Addiction*. 2014;2019(12):2060-2061. Wodak A, et al. *Subst Use & Misuse*. 2006;41:777-813. Abdul-Quader AS, et al. *AIDs Behav*. 2013;17(9):2878-2892. Schranz AJ, et al. *Curr HIV/AIDS Rep*. 2018;15(3):245-254.

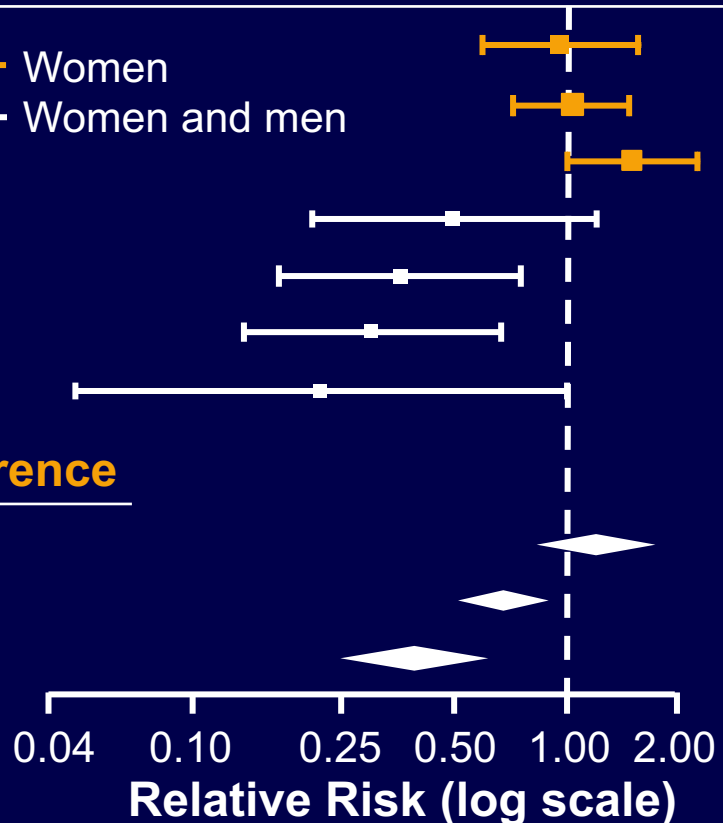
# Meta-analysis: PrEP Strategies in Women

- Meta-analyses of PrEP effectiveness in major trials including women

Study	Drug	Adherence, %		Oral PrEP vs Placebo Relative Risk (95% CI)
1. FEM-PrEP	TDF/FTC	24	— Women	0.95 (0.60-1.52)
2. VOICE	TDF/FTC	29	— Women and men	1.03 (0.73-1.46)
3. VOICE	TDF	30		1.49 (0.98-2.27)
4. TDF2-Botswana	TDF/FTC	81		0.49 (0.20-1.21)
5. Partners PrEP	TDF/FTC	77		0.35 (0.17-0.74)
6. Partners PrEP	TDF	80		0.30 (0.14-0.65)
7. Bangkok	TDF	66		0.22 (0.05-1.01)

## Meta-analyses Regression Estimates, by Adherence

25% adherence	1.19 (0.89-1.61)
50% adherence	0.68 (0.53-0.88)
75% adherence	0.39 (0.25-0.60)





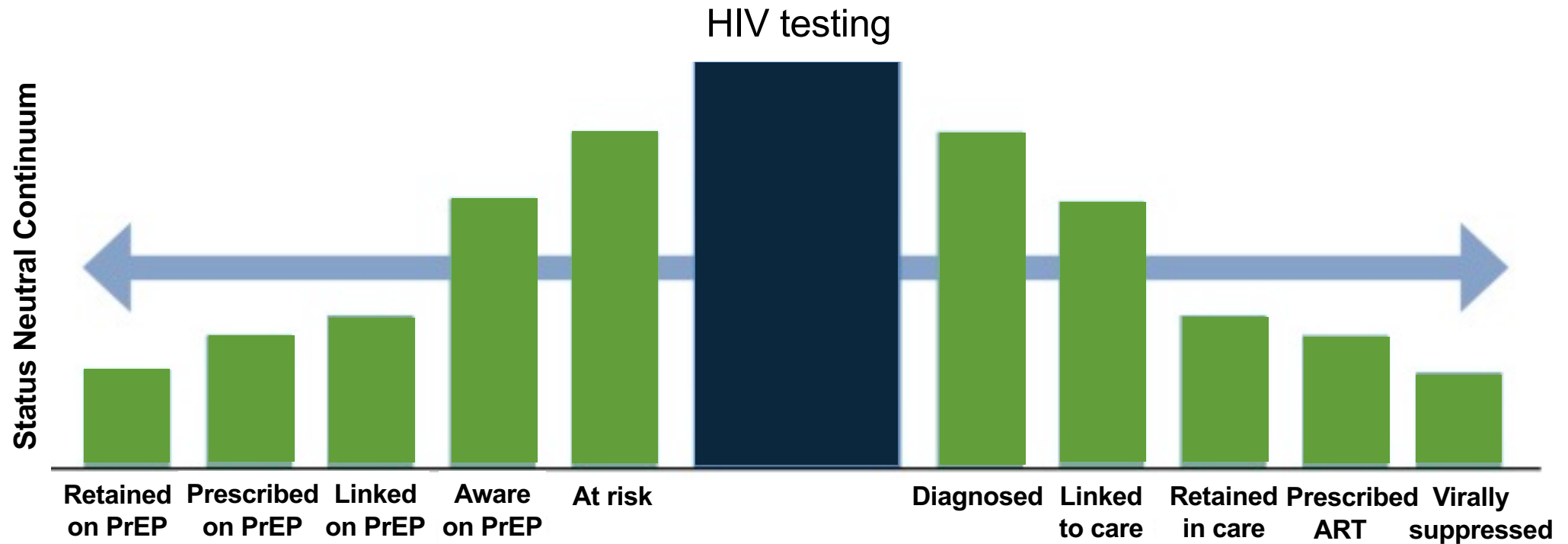


## POWER, PROMISE, PITFALLS OF PREP

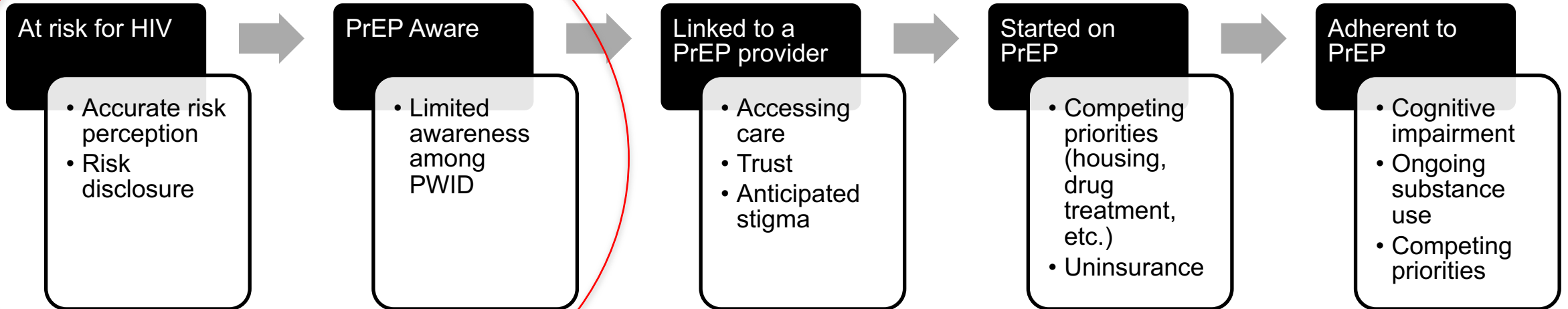
- HIV pre-exposure prophylaxis (PrEP)= highly effective HIV prevention
  - ✓ Fully user controlled (does not require partner participation)
  - ✓ Discreet (obviates need for disclosure)
  - ✓ Effective regardless of risk behavior or partner type
- Efficacy-effectiveness gap
  - 3.2-8.5% of US women meeting indications for PrEP have received it
  - <1% of PWID meeting indications for PrEP have received it
- Decreased PrEP awareness, HIV risk misperception



# The Status Neutral Continuum



# PrEP Care Continuum and Key Challenges for WWUD





# ENTER DECISION AIDS

- Key components: information delivery, deliberation, implementation
  - Personalized, specific, congruent with patient values
- Existing decision aids
  - Various topics: >115 RCTs
  - HIV: 2 (when test, when to start ART)
  - PrEP: 0

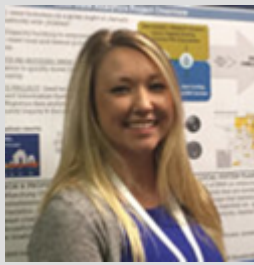




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# PROJECT OPTIONS

- AIM 1: To create a patient-centered HIV prevention decision aid for women with substance use disorders (SUD) entering treatment. **In treatment preference**
- 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. **Using existing data**





# STUDY SETTING

apt | foundation  
TREATMENT. RESEARCH & RECOVERY



# METHODS OVERVIEW

## Phase 1

- Decisional needs assessment
- Selection & drafting

## Phase 2

- Alpha testing
- Revise prototype
- Training

## Phase 3

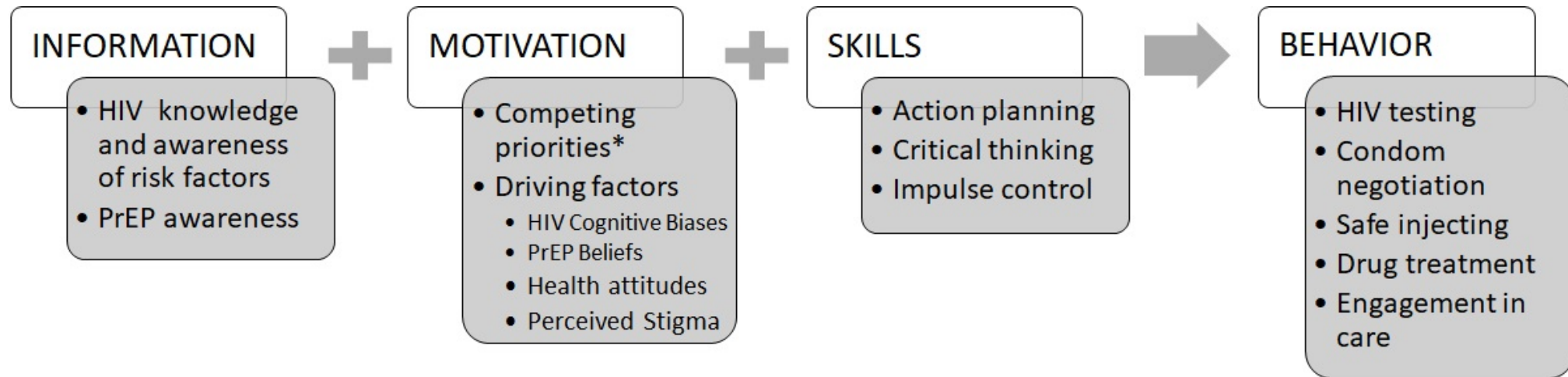
- Beta testing



# PHASE I: FORMATIVE WORK

- Semi-structured interviews at APT Foundation, Inc. with:
  - Members of key target population (women in drug treatment settings) (n=20)
  - Key stakeholders (n=15)
- Evaluated how women make decisions about HIV prevention, including PrEP
- Interviews audio-recorded, transcribed, coded by multiple coders in Dedoose
  - Information-motivation-behavioral skills model
  - Beliefs-goals-choice heuristics framework







"The last time I got high I had to beg my drug dealer...I had to give him oral sex to get those drugs...I didn't really think about [HIV risk] because it didn't really matter. I needed to get high. I was getting high regardless. Even if you told me you had AIDS...and you had a needle that I had to use...I would clean it out, but I'd still use it because I needed to. Sad right? Isn't that sad? It makes me sad to say."  
(WWUD, 25-39yrs old)

"A lot of times, it's just like the addiction comes first, and then they're not really worried about their medical health...we do promote or try to promote safe sex even in recovery because a lot of times, people are not thinking about that. When we're talking about active addiction, I think it's difficult for a lot of people to think about preventive measures." (Administrator)

# **Women's Decision-Making about PrEP for HIV Prevention in Drug Treatment Contexts**

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[journals.sagepub.com/home/jia](https://journals.sagepub.com/home/jia)



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Lisa Puglisi, MD<sup>4</sup>, Lynn M. Madden, PhD<sup>2,5</sup>, and Jaimie P. Meyer, MD, MS<sup>2</sup> **

# AM I AT RISK FOR HIV?

- In the past 6 months have you...
- Had sex without a condom...
  - With a man who had HIV and was not on treatment?
  - With a man whose HIV status you didn't know?
  - With a man who injected drugs?
  - While intoxicated?
- Injected drugs...
  - And shared injecting equipment or works?
- Exchanged sex for drugs/money/shelter?
- Had 5 or more sex partners?
- Been diagnosed with an STI?

0-1 points  
Low risk for HIV

2-3 points  
Medium risk for HIV

4 or more points  
High risk for HIV

# IS PREP RIGHT FOR ME?



## USING PREP

## NOT USING PREP

How do I take PrEP?

PrEP is one pill once a day. You can take it any time of day, with or without food. It takes 21 days before it has the full effect, and 30 days after risk to stay protected. No one needs to know you are on PrEP, but it only works if you take it.

You will still be at risk for HIV.

How does PrEP work?

**PrEP is a pill that includes 2 medications that prevent the HIV virus from getting into your cells even if you are exposed to it. PrEP is not addicting.**

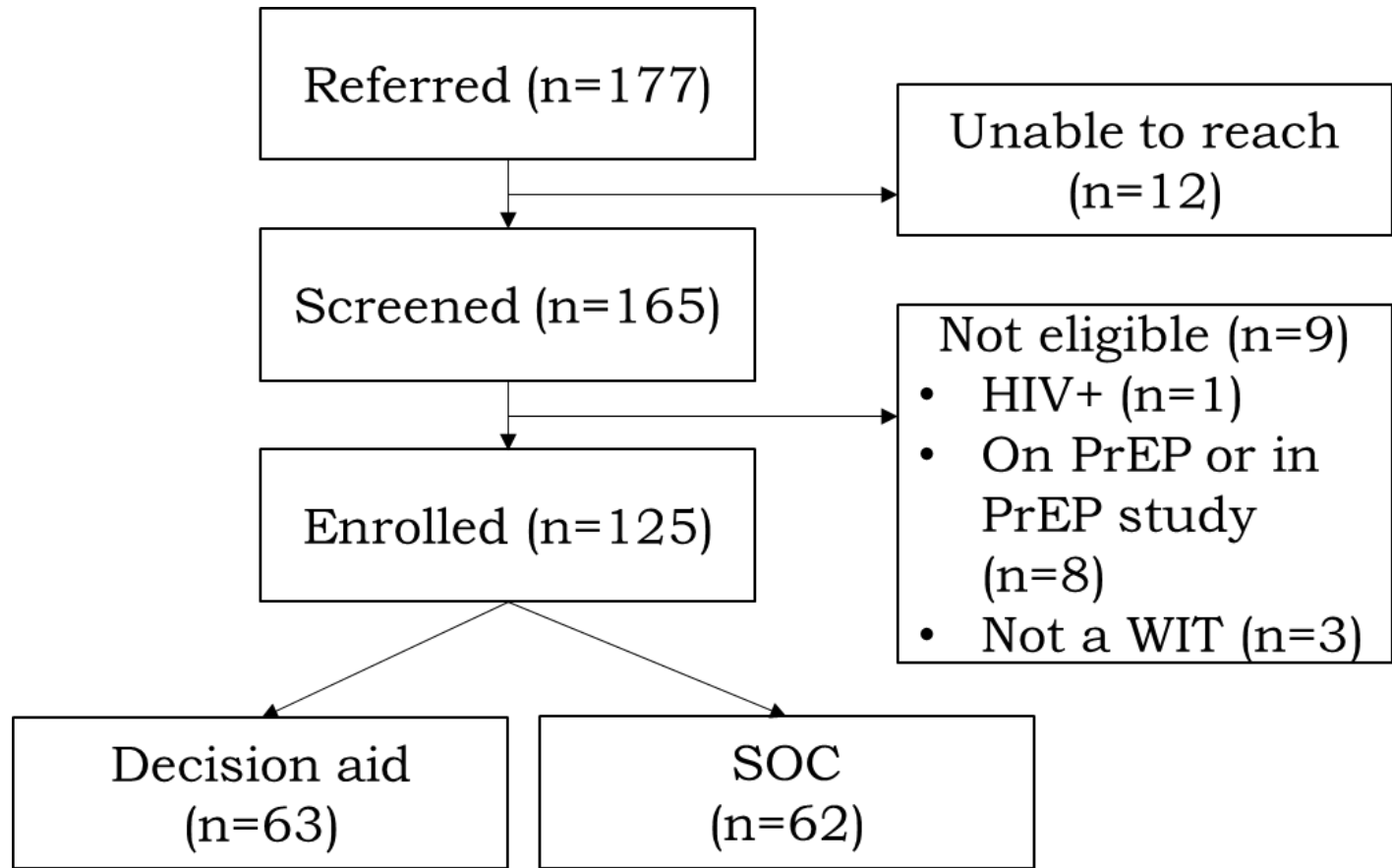
**You will still be at risk for HIV.**

Where can I get PrEP?

PrEP is available only by prescription. You qualify for PrEP if you are at risk for HIV and you are not pregnant.

You will still be at risk for HIV.

# CLINICAL TRIAL

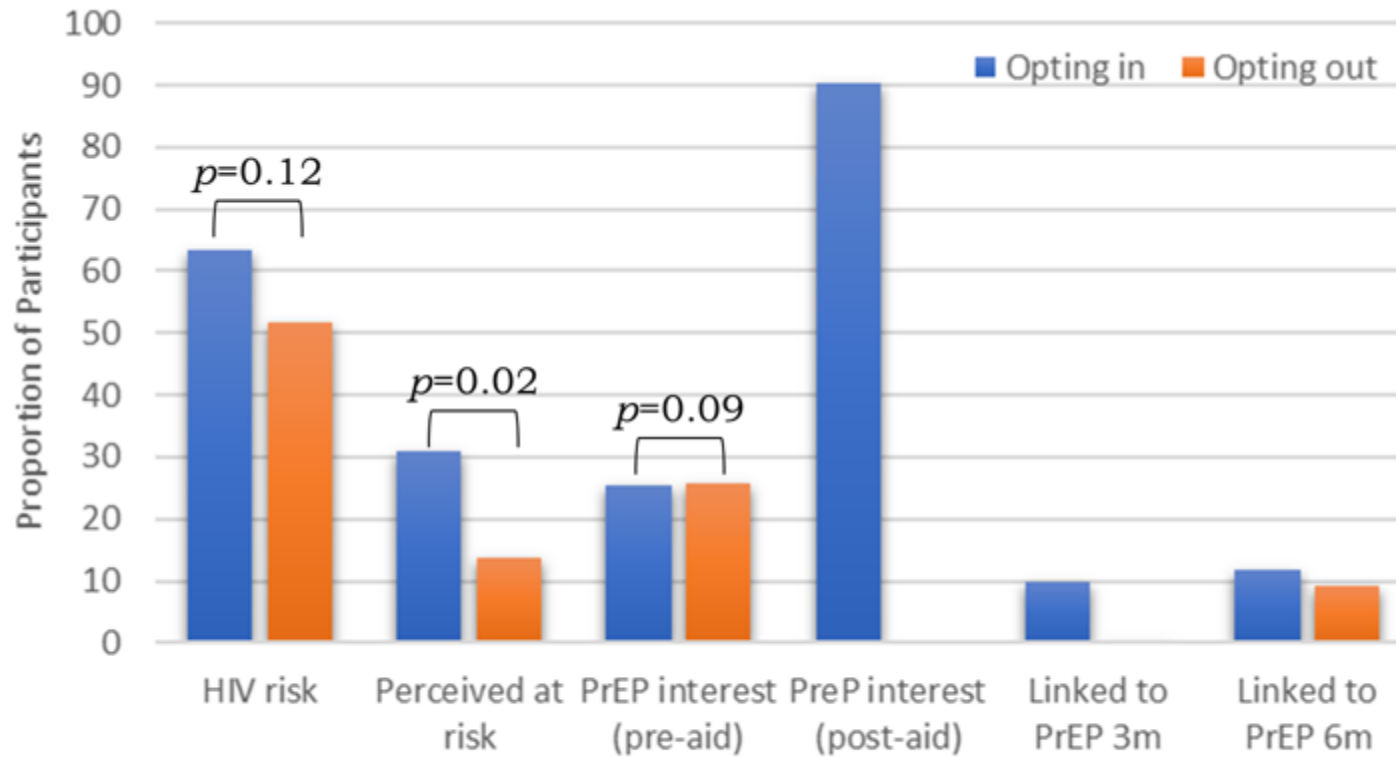


## BASELINE CHARACTERISTICS OF SAMPLE (N=125)

- ✓ Age: M 40.2 (SD 10.3)
- ✓ Race: 71.2% White
- ✓ Ethnicity: 12.0% Hispanic
- ✓ Marital status: 53.2% never married
- ✓ Housing status: 59.2% with children or partner
- ✓ Education completed: 80.8% ≥High school
- ✓ Employment: 80.3% without work in past 30d
- ✓ On methadone: 80.9% overall
- ✓ TRAUMA:
  - ✓ Physical assault: 43.8%
  - ✓ Assault with weapon: 22.5%
  - ✓ Sexual assault: 39.3%

**No significant differences between arms: Decision aid (n=63) vs. SOC (n=62)**

# PREP CARE CONTINUUM





# SO WHAT?

## IMPLICATIONS

- First PrEP decision aid
- Specific to women in drug treatment settings
- Feasible, acceptable, effective
  - Decisional preference for PrEP
  - PrEP uptake
- Linkage to services

## NEXT STEPS

- Integrate into drug treatment settings: training up staff
- Expanding into other settings
  - DV service providers
  - Other PrEP clinical trials
- Incorporating in new issues as they arise
  - Flexibility to accommodate new science: TAF/FTC; injectables

# ACKNOWLEDGEMENTS

## Research team

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## Collaborators

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Women of York CI



# HIV PREVENTION VS. TREATMENT WHERE AND HOW?

## PREVENTION

- Lack of a diagnosis
- Episodic (event-driven?) PrEP
  - Most impactful during periods of risk
- Not supported by Ryan White funding, ADAP
- Delivery setting: HIV/primary care?
  - Other: gyn, drug treatment
  - Non clinical settings (pharmacies), SSP, online

## TREATMENT

- Diagnosed HIV+
- Daily, lifelong medication (ART)
  - Easiest? During periods of stability
- Supported by Ryan White funding, ADAP
- Delivery setting: HIV/specialty/primary care

# Strategies to Increase PrEP Uptake Among PWID

- Increase PrEP awareness
  - Inclusive messaging
  - Realign perceptions about risk
- Lower barrier to entry settings for HIV testing and PrEP linkage/initiation
  - Drug treatment programs
  - STD clinics
  - Syringe service programs
  - Emergency departments
  - Primary care
  - Prisons or jails
- Low-threshold PrEP initiation:
  - Rapid start
  - Same-day start
- Peer navigation models

## INNOVATION

What is needed to expand PrEP access to women with substance use disorders?

What do you think about PrEP moving out of traditional clinical settings?

What are the barriers to engaging your clients/patients about PrEP?