PREP FOR WOMEN WITH SUBSTANCE USE DISORDERS

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DISCLOSURES

• I have received research support from a Gilead Sciences Investigator Sponsored Award.

• I have no conflicts of interest to disclose.
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.
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.
7,401 new HIV diagnoses in 2017

HIV AMONG U.S. WOMEN

- Heterosexual contact: 86%
- Other: 1%
- Injection drug use: 14%

- Black/African American: 59%
- Hispanic/Latina: 16%
- White: 20%
- Other races/ethnicities: 4%
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
Combination HIV Prevention for PWID

- Syringe service programs
- Condoms
- Combination HIV Prevention for PWID
- HCV/STI Testing and Treatment
- HIV Testing
- PEP/PrEP
- Treatment for substance use disorders

Meta-analysis: PrEP Strategies in Women

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

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

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

At risk for HIV
- Accurate risk perception
- Risk disclosure

PrEP Aware
- Limited awareness among PWID

Linked to a PrEP provider
- Accessing care
- Trust
- Anticipated stigma

Started on PrEP
- Competing priorities (housing, drug treatment, etc.)
- Uninsurance

Adherent to PrEP
- Cognitive impairment
- Ongoing substance use
- Competing priorities

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

Elwyn BMJ 2010; Stacey Cochrane Syst Rev 2014
• **AIM 1:** To create a patient-centered HIV prevention decision aid for women with substance use disorders (SUD) entering treatment.

• **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.
STUDY SETTING
METHODS OVERVIEW

Phase 1
- Decisional needs assessment
- Selection & drafting

Phase 2
- Alpha testing
- Revise prototype
- Training

Phase 3
- Beta testing
PHASE 1: 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

Qin et al. IAPAC, CT ACP, SGIM NE 2019; Qin et al. JIAPAC
INFORMATION
- HIV knowledge and awareness of risk factors
- PrEP awareness

MOTIVATION
- Competing priorities*
- Driving factors
  - HIV Cognitive Biases
  - PrEP Beliefs
  - Health attitudes
  - Perceived Stigma

SKILLS
- Action planning
- Critical thinking
- Impulse control

BEHAVIOR
- HIV testing
- Condom negotiation
- Safe injecting
- Drug treatment
- Engagement in care
"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

Yilu Qin, MD, Carolina Price, MPA, Ronnye Rutledge, MD, MHS, Lisa Puglisi, MD, Lynn M. Madden, PhD, and Jaimie P. Meyer, MD, MS
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

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>No Prep</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do I take Prep?</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>How does Prep work?</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Where can I get Prep?</td>
<td>Prep is available only by prescription. You qualify for Prep if you are at risk for HIV and you are not pregnant.</td>
<td></td>
</tr>
</tbody>
</table>

| | | You will still be at risk for HIV. |
Referral Process:

- Referred (n=177)
  - Unable to reach (n=12)
    - Not eligible (n=9) • HIV+ (n=1)
    - On PrEP or in PrEP study (n=8)
    - Not a WIT (n=3)
  - Screened (n=165)
    - Enrolled (n=125)
      - Decision aid (n=63)
      - SOC (n=62)
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

**Graph:**
- **Proportion of Participants**
- Categories: HIV risk, Perceived at risk, PrEP interest (pre-aid), PrEP interest (post-aid), Linked to PrEP 3m, Linked to PrEP 6m
- **Statistics:**
  - $p=0.12$
  - $p=0.02$
  - $p=0.09$
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
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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
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?