Utilizing a Stepped Care Approach to Address Substance Use and Increase PrEP Initiation and Adherence among Trans Women and Sexual Minority Men

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Background

- Although PrEP is a highly effective biomedical HIV prevention strategy, PrEP initiation, adherence, and persistence are exclusively behavioral outcomes that are abrogated by substance use.

- In the US most (~70%) annual new HIV infections are among substance-using trans women and sexual minority men (SMM; CDC, 2016).

- A majority of trans women who initiate PrEP do not achieve protective adherence level, (Deutsch et al., 2015) and similar outcomes are observed among high-risk SMM (Hosek et al., 2017, Molina et al., 2015).

- Substance use, especially stimulant use, interferes with PrEP initiation among SMM, (Biello et al., 2017) and has repeatedly been shown to reduce rates of PrEP adherence and/or persistence among both trans women and SMM (Hoenigl et al., 2018, Goodman-Meza et al., 2019).

- Substance use disorder (SUD) is also associated with reduced quality-of-life, and increased overdose deaths, utilization of high-cost healthcare services, engagement in a street economy, and cycles of incarceration (Stotzer, 2014, Anderson-Carpenter et al., 2017).

To improve public health, researchers must identify scalable and cost-effective behavioral interventions to promote PrEP initiation, adherence, and persistence among trans women and SMM with a SUD.
Study Aims

Evaluate a Stepped Care approach promoting advancement along the PrEP Care Continuum (initiation, adherence, persistence), \textit{and} reductions in substance use among trans women and SMM with a SUD.

Determine the individual effects of specific substances (e.g., methamphetamine vs. opioids), routes of administration (injection vs. non-injection), severity of SUD (mild, moderate, severe), social and structural determinants of health (e.g., poverty, housing insecurity, food scarcity, educational attainment, lack of insurance), and differing individual-level characteristics (e.g., sexual/gender identity, racial/ethnic identity, age) as moderators of outcomes among trans women and SMM with a SUD.

Estimate the cost of implementing and sustaining each intervention (Stepped Care with: a] A.S.K.-PrEP + CM; b] CM alone) and conduct a cost-effectiveness analysis to determine the value of each intervention relative to SOC, and to each other, from the healthcare-sector, state-policymaker, and societal perspectives.

Evaluate intervention engagement (# A.S.K.-PrEP sessions in the initial 3-months) and intervention response (responders vs. non-responders) by chosen PrEP modality (i.e., oral daily [Truvada or Descovy] or long-acting injectable [Cabotegravir]).
Study Design
Stepped Care Criteria

At 3-month follow-up assessment for those initially randomized to the A.S.K.-PrEP arm (step criteria are not mutually exclusive):

<table>
<thead>
<tr>
<th>Step Criteria Based on PrEP:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>• Has <strong>not</strong> initiated PrEP (either Truvada, Descovy or Cabotegravir)</td>
<td></td>
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<tr>
<td>• On oral daily PrEP but self-reports non-adherence (missed 4 or more days in a row) in past 3 months</td>
<td></td>
</tr>
<tr>
<td>• On long-acting injectable but has <strong>not</strong> received 2nd dose within +/- 7 day of 28 days (i.e., 35 days) after 1st dose</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Step Criteria Based on Substance Use:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Self-reported drug use of the targeted SUD diagnosed at baseline for 1 (or more) day(s) in the past 14 days</td>
<td></td>
</tr>
<tr>
<td>• Positive urine drug screen for targeted SUD diagnosed at baseline</td>
<td></td>
</tr>
</tbody>
</table>
Methods

• Eligibility
  • Self-identified trans woman or SMM
  • 18 years or older
  • Verified HIV negative
  • Identified as “high risk” based on Los Angeles County criteria:
    • Sex without a condom
    • Methamphetamine use
    • Sex with an HIV-positive partner
    • Injection drug use
  • DSM-5 diagnosed SUD (excluding cannabis and alcohol)

• Enrollment began in May 2023
  • Recruitment span will be approximately 36 months, through May 2026
  • Data collection will be completed in June 2027

• Assessment time points and incentives:
  • Screener = $15
  • Baseline = $50
  • 3-month f/u = $50 with a $25 bonus for completing with +/- 7 days of exact due date
  • 6- and 9-month f/u = $75 each
  • 12-month f/u = $100

• Audio Computer Assisted Self Interview (ACASI) administered through Qualtrics
Ready to PrEP?

You’ve got options – a pill or a shot.

☑ Are you a trans woman, or a gay or bisexual man, or a man who has sex with other men?
☑ Are you 18 years or older? Do you use drugs?
☑ Are you HIV-negative?

If yes, you may be eligible to participate in a 6-month PrEP navigation study to help link you to a PrEP provider or help you with your PrEP adherence. Participants will be randomized to 1 of 2 study conditions. Participation also includes an initial assessment and 4 follow-up assessments all at the study site in Hollywood. You may earn up to $455 or $1,250 (based on randomization and study participation) in gift cards.

CALL or TEXT 323-493-6824
AIDS Project of Los Angeles
AFACE

PrEP Makes Sense

It’s like a safety belt for your health.

☑ Are you a trans woman, or a gay or bisexual man, or a man who has sex with other men?
☐ Are you 18 years or older? Do you use drugs?
☐ Are you HIV-negative?

If yes, you may be eligible to participate in a 6-month PrEP navigation study to help link you to a PrEP provider or help you with your PrEP adherence. Participants will be randomized to 1 of 2 study conditions. Participation also includes an initial assessment and 4 follow-up assessments all at the study site in Hollywood. You may earn up to $455 or $1,250 (based on randomization and study participation) in gift cards.

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AIDS Project of Los Angeles
AFACE
Interested in PrEP Options?

You can take a pill or get a shot.

Are you a trans woman, or a gay or bisexual man, or a man who has sex with other men?

Are you 18 years or older? Do you use drugs? Are you HIV-negative?

If so, you may be eligible to participate in a 6-month PrEP navigation study to help link you to a PrEP provider or help you with your PrEP adherence. Participants will be randomized to 3 of 2 study conditions. Participation also includes an initial assessment and 4 follow-up assessments at all sites in the study. You may earn up to $400 or $1,000 based on navigation and study participation gift cards.

CALL or TEXT 323-493-6824
PharmacyCommunityCare.org

It’s Time for PrEP

Taking care of yourself comes first.

Are you a trans woman, or a gay or bisexual man, or a man who has sex with other men?

Are you 18 years or older? Do you use drugs? Are you HIV-negative?

If so, you may be eligible to participate in a 6-month PrEP navigation study to help link you to a PrEP provider or help you with your PrEP adherence. Participants will be randomized to 3 of 2 study conditions. Participation also includes an initial assessment and 4 follow-up assessments at all sites in the study. You may earn up to $400 or $1,000 based on navigation and study participation gift cards.

CALL or TEXT 323-493-6824
PharmacyCommunityCare.org
A.S.K.-PrEP Intervention Delivery System

Session Activities: S1 and S2-5

S1  PrEP Education/Knowledge/Understanding  
Same-day PrEP Linkage  
Discuss Medication Options (Truvada, Descovy, Cabotegravir) & Clinic Options  
Assess for Adherence Barriers

S2-5  Confirm PrEP Initiation  
Assess PrEP Adherence  
Review Adherence Strategies  
Remove/Reduce Barriers  
(substance use, mental health, IPV,  
food insecurity, housing, hormones, sex work)  
Continued Adherence Support
## Support Text Messages

<table>
<thead>
<tr>
<th>Trans Text Messages</th>
</tr>
</thead>
</table>
| SST
Your trans beautiful body is worth protecting, stay on PrEP |
| HBM
Take PrEP to stay healthy and beautiful. If you don't want to take a PrEP pill, you can get a PrEP shot |
| SCT
Hormones are safe to take with PrEP! PrEP is safe to take with hormones! You can do both! |
| SST
Be good to yourself and stay on PrEP, because you are priceless! |
| HBM
Getting frisky doesn't have to be risky, if you are on PrEP |
| SCT
Hey gurl, you can prioritize PrEP, even if you're high |
| SST
Live a trans healthy life, take your PrEP |
| HBM
Don’t be a statistic. We need every trans woman on PrEP |
| SCT
Doing drugs? You can take your PrEP, too |
| SST
Protect your trans beautiful health by taking PrEP |
| HBM
Don’t skip PrEP, gurl, the consequences can be harmful |
| SCT
You can take care of yourself and your trans community by taking PrEP |

<table>
<thead>
<tr>
<th>SMM Text Messages</th>
</tr>
</thead>
</table>
| SST
Take your health seriously by taking PrEP seriously |
| HBM
Take PrEP to stay healthy. If you don't want to take a PrEP pill, you can get a PrEP shot |
| SCT
If you can see your friends, you can get your PrEP |
| SST
Be good to yourself and stay on PrEP, because you are worth it |
| HBM
Getting frisky doesn't have to be risky, if you are on PrEP |
| SCT
You can prioritize PrEP, even if you’re high |
| SST
Stay on PrEP to maintain your negative status |
| HBM
Don’t be a statistic, don’t forget about PrEP |
| SCT
Doing drugs? You can take your PrEP, too |
| SST
Take PrEP before you PnP |
| HBM
Don't skip PrEP, the consequences can be harmful |
| SCT
Take care of yourself, take care of your sex partners, take PrEP |

SST = Social Support Theory  
HBM = Health Belief Model  
SCT = Social Cognitive Theory
<table>
<thead>
<tr>
<th>Week #</th>
<th>Mon</th>
<th>Wed</th>
<th>Fri</th>
<th>Bonus</th>
<th>Weekly Totals</th>
<th>Total Earned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>$2.50</td>
<td>$3.00</td>
<td>$3.50</td>
<td>$7.50</td>
<td>$16.50</td>
<td>$16.50</td>
</tr>
<tr>
<td>Week 2</td>
<td>$4.00</td>
<td>$4.50</td>
<td>$5.00</td>
<td>$7.50</td>
<td>$21.00</td>
<td>$37.50</td>
</tr>
<tr>
<td>Week 3</td>
<td>$5.50</td>
<td>$6.00</td>
<td>$6.50</td>
<td>$7.50</td>
<td>$25.50</td>
<td>$63.00</td>
</tr>
<tr>
<td>Week 4</td>
<td>$7.00</td>
<td>$7.50</td>
<td>$8.00</td>
<td>$7.50</td>
<td>$30.00</td>
<td>$93.00</td>
</tr>
<tr>
<td>Week 5</td>
<td>$8.50</td>
<td>$9.00</td>
<td>$9.50</td>
<td>$7.50</td>
<td>$34.50</td>
<td>$127.50</td>
</tr>
<tr>
<td>Week 6</td>
<td>$10.00</td>
<td>$10.50</td>
<td>$11.00</td>
<td>$7.50</td>
<td>$39.00</td>
<td>$166.50</td>
</tr>
<tr>
<td>Week 7</td>
<td>$11.50</td>
<td>$12.00</td>
<td>$12.50</td>
<td>$7.50</td>
<td>$43.50</td>
<td>$210.00</td>
</tr>
<tr>
<td>Week 8</td>
<td>$13.00</td>
<td>$13.50</td>
<td>$14.00</td>
<td>$7.50</td>
<td>$48.00</td>
<td>$258.00</td>
</tr>
<tr>
<td>Week 9</td>
<td>$14.50</td>
<td>$15.00</td>
<td>$15.50</td>
<td>$7.50</td>
<td>$52.50</td>
<td>$310.50</td>
</tr>
<tr>
<td>Week 10</td>
<td>$16.00</td>
<td>$16.50</td>
<td>$17.00</td>
<td>$7.50</td>
<td>$57.00</td>
<td>$367.50</td>
</tr>
<tr>
<td>Week 11</td>
<td>$17.50</td>
<td>$18.00</td>
<td>$18.50</td>
<td>$7.50</td>
<td>$61.50</td>
<td>$429.00</td>
</tr>
<tr>
<td>Week 12</td>
<td>$19.00</td>
<td>$19.50</td>
<td>$20.00</td>
<td>$7.50</td>
<td>$66.00</td>
<td>$495.00</td>
</tr>
</tbody>
</table>

**Maximum CM Payout:** $495.00
### Baseline Sociodemographics as of 5/15/24 (n=94)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>n (%) or Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex/Gender</td>
<td>Male (cisgender)</td>
<td>82 (87.2%)</td>
</tr>
<tr>
<td></td>
<td>Trans female/feminine</td>
<td>12 (12.8%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>45 (13.2)</td>
</tr>
<tr>
<td>Race/Ethnicity*</td>
<td>Latinx</td>
<td>30 (26.6%)</td>
</tr>
<tr>
<td></td>
<td>White</td>
<td>21 (18.6%)</td>
</tr>
<tr>
<td></td>
<td>African American/Black</td>
<td>38 (33.6%)</td>
</tr>
<tr>
<td></td>
<td>Other/Multi</td>
<td>24 (21.2%)</td>
</tr>
<tr>
<td>Sexual Identity</td>
<td>Gay</td>
<td>43 (43.8%)</td>
</tr>
<tr>
<td></td>
<td>Bisexual</td>
<td>32 (33.3%)</td>
</tr>
<tr>
<td></td>
<td>Heterosexual/Straight</td>
<td>9 (9.4%)</td>
</tr>
<tr>
<td>Unstable Housing</td>
<td>Other</td>
<td>10 (12.5%)</td>
</tr>
<tr>
<td>Education Attainment</td>
<td>Yes</td>
<td>39 (40.6%)</td>
</tr>
<tr>
<td></td>
<td>Less than High School</td>
<td>11 (11.5%)</td>
</tr>
<tr>
<td></td>
<td>High School Diploma/GED</td>
<td>26 (27.1%)</td>
</tr>
<tr>
<td></td>
<td>Some College</td>
<td>36 (28.1%)</td>
</tr>
<tr>
<td></td>
<td>College Graduate/Postgraduate</td>
<td>21 (21.8%)</td>
</tr>
</tbody>
</table>

*not mutually exclusive
# Substance Use Disorder at Baseline as of 5/15/24 (n=94)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methamphetamine</td>
<td>6</td>
<td>4</td>
<td>48</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>2</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Cocaine</td>
<td>2</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Hallucinogens</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Inhalants</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Opiates</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>PCP</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sedative/Benzo</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>10</td>
<td>9</td>
<td>75</td>
</tr>
</tbody>
</table>
PrEP Initiation as of 5/15/24

- Slightly over one-third, n=94 (38%), of the total # of participants have enrolled in the study; 70 have been randomized into the A.S.K.-PrEP arm and 24 into the Standard of Care (SOC) arm

- 58/70 (83%) of those randomized to A.S.K.-PrEP have been linked to a PrEP provider

- As of 5/15/24, 52 participants completed their 3-month follow-up assessment

**At the 3-month follow-up assessment,**
23/35 (57%) of those randomized to A.S.K.-PrEP initiated PrEP
  - 21 initiated oral-daily PrEP
  - 2 initiated long-acting injectable PrEP

**At the 3-month follow-up assessment,**
4/17 (24%) of those randomized to SOC initiated PrEP
  - 2 initiated oral-daily PrEP
  - 2 initiated long-acting injectable PrEP
Stepped Care Status as of 5/15/24

- **At the 3-month follow-up assessment**, 27/35 (77%) have been identified as non-responders based on the following criteria (not mutually exclusive):
  - Did not initiate PrEP = 15
  - On oral daily but non-adherent = 3
  - On LAI but no 2nd dose = 0
  - Self-reported drug use of targeted SUD = 14
  - Positive urine drug screen for targeted SUD = 11

- 14/27 (52%) of non-responders were re-randomized to **A.S.K.-PrEP + CM**
- 13/27 (48%) of non-responders were re-randomized to **CM alone**

- Out of a possible 948 CM visits, 337 were attended (36%)
  - 293/337 (87%) had a nonreactive urine sample for their targeted SUD

- Among those randomized to **A.S.K.-PrEP + CM**, out of a possible 496 CM visits, 163 were attended (33%)
  - 128/163 (79%) had a nonreactive urine sample for their targeted SUD

- Among those randomized to **CM alone**, out of a possible 452 CM visits, 174 were attended (38%)
  - 165/174 (95%) had a nonreactive urine sample for their targeted SUD
Conclusions

There is an urgent need for effective, scalable behavioral interventions that can encourage PrEP initiation and advancement along the PrEP Care Continuum.

**Sociodemographics & SUD**
To date, most participants have identified as gay/bisexual SMM and BIPOC. Mean age: 45 years (13.2). 41% reported unstable housing, and 39% earned a high school diploma or less. Most participants (62%) were diagnosed with a Methamphetamine Use Disorder; 51% severe.

**PrEP Linkage & Initiation**
PrEP linkage has been strong with 83% in the A.S.K.-PrEP arm linked to a PrEP provider. PrEP initiation has been greater among those in the A.S.K.-PrEP arm than those in SOC (57% vs. 24%).

**Stepped Care**
At 3-mo f/u, 27/35 (77%) were identified as a non-responder, primarily due to non-PrEP initiation (56%) and/or substance use (52%) and stepped up to a CM intervention.

**Contingency Management**
Thus far, adding PrEP navigation (A.S.K.-PrEP) to CM has not increased attendance at CM visit, nor increased nonreactive urine samples for targeted SUD.

Recruitment and enrollment will continue through May 2026.


Hoenigl M, Jain S, Moore D, et al. Substance use and adherence to HIV preexposure prophylaxis for men who have sex with men. *Emerging Infectious Diseases*. 2018;24(12):2292


Acknowledgements

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Thank You!

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reback@friendsresearch.org