Enhancing Pre-Exposure Prophylaxis (PrEP) Adherence in Men Who Have Sex with Men: Determining Optimal Content for a PrEP Adherence Package

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What We Know…

- **The iPrEx Study:** Adherence to PrEP was associated with greatly increased protection from HIV infection.

- **The FEM-PrEP Study:** Along with other variables, inadequate adherence may have contributed to the 33 HIV-infections before study was discontinued.

- **Partners PrEP Study:** Drug levels/adherence correlated with protective effect.

- **Cognitive Behavioral Therapy (CBT)-based** adherence interventions have been associated with improved adherence to ART.
Project PrEPare

**Purpose:** To determine the optimal content for a PrEP adherence intervention for MSM who are at high risk for HIV acquisition and to test its feasibility in a RCT.

**Stage 1: Formative Exploration**

- **Focus groups**
  - Two groups of former participants in one of two PrEP trials conducted at Fenway Health
  - Two groups of naïve participants

**Stage 2: Open Pilot (N=10)**

**Stage 3: Feasibility RCT (N=50)**
Focus Group Procedures

Focus Group Entry Criteria

<table>
<thead>
<tr>
<th>PrEP Experienced</th>
<th>PrEP Naïve</th>
</tr>
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<tbody>
<tr>
<td>MSM</td>
<td>MSM</td>
</tr>
<tr>
<td>HIV-uninfected</td>
<td>HIV-uninfected</td>
</tr>
<tr>
<td>UAI in past 3 months</td>
<td>UAI in past 3 months</td>
</tr>
<tr>
<td>Participated in iPrEX or CDC PrEP studies</td>
<td>PrEP Naïve</td>
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</tbody>
</table>

- 4 groups <12 participants per group (total N=39)
- Duration: ~2 hours
- Facilitated discussion
- Semi-structured interview guide
- M.D. in attendance to field specialized medical questions
Setting: Fenway Health

- Founded 1971: Primary care neighborhood health center
- Diverse populations, specializing in care for sexual and gender minorities
- Largest primary care center for LGBT patients in New England
- >20,000 primary care patients
- >1700 HIV+ patients in care
Methodology

Qualitative Description
- Naturalistic Inquiry
- Low-level interpretation

Content Analysis
- Within-case/across-case review
- Line-by-line coding

Significant Statements
- Emerging themes
- Integration into the literature and/or intervention
## Participant Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>PrEP Groups (N=19)</th>
<th>Naïve Groups (N=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (in years)</strong></td>
<td>44.37 (6.98)</td>
<td>44.05 (11.00)</td>
</tr>
<tr>
<td><strong>Sexual Orientation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterosexual/straight</td>
<td>1 (5.0)</td>
<td>2 (10.5)</td>
</tr>
<tr>
<td>Homosexual/gay</td>
<td>13 (65.0)</td>
<td>11 (57.9)</td>
</tr>
<tr>
<td>Bisexual</td>
<td>4 (20.0)</td>
<td>3 (15.8)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (5.0)</td>
<td>3 (15.8)</td>
</tr>
<tr>
<td><strong>Racial Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black/African American</td>
<td>5 (25.0)</td>
<td>12 (63.2)</td>
</tr>
<tr>
<td>White</td>
<td>15 (75.0)</td>
<td>6 (31.0)</td>
</tr>
<tr>
<td>American Indian</td>
<td>0 (0)</td>
<td>1 (5.3)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High School or Less</td>
<td>6 (30.0)</td>
<td>6 (31.6)</td>
</tr>
<tr>
<td>Some College</td>
<td>3 (25.0)</td>
<td>4 (21.1)</td>
</tr>
<tr>
<td>College Graduate</td>
<td>5 (25.0)</td>
<td>4 (21.1)</td>
</tr>
<tr>
<td>Graduate Work</td>
<td>6 (30.0)</td>
<td>5 (36.0)</td>
</tr>
<tr>
<td><strong>Alcohol Use (any)</strong></td>
<td>11 (55.0)</td>
<td>15 (79.0)</td>
</tr>
<tr>
<td><strong>Substance Use (any)</strong></td>
<td>11 (55.0)</td>
<td>11 (57.9)</td>
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</tbody>
</table>
5 Emerging Themes
I think there needs to be more education about how it (PrEP) effects our health, because I read an article and it wasn’t clear to me. I wasn’t convinced that this really can benefit the community.

AA, 48 y/o, Naïve

What if someone’s taking this inconsistently, and they do become positive, and they’ve taken it for a long time, they probably wouldn’t be able to take this once they became positive, right?

C, 49 y/o, Naïve
I wanted the protection. And then the idea of contributing to a larger good, that this might become common knowledge that this pill works... But my primary motivation was my behavior was not under control; I want to find out if this pill can protect me.

C, 52 y/o, PrEP

Being part of something that was part of the community -- that’s why I got involved. It gave me what I was looking for. There’s no doubt about that. Very positive.

C, 50 y/o, PrEP
Potential Barriers to Adherence

**Mental Health Burdens:** I have problems with anxiety and insomnia. When it was at its worst, it was when I couldn’t take the medication.

C, 44 y/o, PrEP

**Perceived Stigma:** Truvada is a medication for people who are HIV, right? If somebody finds out you’re taking Truvada, they’re going to think you’re HIV.

AA, 48 y/o, Naïve

**Provider Relationship:** Some people aren’t “out” to their provider, let alone telling them ‘I’m engaged in risky sexual behaviors.’ I think those conversations don’t happen very often.

C, 38 y/o, PrEP
Potential Facilitators of Adherence

C, 51 y/o, PrEP

I have a double ritual [schedule], which is at night I take the pill out and I put it by the bed, so in the morning, I take it.

C, 38 y/o, PrEP

I travel with it, so if I was going to work, I’d put it in a bag with vitamins and have a couple extra, because if I forgot it at home, I would take it at work.

AA, 45 y/o, Naïve

You could have phone calls, or emails, telling you to take it, just automatically generated on a daily basis.
Sexual Decision Making

The first thing that comes to mind when I hear about a pill such as that would be that I could push the condom aside and I can have this pill, so if something goes wrong this is the contraceptive.

AA, 30 y/o, Naïve

I’m thinking to myself, if I fell in love with somebody who was HIV-positive, and I was a “bottom,” that PrEP would be perfect for me. It would allow us to have a little bit less stress around our intimacy. And, I’m not saying we shouldn’t still be safe.

C, 30 y/o, Naïve
How Can These Themes Inform a PrEP Adherence Intervention?

<table>
<thead>
<tr>
<th>Emerging Themes</th>
<th>Putative Intervention Content Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrEP Education</td>
<td>Information&lt;br&gt;Empirically informed curricular content</td>
</tr>
<tr>
<td>PrEP Motivations</td>
<td>Identify individualized motivated targets for adherence</td>
</tr>
<tr>
<td>Barriers to Adherence</td>
<td>Adherence Problem Solving</td>
</tr>
<tr>
<td>Facilitators of Adherence</td>
<td>Novel approaches (e.g., texting, smartphone apps, creative dosing, storage)</td>
</tr>
<tr>
<td>Sexual Decision Making</td>
<td>Sexual risk appraisal, sexual risk education, PrEP disclosure</td>
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Project PrEPare: Next Steps

- Openly pilot CBT-based adherence intervention with up to 10 participants
  - Adapt implementation iteratively
  - Augment the CBT-based intervention
  - Use wise pill delivery/text messaging

- Randomized Control Trial: Pilot (N=50)
  - To conduct a feasibility RCT trial of a PrEP prescription plus adherence package compared to an active, time-matched control:
    - Experimental group: **Novel CBT-based Adherence Intervention**
    - Comparison/control group: **Health Education and Supportive Counseling**
Acknowledgments

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**Focus group physician**
- Dr. Douglas Krakower

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