Improving the PrEP Care Continuum for Sexual and Gender Minorities: Diverse Strategies for Diverse at-risk Groups

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• Trends in HIV incidence in the United States differ across risk groups

HIV Prevention Works!

Ways to Prevent HIV:
- Test
- Condoms
- Prep
- U=U

Source: London HIV Prevention Programme
PrEP for HIV Prevention

- Daily oral PrEP works—with near perfect efficacy—when taken as prescribed

- PrEP is underutilized and, among those who take PrEP, adherence is suboptimal
Barriers to Optimal PrEP Use

How do we support individuals—often with complex barriers—to use PrEP consistently and correctly?

PrEP for Young MSM
MyChoices

Mobile app designed to increase HIV testing and support PrEP uptake among YMSM
Prototype Development - complete
• 6 focus groups with 33 YMSM in Boston, Chicago and Los Angeles that led to prototype
• Led to major changes in UI, functionalities

Theater Testing - complete
• 4 groups with 28 YMSM in Boston, MA and Bronx, NY
• Led to adjustments to format and language

Open Technical Pilot - complete
• 11 YMSM across in Boston, MA and Bronx, NY
• Led to improvements in internal processes

Pilot RCT – in final follow up
• 60 YMSM in Boston, MA and Bronx, NY
• Ensure feasibility and acceptability

3-Arm RCT Efficacy Trial – start date: TBD
• Must meet go/no-go criteria in pilot RCT
• 450 YMSM in 7 cities across the US
• Will assess efficacy to improve HIV testing and PrEP uptake compared to another app and SOC (i.e., referrals)

MyChoices Pilot RCT – Preliminary Results

**Age**
- Age Range: **16-24 years**
- Average: **21 years**

**Race**
- 5% Black, Non-Hispanic
- 15% Hispanic
- 58% White, Non-Hispanic

- Average app usage: **5 times** (range: 1-11) over 3 months
- Average duration: **4.1 minutes** per session (range: 0-33) over 3 months

- Mean System Usability Scale (0-100) score: **75** (i.e., above-average)
- 86% reported MyChoices was **useful**
- 84% would **recommend** MyChoices to a friend
The pipeline of non-vaccine HIV prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable antiretrovirals and more. Also pictured are the range of multipurpose prevention technologies in development that aim to reduce the risk of HIV and STIs and/or provide effective contraception for women. (Visit www.avac.org/hvad for vaccine and broadly neutralizing antibody pipelines.)

### Multipurpose Prevention Technologies (MPTs)

<table>
<thead>
<tr>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II/III</th>
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<tbody>
<tr>
<td>Preclinical</td>
<td>IPM*</td>
<td>GSK/ViV</td>
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<tr>
<td>Merck</td>
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<td>Gilead</td>
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<td>IPM</td>
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<td>IPM</td>
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<td>Northwestern University</td>
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<td>University of Pittsburgh</td>
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### Delivery System

- **Oral pills**
- **Vaginal gel**
- **Vaginal ring**
- **Vaginal film**
- **Phosphate buffered saline**
- **Enema**
- **Fast-dissolving insert**
- **Intrauterine device**
- **Vaginal tablet**
- **Rectal gel**
- **Long-acting injectable**
- **Micro-array patch**
- **Nano-fiber**
- **Subcutaneous injection**
- **Diaphragm**
- **Implant**

### Active Drug

- **TFV**
- **TDF**
- **NNRTI**
- **NNRTI**
- **CART**
- **ART**
- **ART**
- **ART**
- **ART**
- **ART**
- **ART**

* This formulation is for a 3-month vaginal ring.
Next Generation PrEP

- YMSM’s recruitment in these next generation PrEP trials has been limited, particularly youth under 18 years

- Limited research has examined the perceived acceptability of emerging modalities among YMSM

- Even if found to be efficacious, the absence of YMSM’s perspectives on product characteristics could lead to low acceptability, slow uptake and suboptimal adherence
PrEP Product Preferences – a National Online Survey

- Led by Biello and Mayer, funded by Viiv
- Brief (~10 min) online assessment
- 4600+ MSM/TGMSM/TGWSM in US via 2 hookup apps
  - 18+ y/o; HIV(-); assigned male sex and/or identified as male; reported ever having anal sex with a man
  - Push notifications asking for their participation were sent daily (for 10 days) to all active users of each app in March 2016 (n=>1 million)

Product Interest and Preference

Preference for Injectable vs. Daily Pill

- 47% Injectable PrEP
- 36% Daily Pill
- 17% Unsure

Very interested
Somewhat interested
Neutral
Somewhat uninterested
Very uninterested
<table>
<thead>
<tr>
<th>Measure</th>
<th>aOR (95% CI)</th>
<th>p</th>
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<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-21</td>
<td>1.71 (1.05, 2.79)</td>
<td>0.031</td>
</tr>
<tr>
<td>22-25</td>
<td>1.71 (1.14, 2.55)</td>
<td>0.010</td>
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<tr>
<td>26-29</td>
<td>1.97 (1.33, 2.93)</td>
<td>0.001</td>
</tr>
<tr>
<td>30-39</td>
<td>1.94 (1.41, 2.68)</td>
<td>&lt;0.001</td>
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<tr>
<td>40-49</td>
<td>1.11 (0.81, 1.51)</td>
<td>0.528</td>
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<tr>
<td>50+</td>
<td>1.0</td>
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<tr>
<td><strong>Race/ethnicity</strong></td>
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<td></td>
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<tr>
<td>White</td>
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</tr>
<tr>
<td>Black</td>
<td>1.58 (1.17, 2.12)</td>
<td>0.003</td>
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<tr>
<td>Latino</td>
<td>1.45 (1.00, 2.12)</td>
<td>0.053</td>
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<tr>
<td>Asian/PI</td>
<td>1.18 (0.71, 1.96)</td>
<td>0.513</td>
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<tr>
<td>Multiracial</td>
<td>1.03 (0.67, 1.57)</td>
<td>0.906</td>
</tr>
<tr>
<td>Other</td>
<td>1.12 (0.46, 2.73)</td>
<td>0.801</td>
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<tr>
<td><strong>Condomless anal sex acts, past 3 mos.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1.0</td>
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<tr>
<td>1</td>
<td>1.11 (0.78, 1.57)</td>
<td>0.559</td>
</tr>
<tr>
<td>2+</td>
<td>1.52 (1.21, 1.91)</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>Oral PrEP experienced</strong></td>
<td></td>
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<tr>
<td>Yes</td>
<td>1.39 (1.02, 1.89)</td>
<td>0.038</td>
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Qualitative Examination of New Product Preferences

- 6 focus groups with 36 YMSM/TGMSM/TGWSM in Boston (n=8), Chicago (n=20) and Los Angeles (n=8)
  - 15-29 y/o; HIV(-); assigned male sex and/or identified as male; reported CAS with a man in the 3 mos. prior
  - PrEP experienced and PrEP naïve groups

- FG domains: perceived barriers, advantages/ disadvantages to oral and injectable PrEP

Focus Group Results

- Barriers to PrEP
  - Stigma
  - Lack of knowledge/narrow targeting
  - Preferences for injectables
  - Depend on prior PrEP experience
  - Ppl with adherence difficulties and/or more frequent sex
  - Concerns about injectables
    - Frequent visits, missed injections
    - Length of side-effects
    - Injecting foreign substance/mistrust
  - Other modalities
    - On-demand method

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**Mean (SD)**
- Number condomless anal sex partners, past 3 months (range 0-15): 1.6 (2.7)
- Race/ethnicity:
  - Latino: 17%
  - Black, non-Latino: 69%
  - White, non-Latino: 6%
  - Other: 8%
- Male gender identity: 67%
- High school diploma or less: 59%
- Past year STI test: 81%
- Past year HIV test: 83%
- Ever PrEP use: 36%

**Quotes**

- "We [Black MSM] have too many stories and reasons not to trust vaccines."
  (Boston participant, PrEP experienced group)

- "I would stay with the pill. I don’t know exactly how much of a dose the 3 month shot would be and I’m concerned about side effects."
  (Chicago participant, PrEP experienced group)

- "I am very forgetful and sometimes even forget to take my pills. Having an injection every 3 months...would be so much easier to keep track of, just put it in my calendar."
  (LA participant, PrEP naïve group)

- "Not everyone is sexually active every single day so not everyone wants to take a pill everyday if they don’t need it. It would be better if you could just take the pill around the time you know you’ll be sexually active."
  (LA participant, PrEP naïve group)

- "All the advertisements for PrEP seem to be targeted only at gay men and I never see them for trans women or even just women...it’s not advertised enough for us to be like ‘Oh, we can do it, too’" (LA participant, PrEP naïve group)
NextChoices

• ATN/iTech protocol seeks to ensure the inclusion of YMSM’s perspectives (age 15-24 years) as next generation biomedical prevention products are being developed
  • SA1: Use natural language processing techniques to analyze social media content in order to improve our ability to inform message framing and communicate with youth about next generation biomedical prevention
  • SA2: Conduct up to 20 cognitive interviews to improve measures and methods to assess preferences for diverse HIV prevention products in acceptability surveys
  • SA3: Examine via a national web-survey (N≈1500) acceptability of next generation biomedical prevention
PrEP for Male Sex Workers
Male Sex Workers are at high risk for HIV

- Men who engage in transactional sex with other men in the US have nearly **25 times** the risk of HIV compared to other men.

- Sex work is associated with:
  - more sexual partners
  - more frequent anal sex
  - higher burden of psychosocial problems, including substance use

- Street-based MSM sex workers have the highest rates of HIV risk behavior with clients and non-transactional partners.
The NEXUS Study

- Longitudinally evaluate and describe the social, sexual, and drug abuse networks of high-risk MSM sex workers in Boston and Providence

- Enrolled 100 men who engage in frequent transactional CAS

- NIDA-funded R21 (MPIs: K. Biello, M. Mimiaga)
PrEP for MSWs

- MSWs who identified as gay were 3 times as likely to have heard of PrEP compared to those who did not identify as gay.

- Targeted expansion of PrEP to MSWs, new HIV infections would be reduced by 58% and cost-effectiveness of PrEP would improve by 60%.

PrEP Barriers among MSWs

- Cost/lack of insurance
- Disclosure of sexual behavior to providers
- Inconsistent routines
- Need for covert use
- Fluctuating periods of risk
- Heavy substance use
- Concerns about side effects and risks

PrEPare for Work Intervention

- NIMH R34 (MPIs: Biello, Mimiaga, Chan)
- “PrEPare for Work” addresses uptake of PrEP, and provides skills training to optimize adherence
  - Based on the Social Cognitive Theory and uses principles of motivational interviewing and cognitive behavioral therapy
- A pilot RCT of 110 MSWs in Rhode Island, using a two-stage randomization
  - Stage 1: Strength-based Case Management for PrEP uptake
  - Stage 2: CBT-based PrEP adherence counseling by a trained, masters-level counselor with daily text messaging
P4W Preliminary Results

• Participants randomized to SBCM were nearly 3 times as likely (95% CI=1.46-5.27, p=.001) to initiate PrEP compared to those in SOC.

• In Stage 2, participants randomized to the CBT-based adherence counseling were 1.6 times as likely to be adherent to PrEP compared to those in SOC.

Figure 2. Proportion of PrEP initiators by intervention condition, pilot RCT of PrEPare of Work (n=110)

- SOC: 20% PrEP Starters, 80% PrEP Non-starters
- SBCM: 56% PrEP Starters, 44% PrEP Non-starters

Straightforward, simple, fast, efficient

All the resources were there, it was perfect!

I had a great experience

Discrete yet welcoming

Looking ahead…

• Continue developing and testing technology-enhanced interventions

• Integrating new prevention modalities as they come to market

• Focusing on highest risk, and most marginalized, groups – SGM youth, sex workers, transgender women and PWID

• Responding to U=U by developing and testing interventions to improve adherence and viral suppression among PLWH

• Local, regional, national and international
  • MA, RI, Northeast, US, India, Vietnam, Brazil
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