Sexual Risk Behaviors and Sexually Transmitted Infections Among MSM participating in the US PrEP Demo Project

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THE DEMO PROJECT

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Background

• Several RCTs have shown that daily oral TDF/FTC is effective in preventing HIV infection1-4

• Whether individuals taking PrEP will increase sexual risk behavior (i.e. risk compensation) is unclear

• PrEP demonstration projects, in which clients are educated about the efficacy of TDF/FTC and take it in an open-label fashion, are optimal settings for assessing whether risk compensation occurs

1 Grant NEJM 2010; 2 Baeten NEJM 2012; 3 Thigpen NEJM 2012; 4 Choopanya Lancet 2013

The Demo Project

• Multisite, open-label PrEP Demonstration Project in MSM and transgender women in two STD clinics and a community health center in the US

• Key objectives
  – PrEP uptake1-2
  – Adherence and retention1-3
  – Safety and tolerability4
  – HIV incidence and resistance3
  – Sexual behaviors
  – STI incidence

1 Cohen S CROI 2014, 2 Cohen JAIDS 2015; 3 Liu IAS 2015

Methods: Demo Project Sites

San Francisco City Clinic (N=300)

Miami-Dade County Downtown STD clinic (N=157)

Whitman Walker Health, Washington, DC (N=100)

Annual HIV seroconversion rate among MSM >2% across clinics

Methods: Eligibility and follow-up

• HIV-negative MSM and transgender women enrolled between Oct 2012 - Jan 2014

• Behavioral risk criteria (last 12 mo):
  – Condomless anal sex with 2+ partners
  – 2+ episodes of anal sex with HIV+ partner
  – Self-reported diagnosis of syphilis, rectal gonorrhea or rectal chlamydia

• CrCl ≥ 60 ml/min, negative/trace protein on urine dipstick, HBsAg negative

• Participants offered up to 48 weeks of TDF/FTC PrEP

• Followed at weeks 4, 12, 24, 36 and 48 for HIV/STI testing, counseling, clinical monitoring, drug level testing and PrEP dispensation
Methods: Assessment of sexual risk

- At screening and quarterly visits, participants completed an interviewer administered questionnaire regarding sexual and drug use behaviors, HIV risk perception, and serosorting intentions
- Composite measure of sexual risk assessed using modified “San Diego Early Test” (mSDET) Score:
  In the last 3 months -
  - Any condomless receptive anal sex (CRAS) with HIV+ partner (3 points)
  - Combination of any CRAS plus ≥ 2 male anal sex partners (3 points)
  - ≥ 5 male anal sex partners (2 points)

\(^{1}\)Hoenigl CID 2015

Baseline characteristics of enrolled participants (N=557)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median)</td>
<td>35 years with 20% &lt; 25 years</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>48%</td>
</tr>
<tr>
<td>Latino</td>
<td>35%</td>
</tr>
<tr>
<td>Black</td>
<td>7%</td>
</tr>
<tr>
<td>Other</td>
<td>10%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>98%</td>
</tr>
<tr>
<td>Transgender</td>
<td>3%</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
</tr>
<tr>
<td>≤ High School</td>
<td>15%</td>
</tr>
<tr>
<td>Some college or higher</td>
<td>85%</td>
</tr>
<tr>
<td>Any recreational drug use</td>
<td></td>
</tr>
<tr>
<td>Popper, cocaine, meth, or club drug use</td>
<td>74%</td>
</tr>
<tr>
<td>Number of anal sex partners, past 3 months (mean)</td>
<td>11</td>
</tr>
<tr>
<td>Condomless receptive anal sex, past 3 mo</td>
<td>67%</td>
</tr>
<tr>
<td>HIV+ primary partner</td>
<td>24%</td>
</tr>
<tr>
<td>Lab confirmed STI (GC, CT, syphilis) at baseline</td>
<td>20%</td>
</tr>
</tbody>
</table>

Methods: Statistical analysis

- Trends over time in absolute numbers of sexual partners and episodes, by partner HIV status, position and condom use were assessed using orthogonal contrasts in the weekly means, based on a Poisson regression model with robust standard errors to account for clustering by participant of the repeated outcomes.
- Covariate effects on changes in the mSDET scores were also estimated using Poisson models with robust SEs, using interactions between each covariate and an indicator for follow-up vs baseline.
- Heterogeneity across weeks in positivity of STI tests was assessed using logistic models with robust SEs to account for clustering.

# Anal Sex Partners, by HIV status and condom use

Sig decline in total # of sex partners from 10.9 to 5.3

# Insertive and Receptive Anal Sex Episodes, by condom use

Mean number of anal sex episodes declined from 34.8 to 28.1 (p=0.007)

Serosorting Practices

CRAS = Condomless receptive anal sex
CIAS = Condomless insertive anal sex
CAS = Condomless anal sex

\(^{1}\)Hoenigl CID 2015
**Serosorting Intentions:**
“When having sex with an HIV-positive partner I would…”

**HIV Risk Perception**

Change in overall risk as measured by mSDET risk score

Results: STI positivity

Limitations
- Sexual risk behavior collected by interviewer-administered questionnaire, subject to social desirability bias
- Observational cohort with no comparison group
- Non-differential follow-up by level of risk could bias results
- Blacks and transgender women underrepresented
- Results may not generalize to broader MSM populations in these or other US cities, international settings
- Demo Project provided risk reduction counseling at each quarterly visit, may not apply in settings in which counseling not offered

Conclusions
- By multiple measures, including number of anal sex partners, episodes and a composite sexual risk score, sexual risk behavior was stable or declining over the course of the study.
- While self-reported behaviors did not reflect a change in seroadaptive practice, intentions around seroadaptation did change; over time, this could have implications for sexual networks and STI risk.
- 50% of participants had a variation in risk score from visit to visit – re-assessing risk among clients using PrEP is important.
- High incidence of STIs reflects importance of comprehensive sexual health support and quarterly STI screening, including testing at extragenital sites, for MSM taking PrEP.
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Study participants

mSDET Score (distribution and mean) over time