Supplemental Digital Content 1

*Standardized script for verbal consent for pre-screening*

“We want to tell you a little about PrEP, and to see if you are eligible to get PrEP through a demonstration project here. PrEP involves taking one pill daily to help prevent HIV infection. This pill contains two medications that are routinely used to treat people with HIV. Studies with men who have sex with men (MSM) and transgender women showed that people who took PrEP were less likely to become infected with HIV than those who did not take it, and had minimal side effects. Do you have any questions about PrEP at this point? I would like to ask you a few questions to see if this might be a good option for you. It will only take a few minutes of your time and your name is not linked to these questions. If you are eligible we’ll discuss PrEP and the study in more detail, and you can decide if you think PrEP is right for you. Do you have any questions about this? May I now ask you the questions?”
PrEP

Pre-Exposure Prophylaxis Demonstration Project
We need new HIV prevention strategies.

- HIV infections are increasing worldwide. 34,000,000 living with HIV/AIDS. (2.5 million/year)
- In SF, an estimated 10-15 new infections will occur every week. In 2011, 1 in 5 men who have sex with men (MSM) were HIV positive in San Francisco.
- In the U.S., more than 50,000 people are estimated to have become infected each year since the mid- to late-1990s. That’s about 800,000 new infections since then.
What is PrEP?

- **Pre-Exposure Prophylaxis (PrEP)** is an HIV prevention method. People who do not have HIV take anti-HIV medication, like **Truvada**, daily to try to help prevent HIV infection.
What is Truvada?

• Made by Gilead Sciences, Inc.

• FDA approved for the treatment of HIV infected individuals and, recently, for HIV prevention in combination with safer sex practices.

Truvada contains two anti-HIV medications: tenofovir and emtricitabine
Why Truvada?

• Truvada has been safely used in combination with other drugs to treat HIV infected people.
• Truvada has also been taken safely in HIV-negative people for prevention.
• Truvada is well tolerated and serious side effects are rare.
Why Truvada?

• The iPrEx study showed that HIV-negative men who have sex with men (MSM) and transwomen given daily Truvada were less likely to become infected with HIV, compared with those given a placebo (dummy pill).
2499 participants
risk-reduction counseling
Of the 36 participants in the Truvada group who contracted HIV, only 9% had detectable levels of the medication in their blood. Some people in iPrEx had difficulty taking Truvada every day.
We know only people who have Truvada in their body at the time of HIV exposure can benefit from it.
Taking Truvada daily is important.

For people who take PrEP regularly, protection from HIV could be as high as 90%.
PrEP Demonstration Project

This study will explore how PrEP can be provided to MSM and transwomen as an HIV prevention method in real world settings such as STD clinics.
What do we want to know?

• **Who** is interested in taking PrEP, for how long, and how frequently they take the medication.

• Whether there will be any change in the **risk behaviors** of PrEP participants.
This study will enroll 600 participants: 100 participants in Washington, DC, 200 participants in Miami, and 300 in San Francisco.
• All participants will receive once **daily** Truvada for up to **12 months.**
If you choose to participate...

• All visits will be conducted at City Clinic.
• You’ll have up to 8 scheduled visits.
Study Visits

• Screening visit: Today
• Enrollment visit: 1-2 weeks after today
• Post enrollment follow up:
  • 1 month after enrollment
  • every 3 months after enrollment
Demonstration Project Timeline

- Screening: Today
- Enrollment: 1-2 weeks
- 1 month
- 3 months
- 6 months
- 9 months
- 12 month study stop
- Follow-up
- Post stop visit: 1 month after stop

○ Indicates study visit
Screening

1. Complete forms and review informed consent

2. Provide brief medical history and physical exam, if needed

3. Provide samples for lab tests, HIV testing, and STD screening

4. Answer questions about demographics and sexual/drug use behavior
Enrollment Visit

1. Brief medical history and physical exam, if necessary

2. HIV testing

3. Risk reduction and adherence counseling and condoms

4. Receive PrEP medication
A few things to consider...

Potential side effects of Truvada include: stomach problems, headache, dizziness, rash, and gas.

PrEP isn't 100% effective and should be combined with other prevention strategies.

There will be blood draws and urine collected at study visits.

You will be asked personal questions about your sexual behaviors and drug use.

You will receive regular HIV and STD testing, and risk reduction counseling.
Follow-up Study Visits

1. Brief medical history and physical exam, as necessary

2. Provide samples for lab tests, HIV testing, STD screening, and monitoring medication levels

3. Answer questions about sexual/drug use behavior

4. Discuss PrEP use and HIV prevention efforts

5. Receive PrEP medication
HIV infection and drug resistance

If you become infected with HIV during this study and continue to take Truvada, there is a risk that the virus may become resistant to one or both of the medications in Truvada.

Truvada contains two anti-HIV medications: tenofovir and emtricitabine.
Study Benefits

- Receive daily PrEP for up to 48 weeks at no cost
- Testing for HIV and other STIs
- Risk reduction counseling and condoms to help protect your sexual health
- Testing and free vaccination for hepatitis B
- You will contribute to an important public health study to help find new ways to administer HIV prevention
Your participation is **voluntary**.

You may quit the study **at any time** without affecting your relationship with or ability to access services through the San Francisco Department of Public Health.

Taking **PrEP** is a personal choice.
Thank you for your time!

When you are finished with this slideshow, please let study staff know.
### eTable 1. Reasons for enrolling in The Demo Project

<table>
<thead>
<tr>
<th>Reason</th>
<th>Listed as main reason N (%)</th>
<th>Included as one reason N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>To protect myself against HIV</td>
<td>371 (66.6)</td>
<td>549 (98.6)</td>
</tr>
<tr>
<td>To help the community/to help fight the HIV epidemic</td>
<td>83 (14.9)</td>
<td>499 (89.6)</td>
</tr>
<tr>
<td>Because my partner has HIV</td>
<td>58 (10.4)</td>
<td>164 (29.4)</td>
</tr>
<tr>
<td>To make it safer for me to have sex without condoms</td>
<td>26 (4.7)</td>
<td>328 (58.9)</td>
</tr>
<tr>
<td>Wants to contribute to research</td>
<td>10 (1.8)</td>
<td>20 (3.6)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (0.5)</td>
<td>15 (2.7)</td>
</tr>
<tr>
<td>Because joining the study is the only way to get PrEP where I live</td>
<td>2 (0.4)</td>
<td>116 (20.8)</td>
</tr>
<tr>
<td>Feel safer and decrease anxiety related to HIV risk</td>
<td>2 (0.4)</td>
<td>8 (1.5)</td>
</tr>
<tr>
<td>Because I was strongly encouraged or pressured by a friend or sexual partner to join the project</td>
<td>1 (0.2)</td>
<td>51 (9.2)</td>
</tr>
<tr>
<td>Because the reimbursement money is helpful</td>
<td>1 (0.2)</td>
<td>37 (6.6)</td>
</tr>
<tr>
<td>Because this is the only way for me to get healthcare</td>
<td>0</td>
<td>37 (6.6)</td>
</tr>
<tr>
<td>To get HIV medication to help treat someone close to me who is HIV positive</td>
<td>0</td>
<td>4 (0.7)</td>
</tr>
<tr>
<td>To get HIV medication to help prevent someone close to me who is HIV negative from getting HIV</td>
<td>0</td>
<td>10 (1.8)</td>
</tr>
<tr>
<td>Recommended by my doctor</td>
<td>0</td>
<td>2 (0.4)</td>
</tr>
</tbody>
</table>

*Sums to greater than 100% because participants could list more than one reason for enrolling*