Bridge HIV at the SFDPH: Update for MTN-017

Albert Liu, Site Principal Investigator
Hailey Gilmore, Site Study Coordinator

23 February 2014
## Study Progress

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Activation</td>
<td>24 September 2013</td>
</tr>
<tr>
<td>First Enrollment</td>
<td>29 October 2013</td>
</tr>
</tbody>
</table>

### Screening, Enrollment, and Retention Figures

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants screened</td>
<td>32</td>
</tr>
<tr>
<td>Number of participants enrolled</td>
<td>9</td>
</tr>
<tr>
<td>Screen to enroll ratio</td>
<td>3.6 : 1</td>
</tr>
<tr>
<td>Retention figures</td>
<td></td>
</tr>
<tr>
<td>Mid-Period 1: 100% (6/6)</td>
<td></td>
</tr>
<tr>
<td>End-Period 1: 67% (2/3)</td>
<td></td>
</tr>
<tr>
<td>Initiate Period 2: 100% (1/1)</td>
<td></td>
</tr>
<tr>
<td>Mid-Period 2: 100% (1/1)</td>
<td></td>
</tr>
</tbody>
</table>
Best Study Practices

- “Dress-rehearsing”: visit walk-throughs
- Increasing frequency, number, and variety of community education presentations
- Implementing 3-visit screening approach
- Ensuring multiple points of staff contact
- Utilizing “demo kits” during study education process
- Additional screening questions on clinical forms
- Discussion at weekly team meetings
- Recruiting roll-over participants/capitalizing on pre-existing relationships
- Innovative social media
Today is world AIDS Day. Join the conversation.
Roses are red,
Truvada is blue.
Our volunteers are sweet,
And you can be too...!

-JoinPrEP

#weheartvolunteers
Challenges implementing MTN-017

• PrEP awareness and availability in San Francisco

• Longer study visits = need for more staff time

• Ruling out “suspected” acute infection
  • Symptoms common during flu season, population with background risk
  • Local standard for HIV testing includes HIV RNA
Strategies to Address Identified Challenges

- PrEP awareness and availability in San Francisco
  - Discussion of PrEP early in pre-screening/screening
- Longer study visits = need for more staff time
  - Cross-training additional staff
- Ruling out “suspected” acute infection
  - Discuss with protocol team possibility of using HIV RNA to rule out acute HIV infection
Unresolved Challenges

• Ruling out “suspected” acute infection
• Interpreting “low risk”: additional guidance/criteria across sites may be helpful
• Encountering stool during ARE
• More resources for participants and staff to “troubleshoot” the RAI gel regimen
Lessons Learned

• Study product descriptors: microbicide vs. lube or gel
• “Rectally-specific” language in media campaigns and printed materials
• Need for ongoing training, review of complex protocol procedures
• PrEP referrals for interested participants
• Discuss specifics on how study participation might fit into people’s lives?
WE TESTED THE PILL. NOW WE’RE TESTING THE LUBE.

BE A HERO.
VOLUNTEER FOR A PrEP RESEARCH STUDY.

joinprep.org
LUBE IT LIKE A POWER BOTTOM

IS LUBE THE NEXT PrEP?
help us find out.

joinprep.org
THIS AINT YOUR DADDY’S LUBE

IS LUBE THE NEXT PrEP?
help us find out.

joinprep.org
Pharmacy Update

- 2 applicators missing plungers (one retained by participant to be returned at next visit, one not)
- No temperature excursions or dispensation errors
- Timely deliveries by courier service
- Area for improvement: reconciling product preparation time with time product dispensed from clinic to study site
- Participant feedback: strong smell of GCL lube
Behavioral Update

**CASI**
- 2 participants enrolled on 2\(^{nd}\) attempt, but had previously taken CASI and were unable to repeat: FIXED

**SMS**
- 2 days ppts reported not receiving SMS: KNOWN OUTAGES
- SMS arriving as multiple messages: REFERRED TO RG
- 2 ppts continued receiving SMS during break: RESOLVED
- 1 ppt did not reply for >2 days: CARE CALL, PPT RETAINED
- Overall SMS response rate: 97% (457 of 470)
Behavioral Update, continued

DCI & PK DCI

- Format of SMS calendar can cause discrepancy with actual use and product count (off by 1)
- PK is challenging because qualitative (need to be recorded?)

IDI

- No one selected yet!
- Has this started yet?
Laboratory Update

• LDMS learning curve, but on track now after troubleshooting and retraining
• PK results have all been received within adequate time
• Continue to ship PK specimens regularly – minor issue with return of specimen boxes
• Recently shipped first batch of HPV specimens
• Turn-around time for safety and STI labs adequate
Counseling Update

Protocol Adherence
• Feels repetitive – guidance on how to keep fresh?

HIV/STI Risk Reduction
• Participants prefer other (premium) condoms
• Study condom use as top or bottom? “penetrative” sex in protocol
• Product use/study participation viewed as a form of risk reduction

Product Use/Adherence
• Participants continue to express confusion around RAI gel use
  • Would like to be able to format FHI-provided guidance for ppt use
  • “How do I figure out when to use it?” → puts burden and frustration on participants...is this really “user-friendly”?
  • Confusion around the 6th day rule (if haven’t used it that week)
• Product use instructions sheets have really small font and images
Questions?