

Bridge HIV at the SFDPH: Update for MTN-017

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Study Progress

Milestone	Date
Site Activation	24 September 2013
First Enrollment	29 October 2013

Screening, Enrollment, and Retention Figures	
Number of participants screened	32
Number of participants enrolled	9
Screen to enroll ratio	3.6 : 1
Retention figures	Mid-Period 1: 100% (6/6) End-Period 1: 67% (2/3) Initiate Period 2: 100% (1/1) Mid-Period 2: 100% (1/1)

Best Study Practices

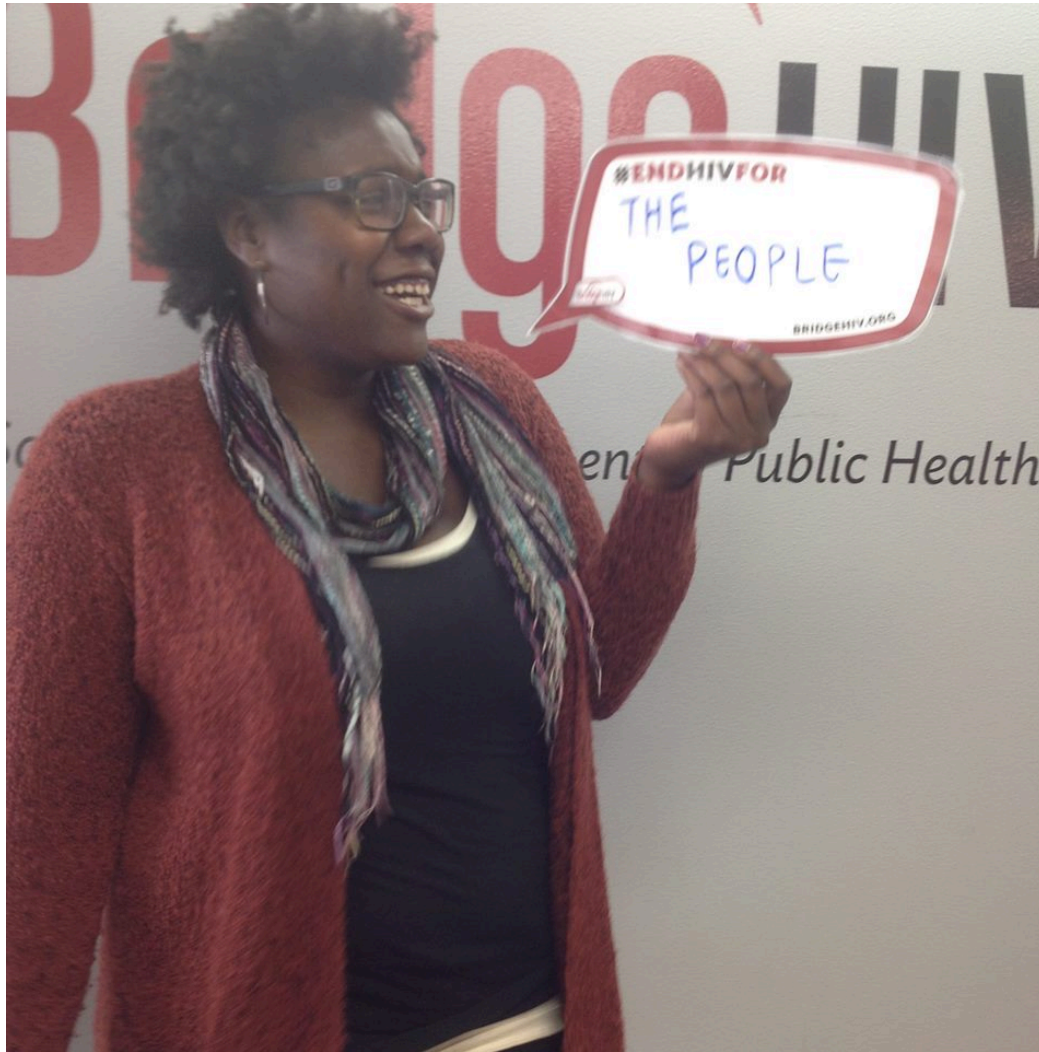
- “Dress-rehearsing”: visit walk-throughs
- Increasing frequency, number, and variety of community education presentations
- Implementing 3-visit screening approach
- Ensuring multiple points of staff contact
- Utilizing “demo kits” during study education process
- Additional screening questions on clinical forms
- Discussion at weekly team meetings
- Recruiting roll-over participants/capitalizing on pre-existing relationships
- Innovative social media

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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?



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IS LUBE THE NEXT PrEP?
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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 2nd 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?