



Recruitment Strategies for Microbicide Trials

Rita Lisa Labbett, MPH
Research Coordinator
University of Pittsburgh/UPMC





RECRUITMENT

- What makes a good Microbicide Participant?
- MSM population – what we know and what to keep in mind when designing trials
- Community outreach, engagement and trust-building



RECRUITMENT

- Pre-screening process (best practices)
- Concierge Service – its affect on retention, continued participation and participant referrals
- Recruitment in the social media/high-tech age
- Questions/Comments



Participant Profile

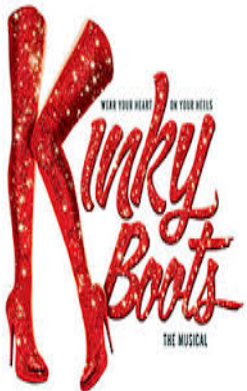
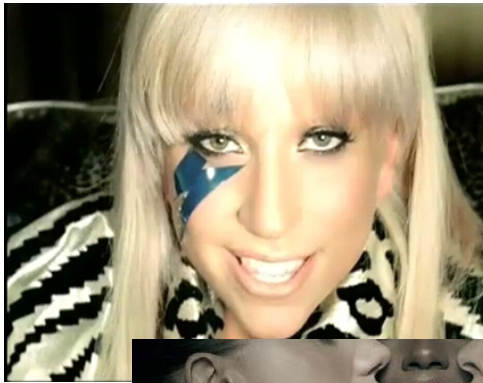
- The “right” participant does not have a certain look - they vary by:
 - Race
 - Age
 - Socio-economic status
 - Education
 - Background

Good Trial Participants

- The “right” participants have common characteristics:
 - They ask thought-out questions
 - They understand the purpose of the study, and can explain it back to you (and their friends)
 - They understand what is required of them and why
 - They are genuinely interested and motivated by altruism (even if they are motivated by compensation as well)

**Flyers/ads state “compensation will be provided” but no actual amount is listed*

The MSM Population





Recruitment Challenges

- Highest HIV prevalence (especially in minorities);
- Varied definitions of “relationship” (friends with benefits, primarily monogamous but in open relationships, rules/boundaries); these relationships define condom usage;
- They can be “functional” substance abusers (maintain work, school, activities);



Recruitment Challenges

- Rapid HIV testing can harm this population's perception of their own risk;
- The more confidence they have, the more empowered they are in taking control of their sexual health;
- The more support they have (particularly family) the overall better choices they make;
- PrEP not so easily embraced (“Truvada Whore” stigma, cost).



Things to Consider

- Sexually active timeline – 30 days since last receptive anal intercourse not realistic. Increase this window to 60 or 90 days;
- Flexible clinic hours, if possible – early morning/afternoon/evening;
- Substance abuse criteria – more than four drinks a week as an exclusion criterion alienates the very population at risk.



Things to Consider

- Utilizing Smartphones for self-report, surveys, reminders;
- If diagnosed with GC/CT, allow them to get treated then re-screen;
- Offer unique health screenings, vaccinations (HPV, Hepatitis) as bonus compensation for study participation.



Community Outreach

- BARRIER - May be wary of trusting researchers, especially black and ethnic minority MSM.
- SOLUTION - Recruiters must repeatedly involve themselves in the population's culture such as ball scene, bars/clubs, events, and activities.



Managing Concerns

- BARRIER - Fear of invasive procedures (rectal exams, needles, biopsies).
- SOLUTION – Having honest and frank discussions of what's involved, explaining risks/benefits and giving them a tour of clinic prior to enrollment in studies helps ease concerns.



HIV Stigma Issues

- BARRIER – Fear of knowing their HIV/STI status (stigma, privacy).
- SOLUTION – Explaining reporting laws regarding HIV/STI but assuring them they will know their status first. Empower them with community connections should they test positive and touch base to see how they are doing. Treat them as “human”; not a human subject.



Cultural Barriers

- BARRIER - Each culture has their own barriers we need to consider in regards to their participation in HIV prevention research.
- SOLUTION – Listen. Don't be dismissive (“Well you have anal sex so what's the big deal with a rectal exam?”).



Pre-Screening

- Participants are pre-screened by study staff (recruiter) who is culturally competent and familiar with study protocol
- Phone screens include an explanation of the study focusing on time commitments and participant expectations
- Eligibility criteria are reviewed



Pre-Screening

- Increased detail in phone screen helps identify most appropriate participants
- Respond to inquiries within 24 hours, if possible (strike while iron is hot)
- Schedule pre-screen interviews to avoid “phone tag”

Informed Consent

Visual Informed Consent “Cheat Sheet”

MTN-017: A Study of Truvada Pills and Tenofovir Gel

Contact the Study staff with any concerns:

Stacey xxx-xxx-xxxx

Carol xxx-xxx-xxxx

Carly xxx-xxx-xxxx

Purpose: To look at the safety of tenofovir gel and Truvada pills, and find out how men feel about using them

Screening Visit: (about xxx hour)

- Review a consent form
- Complete paperwork
- Physical exam
- Rectal exam
- STI and HIV tests

Tenofovir is a medication which is experimental for HIV prevention. This means we do not know if it works to protect against HIV. It may cause burning or soreness in the genital area and pain in the pelvic area.

Truvada is a pill taken for HIV prevention. The most common side effect is nausea/upset stomach

After a screening visit you will try three sets of pills and gels for 8 week each. During each of these eight week periods you will have 3 visits (beginning, middle, and end)



*Beginning Visit:

- Blood and STI testing
- Rectal Sponges (anoscope)
- Receive Product

4 weeks product use

Middle Visit:

- HIV Test
- Rectal Sponges (Anoscope)
- Return and Receive Product

4 weeks product use

End Visit:

- HIV Test
- Computer Questionnaire
- Rectal Biopsies (Flex Sig)
- Rectal Sponges (Anoscope)
- Blood and STI testing
- Return Product

Risks: You may experience discomfort or embarrassment with anal swabs, exams, and questions; Fear or worry about test results. Blood draw may cause pain, bruising, or dizziness.

Biopsies: Biopsies are pieces of tissue approximately the size of a pin head. These should not be painful. There is a small risk of damaging the rectum or causing irritation or infection. They may cause slight bleeding with bowel movements for 1-2 days.

Enema: The tip of an enema bottle will be inserted into your anus, and about 4 ounces of fluid will be squeezed into your rectum. Holding and releasing this fluid may be uncomfortable

*The first beginning visit

- Rectal Biopsies
- Blood draw; HIV Test
- Computer Questionnaire



Phone Interview Script

- Specifics (principal investigator(s), where study is taking place)
- Why the study is being conducted
- Specifics regarding procedures being done (especially rectal/vaginal)
- Time/dedication required to do study
- Operation of clinic (when study visits can occur)
- Compensation



Phone Interview Script

- Collection of personal information/how used/how protected
- Specific inclusion/exclusion criteria questions
- Contact information so appointment can be scheduled and how they heard about study (remember to ask if texting is alright)
- Sign, date and initial each page of the questionnaire



Concierge Service

- Text (if participant agrees) to remind them of appointments. This has yielded high retention results. Texting is the preferred method of communication.
- Greet them. Meet them in the lobby. Introduce them to staff. Offer them a drink/snack. Make them feel welcomed and relaxed.



Concierge Service

- The recruiter serves as the “hand holder” during the process. This is the person the participant feels comfortable with and can text/call if they have questions.
- Get to know your participants.
Remembering details they share with you (example: a new relationship, a test or project) makes them feel special and more than just a “body” in a research study.

Results

- Retention Rates in completed & ongoing trials:
 - MTN-006/RMP-02 (100%)
 - 8 flexible sigmoidoscopies with biopsies
 - MTN-007 (100%)
 - 3 flexible sigmoidoscopies with biopsies
 - Project GEL Stage 2 (100%)
 - 3 sets of anoscopic biopsies
 - TMC-278 / ON Study (100%)
 - Multiple cervical/vaginal/rectal biopsies



Recruitment & Social Media

- Use of current social media and technology - (Craigslist, MSM chat/date sites, Facebook, Twitter, smartphones)
 - Craigslist has been highly effective, whereas Facebook/Twitter have not.
 - MSM dating sites – limited marketing potential but can produce interest.
 - Popularity of MSM dating sites vary by geographical location.



Advertising



Be A Hero!

by taking part in an
HIV Prevention Research Study
www.hivregis.pitt.edu

University of Pittsburgh 




Get a Heart-On for HIV Prevention Research

Thursday, February 9th from 6-9 p.m.
at **The Warhol Museum**
Good Food Music Prizes Free Parking

Featuring What's-Going-On in HIV Prevention Research for men who have sex with men, and their LGBT healthcare providers, presented by local researchers. Many studies are open and more will open soon! Your host is the University of Pittsburgh HIV Prevention Research team. **Bonus:** The wild BMW M1 race car Warhol painted in 1977 will be on display that night!

If you're gonna come... call 412-383-1313
(if we know by the 6th it helps us plan the food)


BE A HERO. HIV Prevention RESEARCH STUDY



The University of Pittsburgh is looking for HIV-negative men 18 years of age and older who have sex with men for a research study that is looking at anti-HIV pills and lubricants for future use to prevent HIV transmission.

COMPENSATION WILL BE PROVIDED.

For more information, please call
412-956-9686

 University of Pittsburgh
www.hivregis.pitt.edu



Thank You



QUESTIONS?

COMMENTS?