Participant Selection: who do we want in ASPIRE’? 

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2013 MTN Annual Meeting
ASPIRE TEAM

Malawi College of Medicine – JHU Research Project

UNC Project - Malawi
It is a process....

• How do ensure we’re recruiting participants likely to be retainable & adherent to study procedures
  – Why would someone uninterested in the study product want to get into the study
    – Peer influence/ social pressures (Use of Community volunteers)
    – Standard of care incentives
    – Transport reimbursement
  – In my community setting what are good proxies to retention & adherence?
    – Is it risk-perception level?
    – Women in stable family settings (Durban/Cape Town)
Often, we lack.......  

- Clarity on which woman will likely be most motivated to adhere to study visits & product  

- Some insights from sero-discordant couple study  
  - Tendency is to avert known/perceived risk  
    - Less condom use with outside partner of unknown HIV status  
    - Adherence high during periods of perceived high risk (seen with partner change)
Adherence is critical for ART based approaches to HIV prevention

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<tr>
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<th>Efficacy</th>
<th>Adherence*</th>
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<tbody>
<tr>
<td>Partners PrEP</td>
<td>75%</td>
<td>82%</td>
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<tr>
<td>iPrEx</td>
<td>44%</td>
<td>51%</td>
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<tr>
<td>Fem-PrEP</td>
<td>6%</td>
<td>26%</td>
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* Based on tenofovir levels in non-seroconverters

Baeten CROI 2012, Abstract 29
Donnell CROI 2012, Abstract 30
Grant NEJM 2010
Van Damme CROI 2012, LB32
FemPrEP study:
• Up to 70% of participants didn’t perceive themselves to be at risk of HIV acquisition
  – Adherence by drug levels 26%

• How can we attempt to assess risk perception for ASPIRE enrollees?
  – ? Disconnect between risk & perception of risk (qualitative work in FemPrEP)

• How can we educate people about their level of risk?

But what else seems to drive non-adherence?
• Insight on the thinking of an ordinary woman in South Africa
Study staff need to........

• Develop key messages for specific populations
  – In KZN province alone, >350 HIV infections occur every day
  – ? In Eastern Cape

• Explore specific messaging that speaks to the individual (move towards promoting altruism)
  – Loss of a loved one to HIV
  – If one has children or young sisters, how will epidemic likely affect them if we did nothing now
Individualized messaging key.....

Not all women are the same

Rachel:
• Personal experiences (Infected friends & relatives, worries about partner, HIV incidence/prevalence in population

Kat:
• Motivation to use dependent on ease/comfort in using
• A little extra trade-off for comfort if she knew product protective
How are sites doing?

MUJHU-Uganda

- Voice lessons = No-go zones & red-tagging specific categories
  - Highest level of clinician discretion not to enroll
  - Pre-enrollment education visit

- 100% retention (90 enrolled, 1st ppt at M-6 visit)

- Few reported ring expulsions (no trends & reporting timely)

- Self collected swab & ring swap in full view of clinician (makes non-adherence an active process)
Cape Town

• Prescreening protocol – PDG’s
• Assessment of commitment, understanding & importance of participation prior to enrollment – IC DG’s
• The participant is thoroughly educated about the research site, MTN, and ASPIRE before she screens for the trial.
? Pre-emptive discussions around ways to fool system on ring use

• Is it necessary?

• Appeal to ppt
  – Key msgs around motivating ppts to adhere
  – Why they should be the key stakeholder
  – Why are you in this yourself
    • Your Passion/Commitment to what you do easily read by the ppt
Zimbabwe CTU

- There's always room for improvement on any specific front
- New enrollment strategy

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<th>ASPIRE</th>
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<td>Recruitment was done throughout the catchment areas with no specific area considerations.</td>
<td>Recruitment efforts are more targeted at hot spots. Identification of hot spots done in collaboration with CAB.</td>
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<td>Women who were into cross borderer trading were enrolled without special consideration.</td>
<td>Women with long history of cross borderer trading and spend months out of the country are considered ineligible.</td>
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<td>Participant risk perception was considered not as much as in ASPIRE</td>
<td>More consideration is put on participant's self - perception of risk</td>
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Counseling Notes:

- Offer condoms
  - Accepted condoms
  - Did not accept condoms

PRETEST COUNSELLING

She reported new risk factors today. She is a divorcee with 2 regular sexual partners who are married men. She also has other casual sexual partners. Participant said the 2 regular sexual partners do not pay her for sex but they are in love. The partners' occupation are Airforce worker and cross-border trader.

She reported inconsistent condom use with any of her partners. She was ready and willing to be tested for HIV. She said some
WRHI

• Probably most challenging population
• VOICE: lessons learned approach to retention
  • Asylum seeker permits
  • Verifications of the 3 additional contacts
• CHW-paired to participant (flexibility for swapping)
• Nurse/CHW - participant rapport seems conducive to better adherence
• Anecdotes & used ring appearance providing insights to adherence counseling
  • Why are we doing the study?
Main focus out of VOICE was improving retention

Making participants aware of the impact poor adherence has on trial outcomes

From pre-screening to enrolment: Clinician will ask pt why she wants to join study and that if she does enrol she must be committed to visit schedule and product use
Where should we focus

• **Site leadership** – Needs to constantly figure how to motivate teams to be as invested & carry the same to participants?

• **Clinical teams** – Figure how to establish a culture where feel a compulsion to contribute to fighting the epidemic

• **Counseling teams**
  – Critical for staff to promote comfort and openness in discussing ring experiences
  – Speak to the heart

• **Community teams** – Keep the ear to the ground. Take every opportunity to educate.