Participant Selection: who do we want in ASPIRE'?

ASPIRE

A Study to Prevent Infection with a Ring for Extended Use

Patrick Ndase

2013 MTN Annual Meeting

ASPIRE TEAM

Malawi College of Medicine – JHU Research Project

UNC Project - Malawi

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

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)

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

Often, we lack…….

- Clarity on which woman will likely be most motivated to adhere to study visits & <u>product</u>
- 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)

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

Adherence is critical for ART based approaches to HIV prevention

	Efficacy	Adherence*
Partners PrEP	75%	82%
iPrEx	44%	51%
Fem-PrEP	6%	26%

* 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

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

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

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

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

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

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)

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

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.

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

? 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

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

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

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 crossborder 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?

eThekwini

- 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.

ASPIRE
A Study to Prevent Infection with a Ring for Extended Use