

Ensuring Retention from Day 1: Pre-screening and ensuring motivation for Microbicide trial MTN 020 (ASPIRE)

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Lilongwe site



OVERVIEW

- Rationale for pre screening.
- Evaluating participant willingness and commitment.
- Challenges and Lessons Learnt.

RATIONALE

- Studies in Malawi have shown that women between the ages of 18 – 30 are sexually active and have higher incidence of HIV than rest of population.
- There is a high incidence of HIV in women that have a history of STIs.
- The Lilongwe site has strategized in recruiting high risk women for MTN study.
- Recruitment of High Risk women must be balanced with ability to retain participants.

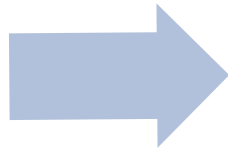
PRESCREENING PROCEDURES

- The clinic conducts 2 prescreening before the study screening procedure.
- Discussion are mainly with Research Nurses
- Using a pre screening guide the individual client discussion is recorded in clinic notes.

NOTE: The site normally provides Family Planning and HIV testing services for all persons visiting our facility as part of service to the community. Site is registered with MOH to provide these services.

PRESCREENING GUIDE

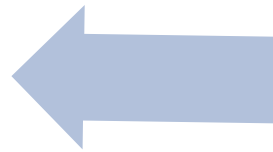
Demographics- Name, Age, location, phone number



Marital status, other relationships, number of sexual partners



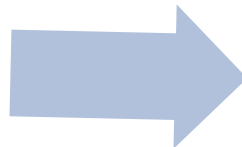
Occupation of potential participant and partner + education level



Referral source
Evaluating willingness and commitment



Family planning method, breastfeeding, pregnancy test, and HIV testing



Any other discussion- cervical cancer screening, discussion on UNC Project Studies.

Referral source
Evaluating willingness
and commitment

Assess information about the study (given at referral sources)

- How the ring is used
- Who will use this ring
- How long the study is?

Education about the study to potential participant.

- Basic study information (eligibility criteria not tackled unless asked)
- Questions and answers

Referral source
Evaluating willingness
and commitment

Assessing motivation

- If they heard anything about this study and where did you hear about it?
- Enquire about any misconceptions.
- Are they willing to join the study?
- Why they want to join the study
- What could be the benefit

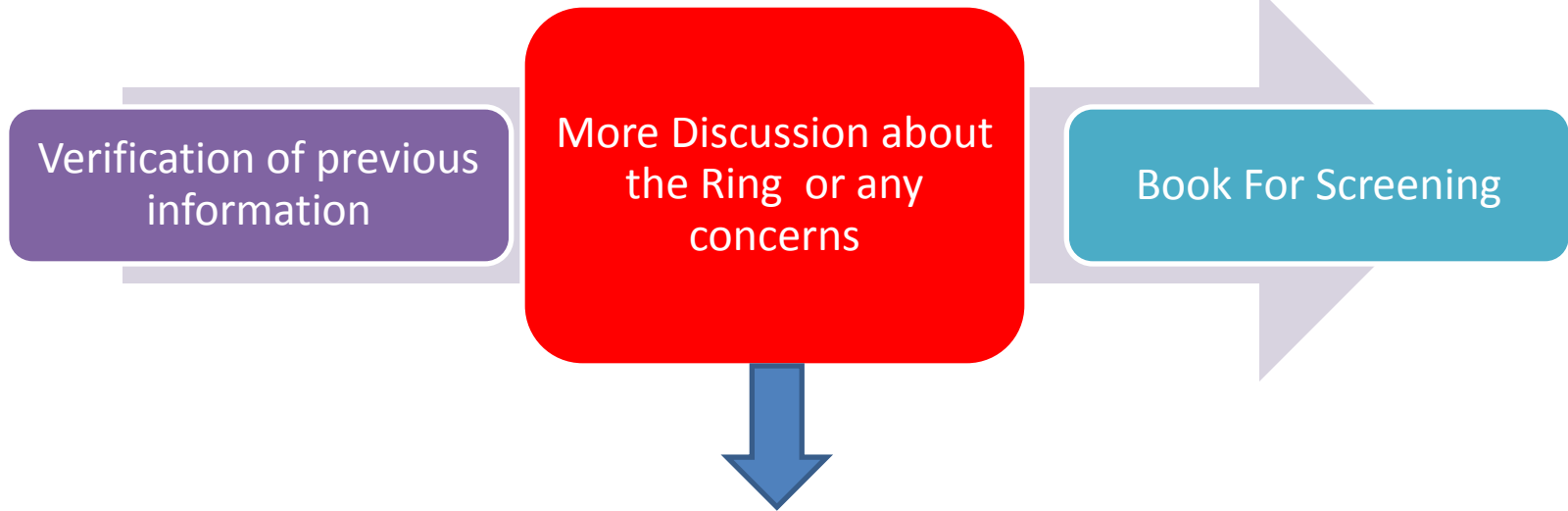
Evaluating willingness and commitment

- Ask them about discussions with relatives, partner about the study.
- Encourage her to discuss with partner and family
- Commitment to study visits.

Indicators of non commitment and willingness

- Not willing to be on Family planning
- Intends to be pregnant
- Missed 2nd prescreening

Second Pre screening



- Find out if she discussed about the study with partner, relatives or guardians, friends.
 - If yes, any concerns? How does she think she can address their concerns?
 - Would she like the study team to talk with them.
- Any issues that came up
- Find out her final decision

Motivation to join study

- ❑ The primary care that is offered. i.e. STI screening, Pap smears, more than 50%.
- ❑ Intrigued by investigation of a ring that would prevent HIV transmission.

Pre screening challenges & resolutions

- Inadequate documentation in the health passport books- on Family Planning and participants would lie about Family planning**
 - Discuss need for family planning e.g. loop strings, Jadelle strips, Depo for all women in reproductive age
 - Offer service if not on product
 - If on product advised to bring documentation at next prescreening visit.

Pre screening Challenges & Resolutions

- Intention to disclose study participation to partner and relatives prior to screening.**
 - The study team in a continued effort to educate potential participants about partner disclosure
 - Offer by study team to talk to partner
 - Community education
 - Male Involvement through special sensitization meetings with men in community
 - Others prefer non disclosure.

Recruiting 'well-suited' participants

❑ The site had developed strategies in ensuring recruitment of well suited participants.....



❑ But there were indicators

Lessons Learnt 1

❑ **School going women and/living with parent/guardian.**

❑ Potential participants who resided with guardians or other persons other than their partners irrespective of parity and above legal age of 18 years and have multiple sexual partners.

❑ **Lesson learnt:** They would still need consent from their parents/guardians irrespective of age. Most parents/guardians find it difficult to accept wards are sexually active and need some form of FP let alone participate in a study which has something to do about potential participants having sex.

Lessons Learnt 2

❑ **Missing 2nd prescreening appointment date**

❑ After 1st prescreening potential participants were given a 2nd prescreening date. The potential participants would miss completely or show up on another day, without contacting the clinic.

❑ **Lesson learnt.** These participants may pose problem in adhering to study visits. Not a good candidate to recruit into study, no need for follow up.

Lessons Learnt 3

- ❑ **Forged Information on FP in health passport book**
 - ❑ Potential participants would bring health passport books with information written by them, on family planning, or tear off pages to hide information.
- ❑ **Lesson learnt:** Dishonest participant likely to lie about adherence and other information in the study.

Lesson Learnt 4

- ❑ **Information given to potential participants:**
 - ❑ Potential participants coming to the clinic and community tend to have various misconceptions based on too much information provided by friends and study team in the community.
- ❑ **Lessons Learnt:** Too much information too early is recipe for disaster. Information in the community needs to be short and precise.

Conclusion

- No shortcuts to prescreening.
- Need for early involvement of partner, parents or guardians.
- High risk group poses a challenge to retention.
- Early community involvement to minimize misconceptions (find the men in the community at all costs and educate them)
- Pay attention to information related to eligibility that potential participants present.

Acknowledgement

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- Study team
- Potential participants

