

## MTN-020

### Focus Group Discussion (FGD) Topic Guide

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#### **INSTRUCTIONS for the Facilitator: How to use the FGD Guide**

1. There are two levels of questions:
  - Primary discussion questions: appear in **bold** text. They address the topics that you as the facilitator must ask and discuss with participants. The questions are suggestions for getting the discussion going. You are not required to read them verbatim, but they are written to ensure some consistency across FGDs. You may adapt the questions and/or ask them in a different order, depending on how the discussion develops. However you will have to ensure that by the end of the interview, all the topics and key themes have been covered.
  - Probing topics: are indicated with a bullet. If you find that the participants provide little information in response to the primary question, these probing topics may be used to encourage further discussion. You are not required to cover every topic listed. So, depending on what has already been discussed, and the FGD context, you may ask these probes or not.
2. *Instructions/suggestions to facilitator are in italics and [brackets].*
3. The FGD guide is not meant to be used to take notes. Rather, you should use the separate notes form, where you will also insert your initials, the PTIDs of all participants, as well as the date, start and end time of the discussion.

#### **Before starting the FGD, the facilitator reminds the group of:**

- The purpose of the FGD
- Ground rules for FGD (per study SSP), including importance of confidentiality and use of pseudonyms
- That tape recording will now begin

**[Facilitator starts the tape recorder and reads:]** Monga mukudziwa muchikalata chanu chachivomerezo, zokambirana zathu zapagulu zijambulidwa lero. Tisanayambe, chonde vomerani kuti mukudziwa kuti mujambulidwa ndipo palibe vuto ndi inu *[be sure to get a verbal okay from all members of the focus group before continuing]*.

<b>Community</b>
<b>Choyamba ndikufuna ndinene za dera lomwe mukukhala ...</b>
<p><b>1. Kodi anthu a mdera lanu amaganiza zotani zokhudza HIV?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Attitudes towards people/women/men/children living with HIV</li> <li>• Attitudes towards HIV prevention, including the use of condoms</li> <li>• Attitudes towards HIV testing in general, including women who get tested (either in trials, in clinics, or mandatory testing when pregnant)</li> <li>• Attitudes towards HIV prevention research</li> </ul>
<p><b>2. Kodi anthu a mdera lanu amayankhula zotani zokhudza kafukufuku wa chibangiri?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Knowledge of study and the ring</li> <li>• Positive and negative attitudes/comments/rumors about study or ring</li> <li>• Positive and negative attitudes/comments/rumors about ASPIRE participants</li> <li>• Effects of attitudes/comments/rumors on participants</li> </ul>
<b>Motivation to Join in ASPIRE</b>
<p><b>3. Mu zonse mukuganiza kuti amayi omwe anasankha kulowa nawo mukafukufuku akusiyana bwanji ndi amayi ena m'madera mwawo?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Describe what kind of women come to get screened in a research study</li> <li>• Differences in their personal relationships, including with male partners and with family members</li> <li>• Differences in their HIV risk (e.g. awareness of partner having other partners or herself having multiple partners)</li> <li>• Differences in their resources</li> <li>• Differences in their personalities</li> </ul>
<p><b>4. Chifukwa chani amayi ena sakufuna kutenga nawo mbali mu kafukufuku wa chibangiri?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Requirements of participating in trial, such as clinical procedures/testing</li> <li>• Aspects of participants' personal lives (i.e. work commitments, fear or lack of support from partners, etc.)</li> <li>• Aspects of the community/the place where the participants live (i.e. transport, safety, distrust of research, rumors, fear of abuse, violence, rape, HIV stigma, etc.)</li> <li>• Concerns about becoming a research participant, testing an investigational product</li> </ul>
<b>Disclosure and Influence of Others</b>
<p><b>5. Kodi amayi a mu kafukufuku wa chibangiri anauzako ndani zakutenga mbali kwawo komanso anabisira ndani?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Types of people disclosed to and why</li> <li>• Types of people <i>not</i> disclosed to and why, including role of fear or experience of violence</li> </ul>

**6. Kodi anthu anachilandira bwanji atazidwa za kafukufuku wa chibangiri kuchokera kwa amayi omwe akutenga nawo mbali mu ASPIRE?**

Possible probing topics:

- Initial reaction and changes in opinions/attitudes – who was supportive, who was discouraging
- Specific actions/reactions of people that made participant feel supported/judged/discouraged
- How reactions of people differed from what the participant anticipated/expected their reactions to be
- Feelings/influence of these people’s reactions on participants

**Experience in ASPIRE**

**Tsopano tikambirana zambiri zimene amayi akukumana nazo chifukwa chotenga nawo mbali mukafukufuku wa chibangiri ...**

**7. Tanduzani kodi zinali zotani kwa inu kukhala mmodzi wa otenga nawo mbali mukafukufuku wa chibangiri.**

Possible probing topics:

- Benefits and challenges of participation
- Expectations of staff and/or the trial
- Experiences resulting from being a participant, including during study visits or at the clinic
- Effects of study on daily life (activities, home/responsibilities, schedule) for participant, partner(s), and others (peers/friends, family members)
- Changes in relationships, including how study participation influenced decision-making and communication around HIV prevention method use, contraceptive use, sexual health and STI treatment needs (if applicable) with male partners
- Changes in social life or alcohol/drug use

**8. Kodi ma ubale anali otani pakati pa otenga mukafukufuku wa chibangiri?**

Possible probing topics:

- Level of interaction, including discussions in waiting area and outside of the clinic setting
- General feelings about/attitudes towards other participants
- Attitudes of other participants towards the study and ring
- Influence of other participants on study experience/ring use, including discouragement or support

**9. Kodi mungafotokeze mmene ogwira ntchito mukafukufuku amapelekerka chithandizo kwa otenga nawo mbali mukafukufuku wa chibangiri?**

Possible probing topics:

- Feelings about different types of staff
- Perceived level of support and what contributed to feeling supported
- Perceived level of judgment and what contributed to feeling judged
- Influence of staff on experience in ASPIRE/use of the ring
- Influence of feedback based on ring appearance, or site level adherence measurements on relationship with staff

**10. Kodi otenga nawo mbali anali ndi maganizo otani pa maphunziro, misonkhano ndi zochitikachitika zina ku kiliniki?**

Possible probing topics:

- What was useful or not useful (e.g. clinical ring use inspections, adherence counseling or other site specific activities, such as male partner engagement events, morning meetings, adherence scenarios, adherence workshops, educational sessions, etc.)
- Impact of these activities on visit attendance and ring use
- Perceived peer or staff pressure about reporting behaviors while in the trial

Experience using the ring
<p><b>11. Tandiuuzani kodi zinali zotantikwa otenga nawo mbali kugwiritsa ntchito chibangiri.</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Physical experiences of ring use during daily activities</li> <li>• Side effects or other effects of the ring</li> <li>• Likes and dislikes of ring and ring use</li> <li>• Ease or difficulty of use</li> <li>• Experiences of expulsion or removal, including circumstances and responses</li> </ul>
<p><b>12. Kodi abwenzi amuna a otenga nawo mbali amakhudzidwa bwanji mukafukufuku komanso pa kagwiritsidwe ntchito ka chibangiri?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Level and ways male partners were involved, including in decision-making around participation/ring-use, and why</li> <li>• Influence of partner attitudes and involvement on experience or ring use</li> <li>• Change in partner attitude about study participation/ring use over time</li> <li>• Attitudes towards activities geared towards couples vs. male partners only</li> <li>• Communication around other health related issues raised by the study</li> </ul>
<p><b>13. Kodi kugwiritsa ntchito chibangiri kumakhudza bwanji moyo ogonana wa otenga nawo mbali?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Her or partner's feeling of/ towards the ring during sex, both initially and later in the study</li> <li>• Positive and negative physical or emotional changes with sex</li> <li>• Changes in sexual practices, intimacy, sexual partners, frequency, or reasons for having sex, etc.</li> <li>• Overall occurrence of ring removals before or during sex</li> </ul>
<p><b>14. Kodi kuyesedwa magazi mwezi uliwonse mukafukufuku wa chibangiri kuti awone ngati muli HIV kunakhudza bwanji ka gwiritsidwe ntchito ka chibangiri pakati pa otenga mbali?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Change in level of worry about HIV and why</li> <li>• How worries influenced decision to stay in ASPIRE and use the ring</li> <li>• How worries influenced other HIV prevention behaviors</li> </ul>
<p><b>15. Kodi kugwiritsa ntchito njira zolera pakati pa otenga mbali panthawi yakafukufuku wa chibangiri unakhudza bwanji kagwiritsidwe ntchito kawo ka chibangiri?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Changes in contraceptive methods used</li> <li>• Experience of and concerns around contraceptive side effects (including changes in menstrual cycle and symptoms)</li> <li>• Impact of experience or concerns around contraceptive side effects on participation/ring use</li> <li>• Concerns around fertility associated with contraceptives and why</li> <li>• Knowledge/attitude/feelings of participant and male partners toward use of or changes in contraceptive use</li> </ul>
<p><b>16. Kodi chinachitika ndi chani ku mbali yakagwiritsidwe ntchito kakondomu panthawi yomwe otenga nawo mbali anali mukafukufuku wa chibangiri?</b></p> <p><u>Possible probing topics:</u></p> <ul style="list-style-type: none"> <li>• Changes in patterns of condom use (study condoms or other condoms), including ability to negotiate their use with partners</li> <li>• Reasons for changes, if any</li> <li>• Experience for her and partner managing/negotiating use of both condom and ring simultaneously</li> </ul>

**17. Kodi kagwiritsidwe ntchito ka chibangiri kamakhudzana bwanji ndi nsambo kapena miyambo yokhudzana ndi kutsuka kapena kubweza njira ya abambo?**

Possible probing topics:

- Preference for use/non-use of ring during menses and why
- Perception of ring's impact on menses and/or fertility
- Perception of hygiene, cleanliness/dirtiness of ring related to use during menses
- Change in vaginal practices and their relation to the study or ring use

**Recommendations and Feasibility of Future Use**

**Tikupita kumapeto kwa zokambirana zathu. Tisanamalize, ndikufuna ndithokoze nfundo zothandiza zanu ndi maganizo anu zomwe zizatithandize pa ntchito zathu mtsogolo muno ...[Only ask these questions if study results are not yet publicly known, otherwise skip to question 20]**

**18. Ngati chibangiri chizapezeke chothandiza mtsogolo, kodi mukuganiza kuti angakonde kuzayigwiritsa ntchito kwambiri ndi ndani?**

Possible probing topics:

- Types of women most likely to use ring (e.g. girls, older women, married/unmarried, sex workers, "promiscuous" women, women who occasionally drink alcohol or who use alcohol frequently, women who experience violence at home)
- Types of women that community members would expect to use the ring (e.g. see above)

**19. Ngati chibangiri chizapezeke kuti chikuteteza HIV, kodi ndi zinthu ziti zomwe zikhoza kulimbikitsa maganizo anu anu ogwiritsa ntchito chibangiri kapena ayi?**

Possible probing topics:

- Perception of whether you are at risk of HIV
- How partners are made aware of and involved in encouraging ring use, including their reactions to and experience with the ring
- Ability to participate in the open-label extension study
- Ability to use and interest in using the ring compared to other available alternatives
- Issues around cost, access, storage, disposal, discreetness
- Issues around physical ring appearance, such as color, texture, and size
- Availability of single vs. multi-purpose ring (i.e. for HIV and FP)
- Concerns about *short term vs. long term use on fertility/health or hygiene*
- Concerns about wearing a device in the vagina versus being exposed to the drug
- Concerns about experiencing social harms, violence or rape
- Impact of perceived community or others individuals' attitudes towards the ring
- Reaction/attitudes of people towards women who would use the ring and reasons for these reactions – concerns about promiscuity, stigma, etc.

**Stopping Early for Futility, Efficacy, or Due to Harm [Only ask these questions if either the ASPIRE or Ring (i.e. IPM 027) study is stopped early for any reason, otherwise skip to question 24]**

**20. Kodi munamva zoti chani zokhudzana ndi kafukufuku wa chibangiri [wa ASPIRE/wa chibangiri wa IPM 027] kuyimitsidwa msanga?**

Possible probing topics:

- Source(s) of information
- Understanding of results
- Who was talked to and who have you not talked to about the study stopping early
- Other people's reaction to this, including people they disclosed to, other participants, etc.

**21. [Ask only if one of the studies is stopped for futility] Kodi mukumva bwanji ndi uthenga wakuti mukafufuku wa chibangiri wa [wa ASPIRE/wa chibangiri wa IPM 027], chibangiri chinawonetsa kuti sichikuteteza ku HIV?**

Possible probing topics:

- Change in feelings towards study, ring, or research in general
- Why it didn't show protection

**22. [Ask only if one of the studies is stopped due to efficacy] Kodi mukumva bwanji ndi uthenga wakuti i chibangiri mukafufuku wa [wa ASPIRE/wa chibangiri wa IPM 027] chinapezeka kuti chitha kuteteza ku HIV?**

Possible probing topics:

- Change in feelings toward study or ring
- Feelings about/understanding of partial efficacy (i.e. that the ring may not protect women 100% of the time), how this would influence ring use, how this would influence condom negotiation with partners
- Interest in participating in open label ring extension study, why or why not
- Thoughts about use of ring outside the research study context
- Potential change in other HIV prevention behaviors, such as condom use or HIV testing

**23. [Ask only if one of the studies is stopped due to harm] Kodi mukumva bwanji ndi uthenga wakuti chibangiri mukafufuku wa [wa ASPIRE/wa chibangiri wa IPM 027] chinapezeka kuti chimabweretsa chiwopseza?**

Possible probing topics:

- Change in feelings toward study or ring
- Change in feelings toward research in general

#### **Wrap-up**

**24. Takambirana zambiri lero. Tisanamalize, sindikudziwa ngati pali maganizo pa zomwe tingathe kuchita kuti tisinthe zomwe mukukumana nazo mukafufuku wa chibangiri kapena pakugwiritsa chibangiri?**

Possible probing topics:

- Study visits, study procedures, clinic
- Interaction with staff, counseling sessions
- Male partner involvement and/or couples counselling
- Providing information or education to others, including facilitated disclosure to others such as partners or family members
- Instructional materials, or how the instructions were provided
- Changes in physical design of ring, insertion, removal method, frequency of ring replacement

Tafika kumapeto a zokambirana zathu. Muli ndi mafunso ali wonse kapena zoonjezera pa zomwe mukukumana nazo mukafufuku wa chibangiri? Zikomo kwambiri chifukwa chotenga nthawi kuti mulankhule nane lero ndikugawana nane maganizo anu. Tikuthokoza kwambiri chifukwa cha kudzipereka kwanu kutenga nawo mbali ndiku kambirana nanu pazomwe mukukumana nazo.

**[At this time, the facilitator should answer any unanswered questions and clarify any misconceptions, or refer participants to someone who can.]**