MTN-020

Focus Group Discussion (FGD) Topic Guide

INSTRUCTIONS for the Facilitator: How to use the FGD Guide

- 1. There are two levels of questions:
 - <u>Primary discussion questions:</u> 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.
 - <u>Probing topics:</u> 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 confidentially and use of pseudonyms
- That tape recording will now begin

[Facilitator starts the tape recorder and reads:] Sezvo muchiziva kubva mugwaro retenderano renyu, hurukuro yemuboka iyi ichatapwa nhasi. Tisati tatanga, tapota taridzai nemanzwi kuti munoziva kuti tiri kutapa hurukuro ino uye kuti munowirirana nazvo [be sure to get a verbal okay from all members of the focus group before continuing].

Community

Kutanga ndinoda kutaura pamusoro penharaunda yenyu yamunogara...

1. Nharaunda yenyu inoona sei HIV?

Possible probing topics:

- Attitudes towards people/women/men/children living with HIV
- Attitudes towards HIV prevention, including the use of condoms
- Attitudes towards HIV testing in general, including women who get tested (either in trials, in clinics, or mandatory testing when pregnant)
- Attitudes towards HIV prevention research

2. Vanhu vemunharaunda yenyu vaitaura sei pamusoro pe ASPIRE?

Possible probing topics:

- Knowledge of study and the ring
- Positive and negative attitudes/comments/rumors about study or ring
- Positive and negative attitudes/comments/rumors about ASPIRE participants
- Effects of attitudes/comments/rumors on participants

Motivation to Join in ASPIRE

3. Tichitarisa zvose, munofunga kuti madzimai anosarudza kupinda mutsvakurudzo dzeongororo akasiyana sei nemamwe madzimai ari munharaunda dzavo?

Possible probing topics:

- Describe what kind of women come to get screened in a research study
- Differences in their personal relationships, including with male partners and with family members
- Differences in their HIV risk (e.g. awareness of partner having other partners or herself having multiple partners)
- Differences in their resources
- Differences in their personalities

4. Nemhaka yei mamwe madzimai angasarudza kusapinda muASPIRE?

Possible probing topics:

- Requirements of participating in trial, such as clinical procedures/testing
- Aspects of participants' personal lives (i.e. work commitments, fear or lack of support from partners, etc.)
- 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.)
- Concerns about becoming a research participant, testing an investigational product

Disclosure and Influence of Others

5. Madzimai ari mu ASPIRE vakataurira ani pamusoro pekuva kwavo mutsvakurudzo uye ndiani wavakavanzira?

Possible probing topics:

- Types of people disclosed to and why
- Types of people not disclosed to and why, including role of fear or experience of violence

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6. Vanhu vakataurirwa nemadzimai nezveASPIRE vakazvitora sei?

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

Ikozvino tave kuzotaura zvakawanda pamusoro pechaizvo zvakasanganikwa nazvo nemadzimai mukuva nhengo yetsvakurudzo yeASPIRE...

7. Nditaurirei kuti zvaiita sei kuva nhengo yetsvakurudzo yeASPIRE.

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. Ukama hwaiva hwakamira sei pakati pevaiva mutsvakurudzo yeASPIRE?

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. Mungatsanangure here kuti vaiva mutsvakurudzo vaibatwa sei nevashandi vetsvakurudzo yeASPIRE?

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. Ndeapi mafungiro nemanzwiro evaiva mutsvakurudzo pamusoro pedzidziso dzemumapoka, misangano nemimwe mitambo yaiitwa pakiriniki?

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

11. Nditaurirei kuti zvaiva zvakaita sei kune vaiva mutsvakurudzo kushandisa ring.

Possible probing topics:

- Physical experiences of ring use during daily activities
- Side effects or other effects of the ring
- Likes and dislikes of ring and ring use
- Ease or difficulty of use
- Experiences of expulsion or removal, including circumstances and responses

12. Shamwari dzechirume dzepabonde dzevaiva mutsvakurudzo vaipinzwawo sei munyaya dzetsvakurudzo uyekushandiswa kwering?

Possible probing topics:

- Level and ways male partners were involved, including in decision-making around participation/ringuse, and why
- Influence of partner attitudes and involvement on experience or ring use
- Change in partner attitude about study participation/ring use over time
- Attitudes towards activities geared towards couples vs. male partners only
- Communication around other health related issues raised by the study

13. Kushandisa ring kwakashandura sei hupenyu hwepabonde hwevaiva mutsvakurudzo? *Possible probing topics:*

- Her or partner's feeling of/ towards the ring during sex, both initially and later in the study
- Positive and negative physical or emotional changes with sex
- Changes in sexual practices, intimacy, sexual partners, frequency, or reasons for having sex, etc.
- Overall occurrence of ring removals before or during sex

14. Ongororo dze HIV dzepamwedzi woga woga mu ASPIRE dzakava nechekuita nekushandiswa kwering nevaiva mutsvakurudzo sei?

Possible probing topics:

- Change in level of worry about HIV and why
- How worries influenced decision to stay in ASPIRE and use the ring
- How worries influenced other HIV prevention behaviors

15. Kushandiswa kwenzira dzekuronga mhuri nevaiva mutsvakurudzo munguva yeASPIRE kwakava nechekuita nemashandisiro avo ering sei?

Possible probing topics:

- Changes in contraceptive methods used
- Experience of and concerns around contraceptive side effects (including changes in menstrual cycle and symptoms)
- Impact of experience or concerns around contraceptive side effects on participation/ring use
- Concerns around fertility associated with contraceptives and why
- Knowledge/attitude/feelings of participant and male partners toward use of or changes in contraceptive use

16. Chii chakaitika pakushandiswa kwecondom panguva iyo madzimai vaiva mutsvakurudzo yeASPIRE?

Possible probing topics:

- Changes in patterns of condom use (study condoms or other condoms), including ability to negotiate their use with partners
- Reasons for changes, if any
- Experience for her and partner managing/negotiating use of both condom and ring simultaneously

17. Kushandiswa kwering nevaiva mutsvakurudzo kwaidyidzana sei nekutevera, tsika dzokugeza kana kudzora nzira yababa?

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

Tavakusvika kumagumo kwehurukuro yedu. Tisati tapedza, ndingatenda zvamunokurudzira nepfungwa dzenyu kuti dzitibatsire mubasa remangwana...[Only ask these questions if study results are not yet publicly known, otherwise skip to question 20]

18. Kana ring ikaonekwa kuti inoshanda munguva inotevera, ndiani wamunofunga anganyanyisa kuishandisa?

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. Kana ring ikawanikwa ichidzivirira HIV, ndezvipi zvingakonzera sarudzo yenyu yekuishandisa kana kusaishandisa?

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. Ndezvipi zvamakanzwa pamusoro pekumiswa kwetsvakurudzo ye[ASPIRE/Ring] nguva isati yakwana?

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] Munonzwa sei pamusoro pehumbowo hwekuti mutsvakurudzo ye [ASPIRE/Ring], ring haina kuratidza kudzivirira kubva kuHIV?

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] Munonzwa sei pamusoro pehumbowo hwokuti ring iri mutsvakurudzo ye[ASPIRE/Ring] yakawanika ichidzivirira kubva kuHIV?

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] Munonzwa sei pamusoro pehumbowo hwokuti ring iri mutsvakurudzo ye[ASPIRE/Ring] yakawanika ichikuvadza?

Possible probing topics:

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

Wrap-up

24. Tataura pamusoro pezvinhu zvakawanda nhasi. Tisati tapedza, handizivi kana muine chero zvamungakurudzira zvatingadai takaita kuvandudza zvamakasangana nazvo mutsvakurudzo yeASPIRE kana mukushandisa ring?

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

Ikozvino tasvika kumagumo ehurukuro. Mune chero mubvunzo here kwandiri kana zvamungawedzera pamusoro pezvamakasangana nazvo muASPIRE? Tinokutendai nekutora nguva kutaura neni nhasi uye nekupa maonero enyu. Tinotenda chaizvo kuda kwenyu kupinda uye kukurukura nesu zvamakasangana nazvo.

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