

MTN-025

Serial In-depth Interview (SIDI) 2 Topic Guide

INSTRUCTIONS for the Interviewer: How to use the IDI Guide

1. The guide is divided by sections based on objectives of the qualitative component. The guide does NOT include transition sentences, however, the interviewer should use their discretion to insert transition language between questions or topics as needed.
2. There are two levels of questions:
 - Primary interview questions: appear in **bold** text. They address the topics that you as the interviewer should 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 IDIs. Please adapt the questions and/or ask them in a different order, depending on how the interview 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 participant does not provide much information in response to the primary question, these probing topics may be used to encourage further discussion. While you are not required to cover every topic listed, probes with the words “*KEY PROBE*” written before it are probes that are the most important to try to address. Depending on what has already been discussed, and the IDI context, you may or may not ask the rest of the probes.
3. *Instructions/suggestions to interviewer are in italics and [brackets].*
4. Words found in (parentheses) are meant to provide wording options to interviewers to fit various situations. For example, they often provide a present or past tense verb. In these instances, the present tense verb should be used when the participant being interviewed is continuing with the study, whereas the past tense verb should be used with those participants who are exiting or have finished participating in the study.
5. The IDI 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 participant’s PTID, as well as the date, start and end time of the interview.
6. Purpose statements: appear before a set of questions in *italics*. These should be considered notes to the interviewer and are not meant to be read aloud. They explain the reason for asking that question or set of questions in order to provide more context to the interviewer who can then rephrase in her own words or clarify to the participant as necessary.
7. Inserting participant responses from CRFs: Prior to beginning the interview, interviewers should make sure to fill out the required responses from the Baseline Behavioral Assessment (BBA) and Behavioral Assessment (BA) as well as the information as to whether the participant has accepted or not accepted the ring as written on the guide.

Before starting the IDI, ensure the participant has provided written informed consent.

Acceptor/Non-Acceptor

Serial IDI Visit 2

Insert participant's response to the following items from the most recent Behavioral Assessment (BA)

Visit code of BA:

BA item 21 (circle one): very difficult, somewhat difficult, not at all difficult, not applicable (did not store ring(s) at home), not applicable (never used ring during HOPE)

Fill out check box depending on participant's decision at enrollment:

- Accepted ring
- Did not accept ring

Fill out check box if participant has EVER accepted a ring in HOPE or not during follow up:

- Has ever accepted ring during follow up
- Has never accepted ring during follow up

[Start Recorder and Read Introduction]: My name is _____ . Thank you for returning and agreeing to complete a follow-up interview. I am looking forward to hearing about your experiences since we last spoke. Remember there are no right or wrong answers so please be open and honest with your responses and if you have specific questions during the interview, I will take note of them and answer them directly after the interview or refer you to someone who may be able to help. Before we start, can you confirm for the recorder that you have already provided written informed consent to take part in this discussion? [Wait for oral confirmation to begin].

The main goal of this discussion is to better understand your decision about staying in HOPE and whether or not you are using the ring. Remember that what we discuss here will be kept confidential, and that we will not share your personal information or responses with anyone outside of the study. Additionally, I want to remind you that whether you are using or not using the ring will not affect your ability to continue participating in HOPE.

Warm-Up

Purpose: To ask a broad opening question at the start of the IDI as an opener and to find out how her experience in HOPE might have differed or not from ASPIRE.

1. Tell me about your experience being part of HOPE since we last talked. What has changed or stayed the same?

Possible probing topics:

- Experiences during study visits or at the clinic
- Site specific participant engagement activities
- Effects of continued study participation on daily life for participant, partner(s) and others
- Changes in relationship with male partner(s), including decision-making ability and communication around HIV prevention

Motivations for joining or declining participation in HOPE

Purpose: To get details about all of the reasons why she has stayed in HOPE and accepted or did not accept the ring.

2. What are the reasons you have continued to participate in HOPE?

Possible probing topics:

- **KEY PROBE:** How others were involved in her decision to stay in HOPE
- Aspects of her personal life (partners, work, family, fertility plans, religion, relocation)
- Social benefit in HOPE (e.g. HIV education, support)
- Aspects of the community/neighborhood
- Aspects of study procedures, visits, or staff (e.g. HIV testing, reimbursements)
- Aspects of the ring (e.g. effectiveness, lack of side effects)
- Her perceived HIV risk

3. What have been the reasons you have [chosen/not chosen] the ring as an HIV prevention method since you joined HOPE?

Possible probing topics:

- **KEY PROBE:** If changed in choosing/not choosing ring throughout HOPE; how often and why
- [*If ever accepted a ring*] **KEY PROBE:** Discuss her ability to use the ring or not
- How others were involved in her decision around ring use (e.g. male partner, family members, other participants)
- Aspects of personal life (partners, work, family, fertility plans)
- Aspects of the community/neighborhood (e.g. stigma/rumors/misconceptions of ring or ASPIRE)
- Effectiveness of ring
- Perceived effects (beneficial and adverse) of the ring
- Her perceived HIV risk

Purpose: To gather more in depth information about HIV risk perception and risk reduction strategies.

4. How have your worries about getting HIV changed since we last talked? Tell me about it.

Possible probing topics:

- Influence of behavior changes, including changes in sexual partners/practices, alcohol/substance use, or other risk behaviors
- Influence of study procedures (e.g. HIV testing, counseling)
- How HIV worries influences whether she has been using or not using the ring

5. What are you doing to protect yourself? (e.g. wearing the ring consistently, condoms, HIV testing, medical male circumcision, monogamy)

Attitudes and understanding of VR efficacy [Self-reported understanding of partial efficacy]

Purpose: Find out whether the participant's understanding of the partial efficacy of the ring has changed since joining HOPE, what that level of protection means to her and what impact that has on her interest in using the ring.

6. Can you please explain your current understanding about how well the ring protects against HIV?

Possible probing topics:

- *KEY PROBE:* How her understanding has changed since she joined HOPE

7. In what ways did this level of protection influence your decision to [choose/not choose] the ring in HOPE?

Possible probing topics:

- Interest/lack of interest in the ring as an HIV prevention method vs. other methods with higher efficacy
- Influence due to community, partners or others individuals' opinions about the level of protection of the ring

VR acceptability [in context of known efficacy]

Purpose: Get participant's opinion of the ring and its influence on her decision to choose/not choose use the ring.

8. What is your current opinion of the dapivirine ring?

- *KEY PROBE:* Whether her opinion has changed since her first interview
- Physical attributes:
 - Likes about physical attributes, such as color, texture, and size
 - Dislikes about physical attributes, such as color, texture, and size
- Use attributes:
 - *KEY PROBE:* Change in her opinion since she started in HOPE
 - Likes and dislikes about how it is used
 - How the ring felt in her body (every day, during sex or during menses)
 - Feeling upon initial insertion and once inside
 - Situations when she was more or less aware of the ring
 - Side effects experienced (or heard about)
- Other effects of the ring in her life

9. What worries do you have about the ring?

Possible probing topics:

- **KEY PROBE:** How her current worries influenced her decision to ever accept the ring or not
- **KEY PROBE:** Whether she has more or fewer worries since first interview
- **KEY PROBE :** Whether the type of worries have changed since first interview
- Hygiene
- Issues with insertion/removal or expulsions
- Pain (in general or during sex)
- Partner worries (feel during sex, dislike or disapprove)
- Family members or community members disliking/not approving
- Menses
- Side effects/fear of illness or infection from the ring

Purpose: Explore who she disclosed to about the ring and the circumstances of the disclosure.

10. Who (else) have you told about the ring since we last talked?

Possible probing topics:

- Primary sex partner, other partners, family members, friends, other participants, anyone else
- Circumstances and reasons of disclosure (e.g. during sex or not; voluntary or involuntary)
- What was said, reactions and attitudes to study and ring, and the participant's feelings about the disclosure
- Influence of discussions on ring use or study participation

Purpose: Find out what primary partner's opinion is of the ring and if the partner influenced the participant's decision to choose/not choose the ring.

11. What is your primary sex partner's current opinion of the ring?

Possible probing topics:

- **KEY PROBE:** Whether his opinion has changed since she has been in HOPE
- Partner's likes, dislikes, concerns/worries for himself, thoughts on ring being inserted in vagina, concerns for the participant
- Whether the ring being "female-initiated" influenced his opinions
- Role of ring in introducing/aggravating any problems in the relationship
- Partner's level of involvement in her decision to [choose/not choose] the ring
- Impact on his sexual experience/the sexual relationship
- If multiple partners, opinion of other partners

Purpose: To explore if there are attributes of the ring itself or how the ring was presented that, if changed, would make the participant more interested (resume usage) in the ring and HOPE.

12. What could we have done, if anything, to improve your experience with the ring while in HOPE?

Possible probing topics:

- Facilitate partner disclosure and support
- Counseling or other study procedures
- Changes in design of ring: physical characteristics
- Insertion, removal method, frequency of ring replacement
- Instructional/ educational materials or how these were provided

Purpose: To find out participants' interest in using the ring in the future. For non-acceptors if she would be interested in using the ring in the future if something about the ring or her circumstance changed and what those changes are.

13. If the ring becomes widely available in the future, what would make you interested in using the ring for HIV prevention?

Possible probing topics:

- *KEY PROBE:* If her opinion has changed since first interview
- *KEY PROBE:* Level of interest for the ring among other women in the community
- *KEY PROBE:* Using a ring that is 2 in 1 [i.e. also has contraceptive benefits (Multi-Purpose Prevention Technology - MPT) vs. single purpose (HIV prevention only)]
- Different level of effectiveness/HIV protection
- Use attributes (insertion, removal, duration of use [28 days vs. 3 months])
- Physical attributes (How it looks/feels)
- Access/availability (if she prefers accessing in: research clinic, public health facility, community pharmacies?)
- Cost of the ring
- Change in personal circumstances (e.g. different partner, different level of HIV risk)

Adherence

Purpose: To explore any adherence challenges she has experienced while using the ring in HOPE.

14. [If ever accepted a ring] Tell me about a specific time when you had a challenge using the ring.

Possible probing topics:

- Physical, interpersonal (e.g. with her partner), or emotional challenge
- Any challenges related to alcohol/other substance use
- Timing and circumstances of challenge
- If and how challenge was resolved

Purpose: To explore reasons for and frequency of ring expulsions and removals.

15. [If ever accepted a ring] Tell me about any times when you took the ring out or it came out on its own, either partially or fully.

Possible probing topics:

- Timing and circumstances when ring came out or was removed
- Instances of partner(s) removing the ring
- Position of her body when ring came out
- What did she do about it
- [If re-inserted outside of the clinic] was ring cleaned and how
- Removal reported to the clinic, why or why not.

Attitudes towards combination prevention (i.e., use-related attributes and preferences, access, cost, health system delivery)

Purpose: To find out if the participant and/or partner's preferences for other methods of HIV prevention have changed.

16. Tell me about other HIV prevention methods you have used.

Possible probing topics:

- *KEY PROBE:* Changes in methods since last talked
- Comparison of current method(s) to the ring
- Methods she plans to use in future
- Preference for which methods or combination of methods; why (e.g. cost, access, health system delivery, use-related attributes)
- Partner's preference for which method or combination of methods; why (e.g. cost, access, health system delivery, use-related attributes)

17. How has your participation in HOPE influenced your condom use?

Possible probing topics:

- *KEY PROBE:* Changes in condom use since last talked
- Thoughts on using condoms with the ring
- Changes in patterns of condom use, including ability to negotiate their use with partners
- Reasons for changes, if any

Reports of products storage [issues] and use

Purpose: To explore what participant did with the rings she took from the clinic and her acceptability of receiving 3 rings versus 1 ring.

18. [If ever accepted a ring] Referring to BA item 21, regarding difficulty storing rings at home, will you please tell me more about that experience?

Possible probing topics:

- Where did she store the ring(s)
- Who did she disclose ring(s) storage location; why
- Explore her thoughts on receiving 3 rings versus 1 ring
- Explore any changes in where stored ring throughout the study

19. Did you ever share rings with another person? If yes, what happened?

Possible probing topics:

- Who did she share with
- Explore why that person wanted the ring
- What happened to the ring (e.g. did she collect ring back to turn in or let the person keep)
- Explore if she shared on purpose or someone took ring

20. Did you save any rings for future use? If yes, why?

Possible probing topics:

- For whom did she save the rings (herself, family member, friend)

Perceived feasibility of study visit regimen [quarterly follow up]

Purpose: To explore in depth the participant's thoughts and preferences for quarterly versus monthly follow-up visits.

21. What has your experience been with the quarterly visits compared to the monthly visits you experienced in ASPIRE?

Possible probing topics:

- Preference for quarterly visit schedule (HOPE) or monthly (ASPIRE)
- Explore how visit schedule influenced decision or ability to use/not use the ring

Sexual activity, including condom use

Purpose: Explore the perceived effect of the ring (or the idea of the ring) on sexual activity.

22. How does the ring affect your sexual life? [If ever accepted the ring explore their experiences in HOPE, for non-acceptors explore their concerns]

Possible probing topics:

- **KEY PROBE:** Explore changes since last interview
- Effect on pleasure during sex for her or her partner
- Ring removals before or during sex
- Awareness or lack of awareness of the ring during sex for her and her partner
- Positive or negative physical or emotional changes with sex
- Changes in sexual practices, sexual partners, frequency, or reasons for having sex, etc.

Vaginal practices

Purpose: To understand what the participants wants their vagina to feel like (wet/dry/tight/other) generally and during sex.

23. Since being in HOPE has anything changed in regards to how your vagina feels?

Possible probing topics:

- *KEY PROBE:* How the ring in HOPE has affected desired vaginal state
 - Whether change was positive or negative
 - Did the ring interfere with sexual pleasure
- If changes, positive or negative changes?
- Change in how she wants her vagina to feel?

Wrap Up

24. We have talked about many things today. Before we finish, I wonder if you have any questions for me or if you have any additional comments about your experience in HOPE or about the discussion today?