

MTN-025

Interesting Cases In-depth Interview (IDI) 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. Questions pertaining to the specific interesting cases, C1 through C4 on the final page of this guide, can be asked when the interviewer deems it most appropriate: either immediately after question 1 or all the way at the end of the interview.
3. 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.
4. *Instructions/suggestions to interviewer are in italics and [brackets].*
5. 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.
6. The IDI guide is not meant to be used to take notes. Rather, you should use the separate debrief report form, where you will also insert your initials, the participant’s PTID, the date, length of the interview and other relevant information about this special case IDI, including the answers to the check-boxes at the beginning of this guide on accepting/not accepting the ring and reason for interesting case.
7. 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.
8. Before the participant arrives for the interview, interviewer should familiarize with what the interesting cases is, go through the guide and highlight all relevant questions for that participant based on skip patterns.

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

Interesting Cases

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 accepted ring at least once
- Has never accepted ring

Choose appropriate grouping and check type of interesting case:

- A) Early termination from the study; stopped using the ring; never used
- B) Seroconverter
- C) Social harm
- D) Stockpiled (stored extra) rings;
 - Shared ring(s) with others;
 - other reason not listed (Specify): _____

[Start Recorder and Read Introduction]: My name is _____. Thank you again for your willingness to be a part of this discussion. I am looking forward to hearing about your experiences. The main goal of this discussion is to better understand your experiences as a HOPE participant. 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 and there are no right or wrong answers. What we discuss here will be kept confidential and we will not share your personal information or responses with anyone outside of the study.

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].

Warm-Up

Purpose: To ask a broad opening question at the start of the IDI as an opener.

1. Tell me about your experience being in HOPE.

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

Interviewer can choose to ask interesting cases questions C1-C4 (located at the end of this guide) here or at the end of the interview, before the wrap-up section.

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

Purpose: Find out what the participant understands about partial efficacy of the ring, what that level of protection means to her and what impact that has on her interest using the ring.

2. Please explain your current understanding about how well the ring protects against HIV?

Possible probing topics:

- **KEY PROBE:** What it means to her that in ASPIRE the ring provided partial protection
- Preferred level of protection from the ring
- Who is protected and when
- Influence this understanding has/had on her ring choice

VR acceptability [in context of known efficacy]

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

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

Possible probing topics:

- **KEY PROBE:** How her opinion influenced her decision to accept the ring or not (*accept here means take the ring home from the visit*)
- **KEY PROBE:** How her opinion influenced her decision to use the ring or not (*use means to have inserted and worn the ring at some point between visits*)
- 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 starting 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

Purpose: To explore concerns and worries about ring use, and how this influenced her decision to accept (take home) and use the ring or not.

4. What worries do you have about the ring?

Possible probing topics:

- **KEY PROBE:** How her worries influenced her decision to accept the ring or not
- **KEY PROBE:** How her worries influenced her decision to use the ring or not
- 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.

5. Who have you told about the ring?

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 partner's opinion is of the ring and if the participant discontinued/not use/shared because there was something the partner did not like about the ring or how it works.

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

Possible probing topics:

- **KEY PROBE:** Influence of partner's opinion on her decision to [discontinue, share or stockpile the ring]
- If did not disclose to partner, why
- 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 participant has multiple partners, opinion of other partners besides her primary

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

7. What could be done to improve women's experience with the ring while in HOPE?

Possible probing topics:

- **KEY PROBE:** What could be improved for her personally
- 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

Adherence

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

8. [If ever accepted a ring, otherwise skip] Tell me about a specific time when you had a challenge using the ring (during HOPE).

Possible probing topics:

- **KEY PROBE:** Challenges using the ring during menses
- 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.

9. [If ever accepted a ring, otherwise skip] 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 (e.g. standing up, sitting down, laying down)
- 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

Reports of products storage issues and use

Purpose: To explore what participant did with the rings she took from the clinic and reasons why and with whom if she shared, or had rings taken.

10. What have you heard of other participant's rings going missing? (e.g. shared, taken, lost)

Possible probing topics:

- **KEY PROBE:** Did this ever occur with her rings
- With whom were rings shared; why
- Who took /stole ring(s); why
- What happened to the ring (e.g. did she collect ring back to turn in or let the person keep)

Purpose: To explore circumstances around participants saving rings for future use.

11. What have you heard about participants saving their rings for future use?

Possible probing topics:

- **KEY PROBE:** Did this ever occur with her rings
- For whom did she save the ring(s) (herself, friends, family)
- What made her stockpile the ring
- What happened to the rings (e.g. has she used them, shared them with others, still has them)
- If still has them, explore what she plans to do with them

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.

12. What is your opinion about the HOPE quarterly visits (every three months) compared to the monthly visits like you experienced in ASPIRE?

Possible probing topics:

- If no experience yet with quarterly visits, ask what they think about the plan of having quarterly visits
- Preference for quarterly visit schedule (HOPE) or monthly (ASPIRE- first 3 months of HOPE)
- Explore how visit schedule influenced decision or ability to use/not use the ring

Personal drug level results feedback experience

Purpose: To explore her personal drug level results.

13. [If ever accepted ring, otherwise skip] What feedback were you given by the counselor about your personal ring drug levels in HOPE?

Possible probing topics:

- *KEY PROBE:* Level of understanding of what her results meant (in terms of protection or use)
- If other staff spoke to her about her drug results, discuss that interaction

Purpose: Discuss participant's reactions to receiving her drug level results and how that may influence her interest in using or not using the ring while in HOPE.

14. [If ever accepted ring, otherwise skip] What was your reaction/experience receiving your personal drug level results from the counselor?

Possible probing topics:

- *KEY PROBE:* What are her feelings about getting her results
- *KEY PROBE:* What she finds helpful about receiving her ring drug level results
- *KEY PROBE:* Whether this drug results feedback may change her use/non-use of the ring
- Whether this drug results feedback may change her opinion of the ring
- Whether this information may change her relationship with study staff (e.g. trust)
- Whether this information may change her relationship with other participants
- Opinion on lag in receiving results (e.g. receiving results from month 1 @ month 3 visit)

Sexual activity, including condom use

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

15. How has the ring affected your sexual life?

Possible probing topics:

- **KEY PROBE:** Was this a reason for [discontinuation/ non-use/sharing or stockpiling of the ring]
- 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, condom use, or reasons for having sex, etc.

HIV Worries

Purpose: To gather more in depth information about participant's HIV risk perception and its influence on her use of the ring.

16. [Sero-converters SKIP] How worried are you about getting HIV currently?

Possible probing topics:

- Reasons for her level of worry
- How HIV worries influences whether she has been using or not using the ring

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

Purpose: To find out what HIV prevention method(s) participant and/or partner have used in combination with other methods, and their preference(s).

17. Tell me about all the HIV prevention methods you have used together with other methods. (provide the following examples if necessary: condoms, HIV testing, medical male circumcision, monogamy, ARVs if partner HIV+, reducing risky sexual behaviors, STI testing/treatment, oral PrEP)

Possible probing topics:

- **KEY PROBE:** Comparison of other method(s) to the ring
- **Key PROBE:** 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)
- Method or combination of methods she plans to use in future

If interviewer did not do so after question 1, she should ask interesting cases questions C1-C4 (located at the end of this guide) here.

Wrap Up

18. 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?

Interesting Cases Questions

For Reference, these are the Interesting Cases Groups:

- A) Early termination from the study; stopped using the ring; never used
- B) Seroconverter
- C) Social harm
- D) Stockpiled (stored extra) rings;
Shared ring(s) with others;
Other reason not listed (Specify): _____

Purpose: To get details about this interesting case.

C1. We are interested in your specific experiences with _____ [REASON FOR INTERESTING CASE GROUPS A and D, otherwise skip]. Please tell me more about that.
(Instructions: Insert the appropriate reason that makes the case interesting, i.e. share the ring, stockpile rings, stop using the ring early, exit the study early, persistent non-use, etc.)

Possible probing topics:

- Timing and circumstances
- Aspects of participant's personal life/circumstances contributing to this specific ring/study related behavior, such as major life events (travel/relocation, work, marriage etc.) or her relationship with her current partner
- Any other factors contributing to these circumstances
- Feelings about this specific ring/study related behavior
- Concerns/ problems with the ring

Purpose: To explore what the participant thinks about how and why she seroconverted.

C2. [For HIV sero-converters ONLY -GROUP B, otherwise skip] If it's okay with you, I'd like to talk about your HIV sero-status...What in your view may have contributed to you getting HIV?

Possible probing topics:

- Discuss any particular time or event where participant thinks she may have gotten HIV
- Discuss any recent changes in personal life, behaviors or circumstances
- Potential source of infection
- Perceived role of study participation on risk of HIV
- Perceived effects (beneficial and adverse) of the ring

Purpose: To determine what may influence early discontinuers to restart ring use.

C3. [For early discontinuers or NEVER used. GROUP A, otherwise skip] What, if anything, would change your decision about discontinuing use of the ring?

Purpose: To explore the social harm that occurred due to being in HOPE.

C4. [For social harm cases Group C, otherwise skip] Can you please tell me what happened in regards to [INSERT SOCIAL HARM]?

Possible probing topics:

- Her perceived causes of the incident
- How she responded
- How partner or person committing social harm responded
- Worries about future harm