

MTN-025

Decliner 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. 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.

Decliner IDI Guide

Insert participant's response to the following items from the Baseline Behavioral Assessment (BBA):

BBA item 26 (circle one): very worried, somewhat worried, not at all worried

BBA item 27 (circle one): little protection, some protection, a lot of protection

BBA item 29 (write in): _____

[Start Recorder and Read Introduction]: My name is _____ . Thank you again for your willingness to be a part of this discussion. We appreciate that you have already answered some survey questions about your reasons for declining participation in HOPE and we are grateful you are willing to speak with us in more detail about those reasons. Please know there are no right or wrong answers and we welcome every opinion about the topics we will discuss, so feel free to share your thoughts, opinions, and views openly. If during our discussion, there are issues or concerns that you would like to talk about, feel free to bring them up, even if I didn't ask about them. If you have specific questions during the interview, I will take note of them and answer them directly after the interview. If I cannot answer them, I can refer you to someone who may be able to help. Before we start, can you confirm for the recorder that you agree to take part in this discussion? [Wait for oral confirmation to begin].

As I mentioned before, the main goal of this discussion is to better understand your decision about not joining HOPE. I want to remind you 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.

Warm-Up

Purpose: To ask a broad opening question at the start of the IDI with no probes to get the participant talking. To characterize the decliner population and be able to compare to enrollers.

1. What is your understanding of the ASPIRE results?

Motivations for joining or declining participation in HOPE

Purpose: To ask about other participants reasons for not enrolling in HOPE as a way to ease into asking about reasons why she declined; she may be more forthcoming talking about other participant's reasons rather than her own.

2. What do you think are some of the reasons former ASPIRE participants would not participate in HOPE? [Instructions: If no open answer is provided, give examples from the probes in Q3]

Purpose: To get details about all of the reasons why she did not join HOPE; if not able to identify, various possible reasons will be offered through probing.

3. What are the reasons why you are not participating in HOPE?

Possible probing topics:

- *KEY PROBE:* How others (or perception of others opinion's) were involved in her decision not to participate
- *KEY PROBE:* Explanation of her response to BBA item 29
- Aspects of her personal life (partners or lack thereof at this point in time, work, family, fertility plans, religion, relocation)
- Social harm (e.g. partner violence or abuse) in ASPIRE/fear of social harm in HOPE
- Aspects of her community/neighborhood (e.g. stigma/rumors/misconceptions of ring or ASPIRE)
- Aspects of ASPIRE study procedures, visits, or staff (e.g. pelvic exams, contraceptive requirement)
- Aspects of the ring (e.g. effectiveness, side effects) or adhering to the ring
- Her perceived HIV risk
- Timing of joining the study/interest in joining at a later time

Purpose: To gather more in depth information about HIV risk perception and assess whether perception of HIV risk affected their decision to not participate in HOPE.

4. How worried are you about getting HIV currently?

Possible probing topics:

- Reasons for level of worry
- How HIV worries influenced decision to not join HOPE

Purpose: To explore what aspects of the ASPIRE trial or clinic setting influenced her decision to decline participation in HOPE. To inform what can be changed in future studies.

5. In what ways did your experience at the ASPIRE clinic influence your decision to not join HOPE? Tell me about it.

Possible probing topics:

- Study visits, study procedures, clinic
- Interaction with staff, counseling sessions
- Participant and partner engagement activities
- Interference with daily life (e.g. length of clinic visits or missing work or other requirements)
- Recommendations to avoid fatigue with study participation/keep participation fresh

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

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

6. Based on ASPIRE results, what is your understanding about how well the ring protects against HIV?

Possible probing topics:

- *KEY PROBE:* Referring to response to BBA item 27 options, assess participant's understanding of what "a little", "some", or "a lot" of protection means
- Thoughts on what she would consider to be "enough" protection for her to want to use the ring

7. In what ways did this level of protection influence your decision to not participate 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 if she declined because there was something she did not like about the ring or how it is used.

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

Possible probing topics:

- **KEY PROBE:** How her opinion influenced her decision to not participate in HOPE
- 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 participated in ASPIRE
 - 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 would you have about the ring?

Possible probing topics:

- **KEY PROBE:** How her worries influenced her decision to decline participation
- **KEY PROBE :** Refer to BBA 26; discuss response to how worried she is about the ring
- 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: Find out what primary partner's opinion is of the ring and if the participant declined because there was something the partner did not like about the ring or how it works.

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

Possible probing topics:

- **KEY PROBE:** If same primary partner as in ASPIRE, any change in partner's opinion since ASPIRE
- **KEY PROBE:** If new partner since ASPIRE, discuss if partner is aware of the ring and HOPE; if aware, explore partner's opinion of the ring
- 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 not use 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 in the ring and HOPE.

11. What could we have done to improve your experience using the ring while in ASPIRE?

Possible probing topics:

- Facilitate partner disclosure and support
- Counseling or other study procedures or requirements (contraception)
- 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 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.

12. 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:** 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)

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 prefers other methods of HIV prevention rather than the ring and why.

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

Possible probing topics:

- **KEY PROBE:** Methods she or her partner(s) used in the past? (e.g. condoms, HIV testing, medical male circumcision, monogamy, ARVs if partner HIV+, reducing risky sexual behaviors, STI testing/treatment, oral PrEP)
- **KEY PROBE:** Method(s) she is currently using
 - 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)

Vaginal practices

Purpose: To understand what the participants wants their vagina to feel like (wet/dry/tight/other) generally and during sex and if they declined participation due to the ring affecting the way their vagina feels.

14. Tell me about the things women insert in their vaginas or use to change the way their vagina feels.

Possible probing topics:

- **KEY PROBE:** What she uses or inserts
 - Purpose of (e.g. hygiene, health, to prepare for sex, or use during and/or after sex)
 - Type of change she is trying to achieve (e.g. what is her desired vaginal state: wet/dry/tight/other)
 - Motivations for the change (partner, society, family influences)
- **KEY PROBE:** How the ring in ASPIRE affected desired vaginal state
 - Whether change was positive or negative
 - Did the ring interfere with sexual pleasure

To characterize the 020 participants who choose not to enroll into -025

Purpose: To assess the participant's plans for pregnancy and contraception use to further characterize the decliner population and determine if that was influence on declining participation in HOPE.

15. What are your plans for having children in the near future? (e.g. wanting to have a baby immediately versus later, currently pregnant or breastfeeding)

Possible probing topics:

- Opinions on using contraception
- Current contraceptive method being used (if any)

Purpose: To determine what may influence her decision to join HOPE later.

16. What, if anything, would change your decision about joining HOPE?

Wrap up

17. 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 the ring, your experience in ASPIRE or about the discussion today?