**MTN-025**

Serial In-depth Interview (SIDI) 1 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.

1. *Instructions/suggestions to interviewer are in italics and [brackets].*
2. 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.
3. 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.
4. 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.
5. 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.**

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| **Acceptor/Non-Acceptor** |
| **Serial IDI Visit 1** |
| *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 31 (write in): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Fill out check box depending on participant’s decision at enrollment*:  🞎 Accepted ring 🡪 If yes, check one of the following:  🞎 Participant enrolled in qualitative component as an Acceptor  🞎 Participant enrolled in qualitative component as a Product Switcher  🞎 Did not accept ring (participant enrolled in qualitative component as a Non-Acceptor) |
| [*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. 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 joining HOPE and whether or not you have chosen the ring as an HIV prevention method. 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. Additionally, I want to remind you that whether you have chosen the ring or not 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 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 get details about all of the reasons why she joined HOPE and accepted or did not accept the ring.*   1. **What are the reasons you have chosen to join HOPE?**   *Possible probing topics:*   * *KEY PROBE:* How others were involved in her decision to participate * *KEY PROBE:* Explanation of her response to BBA item 31 * *KEY PROBE* : Reasons former ASPIRE participants would NOT participate in HOPE * Aspects of personal life (partners, work, family, fertility plans, religion, relocation) * Social benefit in ASPIRE/expectation of social benefits 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 |
| 1. **What are the reasons you [chose/did not choose] the ring as an HIV prevention method at enrollment?**   *Possible probing topics:*   * *KEY PROBE*: If applicable, change in decision to accept/not accept ring since enrollment; why * [*For Acceptors*] *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) * Adherence in ASPIRE and how that impacted her decision to choose the ring in HOPE or not * Aspects of personal life (e.g. 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.*   1. **How worried are you about getting HIV currently?**   *Possible probing topics:*   * Reasons for her level of worry * How HIV worries influenced her decision to join HOPE * How HIV worries influenced whether she chose to accept or not accept the ring |
| 1. **What are you doing to protect yourself?** (*e.g. wearing the ring consistently, condoms, HIV testing, medical male circumcision, monogamy*)   *Possible probing topics:*   * What was she doing to protect herself between ASPIRE and HOPE |
| *Purpose: To find out how her experience in HOPE might influence her use of the ring.*   1. **Tell me about your experience being part of HOPE so far.**   *Possible probing topics:*   * *KEY PROBE*: Differences between HOPE and ASPIRE * *KEY PROBE:* How this has impacted her decision to accept the ring or not * Likes and dislikes about HOPE and reasons * Experiences during study visits or at the clinic, * Site specific participant engagement activities * Experiences interacting with other participants * Effects of study 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 |
| **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 choosing the ring.*   1. **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 * Preferred level of protection from the ring |
| 1. **In what ways did this level of protection influence your decision to participate in HOPE?**   *Possible probing topics:*   * *KEY PROBE*: How perceived level of protection influenced decision to choose/not choose the ring as HIV prevention method * 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 the ring.*   1. **What is your current opinion of the dapivirine ring?**   *Possible probing topics:*   * *KEY PROBE*: How her opinion influenced her decision to 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 |
| 1. **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* : 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: Explore who she disclosed to about the ring and the circumstances of the disclosure.*   1. **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 primary partner’s opinion is of the ring and if the partner influenced the participant’s decision to be a part of HOPE and choose/not choose the ring.*   1. **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 [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 in the ring.*   1. **[***NON-ACCEPTORS*only**] What could we have done to improve your experience using the ring while in ASPIRE?**   *Possible probing topics:*   * *KEY PROBE:* What would have influenced her decision about choosing/not choosing the ring in HOPE * 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 * Other things besides experience in ASPIRE would have changed her decision about choosing/not choosing the ring |
| **Adherence** |
| *Purpose: To explore any adherence challenges she has experienced while using the ring (either in ASPIRE or so far in HOPE).*   1. **Tell me about a specific time when you had a challenge with using the ring.** [*For acceptors ask about HOPE and for non-acceptors ask about experience in ASPIRE].*   *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.*   1. **Tell me about any times when you took the ring out or it came out on its own, either partially or fully.** [*For acceptors ask about HOPE and for non-acceptors ask about experience in ASPIRE*].   *Possible probing topics:*   * Timing and circumstances when ring came out or was removed * Times when someone else took the ring out * Instances of her partner(s) removing ring * Position of her body when ring came out * What she did 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 prefers other methods of HIV prevention rather than the ring and why.*   1. **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*) |
| 1. **How has your participation in HOPE influenced your condom use?**   *Possible probing topics:*   * 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 |
| **Sexual activity, including condom use** |
| *Purpose: Explore the perceived effect of the ring (or the idea of the ring) on sexual activity.*   1. **How does the ring affect your sexual life? *[For Acceptors explore their experiences in HOPE, for Non-Acceptors, explore their concerns or their experience in ASPIRE]***   *Possible probing topics:*   * *KEY PROBE*: Was this a reason for choosing/not choosing ring * *KEY PROBE*: Ring removals before or during sex (frequency of sex without ring inside) * Effect on pleasure during sex for her or her partner * Awareness or lack of awareness of the ring during sex for her and her partner * Positive or negative physical or emotional (ie. concerns or feeling protected) 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.*   1. **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 enroller population in order to compare to decliner population.*   1. **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) |
| **Wrap up** |
| 1. **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?** |