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MATRIX-002 Study Qualitative Operational Guidance: Use of In-Depth Interview (IDI) Guides in situations where time available to conduct an IDI may be limited (for participants and sexual partners)

Issued: v1.0, 8 December 2023

This operational guidance document applies to the qualitative component of MATRIX-002 at all sites. The purpose of this document is to provide guidance for conducting In-Depth Interviews (IDIs) using the existing IDI guides in situations where time limitations may make it difficult to ask all questions currently provided in the IDI guides. This operational guidance provides teams with information regarding which topic areas and questions are most important to cover during each IDI, for both participants and their sexual partners. No additional questions have been added to the IDI guides.


1. Each IDI guide is included as an appendix with this operational memo. The questions **highlighted in yellow** are high priority and should be covered in all interviews, as relevant and appropriate.
2. If the cadence of the interview suggests that time limitations will not be an issue, interviewers should consider asking the questions not highlighted, as appropriate.

Please note that this Operational Guidance is official study documentation, and it should be filed as part of Essential Documents.

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Appendix 1: Participant IDI guide, priority questions highlighted

MATRIX-002: Participant In-Depth Interview Guide

Trial to Assess Acceptability and Safety of Two Placebo Prototype Vaginal Films

Version 1.0, 2June2023

[Start Recorder and Read Introduction]:

My name is _____. Thank you again for your willingness to be in this study. The main goal of this conversation-style interview today is to better understand your experience participating in this study and using the vaginal film. I want to remind you that there are no right or wrong answers, and what we discuss here will be kept confidential; we will not share your personal information or responses with anyone outside of the study.

	Questions	Probes
1. Introductory Questions		
<i>To begin our conversation, I would like us to talk about the community that you live in. This will help me get an understanding and background of your community.</i>		
1.1	Please tell me about the community you live in.	<ul style="list-style-type: none"> • Roles of women and men in your community • Who is generally responsible for making sexual health decisions in your community? • Community attitudes on HIV prevention • Community attitudes on vaginal products (including for non-HIV prevention purposes)
1.2	And how about you – what is your life like?	<ul style="list-style-type: none"> • Education/work • Household/family • Social life
2. Context of HIV prevention in your community		
2.1	Tell me about the methods or products you have used to prevent HIV?	<ul style="list-style-type: none"> • Let us discuss what you have used. • Why did you choose this option? • What did you like about it? • What did you dislike about it? • Why did you not choose a different strategy?
2.2	Can you describe a situation or relationships where you felt you may have used something to prevent HIV but you did not?	<ul style="list-style-type: none"> • What stopped you from using something to prevent HIV? (e.g., cost, privacy) • Challenges with using HIV prevention consistently?
3. General Vaginal Film Use		
<i>We are now going to talk about your experiences in the study, and we want to hear about your experience with the film. Remember, we are still developing this product so you should feel free to tell us about what you liked and disliked, and what changes you would make to the product as well. This information will be shared with the scientists developing the film and they are eager to learn from you about what you experienced. Your opinions are important to them in designing a product that women would like to use.</i>		
3.1	What were your initial impressions of the film before you used it?	<ul style="list-style-type: none"> • What would others in your community think about it?
3.2	Overall, how did you feel about inserting the film into your vagina?	<ul style="list-style-type: none"> • How many insertions/attempts did you make when inserting for the very first time? Describe how you inserted it (what worked, what was difficult?). • How about any differences between the 1st month and 2nd month? • Did you encounter any challenges and/or success? • Did you feel comfortable with vaginal film insertion? • Did you feel confident with how you placed it in your vagina?



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3.3	Describe your experience using the vaginal film over the past two months. How did it go for you?	<ul style="list-style-type: none"> • Before you started using the film, what did you expect the experience to be like? Did you have any concerns prior to use? • How did those expectations or concerns play out compared to using the films over the last 2 months? • Did it get easier or harder to use the film over time? Why? • What kinds of challenges did you experience? • Did you get help with the film from the study clinician or counsellor during your time in the study? In what ways? • Did anything about the film surprise you when you were using it? [<i>probe</i>: in positive ways and in ways that you did not like]. • Did you ever notice any of the film coming out of your vagina? Describe (activities engaged in, circumstances of noticing film, timing post-insertion).
3.4	Did you experience any side effects while using the film? Describe.	<ul style="list-style-type: none"> • What changes did you notice in your vaginal environment? (e.g., wetness, dryness, discharge) <ul style="list-style-type: none"> ○ Anything done to manage changes? ○ How she felt about the changes
3.5	What are your overall opinions about the vaginal film now that you have used it for two months?	<ul style="list-style-type: none"> • What aspects of the product have worked well for you? What did not work well (challenges/dislikes)? • What did you think about the: <ul style="list-style-type: none"> ○ size ○ shape ○ texture ○ colour ○ method of insertion ○ perceived protection from this type of technology ○ monthly duration (of use) ○ film insertion instruction pamphlet

4. Vaginal Film Discreetness and Disclosure

I would now like to ask you questions about your decisions regarding disclosing your use of the vaginal film to others and discreet (or private) use of the vaginal film.

4.1	<p>Using the vaginal film in this study is a personal choice, and some people may keep their use of the film to themselves, while others may prefer to disclose their vaginal film use to other people.</p> <p>Who did you tell about using the vaginal film?</p>	<p>If disclosed:</p> <ul style="list-style-type: none"> • To whom did you disclose? <ul style="list-style-type: none"> • What did you tell them about the film? • How did they respond to your disclosure? • Why did you disclose? <p>If not disclosed:</p> <ul style="list-style-type: none"> • Why did you choose not to disclose? • [If sexual partner is not mentioned probe specifically the reason/s for not disclosing]
4.2	How important was it for you that you could use the vaginal film discreetly, i.e., without others knowing (even if you did disclose to others)?	<ul style="list-style-type: none"> • Were there any times where someone found out about your vaginal film use without you telling them? How did they find out? • Were you nervous that other people would find out? How did you handle this over the study?

5. Life Fit and Relationship Fit

Now I am going to ask you questions about how the vaginal film fit into your life in general as well as in a few key ways, including your sexual relationship with your partner. Please remember that whatever you tell me will remain confidential, so please feel free to share anything you feel comfortable talking about.

5.1	Can you tell me more about your current sexual partner?	<ul style="list-style-type: none"> • What kind of relationship are you in? • How often do you see each other? • How easy/difficult is it for you to make your own decisions and choices about sex and health in this relationship? What makes it easy/difficult for you?
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5.2	How did the film fit in (or not) with your sexual relationship?	<ul style="list-style-type: none"> • How did the film affect your sex life overall while you were in the study? • We know it isn't always possible to follow all the instructions in studies like this: how did it go to refrain from sex (and using other vaginal products) during the first month? • What was it like to have sex with the film in? Describe the experience. • In what ways, if any, did it affect sexual pleasure (for you and your partner)? • Did your partner say anything about what it was like for them? • What role did your sexual partner have in your liking – or not liking - the film? • How did your sexual partner support you, if at all? In what ways did you find them unsupportive? • How did your sexual partner give you worries or stress about the film?
5.3	Can you tell me how the vaginal film fit – or did not fit - into your life?	<ul style="list-style-type: none"> • What adjustments, if any, did you make to your life when using the film? Did any of this change over time for you? • How did using the film affect your use of menstrual products? Your hygiene or cleansing? • How did using the film affect your use of other vaginal products? <p><i>[For changes noted: How did you feel about these changes? How did you adjust to them]</i></p>
5.4	Who else had influence on your use of the vaginal film over the last 2 months?	<ul style="list-style-type: none"> • Other sexual partner(s), friends, family, others in the community? • What was it like? • How did they change your attitudes and behaviours? • Are there any myths associated with using these kinds of products? • Are there any beliefs (religious/traditional) that are associated with using these kinds of products?
<p>6. Messaging and Future Use</p> <p><i>Now we are going to talk about your factors that would make the vaginal film an option that women would choose to use in the future. Remember that this vaginal film is still in its developmental stage, so your input and knowledge as someone who tried the vaginal film for the past two months is very important and valuable to us.</i></p>		
6.1	<p>You have used the product for two months and have a good sense of what it is like to use it.</p> <ul style="list-style-type: none"> • What would appeal to women in your community about using this vaginal film? • What concerns or questions do you think women in your community would have? 	<ul style="list-style-type: none"> • How would women in your community feel about the discreetness of using the film? What about the design and look of the film? What about the color and texture of the film? • How do you think other women would view inserting the film once a month?



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6.2	<p>What did you think of the packaging of the vaginal film?</p> <p><i>[Demonstration packaging available]</i></p>	<ul style="list-style-type: none"> • What did really you like about the packing for the film? Describe. • What did really you not like about how the film was packaged? Describe. • What do you think about how easy/hard it would be to keep the packaged films private? • How easy/hard would it be to take the packaged film with you if you are traveling away from home? • What suggestions do you have for how you would have liked the film to be packaged?
6.3	<p>Now, think way ahead into the future: If the vaginal film is shown to prevent HIV in future studies where it has medication in it - and makes it into the market, would you consider using vaginal film? Why or why not?</p>	<ul style="list-style-type: none"> • How much would you prefer it to cost? [Insert relevant country currency] What is the most you would be willing to pay per month for the film? • Where would you like to get it from and what are your reasons for preferring this type of location(s)? (e.g., clinic, pharmacy) • We know it will take some time for the film to dissolve and start to work after being inserted in the vagina. The person using the film should not have sex while it starts to dissolve. How long would you be willing to wait after inserting it, before having sex?
6.4	<p>The scientists developing this film for HIV prevention are also working on a film that could prevent HIV and pregnancy at the same time. It would have two drugs in it so would be a "2-in-1" film. What are your thoughts about that concept?</p>	<ul style="list-style-type: none"> • What appeals to you about a 2-in-1 film? • Does anything bother or raise concerns for you about a 2-in-1 film? • What questions do you have about this idea?
6.5	<p>Remember that we said this vaginal film is still being developed, we are interested in hearing your thoughts about any important changes we could make to this product that would make it better and easier to use for women like you.</p> <p><i>[For example, in this study we used two films with different shapes (rounded and squared corners). This was in response to other research where women had different opinions about the film's shape.]</i></p>	<ul style="list-style-type: none"> • What do you think of this one you used compared with this one? (Show example of two film designs and packaging) • Which one do you prefer and why? • If the film had been made like this (e.g., square), how might it affect how you feel about the film? • How might it affect how you use the film? • What other design changes to the film or ideas would you like the scientists developing it to consider? <ul style="list-style-type: none"> • How important would these changes be to you?
6.6	<p>If you had an opportunity to change how the vaginal film is used or how it looks or feels, how would you change it?</p>	<ul style="list-style-type: none"> • What would those changes do – why would you make them?
7. Conclusion		
7.1	<p>Thank you, you have answered my questions. We appreciate all that you've shared today. Your experiences are important, and you sharing so openly during this interview is really valuable.</p> <ul style="list-style-type: none"> • Thinking about your overall experience during the study, is there anything else that you think it would be helpful for us to know? <p>Thank you for taking the time to share your opinions with me today. We really appreciate your time.</p>	



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Appendix 2: Sexual Partner IDI guide, priority questions highlighted

MATRIX-002: Sexual Partner IDI Guide

Trial to Assess Acceptability and Safety of Two Placebo Prototype Vaginal Films
 Version 1.0: 5June2023

	Questions	Probes
<p style="text-align: center;">1. Introductory Questions</p> <p style="text-align: center;"><i>Thank you for making the time to have this conversation with me. To begin our conversation, I would like us to talk about the community that you live in, and for you to share a bit of a background about you and your relationships. You have a right not to answer any question that you may feel uncomfortable with. Also, please remember that whatever we talk about in this room is confidential and will not be shared with your partner. This will help me get an understanding and background about you and your community.</i></p>		
1.1	<p>Please begin by telling me about the community you come from and about yourself. Describe your current relationship(s).</p>	<ul style="list-style-type: none"> • Can you tell me a bit about your background? If you're working, what do you do for work? • How did you and your partner in the study meet? How long have you been together? • How would you describe your relationship with your partner who was in the study? (for example, main partner/other). • How do you usually spend time with this partner? What kinds of things do you do together? • If you have other romantic and/or sexual partners, how do you usually spend your time when you are with them? What kinds of things do you usually do together?
1.2	<p><i>Interviewer note: Refer to Question 8 on the Sexual Partner Demographic CRF. Skip to 1.3 if sexual partner reported an HIV+ status.</i> Can you tell me about a situation where you thought you may have been at risk of being infected with HIV?</p>	<ul style="list-style-type: none"> • How has this situation influenced your attitude towards HIV? • Understanding of HIV and other STIs? • Your level of concern of getting HIV? • What would you say are your chances of getting HIV? What things factor into your thinking?
1.3	<p><i>For HIV negative participants:</i> How do you protect yourself and your partner against HIV infection?</p> <p><i>For HIV positive participants:</i> How do you protect your partner against HIV infection?</p>	<ul style="list-style-type: none"> • What, if anything, are you using (or doing) in your current relationship(s)? – How consistent are you? • Why do you use this/these versus other strategies? • What other strategies, if any, have you used in the past? • How do you feel about trying new HIV prevention options? • Describe your role in HIV prevention within your relationship(s).
<p style="text-align: center;">2. Experience using Vaginal Film</p> <p style="text-align: center;"><i>Now, I would like to ask you questions about the vaginal film from this study. First, I would like to ask you about your thoughts on a vaginal film and then about you and your partner's experience with using the film during the study.</i></p>		
2.1	<p>Please tell me about what you know about your partner's use of the vaginal film?</p>	<ul style="list-style-type: none"> • How did you find out that your partner was participating in this study and using the vaginal film as part of her participation? • What was your initial thought when you found out? • Have your thoughts or feelings about the film changed over the course of the study?
2.2	<p>What did your partner tell you about how the vaginal film is used?</p>	<ul style="list-style-type: none"> • Where it is inserted • How it is inserted • How long it is going to be there • Period of no sexual intercourse during study participation and how did you feel about abstaining from sex during this period?



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2.3	Were there any changes that you noticed to your partner's vagina?	<ul style="list-style-type: none"> • Changes in vaginal environment • Changes in your sexual pleasure/sensation [<i>note experience during sex explored below</i>] • What did you expect might happen? • What was your actual experience?
3. Vaginal Products, Film Attributes, Acceptability and Preferences <i>We will talk next more generally about prevention products that are inserted in the vagina. I will also ask your opinions about the vaginal film as a new technology for HIV prevention and ask you to think about how it compares to existing HIV prevention options.</i>		
3.1	How do you feel about the use of vaginal products in general?	<ul style="list-style-type: none"> • Do you feel differently about medical/traditional products that are inserted in the vagina? • Are there any myths or stories surrounding vaginal products that might affect views of the film? • What vaginal products are most common in your community? • What are they used for (e.g., sexual pleasure, hygiene purposes)?
3.2	How do you feel about this vaginal film in particular? [<i>consider having film available to touch/feel and whether to include vaginal model/placement demo</i>].	<ul style="list-style-type: none"> • What do you think of how it looks and feels? • What do you think of where it is placed in the vagina?
3.3	How confident are you that a technology such as the vaginal film would succeed in preventing HIV infection (if it had medication in it to prevent HIV)?	<ul style="list-style-type: none"> • Explore factors shaping these perceptions.
3.4	How do you feel about women being able to use a product like the vaginal film in the future without having to disclose to their partners?	<ul style="list-style-type: none"> • How do you feel about HIV prevention products that women could use independently (on their own)? • Sexual and reproductive health power shifts? Feeling about changes in prevention responsibility (compared to male condoms)? • Opinion about her discreet use and disclosure to her SP? • What do you think is the role of the sexual partner in the use of a product like the vaginal film to prevent HIV?
3.5	How does a vaginal film (as a possible future HIV prevention option) compare to using condoms (male and female), oral PrEP pills, and other HIV prevention strategies? <i>Interviewer note: Ensure that participant is familiar with oral PrEP when probing.</i>	<ul style="list-style-type: none"> • Impacts on sexual pleasure and sensation
4. Physical Sensation of the vaginal film use during sex <i>I now would like to ask you a few questions about your sexual experience during your partner's vaginal film use.</i>		
4.2	When you and your partner had sex while she was in the study, how would you describe how it felt?	<ul style="list-style-type: none"> • Did you notice the film? In what ways? • (If she did disclose) Do you think that you would you have noticed if she had not told you she had inserted a vagina film?
4.3	What were the notable changes during sex, if any, that you can share with me?	<ul style="list-style-type: none"> • Did you notice a change in sexual sensation or pleasure? Describe. • Was there a difference in the vaginal environment? • Was there a change in vaginal dryness or wetness that you noticed? • How did you notice these changes? Did you discuss them?



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5. Perceived benefits and concerns/challenges with the vaginal film

Now, I would like to ask you about how you think this vaginal film might offer benefits in the future to sexual partners (like you), and your perceived concerns/challenges with vaginal films.

5.1	How do you feel about your partner having been in this vaginal film study?	<ul style="list-style-type: none"> Why did you feel that way? What did she tell you about the study? Did you do anything to motivate her to stay in the study? What kind of support did you provide her?
5.2	What would you say you liked and/or disliked about your partner's use of a vaginal film?	<ul style="list-style-type: none"> Did you experience any changes in sexual interests, either from you or from your partner? What were the benefits for you?
5.3	What would you say to other sexual partners of women who want to use a vaginal film for HIV prevention in the future (if it is found to be effective)?	<ul style="list-style-type: none"> Why would you encourage/discourage them?

6. Messaging and Future Use

Now I am going to ask you a couple of questions about what you feel other people close to you may think about vaginal film use by their sexual partners and if people would be willing to use it in the future. Remember that this vaginal film is still in its developmental stage, so your input and knowledge as someone who has had a sexual partner use a vaginal film for the past two months is very important and valuable to us.

6.1	If you can take a moment and think about your circle of friends, how do you think they would feel about their sexual partner using a vaginal film for HIV prevention?	<ul style="list-style-type: none"> How do you think her peers or friends would feel? How would your peers or friends feel about a vaginal film?
6.2	How would you describe a vaginal film to someone who does not know what it is?	<ul style="list-style-type: none"> What is the purpose of a vaginal film? How is it used?
6.3	How would you feel if – in the future – these vaginal films were found to work to prevent HIV and were for sale?	<ul style="list-style-type: none"> Where would you want to get it from? At what cost (insert currency) Thinking about your current and past relationships, in what types of relationships do you think the film could be an ideal HIV prevention option? In which ones do you think the film would not be a good choice?
6.4	How would you feel if -in the future – the vaginal film could include pregnancy prevention/contraception in addition to HIV prevention?	<ul style="list-style-type: none"> Would this change your view of the vaginal film? Would you want your partner to use this kind of vaginal film?

7. Conclusion

7.1	Now that I have asked you all the questions that I have, I might have left out very important things that we should know about the vaginal film. Is there anything else that I may have missed that you would like to tell me about your experiences with the vaginal film?	Anything you would like to be sure the scientists who are developing the films know about your film experiences/views?
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Thank you, you have answered my questions. We appreciate all that you've shared today. Your experiences are important, and I appreciate you sharing so openly during this interview.