

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>1. Introductory Questions</p> <p><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></p> <p>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>2. Experience using Vaginal Film</p> <p><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	Please tell me about what you know about your partner's use of the vaginal film?	<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	What did your partner tell you about how the vaginal film is used?	<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?
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?
<p>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></p>		
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	<p>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?</p> <p><i>Interviewer note: Ensure that participant is familiar with oral PrEP when probing.</i></p>	<ul style="list-style-type: none"> • Impacts on sexual pleasure and sensation
<p>4. Physical Sensation of the vaginal film use during sex</p> <p><i>I now would like to ask you a few questions about your sexual experience during your partner's vaginal film use.</i></p>		
4.2	<p>When you and your partner had sex while she was in the study, how would you describe how it felt?</p>	<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	<p>What were the notable changes during sex, if any, that you can share with me?</p>	<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?
<p>5. Perceived benefits and concerns/challenges with the vaginal film</p> <p><i>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.</i></p>		
5.1	<p>How do you feel about your partner having been in this vaginal film study?</p>	<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	<p>What would you say you liked and/or disliked about your partner's use of a vaginal film?</p>	<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	<p>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)?</p>	<ul style="list-style-type: none"> • Why would you encourage/discourage them?
<p>6. Messaging and Future Use</p> <p><i>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.</i></p>		
6.1	<p>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?</p>	<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?
<p>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.</p>		

Staff initials: _____

Date: ___ / ___ / _____ (dd/mm/yyyy)