



MATRIX-001, SBR Operational Guidance #2


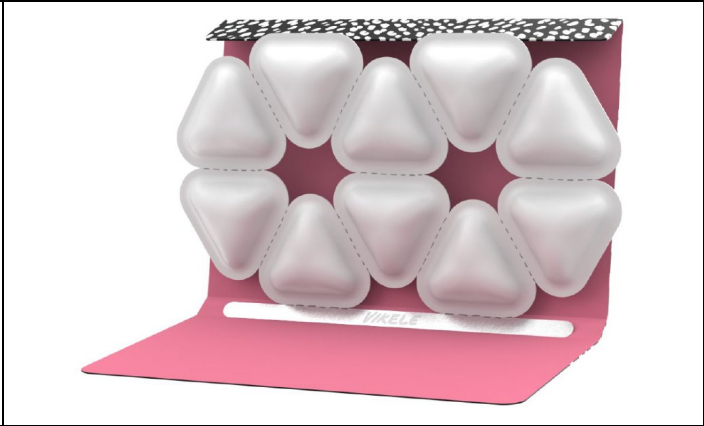
Operational Guidance Category:

- Clinical Procedures
 Pharmacy
 Laboratory
 Other, specify: SBR

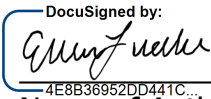
Brief Description: In-Depth Interview Updated Question by Question Guidance for Interviewers and New Packaging Prototype

The purpose of this Operational Guidance document is to provide guidance for (1) conducting In-Depth Interviews (IDIs) using the existing MATRIX-001 guide and (2) the use of updated prototype packaging while conducting IDIs.

- 1. Question-by-Question Guidance for Interviewers:** This operational guidance provides teams with an updated question-by-question guidance for the MATRIX-001 IDI guide to provide more contextual information about key probes to interviewers and to reflect updates in the prototype packaging for IDIs beginning on 23 May, 2024 and thereafter. The IDI guide is included as Appendix 1 with this operational memo. The guidance for interviewers is presented in *italicized blue text, with a gray background* with updated guidance indicated with *yellow highlight*.
- 2. Prototype Packaging:** In collaboration with other MATRIX Hubs, CONRAD has developed a new updated prototype packaging option for their vaginal insert, shown in image B (next page) and in a visual tool included as Appendix 2. The new images and model packaging should be used together during IDIs (question 6.4) to discuss the proposed packaging and options for how many inserts are included in each pack. The prototype hybrid blister domes that you have received are a model, and thus while they look like the proposed packaging, they do not feel or function in the same way. Please retain the previous packaging shown in image A to support discussions around the colors, V branding, and the idea of single sachets (or blister domes) in a box vs. a wallet design. Please see updated guidance for interviewers related to packaging under question 6.4 of the revised IDI guide in Appendix 1.

<p>A. Previous prototype packaging Use to support discussions about packaging colors, V brand, or to support the idea of single sachets in a box vs. wallet design.</p>	<p>B. Updated prototype packaging: Hybrid Blister Dome Use as primary packaging prototype example during interviews beginning 23 May 2024.</p>
	

Operational Guidance memos, once signed, must be distributed to MATRIX sites via email. Sites are responsible for ensuring that appropriate staff review and understand the content of each memo and file the memo with their essential documents. Operational Guidance memos must also be posted to the appropriate MATRIX webpage. As per SSP section 13, the memos are official study documentation and will be considered an official part of the MATRIX SSP Manual. The Operational Memo becomes effective the date it is signed.

DocuSigned by:

4E8B36952DD441C...

Name of Author: Ellen Luecke
Title: MATRIX/D2D Pillar 2 Study Coordinator, RTI International

5/22/2024
Date

Appendix 1: MATRIX-001 IDI guide, question by question guidance for interviewers updated 22 May 2024

<i>Before you begin:</i>	
<ul style="list-style-type: none"> • Start Recorders and introduce yourself. • Thank the participant for participating, and state PTID, date, and time on the recording. • Outline that the goal of the interview is to better understand their experience participating in the study and using the vaginal insert. • Remind them that there are no right or wrong answers, and that what you discuss will be kept confidential – you will not share their personal information or responses with anyone outside of the study. 	
Questions	Probes
1. Introductory Questions	
1.1	<p>Can you tell me about the community you live in?</p> <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 about HIV prevention and vaginal products <p><i>GUIDANCE FOR INTERVIEWERS: This is an icebreaker, to set the tone for the next questions. The intention is to describe where they currently live, not where they come from. You can lead into this by probing the participant to tell you about themselves, where they live, and the people who live where they live.</i></p>
2. Context of HIV and other STI Prevention in your community	
2.1	<p>Have you ever had a close call, where you thought you may have been at risk of being infected with HIV?</p> <ul style="list-style-type: none"> • If so, what did you do or consider doing to prevent it from happening again? • What challenges did you encounter while trying to prevent it from happening again? <p>Has any of your friends/family or anyone you know ever thought they may have been at risk of being infected with HIV? If yes, what did they do to prevent it from happening again?</p>
2.2	<p>The vaginal insert that you were using in this study hopes to prevent HIV and some STIs (i.e., herpes) in the future, how do you feel about a product that could prevent multiple STIs?</p> <ul style="list-style-type: none"> • What would be any issues or problems with this? • Any benefits to this? • How likely would you be to use it if it prevented pregnancy as well?

3. General Vaginal Insert Use

We are now going to talk about your experiences in the study, and we want to hear about your experience. 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 insert. Your opinions are important to them in designing a product that women would like to use.

3.1	Tell me what you thought of the vaginal insert when you first saw it and how it is used.	<ul style="list-style-type: none"> How would others in your community think about it? Your friends? Your family?
3.2	How did you feel about the way you had to insert the vaginal insert into your vagina?	<ul style="list-style-type: none"> What did you use to insert it? Challenges and success encountered
<p><i>GUIDANCE FOR INTERVIEWERS: We'd like to know what was easy or frustrating about insertion. Please probe on whether the instructions were clear, use of fingers, etc.</i></p> <p><i>The probe "What did you use to insert it?" is intended to understand whether a participant used anything other than their fingers to aid in insertion. If they raise a desire for an applicator or proposed changes to insertion technique, please probe on this further. It will be useful for product developers to know whether the lack of applicator is a barrier to use or simply a preference. In other words, if there is no applicator would it be a deal-breaker that would cause someone to not use the product?</i></p>		
3.3	Can you describe your experience using the vaginal insert over the past two months? How did it go for you?	<ul style="list-style-type: none"> Ease of use over time Comfort Side-effects encountered. Hygiene impacts: vaginal insert vs other vaginal products Did it get easier to use over time? How did you fit it into your daily routine? How did your impressions change over the course of the study? Effect on sex?
<p><i>GUIDANCE FOR INTERVIEWERS: We'd like to know what was easy or frustrating about insertion. Please probe on whether the instructions were clear, use of fingers, etc. If they raise a desire for an applicator or proposed changes to insertion technique, we are interested in learning more about this as well.</i></p> <ul style="list-style-type: none"> <i>If side effects are mentioned, we are also interested in how they were managed.</i> <i>Hygiene impacts also includes any questions/concerns about use during menses.</i> <i>The probe about "fit into your daily routine" is duplicative of a question below, and can be de-emphasized or skipped for time here, unless it comes up naturally.</i> 		
3.4	Can you share your thoughts on the vaginal insert, and how it has met your needs and preferences as a user?	<ul style="list-style-type: none"> What aspects of the product have worked well for you? What would you change to improve the insert? (Size, design, texture, colour, insertion, perceived protection, effect on sex, etc)
<p><i>GUIDANCE FOR INTERVIEWERS: The probe about changes to improve the insert is duplicative of a question below, and can be de-emphasized or skipped for time here, unless it comes up naturally.</i></p>		

3.5	How did you feel about inserting the product into your vagina on your own?	<ul style="list-style-type: none"> • Comfort with vaginal insert use. • Familiarity with your vagina • Confidence with placement • Number of insertions/attempts when inserting for the very first time. • Did you find it easier the second time and so forth?
<p><i>GUIDANCE FOR INTERVIEWERS: For questions related to comfort and familiarity with the vagina, you might probe on whether they have used other products that are inserted into the vagina, or ask how easy it was to guide the product into their vagina. If the participant expresses interest in an alternate way of inserting the vaginal insert, including an applicator, please explore that here.</i></p>		
<p style="text-align: center;">4. Vaginal Insert Discreetness and Disclosure</p> <p><i>I would now like to ask you questions about your decisions regarding disclosing your use of the vaginal insert and discreetness use of the vaginal insert.</i></p>		
4.1	Using the vaginal insert is a personal choice, and some people may prefer to keep this private until they are ready to talk about it, while some would prefer to disclose that they are using a vaginal insert much earlier than others. How did you decide who you did and didn't tell about using the vaginal insert?	<p>If Yes:</p> <ul style="list-style-type: none"> • Who did you disclose to? • What did you tell them (those that you disclosed to) • How did they respond to your disclosure? • Why did you disclose? <p>If No:</p> <ul style="list-style-type: none"> • Why did you choose not to disclose?
4.2	How important was it for you that you could use the vaginal insert discreetly, i.e., in secret?	<ul style="list-style-type: none"> • How about any times where someone found out about your vaginal insert use without you telling them?
<p><i>GUIDANCE FOR INTERVIEWERS: You can first probe on whether anyone found out about them using the vaginal insert without being told, and following up to understand what happened.</i></p>		
<p style="text-align: center;">5. Life Fit and Relationship Fit</p> <p><i>Now I am going to ask you questions about how the vaginal insert impacted your life in general as well as your sexual relationship with your partner. Please remember that whatever you tell me will remain confidential, so please feel free with sharing your responses.</i></p>		
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 it is for you to make your own decisions and choices about sex and health in this relationship?
5.2	Please can you tell me how the vaginal insert fitted or did not fit into your life?	<ul style="list-style-type: none"> • What adjustments did you have to make to your life when using it? • Did it have any impact on how you engaged with others? With your partner? • Were you nervous that other people would find out?
<p><i>GUIDANCE FOR INTERVIEWERS: When asking about life fit and adjustments, please also note any challenges with adherence/using the insert as instructed and when instructed. If the participant indicates that it did not fit well into their life, try to understand if this impacted their ability to adhere. The final probe about nervousness about other people finding out about product use may have already been sufficiently addressed in the questions above about discreetness. Please de-emphasize or skip for time if this has been addressed.</i></p>		

5.3	How influential were your partner, your friends and family, and others in the community on vaginal insert use?	<ul style="list-style-type: none"> • Who had an influence and what was it like? • How did they change your attitudes and behaviours? • Associated myths. • Beliefs (religious/traditional).
<p><i>GUIDANCE FOR INTERVIEWERS: This is intended to understand how much influence partners or other people had on the participant's vaginal insert use.</i></p>		
<p>6. Messaging and Future Use</p>		
<p><i>GUIDANCE FOR INTERVIEWERS: The questions after this point are looking toward the future use of this product, not just experiences during the trial.</i></p>		
<p><i>Now we are going to talk about factors that would make women want to use the vaginal insert in the future. Remember that this vaginal insert is still in its developmental stage, so your input and knowledge informed by having used the vaginal insert 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 insert? • What other concerns or questions do you think women in your community would have? 	<ul style="list-style-type: none"> • Discreetness. • Design. • Number of insertions per certain timeframe. • What would they find challenging? • Who would it be a good option for • If used only when needed – either before sex or after sex
<p><i>GUIDANCE FOR INTERVIEWERS:</i> <i>Participants have been involved in the study for about 2 months, but have not used the product regularly during this time. Please feel free to clarify if the participant is confused.</i></p> <p><i>“Number of insertions per certain timeframe” probe: In the study, participants used the product daily or every-other-day; however, in the future it is possible that the product could be used only when needed – with a single vaginal dose of the insert expected to provide protection for at least a day, regardless of the number of sex acts and even if used within a few hours after sex. We are interested in hearing their thoughts on different insertion scenarios.</i></p> <p><i>“If used only when needed – either before or after sex” probe: This is a key probe. In the future, it is possible that this product could be used either before sex <u>or</u> after sex.</i></p> <ul style="list-style-type: none"> • <i>It is most likely that the product will be marketed for use before sex, with messaging that it could be used after sex if it wasn't used in advance. In other words, the schedule for using this product has some flexibility.</i> • <i>The product developer is interested in whether future users will understand the idea of a prevention product that can also be used after a sexual exposure. This is not so much about whether a participant would prefer to use the product before sex versus after sex, but whether this idea that it could be used at either time makes sense.</i> • <i>Explore questions related to the potential for the insert to be “forgiving” regarding the timing of use, how they understand this concept, and their views of an insert that could be used after sex.</i> 		
6.2	What did you think of the packaging of the vaginal insert?	<ul style="list-style-type: none"> • Likes and dislikes.
<p><i>GUIDANCE FOR INTERVIEWERS: The packaging will likely be updated from what was used during the trial. If you are running short on time, this question may be de-emphasized or skipped, focusing instead on the packaging questions in 6.4</i></p>		

<p>6.3</p>	<p>If the vaginal insert is shown to prevent HIV in larger studies and makes it into the market,</p> <ul style="list-style-type: none"> • how much would you prefer it to cost? [Insert relevant country currency] • where would you like to get it from? E.g., clinic, pharmacy, etc. 	<ul style="list-style-type: none"> • What is the most they would be willing to pay?
<p><i>GUIDANCE FOR INTERVIEWERS: please probe to understand how the participant determined the cost, as it may be influenced by how long they think the insert will last, how many they would need per week/month, etc.</i></p>		
<p>6.4</p>	<p>Remember that we said this vaginal insert 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>For example, after doing research with other groups, it was suggested that the insert shape be changed like this (show dimpled insert), and packaging like this.</p>	<ul style="list-style-type: none"> • What do you think of this one you used (show example of study design and packaging) compared to this one? • If it had come like this (new), how would you have used it differently in this study?) • How does it affect how you feel about it? • How does it affect how you use it? • How would the community feel?
<p><i>GUIDANCE FOR INTERVIEWERS: Focus these questions on packaging of the product. The product developer is interested in the packaging options and getting user input now. Please do not provide examples related to product shape.</i></p>		
<p><i>Show participant packaging options, focusing on the hybrid blister dome packaging prototype. Show the images that present options for how many should be included in a pack. This includes: single dome packs sold in a box (with 10 or 30, but ease of taking 1 on the go), packs of three sold in a box, or the wallet design of 10 or more tear-off doses in a multi-pack “wallet” style packet.</i></p>		
<p><i>Solicit participant feedback on the following, drawing on the visuals to provide models for discussion:</i></p>		
<ul style="list-style-type: none"> • <i>Single doses in a box vs. tri-packs in a box vs. 10+ tear-off doses in a multi-pack “wallet”</i> • <i>Color/graphics on the packaging. How important is this? Reactions to the V-brand colors/themes. Do they create an unwanted barrier for the product? If yes, explore in what ways and what should be different.</i> • <i>How participant envisions use/storage/transport of the insert and how packaging helps or hinders this. Any barriers or preferences for single doses stored loose in a box or multi-packs with tear-offs (make packaging more compact).</i> 		
<p><i>Note that the sample products in the blister pack have the “dimple” shape. If the participant asks about this, please indicate that this is simply an example of a similar product, and to imagine the packaging being used with the study product as it exists now.</i></p>		
<p><i>Rather than spending time comparing to the study packaging, we are more interested in pros/cons of the new options – and whether either option would make them more or less likely to use the product.</i></p>		
<p>6.5</p>	<p>If you had an opportunity to further change its looks, or how it is used, how would you change it?</p>	<ul style="list-style-type: none"> • What would those changes do – why would you make them?

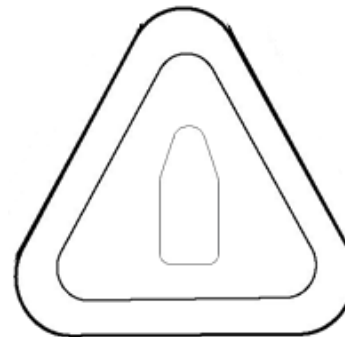
7. Conclusion

GUIDANCE FOR INTERVIEWERS: Thank the participant and tell them that they have answered your questions. Tell them that you appreciate everything they have shared, and emphasize that their experiences are important and that sharing openly during the interview is valuable.

7.1 Now that I have asked you all the questions that I wanted to ask you, I might have left out very important things that we should know about the vaginal insert. Is there anything else that I may have missed that you would like to tell me about your experiences with the vaginal insert?

GUIDANCE FOR INTERVIEWERS: Thank the participant for taking the time to share their opinions, and complete the interview. State the time that the interview ended while the recorders are still on. Review the checklist to ensure that you have completed all appropriate forms.

Appendix 2: MATRIX-001 Hybrid Blister Dome Packaging Prototype



How many in a pack?

Single Pack



1.35 inches
(34mm)

Tri-Pack Shuttle
(Pack of 3's)



1.6 in
(41mm)



2.95 inches
(75mm)

Wallet Design



2.8 in



4.7 in