

**Options in HIV Prevention:
A Client-Centered Counseling Approach
for
The HOPE Study (MTN-025)**

Developed by

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Instructions for Recordings

All counseling sessions are to be audio-recorded and uploaded to Atlas for review. Although participants are allowed to refuse that the session be recorded, prior studies indicated that this should be a very rare occurrence. What is key to participant acceptance of the recording is how it is presented by the counselor—the more comfortable the counselor is presenting the recording, the more comfortable the participant is in accepting it. Below is a sample introduction that can be used—but feel free to use your own words. Keep in mind that the participant will probably already know about the recording because it is included in the text of the consent forms at most study sites.

In this study, we are doing something different, which is that we are recording all of our counseling sessions with our participants. The purpose is really to ensure that we, the counselors, are consistent in how we do the counseling across all the study sites. The recordings are then reviewed by one of the researchers who specializes in counseling and he speaks with us about how to make the sessions better and, hopefully, more helpful to our participants. So, the focus of the recording is not so much on what you are saying, but on making sure I am doing the best counseling possible. Is it okay if I turn on the recorder now?

Below are the instructions for labeling and uploading the recordings.

Labeling Recordings

Your recordings should be labeled using the following format:

YourName_Participant ID_VISIT#_day-month-year

It would look this: IvanBalan_1002345_V2_07July2016

Uploading Recordings

This is the link to the site, where you will have to enter your email and password.

<https://atlas.ssharp.org/cpas/project/MTN/025/Audio%20Files/begin.view>

When you enter you will see that there are separate folders for each site. You will upload your sessions to folder labeled with the site where you work.

Here are the instructions for uploading your recordings onto the Atlas site:

This is the link to the MTN-025 site: <https://atlas.scharp.org/cpas/project/MTN/025/begin.view>

Once on the MTN-025 ATLAS webpage, please click on the “Site-specific Materials” link under the MTN-025 Secure Sections heading.

MTN 025 Secure Sections

ACASI
AE Data
Protocol Deviations
PSRT Reports and Queries
Site-specific Materials (Participant Eligibility Lists, Audio Files, and Vaginal Ring Residual Drug Feedback)
Study Monitoring Committee (SMC) Reports

When you click on Site-specific materials, you will be asked for your email address and password. If this is your first time using the site, click on “forgot password” so that you can reset a password and access the system.

Once you enter the system you will see a page with all of the sites listed and below the site name, a link for “audio files.” Once you click on “audio files” you will be able to upload your files.

Links

- ~~CAPRISA - eThekweni~~
 - ~~Audio Files~~
 - Participant Eligibility Lists
 - Vaginal Ring Residual Drug Feedback
- ~~Emavundleni - Cape Town~~
 - ~~Audio Files~~
 - Participant Eligibility Lists
 - Vaginal Ring Residual Drug Feedback
- Med-JHU Blantyre
 - Audio Files
 - Participant Eligibility Lists
 - Vaginal Ring Residual Drug Feedback
- MRC - Botha's Hill
 - Audio Files
 - Participant Eligibility Lists
 - Vaginal Ring Residual Drug Feedback
- MRC - Chatsworth
 - Audio Files
 - Participant Eligibility Lists
 - Vaginal Ring Residual Drug Feedback
- MRC - Isipingo
 - Audio Files
 - Participant Eligibility Lists
 - Vaginal Ring Residual Drug Feedback
- MRC - Tzaneen

To **upload** files, please use the following steps:

1. Click on Upload Files
2. Use the 'Browse' button to locate the file on your computer or network
3. Click the 'Upload' button

To **download** files, please use the following steps:

1. Go to the "Audio File" folder where the audio file you want to download lives
2. There are two ways to download a file:
 - o You can double-click on the file name itself (depending upon your browser settings you might open an audio file in your browser. If that happens please use the next method)
 - o You can use the checkbox to the left of the file name to select the file(s). If you use the checkbox method, click the 'Download' icon (it looks like a down arrow) to start the download
3. Save the file to your computer or network

Note to Sites: When uploading audio files (.wma), your file name must be unique for each upload. The maximum upload size is 250MB.

ENROLLMENT VISIT

OVERVIEW OF SESSION

The purpose of this session is to orient the participant to HIV prevention counseling that will occur during MTN-025, help her make an informed decision about accepting or not accepting the ring as an HIV prevention method, and reinforce the value of open communication about her use of the Ring and/or other HIV prevention approaches and challenges encountered in implementing he HIV prevention plan.

This is the session that will establish the client-centered spirit of the counseling sessions, thus the counselor should focus on building a relationship with the participant, affirming their willingness to take part in the study, and the appreciation for their role in helping the researchers understand how these products might be used by the community.

ENROLLMENT SESSION

1. Introduction, welcome, affirm attendance

Goals:

- To build relationship with participant
- To affirm participant's attendance at the session

Example: *Hello and welcome. My name is _____ and I am going to be your counselor during this study. Before we begin, though, I want to thank you for taking the time to come in for your appointment. Having been a participant in ASPIRE, you know these studies depend on our participants showing up for the appointments, so I really appreciate your commitment to following through with the study.*

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2. Provide overview of counseling sessions

Goals:

- To inform the participant about the counselor's role
- To provide an overview of what will occur during the counseling sessions.

Approach: The counselor provides an overview of the adherence counseling session and stresses the importance of openly speaking about the participant's experience using the Ring or whatever other HIV prevention approach she decides to use. This is stressed more than using the product as indicated. This is done so that the participant feels more comfortable reporting problems with using the product.

Example: *As a participant in ASPIRE, you know that we meet during each study visit with our participants. However, we are doing these sessions quite differently from how they were done in ASPIRE.*

For example, in ASPIRE, the adherence counseling sessions were focused on getting the participants to use the Ring as instructed. Then, the counselor worked with you in case you had problems using the Ring. Using the Ring as indicated was critical for that study.



Slide 4

In HOPE, the focus is on:

- helping each participant choose an effective HIV prevention method or methods*
- open conversation about decisions regarding HIV prevention methods*

For example, for women who choose to use the Ring, we want to speak openly about why they chose the Ring versus another approach, difficulties they might have in using the Ring, and even why some women may decide to use the Ring, but later on decide not to use it any longer. We also want to learn why some women choose not to use the Ring and we want to speak with them openly about the reasons they prefer other HIV prevention approaches.

We learned in ASPIRE that not every woman wants to use the Ring and that was very important to learn. In this study, we want to learn more about those decisions. And, throughout the study, whether you choose to use the Ring or not, we will work together to figure out how to decrease your risk of HIV infection.

In these sessions, we will:



Slide 5

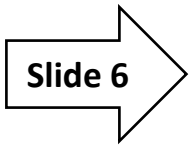
- talk about how you are doing with using the Ring of whatever other measure you chose to prevent HIV*
- help you decide whether you are comfortable with your plan or if you think something might change*
- help you adjust your plan*

If you choose the ring, during some of these meetings, I will also share with you the results tests that look at how much study drug (dapivirine) is left in the ring at the end of the month. This helps us understand how much drug left the ring and went into your body during the month and how that might impact the degree to which you may be protected from HIV.

3. Review counselor role

Goal: To clarify the counselor's role for the participant.

Approach: The counselor explains their approach in working with the participant, highlighting respect for their decisions on whether or not they want to use the Ring or other HIV prevention approaches.



Example: *Now that I have spoken with you about what will happen during our counseling sessions, let me tell you a bit of how I will work with you. My role is not to push you to use the Ring or any other HIV prevention approach. I am here to present you with information about the Ring as well as other HIV prevention approaches so that you can decide which might be best for you. Once you do that, I am here to help you set up a plan to use which ever approach you select and to help you overcome any problems that come in using it. It is clear that you don't want to be infected with HIV and my role is to **help you achieve your goal.***

Also, some women are not aware of how they might be at risk of HIV infection. If you have questions about how you might be at risk, please let me know and we can also speak about that.

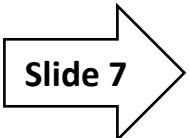
HOW DOES ALL THIS SOUND TO YOU? WHAT QUESTIONS DO YOU HAVE SO FAR?

4. Explore participant's interest in joining another Ring study

Goal: to understand the participant's motivations for entering into another Ring study

Approach: The counselor takes an exploratory approach to understand these motivations. Be curious about that part of the participant that wants to be part of this study. Below are some questions that can guide the exploration. The counselor should keep in mind that for some participants, the motivations for entering the study may not be related specifically to gaining access to the Ring. That is okay, it is just important for the counselor to understand and be accepting of those.

Example: *So here you are, entering another Ring study.*



- *Tell me about your decision to enter this study...*
- *What benefits did you see to being in the previous study?*
- *How do you think this study may be beneficial to you?*

5. Review ASPIRE results and lessons learned

Goal: To ensure that the participant is knowledgeable about the ASPIRE results so that she can make an informed decision as to whether or not to use the Ring in this study.

Approach: In order to tailor the information given to each participant, the counselor firsts asks the participant what they know about the ASPIRE results. Correct information provided by the participant is affirmed. Then, the counselor asks permission to share

more information with the participant. Once permission is granted, the counselor gives more information. Information should be concise and not overwhelming. If the information is going to be lengthy, it should be broken up into segments with feedback sought from the participant in between the segments.

Information should be provided in a neutral manner, not with the intent of convincing the participant to use the Ring.

Example: *What have you heard about the results of the previous study, the ASPIRE study? What else?*

Slide 8

That is correct! it sounds like you have been paying close attention to what we learned in that study. Can I share with you some more information that may be helpful to you in deciding whether or not to use the Ring?

Continue if the participant says YES... Provide other information that participant may not have been aware of.

Slide 9

What do you think about that?

Lastly, summarize the conversation that was just had about the Ring and the ASPIRE findings.

6. Inquire about interest in using Ring

Goal: To assess the participant's interest in using the Ring

Approach: After highlighting that it is the participant's decision, the counselor asks the participant if they would like to use the Ring or to use another HIV risk reduction strategy. Afterwards affirm the participant for their open discussion with you about whether or not they want to use the Ring.

Example: *This brings us to our first decision in the study, which is whether you would like to use the Ring or whether you prefer to use other HIV prevention approaches. As I have mentioned throughout our session, this is really your choice and I and the rest of the study respects that. This page on the flipchart shows some options for you.*

Slide 10

So, which of these best reflects how you are feeling about using the Ring? As I said, it is really up to you.

After the response, affirm the decision (not her specific choice) and remind her she can change her mind at any point during the study....

That is great, you seem clear about your decision and you know yourself best. We will proceed with the session based on your decision. But, just so you know, at any point during the study, you are free to change your mind and that is okay, the only thing I ask is that you speak with me about it so I can learn from your decision. Okay?

7. Explore Ring use with participant (If participant is not going to use Ring, go to step 8.)

Goal: Understand participant's decision to use the Ring and help the participant develop a plan for using the Ring.

Approach: The counselor should use a curious approach to explore why the participant has decided to use the Ring. In moving to develop a plan for Ring use, the counselor uses the participant's self-knowledge and prior experiences with Ring use to inform the plan for using the Ring in this study.

Example: *Help us learn from your decision to use the Ring. What made you decide to use the Ring? What else? Why do you think the Ring is a good HIV prevention option for you?*

Begin to develop the plan for using the Ring....

Slide 11

The ASPIRE study gave a really good idea of what Ring use would be like. Based on your experience using the ring, and what we now know about the Ring, what is your plan for using the Ring?

What would you do differently, if anything from the last time you used the Ring? How can overcome the challenges that you had last time?

Discuss challenges to Ring use



Slide 12

These are some of the concerns or challenges about using the Ring that we heard from women in the ASPIRE study. Which of these are concerns that you might also have that might impact your ability to use the Ring consistently?

Listen to the participant's concerns and inquire about what might be helpful in reducing the concern (ie. Does she need more information, etc.). Also, help the participant problem-solve the challenges that she identifies might impede her from using the Ring.

What might you do to reduce your concerns or to overcome these challenges?

8. Explore decision NOT to use the ring

Goal: Understand participant's decision not to use the Ring.

Approach: The counselor should use a curious approach to explore why the participant has decided to not use the Ring, being careful to respect the decision and to appear judgmental about the decision. Lastly, affirm the participant for openly discussing their decision not to use the Ring.

Example: *Help us learn from your decision to not use the Ring. What made you decide not to use the Ring? What else? Why do you think the Ring is not a good HIV prevention approach for you?*



Slide 10

Thank you, I am glad that you felt comfortable telling me that you did not want to use the Ring. As I mentioned to you, in this study we are equally interested in learning from women who decide to use the Ring as from those who decide not to use it, what is really helpful to us is speaking openly about this decision.

9. Other HIV Prevention Approaches

Goal: To engage participant in employing other HIV prevention approaches.

Approach: This step is completed with both Ring users and Ring non-users. Using the flip board, the counselor presents a menu of HIV prevention options and assists the participant in selecting which ones might work best for her. Afterwards, the counselor works with the participant to develop a plan for implementing the approach consistently. Lastly the counselor and participant identify possible obstacles to the approach selected and ways to overcome those obstacles.



Slide 13

Example: *Here are some other approaches that can be used to reduce the risk of HIV infection. Which do you think might work best for you? In general, we usually recommend a combination of these approaches. But, again, that is up to you.*

Tell me about this approach you have selected, why do you think that will be a good approach for you?

How has it worked for you in the past? What has gone well in using that approach? What might you need to do differently in the future?

Summarize the discussion, then help develop a plan for using the selected approach(es).



Slide 14

You know best how to make these approaches work for you. Take me through how you will implement this approach. What will you do to use these approaches consistently to avoid HIV infection?

As you think about your plan, what might make it difficult for you to use the approaches you selected?

-What can you do to overcome those difficulties?



Slide 15

Here are some challenges that women face in using some of these HIV prevention approaches. And you actually mentioned some of them. Aside from those you mentioned, which other ones do you think might affect you?

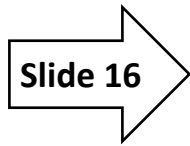
What do you think you could do to overcome the challenges you mentioned?

Summarize plan with participant as well as plan to overcome challenges.

10. Assess Importance of implementing these approaches (Ring and/or other HIV prevention approaches) in her life

Goal: Assess the importance that participant places using the approaches selected to avoid HIV infection.

Approach: An importance ruler is used to assess level of importance. More important, however, is the follow-up questions, which evokes from the participant the reasons why implementing these approaches is important to her. The counselor should be curious about the participant's response, asking for other reasons its important, etc.



Example: *As you think about our discussion today, on a scale of 0 to 10 where 0 is not important at all and 10 is extremely important, how important is it for you use the approaches you selected to avoid becoming infected with HIV?*

“What makes it a _____ and not a 0 or a 1?” Why else?

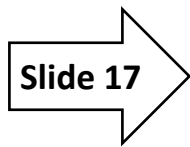
NOTE ON USING IMPORTANCE AND CONFIDENCE RULERS WITH PARTICIPANTS WITH LOW LITERACY: Counselors can simplify the rulers for use with participants of low literacy levels by not focusing on the numbers. For example, by highlighting the endpoints of the scale (“not important at all” and “extremely important”) and asking participants to place their finger along the scale and, similarly, by pointing to the participant’s response and pointing to the lower end of the scale to highlight the participant’s level of importance of confidence.

11. Assess confidence in implementing selected HIV prevention approaches

Goal: Assess the level of confidence that the participant feels in her ability to implement the HIV risk reduction approaches she has selected.

Approach: A Confidence Ruler is used to assess level of confidence. More important, however, is the follow-up questions, which evokes from the participant the reasons they feel confident (self-empowered) to implement her HIV prevention approaches. Again, the counselor should be curious about the participant’s response, asking for other reasons she feels confident in her ability to implement her plans.

Example: *Now, lets do something similar but in regards to your confidence.*



On a scale of 0 to 10 where 0 is not confident at all and 10 is extremely confident, how confident are you that you will be able to (insert the HIV prevention approaches here—ie., use the Ring every day, use a condom every single time you have intercourse, etc)?

Why is it a ___ and not a 0 or 1? Why else is it a ___ and not a 0 or 1?

What would help move it up 1 or 2 numbers higher??

How might you achieve that?

12. Explore other remaining questions that participant might have

Goal: Provide the participant with an opportunity to discuss other issues that may affect her use of the Ring or other HIV prevention approach

Approach: The Counselor asks an open ended question, inviting a discussion of these issues.

Example: *We are coming to the end of today's session. As you think of the next four weeks until we next meet, what other concerns or questions do you have about the Ring (or the HIV prevention approaches you have selected)?*

Slide 18

What else would you find helpful to discuss about these HIV prevention approaches that would allow you to leave here feeling more comfortable about using them?

13. Wrap-Up

Goals:

- To affirm the participant for attending the session and for open discussion of concerns.
- To provide an overview for participant of the upcoming counseling sessions.

Approach: First, the counselor affirms the participant for attending the session, working hard to develop an HIV prevention plan, and for her open-ness in discussing thoughts about using the Ring or other HIV prevention approaches. Highlight the importance of such open discussion in this study. Then, the counselor provides a brief explanation of upcoming counseling sessions. It is important to remind participants that visits are monthly during the first three months, then every three months.

For participant who choose the Ring, it is critical to include mention that beginning in Month 3, the counselor will share with them the residual drug results

Example: *Well, we have come to the end of our session for today. Thanks so much for making the time to come to your appointment and for all your hard work in developing an HIV prevention plan for yourself. I also really appreciate your openness in speaking about some of your concerns about the Ring—that really helps us learn a lot about women's views on the Ring.*

Slide 19

For participants who chose the Ring....

Remember that during the first three months of the study, we meet every month, so I will see you in a month. In that visit, we will have time to speak about how things went with implementing your HIV prevention approaches, including the Ring. If things go well this month, then we will talk about how to keep doing so well, and if you had some difficulties in using the Ring or your other HIV prevention approaches, we can also talk about that to help you figure out what you might want to do differently. Talking about those difficulties gives us an opportunity to develop a plan that works for you so you stay HIV-negative.

Also, very importantly, please remember to bring back your Ring at your next visit. What we will do with that Ring is send it to the lab to be analyzed so that we can get an idea of how much HIV prevention medication was released into your body. It takes some time for us to get those results from the lab, but beginning with your third study visit, I will be able to share those results with you so we can discuss them since this can give us a general indication of your level of protection from HIV. Do you have any last questions before we end?

See you next month!

For participants who did not choose the Ring...

Remember that during the first three months of the study, we meet every month, so I will see you in a month. In that visit, we will have time to speak about how things went with implementing your HIV prevention approaches. If things go well, then we will talk about how to keep doing so well, and if you had some difficulties in using the HIV prevention approaches you selected, we can also talk about that to help you figure out what you might want to do differently. Talking about those difficulties gives us an opportunity to develop a plan that works for you so you stay HIV-negative. Do you have any last questions before we end?

See you next month!

FOLLOW-UP VISITS
Months 1, 2, 3, 6, 9

Follow-Up Visits

1. Welcome participant and set structure for session

Goals:

- To affirm participant's attendance at the session and inform the participant of what will occur during the session.
- To normalize difficulties with implementing an HIV prevention approach, whether it's the Ring or a different approach

Approach: The counselor uses a client-centered approach to welcome the participant back for another visit and affirms the participants continued interest and commitment to the study. Then, the counselor offers an overview of what will occur during the session.

Example: *First of all, thank you for taking the time to come in for your appointment, as you know studies are dependent on their participants showing up for the appointments, so I really appreciate your commitment to following through with the study.*

Slide 21

During our time together, we are going to be discussing how it has been going for you in regards to the HIV prevention approaches you decided to use during our last visit.

We know that, for some women, (using the Ring) sticking to an HIV prevention approach is not as easy as they thought, so in these sessions we just want to hear how it has gone for you, whether it has gone well or not. We learn a lot from women who (use the Ring) are able to implement HIV prevention approaches and from those who do not, so being able to speak openly about this is very helpful to us!

Slide 22

So, if things went well and you were able to implement your plan (use the Ring as you wanted) that is great and we can discuss how to continue doing well. And, if you were having problems in (using the Ring) or reducing your HIV risk the way you had hoped, don't worry, I am not going to judge you. If you would like, we can discuss ways of overcoming the difficulties you had, if you are interested I can even share with you how other women have overcome those obstacles in case you want to try them and see how it goes.

For women using the Ring, beginning in Month 3, add...

I also have the results from the ring that you returned at Visit 1 that give us an idea of how much of the drug in the ring was released into your body. I will share those results with you so that you can keep that in mind as we discuss how things have gone for you with the HIV prevention approaches you have selected.

How does that sound?

What else about (the Ring) HIV prevention or your participation in the study would you like to discuss today?

2. Present information on Drug Level Results (DO THIS SECTION ONLY FOR PARTICIPANTS WHO CHOSE THE RING)

Goal: To provide the participant with information about what the Drug Levels mean and how they related to HIV prevention.

Approach: The counselor provides clear information about how the Ring releases drug into the system and how the amount of drug released affects the level of protection that the participant receives from HIV infection.

NOTE: The information is provided in a completely neutral manner. Note that the example below speaks in generalities and does *not* say “if you use the Ring...” This is important because it makes it clear to the participant that this is not about her use of the Ring. This information can be reviewed more quickly in subsequent sessions.

Depending on the session, you may want to introduce this discussion in different ways (some suggestions are offered below). For the Month 2 visit the counselor can also review the information, making sure to ask the participant if she has questions. However, note that before the counselor provides the information, he/she always starts with getting permission from the participant to share information.

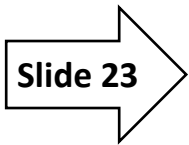
Example: For visits in Month 1 and 2, when no residual drug levels will be provided, you can begin this discussion in this way:

Today, you returned the Ring that you used during the past month. As you know, beginning in your Month 3 visit, we will begin to share with you the drug levels from that Ring in order to give you an idea of the level of protection you received from the Ring. In preparation for those Visits, can I share with you some information about how the drug levels work and what that means to your level of protection from HIV?

Example: For Month 3 visit onward, during which participants will receive drug level results

Today, we I will be sharing with you drug level results for a Ring that you returned. Before I share with you the level of protection you are receiving from the Ring, can I share with you some information about how the drug levels work and what that means to your level of protection from HIV?

After the introduction, continue with the explanation.....



Starting at the top we see that usually, with low use of the Ring, little drug is released into the body (counselor points to the gray dots above the Ring on the left) and that results in very little or no protection from HIV (counselor points under the Ring). As we move from left to right, we see that with higher use of the Ring, there is more and more drug released into the body, and down here we see that there is higher and higher protection from HIV. So, when I share with you the results, I will share with you a number, like these 0,1,2, and 3 that will give us an indication of how much drug was released into your body and, more importantly, how much protection you are getting from HIV.

Results of 0 or 3 are pretty clear in terms of protection, 0 is no protection and 3 is high protection. For levels 1 and 2, the level of protection can vary depending on how the Ring was used. For example, if a woman removes the ring during menses, the level on this report will probably drop to a 2. However, she may still have high protection if she ALWAYS used the ring during the remainder of the month and NEVER had sex while the ring was out. So, if the level is 1 or 2, it is very helpful for us to talk about how you used the ring in order to give you a better idea of the level of protection you would receive from the Ring.

“What do you think about this?”

“What questions do you have about this?”

3. Remind participant about the purpose of sharing the residual drug levels (DO THIS SECTION BEGINNING AT MONTH 3 ONLY FOR PARTICIPANTS WHO CHOSE THE RING- OTHERWISE, SKIP TO SLIDE 26: EXPLORE HOW HIV PREVENTION PLAN IS GOING)

Goal: To decrease the possibility that the participant will feel confronted or judged by the drug level results.

Approach: The counselor highlights the key points included on Page 24 of the flipchart, especially that it is the participant's choice what to do with this information.

Example: *Just one more thing before I share with you your results. Keep a few things in mind. First, these results may not be 100% accurate, since occasionally errors occur. Also, remember that the purpose of sharing these results with you is to give you an idea of the level of protection you received from the Ring during that period of time. Based on the results, you can decide if you want to use the Ring differently so that gives you more protection. But remember, what you decide to do with this information is always your choice.*

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Slide 24

4. Share residual drug level results (DO THIS SECTION BEGINNING AT MONTH 3 ONLY FOR PARTICIPANTS WHO CHOSE THE RING)

Goal: To share with the participant the residual drug results in order to give her a general idea of her level of protection against HIV being provided by the Ring

Approach: The counselor proceeds to share the results in a collaborative and neutral manner. **The results should not be presented in a way that it is even slightly confrontational or judgmental.** Then, the counselor asks the participant for her thoughts about the results and what they mean to their HIV prevention potential.

The counselor should carefully listen for the participant's reaction to the results. If the participant gets defensive, the counselor should remind her that the results are not meant to be confrontational, but helpful to her, and that in this study CHOICE is key, so it is the participant's choice to use the Ring and whether to use the drug level information provided, that her decision will be respected (see example below).

Lastly, the counselor uses Appendix 1 to mark the level of protection for the Ring discussed. During the study, the counselor will mark the level of protection for each Ring so that the participant can see her progression

during the course of the study. Appendix 2 provides a color description of when the drug levels for a specific Ring will be discussed during the study.

Example: (Show Appendix I: Residual Drug Level Feedback Timeline) *Today, I will share with you the results of the Ring that you returned on Month _____. Okay, so here is the report from the laboratory and it says that the level of protection you had from the Ring during that period of use was 2 (point to 2 on page).*

What do you think about this?

How do you feel about the level of protection you received from the Ring?

What does this mean for your HIV prevention plan?



Slide 25

Example of defensive participant: *I am sorry, it sounds like these results have bothered you and that was certainly not the intent. As I have mentioned to you during our sessions, this study is really about choice and I fully respect the choices that you make for yourself. If this low level of protection leads you to decide not to use the Ring, I will respect that choice and we can discuss other ways of protecting yourself from HIV. On the other hand, if this low level of protection leads you to decide that you want to figure out how to use the Ring more regularly, I will respect that decision also and we can discuss ways of helping you achieve that. Really, it is your choice.*

So, how do you feel about the level of protection you received from the Ring?

GUIDANCE FOR MONTH 6 and MONTH 9 DRUG LEVEL DISCUSSION

Beginning with Month 6, participants will receive results for multiple Rings. On the Month 6 visit, she will receive results for two Rings. In this case, the counselor should provide the level of protection for each individual Ring and use the questions below to explore the participants' reaction to the results.

In Month 9, participants will receive residual drug levels from 3 Rings. Results will be provided individually for each Ring and there will be an overall level of protection provided for the 3-month period. The counselors should first present the Overall level of protection, then present the level of protection for the individual rings.

Example: *For this Month 9 visit, we are going to share with you the results of the level of protection you received from the three Rings you returned on Month _____ (Show Appendix I: Residual Drug Level Feedback Timeline). First I will share with you the level of protection you had during the entire 3-month period and then the level of protection from each individual Ring.*

The overall level of protection for the entire 3-month period was 3.

- *What do you think about this?*
- *How do you feel about the level of protection you received from the Ring during this 3-month period?*

Now, let me show you the level of protection you got from each Ring. The level of protection was 3 for the Ring you used this month, 2 for the Ring you used this next month, and 3 for the Ring you used this following month.

- *What do you think about this?*
- *How do you feel about the level of protection you received from the Ring?*
- *(If applicable) What do you think about the different levels of protection across the three months? What might that be due to?*
- *What does this mean for your HIV prevention plan?*

As Appendix II “Drug Level Feedback Over Time Worksheet” is filled with Xs marking the level of protection for each Ring returned, the counselor can also explore the participants reactions to what she sees on the Worksheet. For example:

- *What are your thoughts as you look at the level of protection you have received from the Ring during your time in the study?*
 - *How do you feel about that?*
 - *What does this mean in terms of you remaining HIV negative?*

5. Explore how participant is doing with her HIV prevention plan.

Goals:

- To review participant’s HIV prevention plan
- To explore how well the participant was able to (use the Ring) implement her HIV prevention approaches

Approach: The counselor begins the conversation by presenting the various options for HIV prevention and asking the participant which she had selected. The counselor again highlights that behavior change can be difficult, then inquires about how things went for the participant with each of her selected approaches. Throughout, the counselor is empathic to the experiences of the participant, actively trying to understand any challenges encountered and avoiding any judgment on the participant’s difficulties.

Example: Here is the list I showed you last time about the different approaches to reduce risk of HIV infection. **Which did you select to use during this past month?**

Slide 26

So, keeping in mind, how difficult it can be to implement new behaviors into one's life, how did it for you using (the Ring and/or other HIV prevention approaches) during the past month? I would like to hear about how each of the approaches you selected worked for you, including what went well and what did not go so well. Feel free to start with whichever approach you want to speak about first.

Slide 27

- How did that approach work for you?
- What went well?
- What did not go so well?
- What obstacles or difficulties did you encounter?
 - What did you do to overcome those difficulties?

6. Assess how participant is feeling about her HIV prevention choices

Goals:

- To assess how the participant feels about their HIV prevention choices
- To open a discussion about ways of improving use of current approaches or changing to different approaches

Approach: The counselor should be very respectful of the participant's choice of HIV prevention approach, and whether or not they want to improve it or change it. This really is a decision for the participant to make. To help the discussion, the participant is shown a flip-chart page with 3 statements aimed at normalizing challenges to implementing HIV prevention approaches in order to begin the discussion. The counselor asks the participant which of the following statement best reflects how she is feeling about her HIV prevention approaches.

Lastly, the counselor affirms the participant's openness in sharing her thoughts on her HIV prevention choices.

Example: So, what are your thoughts about the HIV prevention approaches you used during since our last meeting? Here are some statements that might indicate how you are feeling. Which comes closest to how you are feeling?

You selected XX. Tell me about that.

(RED LIGHT—NEEDS TO CHANGE PREVENTION PLAN)

Sounds like it was really tough using the Ring (or implementing your HIV prevention plan), I am sorry to hear that. Sounds like you want to do something completely different (the counselor can be more specific to the participant’s plan, such as saying, “sounds like using the Ring did not work for you and you want to try something else” or “sounds like you could not get your partner to use condoms so you now want to try something else”) As we have said throughout this study, this is your decision and we fully respect that. So that we can learn from your experience, can you tell me about what led you to make this decision?

Slide 28

(YELLOW LIGHT-Experienced some difficulties) *Well, thank you very much for sharing your opinions about this openly with me, it is very helpful for us to really understand how difficult it can be to consistently work to prevent HIV infection and I appreciate you discussing that with us honestly so that we can learn from your experience.*

(GREEN LIGHT-Plans went well) *That is great, you have been able to use the Ring (implement your HIV prevention plan) consistently and remain committed to doing so. On top of that, you are also very open in asking your partner to use a condom, which brings you another level of protection. How do you feel about that?*

IF PARTICIPANT DECIDES TO STOP USING THE RING AT THIS POINT, REMIND HER THAT SHE CAN CHANGE HER MIND IN THE FUTURE

And, just so you know, if at a later time you decide you want to try the Ring again, that is fine, just let us know.

(Wants to start using the Ring) *Sounds like thoughts of the Ring stayed in your mind. As you know, that is perfectly fine and we can start you on the Ring today.*

-Tell me, what is making you decide to start using the Ring?

-How do you think it will be helpful to you?

7. Problem-solve ways to maintain or improve HIV prevention plan

Goal: Based on the participant’s desire to maintain, improve, or change her HIV prevention approaches, help the participant identify steps she could take to achieve her goals.

Approach: Slide 29 provides questions that can be used to guide this discussion based on what the participant would like to do with her prevention plan.

For participants who express that they are happy with their use of HIV prevention

approaches and don't seek to improve upon any of them, the counselor can highlight the opportunity to explore what is helping them achieve their goal and how they can continue to do that until the next study visit.



Slide 29

The task of the counselor is to help the participant develop and think through how to use their desired HIV prevention approach consistently. Thus, the conversation does not end with the participant identifying what she will do, but when there is a solid exploration of how she will do it.

Lastly, at the end of problem-solving (and regardless of the specific scenario), affirm the participant's interest in taking steps to reduce her risk of HIV infection and for her open discussion of how difficult it can be.

KEY POINT

When developing solutions for using the product consistently, use the participant's expertise about themselves and FIRST ask the participant for what they might do. AFTERWARDS, if necessary, offer to provide the participant with some suggestions.

Example (GREEN: participants who successfully implemented their HIV prevention plan):

That is great, you feel comfortable with the risk reduction approaches you selected and you are also happy with how you been able to implement them in your day to day life.



Slide 29

What helped you succeed in using the Ring (using the HIV Prevention approaches you selected)?

What can you do to continue using the Ring or other HIV prevention approaches consistently?

Example (YELLOW: participants seeking to improve their implementation of their HIV prevention plan):

Sounds like you were able to implement some of the HIV prevention approaches we discussed, but some issues came up and you weren't able to do it as regularly as you would like. It is great that you want to improve things so that you can reduce your risk of HIV infection.

You know yourself best, so as you think about what happened that you weren't able to (ie., use condoms, etc), what might you do differently to help you be more consistent in your risk reduction practices?

- *What parts of your plan need to work better?*
- *What might you do differently in order to succeed?*
- *What can we do during our session that will help you succeed?*

Slide 29

Those sound like very good ideas. A little while ago you also mentioned some of the things that work for you now, like making sure you always having condoms with you, or not drinking too much when you go out so you don't get carried away in the moment. I am wondering, what might you do to make sure those things happen more regularly?

Sounds like you are not sure what you might be able to do and it also sounds as though what interferes most with you using the product is forgetting to use it. Can I offer you some ideas that I have heard from other women in similar situations?

Counselor waits for permission, then continues by offering a variety of options for the participants and asks which might be helpful to her.

Well, some people....

Even if none of these are perfect solutions for you, I am wondering which might be a good one to talk about so we can make it more helpful to you.

Counselor then works with the participant to tailor the general suggestions to her particular situation.

Example (RED: participant seeks to completely change her plan because it is not working):

So you feel that the HIV prevention options you selected will not work for you and you want to try something different. Here are the different options I showed you before (show the flipchart page with all the HIV prevention options)

Slide 29

- What other HIV prevention option might work better for you?
- What can you do to make this option more successful for you?

6. Assess any upcoming events that might affect HIV prevention plan.

Goal: To help the participant pre-emptively identify and address any upcoming challenges to her HIV prevention plan.

Approach: The counselor invites the participant to think ahead over the next few weeks for any possible changes in her routine that may affect her HIV prevention plan.

Beginning in Month 3, the counselor also addresses that the visits will be quarterly and help the participant prepare for maintaining her HIV prevention approaches for that duration of time.

Slide 30

Example: *Lastly, again looking at the next few weeks, is there anything new coming up that might interfere with you using your HIV prevention approaches consistently? For example, sometimes I hear that when people travel or have friends or relatives visiting, or even when they start school or have to change their schedule, or even get a new boyfriend, this changes their routine and they have to adjust to these changes. Anything like these examples, or even other events, that might affect your HIV prevention approaches during the next few weeks?*

IF there are such events, help problem solve...

Okay, so it sounds like there might be a little change coming up. What might you do to continue using these approaches to protect yourself from HIV? What else?

Beginning in Month 3...

The other thing we should discuss a bit is that our next session together will be in 3 months.

-What might this do to your HIV prevention plan?

-What would help you sustain your plan for those 3 months?

7. Assess confidence in implementing HIV prevention plan

Goal: Assess the level of confidence that the participant feels in her ability to implement the HIV risk reduction approaches she has selected.

Approach: A Confidence Ruler is used to assess level of confidence. More important, however, is the follow-up questions, which evokes from the participant the reasons they feel confident (self-empowered) to implement her HIV prevention approaches. Again, the counselor should be curious about the participant's response, asking for other reasons she feels confident in her ability to implement her plans.

Example: Let's see how comfortable you are feeling that you will be able to continue with (using the Ring) your HIV prevention plan.



Slide 31

On a scale of 0 to 10 where 0 is not confident at all and 10 is extremely confident, how confident are you that you will be able to (insert the HIV prevention approaches here—ie., use the Ring every day, use a condom every single time you have intercourse, etc)?

Why is it a ___ and not a 0 or 1? Why else is it a ___ and not a 0 or 1?

What would help move it up 1 or 2 numbers higher??

How might you achieve that?

8. Explore other remaining questions that participant might have

Goal: Provide the participant with an opportunity to discuss other issues that may affect her use of the Ring or other HIV prevention approach

Approach: The Counselor asks an open ended question, inviting a discussion of these issues.

Example: *We are coming to the end of today's session. As you think of the next four weeks until we next meet, what other concerns or questions do you have about the Ring (or the HIV prevention approaches you have selected)?*



Slide 32

What else would you find helpful to discuss about these HIV prevention approaches that would allow you to leave here feeling more comfortable about using them?

9. Wrap-Up (Visits 1 and 2—See #10 for Wrap-Up for Months 3, 6, and 9

Goals:

- To affirm the participant for attending the session and for open discussion of concerns.
- To provide an overview for participant of the upcoming counseling sessions.

Approach: First, the counselor affirms the participant for attending the session, working hard to develop an HIV prevention plan, and for her open-ness in discussing thoughts about using the Ring or other HIV prevention approaches. Highlight the importance of such open discussion in this study. Then, the counselor provides a brief explanation of upcoming counseling sessions. It is important to remind participants that visits are monthly during the first three months, then every three months.

For participant who choose the Ring, it is critical to include mention that beginning in Month 3, the counselor will share with them the residual drug results

Slide 33

Example: *Well, we have come to the end of our session for today. Thanks so much for making the time to come to your appointment and for all your hard work in developing an HIV prevention plan for yourself. I also really appreciate your openness in speaking about some of your challenges and concerns about the HIV prevention methods you chose.*

For participants who chose the Ring....

Remember that during the first three months of the study, we meet every month, so I will see you in a month. In that visit, we will have time to speak about how things went with implementing your HIV prevention approaches, including the Ring. If things go well this month, then we will talk about how to keep doing so well, and if you had some difficulties in using the Ring or your other HIV prevention approaches, we can also talk about that to help you figure out what you might want to do differently. Talking about those difficulties gives us an opportunity to develop a plan that works for you so you stay HIV-negative.

Also, very importantly, please remember to bring back your Ring at your next visit. What we will do with that Ring is send it to the lab to be analyzed so that we can get an idea of how much HIV prevention medication was released into your body. It takes some time for us to get those results from the lab, but beginning with your third study visit, I will be able to share those results with you so we can discuss them since this can give us a general indication of your level of protection from HIV. Do you have any last questions before we end?

See you next month!

For participants who did not choose the Ring...

Remember that during the first three months of the study, we meet every month, so I will see you in a month. In that visit, we will have time to speak about how things went with implementing your HIV prevention approaches. If things go well, then we will talk about how to keep doing so well, and if you had some difficulties in using the HIV prevention approaches you selected, we can also talk about that to help you figure out what you might want to do differently. Talking about those difficulties gives us an opportunity to develop a plan that works for you so you stay HIV-negative. Do you have any last questions before we end?

See you next month!

10. Wrap-Up (Visits 3, 6, and 9)

Goals:

- To affirm the participant for attending the session and for open discussion of concerns.
- To provide an overview for participant of the upcoming counseling sessions.

Approach: First, the counselor affirms the participant for attending the session, working hard to develop an HIV prevention plan, and for her open-ness in discussing thoughts about using the Ring or other HIV prevention approaches. Highlight the importance of such open discussion in this study. Then, the counselor provides a brief explanation of upcoming counseling sessions. It is important to remind participants that visits now every three months.

For participant who choose the Ring, it is critical to include a reminder to bring back her used Ring so we can share with her information about residual drug levels.

Example: *Well, we have come to the end of our session for today. Thanks so much for making the time to come to your appointment and for all your hard work in developing an HIV prevention plan for yourself. I also really appreciate your openness in speaking about some of your challenges and concerns about the HIV prevention methods you chose.*

Slide 33

For participants who chose the Ring...

We are now concluding the first three months of the study, so our next appointment will be 3 months. In that visit, we will have time to speak about how things went with implementing your HIV prevention approaches, including the Ring. If things go well these 3 months, then we will talk about how to keep doing so well, and if you had some difficulties in using the Ring or your other HIV prevention approaches, we can also talk about that to help you figure out what you might want to do differently. Talking about those difficulties gives us an opportunity to develop a plan that works for you so you stay HIV-negative.

Also, very importantly, please remember to bring back your all 3 Rings at your next visit. As you know, we will send them to the lab to be analyzed so that we can get an idea of how much HIV prevention medication was released into your body. I will share the results of the one you returned today next time I see you so you can get a general indication of your level of protection from HIV. Do you have any last questions before we end?

See you next month!

For participants who did not choose the Ring...

Remember that during the first three months of the study, we meet every month, so I will see you in a month. In that visit, we will have time to speak about how things went with implementing your HIV prevention approaches. If things go well, then we will talk about how to keep doing so well, and if you had some difficulties in using the HIV prevention approaches you selected, we can also talk about that to help you figure out what you might want to do differently. Talking about those difficulties gives us an opportunity to develop a plan that works for you so you stay HIV-negative. Do you have any last questions before we end?

See you next month!

END VISIT
Month 12

1. Welcome participant and set structure for session

Goals:

- To affirm participant's attendance at the session and inform the participant of what will occur during the session.
- To affirm patient's commitment to the study for completing all study visits.
- To help participant plan for her continued HIV prevention activities

Approach: The counselor uses a client-centered approach to welcome the participant back for another visit and affirms the participants continued interest and commitment to the study. Then, the counselor offers an overview of what will occur during the session.

Example: *First of all, thank you for taking the time to come in for your appointment and thank you for your commitment to the study and completing it all, that is really wonderful!*

Slide 35

During our time together, we are going to be discussing how it has been going for you in regards to the HIV prevention approaches you decided to use during our last visit.

Slide 36

If things went well with using the Ring or the other HIV prevention approaches you selected that is great and we can discuss what helped you to be successful. If things did not go well using the Ring or the other HIV prevention approaches you selected, we can speak about what happened that made it difficult.

For women using the Ring, add...

I also have the results from the ring that you returned at your last visit which will give us an idea of how much of the drug in the ring was released into your body. I will share those results with you so that you can keep that in mind as we discuss how things have gone for you with the HIV prevention approaches you have selected.

How does that sound?

What else about (the Ring) HIV prevention or your participation in the study would you like to discuss today?

2. Review information on Drug Level Results

Goal: To remind participant about what the Drug Levels mean and how they related to HIV prevention.

Approach: The counselor provides clear information about how the Ring releases drug into the system and how the amount of drug released affects the level of protection that the participant receives from HIV infection.

NOTE: The information is provided in a completely neutral manner. Note that the example below speaks in generalities and does *not* say “if you use the Ring....” This is important because it makes it clear to the participant that this is not about her use of the Ring. This information can be reviewed more quickly in subsequent sessions.

Example: We have discussed this already in previous sessions, but I will review this quickly just remind you about how the Ring provides protection. *Starting at the top we see that usually, with low use of the Ring, little drug is released into the body (counselor points to the purple dots above the Ring on the left) and that results in very little or no protection from HIV (counselor points under the Ring). As we move from left to right, we see that with higher use of the Ring, there is more and more drug released into the body, and down here we see that there is higher and higher protection from HIV. So, when I share with you the results, I will share with you a number, like these 1,2,3, and 4 that will give us an indication of how much drug was released into your body and, more importantly, how much protection you are getting from HIV.”*

Slide 37

Results of 0 or 3 are pretty clear in terms of protection, 0 is no protection and 3 is high protection. For levels 1 and 2, the level of protection can vary depending on how the Ring was used. For example, if a woman removes the ring during menses, the level on this report will probably drop to a 2. However, she may still have high protection if she ALWAYS used the ring during the remainder of the month and NEVER had sex while the ring was out. So, if the level is 1 or 2, it is very helpful for us to talk about how you used the ring in order to give you a better idea of the level of protection you would receive from the Ring.

“What do you think about this?”

“What questions do you have about this?”

3. Remind participant about the purpose of sharing the residual drug levels

Goal: To decrease the possibility that the participant will feel confronted or judged by the drug level results.

Approach: The counselor highlights the key points included on Page 24 of the flipchart, especially that it is the participant's choice what to do with this information.

Example: *And remember...these results may not be 100% accurate, since occasionally errors occur. Also, remember that the purpose of sharing these results with you is to give you an idea of the level of protection you received from the Ring during that period of time. Based on the results, you can decide if you want to use the Ring differently so that gives you more protection. But remember, what you decide to do with this information is always your choice.*

Slide 38

4. Share residual drug level results (DO THIS SECTION BEGINNING AT MONTH 3 ONLY FOR PARTICIPANTS WHO CHOSE THE RING)

Goal: To share with the participant the residual drug results in order to give her a general idea of her level of protection against HIV being provided by the Ring

Approach: The counselor proceeds to share the results in a collaborative and neutral manner. **The results should not be presented in a way that it is even slightly confrontational or judgmental.** Then, the counselor asks the participant for her thoughts about the results and what they mean to their HIV prevention potential.

The counselor should carefully listen for the participant's reaction to the results. If the participant gets defensive, the counselor should remind her that the results are not meant to be confrontational, but helpful to her, and that in this study CHOICE is key, so it is the participant's choice to use the Ring and whether to use the drug level information provided, that her decision will be respected (see example below).

At this visit, participants will receive residual drug levels from 3 Rings. Results will be provided individually for each Ring and there will be an overall level of protection provided for the 3-month period. The counselors should first present the Overall level of protection, then present the level of protection for the individual rings.

Lastly, the counselor uses Appendix 1 to mark the level of protection for the Ring discussed. During the study, the counselor will mark the level of protection for each Ring so that the participant can see her progression

during the course of the study. Appendix 2 provides a color description of when the drug levels for a specific Ring will be discussed during the study.

Example: *For this Month 12 visit, I am going to share with you the results of the level of protection you received from three Rings that you returned on Months _____. (Show Appendix I: Residual Drug Level Feedback Timeline). First I will share with you the level of protection you had during the entire 3-month period and then the level of protection from each individual Ring.*

The overall level of protection for the entire 3-month period was 3.

- *What do you think about this?*
- *How do you feel about the level of protection you received from the Ring during this 3-month period?*



Slide 39

Now, let me show you the level of protection you got from each Ring. The level of protection was 3 for the Ring you used this month, 2 for the Ring you used this next month, and 3 for the Ring you used this following month.

- *What do you think about this?*
- *How do you feel about the level of protection you received from the Ring?*
- *(If applicable) What do you think about the different levels of protection across the three months? What might that be due to?*
- *What does this mean for your HIV prevention plan?*

Example of defensive participant: I am sorry, it sounds like these results have bothered you and that was certainly not the intent. As I have mentioned to you during our sessions, this study is really about choice and I fully respect the choices that you make for yourself. If this low level of protection leads you to decide not to use the Ring, I will respect that choice and we can discuss other ways of protecting yourself from HIV. On the other hand, if this low level of protection leads you to decide that you want to figure out how to use the Ring more regularly, I will respect that decision also and we can discuss ways of helping you achieve that. Really, it is your choice.

So, how do you feel about the level of protection you received from the Ring?

As Appendix II “Drug Level Feedback Over Time Worksheet” is filled with Xs marking the level of protection for each Ring returned, the counselor can also explore the participants reactions to what she sees on the Worksheet. For example:

- *What are your thoughts as you look at the level of protection you have received from the Ring during your time in the study?*
 - *How do you feel about that?*
 - *What does this mean in terms of you remaining HIV negative?*

5. Explore how participant is doing with her HIV prevention plan.

Goals:

- To review participant’s HIV prevention plan
- To explore how well the participant was able to (use the Ring) implement her HIV prevention approaches
- To help the participant begin to think what other HIV prevention approaches may be useful to her in the future

Approach: The counselor begins the conversation by presenting the various options for HIV prevention and asking the participant which she had selected. The counselor again highlights that behavior change can be difficult, then inquires about how things went for the participant with each of her selected approaches. Throughout, the counselor is empathic to the experiences of the participant, actively trying to understand any challenges encountered and avoiding any judgment on the participant’s difficulties.

Example: Here are the different HIV prevention approaches that I have shown you before.

Slide 40

Which ones have you used during the study? So, keeping in mind, how difficult it can be to implement new behaviors into one’s life, how did it for you using (the Ring and/or other HIV prevention approaches) during the past month? I would like to hear about how each of the approaches you selected worked for you, including what went well and what did not go so well. Feel free to start with whichever approach you want to speak about first.

Slide 41

- *How did that approach work for you?*
- *What went well?*
- *What did not go so well?*
- *What obstacles or difficulties did you encounter?*
 - *What did you do to overcome those difficulties?*

6. Looking towards future

Goal: Have participant assess what has worked for her in terms of reducing her HIV risk that she could continue to use in the future.

Approach: The counselor uses open-ended questions to help the participant think about what has worked for her during the study to decrease her risk of HIV infection and what they will plan to do in the future.



Slide 42

Example: *As you know, this is our last of the HIV prevention counseling sessions.*

As you look back on your experience using (include some or all of the approaches used by the participant), how do you think those have worked for you?

Continue with...

And as you look to the future, which do you think you might use to continue to decrease your risk of infection with HIV??

5. Assess confidence in remaining HIV negative

Goal: Assess the level of confidence that the participant feels in her ability to remain HIV negative.

Approach: A Confidence Ruler is used to assess level of confidence. More important, however, is the follow-up questions, which evokes from the participant the reasons she feels confident (self-empowered) in her ability to remain HIV negative. Again, the counselor should be curious about the participant's response, asking for other reasons she feels confident in her ability to implement her plans.

Example: *During these sessions, I have asked you about your confidence in implementing the HIV prevention approaches you have selected. Today, I will ask you something a little different.*



Slide 43

On a scale of 0 to 10 where 0 is not confident at all and 10 is extremely confident, how confident are you that you will be able to remain HIV negative?

Why is it a ___ and not a 0 or 1? Why else is it a ___ and not a 0 or 1?

What would help move it up 1 or 2 numbers higher?? How might you achieve that?

6. Explore other remaining questions that participant might have

Goal: Provide the participant with an opportunity to discuss other issues that may affect her use of the Ring or other HIV prevention approach

Approach: The Counselor asks an open ended question, inviting a discussion of these issues.

Example: *We are coming to the end of today's session. What else would you find helpful to discuss about these HIV prevention approaches that would allow you to leave here feeling more comfortable about using them?*



Slide 44

7. Affirmation and Closure

Goal: To express gratitude and acknowledgement to the participant for her role in the study and the work she did during the study






















Approach: The counselor genuinely acknowledges the work of the participant throughout the study and her commitment to seeing the study to its end.

Example: Well, we have come to the end of the session. It has been wonderful experience working with you. I greatly appreciate your commitment to the study, staying in it all the way to the end. It is obvious that you are committed to remaining HIV negative and I could see the hard work you did to overcome some of the challenges you encountered with your prevention plan. That is clear evidence of your strength and determination. And thank you for the open discussions we had about the Ring, your concerns about it, and sharing with me your decisions, so that I and the rest of the study team could understand more clearly the decisions that women make about using the Ring. That was a key part of this study, so thank you for contributing to that.



Slide 45

Appendix I: Residual Drug Level Feedback Timeline

	Enrollment Visit (V2)	Month 1 Visit (V3)	Month 2 Visit (V4)	Month 3 Visit (V5)			1 st Quarterly Visit - Month 6 (V6)			2 nd Quarterly Visit - Month 9 (V7)			PUEV - Month 12 (V8)
Dispensed	 Ring 1	 Ring 2	 Ring 3	 Ring 4  Ring 5  Ring 6			 Ring 7  Ring 8  Ring 9			 Ring 10  Ring 11  Ring 12			
Feedback Provided				 <i>Ring 1</i>			 <i>Ring 2</i>  <i>Ring 3</i>			 <i>Ring 4</i>  <i>Ring 5</i>  <i>Ring 6</i>			 <i>Ring 7</i>  <i>Ring 8</i>  <i>Ring 9</i>

Appendix II: Drug Level Feedback Over Time Worksheet

<div style="text-align: center;"> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 0 auto;">High Protection</div> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 0 auto;">No Protection</div> </div>	 3									
	 2									
	 1									
	 0									
Study Ring Use Period:	Enr-M1	M1-M2	M2-M3	M3-M4	M4-M5	M5-M6	M6-M7	M7-M8	M8-M9	
Notes:										

Appendix III: HOPE Counseling Q&A

This document was developed to help counselors address some of the obstacles and questions that participants often have about the Ring. It is divided into two sections. Part 1 provides guidance on some possible solutions that you can share with the participant to help her overcome some common obstacles to using the Ring. Part 2 provides answers to some of the questions that participants asked during ASPIRE. Each part begins with an example of how this information can be shared with the participant. We anticipate that over time, we will add to this document as we hear about new questions being asked by participants and we learn about new ways to overcome some of the common obstacles that participants experience in using the Ring.

PART 1: OVERCOMING COMMON OBSTACLES TO USING THE RING

This document was developed to assist counselors in problem-solving issues that can impede consistent Ring use among study participants. Note that it is meant to be used as a resource and not something to be distributed or read word for word to the participant. The counselor should provide the information and possible solutions to the participant in a client-centered way, meaning that permission should first be obtained from the participant before proceeding with information or suggestions. Here is an example:

Counselor: One of the challenges to using the ring that you mentioned was that you feel that keeping it inside you for a month is not clean. Can I offer you some information about that?

Participant: Yes, okay.

Counselor: Because the vagina is a self-cleaning environment, it is not necessary to clean the ring. The vagina naturally takes care of that. What do you think about that?

Participant: Yes, that is what I was told. But, you know it still does not feel clean to leave it in there.

Counselor: I can understand that, for you feeling clean is very important and regardless of that information, it just still does not feel clean to you. Can we discuss some possible solutions to that?

Participant: Sure!

Counselor: Well, it's okay to clean the ring. What is important is to remember to use clean water at room temperature or cool; and remember to not use hot water or soap to clean the ring. If you decide to clean the ring, the other thing we recommend is that you figure out when is the best time to do it so that you can remove it, clean it, and reinsert it immediately so that you don't lose the protection from HIV.

Participant: Oh, that would be great if I can clean it sometimes.

Counselor: I am glad that was helpful to you in overcoming that concern. As you think about taking it out to clean, when would you do it, so that you are able to reinsert it right away?

Participant: Well, I can probably do it maybe once per week when I take my bath, that way I am in private and can take it out, rinse it, and put it back in.

1. PARTICIPANT HAS CONCERNS ABOUT USING THE RING DURING MENSES

INFORMATION:

- The ring is safe to use during menses.
- It is recommended that the ring remain in place during a woman's period to maintain consistent protection from HIV, especially if she may be having sex during this time.
- The ring will not block the menstrual flow.
- The ring does not require cleaning after menses.
- It is safe to use tampons and the ring at the same time.

POSSIBLE SOLUTIONS:

- Women who still prefer to clean the ring during or after menses can rinse it with clean, room temperature or cool water and reinsert it right away. Do not use soap or hot water to clean the ring.
- For women who prefer not to use the ring during menses or still have concerns about cleanliness:
 - o If the participant prefers to remove the ring during menses, consider what other HIV prevention method(s) can be used if she is having sex during this time. The ring can only reduce the risk of HIV infection if inserted.
 - o If the ring is removed, store the ring in a clean and safe place during the time it is removed and consider strategies to remember to reinsert the ring immediately after the end of the menstrual period.
 - o Depending on timing of menses and personal preferences, the participant could choose to insert a new ring at the end of menses. This strategy may be appealing to participants who remove their rings during menses as well as those who leave the ring inserted during menses, but have concerns about its cleanliness.

2. PARTICIPANT HAS CONCERNS ABOUT HYGIENE/WANTS TO CLEAN THE RING

INFORMATION:

- It is not necessary to clean the ring.
- Inside the vagina is a self-cleaning environment.

POSSIBLE SOLUTIONS:

- Women who still prefer to clean the ring can rinse the ring in clean water which is at room temperature or cool before reinsertion.
- Do not use soap or hot water to clean the ring .
- Consider the best time to do this so that the ring can be reinserted immediately afterwards.

3. WHAT TO DO IF THE RING FALLS OUT

INFORMATION:

- It is unlikely that the ring will fall out, but sometimes this does happen.

POSSIBLE SOLUTIONS:

- If the ring is removed or falls out, rinse the ring in clean water which is at room temperature or cool before reinsertion.
- If the ring falls out somewhere that is unsanitary (not clean), like the toilet, it is okay not to retrieve the ring.

- Dirty rings should not be reinserted. Instead, insert a new ring right away. If you do not have a new ring, contact or return to the clinic to get a new ring as soon as you can. Make sure to use other HIV prevention methods while the ring is not inserted.
- If you find that the ring falls out often, you can try to reposition it by inserting a clean finger into your vagina and pushing the ring farther in.
- You can also contact us or come to the clinic to review how to insert the ring so it does not continue to happen.

4. PARTNER DISCLOSURE AND ADDRESSING PARTNER QUESTIONS

INFORMATION:

- Study staff can help you think through whether or not to disclose to your partner(s), but only you can decide which option is best for you.
- Partner disclosure is an individual choice and will not impact your ability to participate in HOPE. Disclosure can range from telling your partner(s) about the study, the ring, or both. Some women may decide to disclose to some partners but not others.
 - o *Potential positive* outcomes of disclosure: support of participation or ring use, feeling increased openness or closeness in relationship(s), minimize risk of harm or problems in relationship(s) due to ring use or participation without partner knowledge
 - o *Potential negative* outcomes of disclosure: disapproval of participation or ring use, risk of harm or problems in relationship(s) if partner does not approve
- Partners who are aware of study participation and/or ring use may have questions about how the ring impacts them. In general:
 - o The ring cannot protect your partner from HIV.
 - o The ring will not harm or impact your partner's health in any way.
 - o Most men cannot feel the ring during sex, but it is possible.
 - o Partners are welcome to come to the clinic any time.

POSSIBLE SOLUTIONS:

- Study staff will support whatever decision you make about partner disclosure and give you tools to help you successfully implement your plan (e.g. help you think through how to talk to your partner or how to use the ring discretely).
- Study staff can help you practice what you may want to say to him.
- Study staff can be available to speak with your partner.
- Study staff can also offer you written information to share with your partner(s) at home.
- If the Ring is uncomfortable for you or your partner, you can try readjusting the position of the ring. We encourage you to speak to study staff if you continue to have this difficulty.

5. USING THE RING DURING SEX

INFORMATION:

- Some women or their partners may feel the ring in the vagina during sex, but this will not harm either of them.
- We know that protection from HIV is highest when the ring is used all the time, and that the ring offers no protection if it is not used. It is important to know that if you wear the ring most of the time, but it is not in place when you are exposed to HIV (for example, if you take it out when you have sex), you may not be protected.

- Some women or their partners report changes in how sex feels while using the ring. These changes can be positive or negative and may relate to libido, enjoyment of sex, vaginal tightness and wetness, odor, or comfort during sex.
- If you have discomfort, or if your partner tells you he can feel the ring during sex, this may be due to the placement of the ring.

POSSIBLE SOLUTIONS:

- Discomfort or Partner Feeling the Ring: Wash hands, and try to gently push the ring further into the vagina. It's impossible for the ring to be pushed too far up or get lost inside the body.
- Partner Concerns: It may help to understand what your partner's concerns are with the ring. If you do not feel comfortable having these conversations, we are here to help. We can provide informational material, or even speak with your partner directly about his concerns if he is willing.
- For women who have challenges or still prefer not to use the ring during sex:
 - o Consider what other methods of HIV prevention can be used to help reduce the risk of HIV infection.
 - o If the ring is removed for sex, it should be inserted for as long as possible before sex and reinserted immediately afterwards.
 - o Consider ways to remember to reinsert the ring immediately afterwards.

6. USING THE RING BEYOND 1 MONTH

INFORMATION:

- The ring is designed to be used for approximately one month, after which time it should be replaced with a new ring.
- Replacing the ring with a new ring each month ensures that there is enough drug left in the ring to protect against HIV infection.
- There is no maximum time that would require removal of the ring for safety reasons. However, the same ring should not be worn forever, and we do not know how well the ring works to prevent HIV when worn longer than one month.

POSSIBLE SOLUTIONS:

- If you need to, it is better to use the ring for slightly longer than one month than to take it out and not have protection. If you have worn the same ring for longer than one month and need a replacement, contact the clinic to get a new ring as soon as you can.
- You should consult with the study staff ahead of time if you think you may need to wear the ring longer than one month.
- You should remove the ring if you do not want to participate in the study anymore.

7. QUESTIONS ABOUT RING SIDE EFFECTS & SAFETY

INFORMATION:

- The ring is flexible and small enough to fit inside of the vagina without causing any changes to the size of the vagina. It does not cause the vagina to widen.
- The material of the ring is very durable, and the ring will not break, dissolve, or disappear inside the body. During ASPIRE, it was proven that the ring could be kept in place without becoming damaged or causing harm to the vagina.

- Many previous trials with the ring, including ASPIRE, have proven that the ring is safe to use and the study drug does not cause any negative health effects in women. The ring does not cause infertility or cervical cancer, and it does not harm bodily tissue.
- The ring does not interfere with a woman's menses or menstrual cycle. It will not cause increased menstrual flow or other changes to the cycle.
- *(See also the "Ring FAQ Factsheet" for more information)*

POSSIBLE SOLUTIONS

- If you experience any health issues or changes in your vagina during the study, please report them to study clinicians so that they can provide any necessary care and treatment, or referrals if they cannot provide the care you need at the clinic.
- If you experience any serious health issues, the clinician may decide it is best for your health to stop ring use until you are better.

8. QUESTIONS ABOUT INTERMITTENT USE

INFORMATION:

- We know that protection from HIV is highest when the ring is used all the time, and that the ring offers no protection if it is not used.
- It is important to know that if a participant wears the ring most of the time, but she is not wearing it when she is exposed to HIV, she may not be protected.
- *(See also "RING USE DURING SEX" and "PARTICIPANT HAS CONCERNS USING RING DURING MENSES" and "Choice, Adherence, and Open Reporting Factsheet" for more information)*

POSSIBLE SOLUTIONS

- If a participant does not feel comfortable wearing the ring with all of her partners, she could protect herself by using a backup method for HIV prevention when she is not using the ring.
- If a participant prefers only wearing the ring at certain times, it may help to review and consider adding other HIV options.

9. SAFE STORAGE OF RINGS/OPTIONS FOR DISPENSATION

INFORMATION:

- Used and dirty rings should always be stored sealed in the white bag provided to you. Store unused rings in their packaging until needed for use. If you do not have the bag provided, you may use another bag or container available to store your used ring.
- Do not store used or unused rings in the refrigerator or in direct sunlight.
- Store out of reach of children and pets.

POSSIBLE SOLUTIONS:

- If you have lost your rings, or at any point need a new ring for any reason, please contact the clinic for assistance.
- If you do not feel you are able to keep unused rings safely at home, staff can talk with you about options for receiving rings monthly.

PART 2: RESPONDING TO COMMON QUESTIONS ABOUT THE RING

The below information is meant to give further detail on questions that participants may ask during their counseling sessions. Counselors can provide this information to participants to help them become more informed and gain a greater understanding of these topics, but the information should not be used in an attempt to convince participants to make any particular decision. As is done in client-centered counseling, information is provided ONLY after obtaining permission to do so from the participant. This happens by either 1) the participant asking the question directly or 2) if the counselor asks the participant if she can provide some information to them. This second approach may be particularly relevant in situations in which the counselor hears the participant is doing something that is inconsistent with study recommendations and wants to provide correct information. Information should be provided and then followed by an open-ended question to the participant soliciting their reaction and thoughts in response to the new information. Here is an example:

Counselor: So you are wondering whether you have to use condoms if you use the Ring. Can I share some information with you about that?

Participant: Yes, okay.

Counselor: PROVIDES THE INFORMATION IN #1, then asks, "What are your thoughts about that?"

OR

Counselor: You mentioned that you are thinking of sharing the Ring with your sister while her boyfriend is in town. Sounds like you want to take care of her. I am a little concerned about that and I am wondering if I can share my concerns with you?

Participant: Yes, okay.

Counselor: PROVIDES THE INFORMATION IN #3, then asks, "What are your thoughts about that?"

1. RING USE AND CONDOMS

INFORMATION

- There are many ways women can reduce their risk of HIV and the goal of study staff is to help each participant maximize her chances of preventing HIV. That is why study staff encourage combining ring use with other prevention methods, including condoms.
- The ring reduces the risk of HIV but does not prevent pregnancy or other STIs. Correct and consistent condom use reduces the risk of HIV, other STIS, and prevents pregnancy.
- Consistent ring use reduces the risk of HIV infection, but is not 100% effective.
- Condom use has been encouraged as a way to prevent HIV for many years, but people continue to get infected with HIV because it is hard to use condoms correctly and consistently all the time. Using the ring can help protect women from HIV when condoms are not used or if they fail.
- It is safe to use the ring and condoms at the same time.
- *(See also "HIV Prevention Options Factsheet" for more information)*

2. SEROCONVERSION & RESISTANCE CONCERNS

INFORMATION

- Results from ASPIRE and other recent studies did not show increased levels of HIV drug resistance in women who seroconverted while using the dapivirine ring.
- Researchers are continuing to follow-up women who seroconverted in ASPIRE to check on their health and make sure the medicines they are taking for HIV treatment continue to work for them. You will be informed of any new information from these ongoing studies.
- Any HOPE participant who feels that she may have been exposed to HIV is encouraged to come to the research site for testing and support. If a participant seroconverts, the site team will collect the ring and provide her with referrals to HIV treatment and other resources.
- *(See also "HIV Resistance Factsheet" for more information.)*

3. QUESTIONS ABOUT RING SHARING

INFORMATION:

- For now, the ring is only available for women who are HOPE participants.
- It is important not to share the ring or give it away. Women who are not in the study may not get regular HIV or pregnancy testing, or regular medical care. If they use the ring and develop problems, they may not have access to the care they need.
- The ring can only protect you from HIV if you are using it at all times, which means not giving it to others.
- *(See also "Choice, Adherence and Open Reporting Factsheet" and "HIV Resistance Factsheet")*

4. RING EFFICACY AND AGE

INFORMATION:

- In ASPIRE, women younger than 21 years old who were assigned to the dapivirine ring got HIV at the same rate as women assigned to the placebo ring.
- However, we know that the biggest factor limiting the dapivirine ring's effectiveness for young women in ASPIRE was inconsistent use.

- Researchers are doing specific studies to confirm if any other factors might impact the effectiveness of the ring in younger women.
- High adherence among women who choose the ring in HOPE will allow us to understand more about the efficacy of the ring when used all the time.
- This information is important to know for potential future introduction of the ring in the community.
- *(See also "Choice, Adherence and Open Reporting Factsheet" for more information)*

5. DURATION THE RING CAN BE OUT AND THEN REINSERTED

INFORMATION:

- It is okay to reinsert the ring for the current month no matter how long it has been removed during that month, provided that it is intact and clean.
- If it gets close to the time you would normally be inserting a new ring (in other words, the next month), then insert a new ring instead.