

Healthy Mothers:

**Client-Centered Adherence Counseling
for
DELIVER (MTN-042) and B-PROTECTED (MTN-043)**

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 to have their sessions 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 will be accepting it. Below is a sample introduction that can be used, but you should also feel free to use your own words. Keep in mind that the participant will probably already know about the recording because it is mentioned in the consent forms at most study sites.

As you know, In this study, we will be 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 our counseling across all of the study sites. The recordings are then reviewed by one of the researchers who specializes in counseling so he can speak with us about how to make the sessions better and, hopefully, more helpful to you, our participants. So, the focus of the recording is not so much what you are saying, but rather on making sure that I am doing the best counseling possible. Is it okay if I turn on the recorder now?

Below are 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_15October2019

Uploading Recordings

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

<https://atlas.scharp.org/cpas/project/MTN/042/begin.view?>

When you enter you will see that there are separate folders for each site under the “Site-specific Materials” section. You will upload your sessions to folder labeled with the site where you work (i.e., Blantyre, MU-JHU, Wits RHI Shandukani, or Zengeza).

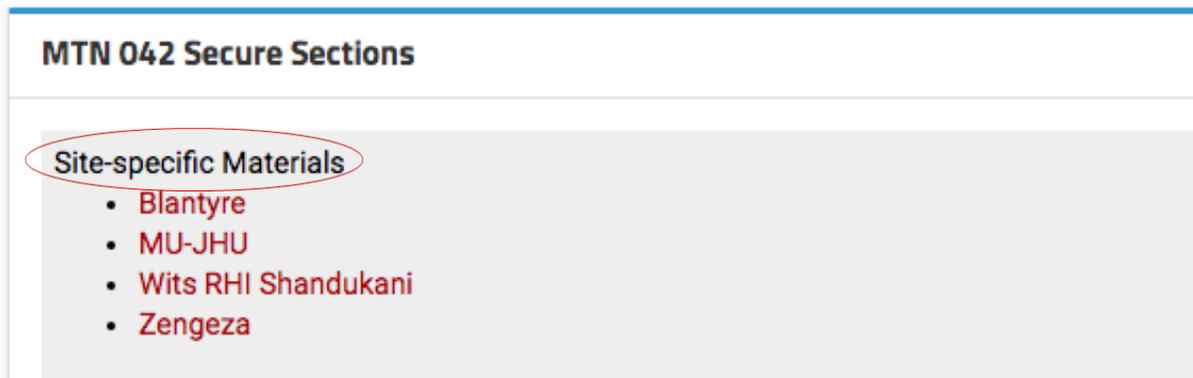
Here are the instructions for uploading your recordings onto the Atlas site:

This is the link to the MTN-042 site: <https://atlas.scharp.org/cpas/project/MTN/042/begin.view?>

In order for you to be able to upload sessions to ATLAS, we need to obtain permission from SHARP. We have already obtained permission for all of the current counselors at each site. However, if there is

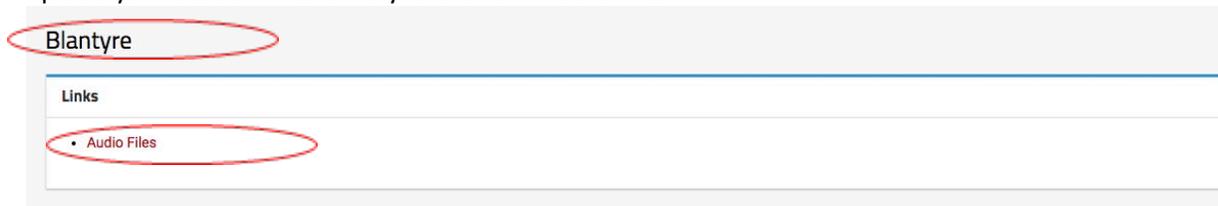
someone at the site who also needs to have permission to upload the files, please send that person's name and email address to your Rebecca (Rebecca.giguere@nyspi.columbia.edu) she can forward the email address to SHARP.

Once on the MTN-042 ATLAS webpage, please click on your site's name under the "Site-specific Materials" heading.



When you click on the name of your site, 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 link for your site, you will see a page with a link for "audio files." You will be able to upload your session files once you click on "audio files".



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 is housed
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.

Use of this Manual

This manual provides a detailed guide for conducting the Healthy Mothers adherence counseling intervention for Deliver (MTN-042) and B-Protected (MTN-043). It breaks down the sessions into a series of tasks and for each task, presents the goal of the task, the approach that is taken by the counselor, and an example of how the counselor can achieve this task. Each section includes a corresponding slide on the counseling flipchart, which acts as a reminder of the different tasks in the session. Because the Ring flipchart has one extra slide in each session (that focuses on Removing the Ring at Childbirth), the numbering differs after slide 9 in the Enrollment Visit. As such, we include two flipchart numbers, one in a Ring shape and the other in a Pill shape, for the corresponding flipchart.

One key thing to remember is to **make the counseling helpful to the participant**, not just a study procedure to be checked off, so adjust your sessions accordingly. Here are some things to keep in mind when using this manual:

1. To conduct Healthy Mothers well, **learn the manual in order to understand the goal of each task and how to achieve that goal.** The flipchart is a memory aid, it alone will not be sufficient to conduct Healthy Mothers well as you need to understand the underlying goals and have an idea of how to phrase each task in a client-centered manner.
2. **The examples provided should not be considered a script** to be read to participants. Instead, they are just examples of how to phrase the task. You are allowed to change questions as long as they still achieve the goal of the task (i.e., evoke change talk, explore concerns) and done in a client-centered manner.
3. **The more someone speaks of wanting to change, the more likely it is that they will do it**, which is why there are plenty of opportunities in the sessions to discuss benefits of using the Ring or Truvada. Oftentimes, individual's answers will change a bit depending on the specific question asked and they may deepen their reasons for wanting to use the product. However, if you find that the questions are evoking similar material, **if you are concerned that it is becoming repetitive, change the questions a bit** (see some alternatives of how you can do this on page 12)

ENROLLMENT VISIT

***If the participant has been assigned to use the Ring, you should utilize the Ring version of the flip chart when referring to this manual**

(Corresponding flipchart slide numbers are shown like this:



***If the participant has been assigned to use Oral Truvada (referred to as “the pill”), you should utilize the Pill version of the flip chart when referring to this manual**

(Corresponding flipchart slide numbers are shown like this:



OVERVIEW OF SESSION

The purpose of this session is to orient the participant to the HIV prevention/adherence counseling that will occur during MTN-042/MTN-043, ensure that she is fully informed about the primary HIV prevention method (i.e., the Ring or the pill) to which she has been assigned, and provide a safe, non-judgmental space in which the participant can openly discuss and work through any concerns she has about her assigned product. The goal is to help the participant become as comfortable as possible so that she can confidently work with the counselor to develop a product use plan that works best for her, as well as brainstorm how she might overcome potential challenges, stay motivated, and utilize other HIV prevention methods in an effort to remain HIV-negative.

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 her willingness to take part in the study, and showing appreciation for the participant's role in helping researchers to understand how these products might be used by the community.

ENROLLMENT SESSION

1. Provide an overview of today's session

Goal: To orient the participant to what will occur during today's session.

Example: *We're now going to begin your first Healthy Mothers counseling session! First, I just want to give you a little information about our session together so you know what to expect. The focus of today's counseling will be for me to learn more about your interest in participating in this study, as well as help you prepare to use [the Ring or the pill] that you've been assigned. Through our discussions, I hope to understand any concerns you still have about using [the Ring or the pill] and help you develop a plan for using it and overcoming any possible obstacles you expect to encounter. Lastly, I will give you an opportunity to ask any questions that you have about using [the Ring or the pill] so that you can leave today with all the information you need about your study product.*

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2. Provide an overview of the counselor's role

Goal: To inform the participant about the counselor's role.

Approach: The counselor provides an overview of her role in the counseling session and stresses the importance of speaking openly about the participant's experience using the study product (i.e., the Ring or the pill) during their sessions together. The emphasis of this task should remain on helping the participant to understand that the purpose of these visits is to aid her in maintaining motivation and developing her own plans for using her assigned study product. The counselor normalizes discussions of imperfect adherence to ensure that the participant will feel more comfortable reporting problems she had when using the product. The counselor also highlights the fact that they will not tell participants what to do, judge them, or push them to take the study product or use it more regularly.

Example: *Now that you have a better idea of what to expect today, I would like to take some time to discuss what my role will be in working with you during our sessions together.*

In this study, the focus will be on supporting you, the participant, in using [the Ring or the pill]. I will meet with you during each of your study visits so that we can discuss how things have been going and so you can share how you're feeling about [the Ring or the pill] and any other HIV prevention methods you might choose to use. My goal is

to help you develop a plan for using this product to reduce the risk of you acquiring HIV.

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*During our counseling sessions, my role is not to judge you, tell you what to do, or push you to use [the Ring or the pill]. Instead, I am here to listen to your experiences using your study product. I know that sometimes things can happen that prevent us from using these products as instructed, and I want you to know that this is perfectly normal. Should you experience any challenges, I encourage you to share them so that we can have an open conversation and develop a plan that you think might work better for you. It is clear that you don't want to be infected with HIV and my role is to **help you achieve your goal**. You should also know that anything you discuss with me today will remain completely confidential; I will not share your personal experiences with anyone else.*

How does all this sound to you? What questions do you have so far?

3. Explore participant's interest in joining the study

Goal: To understand the participant's motivations for entering the present study.

Approach: The counselor takes an exploratory approach to understand these motivations and is curious about why the participant wants to be a part of this study. Below are some questions that can guide the exploration. Keep in mind that, for some participants, the motivations for entering the study may not be specifically related to gaining access to the study product. This is perfectly fine; it is still important for the counselor to understand and be accepting of these motivations. To ensure that the participant feels heard and acknowledged, it is helpful to probe and reflect back her responses throughout this task.

Example: *So here you are, entering a new research study.*

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5

- *Tell me about your decision to enter this study...*
- *What concerns do you have about getting HIV?*
- *What are some benefits you're hoping to get from this study?*

4. Inquire about how the participant is feeling about her assigned study product

Goal: To elicit how the participant is feeling about her assigned study product.

Approach: Using the flipchart emojis, the counselor asks how the participant is feeling about the study product she has been assigned. The key here is to remain *empathic* when probing about the participant’s feelings to ensure that she feels comfortable expressing any disappointment she might be experiencing. The counselor **should not** offer reasons to convince the participant that her assigned product is also good but should work to engage the participant to come up with a plan during the remainder of the session.

Example: *As you know, you’ve been assigned to use [the Ring or the pill] for this study. How do you feel about being assigned to [the Ring or the pill]?*



If participant selects “Very Happy”: *That’s great! I’m happy to hear that you’ve been assigned to the product that you wanted to use.*



If participant selects “Fine”: *I’m glad that you’re feeling fine about the product you’ve been assigned. If at any time you develop other feelings about [the Ring or the pill], then please feel free to share those with me.*

If participant selects “Disappointed”: *Thank you for being open about your feelings, and I’m sorry that you were not assigned to the product that you wanted.*

Why did you prefer the other product? [The counselor should listen empathically and try to see how some of the perceived problems with the assigned product might be addressed throughout the session]

Hopefully I can help you to develop a plan for using [the Ring or the pill] with which you will still feel comfortable and which will still reduce your risk of HIV infection.

5. Review participant’s knowledge of the study product

Goals:

- To elicit the participant’s knowledge of her assigned study product.
- To ensure the participant is informed about her product and how it relates to HIV prevention.

Approach: In order to tailor the information given to each participant, the counselor first asks the participant what she knows/has heard about her assigned study product. Correct information is affirmed to ensure the participant knows that what she’s saying is correct. Then, the counselor asks for permission to share more information with the participant. Once permission is granted, the counselor can utilize the flip chart to help share important information in a brief, easily comprehensible way. After

sharing extra information, the counselor checks in with the participant to make sure she has understood everything and to see if she has any questions.

It is important for information to be provided in a neutral manner - not with the intent of pushing the participant to use the study product.

Example: *So, you have been assigned to use [the Ring or the pill]. What have you heard about this product? [Pause for the participant to share information.]*

7

What else?

7

If participant shares correct information: *That is correct! It sounds like you have researched this product well and are already knowledgeable about it. Can I share some more information with you that may be helpful for you to know as you begin using this product at home?*

If participant shares incorrect information: *Thank you for sharing your thoughts. Can I share with you some additional information and add to what you told me?*

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If the participant says YES: [Reference the bulleted points on Slide 8 and share any information that the participant has not already discussed with you. Be sure to clarify any incorrect information that she shared and avoid repeating information that she already knows.]

8

Once you have finished sharing the information: *What do you think about this information? What questions do you have?*

6. Discuss potential concerns and benefits to product use

Goals:

- To discuss the participant's concerns about using her assigned study product and how she might overcome them.
- To discuss the potential benefits the participant sees to using her assigned study product.

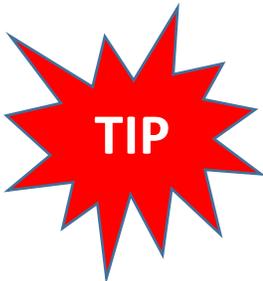
Approach: To facilitate open and honest conversation, the counselor neutrally inquires about what benefits and/or concerns the participant has about using her assigned product.

During this step, it is helpful to reflect back and further probe the participant's responses to ensure she is able to adequately explore her perceived benefits and concerns. For any concerns that the participant shares, the counselor asks the participant what might help her to overcome them. It is important here that the participant leads the discussion on how she might overcome various concerns, as this gives her the chance to start developing a plan that will work best for her.

Example: *Now that you know more about it, I'd like to know how you're feeling about using [the Ring or The pill].*



- *What do you think are the benefits to using [the Ring or the pill]?*
- *What concerns do you have about using [the Ring or the pill]?*



If the participant has already expressed benefits and concerns and the counselor fears being too repetitive, change this up a bit using any of these approaches:

1. Have the participant select her top benefits and concerns: *You have already mentioned a few benefits and concerns that you have about using the Ring (or Pill)...what would you consider to be the top two benefits for you of using the Ring (or Pill). And what are the top two concerns?*

OR

2. Summarize what the participant has said and ask for any other remaining benefits or concerns: *We have been speaking about some of the benefits you see to using the Ring (or Pill) and also some of the concerns you have. Here is what I have heard so far... (offer a summary of the concerns, then of the benefits)...what would you add to those, if anything?*

SKIP this slide if the participant has shared some of her concerns.

If she has not shared concerns, use this slide to begin an exploration of concerns she may have but has not felt comfortable expressing.



- *Here we have some examples of concerns about [the Ring or the pill] that other women in research studies have shared. Which of these are concerns that you also have and may impact your ability to use [the Ring or the pill] consistently?*



7. Explore participant's readiness to start using her assigned product

Goals:

- To assess how the participant feels about starting to use her assigned study product.
- To address the participant's remaining concerns and help her feel more comfortable beginning product use.

Approach: In this task, the counselor explores how the participant is feeling about beginning product use while remembering that the goal is not to push the participant to use the study product before she is ready. A nonjudgmental approach is key here. After assessing how the participant is feeling about beginning study product use, the counselor probes those feelings using the flipchart cues to elicit a richer discussion. If the participant still has concerns, the counselor discusses them with the participant and, if requested, helps her to overcome them.

Example: *You have shared some of the benefits you see to using [the Ring or the pill] and some of your concerns. How are you feeling about starting to use [the Ring or the pill]? If you look at the flipchart, you'll see that there are three emojis that each correspond to a particular feeling: "I am still very unsure about starting," "I still have some concerns about starting," and "Yes, I am ready to go." Which of these statements best reflects how you are feeling right now?*

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After the participant responds, affirm her for sharing her feelings and move to slide 12. Here, you will ask the follow-up questions that correspond to the participant's choice on slide 11.

Thank you for sharing how you're feeling about starting to use [the Ring or the pill]. You know yourself best, and I will proceed with the session based on your feelings so we can talk through them together. Now...

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If the participant says "I am still very unsure about starting": *You mentioned that you are still not ready to start using [the Ring or the pill].*

- *What concerns remain?*
- *How can I be of help?*

If the participant says "I still have some concerns about starting:" *You mentioned that you are not sure about starting to use [the Ring or the pill].*

- *What would make you feel more comfortable in starting?*
- *How can I be of help?*

If the participant says “Yes, I am ready to go”: *You mentioned that you are ready to start using [the Ring or the pill].*

- *Tell me more about that!*

8. Help participant develop a plan for using her assigned study product

Goals:

- To help the participant develop a plan for using her assigned study product over the coming weeks.
- To explore any challenges to product use that the participant might anticipate and help her brainstorm how she might overcome them.

Approach: In this step, the counselor helps the participant to develop a plan for using her assigned study product over the coming weeks. It is important to let the participant lead these discussions, as she knows herself best and the goal is to help her develop a plan that will work well for her. In addition to probing about the participant’s plans for using the product as instructed over the coming weeks, the counselor also inquires about potential challenges to consistent use, referencing the flipchart as necessary. If the participant shares any potential challenges, the counselor works with the participant to develop a plan for dealing with them. Further, the counselor asks the participant who she would/would not like to tell about her product use to support her in her efforts to use it and remain HIV-negative. If requested, the counselor helps the participant to plan out how she could disclose product use to individuals she thinks she will have a difficult time telling. The key here is to respect and affirm her decisions and help her plan out how to tell individuals who she would like to be informed about her product use.

Example: *Before you take [the Ring or the pill] home, let’s talk about how you might use it over the next few weeks...*

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- *How are you supposed to use [the Ring or the pill]?*
- *What are your plans to achieve that?*

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After the participant has developed a plan and discussed some strategies she might use:

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- *Here we have some challenges to using [the Ring or the pill] that other women in research studies have shared. Which challenges do you think you might encounter and could impact your ability to use the study product as intended?*

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- *How might you overcome those challenges?* [Probe about each challenge.]

After the participant has developed a plan for dealing with each of her potential challenges:

Some women decide that it would be helpful to them to let some people in their life know that they are using [the Ring or the pill]. This is really a decision for each woman to make and if you decide that you do or don't want to speak with anyone about this, we fully respect that. As you look at this page...



- *Are there people listed here with whom is it important for you to discuss using [the Ring or the pill]? Why? How might you go about telling them? Take me through the conversation that you would have with these individuals...*



- *Are there people here with whom is it important for you to NOT discuss using [the Ring or the pill]? Why not?*

9. Planning for removal of ring before labor (only for 042 RING participants)

Goal: To help the participant plan for removal of the ring prior to labor.

Approach: The counselor reviews the instructions about removing the ring prior to labor. Then they engage the participant in thinking through a plan for the removal and storage of the ring, which is to be brought to the next study visit.

Example: *There is one more thing we should plan for in terms of the ring... removing it prior to you giving birth. As you know, you were instructed to remove the ring or have your doctor or nurse remove it before Week 42 or when your contractions start; we then told you to place it in the bag we gave you so that you can return it during your next study visit. Let's think through how you might accomplish this. Here are some questions that we can think about to help us plan:*



- *Who might help you remove the Ring if needed?*
- *How will you remember to remove the Ring before delivery?*
- *How and when will you let your doctor or nurse know about the Ring?*
- *Where will you keep the Ring bag for easy access?*
- *How will you remember to remove the Ring before Week 42?*

[Continue to probe until the participant has developed a plan for removal that includes all of the above elements.]

10. Assess Importance of implementing her assigned study product (the Ring or the pill) in her life

Goal: Assess the importance that the participant places on using her assigned study

product to avoid HIV infection.

Approach: An importance ruler using a growing tree is used to assess level of importance in this task. More important, however, is the follow-up question, which evokes from the participant the reasons why implementing her assigned product is important to her. The counselor is curious about the participant's responses, asking for other reasons why using this product is important to her, 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 to use [the Ring or the pill] to avoid becoming infected with HIV? [Refer to images along the ruler to aid with comprehension as needed.]*

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- *What are some reasons that you chose that number and not a 0 or a 1?*
- *Why else?*

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TIP

This is a place where the importance ruler can evoke repetitive material from the participant. If the participant has spoken a few times about the importance of using the product to remain HIV negative, have her select the top two or three reasons:

You have already mentioned some reasons why it might be a 9 and not a 0 or a 1, but what would you say are your two top reasons why using the ring to remain HIV negative is so important to you?

NOTE ON USING IMPORTANCE AND CONFIDENCE RULERS WITH PARTICIPANTS WITH LOW LITERACY:

Counselors can simplify the rulers for use with participants with low literacy 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 somewhere along the scale. Similarly, the counselor can point to the participant’s response and then point to the lower end of the scale to highlight the participant’s level of importance or confidence.

11. Assess confidence in implementing assigned study product

Goal: Assess the level of confidence that the participant feels in her ability to implement the study product she has been assigned.

Approach: A confidence ruler using a growing tree is used to assess level of confidence in this task. More important, however, are the follow-up questions, which evoke from the participant the reasons that she feels confident (self-empowered) to implement her assigned study product. Again, the counselor is curious about the participant’s

responses, asking for other reasons why she feels confident in her ability to implement her assigned study product into her life. If the participant rates her confidence at a value less than 10, the counselor helps her to think through how she might improve her confidence. If the participant rates her confidence at a value of 10, the counselor helps her to think through how she might maintain that level of confidence throughout the study.

Example: *Now, let's do something similar with 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 use [the Ring or the pill] consistently? [Refer to images along the ruler to aid with comprehension as needed.]

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If the participant selects a 0-9 on this task:

- *What makes your confidence that number and not a 0 or 1?*
- *Why else is it a ___ and not a 0 or 1?*
- *What would help to move it up?*
- *How might you achieve that?*

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If the participant selects a 10 on this task:

- *What makes your confidence a 10 and not a 0 or a 1?*
- *Why else is it a 10 and not a 0 or a 1?*
- *What might you do to keep your confidence at a 10 over the coming weeks?*

12. What else? Explore participant's remaining questions

Goal: Provide the participant with an opportunity to discuss other issues that may affect her use of the assigned study product.

Approach: The counselor asks an open-ended question to invite discussion of additional issues. If the participant has a question, the counselor addresses it and, before moving on, ensures that the participant does not have any additional questions. If the participant does not have additional questions, the counselor asks a second open-ended question just to make sure.

Example: *We are coming to the end of today's session. What else would you like to discuss today about [the Ring or the pill] or your other HIV prevention approaches?*

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If the participant shares a question or concern: [Address the question and then proceed.]

- *What other questions or concerns do you have?*

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If the participant does not have a question or concern:

- *What questions or concerns do you have about everything we've discussed today?*

13. Wrap-Up

Goals:

- To affirm the participant for attending the session and openly discussing her concerns and experiences.
- To provide an overview of the upcoming counseling sessions.

Approach: First, the counselor affirms the participant for attending the session, working hard to develop a product use plan to help her prevent HIV infection, and for her openness in discussing her feelings and concerns about using her assigned product. The importance of having such open discussions in this study is highlighted. Then, the counselor provides a brief overview of the upcoming counseling sessions, just so the participant knows what to expect during these visits.

Example: *Well, we have come to the end of our session for today. Thank you so much for taking the time and effort to attend your appointment, and for all of 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 or the pill] – these discussions really help us to learn a lot about how women view [the Ring or the pill].*

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Remember that we will meet every time you come for a study visit. Next time we meet, we will have time to speak about how things went with implementing [the Ring or the pill] and your other HIV prevention approaches. If things go well, then we will talk about what you can do to keep doing so well. If you had some difficulties in using your HIV prevention approaches, then we can also talk about those challenges to help you figure out what you might want to do differently. Talking about these difficulties gives us an opportunity to develop a plan that works for you so you can achieve your goal of remaining HIV-negative.

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What final questions do you have before we end? [If so, address the question(s) and ask this again.]

Great, I will see you at your next study visit!

FIRST FOLLOW-UP VISIT

***If the participant has been assigned to use the Ring, you should utilize the Ring version of the flip chart when using this manual**

***If the participant has been assigned to use Oral Truvada (referred to as “the pill”), you should utilize the pill version of the flip chart when using this manual**

Follow-Up Visit Week 4

1. Provide overview of today's session

Goals:

- To orient the participant to what will occur during today's session.
- To normalize difficulties with implementing an HIV prevention approach, whether it's [the ring or the pill] or a different approach.

Approach: The counselor offers an overview of what will be discussed during today's counseling session, emphasizing that she'd like to hear how things went with the participant using their assigned study product since the last visit. The counselor expresses that she'd also like to hear about any challenges the participant encountered and is there to help her make any changes to her prevention plan that she deems necessary. To promote honest and open conversations, the counselor normalizes potential difficulties with product use.

Example: *Welcome back to your next Healthy Mothers counseling session! As always, I just want to give you a little information about our session together so you know what to expect. The focus of today's counseling will be for us to discuss how it went for you using [the Ring or the pill] and your other HIV prevention approaches since your last study visit. During these discussions, I'd like to hear what went well and what didn't go so well. My goal is to help you overcome any challenges that you encountered and help you to make any changes to your HIV prevention plan that you think are necessary. Lastly, I will give you an opportunity to ask any questions that you have about using [the Ring or the pill] so that you can leave today with all the information you need about your study product.*

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We know that for some women using [the Ring or the pill] and other HIV prevention approaches consistently 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 or the pill] and are able to implement their HIV prevention approaches consistently, as well as from those who are not, so being able to speak openly about your experiences is very helpful to us!

If things went well and you were able to implement your plan (use [the Ring or the pill] the way you wanted), then that is great and we can discuss how you might continue doing well. Similarly, if you had problems using [the Ring or the pill] or reducing your HIV risk the way you had hoped, then don't worry, I am not going to

judge you. If you would like, we can discuss ways of overcoming the difficulties that you had, and if you are interested I can even share with you how other women have overcome those obstacles in case you want to try some of their strategies and see how things go.

How does that sound?

What else would you like to discuss today so I can make sure to leave some time for that?

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

Goals:

- To explore how things went with the participant's HIV prevention plan, particularly [the Ring or the pill].
- To discuss challenges to adherence and how the participant did/did not overcome those challenges.
- To explore participant's experience with discussing [Ring or the pill] use with others.

Approach: The counselor begins the conversation by asking the participant to list the HIV prevention methods she had decided to use during the last visit (including [the Ring or the pill]). The counselor again highlights that behavior change can be difficult and then inquires about how things went for the participant using her approaches. Throughout, the counselor is empathic to the experiences of the participant, actively trying to understand any challenges she encountered and avoid judging the participant's difficulties. Finally, the counselor asks how things went for the participant in telling loved ones (who she wanted to know) that she was using [the Ring or the pill].

Example: *Now let's talk about how things went for you in using your HIV prevention approaches. First, can you remind me of the methods you had planned to use at your last visit? [Pause for the participant to share; be sure to reminder her if she does not mention the Ring or the pill.]*

24

Great, thank you for sharing that information. Keeping in mind how difficult it can be to implement new behaviors into one's life, how did it go for you in using [the Ring or the pill] and your other HIV prevention approaches since your last visit? I would like to hear about how each of your approaches 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.

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- *How did things go?*
- *What worked?*
- *What didn't?*
- *What obstacles did you encounter?*
 - *How did you overcome them?*

If the participant said there were people she wanted to tell about her product use during her last visit:

As part of your plan, you also mentioned during your last visit that you wanted to tell some people about your [Ring or the pill] use. Looking at the flipchart for reference, who had you planned on telling? [Pause for participant to share.]

25

- How did things go with these people?
- Who were you able to tell?
- Who were you not?
 - Why not? How might you go about telling them?
- What challenges did you experience?
 - How did you overcome them?

24

If the participant said she was not going to be telling anyone, still show the flipchart page and say something like...

I know that you were not planning on telling anyone about your [Ring or the pill] use. I was wondering, did you wind up speaking with anyone about it, even though you had not planned to do so? It is okay if you didn't, as I mentioned, it is totally your decision. I was just curious to see if it had happened and how it went.

3. Assess how participant is feeling about continuing product use

Goals:

- To assess how the participant feels about continuing to use [the Ring or the pill] and her other approaches.
- To open a discussion about ways of improving the participant's use of her current approaches and talk through any concerns she might have.

Approach: The counselor neutrally inquires about how the participant feels continuing to use [the Ring or the pill] and her other approaches. The key here is to be respectful of the participant's feelings and not judge her for any challenges she might be experiencing. To begin the discussion, the participant is shown a flip-chart page with 3 statements aimed at normalizing her feelings regarding continuing product use.

The counselor asks the participant which of the statements best reflect how she is feeling. After the participant responds, the counselor affirms her for her openness in sharing her feelings and then proceeds to the next flip-chart page, asking the follow-up questions that correspond to option the participant chose. These questions are geared at maintaining the participant’s motivation (when things went well) and helping her to think through what she might do differently (when things didn’t go so well).

Example: *I’d like to check-in with you and see how you’re feeling about continuing to use [the Ring or the pill] and your other HIV prevention methods. If you look at this flip-chart page, you’ll see three emojis, and each one is paired with a particular feeling: “No, I can’t continue,” “Hmmm... I am still stressed about it,” and “It’s good and I am ready to keep going.” Looking at these statements, which best reflects how you feel about continuing your product use?*

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25

If participant selects “No, I can’t continue”: *Thank you for your openness in sharing how you’re feeling about continuing to use your HIV prevention approaches. I know that sharing challenges can sometimes be very difficult, and I appreciate your honesty. Now...*

27

- *What concerns remain?*

26

If participant selects “Hmmm... I am still stressed about it”: *Thank you for your openness in sharing how you’re feeling about continuing to use your HIV prevention approaches. I know that sharing challenges can sometimes be very difficult, and I appreciate your honesty. Now...*

- *What would make you feel more comfortable continuing?*
- *What might you do differently in order to succeed?*
- *How can I be of help?*

If participant selects “It’s good and I am ready to keep going”: *Thank you for your openness in sharing how you’re feeling about continuing to use your HIV prevention approaches. It’s great that you’ve been doing well, and I’d love to hear more about that. Now...*

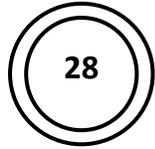
- *What helped you succeed?*
- *How will you continue using [the Ring or the pill]?*

4. Review plans for removing ring prior to labor (only for 042 RING participants)

Goal: To check in with the participant’s plan for removal of the ring prior to labor.

Approach: The counselor asks an open-ended question to prompt the participant to review her plan for removing the ring.

Example: Last time we met, we discussed your plans for removing the ring prior to labor and storing it in the bag we provided so you can return it to us at the following visit. Now that you have some experience with the Ring, how has that affected your plans for removing the Ring prior to giving birth?



5. Assess confidence in using assigned study product

Goal: Assess the level of confidence that the participant feels in her ability to implement her assigned study product.

Approach: A confidence ruler is used to assess level of confidence in this task. More important, however, are the follow-up questions, which evoke from the participant the reasons that she feels confident (self-empowered) to implement her assigned study product. Again, the counselor is curious about the participant's responses, asking for other reasons why she feels confident in her ability to implement her assigned study product into her life. If the participant rates her confidence at a value less than 10, the counselor helps her to think through how she might improve her confidence. If the participant rates her confidence at a value of 10, the counselor helps her to think through how she might maintain that level of confidence throughout the study.

Example: *Now that we've discussed how you're feeling, let's talk about how confident you feel in your ability to implement [the Ring or the pill] in your life over the coming weeks.*



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 use [the Ring or the pill] consistently? [Refer to images along the ruler to aid with comprehension as needed.]



If the participant selects a 0-9 on this task:

- *What makes your confidence that number and not a 0 or 1?*
- *Why else is it a ___ and not a 0 or 1?*
- *What would help to move it up?*
- *How might you achieve that?*

If the participant selects a 10 on this task:

- *What makes your confidence a 10 and not a 0 or a 1?*
- *Why else is it a 10 and not a 0 or a 1?*
- *What might you do to keep your confidence at a 10 over the coming weeks?*

6. What else? Explore participant's remaining questions

Goal: Provide the participant with an opportunity to discuss other issues that may affect her use of the assigned study product.

Approach: The counselor asks an open-ended question to invite discussion of additional issues. If the participant has a question, the counselor addresses it and, before moving on, ensures that the participant does not have any additional questions. If the participant does not have additional questions, the counselor asks a second open-ended question just to make sure.

Example: *We are coming to the end of today's session. What else would you like to discuss today about [the Ring or the pill] or your other HIV prevention approaches?*

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If the participant shares a question or concern: [Address the question and then proceed.]

- *What other questions or concerns do you have?*

28

If the participant does not have a question or concern:

- *What questions or concerns do you have about everything we've discussed today?*

7. Wrap-Up

Goals:

- To affirm the participant for attending the session and openly discussing her concerns and experiences.
- To provide an overview of the upcoming counseling sessions.

Approach: First, the counselor affirms the participant for attending the session and for her openness in discussing her feelings and concerns about using her assigned product. The importance of having such open discussions in this study is highlighted. Then, the counselor provides a brief overview of the upcoming counseling sessions, just so the participant knows what to expect during these visits.

Example: *Well, we have come to the end of our session for today. Thank you so much for taking the time and effort to attend your appointment. I really appreciate your openness in speaking about some of your concerns about [the Ring or the pill] – these discussions really help us to learn a lot about how women view [the Ring or The pill].*

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Remember that we will meet during each of your study visits during which you will be using [the Ring or the pill]. At our next session, we will again have time to speak about how things went with using [the Ring or the pill] and your other HIV prevention approaches. If things go well, then we will talk about what you can do to keep doing so well. If you had some difficulties in using your HIV prevention approaches, then we can also talk about those challenges to help you figure out what you might want to do differently. Talking about these difficulties gives us an opportunity to develop a plan that works for you so you can achieve your goal of remaining HIV-negative.

What final questions do you have before we end? [If so, address the question(s) and ask this again.]

Great, see you at your next visit!

APPENDIX

BRIEF OUTLINE FOR REMAINING FOLLOW-UP VISITS

COUNSELING SESSION OUTLINE

Follow-Up Visits

To decrease repetitive content in the adherence counseling sessions and minimize participant burden, the following Follow-Up Session Outline can be used beginning with the SECOND follow-up visit for MTN 042 and 043 (See Counseling schedule below for guidance on when to use the flipchart and when the Session Outline can be used). This outline is meant to help you streamline your counselling sessions by focusing on key goals and facilitating more natural, engaging conversations with participants.

Counseling Visit Schedule

MTN-042 Cohort 2		
Visit Type	Week Number	Counseling Guide
Enrollment	0	Flipchart
Follow-Up	2	Flipchart
Follow-Up	4	Outline
Follow-Up	6	Outline
Follow-Up	8	Outline
Follow-Up	10	Outline
Follow-Up	Until Delivery	Outline

MTN-043		
Visit Type	Week Number	Counseling Guide
Enrollment	0	Flipchart
Follow-Up	1	Flipchart
Follow-Up	2	Outline
Follow-Up	4	Outline
Follow-Up	8	Outline
Follow-Up	12	Outline

The outline is consistent with the flipchart but simplifies discussions. However, the goal remains a good exploration of how participants are experiencing product use, any obstacles faced, and figuring out solutions to any obstacles raised. As with the flipchart, the goal is still to engage in a supportive, non-judgmental conversation with participants, not just a question-answer interaction. The outline includes some key questions to get the conversations started. You can ask these questions as written or similar ones that explore the same issues. You can use some of your favorite questions from the flipchart and also use your counseling skills to ask follow-up questions as needed. Lastly, make sure you are using open-ended questions and reflections throughout the session and remember to affirm participants for achieving or taking steps to achieve their goals. Note: the flipchart should be used for follow-up visits with participants who have been experiencing adherence challenges.

COUNSELING SESSION OUTLINE

Follow-Up Visits

- Remember:*
- *Be curious about your participant's experience with product use and reasons for wanting to protect herself and her baby from HIV*
 - *Be as curious about what helped the participant succeed with her adherence and disclosure goals as you are about any obstacles she might have encountered.... exploring successes builds self-confidence!*
 - *Use open-ended questions and reflections throughout the session*

1. Welcome

- a. Remind participant that this is a safe opportunity to discuss challenges and successes to using the ring/pill and you are not here to judge her.

2. Explore how things are going with the pill/ring since last session.

- a. How are things going with using the pill/ring since we last met?
- b. What obstacles, if any, came up? How might I help you resolve it?
- c. [Required in Week 6; Optional other weeks] How have your conversations with others about using the pill/ring gone since we last met?

3. Explore overall feelings about continuing to use the pill/ring.

- a. How are you feeling about continuing to use the pill/ring?
 - i. If it is a positive feeling don't just accept a brief response such as "good", explore it, you want to evoke change talk "What makes you feel good (or whatever word they used) about using the pill/ring?"
 - ii. If the feeling is mixed or negative, ask something like "What would help you feel better about using the ring/pill?" "How might I help?"
- b. [Alternate question for later sessions] How has using the pill/ring been compared to what you were expecting at the beginning of the study?

[Note: if you think it would be helpful to increase motivation and confidence, you can always redo the importance and/or confidence rulers]

4. MTN-042 ONLY: [Required in Weeks 8, 10, 12] Establish or review plans for ring removal prior to delivery

- a. Week 8: Use flipchart pg. 28 to develop plan for ring removal.
- b. Week 10 and 12: What changes, if any, have you thought about making to your plans for the removal of the ring prior to delivery?

5. Close session.

- a. What other questions do you have for me today about your pill or ring use?
- b. Affirm participant for coming to session and open discussion of product use.
- c. We will meet again in two weeks to chat again about how things are going with the pill/ring.