Section 9. Counseling Considerations

9. Introduction

This section contains guidance on the following types of counseling provided in MTN-043:

- HIV pre- and post-test and risk reduction counseling (including anal sex counseling)
- Protocol adherence counseling, including study product adherence counseling
- Postpartum and Breastfeeding Health Education and Counseling
- Contraceptive counseling

Refer to protocol Appendix I for the schedule of required counseling procedures. All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, motivation, skills-building, and/or referrals. Participants should be collaborators in the counseling sessions, which should be treated as a time for study staff and participants to exchange information with one another. Participants' experiences and needs are likely to change over time, so it is important to create an environment where they feel comfortable and encouraged to share openly with study staff. The content and focus of counseling discussions should responsively change over time, so specific content to cover or skills to emphasize are not standardized for many of the counseling conversations that will take place. Rather, the *process* for these discussions is standardized to allow for appropriate tailoring and targeting to an individual participant's needs at a given point in time.

All counseling and referrals should be documented in participant study records per site SOPs. Proper documentation may be achieved through the use of counseling checklists/worksheets, and/or chart notes. Sample worksheets are available on the MTN website for HIV pre- and post-test and risk reduction counseling, product use adherence counseling, and contraceptive counseling. To support continuity in the ongoing client-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform subsequent counseling sessions. Sites are encouraged to use flags or alert notes in participant study charts to highlight issues requiring

follow-up at subsequent visits or issues that need to be addressed by study team members outside of the counseling sessions (e.g. referral for clinical issues). Additional documentation requirements and tips are included for each type of counseling described below.

9.1 HIV Pre- and Post-test Counseling and Risk Reduction

9.1.1 HIV Pre- and Post-Test Counseling

The schedule of maternal HIV testing and associated HIV pre- and post-test counseling is outlined in protocol appendix 1. Infant HIV testing is conducted upon confirmation of maternal HIV infection as well as 12 weeks later, and counseling about this testing should be provided to mothers and/or other legal guardians as required per local standards of care. Sites are required to develop and follow SOPs for HIV counseling and testing, which should include details about pre- and post-test counseling for both mothers and infants. All HIV pre- and post-test counseling should be provided in accordance with local counseling standards and study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithm in protocol Appendices III and IV. Client-centered approaches should be used to assess participant knowledge of relevant information, dispel misconceptions, ensure participant readiness for HIV testing, and confirm participant understanding of test results. Information should be provided in a manner that is respectful and interactive. Referrals should be provided when indicated.

At all mother visits when HIV testing is required, two rapid HIV tests will be conducted. Counseling messages following rapid HIV test results are provided in Table 9-1.

Table 9-1: Counseling Messages following Rapid HIV Test Results

Test Result	Counseling Message
Two negative Rapid tests	1. Test results indicate that you **are not infected** with HIV.
Two positive Rapid tests	1. Test results indicate that you **are infected** with HIV. If at screening or enrollment: 1. You are not eligible for MTN-043. **Note:** Additional post-test counseling and referrals should be provided. Confirmatory testing may be provided as a service, per site discretion, but is not required per protocol. If testing will not be done, skip the rest of these messages 2. If you choose, additional testing will be done today to confirm this result. 3. The testing will be done from a new blood sample and can be conducted today in our lab. 4. The additional testing is done to give you information about your health and is not part of the study. 5. It is unusual for the additional testing to show a different result. 6. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results. If during follow-up: 1. Additional testing will be done today to confirm this result. 2. The testing will be done from a new blood sample and can be conducted today in our lab. 3. It is common for HIV prevention studies to do additional testing for study purposes in this situation. 4. It is unusual for the additional testing to show a different result. 5. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and

	receive confirmatory results today, or schedule a separate visit for results.
One positive Rapid test, one negative Rapid test	1. Test results **are unclear**. If at screening or enrollment: 1. You are not eligible for MTN-043. **Note:** Additional post-test counseling and referrals should be provided. Confirmatory testing may be provided as a service, per site discretion, but is not required per protocol. If testing will not be done, skip the rest of these messages 2. Additional testing to determine your HIV status is recommended. 3. The testing will be done from a new blood sample and can be conducted today in our lab. 4. The additional testing is done to give you information about your health and is not part of the study. 5. The additional test will help to clarify your HIV status. 6. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results. If during follow-up: 1. Additional testing is necessary to determine your HIV status. 2. The testing will be done from a new blood sample and can be conducted today in our lab. 3. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results. (Note: If Geenius is negative following discordant rapids, per algorithm a viral load to rule out acute infection is necessary. In this case, site should provide additional information about test result timeframes). 4. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results. (Note: If Geenius is negative following discordant rapids, per algorithm a viral load to rule out acute infection is necessary. In this case, site should provide additional information about test result timeframes).

Depending on the results of the rapid HIV tests, Geenius confirmatory testing may be required. If Geenius confirmatory testing is going to be conducted, counselors should explain this testing, what it is for, and how it will be conducted when giving the rapid test results, as indicated in Table 12-1. Table 12-2 contains post-test counseling messages to provide to participants once the results of the Geenius confirmatory testing are known.

Table 9-2: Interpretation of HIV Tests Results Following Geenius Confirmatory Testing

Test Result	Status	Counseling Message
Two positive Rapid tests → Geenius positive	HIV-infected	1. Test results confirm that you **are infected** with HIV. 2. Your infant will also receive HIV testing as soon as possible (and no later than your next clinic visit). As long as the results remain negative, testing will be repeated in 4-6 weeks and again in 12 weeks. [If infant is confirmed infected at any of these testing points, see item #3 below]. 3. [Provide post-test counseling and referrals for HIV-infected participants as per site SOPs.]

Two positive Rapid tests → Geenius negative, HIV-1 indeterminate or other*	HIV status not clear	1. Although the HIV rapid tests we ran indicated that you are infected with HIV, the additional tests now indicate unclear results. 2. Further testing is needed to determine your HIV status. 3. The additional testing may show whether you are infected with HIV or not. No more blood needs to be taken at this time; we will use samples we have already collected. 4. You may need to give blood for testing at future visits for your status to be known. 5. We expect these additional results to be available [INSERT TIME FRAME – for Gene Xpert sites, probably 1-3 hours (with option for participant to wait at the clinic for results) and for non-Gene Xpert sites, up to 2 weeks].
One positive Rapid test, one negative Rapid test → Geenius negative, HIV-1 indeterminate or other*	HIV status not clear	1. Test results **are unclear**. 2. Further testing is needed to determine your HIV status. If at screening or enrollment: 1. [Sites to perform additional testing and associated counseling per local standards of care (as outlined in SOPs) and as directed by the LC.] If during follow-up: 1. The additional testing may show whether you are infected with HIV or not. No more blood needs to be taken at this time; we will use samples we have already collected. 2. You may need to give blood for testing at future visits for your status to be known. 3. We expect these additional results to be available [INSERT TIME FRAME – for Gene Xpert sites, probably 2-3 hours and for non-Gene Xpert sites, up to 2 weeks].
One positive Rapid test, one negative Rapid test → Geenius HIV-1 positive	HIV infected	1. Test results confirm you **are infected** with HIV. 2. Your infant will also receive HIV testing as soon as possible (and no later than your next clinic visit). As long as the results remain negative, testing will be repeated in 4-6 weeks and again in 12 weeks. [If infant is confirmed infected at any of these testing points, see item #3 below]. 3. 4. [Provide additional post-test counseling and referrals for HIV infected participants as per site SOPs.]

*Same counseling message for Geenius results of HIV-2 positive; HIV-2 indeterminate; HIV-2 positive with HIV-1 cross reactivity; HIV untypable

Additional results interpretations and counseling messages for the rare cases when a second Geenius test and HIV RNA viral load testing is required are provided in Table 9-3. These informational resources should be referenced as needed when providing pre-test and post-counseling.

Table 9-3: Interpretation of Additional HIV Tests Performed During Follow-up Per Protocol Appendix IV

Test Result	Status	Counseling Message
Additional Testing – Counseling Message Given at a future interim visit		
Geenius negative or HIV-1 indeterminate* → HIV-1 viral load negative (below limit of detection)	HIV-uninfected	1. Test results show that you **are not infected** with HIV.

Geenius negative or HIV-1 indeterminate* → HIV-1 viral load positive (above limit of detection)	HIV infected	1. Test results show that you **are infected** with HIV. 2. Additional testing is needed to confirm your HIV infection for study purposes. 3. [Provide post-test counseling and referrals or follow-up on referrals previously provided as per site SOPs.] 4. This additional testing will be done from a new blood sample**.** This testing will occur [provide date – testing should occur about 1 month after her positive rapid test(s), or when advised by the LC].* 5. It is common for HIV prevention studies to do additional testing in this situation. 6. It is unusual for the additional testing to show a different result. *Per protocol, infant testing will also take place if/when maternal HIV infection has been confirmed (positive Geenius test). Prior to this confirmation, sites may offer infant testing as part of standard of care treatment or in cases where there is clinical indication to do so.
Geenius HIV-1 positive→ HIV-1 viral load positive (at or above limit of detection)	HIV-infected	1. Test results show that you **are infected** with HIV. 2. Your infant will also receive HIV testing as soon as possible (and no later than your next clinic visit). As long as the results remain negative, testing will be repeated in 4-6 weeks and again in 12 weeks. [If infant is confirmed infected at any of these testing points, see item #3 below]. 3. 4. [Provide post-test counseling and referrals or follow-up on referrals previously provided as per site SOPs.]

*If Geenius results are HIV-2 positive; HIV-2 indeterminate; HIV-2 positive with HIV-1 cross reactivity; HIV untypable, HIV-1 viral load (Abbott M2000, Roche TaqMan or Gene Xpert) should not be performed. Please consult the MTN LC for guidance to confirm HIV-2 infection and for additional counseling messages, as needed.

Should you receive a result that is not outlined in one of the tables above, counsel the participant that her results are unclear and additional testing may be required. Contact the MTN Laboratory Center for guidance and additional counseling messages, as needed.

9.1.2 HIV Risk-Reduction Counseling

Like HIV pre- and post-test counseling, risk-reduction counseling is required at all visits when HIV testing will be conducted. This session may be incorporated into HIV pre- or post-test counseling, as specified in site SOPs, or may occur as a stand-alone session. Risk reduction counseling sessions should start with an assessment of recent risk behavior during which counselors should ask open-ended questions, actively listen to participant responses, and probe as needed for further information. As with all counseling sessions, efforts should be made to create a neutral and non-judgmental environment so the participant feels comfortable sharing her risk behaviors. Ideally, the counselor will guide the participant in self-identifying her risk factors, though if it seems that the participant is struggling with identifying experiences or behaviors that could potentially expose her to HIV, the counselor can help point out these risks. Counselors should make sure to emphasize that there is increased vulnerability to HIV acquisition during the postpartum period.

Once potential risks have been identified, the conversation should progress to a discussion of possible risk reduction strategies and, eventually, to the development of an individualized risk reduction plan. When exploring risk reduction strategies, the counselor should first ask what the participant's experience with risk reduction strategies has been prior to the current study visit. Counselors might want to ask what strategies the participant has tried, what worked or didn't work,

and what facilitators or barriers she encountered when trying to implement her risk reduction plan. Building off of this information, the counselor can then correct any misinformation and/or review additional HIV risk reduction strategies.

Consistent use of the study products may be part of a participant's risk reduction plan, but all participants should be encouraged to utilize other strategies for risk reduction as well. When discussing the study products, site staff should review with the participant the approximate amount of time that the study product takes to become effective after it is started. For example, it is estimated that it takes between 1-3 weeks for Truvada to reach high levels of protection in the body. When used every day, Truvada can provide greater than 90% protection from HIV risk. Protection from the Dapivirine ring is highest with regular and consistent use. The ring does not offer protection if it is not used at all. In previous studies, among women who appeared to use the ring most or all the time, HIV risk was reduced by at least half, and in some cases, by 75% or more. It is important for participants to know that if the ring is worn most of the time, but not in place at the time of exposure to HIV (for example, if it is taken out before sex), then they may not be protected.

The final step in the risk reduction counseling session should be to develop a risk reduction plan for the participant to use until her next study visit. Risk reduction plans should be participant-driven and responsive to the participant's unique HIV risks and life circumstances. Risk reduction plans should be practical, yet challenge the participant toward risk reduction. For participants whose risk reduction barriers are significant, risk reduction plans may need focus on very small, incremental, and achievable steps. When helping a participant develop her risk reduction plan, remember:

- Successful strategies should be continued;
- Additional strategies may be identified to achieve further risk reduction;
- Alternative strategies may be identified if current strategies are not feasible or being successful.

HIV counseling for partners should always be offered, either as an individual session or as a couple's session. Some suggestions on how to conduct a couple's counseling session are provided below.

Table 9-4 below provides some examples of risk reduction (RR) conversations which can be used at pre- or post-test HIV counseling after providing necessary information about the HIV-test.

Table 9-4: Examples of Risk Reduction Conversations

Key Points	INDIVIDUAL	COUPLES
Check in on recent experiences (previous RR plan)	Over the last month, what have your experiences around protecting your sexual health been? [How did things go with your RR plan from last visit?] Do you feel comfortable enough to tell me what kinds of sex you currently engage in? {inquire about vaginal sex and anal sex}	Over the last month, what has it been like for you both in terms of protecting each other's sexual health? [How did things go with the RR plan from last visit?] Do you feel comfortable enough to share with me the kinds of sex you engage in. {inquire about vaginal sex and anal sex}
Ask about prevention strategies	What are you doing now, or thinking of doing, to protect yourself sexually?	What are some of the things you are doing or thinking about doing to reduce your risks of getting HIV?
Provide permission	A lot of people find it difficult to use strategies to protect their sexual health in different kinds of situations.	A lot of couples find it difficult to use strategies to protect their sexual health in different kinds of situations.
Ask about situations, conditions, or factors that increase risk of HIV exposure	What are the situations, conditions or other things that make protecting yourself really hard to do?	What are the situations, conditions or other things that make protecting yourself or each other difficult to do?
Discuss continuing with strategies in place and/or	What would need to happen for your sexual health to be better protected? How can you see that happening?	I would like to ask each of you to share what you think would need to happen for your sexual health to be better protected.

adopting new strategies		
Identify plan	Summarize needs and strategies discussed. Ask participant if the strategy (strategies) identified (existing or new) is something she is willing to continue with or try before the next visit.	Summarize each partner's needs and suggestions. Work towards identifying one or more strategies noted that would offer a compromise (if needed) or a well-matched approach. Continue this process until an agreement to continue with or adopt a new approach is found. Encourage the couple to identify this; do not prescribe.
Build information, motivation, and skills around the strategy (strategies) as needed	Discuss strategy and provide skills building as needed.	Discuss strategy and provide skills building as needed.
Set a goal for next visit	Confirm plan.	Confirm plan.

9.1.2.1 Anal Intercourse Counseling as Part of Risk Reduction

The main way HIV is spread sexually is by **anal or vaginal sex without condoms** with an HIV-infected person (see table 9-3 below). As some MTN-043 participants may engage in anal sex, the following information about anal sex could be important to review with B-PROTECTED participants:

Definition of heterosexual anal sex:
Anal sex is when the man puts his penis into a woman's anus or rectum. This is different from having vaginal sex "from behind," where the penis is inserted into the vagina.

Many heterosexuals have tried anal sex and have it as a regular feature of their sexual activities. Regardless of whether or not counsellors are familiar with the practice, all discussions concerning anal sex should, like all topics, be approached in a neutral, non-judgmental way. If counselors anticipate being uncomfortable with conversations about anal sex, it is recommended they speak to their supervisor and/or other counselors.

Anal sex risk and risk reduction:
In terms of risk for HIV-infection, unprotected anal sex is riskier for women than unprotected vaginal sex. This has to do with the potential for damage to the rectum, allowing for greater opportunity for the passing of HIV through bodily fluids. Ways to manage risk with anal sex include using condoms, which is easier to do with the use of extra lubrication (using lubricants you can buy in a store).

Anal sex in the context of MTN-043:
The following facts may be useful when discussing anal sex with a participant:

- Anal sex is <u>not</u> exclusionary in MTN-043.
- Study products and anal sex:
  - The vaginal ring (VR) should ONLY be inserted vaginally. Truvada tablets should ONLY be swallowed orally.
  - It is not known if the VR, even if effective for vaginal sex, can protect from HIV transmission through anal sex. Because of this, we ask for open reporting of anal sex practices throughout the duration of the study. If the participant seroconverts, this will help the research team understand if this could have been due to practices that may not be protected through VR use.
  - The Truvada tablet has been shown to offer protection from HIV transmission through anal sex in non-pregnant women and in men.
- For all participants who report having anal sex, suggest strategies for risk reduction (e.g. condom use, reduction in number of partners, replacing some anal sex with less risky behaviors for anal sex) and support risk reduction strategies already in place.

Table 9-5 below outlines a range of sexual activities and their levels of risk for HIV and other STIs. The counselor can use the information in the table combined with HIV prevention options counseling manual and HIV prevention options factsheet to discuss risk reduction options, and the obstacles that may be associated with them, with the participant.

Table 9-5: HIV and STI Sexual Risk and Risk Reduction

Sexual Activity	Bodily Fluids Involved	Risk for HIV /STIs	Risk reduction options for women
Holding hands	None	None	These activities can be a viable alternative to higher risk behaviors.
Kissing	Saliva	None	
Masturbation	Vaginal fluid/semen	None	
Thigh sex	Vaginal fluid/semen	Low/negligible	
Mutual masturbation	Vaginal fluid/semen	Low/negligible	
Oral sex	Saliva/vaginal fluid/semen/blood	Condomless: Low (for HIV) to high (for some STIs) With Condom: Low	Use male condom; dental dams; abstinence; this can be a viable alternative to higher risk behaviors
Vaginal sex	Vaginal fluid/semen/blood	Condomless: High With Condom: Low	Use a condom; use dapivirine ring; get both partners tested and practice mutual monogamy; adopt alternative sexual behaviors; abstinence
Anal sex	Semen/blood	Condomless: Very High With Condom: Low	Use a condom; get both partners tested and practice mutual monogamy; adopt alternative sexual behaviors, abstinence

9.1.2.2 Modified Risk Reduction Counseling for HIV Positive Participants

Although HIV pre- and post-test counseling will be discontinued for participants who seroconvert during the study, risk reduction counseling should continue. Sessions should be tailored to focus on secondary prevention and, as applicable, prevention of vertical transmission during breastfeeding. Condoms should continue to be offered at all visits and counseling should include skills building on condom use and condom negotiation strategies.

Counseling should also include HIV/AIDS education, discussion of disclosure issues and emotional support, discussion of healthy living strategies, discussion of stressors and potential strategies to address these, and provision of referrals. For participants taking medications for opportunistic infection prophylaxis and/or taking antiretroviral therapy, counseling should include reinforcement of adherence support messages. At each counseling session, issues requiring follow-up from the prior session should be reviewed and updated, and plans should be made for actions to be taken between the current session and the next session.

In addition to the above, HIV counseling and testing should be offered for participants' partners and their infants. Counseling may be provided to partners individually and/or through couples counseling. Study sites are encouraged to provide counseling staff with training in both individual counseling and couples counseling.

At each visit after a referral is made, study staff should actively follow-up on the referral to determine whether the participant sought the services to which she was referred, determine the outcome of the referral, and determine whether additional referrals are needed. Additional counseling also may be needed to help ensure the participant receives services that may be beneficial to her and her baby. All follow-up actions, outcomes, counseling, and plans for next steps should be documented.

9.1.2.3 Documentation of HIV Pre-Test, Post-Test, and Risk Reduction Counseling

HIV pre-test, post-test, and risk reduction counseling should be fully documented in chart notes and/or other source documents as specified in site-specific SOPs for source documentation. Sites may choose to implement counseling checklists, worksheets, and other tools, as desired. At a minimum, documentation should include questions that arise during the counseling session, the participant's acknowledgement of testing readiness, confirmation that the participant understood the results that were presented to her, any referrals that may have been provided, and a summary of her risk reduction plan until the next visit. During study visits when both rapid tests and Geenius confirmatory testing are conducted, testing readiness and understanding of results must be documented for *each* test. Sample HIV counseling worksheets are available on the study implementation tools section of the MTN-043 website.

9.2 Protocol Adherence Counseling

The term "Protocol adherence counseling" as referenced in the protocol encompasses both protocol counseling and product use adherence counseling. Sections 9.2.1 and 9.2.2 explain these two components of protocol adherence counseling in more detail. Sites are strongly encouraged to have different staff cadres (or at a minimum, different individuals, even if part of the same cadre) provide product use adherence counseling and protocol counseling .

9.2.1 Protocol Counseling

Protocol counseling is required at mother study visits starting at enrollment through PUEV. The primary purpose of protocol counseling is to remind the participant about general study guidelines (i.e. do's and don'ts), the study schedule, and the importance of maintaining routine antenatal, postpartum, and well-baby care. The content of these messages varies depending on the visit type and components of protocol counseling at each visit are explained in detail on the MTN-042 Protocol Counseling Guide, which is available on the MTN-042 study website. The protocol counseling is didactic in nature, but staff members conducting the counseling should be sure to allow adequate time for participant questions. Completion of the protocol counseling should be documented on visit checklists and, if needed (e.g. if the participant raised any specific questions or concerns), in chart notes.

9.2.2 Product Use Adherence Counseling

A product use adherence counseling session will occur at Enrollment and all follow-up visits before the PUEV. Only counselors who are certified (see Section 9.2.1.4 for details on the certification process) may conduct the product use adherence counseling. While any certified counselor can conduct adherence counseling, site teams should be thoughtful about their pairing of counselors to participants. Sites are strongly encouraged to have participants see the same counselor at each study visit, if at all possible. Site teams might consider factors such as counselor age, sex, communication style, and participant requests when pairing counselors with participants. In addition, in order to promote an open and neutral environment, staff conducting the adherence counseling must be different than those who conduct other behavioral procedures during the visit (e.g. administration of MTN-043 behavioral questionnaires, qualitative interviews, other components of protocol adherence counseling, etc.). Ideally, a different cadre of staff should conduct the adherence counseling and behavioral assessments. Detailed guidance regarding the product use adherence counseling at enrollment and during follow-up is provided in the manual titled "Healthy Mothers: A Client-Centered Adherence Counseling Approach for the DELIVER (MTN-042) and B-PROTECTED (MTN-043) Studies" available on the B-PROTECTED website. A flipchart has also been developed for use during the product use adherence counseling session and is available online on the MTN-043 website. For participants on a product hold or permanent discontinuation, including those who seroconvert during the study, product use adherence counseling sessions should be discontinued.

9.2.2.1 Product Use Adherence Counseling at Enrollment

The purpose of the product use adherence counseling at enrollment is to orient the participant to the purpose and content of these sessions in B-PROTECTED, to discuss any concerns she may have

about her assigned study product, to develop a plan for study product use, to discuss other HIV prevention strategies (building upon the risk reduction counseling provided separately), and reinforce the importance of accurate reporting of adherence to study product use to the overall goals of the study. Just as important as the actual content of the session is the relationship building between counselor and participant and the establishment of the counseling sessions as a collaborative process that benefits both the participant and the study.

9.2.2.2 Follow-Up Product Use Adherence Counseling

After enrollment, product use adherence counseling will focus on the product use plans developed at the previous session, including an exploration of what worked well and what obstacles were encountered. The conversation should also include a discussion study participation and/or product use disclosure and how the participant is feeling about her continued study product use. Counselors should provide informational support, such as a review of the MTN-043 Vaginal Ring Use Instructions or the MTN-043 Truvada Use Instructions, as needed. During follow-up, it is recommended that adherence counseling occur after the administration of any behavioral assessments, but also that it be completed as early as possible in the visit. This will prevent fatigue and encourage more active participation in the counseling session. Sites may choose to conduct product use adherence counseling prior to completion of clinical/lab assessments to improve visit flow. Note that in this situation, some participants may receive counseling, but subsequently be put on product hold during the visit and not receive product.

9.2.2.3 Documentation of Product Use Adherence Counseling

Product use adherence counseling sessions should be documented in chart notes and/or other source documents as specified in site-specific SOPs for source documentation. Ideally, documentation of the counseling discussion would take place *after* closing the session. If needed, staff can take brief notes during the counseling session, but should always show the participant what they are writing. Counseling notes do NOT need to summarize the procedural aspects of the counseling approach, which are the same across participants, since signing off on product use adherence counseling sessions on visit checklists is an indication that these procedures were done in accordance with protocol and SSP requirements. Counseling notes should instead focus on the unique aspects of each conversation and should include sufficient information and detail to inform and guide the participant's next counseling session.

Sites may choose to implement counseling checklists, worksheets, and other tools, as desired. An example of a product use adherence counseling worksheet is available for download on the MTN-043 website.

9.2.2.4 Quality Assurance and Mentorship for Study Product Adherence Counselors

To ensure fidelity to the counseling approach in B-PROTECTED, each staff member who will be responsible for conducting study product adherence counseling in MTN-043 will be required to become certified prior to seeing study participants. This will be accomplished through the conduct of mock counseling sessions in English with a peer on site. To become certified, each counselor must complete two mock sessions that meet or exceed pre-established fidelity criteria, as defined and evaluated by the Behavioral Research Team at the HIV Center for Clinical and Behavioral Studies at Columbia University. At least one counselor must be certified prior to site activation for B-PROTECTED.

Once certified, counselors may begin seeing participants at their B-PROTECTED study visits. Ongoing fidelity monitoring will take place throughout the trial by a systematic review of audio-recorded counseling sessions. All participants will be informed of audio recording as part of the informed consent process for screening and enrollment and all study product adherence counselling sessions will be digitally recorded, unless the participant specifically declines this procedure. After each interview, audio files will be uploaded to SCHARP's Atlas website. Additional details regarding how to record and upload counseling sessions can be found in the counseling manual, "Healthy Mothers: A Client-Centered Adherence Counseling Approach for the DELIVER (MTN-042) and B-PROTECTED (MTN-043) Studies" available on the B-PROTECTED website. Columbia's behavioral researchers will create a small team of staff to listen to and rate sessions in each of the B-PROTECTED study languages. Once counselors begin seeing study participants, their first 3

Enrollment Visits and first 3 Follow-up Visits will be reviewed. Subsequently, one in 10 sessions will be reviewed and rated. Completed rating forms will be sent to the counselor who completed the session.

Using information gleaned from the counseling recordings, the Columbia team will convene monthly coaching calls in order to provide mentorship to the counselors at each site. Coaching calls may contain counselors from multiple sites and will involve feedback from the session ratings, discussion of challenges in delivering the counseling, and live review of recorded counseling sessions. Coaching calls that include review of non-English language sessions may also include the staff member at Columbia who rates the sessions in that language. These calls are not intended to be punitive in nature, but rather are designed to build capacity of counseling staff and improve the quality of the counseling at site. Mobile messaging apps (e.g. Slack) may also be used to facilitate peer-to-peer communication and communication between counselors and the Columbia team between coaching calls.

9.3 Postpartum and Breastfeeding Health Education and Counseling

Although not required study procedures, postpartum and breastfeeding health education and counseling should be incorporated into MTN-043, as site staff deem appropriate. Because study visits will not take the place of regular postpartum or infant care, study staff should ensure that participants are adequately linked to care providers in the community who can provide these services. Sites should familiarize themselves with the local care providers in their area in order to make any referrals that may be necessary.

When preparing for study implementation, site staff should consider if there are important topics related to postpartum or infant care or breastfeeding that could be discussed during the counseling and clinical portions of the visit or incorporated as topics during waiting room education or group engagement events. A list of sample topics is provided below:

- Postpartum:
    - Family planning needs/options
    - Postpartum mental health
    - Infant care, including nutrition, safe sleep, well-baby visits, and vaccinations
    - Continued breastfeeding information and support

Site staff should make use of any educational resources available from ministries of health, the World Health Organization, or other organizations that might have materials related to these or other identified topics. Suggested resources are available at the following links:

- https://health-orb.org/ (multimedia materials from multiple organizations, with a focus on maternal and child health)
- https://www.who.int/maternal-health/en/ (World Health Organization maternal health information, guidance documents, and infographics)
- https://www.who.int/topics/breastfeeding/en/ (World Health Organization breastfeeding information, guidance documents, and infographics)

9. 4 Product Use Instructions

9.4.1 Participant Instructions for Ring Insertion and Removal

If the mother participant has been randomized to use vaginal ring, she should receive detailed instructions regarding vaginal ring insertion and removal prior to inserting the ring for the first time. Staff should utilize the 3-page MTN-043 Vaginal Ring Use Instructions sheet, which is available on the MTN-043 website. Note that the 'Important Information' side of this guide highlights key information for correct ring use, and should be supplemented with additional information provided verbally to participants as needed. For example, additional rationale for the 'avoid' message may be provided to encourage healthy vaginal practices. Study staff can explain that douching, vaginal devices, and other vaginal practices that involve using detergents and soaps inside the vagina are discouraged because they may have a negative impact on vaginal health and effect sample collection. Staff are

encouraged to reference other study resources such as study factsheets for help with addressing participant questions.

The MTN-043 Vaginal Ring Use Instructions sheet should also be translated into local languages and approved by local IRBs so that it may be provided to participants to take home, if desired. While reviewing these instructions with participants, staff should also use visual aids and pelvic models (if available) to help explain ring insertion and removal.

Participant Instructions for Ring Insertion: Review steps 1-7 on Vaginal Ring Use Instructions sheet.

Participant Instructions for Ring Removal (provide verbally to participants):

If you need to exchange your ring for a new one during study follow-up, or have the need to remove your ring for any reason, you can do this yourself. Typically, ring removal will occur in the clinic at your scheduled study visits. If you need help, clinic staff can assist you.

1. Before removing the ring, wash and dry your hands.
2. Choose a comfortable position (can reference ring insertion instructions for illustrations of different positions).
3. Put a finger into your vagina and hook it through the ring.
4. Gently pull down and forward to remove the ring.
5. If you will be reinserting the ring, follow the ring insertion instructions, and wash your hands when you are done. If you will not be reinserting the ring, continue to steps 6-9.
6. Place the used ring in the bag provided by clinic staff.
7. Wash your hands.
8. Place the bag with the used ring inside in a safe and private area out of reach of children or other occupants of the home.
9. Bring any used ring (in its bag) with you to the clinic during your next study visit.

9.4.2 First Ring Use

After providing product insertion instructions and answering any questions the participant may have, study staff will ask the participant if she is ready to try inserting the VR herself. Staff should be sensitive to the fact that women may not feel comfortable inserting the ring themselves or may find the task physically challenging. In these cases, a study clinician/designee should offer to assist. The Ring Assessment CRF collects information about whether the participant attempted to insert the ring herself, but additional details about the participant's first product use experience and preferences regarding self- or clinician-assisted ring insertion should be documented in chart notes. Any issues or problems raised by the participant should be addressed by the study staff and documented in the participant chart so the information is easily available for reference at study follow-up visits.

A digit exam to check ring placement is required at first product use; this check is only done if indicated for subsequent vaginal rings (e.g. the participant expresses discomfort after inserting the ring and wants reassurance that it has been placed correctly).

The following is the procedure that should be used to verify ring placement:

1. After ring placement, the participant should walk around prior to verification of correct ring placement.
2. The participant should then lie comfortably on the examination couch in supine position (on her back).
3. Upon genital inspection, the ring must not be visible on the external genitalia. If the ring is visible, the placement is not correct.
4. The ring should not press on the urethra.
5. On digital examination, the ring must be placed at least 2cm above the introitus beyond the Levator Ani muscle.
6. If, on inspection, the ring is found to be inserted correctly, the ring should be removed and reinserted correctly by the participant or the study clinician.

After correct placement is confirmed, staff may ask the participant if she would like to feel the position of her ring. This will help ensure that she understands what correct placement feels like, should she need to check this between study visits. This instruction may be repeated at any visit, as needed.

9.4.3 Participant Instructions for Tablet Use

If the mother participant has been randomized to use Truvada tablets, she should receive detailed instructions regarding how to take Truvada before using it for the first time. Staff should utilize the three-page MTN-043 Truvada Use Instructions sheet, which is available on the MTN-043 website. Note that the 'Important Information' side of this guide highlights key information for correct Truvada use, and should be supplemented with additional information provided verbally to participants as needed (see SSP Section 9.4.1 for examples). Staff are encouraged to reference other study resources such as study factsheets for help with addressing participant questions.

The MTN-043 Truvada Use Instructions sheet should also be translated into local languages and approved by local IRBs so that it may be provided to participants to take home, if desired. While reviewing these instructions with participants, staff should also use visual aids and discuss tips for taking oral Truvada, as needed.

9.4.4 First Truvada Use

After providing product use instructions and answering any questions the participant may have, study staff will ask the participant if she is ready to try taking her first Truvada pill. Per Protocol Section 6.2.2, participants should take their first Truvada dose at the clinic under direct observation. The Tablet Assessment CRF collects information about whether the participant attempted to swallow the pill herself and how easy or difficult she found it, but additional details about the participant's first product use experience should be documented in chart notes. Any issues or problems raised by the participant should be addressed by the study staff and documented in the participant chart so the information is easily available for reference at study follow-up visits. If the participant experienced challenges taking her first pill, review the "Easy Methods for Taking Large Pills" information on the third page of the MTN-043 Truvada Use Instructions sheet.

9.5 Contraceptive Counseling

Contraceptive counseling is required at all study visits with the exception of study weeks 1 and 2.. All contraceptive counseling should be provided in accordance with local counseling standards, site-specific SOPs, and World Health Organization (WHO) guidance, which is available in the following resources:

- Medical Eligibility Criteria for Contraceptive Use (5th Edition, 2015): http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/
- Family Planning: A Global Handbook for Providers (WHO/USAID/Johns Hopkins Bloomberg School of Public Health, 2011): http://www.who.int/reproductivehealth/publications/family_planning/9780978856304/en/

All contraceptive counseling should be provided in a client-centered manner and should guide and support each participant in making the best contraceptive method choice for her. Site staff should provide comprehensive information on available contraceptive methods to study participants, including how each method is taken or administered, mechanism of action, potential side effects, level of effectiveness, and local availability. Counselors should familiarize themselves with local standards of care and scientific evidence around initiating family planning methods during the postpartum period and should be knowledgeable about the potential impacts of contraception on breastfeeding continuation and exclusivity, as well as milk supply (see link to the WHO's Medical Eligibility Criteria for Contraceptive Use above). Extra care should be taken during counseling sessions with participants who have never been on a contraceptive method before or who will be initiating a new method postpartum to make sure information shared is thorough and well understood. All participants, including those who choose to initiate another form of contraception, should also be encouraged to use male and/or female condoms, which will be offered at every visit.

At the screening visit, the staff member providing contraceptive counseling should first establish whether the participant has initiated the use of a postpartum contraceptive method. If so, the

counselor should review any participant problems or questions about the method, help the participant identify potential strategies to address these, and once again emphasize the importance of dual protection through the use of male or female condoms. If the participant has not initiated a contraceptive method, the counselor should review options and help the participant make a decision regarding which family planning method is best for her. Note that use of an effective contraceptive method as defined in the study protocol is required for study participation..

All sites should offer emergency contraception to study participants when applicable. The term emergency contraception refers to back-up methods for contraceptive emergencies which can be used within the first few days after unprotected intercourse to prevent unwanted pregnancy. The WHO-recommends two methods of emergency contraception: emergency contraceptive pills and copper bearing IUDs. Please see the WHO Fact Sheet re-printed at https://www.who.int/news-room/fact-sheets/detail/emergency-contraception for more information on emergency contraception. Site staff are encouraged to incorporate information about emergency contraception into the contraceptive counseling sessions, as needed, in B-PROTECTED to increase participant understanding of how emergency contraception works and its availability at the clinical research site.

9.5.1 Documenting Contraceptive Counseling Sessions

Contraceptive counseling sessions should be fully documented in chart notes and/or other source documents as specified in site-specific SOPs for source documentation. Sites may choose to implement counseling checklists, worksheets, and other tools, as desired. An example of a contraceptive counseling worksheet is available for download on the MTN-043 website.