

## Section 12 - Counseling Considerations

---

This section contains guidance on the following types of counseling provided in MTN-014:

- HIV counseling
- HIV/STI risk reduction counseling
- Contraceptive Counseling
- Study product adherence counseling
- Protocol adherence counseling
- Biopsy procedural counseling

All counseling should be provided in a non-judgmental participant-centered manner that responds to current participant needs for information, education, support, skills-building, and/or referrals. Participants' needs are likely to change over time; thus the content and focus of counseling discussions should also responsively change over time. Because of this, specific content to cover or skills to emphasize are not standardized. 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 should be documented in participant study records. Proper documentation may be achieved through the use of counseling checklists, worksheets, and other tools, and/or chart notes. 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.

### 12.1 HIV Counseling

HIV testing is required at Screening, Enrollment/Initiate Period 1 (Visit 2), Initiate Period 2 (Visit 18), and Period 2 End (Visit 32) visits. Therefore, HIV pre-test and post-test counseling is required at each of the above-listed visits when HIV testing is required and at those times when HIV testing is clinically indicated (e.g. Period 1 End (Visit 16) and the Washout visit (Visit 17)).

All HIV counseling should be provided in accordance with local counseling standards. Study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithms in protocol Appendix II. Information on interpretation of test results is provided in Table 12-1. These informational resources should be referenced as needed when providing pre-test and post-test counseling.

When providing pre-test and post-test counseling, participant-centered approaches should be used to assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results.

**Table 12-1  
Interpretation of HIV Test Results Per Protocol Appendix II**

<b>Test Result</b>	<b>Interpretation</b>
Both rapid tests/EIA negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Both rapid tests/EIA positive	HIV-infected; test results indicate that you are infected with HIV. During follow-up additional protocol-specified testing is required to confirm results.
Discordant rapid tests (one negative, one positive) or EIA Indeterminate	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status. (Please note, for screening participants, a participant is not eligible if results are discordant.)
Western blot positive	HIV-infected; test results indicate that you are infected with HIV.
Western blot negative or indeterminate	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status. Consult the NL.

Counselors should provide and explain test results in a private setting per site SOPs. Counselors should assess participant understanding of results and provide clarification and further information as necessary. Regardless of status, continued risk-reduction should be emphasized.

## **12.2 HIV/STI Risk Reduction Counseling**

HIV/STI risk reduction counseling is required per protocol at Visits 1, 2, 16, 17, 18, and 32. The site is required to develop and follow SOPs for HIV pre- and post-test counseling as well as HIV risk reduction counseling. Participant-centered approaches should be used when assessing participant risk for HIV infection and providing risk reduction counseling. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address reported risk factors and barriers.

Risk reduction plans, identified by the participant, should reflect and respond to her current risk assessment and should be practical, yet challenge the participant toward further risk reduction. For participants whose risk reduction barriers are significant, risk reduction plans may need to be incremental. For participants whose risk reduction barriers change over time (e.g., due to a partner change), risk reduction plans may need to change over time. Importantly, all risk reduction plans should be agreed upon by the participant and should be documented in the participant's study records, with a copy made available to the participant if she wishes.

A sample HIV Counseling Worksheet is available for use and is posted on the MTN-014 Study Implementation webpage. This worksheet provides a guide to the minimum requirements for HIV and risk reduction counseling sessions; this worksheet may be tailored for use at the study site. It incorporates a structure that counselors may find helpful for documenting current risk factors and barriers, experiences with risk reduction since the last session, and risk reduction plans until the next session.

At each counseling session, the risk factors, and risk reduction plans identified at the previous sessions should be reviewed and discussed with the participant to determine:

- What was her experience since last session?
- How did the strategies in the risk reduction plan from last visit work or not work for her?

Risk reduction plans the participant identified and agreed upon at the current session should then build on experience since the last session:

- Successful strategies should be continued;
- Additional strategies may be identified to achieve further risk reduction;
- Alternative strategies may be identified if strategies tried since the last session were not successful

Risk reduction counseling sessions should also offer skills building to the participant when indicated, e.g., on how to use condoms, how to discuss sensitive issues with partners and other influential persons. HIV counseling for partners should always be offered, either as an individual session or as a couple's session.

Referrals are expected components of risk reduction plans when indicated based on participant needs. When referrals are provided, these should be fully documented in participant study records and should be actively followed up at subsequent counseling sessions to determine whether the participant sought the services to which she was referred, what the outcome of the referral was, and whether additional referrals are needed. All such follow-up should also be fully documented in participant study records.

### **12.3 Contraception Counseling**

Contraceptive counseling is required at Screening and at all other scheduled study visits if indicated. All contraceptive counseling should be provided in accordance with local/state counseling standards, and site-specific SOP.

To be eligible for MTN-014, potential participants must report use of an effective method of contraception at enrollment and intend to use an effective method for the duration of study participation. Per protocol, these include birth control pills, continuous combination oral contraceptive pills or another hormonal-based method (except for vaginal rings), or an intrauterine device (IUD), unless they are sterilized or identify as a woman who has sex with women exclusively; and/or have been sexually-abstinent for more than 90 days and intend to remain abstinent for duration of the study. For those participants who report sterilization, study staff must verify the sterilization per site SOPs; the site is strongly encouraged to obtain credible medical records as part of their verification procedures. Study staff who provide contraceptive counseling should be trained to do so per local practice standards and should also be trained on MTN-014 protocol specifications related to contraception.

The site 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. Emergency contraception prevents pregnancy but cannot cause abortion. For further information on the WHO-factsheet (dated June 2012) recommended regimen for emergency contraception, review (<http://www.who.int/mediacentre/factsheets/fs244/en/index.html>).

All contraception 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 and in maintaining adherence to an effective method. When providing information on various contraceptive methods to study participants, in addition to standard information on how each method is taken or administered, mechanism of action, and level of effectiveness, information on the potential advantages and disadvantages of each method should be provided in the context of daily product use.

At Screening, contraception counseling should be provided in the context of the study eligibility criteria related to pregnancy intentions and willingness to use an effective contraceptive method. Counseling provided at these visits should therefore explain which methods are acceptable for study purposes and emphasize that women who cannot commit to use of these methods for the duration of the study should not enroll in the study (this is part of their contraceptive choice).

During follow-up visits, if indicated, client-centered counseling should continue. Issues discussed at the previous counseling session should be reviewed and discussed with the participant as needed and the counselor should determine whether the participant has any current issues, questions, problems, or concerns with her current contraceptive method. For participants with no issues or problems, counseling sessions during follow-up may be brief but should always provide clear method use instructions and always reinforce key adherence messages. For participants with issues or problems with their current method, counseling sessions during follow-up may require more time. In some cases, only counseling and reassurance may be required to address the issues or problems.

All contraception counseling sessions should be fully documented in participant study records. For each session, sufficient information and detail should be recorded to support review and appropriate follow-up at each subsequent visit. A sample of a contraception counseling worksheet is provided on the MTN-014 Study Implementation webpage.

## **12.4 Study Product Adherence Counseling**

Product adherence counseling will be conducted based on client-centered strategies in order to reinforce the value of accurate reporting of adherence to study product use. Although most participants will insert their daily product under direct observation of study staff, some participants may insert the gel at home by themselves, if they are unable to attend a clinic visit. Study product adherence counseling is required at the Initiate Period 1 (Visit 2) and Initiate Period 2 (Visit 18) visits (unless the participant is on a product hold or permanent discontinuation in which case the session conducted at the Period 2 Initiation visit should be tailored to discussions of retention only).

Product adherence counseling should focus on providing the 7 key messages (see Appendix 12-1) and an assessment of any participant concerns regarding product use. Additionally, as the ability to come to the clinic for scheduled visits is directly related to product use, these counseling sessions should also include a check-in about facilitating attendance to study visits.

Each counseling session should be fully documented on the Product Adherence Counseling Worksheet, which is available on the MTN-014 Study Implementation webpage, and in Appendix 12-1.

### **12.4.1 Product Use Instructions**

Participants will be provided product use instructions counseling at the Initiate Period 1 (Visit 2) and Initiate Period 2 (Visit 18) visits.

Participants will be counseled that detailed instructions on product use for each regimen will be provided at each Initiate Period Visit, when a new regimen will start. In addition to verbal instructions, visual aids, such as sample applicators could be used as needed when providing instructions to help ensure participant understanding of proper product use. Adequate time should be taken to thoroughly explain the product use instructions and answer any questions the participant may have. Any questions or concerns raised by the participant should be documented in her study records so this information is easily available for reference at follow-up visits. Further information on product use instructions is available in Section 7 of this manual; product use instruction diagrams are available on the MTN-014 Study Implementation webpage.

## **12.5 Protocol Adherence Counseling**

Protocol adherence counseling is required at Visits 2, 16, 17, and 18. As safety is of the utmost importance, site staff will counsel participants to refrain from using prohibited medications and engaging in certain practices during the course of study participation.

Per protocol section 6.7, participants should be counseled to avoid the following practices:

- Use of non-study vaginal or rectal products during product use periods
- Use of non-study vaginal or rectal products 24 hours prior to Period Initiation and Period End visits (Visits 2, 16, 18, 32).

Non-study vaginal or rectal products include the following:

- Spermicides
- Female condoms
- Diaphragms
- Contraceptive vaginal rings
- Vaginal medications
- Menstrual cups
- Cervical caps
- Vaginal/rectal douches
- Enemas (non-study provided)
- Non-study approved lubricants
- Sex toys
- Tampons

If a participant reports a prohibited practice as, as listed above and in protocol section 6.7, the continuation of the study visit procedures will be performed at IoR discretion. Counseling and discussion of any issues related to protocol adherence may be documented on the Protocol Adherence Worksheet, located on the MTN-014 Study Implementation webpage and in Appendix 12-2. Additionally, documentation of prohibited practices or products should be documented on the Vaginal and Rectal Practices CRF.

## **12.6 Biopsy Procedural Counseling**

Prior to biopsy collection, biopsy procedural counseling will be conducted that includes the following information:

- Abstain from using NSAIDs, aspirin and/or other drugs that are associated with the increased likelihood of bleeding for 72 hours prior to and following biopsy collection

- Abstain from inserting any non-study products in the vagina or rectum for 72 hours prior to and following the collection of biopsies
- Abstain from sexual activity for 72 hours after the collection of samples
- If heterosexually active, reminder to use male condoms with each sex act, as biopsy participants are at increased risk of HIV/STI transmission following biopsy collection

Note, if a participant reports use of a NSAID, aspirin and/or other drug associated with increased bleeding prior to biopsy collection, samples may still be collected per IoR discretion. Participants should be counseled regarding potential risks of biopsy collection and documentation of this counseling and added risk should be included in the participant binder. Each counseling session should be fully documented on the Biopsy Procedure Counseling Worksheet, which is available on the MTN-014 Study Implementation webpage and in Appendix 12-3.

**Appendix 12-1**  
**Product Adherence Counseling Worksheet**

**Period Initiation Visits (Visit 2 and 18)**  
**Product Adherence Counseling Worksheet**

**PTID:** \_\_\_\_\_ **Visit Date:** \_\_\_\_\_ **Visit Code:** \_\_\_\_\_

**Discuss key adherence messages and use instructions to the participant**

- Return to the clinic to insert one applicator into the (vagina or rectum) every day
  - at approximately the same time every day
  - if you are unable to come to the clinic, contact clinic staff and insert gel at home using one of your extra gel doses
  
- It is important not to miss any doses
  - If you miss a dose, apply the missed dose as soon as possible. If the next dose is due within 6 hours, the missed dose will be skipped and the next dose will be administered as originally scheduled.
  
- Keep your product supplies in your possession
  - Do not remove labels from the applicator overwrap
  
- Keep product supplies in secure, dry place
  - Store at room temperature, out of the sun
  - Keep the gel out of reach of children
  
- Do not share your product and do not use other participant's product
  
- Return all remaining unused applicators to the study staff at the end of each period
  
- Provide instructions to contact study staff:
  - For any questions or if she needs more product between visits
  - Any problems inserting gel, keeping gel for her use only or any other problems (such as partner or family issues)

**Discuss and assess expectations or concerns about adherence to product use**

*Does she anticipate having any difficulties? Does she have any concerns about using gel at home?*

---

---

---

---

---

---

---

**Appendix 12-2**  
**Protocol Adherence Counseling Worksheet**

**Protocol Adherence Counseling Checklist**

**Required at Visits 2, 16, 17, and 18**

**PTID:**

**Visit Date:**

**Visit Code:**

**Provide guidance on prohibited practices, products or medications**

- Refrain from using non-study vaginal or rectal products during product use periods
- Refrain from using non-study vaginal or rectal products 24 hours prior to Period Initiation and Period End Visits

Abstain from using the following products:

- Spermicides
- Female condoms
- Diaphragms
- Contraceptive vaginal rings
- Vaginal medications
- Menstrual cups
- Cervical caps
- Vaginal and/or rectal douches or enemas
- Non-study approved lubricants
- Sex toys
- Tampons

**Discuss and assess expectations or concerns about protocol adherence**

---

---

---

---

---

---

---

---

---

---



**Appendix 12-3**  
**Biopsy Procedural Counseling Worksheet**

**Biopsy Procedural Counseling Checklist**  
**Required at Screening, Visit 16 and Visit 32**

**PTID:**

**Visit Date:**

**Visit Code:**

**Provide guidance on biopsy procedure requirements**

- Refrain from NSAIDs, aspirin and/or other drugs that are associated with the increased likelihood of bleeding for 72 hours prior to and following biopsy collection
- Abstain from inserting any non-study product in the vagina or rectum, including abstaining from sexual activity, for 72 hours prior to and after the collection of biopsies
- If heterosexually active, remember to use male condoms with each sex act, as biopsy participants are at increased risk of HIV/STI transmission following biopsy collection

**Discuss and assess concerns about biopsy procedure and prohibited practices:**

---

---

---

---

---

---

---

---

---

---