

Section 10 – Counseling Considerations

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This section contains guidance on the following types of counseling provided in MTN-026:

- HIV Pre- /Post-Test Counseling
- HIV/STI Risk Reduction Counseling
- Contraceptive Counseling
- Study Product Adherence and Product Use Instructions Counseling
- Protocol Adherence Counseling
- Biopsy procedural counseling
- Rectal Biopsy/Fluid 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; counseling provided should also change over time accordingly. 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, as well as counselors chart notes. To support ongoing participant-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform and guide the participant's next counseling session. During counseling, a worksheet or site-specific tool may be used to guide any of the counseling sessions. During the session, counselors should engage in the discussion rather than focusing on taking notes. A summary of the counseling session should be written once the session is completed.

10.1 HIV Pre- /Post-Test Counseling

HIV testing is required at Screening, Enrollment, Visits 7 and 16. HIV pre-test and post-test counseling is required at each visit in which HIV testing is performed. The sample HIV/STI Risk Reduction Counseling Worksheet available on the MTN website provides a guide to the minimum requirements for MTN-026 HIV and risk reduction counseling sessions; this worksheet may be tailored for use at all study sites.

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 also be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithm in protocol Appendix II.

Information on interpretation of screening, enrollment, and follow-up test results is provided in Table 10-1 which can be referenced as needed 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. 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.

Table 10-1
Interpretation of HIV Test Results Per Protocol Appendix II

Test Result	Interpretation
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.)
Confirmatory test positive	HIV-infected; test results indicate that you are infected with HIV.
Confirmatory test 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 MTN LC.

10.2 HIV/STI Risk Reduction Counseling

Risk reduction counseling is required per protocol at Screening, Enrollment, Visits 7 and 16. Site are required to develop and follow SOP(s) 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 and STI 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 his/her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

Supported and facilitated by the counselor, the risk reduction plans identified by the participant should reflect and respond to his/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 he/she wishes.

The sample HIV/STI Risk Reduction Counseling Worksheet posted on the MTN website (<http://www.mtnstopshiv.org/node/6908>) 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 the participant's experience since the last session?
- Was the participant able to carry out strategies and plans?

- What were the outcomes?

Risk reduction plans identified and agreed upon with the participant 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/STI risk reduction 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 s/he 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 and/or on applicable counseling worksheets.

10.3 Contraceptive Counseling

Contraceptive counseling should be provided at Screening and Enrollment visits, and at other study visits if indicated. Study staff who provide contraceptive counseling should be trained to do so per local practice standards and should also be trained on MTN-026 protocol specifications related to contraception. Contraception may be provided on site or sites may opt to refer participants to non-study providers for contraception.

To be eligible for the study, potential female participants must report use of an effective method of contraception for at least 30 days prior to enrollment and intend to use an effective method for the duration of study participation. Per protocol, effective method of contraception include: hormonal methods (except contraceptive ring), intrauterine device (IUD), sterilization (of participant and/or partner, as defined in site SOPs), or sexually abstinent for 90 days prior to Screening.

Note: For those participants who report sterilization, study staff must verify the sterilization per site eligibility SOPs; the site is encouraged to obtain medical records as part of their verification procedures.

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. When providing information on various contraceptive methods to study participants, standard information should include how each method is taken or administered, mechanism of action, potential side effects, and level of effectiveness.

At Screening and Enrollment, 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). Participants must have no intention to become pregnant within the approximate two months following screening or enrollment.

During follow-up, contraceptive counseling should be offered if indicated. 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 and supportive. For participants with issues or problems with their current method, counseling sessions during follow-up include discussion of the specific problems encountered and identify potential strategies to address these, which may include switching methods.

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 (dated July 2012) for more information on emergency contraception: <http://www.who.int/mediacentre/factsheets/fs244/en/>.

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-026 Study Implementation webpage.

10.4 Product Use Instructions

Participants will be provided product use instructions counseling at Visit 3 and during Visits 7-13 as needed. 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 his/her study records so this information is easily available for reference at follow-up visits.

Product use instruction diagrams are available for reference on the MTN-026 Study Implementation Materials webpage (<http://www.mtnstopshiv.org/node/6908>).

10.5 Study Product Adherence Counseling

Study product adherence counseling is required at Visits 3 and during Visits 7-13. 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.

Product adherence counseling should focus on providing the key messages (as noted below) 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 in chart notes.

Key Messages

1. **While in the clinic, you will be asked to insert one dose of gel (one applicator) into your rectum.**
 - a. You will also be given one applicator to take home with you just in case you are unable to come to the clinic for one of your scheduled visits.
 - b. If you need to insert a dose at home, insert one dose (one applicator) into your rectum at the same time of the day that all other daily doses were inserted.
 - c. It is important that you don't miss any doses. If you miss any doses, please contact study staff.
2. **Avoid practices that could cause discomfort or any additional side effects.**
 - a. Do not insert the applicator without lubricant. Inserting a dry applicator may cause discomfort.
 - b. Do not force the applicator into the rectum.
 - c. Do not wash or wipe off the applicator prior to insertion.
 - d. **Please remember you are asked to refrain from engaging in sexual activity for seven consecutive days while you are using the study gel.**
3. **You are also asked not to have sex 72 hours prior to each of your scheduled visits. See the Information Booklet for a detailed list of these times. If you do engage in sex at any time during the study, please be sure to use a condom.**
4. **Keep the gel applicator in your possession at all times.**
 - a. Do not share your gel applicator with other people. It is important that you only use the gel assigned to you.
 - b. Store at room temperature in a safe, cool, dry place.
 - c. Keep the gel applicator out of reach of children.
 - d. Keep the gel applicator in its original wrapper until it is time to use (if necessary).
 - e. Do not remove labels from the applicator overwrap.
 - f. Do not use the gel if the wrapper is open or seems broken or any part of the applicator is missing. If you notice a problem with the applicator, please bring the gel back to the clinic and give it to clinic staff.
 - g. If you do not use your gel applicator at home, please bring the unused applicator and lubricant back to the clinic at Visit 13.
5. **The study staff is here to help and support you. Please contact study staff if you have:**
 - a. Any questions or concerns.
 - b. Problems using the gel.
 - c. New symptoms or worsening of any continuing medical symptoms.

10.6 Protocol Adherence Counseling

Protocol adherence counseling is required at each scheduled study visit. 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, participants should be counseled to refrain from using the following for the entire duration of study participation:

- Heparin, including Lovenox®, Warfarin, Plavix®*
- Hormone-replacement therapy including hormone therapy (tablet, injectable or gel form)*
- Aspirin (greater than 81mg)
- Non-steroidal anti-inflammatory drugs (NSAIDs) or any other drugs that increase the likelihood of bleeding
- CYP3A inhibitors and inducers

**Use of these medications will result in permanent discontinuation of study product.*

Participants should also be counseled to refrain from engaging in the following **72 hours prior to each of your scheduled visits** and **during the 7-day product use period**:

- Inserting any non-study products in the rectum or vagina

Women are also asked to avoid the above as well as the following activities **7 days after** biopsies are collected:

- Receptive anal intercourse (RAI)
- Penile-vaginal intercourse
- Receptive oral anogenital stimulation
- Vaginal or rectal stimulation via fingers
- Vaginal or rectal insertion of sex toys

Male participants are asked to avoid sexual activities for **72 hours after** biopsies are collected. These include:

- Receptive anal intercourse (RAI)
- Receptive oral anogenital stimulation
- Rectal stimulation via fingers
- Rectal insertion of sex toys

Participants should be counseled that engaging in these practices or using any of the above products while in the study may make the gel work differently. These products and practices could irritate the rectum or vagina and increase the risk of side effects.

If a participant reports use of aspirin (greater than 81 mg) and other non-steroidal anti-inflammatory drugs (NSAIDs), CYP3A inducer(s) and/or inhibitor(s) or any other drugs 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 in chart notes and/or using the Protocol Adherence Counseling Worksheet.

10.7 Counseling on Collection of Rectal Biopsies and Rectal Fluid

Participants will undergo collection of rectal biopsies and fluid for PK, PD, and Mucosal Immunology analysis. At visits in which samples are collected, study staff will explain what procedures will be performed at the visit and what to expect.

Participants will be counseled that a rectal biopsy is a procedure to remove a small piece of rectal tissue (about the size of a grain of rice) for examination. Approximately 15-20 biopsies will be collected at any given time point. In addition, participants will be informed that in preparation for this procedure they will receive an enema in order to empty their bowels completely. This will allow the clinician a clear view of the rectum. Then a lubricated flexible sigmoidoscope is placed into the rectum. Site staff should explain to participants what a flexible sigmoidoscope is and its purpose. A picture of the flexible sigmoidoscope is recommended during counseling for reference. Participants should be counseled that they may experience some cramping or mild discomfort during the procedure, and they may feel an urge to have a bowel movement as this sensation occurs as the instrument is placed into the rectum.