Section 10. Counseling Procedures

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10. Introduction

This section contains guidance on the following types of counseling provided in MTN-035: HIV pre- and post-test counseling, HIV/STI risk reduction counseling, and protocol counseling (inclusive of protocol adherence and product use).

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. Because of this, specific content to cover, or skills to emphasize, are not standardized. Rather, the process for these discussions is to allow for appropriate tailoring and targeting to an individual participant's needs at a given point in time. To support continuity in 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.

All counseling and referrals should be documented in participant study records per site SOPs. Proper documentation may be achieved through use of counseling worksheets, and/or chart notes. Sample counseling worksheets are available on the MTN-035 website for protocol, product use, HIV testing and HIV/STI risk reduction counseling.

10.1 HIV pre- and post-test counseling

HIV testing is required at Screening, Enrollment, and Visit 7. It may be conducted at all other visits if clinically indicated. HIV pre- and post-test counseling is required at visits where HIV testing is performed, regardless of whether the HIV test is conducted because it is required per protocol or if clinically indicated. Post-test counseling should be provided when HIV test results become available. If HIV test results will not be available during the testing visit, post-test counseling may occur upon provision of test results over the phone or in person, as part of a split or interim visit, if indicated per local standard of care. Sites are required to develop and follow SOPs for HIV testing and counseling considerations.

All HIV 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 Appendix II. Further information on interpretation of Screening and follow-up test results is provided in Table 10-1 below. This should be referenced as needed when providing pre- and post-counseling.

Client-centered approaches should be used to assess participant knowledge of relevant information, dispel misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results. Information should be provided in a manner that is respectful and interactive. Participants should be informed of when their test results will be available. 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.

A sample HIV Pre/Post-Test and Risk Reduction Counseling Worksheet is available for use on the MTN-035 webpage under Study Implementation Materials. This worksheet provides a guide to the minimum requirements for HIV testing and counseling sessions; this worksheet may be tailored for use at each study site.

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 participant is not infected with HIV.
Both rapid tests/EIA positive	Test results indicate that participant is infected with HIV, but additional testing is needed to confirm status. Additional testing is required to confirm results.
Discordant rapid tests (one negative, one positive) or EIA indeterminate	HIV status not clear; test results indicate that participant may be infected with HIV but additional testing is needed to confirm status. Consult the MTN LC.
Confirmatory test positive	HIV-infected; test results indicate that participant is infected with HIV. Consult the MTN LC.
Confirmatory test negative or indeterminate	HIV status not clear; test results indicate that participant may be infected with HIV, but additional testing is needed to confirm status. Consult the MTN LC.

10.2 HIV/STI Risk Reduction Counseling

HIV pre-test and post-test counseling is required at each visit that HIV testing is performed.

Sites are required to develop and follow SOP(s) for HIV pre- and post-test counseling as well as HIV/STI 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 s/he wishes.

The sample HIV/STI Risk Reduction Counseling Worksheet posted on the MTN website 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, any risk factors and risk reduction plans identified during previous sessions should be reviewed and discussed with the participant to determine:

- What has been the participant's experience since the last session?
- Was the participant able to carry out strategies and plans?
- What were the outcomes?
- If risk reduction plans identified and agreed upon with the participant at the current session should build on experience since the last session
- Whether successful strategies should be continued
- If additional strategies may be identified to achieve further risk reduction
- If 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., 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 on 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.

PrEP can help prevent HIV infection in people who don't have HIV but who are at high risk of becoming infected with HIV. Truvada for PrEP should be used as part of a comprehensive prevention strategy, as applicable, that includes other prevention measures such as safer sex practices. A comprehensive prevention strategy includes consistent and correct use of condoms, the individual knowing both his/her own status and his/her partner's HIV status, getting regular testing for HIV and other sexually transmitted infections, and informing individuals about and supporting their efforts to reduce sexual risk behavior.

Use of Truvada for pre- exposure prophylaxis is permitted, if approved locally as part of standard of care for HIV prevention. However, if a participant took part in a PrEP research study within 30 days of Enrollment and PrEP is not approved for use per local regulations, oral FTC/TDF as PrEP would be considered an investigational product (and thus, exclusionary per protocol section 5.3).

10.3 Protocol Counseling

Protocol adherence counseling is required at each scheduled study visit, with the exception of the Final (Visit 8)/Early Termination visit. During follow-up, protocol adherence counseling can be abbreviated based on individual participant needs. As safety is of the utmost importance, site staff should counsel participants to refrain from using prohibited medications and engaging in certain practices during study participation.

Per protocol, use of rectally-administered non-study medications and products is prohibited, including any products containing N-9. Should the participant report use of such products or medications, the site should submit a Protocol Deviations Summary and Log CRF. The use of non-study personal lubricants and usual pre-RAI douches that do not contain N-9 is permitted during study participation.

During protocol adherence counseling, study staff should also review the study visit schedule and any retention challenges the participant may be facing.

Counseling should include a review of the protocol requirements and a conversation with the participant about a plan moving forward (e.g., is it possible for him/her to avoid the product or medication in the future? What would help? Are there challenges?).

The Protocol Counseling Worksheet provides a guide to the minimum requirements of protocol adherence counseling sessions and provides a place for documenting these sessions. Alternatively, the session can be documented in chart notes.

10.4 Product Use Counseling

Participants will receive study product and study product use counseling at Enrollment and Product Switch Visits (Visits 4 and 6), and at interim visits as needed. After being informed of their study regimen sequence, participants will receive detailed regimen-specific product use instructions (which have been translated into local languages, if applicable) with illustrations to optimize comprehension, and administer their first dose of study product. A copy of the illustrated instructions should be provided to each participant. Other visual aids (e.g., sample enema bottles, sample inserts, sample suppositories), should be used as needed to help ensure participants' understanding of proper product use.

Adequate time should be taken to explain the product use instructions thoroughly and to 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.

All study participants will insert their first dose in the clinic starting at Enrollment, and at each Product Switch Visit (Visits 4 and 6). The rationale for this is to help ensure participant understanding, comfort, and confidence with proper product use. In particular, any questions or concerns that arise in the context of product use can be addressed by study staff before the participant leaves the clinic.

If the participant has any questions or concerns, these should be documented for future reference and addressed by study staff. When the participant is ready, s/he should be instructed to continue with product use. The first insertion, depending on participant preference and level of comfort, can be done either in a private space with study staff standing by in case the participant requests guidance or technical assistance, or in a private space with direct staff observation. Study staff should not perform any steps in the product use instructions for the participant. Study staff may answer questions, and/or provide prompts or reminders to the participant, but otherwise should limit their involvement to ensure that the participant is able to perform each step on his/her own before leaving the clinic.

After the participant completes the first product use administration, but before proceeding to adherence counseling, study staff should de-brief with the participant on the first product use experience. If the participant has any questions or issues, these should be documented so the information is easily available for reference at study follow-up visits. Product adherence counseling will be conducted using client-centered strategies, to reinforce the value of accurate product use adherence reporting. Product adherence counseling should focus on providing the key messages (see product use instructions) 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 at study visits.

Product use instruction forms are available for reference on the MTN-035 Study Implementation Materials webpage. Each counseling session should be fully documented in chart notes or on the Protocol Adherence Counseling Worksheet. At the end of each product use period, study participants should be instructed to return any unused study product in their possession at their next visit. If clinic staff notices that a participant returns a large quantity of the product which indicates they have not used study product per

protocol guidance (i.e. prior to each act of RAI or at least once a week in the absence of RAI), staff may use this as an opportunity to review/provide additional product use counseling.

Placebo Rectal Douche (Enema)

An enema administration is most commonly used to clean the lower bowel. Participants should insert one dose between 30 minutes to 3 hours prior to engaging in receptive anal intercourse (RAI). They should be instructed that only one dose be used in a 24-hour period.

If the participant forgets to or cannot take a dose before RAI, that dose should be skipped. If participants do not engage in RAI in a given week, they should be instructed to insert a dose of the product in the absence of RAI.

To lessen the pressure felt in the colon, it is recommended that the participant empty their bladder before administering the rectal douche. If lying down during administration, participants should be instructed to place a towel or cloth beneath them in case leaks or expulsion occurs prematurely. It is recommended that administration occur near or in the bathroom, as evacuation may need to occur as soon as the douche is administered. Participants should never force the tip of the douche into the rectum as it can cause irritation and damage to surrounding tissue. Should the participant experience any rectal bleeding or severe pain, they should be instructed to consult site staff.

The tip of the rectal douche is pre-lubricated to ease rectal insertion. In the rare event additional lubricant is required to ease any discomfort or difficulty from insertion, participants may apply some to the anus. If non-study lubricant is used for this purpose, site staff must record it on the Concomitant Medications Log CRF.

Once the douche tip is fully inserted into the rectum, the participant will administer the fluid by squeezing the bottle to push the liquid into the rectum. Participants should be instructed to squeeze the bottle from the bottom until nearly all liquid is gone. Once the fluid is released into the rectum, they should slowly withdraw the nozzle from the rectum and hold the fluid until a strong urge is felt to expel the liquid. The used douche tip and any unused water remaining in the bottle should be properly disposed of. As it may be necessary to use the toilet several times until all liquid is expelled, it is recommended that participant stay close to a toilet after product administration, at his/her discretion.

When dispensed, participants are supplied empty enema bottles and tips. The enema bottles are intended to be reused, however, the tips should be disposed after each use. Participants should rinse the enema bottle after each use and dispose of the enema tip. After several uses the participant may decide to dispose of the enema bottle and use a new one. If additional enema bottles and/or tips are needed, the participant should be instructed to contact the study clinic to be resupplied additional enema bottles or tips as needed.

Participants should be counseled that douching after sex does not prevent STIs.

If the participant routinely douches as part of his/her standard cleansing practices prior to receptive anal sex, s/he should be instructed to use their usual douching method first. The study-provided placebo rectal douche should be the last solution administered as part of their regimen.

Placebo Rectal Insert and Placebo Rectal Suppository

Participants should insert one dose between 30 minutes to 3 hours prior to engaging in receptive anal intercourse (RAI) and only one dose should be used in a 24-hour period. It is recommended that participants try to empty their bowels before inserting study product, to help prevent immediate expulsion via a bowel movement. In the event a participant has a bowel movement immediately after study product is inserted, they should be instructed not to insert a second dose until their next scheduled engagement of RAI.

10.5 Contraceptive Counseling

Contraceptive counseling for individuals who can get pregnant is required at Screening, Enrollment and each Product Switch Visit (Visits 4 and 6). When performed at the Screening and Enrollment visits, contraceptive counseling should be provided in the context of assessing study eligibility. Per MTN-035 inclusion criteria, a potential participant must have been using an effective method of contraception for at least 30 days prior to Enrollment and agree to use an effective method of contraception throughout their study participation. Counseling provided at these visits should explain which methods are acceptable for study purposes and emphasize that if the participant cannot commit to using one of these methods during study follow-up, they should not enroll in the study.

Effective methods include:

- Hormonal methods
- Intrauterine device (IUD) inserted at least 30 days prior to Enrollment (but not past the maximum length of recommended usage according to package instructions)
- Sterilization (of participant or, if in a monogamous relationship, of partner, as defined in site SOPs)*
- Abstinence from RVI for 90 days prior to Enrollment, and intention to abstain from RVI for the duration of study participation

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

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 their 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 should include discussion of the specific problems encountered and identification of potential strategies to address these, which may include switching methods.

Study staff who provide contraceptive counseling should be trained to do so per local practice standards and should also be trained on MTN-035 protocol specifications related to contraception. Contraception may be provided on site; however, sites may opt to refer participants to non-study providers for contraception. All sites are strongly encouraged to obtain credible medical records as part of their verification procedures for participant reported contraceptive methods. Starting at Enrollment, staff should monitor when a new contraceptive prescription (e.g., new pill prescription, Depo injection, IUD) is needed and should actively review this information at every follow-up visit to ensure that adequate contraceptive coverage is available for the duration of study participation. Expiration/replacement of a currently prescribed contraceptive can be documented on the counseling worksheet, in chart notes, or other site-specific form.

All contraceptive 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. Staff members providing contraceptive counseling can document details of each session in chart notes.