Section 11. Counseling Procedures

11. Introduction

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 should be flexible enough to allow for appropriate tailoring and targeting to an individual participant's needs at a given point in time. 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.

All counseling and referrals should be documented in participant study records per site SOPs. Proper documentation may be achieved through the use of counseling worksheets, and/or chart notes.

Sample counseling worksheets are available on the MTN-036/IPM 047 website.

11.1 HIV Counseling

HIV testing is required at Screening, Enrollment, and PUEV/Early Termination. At all other visits, HIV testing is performed when clinically indicated. HIV pre-test, post-test, and HIV/STI risk reduction counseling are required at visits when HIV testing is performed, regardless of whether the HIV test was conducted because it was required by the 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 visit, post-test counseling may occur upon provision of test results over the phone or in person as part of a split visit or at an interim visit, if indicated per local standard of care. Referrals should be provided when indicated. 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 11-1 below. This informational resource should be referenced as needed when providing pre-test 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.

As a component of HIV counseling, participant-centered approaches should be used when assessing participant risk for HIV/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 reported risk factors and barriers. Risk reduction counseling should also offer skills-building to the participant when indicated, e.g., how to discuss sensitive issues with partners and other influential persons.

Table 11-1
Interpretation of HIV Test Results Per Protocol Appendix II

Test	Test Result	Interpretation
Sample 1 HIV Immunoassay	negative	HIV-uninfected; test results indicate that you are not infected with HIV.
	positive 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.
Sample 1 Confirmatory Test	positive	**If Screening or Enrollment Visit**: HIV-infected; test results indicate that you are infected with HIV. You are not eligible for enrollment in this study, but additional counseling and referrals for care are available [provide per site SOPs] **If Follow-up Visit**: HIV-infected; test results indicate that you are infected with HIV; however, additional testing is needed for study purposes.
	negative or indeterminate	HIV status not clear; additional testing is needed to determine your status.
Sample 2 Confirmatory Test	positive	HIV-infected. Test results have confirmed that you are HIV infected. Regular study visits will discontinue at this time, but additional counseling and referrals for care are available [provide per site SOPs]
	negative or indeterminate (the participant may have already been given positive clinical lab results)	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.

A sample HIV Pre- and Post-Test and STI Risk Reduction counseling worksheet is available on the MTN-036/IPM 047 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.

11.2 Protocol Counseling

Protocol counseling for MTN-036/IPM 047 includes three components:

- Contraceptive Counseling
- Protocol Adherence Counseling
- Product Use Counseling

Contraceptive counseling will begin at the screening visit while protocol adherence counseling and product use counseling begin at the enrollment visit. All components of protocol counseling should be conducted during follow-up visits through PUEV. Counseling should be provided in a participant-centered manner and in accordance with standard methods.

A sample Protocol Counseling Worksheet that can be used to guide and document each component of protocol counseling is available on the MTN-036/IPM 047 webpage under Study Implementation Materials. Sites may use this worksheet as-is or tailor it for use. If preferable, sites may choose to use a site-specific counseling worksheet.

11.2.1 Contraception Counseling

Contraceptive counseling is included at all study visits from Screening to Visit 10/PUEV. However, participants who have undergone supracervical hysterectomy or bilateral oophorectomy as verified by medical records are exempt from receiving contraceptive counseling. When performed at the screening and enrollment visits, contraception counseling should be provided in the context of assessing study eligibility criteria. Per MTN-036/IPM 047 inclusion criteria, a potential participant must have used an effective method of contraception for at least 30 days (inclusive) prior to enrollment and agree to use an effective method of contraception throughout the duration of the participant's study participation. Counseling provided at these visits should explain which methods are acceptable for study purposes and emphasize that if s/he cannot commit to using one of these methods during study follow-up, s/he should not enroll in the study.

Effective methods include:

- hormonal methods (except contraceptive ring)
- intrauterine device (IUD)
- sterilization (of participant or partner, as defined in site SOPs)
- having sex exclusively with cis-women
- abstinence from penile-vaginal intercourse (PVI) for 90 days prior to Enrollment, and intending to remain abstinent from PVI for the duration of study participation

During follow-up visits, client-centered counseling should continue, but may be abbreviated. 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.

Some participants may wish to discontinue use of a contraceptive method during follow-up. In these cases, counselors should explore the participant's reasons for this and determine if other options would be acceptable to him/her. If no other options are acceptable, the participant may remain in the study, and continue using study product, even if s/he discontinues contraceptive use. However, the possibility of resuming contraceptive use should be re-visited at each subsequent visit to determine whether the participant's circumstances may have changed.

Study staff who provide contraception counseling should be trained to do so per local practice standards and should also be trained on MTN-036/IPM 047 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 i.e. 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 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. Staff members providing the contraceptive counseling can document details of each session on the Protocol Counseling Worksheet, a site-specific counseling worksheet, or in chart notes.

11.2.2 Protocol Adherence Counseling

Protocol adherence counseling begins at the enrollment visit and continues at all follow-up visits through Visit 10/PUEV. During follow-up, protocol adherence counseling can be abbreviated based on each individual participant's needs.

The MTN-036 Study Adherence Guidelines document has been created to help guide study staff through the required elements of this counseling. This resource should be referenced during the counseling session and participants should be offered a copy to take home (note that although protocol adherence counseling is not required at screening, sites may want to consider providing a copy of the Study Adherence Guidelines during or after the informed consent session). During protocol adherence counseling, study staff should begin with a review of the study visit schedule and any retention challenges the participant may be facing. As safety is of the utmost importance, site staff will also counsel participants to refrain from engaging in certain practices and/or using prohibited medications at certain points throughout study participation, as outlined on the Study Adherence Guidelines document. Engaging in these prohibited practices or taking any of the prohibited medications could potentially increase the possibility of adverse events or compromise the results of the study.

At enrollment, if a participant shares that s/he has engaged in any of the practices or used any of the products or medications that are prohibited during the 24 hours prior to enrollment, the visit should be rescheduled and the counselor should review the protocol requirements with him/her. During follow-up, if any prohibited practices or medications are reported by the participant, document them in counseling notes and on the appropriate CRFs. Note that protocol deviation reporting may be a required component of this documentation. 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 behavior, product, or medication in the future? What would help? What are challenges?).

The Protocol Counseling Worksheet provides a guide to the minimum requirements for protocol adherence counseling sessions and provides a place for documenting these sessions.

11.2.3 Product Use Counseling

Participants will be provided with VR use instructions and related study product adherence counseling for the first time at the enrollment visit. Product use counseling should continue at all follow-up visits through PUEV, but may be abbreviated based on participant needs.

At enrollment, study participants will be given detailed verbal instructions in the clinic on proper vaginal VR insertion procedures. In addition, a copy of the Vaginal Ring Use Instructions sheet, available on the MTN-036/IPM 047 webpage under Study Implementation Materials, should be given to each participant. This sheet includes illustrated VR insertion instructions, which may be helpful to some participants. Other visual aids, such as sample VRs and pelvic models should be used as needed when providing instructions to help ensure participant understanding of proper product use.

After the VR is inserted for the first time at enrollment, clinicians will check for proper VR placement and study staff should de-brief with the participant on his/her experience. Any issues or problems raised by the participant should be addressed by the study staff and documented the participant's chart.

In addition to reviewing instructions for inserting the VR, it is important to also discuss instructions for VR removal. The participant should be reminded that s/he should not remove the VR in between study visits, however if VR removal is needed, the below procedures should be followed:

- Before removing the ring, wash and dry your hands.

- Choose a comfortable position (can reference ring insertion instructions for illustrations of different positions).
- Put a finger into your vagina and hook it through the ring.
- Gently pull down and forward to remove the ring.
- 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, rinse the ring and place the used ring in the bag provided by clinic staff or other suitable container if the bag is not available. Store the ring a safe and private area out of reach of children or other occupants of the home.
- Wash your hands.
- Bring used ring with you to the clinic during your next study visit.

Additional product use instructions are outlined on the Vaginal Ring Use Instructions sheet on the side labeled Vaginal Ring Important Information. Adequate time should be taken to thoroughly explain the product use instructions and answer any questions the participant may have to help ensure participant understanding and comfort with VR use.

At follow up visits, the Vaginal Ring Use Instruction sheet should be referenced, as needed, but product use counseling will primarily focus on each participant's experience with VR use so far and any questions or challenges s/he may have.

Like the protocol adherence counseling, product use counseling may be documented on the Protocol Counseling Worksheet, a site-specific form, or in chart notes.