

Section 9. Counseling Considerations

This section contains guidance on the following types of counseling provided in MTN-024/IPM 031: HIV pre/post-test counseling, HIV/STI risk reduction and male condom counseling, study product adherence counseling, protocol adherence counseling.

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' 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 are 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-024/IPM 031 website for HIV testing, risk reduction, study product adherence and protocol adherence counseling.

9.1 HIV Pre and Post Test Counseling

HIV testing is required at Screening and at the 12-Week Final Clinic/Early Termination Visit. HIV testing is performed when clinically indicated at all other visits. HIV pre-test and post-test counseling required at visits when HIV testing is required or when performed when clinically indicated. Referrals should be provided when indicated. Sites are required to develop and follow SOPs for HIV pre- and post-test counseling.

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 9-1 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.

**Table 9-1
Interpretation of HIV Test Results Per Protocol Appendix II**

Test Result	Interpretation
EIA negative	HIV-uninfected; test results indicate that you are not infected with HIV.
EIA 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 Western blot positive	If Screening Visit: HIV-infected; test results indicate that you are infected with HIV If Final Visit: HIV-infected; test results indicate that you are infected with HIV; however, additional testing is needed for study purposes.
Sample 1 Western blot negative or indeterminate	HIV status not clear; additional testing is needed to determine your status.
Sample 2 Western blot positive	HIV-infected. Test results have confirmed that you are HIV infected.
Sample 2 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.

A sample HIV pre- and post-test counseling worksheet is available for use on the MTN-024/IPM 031 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.

9.2 HIV/STI Risk Reduction and Male Condom Counseling

Risk reduction counseling is required at every scheduled in-clinic visit. Male condom counseling is provided when clinically indicated at all other visits. 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 her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address reported risk factors and barriers.

Supported and facilitated by the counselor, the 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 strengths and 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.

At each counseling session, prevention strategies and risk factors previously identified should be used to lead to a risk reduction plan. These plans will be reviewed at subsequent sessions and discussed with the participant to determine:

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

Counselors use this opportunity to reinforce effort, not outcomes, and to frame the current discussion as an opportunity to continue exploring protecting one’s sexual health.

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 was not successful.

Risk reduction counseling sessions should also offer skills-building to the participant when indicated, e.g., on how to use male 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.

A sample HIV/STI Risk Reduction Counseling worksheet which may be tailored for use is available on the MTN-024/IPM 031 Study Implementation Materials webpage under Counseling Tools/Worksheets: <http://www.mtnstopshiv.org/node/4924>.

9.3 Ring Use Adherence Counseling

Participants will be provided ring use adherence counseling for the first time at the Enrollment visit. Ring use adherence counseling will also be provided at the 4-Week and 8-Week visits and interim visits if a new ring is provided. Prior to receiving this counseling, participants will receive their dispensation of the vaginal ring and insert the vaginal ring at the study clinic. Study participants will be given detailed instructions in the clinic on proper vaginal ring insertion and removal procedures.

In addition to verbal instructions, a copy of the illustrated instructions should be provided to each participant. Vaginal ring insertion instructions are available on the MTN-024/IPM 031 webpage under Study Implementation Materials. Other visual aids, such as sample vaginal rings and pelvic models should 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. Site staff should help ensure participant understanding, comfort, and confidence with vaginal ring use from the very beginning of study participation. In particular, any questions or concerns that arise in the context of ring insertion can be addressed by study staff before the participant leaves the clinic.

A Ring Use Adherence Key Messages worksheet is available for use on the MTN-024/IPM 031 Study Implementation Materials webpage under Counseling Tools/Worksheets: <http://www.mtnstopshiv.org/node/4924>. This worksheet provides a guide to the minimum requirements for product use counseling sessions; this worksheet may be tailored for use. Key messages outlined on the Vaginal Ring Insertion Instructions are further detailed on the Ring Use Adherence Key Messages worksheet should be discussed with the participant. As each point is addressed, site staff should mark each message on the worksheet. Discussion points, participant questions should also be noted on page 3 of the worksheet and/or in chart notes and used for future counseling sessions.

9.3.1 First Product 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 insert the vaginal ring herself. Insertion should be performed in a private space, with study staff standing by in case the participant requests guidance or technical assistance.

After three unsuccessful attempts by the participant to self-insert the ring, the study clinician can then assist the participant with insertion. If assistance is required, study clinicians should take time, talk through each step, and whenever possible, demonstrate the insertion steps by guiding participant's hands through the process.

At each visit when a ring is dispensed, staff should discuss ring removal and reinsertion procedures with participant. This is to encourage comfort with removal procedures, and additional practice in case the vaginal ring is removed or accidentally falls out prior to her next clinic visit.

Participant instructions for ring removal (provided verbally to participants):

- 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.

After the vaginal ring is inserted, study staff should de-brief with the participant on her experience. Any issues or problems raised by the participant should be addressed by the study staff and documented on the ring use adherence worksheet and/or in chart notes so the information is easily available for reference at study follow-up visits.

9.3.2 Clinician Instructions for Checking Ring Placement

At each visit, following insertion of the vaginal ring, the study clinician or designee should check placement of the vaginal ring, regardless of who inserted it, to confirm correct placement. The following is the procedure that the IoR or designated clinic staff should use to verify ring placement:

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

After correct placement is confirmed, the clinician should ask the participant 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 Follow-up Study Product Use Adherence Counseling

Study product adherence counseling is required at the 4-Week and 8-Week visits (unless the participant is on a product hold or permanent discontinuation) or at interim visits where a new ring is dispensed. At these follow-up visits, adherence counseling should focus on exploring participant's experiences with ring use, including what makes it easier or harder for her to use the vaginal ring as recommended. Discussion of experiences is framed as an opportunity to gain an understanding from participants of how well this ring may "fit" into the daily and sexual lives of women using it. With that, it is important to gain a sense of what seems to help it be a good "fit" and what seems to make it a poor "fit." 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.

Staff can review the vaginal ring insertion instructions and important information as needed during follow-up visits. As a participant becomes more experienced with ring use, time spent on this information can be tailored to suit participant needs.

During follow-up, adherence counseling should occur after completion of CASI and administration of the Ring Adherence and Vaginal Practices CRFs.

Note: In order to promote an open and neutral environment, it is recommended that staff conducting the adherence counseling be different than those who conduct the adherence assessment questionnaires (Ring Adherence CRF).

Sites may choose to conduct adherence counseling prior to completion of clinical/lab assessments to improve visit flow. Note that in this situation, some participants may receive adherence counseling, but may subsequently be put on product hold during the visit and not receive product.

Further guidance for the adherence counseling session is provided below.

- Review documentation of previous product use adherence counseling sessions in preparation for a new counseling session.
- Emphasize the importance of open communication about ring use at the beginning of each session.
- Use open-ended questions and probes to assess the participant's self-reported adherence since her last counseling session. Note how often the participant reports having removed or expelled the study ring. This will help guide the adherence counseling that she will receive.

When providing adherence counseling:

- Ask the participant what her experience has been using the ring. If it was bad, ask why and when. If it was good, ask how and why.
- Review and discuss with the participant any current barriers/challenges or concerns related to ring use.
- When needed, review ring use insertion instructions with the participant, using the illustrated instruction sheet and any other visual aids that may be helpful to ensure participant understanding of proper product use.
- When needed, provide skills building to the participant, e.g., on how to discuss ring use with partners or other influential persons.

Adequate time should be taken to counsel the participant and address any questions or concerns the participant may have, and work with the participant in a client-centered manner to identify operational strategies to assist her in inserting the ring,

and removing the ring if necessary. She should be encouraged to ask questions and raise issues or problems at any time. Each counseling session should be fully documented in chart notes as needed.

9.5 Protocol Adherence Counseling

As safety is of the utmost importance, site staff will counsel participants to refrain from engaging in certain practices and/or using prohibited medications during the course of study participation which could potentially increase the possibility of adverse events due to agents other than the study vaginal ring.

Protocol adherence counseling is required at Enrollment and the 4-Week and 8-Week visits. Per protocol section 6.7, participants should be counseled to avoid the following practices:

- Refrain from using non-study provided or approved vaginal products or objects during study participation
- Refrain from inserting study approved lubricant 72 hours (3 days) prior to each scheduled visit.
- Refrain from engaging in vaginal intercourse 72 hours (3 days) prior to each scheduled visit.

Note: Refer to Section 7 of this manual for further details on recording use of study provided lubricant. Should the participant report that she has engaged in any of the above, this should be documented on the Vaginal Practices CRF.

Participants are asked to abstain from using the following products:

- Spermicides
- Female condoms
- Diaphragms
- Topical or systemic hormone replacement treatment (i.e. estrogens and/or hormonal contraceptives)
- Vaginal medications
- Menstrual cups
- Cervical caps
- Vaginal douches
- Non-study approved lubricants or moisturizers
- Sex toys (vibrators, dildos, etc.)

If a participant reports a prohibited practice, as listed above and in protocol section 6.7, the participant should be counseled regarding the use of alternative methods. Site staff should refer to protocol section 9.3 and 9.4 for prohibited practices that require temporary or permanent discontinuation of product use including reported use of topical or systemic hormone replacement therapy, PEP or PrEP use. Counseling and discussion of any issues related to protocol adherence may be documented on the Protocol Adherence Worksheet, located on the MTN-024/IPM 031 webpage under Study Implementation Materials or other site-specific worksheet.

In addition to the above mentioned protocol requirements, per protocol section 6.7, participants should abstain from inserting anything into the vagina for 72 hours prior to each clinic visit, including abstaining from the use of study approved lubricant and vaginal intercourse. Therefore, participants should be counseled at the Screening visit to refrain from the aforementioned practices for 72 hours (3 days) prior to the Enrollment and follow-up visits to ensure the cervicovaginal lavage (CVL) and vaginal swabs for biomarker testing are not impacted. Should a participant report engaging in the abovementioned practices during the prohibited period, the visit need not be rescheduled. Any reported practices should be documented on the Vaginal Practices CRF.

9.5.1 Biopsy Procedural Counseling

A subset of 45 participants will undergo a vaginal fluid collection for PK at the 4-Week, 8-Week and 12-Week/Final Clinic visits. Fifteen of these participants will also undergo collection of cervical tissue (biopsies) for PK at the 12-Week/Final Clinic visit. At each of these visits and as part of the provision of protocol adherence counseling, study staff will explain what procedures will be performed at the visit and what to expect.

The participant will be counseling and informed that in order to collect the vaginal fluid and cervical biopsies, a clinician will use an instrument called a speculum. Once the speculum is inserted, the clinician will then insert a vaginal swab to collect fluid from the participant's vagina to see how much of the study drug is present in her vaginal fluid. For those participants who agree to the collection of vaginal fluid and cervical tissue, another procedure will include the collection of cervical tissue. Study clinicians will take two small tissue samples from the participant's cervix, each about the size of a grain of rice. These samples will be used to see how much of the study drug is in her tissue.

Those taking part in the biopsy subset should be counseled to abstain from inserting anything in the vagina, including engaging in vaginal intercourse, for 72 hours after the collection of biopsies as she may be at increased risk for STIs and HIV acquisition, if exposed. Participants should also be counseled that they may experience some pressure or discomfort in her genital area during the pelvic examination and sample collection. During the collection of biopsies, the participant may feel slight to moderate pain (similar to the feeling of being pinched) which usually resolves within a few hours following tissue collection. The participant should be informed that she may have spotting (small amounts of bleeding) for 1 – 2 days following the biopsies and that there is a small risk of the biopsy area becoming infected or having bleeding that is heavier than spotting. The participant should be instructed to contact the study clinic immediately if she experiences heavy bleeding, more than a usual menstrual period, a foul odor or a heavier vaginal discharge (more than usual).