Section 14. Counseling Considerations

This section contains guidance on the following types of counseling provided in MTN-005: HIV risk reduction counseling, contraception counseling, and study product adherence counseling. Each of these types of counseling is required at most if not all study visits.

All counseling should be provided in a non-judgmental client-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.

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 client-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.

14.1 HIV Counseling

HIV testing is required at the screening, and 16-Week/ Study Termination visit, and if clinically indicated throughout the duration of the study. HIV pre-test and post-test counseling is therefore required at these visits as well. Risk reduction counseling is required per protocol at each scheduled visit. As part of risk reduction counseling, male condoms should be offered to all study participants and skills building should be provided to ensure participant understanding of correct condom use. Referrals should also be provided when indicated. Sites are required to develop and follow SOPs for HIV pre- and post-test counseling as well as HIV risk reduction counseling. Detailed counselors notes or counseling worksheets should be used to fully document all counseling sessions and all referrals provided.

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. Additional information on HIV testing during screening and follow-up is provided in Sections 12.6.2 and 6.7 of this manual respectively; further information on interpretation of screening and follow-up test results is provided in Table 14-1. These informational resources 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 any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results.

Table 14-1
Interpretation of HIV Tests Performed During Screening and 16-Week visit
Per Protocol Appendix II

Test Result	Interpretation
EIA negative	HIV-uninfected; test results indicate that you are not infected with HIV.
EIA positive	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 or IFA positive	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 EIA positive	HIV-infected; test results indicate that you are infected with HIV; however, additional testing is needed for study purposes.
Sample 2 EIA 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.
Sample 2 Western blot or IFA positive	HIV-infected. Test results have confirmed that you are HIV infected.
Sample 2 Western blot or IFA 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.

Client-centered approaches should also 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 these.

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 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.

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 her last session?
- Was she able to carry out her 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 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 couples 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.

14.2 Contraception Counseling

Contraception counseling is required at all scheduled study visits. All contraception counseling should be provided in accordance with local counseling standards and World Health Organization (WHO) guidance, which is available in the following resources:

- Medical Eligibility Criteria for Contraceptive Use (WHO, 2004 and Update 2008)

- Family Planning: A Global Handbook for Providers (WHO/USAID/Johns Hopkins Bloomberg School of Public Health, 2007)

For participants who become infected with HIV, further guidance is available in FHI's toolkit for Increasing Access to Contraception for Clients with HIV, which is available at http://www.fhi.org/en/RH/Training/trainmat/index.htm.

Study staff who provide contraception counseling should be trained to do so per local practice standards and should also be trained on MTN-005 protocol specifications related to contraception.

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, standard information should include how each method is taken or administered, mechanism of action, and level of effectiveness. It is generally expected that longer-acting methods will be optimal for many study participants, to minimize adherence burden and reduce pregnancy rates in the study.

At screening and enrollment visits, 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 at least 16 weeks should not enroll in the study.

At follow-up visits, 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. In other cases, consideration of method switching may be indicated.

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 her. If no other options are acceptable, the participant may remain in the study, and continue using study product, even if she 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.

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. Detailed counselors notes or counseling worksheets will be required to document counseling sessions. All sites are strongly encouraged to use flags or flyers in participant study charts to highlight contraception issues requiring follow-up at subsequent visits.

14.3 Study Product Adherence Counseling — Enrollment

Participants will be provided study product adherence counseling for the first time at their study enrollment visits. Prior to receiving this counseling, participants will be informed of their random assignments — to either IVR group or non-IVR group. Participants randomized to the IVR group will also receive their study product, be provided with product insertion instructions, and complete product insertion at the study clinic.

14.3.1 Product Use Instructions

After being informed of their random assignments, participants in the IVR group will have the study product dispensed to them and be provided with detailed product use and insertion instructions.

Product insertion instructions will be provided based on the instructions sheets shown in SSP Figure 9-1, which may be translated into a local language at each site and illustrated to optimize participants' understanding of them. In addition to verbal instructions, a copy of the illustrated instructions should be provided to each participant. Other visual aids, such as sample rings, pelvic models, and product photographs, 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 and insertion 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.

14.3.2 First Product Use and Insertion

All study participants randomized to the IVR arm will complete insertion of their study product at the study clinic during their enrollment visit. Any questions or concerns that arise in the context of product insertion can be addressed by study staff at that time. However, if necessary, the participant may request that the study clinician insert the IVR.

After providing product insertion instructions and answering any questions the participant may have, study staff will ask the participant if she is ready to try inserting the IVR. If the participant has any further questions or concerns, these should be documented for future reference and addressed by study staff. When the participant is ready, she should then be instructed to insert the IVR.

Study staff should instruct the participant to thoroughly wash her hands before and after study IVR insertion. Insertion should be performed in a private space, with study staff standing by in case the participant requests guidance or technical assistance.

Inability to insert the study IVR is expected to be rare. For participants who have difficulty, study staff should provide further information and guidance to address the difficulty encountered. After guidance is provided, the participant should try again to insert the study IVR at the enrollment visit. If she is unable, study staff may insert the IVR for the participant.

After the IVR is inserted, study staff should de-brief with the participant on her experience. Any such issues raised by the participant should be documented in participant study documents so the information is easily available for reference at study follow-up visits.

14.3.3 Adherence Counseling

Study product adherence counseling will be provided at the enrollment visit per the Enrollment Adherence Counseling Checklist shown in Section Appendix 12-1b. At the enrollment visit, counseling will be provided on each of the key messages listed below.

1. **Wash your hands thoroughly before and after study product insertion and/ or removal.**

2. **You should not to remove the ring for the entire 12 week period of the vaginal ring regimen except as directed during study visits, even during menses.**
   - If the ring accidentally comes out of your vagina before your next clinic visit, clean it with warm water and put it back in your vagina.
   - If you have any problems putting the ring back in your vagina, place it in the resealable amber bag provided by the clinic, and call or come to the clinic as soon as possible.

3. **Contact study staff if you have any questions or need another study vaginal ring between visits.**

4. **The study staff are here to help and support you. Please contact us if you have:**
   - Problems inserting the vaginal ring
   - Any other problems (such as partner or family issues)

Each of the above key messages is listed on the Enrollment Adherence Counseling Checklist, together with further guidance for counselors. Each site should translate the checklist into local languages. The formatting of the checklist may also be tailored to individual site needs; however, the key messages should not be modified at any site.

In addition to referring to the Enrollment Adherence Counseling Checklist throughout the counseling session, study staff should use visual aids, such as a sample ring, pelvic model, and product photographs, as needed to help ensure participant understanding of all key messages.

Adequate time should be taken to counsel the participant on all key messages, answer any questions and address any 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 on the Enrollment Adherence Counseling Checklist and in additional counselors' notes as needed.

14.4 Study Product Adherence Counseling — 4-Week and 8-Week visits

During follow-up, study product adherence counseling is required at 4-Week and 8-Week visits only. At these visits, the client-centered counseling approach initiated at the enrollment visit should continue, per the Follow-up Adherence Counseling Checklist shown in Section Appendix 12-1c and 12-1d. Each counseling session should include the following components:

- Assess adherence to study product use since the last counseling session based on participant report
- Discuss challenges with product use adherence
- Reinforce key adherence messages
- Document the counseling session

Each site should translate the Follow-up Adherence Counseling Checklist into local languages. The formatting of the checklist may also be tailored to individual site needs; however, the key adherence counseling messages should not be modified. Sites are encouraged to use *Neutral Assessment* and *Next Step Counseling* methods when discussing participants' product use in the previous month. Staff training tools and examples of these approaches are included on the MTN 005 website under "Training Materials".

Further guidance for the adherence counseling session is provided below.

- Always review documentation of previous adherence counseling sessions in preparation for a new counseling session.
- At the beginning of each session, emphasize the importance of open communication about study product use.

- Remind the participant that one of the reasons we are doing this study is to find out if women are able to use this ring on a regular basis.

- 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 in the previous month. 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 to product use.

    - When needed, review product use insertion and/ or removal 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 product use with partners or other influential persons.

- Reinforce key adherence counseling messages at each session:

    1. **Wash your hands thoroughly before and after study product insertion and/ or removal.**

    2. **You should not to remove the ring for the entire 12 week period of the vaginal ring regimen except as directed during study visits, even during menses.**
        - If the ring accidentally comes out of your vagina before your next clinic visit, e.g., during sex, clean it with warm water and put it back in your vagina.
        - If you have any problems putting the ring back in your vagina, call or come to the clinic.

    3. **Contact study staff if you have any questions or need another study vaginal ring between visits.**

    4. **The study staff are here to help and support you. Please contact us if you have:**
        - Problems inserting the vaginal ring
        - Any other problems (such as partner or family issues)

Fully document each counseling session. Clearly record the challenges/barriers and adherence plan and strategies discussed at each session for ease of reference at the next session, and record further details in additional counselors notes.

Section Appendix 12-1a
Screening Visit Counseling Checklist

PTID: _____ Visit Code: _____ Date: _____

HIV Risk Reduction Counseling

☐ **Perform counseling per site SOPs:**
- ☐ **HIV pre-test counseling**
- ☐ **HIV post-test counseling**
- ☐ **HIV risk reduction counseling**

☐ **Offer condoms.**

Comments:

Signature/Date: _____

Contraceptive Counseling

☐ **For all protocol accepted methods of contraception, discuss:**
- ☐ How each method is taken or administered
- ☐ Mechanism of action
- ☐ Level of effectiveness

☐ **What method of contraception are you currently using?**

☐ **Have you experienced any problems with your current form of contraception?**

☐ **What method do you plan to use throughout study participation?**

Comments:

Signature/Date: _____

Section Appendix 12-1b
Enrollment Visit Counseling Checklist

PTID: _____ Visit Code: _____ Date: _____

HIV/STI Risk Reduction Counseling

☐ **Perform HIV risk reduction counseling per site SOPs.**

☐ **Offer condoms.**

Comments:

Signature/Date: _____

Protocol Adherence Counseling

Agree to abstain from:

- ☐ Spermicide
- ☐ Diaphragms
- ☐ Vaginal medication
- ☐ Sex toys
- ☐ Lubricants
- ☐ Condoms that contain silicone
- ☐ Menstrual cup or douching

Comments:

Signature/Date: _____

Product Use Adherence Counseling

☐ **Wash your hands thoroughly before and after study product insertion and/ or removal.**

☐ **Try not to remove the ring for the entire 12 week period of the vaginal ring regimen except as directed during study visits, even during menses.**

- ☐ If the ring accidentally comes out of your vagina before your next clinic visit, clean it with warm water and put it back in your vagina.
- ☐ If you have any problems putting the ring back in your vagina, call or come to the clinic.

☐ **Contact study staff if you have any questions or need another study vaginal ring between visits.**

☐ **The study staff are here to help and support you. Please contact us if you have:**

- ☐ Problems inserting the vaginal ring
- ☐ Any other problems (such as partner or family issues)

Comments:

Signature/Date: _____

Contraceptive Counseling

☐ **What method of contraception are you currently using?**

☐ **Have you experienced any problems with your current form of contraception?**

☐ **Do you plan to continue using this method throughout study participation?**

Comments:

Signature/Date: _____

Section Appendix 12-1c
4-Week and 8-Week Follow-up Visit Counseling Checklist

PTID: _____ Visit Code: _____ Date: _____

HIV/STI Risk Reduction Counseling

☐ **Perform HIV risk reduction counseling per site SOPs.**

☐ **Offer condoms.**

Comments:

Signature/Date: _____

Protocol Adherence Counseling

Agree to abstain from:

- ☐ Spermicide
- ☐ Diaphragms
- ☐ Vaginal medication
- ☐ Sex toys
- ☐ Lubricants
- ☐ Condoms that contain silicone
- ☐ Menstrual cup or douching

Comments:

Signature/Date: _____

Product Use Adherence Counseling

☐ **Assess adherence to study product use since the last counseling session based on participant report**

☐ **Discuss challenges with product use adherence**

☐ **Reinforce key adherence messages**

- ☐ Wash your hands thoroughly before and after study product insertion and/ or removal.
- ☐ Try not to remove the ring for the entire 12 week period of the vaginal ring regimen except as directed during study visits, even during menses.
  - o If the ring accidentally comes out of your vagina before your next clinic visit, clean it with warm water and put it back in your vagina.
  - o If you have any problems putting the ring back in your vagina, call or come to the clinic.
- ☐ Contact study staff if you have any questions or need another study vaginal ring between visits.

☐ **The study staff are here to help and support you. Please contact us if you have:**

- ☐ Problems inserting the vaginal ring
- ☐ Any other problems (such as partner or family issues)

Comments:

Signature/Date: _____

Contraceptive Counseling

☐ **What method of contraception are you currently using?**

☐ **Have you experienced any problems with your current form of contraception?**

☐ **Do you plan to continue using this method throughout study participation?**

Comments:

Signature/Date: _____

Section Appendix 12-1d
12-Week Follow-up Visit Counseling Checklist

PTID: _____ Visit Code: _____ Date: _____

HIV/STI Risk Reduction Counseling

☐ **Perform HIV risk reduction counseling per site SOPs.**

☐ **Offer condoms.**

Comments:

Signature/Date: _____

Protocol Adherence Counseling

Agree to abstain from:

- ☐ Spermicide
- ☐ Diaphragms
- ☐ Vaginal medication
- ☐ Sex toys
- ☐ Lubricants
- ☐ Condoms that contain silicone
- ☐ Menstrual cup or douching

Comments:

Signature/Date: _____

Contraceptive Counseling

☐ **What method of contraception are you currently using?**

☐ **Have you experienced any problems with your current form of contraception?**

☐ **Do you plan to continue using this method throughout study participation?**

Comments:

Signature/Date: _____

Section Appendix 12-1e
16-Week/ Study Termination Visit Counseling Checklist

PTID: _____ Visit Code: _____ Date: _____

HIV/STI Risk Reduction Counseling

☐ **Perform counseling per site SOPs:**
- ☐ **HIV pre-test counseling**
- ☐ **HIV post-test counseling**
- ☐ **HIV risk reduction counseling**

☐ **Offer condoms.**

Comments:

Signature/Date: _____

Contraceptive Counseling

☐ **What method of contraception are you currently using?**

☐ **Have you experienced any problems with your current form of contraception?**

☐ **Do you plan to continue using this method after study participation?**

Comments:

Signature/Date: _____

Section Appendix 12-1f
Interim Visit Counseling Checklist

PTID: _____ Visit Code: _____ Date: _____

HIV/STI Risk Reduction Counseling
(if indicated)

☐ **Perform HIV risk reduction counseling per site SOPs.**

☐ **Offer condoms.**

Comments:

Signature/Date: _____

Protocol Adherence Counseling
(if indicated)

Agree to abstain from:
- ☐ Spermicide
- ☐ Diaphragms
- ☐ Vaginal medication
- ☐ Sex toys
- ☐ Lubricants
- ☐ Condoms that contain silicone
- ☐ Menstrual cup or douching

Comments:

Signature/Date: _____

Product Use Adherence Counseling
(if indicated)

☐ **Assess adherence to study product use since the last counseling session based on participant report**

☐ **Discuss challenges with product use adherence**

☐ **Reinforce key adherence messages**
- ☐ Wash your hands thoroughly before and after study product insertion and/ or removal.
- ☐ Try not to remove the ring for the entire 12 week period of the vaginal ring regimen except as directed during study visits, even during menses.
  - o If the ring accidentally comes out of your vagina before your next clinic visit, clean it with warm water and put it back in your vagina.
  - o If you have any problems putting the ring back in your vagina, call or come to the clinic.
- ☐ Contact study staff if you have any questions or need another study vaginal ring between visits.

☐ **The study staff are here to help and support you. Please contact us if you have:**
- ☐ Problems inserting the vaginal ring
- ☐ Any other problems (such as partner or family issues)

Comments:

Signature/Date: _____

Contraceptive Counseling
(if indicated)

☐ **What method of contraception are you currently using?**

☐ **Have you experienced any problems with your current form of contraception?**

☐ **Do you plan to continue using this method throughout study participation?**

Comments:

Signature/Date: _____