

Section 12. Counseling Considerations

This section contains guidance on the following types of counseling provided in MTN-003: HIV 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.

12.1 HIV Counseling

HIV testing is required at each scheduled MTN-003 study visit except the Screening Part 2 visit. HIV pre-test and post-test counseling is therefore required at each visit except the Screening Part 2 visit. Risk reduction counseling is required per protocol at each scheduled visit. As part of risk reduction counseling, both male and female condoms should be offered to all study participants and skills building should be provided to ensure participant understanding of correct condom use. Referrals also should be provided when indicated. The sample HIV Counseling Worksheet provided in Section Appendix 12-1 provides a guide to the minimum requirements for MTN-003 HIV counseling sessions; this worksheet may be tailored for use at all study sites. It is generally expected that detailed counselors notes will be required on the second page of the worksheet, in addition to completing the first page, in order 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 algorithms in protocol Appendices II and III. Additional information on HIV testing during screening and follow-up is provided in Sections 4.2.6 and 6.6 of this manual respectively; further information on interpretation of screening and follow-up test results is provided in Table 12-1a and Table 12-1b. These informational resources should be referenced as needed when providing pre-test and post-counseling.

Given that HIV counseling will be provided at nearly all MTN-003 study visits, when providing pre-test and post-counseling in particular, care should be taken to avoid rote repetition of the same information at each counseling session. 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. In the context of repeated HIV-negative test results, care should also be taken to dispel any misconceptions related to the unknown effectiveness of the study products for prevention of HIV infection and the importance of using condoms to avoid infection.

Table 12-1a
 Interpretation of HIV Tests Performed During SCREENING
 Per Protocol Appendix II

| Test Result | Interpretation |
|---|--|
| Both rapid tests negative | HIV-uninfected; test results indicate that you are not infected with HIV. |
| Both rapid tests positive | HIV-infected; test results indicate that you are infected with HIV. |
| Discordant rapid tests (one negative, one positive) | HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status. |
| Western blot negative | HIV-uninfected; test results indicate that you are not infected with HIV. |
| Western blot positive | HIV-infected; test results indicate that you are infected with HIV. |
| Western blot indeterminate | HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status. |

Table 12-1b
 Interpretation of HIV Tests Performed During FOLLOW-UP
 Per Protocol Appendix III

| Test Result | Interpretation |
|--|--|
| All rapid tests negative | HIV-uninfected; test results indicate that you are not infected with HIV. |
| One rapid test negative | HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status. |
| Two rapid tests positive | HIV-infected; test results indicate that you are infected with HIV; however, additional testing is needed for study purposes. |
| Sample 1 Western blot 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 AND HIV viral load negative (below limit of detection) | HIV-uninfected; test results indicate that you are not infected with HIV. |
| Sample 1 Western blot negative or indeterminate AND HIV viral load positive (above limit of detection) | 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 positive | HIV-infected; test results indicate that you are infected with HIV. |
| 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. |

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. The sample HIV Counseling Worksheet in Section Appendix 12-1 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 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 and female 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.

12.2 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-003 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, in addition to standard information on how each method is taken or administered, mechanism of action, and level of effectiveness, information on the potential advantages and disadvantages of each method should be provided in the context of daily use of a study product. It is generally expected that longer-acting methods will be optimal for many study participants, to minimize adherence burden. However, for some participants, it is possible that adherence to both contraception and study product could be enhanced by using a daily contraceptive method.

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 a highly 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 24 months should not enroll in the study (this is part of their contraceptive choice). The study-specific informed consent support booklet and table top flip chart may be useful for explaining and/or reinforcing these concepts during counseling.

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 highly effective 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. While it is generally expected that detailed counselors notes will be required to document counseling sessions, use of flow sheets similar to the sample shown in Section Appendix 12-2 may be useful to track contraception counseling issues over time. All sites are strongly encouraged to use flags or flyers in participant study charts to highlight contraception issues requiring follow-up at subsequent visits.

12.3 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 oral tablets or vaginal gel — receive their first dispensing of study product, be provided with product use instructions, and complete their first product use at the study clinic.

12.3.1 Product Use Instructions

After being informed of their random assignments, participants will receive their first dispensing of study product and then be provided with detailed product use instructions.

Product use instructions will be provided based on the instructions sheets shown in Section Appendices 12-3a and 12-3b, which have been translated into local languages 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 tablet bottles, sample applicators, sample applicator cartons, pelvic models, product photographs, and the study-specific fact sheets, informed consent support booklet, and table-top flip chart, 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. The sample Enrollment Visit Checklist in Section 7 of this manual includes items to record this information (#36-37).

12.3.2 First Product Use

All study participants will complete their first use of their assigned study product at the study clinic during their enrollment visits. The rationale for this is to help ensure participant understanding, comfort, and confidence with proper product use from the very beginning of study participation. In particular, any questions or concerns that arise in the context of first product use can be addressed by study staff before the participant is required to use study product on her own between her enrollment visit and her first follow-up visit.

After providing product use instructions and answering any questions the participant may have, study staff will ask the participant if she is ready to try taking her tablets or inserting her gel. 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 continue with her first product use:

For participants assigned to gel, first insertion should be performed in a private space, with study staff standing by in case the participant requests guidance or technical assistance; study staff should also remind the participant to discard her used wrapper and applicator in the bin provided. Study staff may also provide the participant with a panty liner and remind her of what to expect with regard to possible gel leakage.

For participants assigned to tablets, a private space is not required; study staff should remind the participant to leave the desiccant inside the bottles but discard the bottle seals and cotton wool in the bin provided.

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 in the product use steps to ensure that the participant is able to perform each step herself before she leaves the clinic.

For participants assigned to gel, inability to insert gel is expected to be rare. For participants who have difficulty, study staff should provide further information and guidance to address the difficulty encountered and provide one or more empty applicators for additional hands-on practice by the participant. After guidance is provided, and further practice takes place, the participant should try again to insert gel at the enrollment visit. Throughout this process, study staff should avoid handling dispensed gel supplies.

For participants assigned to tablets, inability to swallow tablets is expected to be rare. For participants who have difficulty, study staff should advise the participant to:

- Take a sip of water and relax
- Place the tablet at the back of the tongue and swallow it with water or juice
- Try drinking water or juice with a straw

After guidance is provided, the participant should try again to take tablets at the enrollment visit. Throughout this process, study staff should avoid handling dispensed tablet supplies.

For all participants, if more than one gel applicator, or more than one of either tablet is used at the enrollment visit, study staff must document this in chart notes and must also inform pharmacy staff, so this information can be taken into account when accounting for the participant's study product supplies at her next study visit.

After the participant completes her first product use, but before proceeding to adherence counseling, study staff should de-brief with the participant on her first product use experience. The sample Enrollment Visit Checklist in Section 7 of this manual includes an item (#39) to guide the de-briefing and record any questions, problems or concerns raised by the participant. Any such issues raised by the participant should be documented so the information is easily available for reference at study follow-up visits.

12.3.3 Adherence Counseling

Study product adherence counseling will be provided at the enrollment visit per the Enrollment Adherence Counseling Checklist shown in Section Appendix 12-4. At each enrollment visit, counseling will be provided on each the 10 key messages listed below.

- 1. Insert one applicator or take one lighter tablet and one darker tablet every day.**
 - As close as possible to the same time every day
 - Even on days when you do not have sex
 - Even on days during menses
- 2. If you miss a dose, insert gel or take tablets as soon as you remember, but skip the missed dose if your next dose is due within 6 hours.**
- 3. Keep your product supplies in your possession.**
 - Do not remove labels from your cartons or bottles
 - Avoid mix-ups with others at the clinic and at home
 - Carry your supplies yourself
 - Discuss with study staff if cannot carry all supplies dispensed at once
 - Discuss with study staff if you usually travel to and from the clinic with other women or if more than one woman in your household is in the study
- 4. At home, keep your product supplies in a secure dry place, out of the sun and safe from children.**
- 5. Contact study staff if you have any questions or need more product between visits.**
- 6. If you will be away, tell study staff in advance and take product with you.**

7. Do not share your product and do not use other women's product.

- This will make it difficult to learn whether the products are safe and effective for preventing HIV
- This could be harmful [refer to resistance fact sheet as needed]

If assigned to tablets:

- It is very important to remember that the tablets given to you for this study are being tested to see if they prevent getting HIV. The tablets should not be used as treatment for people with HIV. As we have discussed, we do not know which tablets you are receiving (tenofovir, Truvada or placebo) and also, 3 ARV medicines are needed to properly treat HIV. If someone who has HIV takes your study tablets, this could be harmful for them. Therefore, please do not share tablets with anyone.

8. Bring all remaining product to all clinic visits.

- Supplies will be counted at pharmacy
- To help account for all supplies used in the study
- To help understand how participants are doing with using their product
- To help clinic and pharmacy staff provide the best possible counseling to address any difficulties

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

- Problems inserting gel or taking tablets
- Problems keeping your gel or tablets for your use only
- Any other problems (such as partner or family issues)

10. Remember, to properly test if the gel or tablets prevent getting HIV, it is very important that women in the study use the gel or tablets they are given every day.

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 sample tablet bottles, sample applicators, sample applicator cartons, pelvic models, product photographs, and the study-specific fact sheets, informed consent support booklet, and table-top flip chart 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 gel or taking tablets as directed every day. Given the amount of information, instructions, and counseling provided at the enrollment visit, the counselor should also reassure the participant that she will be capable of doing what she is being asked to do and that study staff are available to help and support her. She is therefore 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.

12.4 Study Product Adherence Counseling — Follow-up

Study product adherence counseling is required at all scheduled follow-up visits. At follow-up visits, the client-centered counseling approach initiated at the enrollment visit should continue, per the Follow-up Adherence Counseling Checklist shown in Section Appendix 12-5. Each counseling session should include the following components:

- Assess adherence to study product use since the last counseling session based on participant report (checklist items #1-5)
- Review unused product count; discuss with participant as needed and assess adherence to study product based on all available information (checklist item #6)
- Provide adherence counseling and develop adherence plan/strategies for the coming month (checklist items #7-8)
- Reinforce key adherence messages (checklist item #9):
- Document the counseling session (checklist items #10-12 plus counselors notes).

Each of the five components listed above is reflected in the Follow-up Adherence Counseling Checklist, together with further guidance for counselors. Note that pages 1 and 3 of the checklist are used consistently with all participants, whereas three different versions of page 2 of the checklist are available. For this page, the version that is consistent with each participant's current level of adherence should be used.

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 overall structure of the checklist and the key adherence counseling messages should not be modified. Further guidance for use of the checklist is provided below.

- Always review documentation of previous adherence counseling sessions in preparation for a new counseling session. Similarly review the participant's returned product count information (received from the pharmacy) in preparation for a new counseling session.
- At the beginning of each session, emphasize the importance of open communication about study product use.

- Use open-ended questions and probes to assess the participant’s self-reported adherence since her last counseling session. Note whether the participant reports having used her study product all of the time, most of the time, some of the time, or not at all. The purpose of categorizing the participant’s level of adherence is to guide the adherence counseling that she will receive (and not to numerically quantify her product use).
- When assessing adherence in relation to the participant’s returned product count, if discrepancies are identified between the product count and the participant’s self-reported level of adherence, use a neutral and non-judgmental approach to probe and clarify the discrepancies with the participant. The intent of this discussion is not to “catch” the participant but rather to better understand her actual product use so that effective counseling can be provided to her.
- When providing adherence counseling:
 - Include positive reinforcement whenever possible and ask the participant to share any successful strategies that she thinks might work well for other participants.
 - Review and discuss with the participant the adherence plan and strategies identified at her last session and probe as needed for additional information on any current barriers to daily product use. Successful strategies should be continued, but for ongoing or new barriers, additional or alternative strategies may be needed.
 - When needed, review product use 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.
 - Take as much time as is needed to work with the participant in a client-centered manner to identify operational plans and strategies to assist her in inserting gel or taking tablets as directed every day. Plans and strategies should be practical, yet challenge the participant toward high levels of adherence. For participants whose adherence barriers may be significant, plans and strategies may need to be incremental. For participants whose adherence barriers change over time, adherence plans and strategies may need to change over time. Importantly, all plans and strategies 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.

- Reinforce key adherence counseling messages at each session:
 1. **Insert one applicator or take one lighter tablet and one darker tablet every day.**
 - As close as possible to the same time every day
 - Even on days when you do not have sex
 - Even on days during menses

Remember, to properly test if the gel or tablets prevent getting HIV, it is very important that women in the study use the gel or tablets they are given every day.
 2. **Keep your gel or tablets in your possession. At home, keep them in a secure dry place, out of the sun and safe from children.**
 3. **Do not share your gel or tablets with anyone else and do not use other women's gel or tablets.**
 4. **Bring all remaining gel or tablets to all clinic visits.**
 5. **Contact study staff to tell us if you have any questions or problems or need more gel or tablets before your next visit. Likewise, if you will be away, tell study staff in advance and take gel or tablets with you.**
- 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 12-1
Sample HIV Counseling Worksheet

Sample MTN-003 HIV Counseling Worksheet

PTID:

Visit Code:

General

- Greet client and establish rapport
- Review purpose and nature of today's session
- Emphasize confidentiality
- Address any immediate issues or concerns

HIV Education and Pre-Test Counseling

- Review difference between HIV and AIDS
- Review modes of HIV transmission and methods of prevention
- Review HIV tests to be done today and tests to be done if today's tests indicate possible infection
- Review window period and how it may affect test results
- Correct any misconceptions or myths
- Verify readiness for testing

HIV Post-Test Counseling

- Provide and explain test results
- Explain additional testing that may be required per protocol
- Assess client understanding of results and next steps
- Provide further information and counseling relevant to client's test results per site SOP

Risk Assessment

- Use open-ended questions to assess client's HIV risk factors
- Discuss whether risk factors have changed since the last visit
- Probe on factors associated with higher versus lower risk (e.g., what was different about the times when you were able to use a condom compared to times when you were not?)

Main Risk Factors and Barriers to Risk Reduction

Risk Reduction Plan — Experience and Outcomes Since Last Month

Risk Reduction Plan — Strategies for the Coming Month

Sample MTN-003 HIV Counseling Worksheet

| | |
|--------------|--------------------|
| PTID: | Visit Code: |
|--------------|--------------------|

Additional Notes:

Staff Initials and Date

Section Appendix 12-2
Sample Contraception Counseling Flowsheet

Sample MTN-003 Contraception Flow Sheet

PTID:

Page:

| | | | |
|--|--|--|--|
| Visit Date | | | |
| Visit Code | | | |
| Review participant's reproductive history documentation and previous entries on this flow sheet to inform and guide contraceptive counseling provided at each visit. | | | |
| Current contraceptive method | | | |
| Contraceptive issues/questions/ concerns discussed at this visit | | | |
| Issues to follow up at next visit | | | |
| Scheduled date of next contraceptive prescription (or NA) | | | |
| Scheduled date of next contraceptive injection (or NA) | | | |
| Initials and Date | | | |

Section Appendix 12-3a
MTN-003 Tablet Use Instructions

How to Take Tablets



1. You will receive 2 bottles of tablets. One bottle is larger than the other bottle. The tablets in the larger bottle are a darker color than the tablets in the smaller bottle. Take 1 tablet from each bottle, at the same time every day.



2. After washing your hands, open the bottles by pushing the cap down while turning to the left.



4. There is a sealed container inside each bottle that helps keep the tablets dry. Do not open this container, swallow it, or remove it from the bottle.



7. Next, do the same to remove one tablet from the other bottle.



3. The first time each bottle is opened, there will be a seal covering the bottle. Remove and discard this seal. Inside the smaller bottle, there will be cotton wool. Remove and discard this cotton wool.



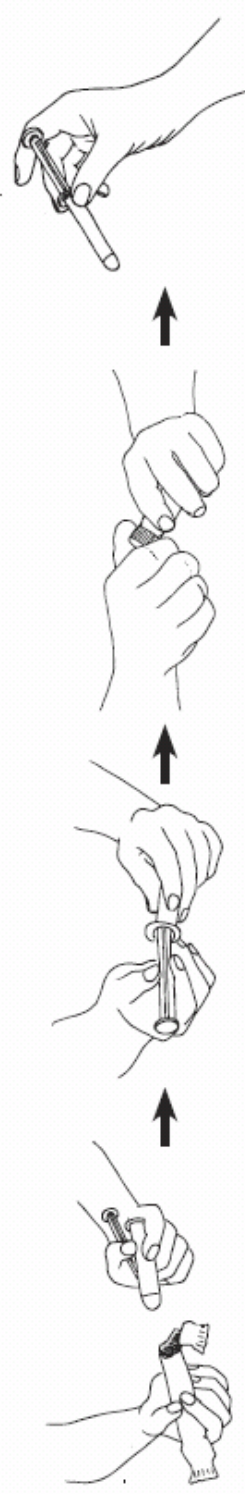
6. Then close this bottle tightly by replacing the cap and turning it to the right.



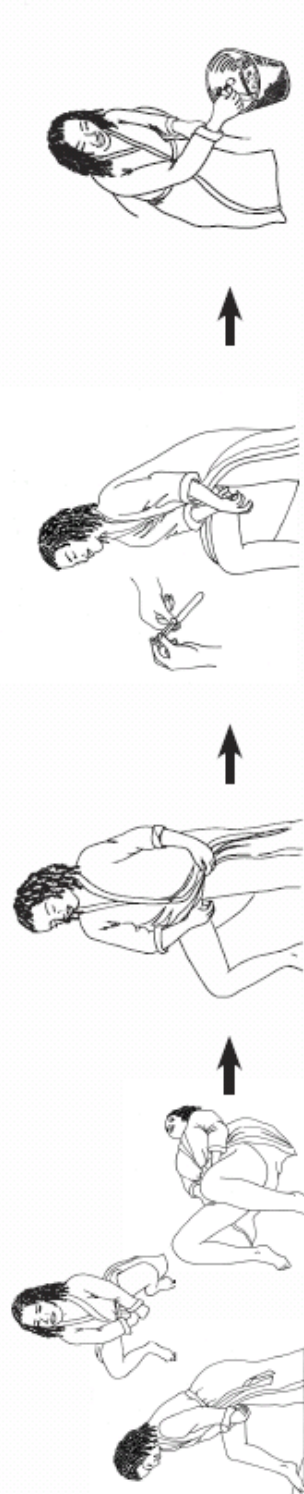
9. Put one tablet in your mouth and swallow it with water or other beverage. Then do the same with the other tablet. Or, if you wish, you may swallow both tablets at the same time.

Section Appendix 12-3b
MTN-003 Gel Use Instructions

How to Insert Gel



1. After washing your hands, tear open the wrapper. Remove the applicator and plunger.
2. Place the small end of the plunger in the hole at the back end of the applicator (opposite the blue cap).
3. Unscrew the blue cap.
4. Hold the applicator with your thumb and middle finger at the grooves on the applicator.



5. Choose a comfortable position for inserting the applicator, for example standing with one leg raised, squatting with your feet apart, or lying on your back with your knees apart.
6. Fold back the skin that covers the opening of your vagina with your other hand. Gently slide the applicator into your vagina as far as it will go comfortably or until your fingers touch your body. The plunger should stay outside your body.
7. While holding the applicator in place with one hand, push the plunger all the way into the applicator with the other hand. Or, while holding the applicator in place, use your forefinger to push the plunger all the way into the applicator.
8. After the plunger has been pushed all the way into the applicator, gently slide the applicator out of the vagina. Discard the wrapper, applicator and blue cap.

Section Appendix 12-4
Enrollment Adherence Counseling Checklist

| | |
|---|--------------------|
| PTID: | Visit Date: |
| | |
| <p><input type="checkbox"/> 1. Insert one applicator or take one lighter tablet and one darker tablet every day.</p> <ul style="list-style-type: none"> • As close as possible to the same time every day • Even on days when you do not have sex • Even on days during menses <p><i>How might you plan to do this? At what time do you think you will insert gel or take tablets each day? Is there an activity you do every day that might help you to remember to insert gel or take tablets every day?</i></p> <p><i>If assigned to gel: You might find that some gel leaks out after insertion. This is normal. Because of this, you may want to use panty liners which we can give you. You also may want to consider inserting gel at bedtime. You should also consider when you and your partner usually have sex, as this could help determine when you would like to insert gel (explore advantages and disadvantages).</i></p> <hr/> <hr/> <hr/> <hr/> | |
| <p><input type="checkbox"/> 2. If you miss a dose, insert gel or take tablets as soon as you remember, but skip the missed dose if your next dose is due within 6 hours.</p> <p><i>Example: Let's say you usually take your dose at about 6:00 pm (around dinner time). If you forget to take a dose, and realize this when you wake up at about 6:00 am the next day, you should take the missed dose immediately, because there are about 12 hours left before the time of your next dose. On the other hand, if you did not realize that you missed a dose until your children come home from school, at about 3:00 pm, you should skip the missed dose, because there are only about 3 hours left before the time of your next dose.</i></p> | |
| <p><input type="checkbox"/> 3. Keep your product supplies in your possession.</p> <ul style="list-style-type: none"> • Do not remove labels from your cartons or bottles • Avoid mix-ups with others at the clinic and at home • Carry your supplies yourself • Discuss with study staff if cannot carry all supplies dispensed at once • Discuss with study staff if you usually travel to and from the clinic with other women or if more than one woman in your household is in the study | |
| <p><input type="checkbox"/> 4. At home, keep your product supplies in a secure dry place, out of the sun and safe from children.</p> <p><i>How might you plan to do this? Where do you think you will keep your supplies?</i></p> <hr/> <hr/> <hr/> <hr/> | |

| | |
|---|--------------------|
| PTID: | Visit Date: |
| | |
| <input type="checkbox"/> 5. Contact study staff if you have any questions or need more product between visits. | |
| <input type="checkbox"/> 6. If you will be away, tell study staff in advance and take product with you. | |
| <input type="checkbox"/> 7. Do not share your product and do not use other women's product. <ul style="list-style-type: none"> • This will make it difficult to learn whether the products are safe and effective for preventing HIV • This could be harmful [refer to resistance fact sheet as needed] <p>If assigned to tablets:</p> <ul style="list-style-type: none"> • It is very important to remember that the tablets given to you for this study are being tested to see if they prevent getting HIV. The tablets should not be used as treatment for people with HIV. As we have discussed, we do not know which tablets you are receiving (tenofovir, Truvada or placebo) and also, 3 ARV medicines are needed to properly treat HIV. If someone who has HIV takes your study tablets, this could be harmful for them. Therefore, please do not share tablets with anyone. | |
| <input type="checkbox"/> 8. Bring all remaining product to all clinic visits. <ul style="list-style-type: none"> • Supplies will be counted at pharmacy • To help account for all supplies used in the study • To help understand how participants are doing with using their product • To help clinic and pharmacy staff provide the best possible counseling to address any difficulties | |
| <input type="checkbox"/> 9. The study staff are here to help and support you. Please contact us if you have: <ul style="list-style-type: none"> • Problems inserting gel or taking tablets • Problems keeping your gel or tablets for your use only • Any other problems (such as partner or family issues) | |
| <input type="checkbox"/> 10. Remember, to properly test if the gel or tablets prevent getting HIV, it is very important that women in the study use the gel or tablets they are given every day. | |

Section Appendix 12-5
Follow-up Adherence Counseling Checklist

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| PTID: | Visit Code: |
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| <input type="checkbox"/> 1. Greet participant and establish rapport. | |
| <input type="checkbox"/> 2. Explain the purpose and nature of today’s session. <i>Example: In this part of your visit today, we are here to talk about how you have been doing since your last visit with [inserting gel] / [taking tablets]. We will also talk about strategies for [inserting gel] / [taking tablets] between today and your next visit. To make the most of our time together, I would like to ask that you share your feelings and experiences as openly and freely as you can. I will also speak freely with you.</i> | |
| <input type="checkbox"/> 3. Ask participant about her study product use since her last visit. Listen to her response then probe for more information to fully understand her experience and reported level of adherence. <i>Example: To begin, can you tell me, what has been your experience with [inserting gel] / [taking tablets] since your last visit?</i> <i>Example probes:</i> <ul style="list-style-type: none"> • How often have you been able to [insert gel] / [take both of your tablets]? • When do you usually [insert gel] / [take your tablets]? Do you have a usual time during the day or evening/night? [If applicable] Do you usually take both of your tablets at the same time? • At your last visit, the plans/strategies that we wrote down for you to try included [specify]. Did you try these plans/strategies? Did they work for you? • Did you have any challenges with [inserting gel] / [taking both of your tablets] every day? If yes, how did you address these challenges? • [If she reports perfect adherence]: Was there even one day when you may have forgotten or were not able to [insert gel] / [take your tablets]? <p>Brief notes (document in detail at end of session)</p> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> | |
| 4. BASED ON HER REPORT, participant has been using study product (mark one): <input type="checkbox"/> All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> Not at all | |
| 5. Does participant’s product count coincide with her reported product use? <input type="checkbox"/> Yes ⇒ Skip to #6 <input type="checkbox"/> No ⇒ Summarize what the product count indicates and explain your interpretation to participant. Probe to clarify discrepancies, using a neutral and non-judgmental approach. <i>Example: Today you returned 8 unused [applicators] / [tablets]. If we count up the number of days since your last visit, and how many [applicators] / [tablets] you were given at your last visit, this would seem to indicate that you did not [insert gel] / [take tablets] on about [X] days since your last visit. This seems to differ from what we just talked about. Can you explain or help me to understand this difference? Is it possible you have forgotten some times when you were not able to [insert gel] / [take tablets]?</i> <p>Brief notes (document in detail at end of session)</p> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> <p><i>Example: Thank you for working through that with me. It is very helpful to understand your experiences.</i></p> | |
| 6. BASED ON ALL OF THE ABOVE, participant has been using study product (mark one): <input type="checkbox"/> All of the time <input type="checkbox"/> Most of the time <input type="checkbox"/> Some of the time <input type="checkbox"/> Not at all | |

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| PTID: | Visit Code: |
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| Adherence Counseling #6 = All of the Time | |
| <input type="checkbox"/> 7. Provide adherence counseling. <i>Counseling should include positive reinforcement, discussion of effective adherence strategies, and planning for the next month. For example:</i> <ul style="list-style-type: none"> • You have been doing a great job [inserting gel] / [taking tablets] every day. • Well done and keep it up! • I would like to know, what helps you to be able to [insert gel] / [take tablets] every day? • Do you have strategies that you would recommend for other women in the study? <p>Brief notes (document in detail at end of session):</p> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> | |
| <input type="checkbox"/> 8. Develop adherence plan/strategies for the coming month. Work with the participant to identify one or more strategies to help her maintain high levels of adherence. <p><i>Example: Based on what we have talked about, you are doing very well with [inserting gel] / [taking tablets]. I would like to write down some strategies that you can use to help make sure you also do well between today and your next visit. Do you foresee any changes or challenges over the next month? What do you think your strategies should be?</i></p> <p>Brief notes (document in detail at end of session):</p> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> | |
| 9. Reinforce key adherence messages: <ul style="list-style-type: none"> <input type="checkbox"/> Insert one applicator or take one lighter tablet and one darker tablet every day. <ul style="list-style-type: none"> • As close as possible to the same time every day • Even on days when you do not have sex • Even on days during menses <p>Remember, to properly test if the [gel] / [tablets] prevent getting HIV, it is very important that women in the study use the [gel] / [tablets] they are given every day.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Keep your [gel] / [tablets] in your possession. At home, keep them in a secure dry place, out of the sun and safe from children. <input type="checkbox"/> Do not share your [gel] / [tablets] with anyone else and do not use other women's gel or tablets. <input type="checkbox"/> Bring all remaining [gel] / [tablets] to all clinic visits. <input type="checkbox"/> Contact study staff to tell us if you have any questions or problems or need more [gel] / [tablets] before your next visit. Likewise, if you will be away, tell study staff in advance and take [gel] / [tablets] with you. | |
| <input type="checkbox"/> 10. Confirm all participant questions/issues/problems have been addressed, then close the session. Document any questions/issues/problems discussed at end of session. <p><i>Example: Do you have any questions? Is there anything else you would like to talk about today?</i></p> <p><i>Example: Thank you once again. We will be looking forward to seeing you at your next visit.</i></p> | |

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| PTID: | Visit Code: |
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| Adherence Counseling #6 = <u>Most</u> or <u>Some</u> of the Time | |
| <input type="checkbox"/> 7. Provide adherence counseling. <i>Counseling should include positive reinforcement, probing, and follow-up on issues/problems/barriers that are preventing higher levels of adherence. For example:</i> | |
| <ul style="list-style-type: none"> • You have done well with [inserting gel] / [taking tablets] on [most OR some] days since your last visit. Can you tell me about the days when you did [insert gel] / [take tablets]? What helped you to be able to [insert gel] / [take tablets] on those days? • Did you try the strategies discussed at your last visit? Were they useful? Which ones? • Are there strategies you would recommend for other women in the study? • Now let us talk about the days when you did not able to [insert gel] / [take tablets]? What was different about those days? Was there one main reason why you were not able to [insert gel] / [take tablets] on those days? Were there other reasons? | |
| Brief notes (document in detail at end of session): <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> | |
| <input type="checkbox"/> 8. Develop adherence plan/strategies for the coming month. Work with the participant to identify her barriers to daily product use and strategies to overcome these. | |
| Brief notes (document in detail at end of session): <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> | |
| <i>Example: You have come up with some good strategies to try between now and the next month. I will write them down so you can tell us how they worked for you at your next visit.</i> | |
| 9. Reinforce key adherence messages: | |
| <input type="checkbox"/> Insert one applicator or take one lighter tablet and one darker tablet every day. <ul style="list-style-type: none"> • As close as possible to the same time every day • Even on days when you do not have sex • Even on days during menses | |
| Remember, to properly test if the [gel] / [tablets] prevent getting HIV, it is very important that women in the study use the [gel] / [tablets] they are given every day. | |
| <input type="checkbox"/> Keep your [gel] / [tablets] in your possession. At home, keep them in a secure dry place, out of the sun and safe from children. | |
| <input type="checkbox"/> Do not share your [gel] / [tablets] with anyone else and do not use other women's gel or tablets. | |
| <input type="checkbox"/> Bring all remaining [gel] / [tablets] to all clinic visits. | |
| <input type="checkbox"/> Contact study staff to tell us you have any questions or problems or need more [gel] / [tablets] before your next visit. Likewise, if you will be away, tell study staff in advance and take [gel] / [tablets] with you. | |
| <input type="checkbox"/> 10. Confirm all participant questions/issues/problems have been addressed, then close the session. Document any questions/issues/problems discussed at end of session. | |
| <i>Example: Do you have any questions? Is there anything else you would like to talk about today?</i> | |
| <i>Example: Thank you once again. We will be looking forward to seeing you at your next visit.</i> | |

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| PTID: | Visit Code: |
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| Adherence Counseling #6 = Not At All | |
| <input type="checkbox"/> 7. Provide adherence counseling. <i>Counseling should include positive reinforcement if applicable but focus on barriers to product use. For example:</i> | |
| <ul style="list-style-type: none"> • <i>It seems that you are having issues/problems/challenges with [inserting gel] / taking tablets]. Can you tell me more about the reasons for this? What do you think is the main or most important reason?</i> • <i>[If applicable] Did you try the strategies discussed at your last visit? Were they useful? Which one?</i> • <i>[If applicable] Earlier in the study, it seems that you were able to [insert gel] / [take tablets] more consistently. What has changed since that time?</i> • <i>[If applicable] Can you tell me about any days when you did [insert gel] / [take tablets]? What made it possible for you to [insert gel] / [take tablets] on those days?</i> | |
| Brief notes (document in detail at end of session): <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> | |
| <input type="checkbox"/> 8. Develop adherence plan/strategies for the coming month. Work with the participant to identify her barriers to daily product use and strategies to overcome these. | |
| Brief notes (document in detail at end of session): <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> | |
| <i>Example: You have come up with some good strategies to try between now and the next month. I will write them down so you can tell us how they worked for you at your next visit.</i> | |
| 9. Reinforce key adherence messages: | |
| <input type="checkbox"/> Insert one applicator or take one lighter tablet and one darker tablet every day. <ul style="list-style-type: none"> • As close as possible to the same time every day • Even on days when you do not have sex • Even on days during menses | |
| Remember, to properly test if the [gel] / [tablets] prevent getting HIV, it is very important that women in the study use the [gel] / [tablets] they are given every day. | |
| <input type="checkbox"/> Keep your [gel] / [tablets] in your possession. At home, keep them in a secure dry place, out of the sun and safe from children. <input type="checkbox"/> Do not share your [gel] / [tablets] with anyone else and do not use other women's gel or tablets. <input type="checkbox"/> Bring all remaining [gel] / [tablets] to all clinic visits. <input type="checkbox"/> Contact study staff to tell us you have any questions or problems or need more [gel] / [tablets] before your next visit. Likewise, if you will be away, tell study staff in advance and take [gel] / [tablets] with you. | |
| <input type="checkbox"/> 10. Confirm all participant questions/issues/problems have been addressed, then close the session. Document any questions/issues/problems discussed at end of session. | |
| <i>Example: Do you have any questions? Is there anything else you would like to talk about today?</i> | |
| <i>Example: Thank you once again. We will be looking forward to seeing you at your next visit.</i> | |

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11. Adherence Challenges/Barriers:

12. Adherence Plan/Strategies:

Additional Counselors Notes:
