Section 10. Counseling Procedures

10. Introduction 10-1
10.1 HIV Pre-and Post-Test Counseling 10-1
Table 10-1 Interpretation of HIV Test Results at Screening and Enrollment Per Protocol Appendix II 10-2
Table 10-2 Interpretation of HIV Test Results at Follow-Up Per Protocol Appendix III 10-2
10.2 HIV/STI Risk Reduction Counseling 10-3
10.3 Contraceptive Counseling 10-4
10.4 Protocol Adherence Counseling 10-5
10.4.1 Product Adherence Counseling at Enrollment, Visit 9 and Visit 16 10-6
10.4.2 Product Adherence Counseling at All Other Follow-up Visits 10-7
10.5 Product Use in Clinic 10-8
10.6 Product Adherence Disclosure Counseling 10-9
Table 10-3 Counseling Sessions with Drug Level Feedback 10-9
10.7 Documentation of Adherence Counseling 10-10
10.8 Quality Assurance and Mentorship for Counselors 10-11
Appendix 10-1 Secondary Prevention and Risk Reduction Counseling with HIV Positive Participants 10-12

10. Introduction

This section contains guidance on the following types of counseling provided in MTN-034: HIV pre/post-test counseling, HIV/STI risk reduction counseling, contraceptive counseling, protocol adherence counseling, and product adherence disclosure counseling.

All counseling should be provided in a non-judgmental, client-centered manner that responds to 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 is to allow for appropriate tailoring and targeting to an individual participant's needs at a given point. To support continuity in the ongoing client-centered counseling over time, documentation of each counseling session should include sufficient participant-specific 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 by using counseling worksheets, visit checklists and/or chart notes.

The following sample counseling worksheets are available on the MTN-034 website: HIV testing, HIV/STI risk reduction, contraceptive counseling, and product adherence counseling.

10.1 HIV Pre-and Post-Test Counseling

HIV testing is required at Screening, Enrollment, and all regularly scheduled monthly visits through Visit 23/Product Use End Visit. HIV pre-test and post-test counseling is required at visits when HIV testing is required or when performed if clinically indicated. Referrals should be provided when indicated. Sites are required to develop and follow SOPs for HIV testing and counseling considerations.

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. Further information on interpretation of screening and follow-up test results is provided in Tables 10-1 and 10-2 below. These 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 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 10-1 Interpretation of HIV Test Results at Screening and Enrollment Per Protocol Appendix II

Test Result	Interpretation
Two HIV rapid tests negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Two HIV rapid tests positive	You are not eligible for the study. Test results indicate that you may be infected with HIV. Note: Additional post-test counseling and referrals should be provided.
Discordant HIV rapid tests	You are not eligible for the study. HIV status not clear; additional testing is needed to determine your status.

Note: Confirmatory testing on positive or discordant rapid tests at Screening and Enrollment is not required per protocol. However, common guidance from the MTN LC will be to perform confirmatory testing if the participant wishes. Additional post-test counseling and referrals should be provided as necessary.

Table 10-2 Interpretation of HIV Test Results at Follow-Up Per Protocol Appendix III

Test Result	Interpretation
Two HIV rapid tests negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Two HIV rapid tests positive	1. Test results indicate that you may be infected with HIV. 2. Additional testing will be done today to confirm this result. 3. The testing will be done from a new blood sample and can be conducted today in our lab. 4. It is common for HIV prevention studies to do additional testing for study purposes in this situation. 5. It is unusual for the additional testing to show a different result. 6. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results.
Two HIV rapid tests discordant	1. HIV status not clear 2. Additional testing will be done today to confirm this result 3. The testing will be done from a new blood sample and can be conducted today in our lab. 4. It is common for HIV prevention studies to do additional testing for study purposes in this situation. 5. Drawing a new blood sample and running the test will take approximately [SITE TO INSERT TIME]. You may wait and receive confirmatory results today, or schedule a separate visit for results.
Confirmatory Test positive	HIV-infected; test results indicate that you are infected with HIV [Provide post-test counseling and referrals for HIV-infected participants per site SOPs.]

Confirmatory Test negative or indeterminate	HIV status not clear; additional testing is needed to determine your status.
HIV RNA negative (below limit of detection)	HIV-uninfected; test results indicate that you are not infected with HIV
HIV RNA positive (at or above limit of detection)	1. Test results show that you are infected with HIV. 2. Additional testing is needed to confirm your HIV infection for study purposes. 3. [Provide post-test counseling and referrals or follow-up on referrals previously provided as per site SOPs.] 4. This additional testing will be done from a new blood sample**.** This testing will occur *[provide date – testing should occur about 1 month after her positive rapid test(s), or when advised by the LC].* 5. It is common for HIV prevention studies to do additional testing in this situation. 6. It is unusual for the additional testing to show a different result.

A sample HIV Pre/Post-Test and Risk Reduction Counseling Worksheet is available for use on the MTN-034 Study Implementation Materials webpage. 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.

10.2 HIV/STI Risk Reduction Counseling

Risk reduction counseling is required at every scheduled in-clinic visit and may be conducted in conjunction with HIV pre/post-test counseling. As part of risk reduction counseling, condoms should be offered to all study participants, as needed.

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 in a non-judgmental manner, 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.

Counselors should support and facilitate risk reduction plans identified by the participant. These plans should reflect and respond to the participant's 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 should 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., 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 Pre/Post-Test and Risk Reduction Counseling Worksheet, which may be tailored for use, is available on the MTN-034 Study Implementation Materials webpage.

10.3 Contraceptive Counseling

Contraceptive counseling is required at Screening and Enrollment and as needed at all other study visits. All contraceptive counseling should be provided in accordance with local counseling standards, site-specific SOPs, and World Health Organization (WHO) guidance, which is available in the following resources:

- Medical Eligibility Criteria for Contraceptive Use (5th Edition, 2015): http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/
- Family Planning: A Global Handbook for Providers (WHO/USAID/Johns Hopkins Bloomberg School of Public Health, 2011): http://www.who.int/reproductivehealth/publications/family_planning/9780978856304/en/

If a participant has never used contraception before, extensive counseling and review of methods should be provided. To help participants compare different methods available to them, sites are encouraged to utilize websites, such as https://www.bedsider.org/ or others. FHI 360 will also provide sites with printed educational materials such as posters and information cards describing available contraceptive options.

At Screening and Enrollment, contraceptive counseling should be provided in the context of assessing study eligibility criteria. Per MTN-034 inclusion criteria, a potential participant must agree to use the same effective method of contraception for at least two months prior to Enrollment and maintain an effective method throughout the duration of her participation. Counseling provided at these visits should explain why contraception is required, describe methods that are acceptable for study purposes and emphasize that if she cannot commit to using one of these methods for a year and a half of follow-up, she should not enroll in the study. During the two months prior to Enrollment, she must use the *same* contraceptive method for that entire period. The goal of the two-month lead period is to allow time for the participant to become familiar with any contraceptive side effects before using study product.

Effective methods for MTN-034 participation include:

- Hormonal methods, except for the contraceptive ring
- IUD

During follow-up visits, client-centered contraceptive counseling should continue as needed. The following questions may be helpful to guide the discussion:

- How important is it to you to avoid pregnancy now?
- What would you do if you became pregnant now?

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.

Study staff who provide contraceptive counseling should be trained to do so per local practice standards and should also be trained on MTN-034 protocol specifications related to contraception. Contraception may be provided on site; however, sites may opt to refer participants to non-study providers for contraception. All sites are strongly encouraged to obtain credible medical records as part of their verification procedures for participant reported contraceptive methods.

All contraception counseling 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, potential side effects, and level of effectiveness. Long acting reversible methods should be emphasized during the counseling process as these are the most effective contraceptive methods available and are appropriate for adolescents and young women.

All contraceptive counseling sessions should be documented in participant study records. Counselor notes or counseling worksheets should be used to document key information discussed or noted during counseling sessions. All sites are encouraged to use flags or flyers in participant study charts to highlight contraception issues requiring follow-up at subsequent visits.

A sample Contraceptive Counseling Worksheet is available on the MTN-034 Study Implementation Materials webpage.

10.4 Protocol Adherence Counseling

Participants will be provided protocol adherence counseling for the first time at the Enrollment visit.

Protocol adherence counseling will also be provided at all monthly clinic visits and regularly scheduled phone contacts. Counseling will include both product adherence counseling and counseling related to protocol requirements as listed in protocol sections 6.6 and 6.7 and described below.

Protocol Requirements:

Per protocol section 6.6, study participants must refrain from engaging in prohibited practices and/or using prohibited products/medications 3 days prior to each scheduled follow up, including the Enrollment visit.

Counseling and reminders related to the protocol requirements are listed in protocol sections 6.6 and 6.7. It is recommended that protocol adherence counseling occur prior to randomization as it could be helpful to provide the participant with more information about the study requirements and study product prior to her final decision to enroll in the study. Key counseling reminders are incorporated into visit checklists; however, sites may utilize chart notes or other site-specific tool to document provision of protocol adherence counseling messages. Of note, during Screening, sites are expected to review protocol adherence requirements during the informed consent process to prepare the participant for the enrollment visit.

The purpose of this counseling is to remind participants about the requirements for the study, including:

- prohibited use of non-study vaginal products for the 3 days prior to each scheduled study follow up visit (such as, spermicides, diaphragms, vaginally applied medication, menstrual cups, cervical caps, douches, and sex toys)
- abstinence from receptive intercourse for the 3 days prior to each scheduled study follow-up visit (vaginal, anal, oral and finger stimulation)
- prohibited use of PEP and non-study provided PrEP
    - Note: Although use of PEP is prohibited per protocol, in the event a participant reports possible exposure HIV, she should be provided or referred for PEP as soon as possible,

ideally within 24-72 hours. If a participant initiates PEP, she will be placed on a temporary product hold until prophylaxis regimen is complete. See SSP section 6 for guidance on how to initiate a product hold. Upon completion of PEP use, the study participant may resume study product use per her visit schedule, after consultation with the PSRT. Counseling provided to participants regarding PEP use should not discourage PEP use if indicated after HIV exposure.

Product Adherence Counseling:

Study product adherence counseling will be provided by site staff as a component of the protocol adherence counseling to all participants. Only counselors who are certified may conduct the product adherence counseling. While any certified counselor can conduct counseling, site teams should be thoughtful about pairing counselors with participants. Sites are strongly encouraged to have participants see the same counselor at each study visit, if possible. Site teams might consider factors such as counselor age, sex, communication style, and participant requests when pairing counselors with participants. In addition, to promote an open and neutral environment, the individual staff person conducting counseling during the visit must be different than the staff person who conducts other behavioral procedures during the visit (e.g. adherence assessments, qualitative interviews, etc.). Ideally, a different cadre of staff should conduct the counseling and behavioral assessments.

Detailed guidance regarding product adherence counseling is provided in the Product Adherence Counseling Session Manuals located on the MTN-034 Study Implementation Materials webpage. Supplemental adherence counseling support tools, which are referenced during each product adherence counseling session are available on the MTN-034 Study Implementation Materials webpage. In addition, each counseling session should be documented; a sample Adherence Counseling Worksheet is available for use on the MTN-034 Study Implementation Materials webpage. Use of this worksheet is optional and sites are free to modify this worksheet to best suit site practice if needed.

The Adherence Counseling CRF records the drug levels and associated qualitative categories for each result available. In addition, sites will be able to enter more than one DBS and/or residual drug result at any given visit. The Adherence Counseling CRF will ask whether the results were available at the scheduled visit. This CRF must be completed in conjunction with any product adherence counseling session conducted.

Counselors should remain fully engaged with participants during sessions. As such, it is acceptable for counselors to complete the Adherence Counseling CRF immediately after the counseling session. Should sites adopt this practice, counselors should set aside 5-10 minutes after each counseling session to complete the CRF. Additional guidance for completing this CRF can be found in the CRF Completion Guidelines on ATLAS.

For participants on a product hold or permanent discontinuation, protocol requirement reminders should continue to be provided. Product adherence counseling sessions can be tailored, as needed (e.g. to discussions of risk reduction), and the Adherence Counseling Session Manuals may or may not be used, depending on the exact circumstances. Counselors should contact the REACH Counseling Lead and FHI 360 CRMs for further guidance on tailoring sessions as needed.

Regardless of whether the participant is on a product hold or has been permanently discontinued from study product, residual drug information should always be shared, if available, using the relevant pages of the product adherence counseling manuals (see section 10.6 for disclosure counseling of residual drug information). Adherence counseling sessions for participants who have seroconverted should use client-centered counseling techniques to focus on secondary prevention and risk reduction. More tips about counseling with seroconverters can be found in Appendix 10-1.

10.4.1 Product Adherence Counseling at Enrollment, Visit 9 and Visit 16

The product adherence counseling session at Enrollment is meant to orient the participant to the purpose of product adherence counseling, and to reinforce the importance of accurate reporting of study product use in relation to the overall study goals and participant protection from HIV. Just as important as the actual content of the session is the relationship building between counselor and participant, and the establishment of the counseling sessions as a collaborative process that benefits both the participant and the study.

The product adherence counseling session should be conducted after the participant has been assigned to a study arm and prior to provision of the study product in effort to better familiarize the participant with the adherence aspects and expectations of the given product before initial use. Additionally, counselors should explain the adherence menu concept (and help participants choose initial adherence menu selections) as well as explain the product drug level disclosure process for the forthcoming sessions. Counselors should use the enrollment product adherence counseling session manual applicable to the participant's study product assignment.

At Enrollment, Visit 9, and Visit 16 (or at any time in the 3rd product use period if the participant switches methods), adequate time should be taken to thoroughly explain the product use instructions, including discussion on secure product storage, and answer any questions the participant may have. In addition to verbal instructions, a copy of the illustrated Ring Insertion or Tablet Instructions/Important Information sheet should be provided to each participant per the study product she is initiating (available on the MTN-034 webpage under Study Implementation Materials.) Importantly, when a participant initiates a new product, site staff should inform the participant of the time to protection, as noted in section 5.5.1 of this manual; as well as the need for dual protection (i.e. condoms) to protect against HIV infection. Other visual aids, such as sample rings, tablets, and pelvic models should be used as needed when providing instructions to help ensure participant understanding of proper product use.

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 product use from the very beginning of study participation.

10.4.2 Product Adherence Counseling at All Other Follow-up Visits

Product adherence counseling during follow-up visits will focus on the adherence menu selection plans developed at the previous session, including an exploration of how the participant is doing with product use. The conversation should include a discussion of what went well or did not go well, and what adherence support is needed for the coming month(s). Counselors should follow the adherence counseling session manual that matches the product the participant will be using for the upcoming month, and if helpful, may refer to manual of the product used leading into this session if different. Counseling sessions should include a check-in about facilitating attendance to study visits as well as other protocol requirements. Informational support, such as a review of the Ring Insertion or Tablet Instructions/Important Information sheet, should also be incorporated, as needed.

During follow-up, it is recommended that this counseling occur after completion of A/CASI and administration of the behavioral CRF(s), but also that it be completed as early as possible in the visit. This will prevent fatigue and encourage more active participation in the counseling session. 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 counseling, but subsequently be put on product hold during the visit and not receive product.

Participants should be counseled to keep each vaginal ring inserted without removing it for approximately one month, after which time it should be replaced with a new ring. It is important to replace the vaginal ring with a new ring each month to ensure there is enough drug remaining in the vaginal ring to protect against HIV infection. Replacement of the vaginal ring will occur in the clinic during her study visit. In the event a participant misses a scheduled visit, efforts should be made to have her return to the clinic as soon as possible to replace her vaginal ring. If the participant expresses that she does not want to continue in the study, she should be instructed to remove the ring and return the used vaginal ring to the clinic as soon as possible. Note there is no maximum time that would require removal of the ring for safety reasons. However, the same vaginal ring should not be worn indefinitely as there is no data to support how well the ring works to prevent HIV when worn longer than a one-month period. Study participants should be instructed to contact study staff in advance if they know they will not be able to return for new study product as scheduled.

10.5 Product Use in Clinic

All study participants will either insert the ring or take their first daily tablet in the clinic, starting at Enrollment and continuing at all monthly visits. The rationale for this is to help ensure participant understanding, comfort, and confidence with proper product use. Any questions or concerns that arise in the context of product use can then be addressed by study staff before the participant leaves the clinic.

Any questions or concerns a participant has should be documented for future reference and addressed by study staff. When the participant is ready, she should be instructed to continue with product use as follows:

Daily Tablet: The first dose for each month should be directly observed by study staff. A private space is not required. Study staff should remind the participant to leave the desiccant inside the bottle(s) but discard the bottle seals in the bin provided.

Note: Inability to swallow tablets is expected to be rare. For participants who have difficulty, study staff should advise the participant to use the techniques listed below:

Pop-bottle method for tablets

- Fill a flexible plastic water bottle or pop bottle with water.
- Put the tablet on the tongue and close their lips tightly around the opening of the bottle.
- Take a drink from the bottle, keeping contact between the bottle and lips by pursing the lips and using a sucking motion. Swallow the water and the tablet right away.
- Don’t let air get into the bottle while swallowing. The participant should feel the bottle squeeze in on itself as she swallows.

Lean-forward technique for tablets

- Put the tablet on the tongue.
- Take a medium sip of water, but do not swallow yet.
- Bend the head forward by tilting the chin slightly toward the chest.
- Swallow the tablet and the water with the head bent forward.

These techniques are also included with illustrations on the Tablet Use Instructions/Important Information sheet. After guidance is provided, the participant should try again to take the tablet. Throughout this process, study staff should avoid handling dispensed tablet supplies. Clinicians should take note of the participant’s tablet taking experience on the Tablet Assessment CRF.

Note: Please inform participants assigned to or using the tablet and continuing with the tablet for the upcoming month to wait to take their daily tablet in the clinic on the day of their study visits. This will help ensure that the participant is able to take her first tablet dose for the new bottle within the clinic and observed by clinic staff. Should a participant have already taken her dose outside of the clinic on the day of her visit and the procedure for observed dose is missed as a result, please make sure to describe the situation clearly in the “Description of deviation” field on the Protocol Deviations log CRF.

Monthly Ring: Insertion should be performed in a private space, with study staff standing by in case the participant requests guidance or technical assistance. If the participant has difficulty inserting the ring herself, the study clinician can 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 the participant through the process.

When a ring is dispensed, staff should also confirm that the participant is able to remove and reinsert the ring. This is to encourage comfort with removal procedures, and additional practice in case the 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 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 in chart notes so the information is easily available for reference at study follow-up visits. Clinicians will check for proper ring placement. Instructions to clinicians can be found in SSP Section 7.2. Clinicians should document the participant's ring insertion experience on the Ring Assessment CRF.

10.6 Product Adherence Disclosure Counseling

Starting at Visit 5, product adherence disclosure counseling will be provided to participants, which includes feedback on residual drug data (ring) or dried blood spot PK data (tablet). This counseling is incorporated into the Product Adherence Counseling session as described in section 10.4. The table below presents a summary of what information is anticipated to be available at respective study visits. However, at counselor discretion, results may be provided to the participant at the visit immediately following availability of results and documented on the Adherence Counseling CRF

Table 10-3 Counseling Sessions with Drug Level Feedback

Product Use Period	Counseling Session	Study Visit	Drug Data Available
1	Visit 5	Month 2	Product dispensed at Enrollment (1st month of use in Period 1)
	Visit 8	Month 5	Product dispensed at Months 1-3 (2nd through 4th months of use in Period 1)
2	Visit 12	Month 8	Product dispensed at Month 6 (1st month of use in Period 2)
	Visit 15	Month 11	Product dispensed at Months 7-9 (2nd through 4th months of use in Period 2)
3 (Choice)	Visit 19	Month 14	Product dispensed at Month 12 (1st month of use in Period 3)

	Visit 22	Month 17	Product dispensed at Months 13-15 (2nd through 4th months of use in Period 3)

The UCT PK testing lab and FARMOVS lab will provide PTID-specific reports via email to site IoRs and study coordinators with participant drug level results from tablet use or ring use, respectively. Information provided in these reports will be identifiable by, study site, study PTID, and Global Specimen ID (LDMS). Further information regarding the drug level testing process is available in the MTN-034 Drug Level Feedback Process Document located on the REACH website. Sites should establish a regular schedule to check for available reports – it is recommended that sites check for reports for all scheduled participants at the beginning of each week. If any reports are not available at first check, site staff should check daily for missing reports until the participant visit. In addition, site staff should do the following when DBS or residual drug results are not available 3 days prior to a scheduled visit:

- Verify that either an IVR or DBS were collected at the last visit
    - If yes, contact your local lab to get the date when the IVR or DBS were shipped.
    - Contact either mtn034rdfeedback@mtnstopshiv.org (for residual drug results) or mtn034dbsresults@mtnstopshiv.org (for DBS results) with this information:
        - PTID
        - Previous visit code and date
        - Date sample was shipped to testing lab
        - Date of upcoming scheduled visit
- Note that the expected turnaround time (TAT) for DBS testing at UCT is 21 days; for residual Drug Analysis at Farmovs it is 14 days. The TAT starts from when samples are received at the testing labs.

Once reports are received, clinicians will enter lab results into the Drug Level Feedback Conversion Tool to determine the drug level category of 'low', 'medium' or 'high,' with the applicable color coding (red, yellow and green, respectively). Site staff will transcribe both the drug level and the category of protection on the Adherence Counseling CRF. If multiple results are available and provided during the same counseling session at a study visit, each result should be documented on a separate log line on the Adherence Counseling CRF.

All available results at the time of the visit should be provided to participants during their adherence counseling session. In the event drug level results are not available for a scheduled counseling session, counselors should still provide adherence counseling, but tailor the session accordingly and let the participant know that she will be contacted when the information is available. As soon as the delayed drug level results are received, sites should provide participants with the associated adherence counseling (and complete the Adherence Counseling CRF) to the participant as part of an interim visit in the clinic or over the phone, or at the next schedule visit if the participant prefers. There may be a scenario in which the participant has results from both products or a product she is no longer using at the given visit due to delayed drug level results or switching products in Period 3. Counselors should modify the adherence counseling session to address results of previously used products and then move to counseling for the product to be used from this visit.

Feedback to participants for drug level results for the 5th and 6th month of each product use period is not required per protocol. However, sites may offer or decide to systematically provide these results to the participant along with associated counseling. UCT and FARMOVS will provide drug level feedback reports for every product use month, regardless of whether the results are scheduled for disclosure to the participant.

Counselors are also encouraged to make use of drug feedback visual tools associated with the Product Adherence Session Manuals to support participants in understanding the information and its timing. English versions of the tools are available on the MTN-034 Study Implementation webpage. Sites may translate the tools in to local languages as desired.

10.7 Documentation of Adherence Counseling

Protocol and product use adherence counseling sessions should be fully documented in chart notes and/or other source documents as specified in site-specific SOPs for source documentation. Sites may choose to implement visit checklists, worksheets, and other tools, as desired.

Ideally, documentation of any participant-specific information identified during the counseling discussion would take place after closing the session utilizing chart notes or the space for notes on the Counseling worksheet. If needed, staff can take brief notes during the counseling session, but should always show the participant what they are writing. Counseling notes do NOT need to summarize the procedural aspects of the counseling approach, which are the same across participants. Signing off on the adherence counseling sessions on visit checklists is an indication that these procedures were done in accordance with protocol and SSP requirements. Counseling notes should instead focus on the unique aspects of each conversation and should include sufficient information and detail to inform and guide the participant's next counseling session.

10.8 Quality Assurance and Mentorship for Counselors

To ensure fidelity to the counseling approach in MTN-034, each staff member who will be responsible for conducting product adherence counseling in MTN-034 will be required to become certified prior to seeing study participants. This will be accomplished through in-person or online training as well as conducting mock counseling sessions in English with a peer onsite. To become certified, each counselor must complete mock sessions that meet or exceed pre-established fidelity criteria. At least one counselor must be certified prior to site activation for MTN-034.

Once certified, counselors may begin seeing participants at their MTN-034 study visits. Ongoing fidelity monitoring will take place throughout the trial by a systematic peer review of audio-recorded counseling sessions by other adherence counselors at the clinical research site. The REACH counseling lead will assign each counselor recordings for review through the ATLAS portal. Feedback on peer-reviewed sessions will be documented on Adherence Support Counseling Feedback Forms and emailed to the REACH counseling lead for review. Participants should be informed of these audio recordings for quality assurance purposes verbally or through the administration of a site-specific information sheet or using the ICF, per local IRB requirements. All counselling sessions will be digitally recorded and, after each interview, audio files will be uploaded to a shared SCHARP ATLAS website. Additional details regarding how to record and upload counseling sessions can be found in the Adherence Support Intervention Manual. Once counselors begin seeing study participants, sessions for each counselor will be reviewed.

Using information gleaned from the counseling recordings, the REACH counseling lead will work with counselors via electronic communication, such as WhatsApp or e-mail, and with phone calls to provide additional instruction, mentoring and guidance. Counselor communication will involve counselors from multiple sites and include feedback from the sessions, discussion of challenges in delivering the counseling, and any difficult participant scenarios that the counselors would like to discuss. Calls and other communications are not intended to be punitive in nature, but rather to build capacity of counseling staff and improve the quality of counseling at site.

Appendix 10-1 Secondary Prevention and Risk Reduction Counseling with HIV Positive Participants

Secondary prevention and risk reduction counseling will be provided routinely to all study participants found to be HIV positive to minimize participant risk of HIV re-infection, minimize participant risk of STI acquisition, and minimize the risk of HIV and STI transmission from participants to others. Condoms should continue to be offered at all visits and counseling should include skills building on condom use and condom negotiation strategies.

Counseling should also include HIV/AIDS education, discussion of disclosure issues and emotional support, discussion of healthy living strategies, discussion of stressors and potential strategies to address these, and provision of referrals. For participants taking medications for opportunistic infection prophylaxis and/or taking antiretroviral therapy, counseling should include reinforcement of adherence support messages. At each counseling session, issues requiring follow-up from the prior session should be reviewed and updated, and plans should be made for actions to be taken between the current session and the next session.

In addition to the above, HIV counseling and testing should be offered for participants' partners. Counseling may be provided to partners individually and/or through couples counseling. Study sites are encouraged to provide counseling staff with training in both individual counseling and couples counseling.

As with all counseling sessions, secondary prevention and risk reduction counseling for seroconverters should be documented in participant study records. Document participant responses to the counseling, any concerns raised by the participant, action planned to be taken by the participant prior to the next counseling session, action to be taken by the counselor (or other study staff members, if applicable) prior to the next session, and issues to be reviewed or addressed at the next session.

At each visit after a referral is made, study staff should actively follow-up on the referral to determine whether the participant sought the services to which she was referred, determine the outcome of the referral, and determine whether additional referrals are needed. Additional counseling also may be needed to help ensure the participant receives services that may be beneficial to her. All follow-up actions, outcomes, counseling, and plans for next steps should be documented.