Section 12. Counseling Considerations

This section contains guidance on the following types of counseling provided in MTN-003: HIV counseling, risk reduction counseling, contraception counseling, and study product adherence counseling. Each of these types of counseling is required at most if not all study visits.

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, skills-building, and/or referrals. Participants' needs are likely to change over time; counseling provided should also change over time accordingly.

All counseling should be documented in participant study records. Proper documentation may be achieved through the use of counseling checklists, worksheets, and other tools, as well as counselors chart notes. To support ongoing client-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform and guide the participant's next counseling session.

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. The sample HIV Counseling Worksheet provided in Section Appendix 12-1 provides a guide to the minimum requirements for MTN-003 HIV and risk reduction 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-test counseling.

Given that HIV counseling will be provided at nearly all MTN-003 study visits, when providing pre-test and post-test 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 of 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

Result	Status	Possible Counseling Message
All rapid tests negative	HIV-uninfected	1. Test results show that you **are not** infected with HIV.
FOR SITES DOING TWO RAPID TESTS: One rapid test negative **and** one rapid test positive **(DISCORDANT RAPID TESTS)**	HIV status not clear	1. Test results show that you **may be** infected with HIV. 2. Additional testing is needed. 3. The additional testing may show whether you are infected with HIV or not. 4. You may need to give blood for testing more than once for your status to be known. 5. We expect these additional results to be available [INSERT TIME FRAME].
FOR SITES DOING TWO RAPID TESTS: Two rapid tests positive	HIV-infected	1. Test results show that you **are** infected with HIV. 2. Additional testing is needed for study purposes. This additional testing will be done using blood already taken for the HIV rapid test **(FOR SITES NOT DOING FINGERSTICK RAPIDS)*,OR** Additional testing is needed for study purposes. This additional testing will be done from a new blood sample **(FOR SITES DOING FINGERSTICK RAPIDS)** 3. The additional testing is done to follow the rules of the study, even though this may differ from your country's HIV testing algorithm. 4. It is common for HIV prevention studies to do additional testing in this situation. 5. It is unusual for the additional testing to show a different result. 6. We expect these additional results to be available [INSERT TIME FRAME].
FOR SITES DOING ONE RAPID TEST: One rapid test positive	Likely HIV-infected	1. Test results show that you **may be** infected with HIV. 2. Additional testing is needed for confirmation. This additional testing will be done using blood already taken for the HIV rapid test (FOR SITES NOT DOING FINGERSTICK RAPIDS), **OR** Additional testing is needed for confirmation. This additional testing will be done from a new blood sample (FOR SITES DOING FINGERSTICK RAPIDS) 3. The additional testing is also done to follow the rules of the

		study, even though this may differ from your country's HIV testing algorithm. 4. It is common for HIV prevention studies to do additional testing in this situation. 5. It is unusual for the additional testing to show a different result. 6. We expect these additional results to be available [INSERT TIME FRAME].
Sample 1 Western blot positive	HIV-infected	1. These test results confirm that you **are** infected with HIV. 2. Additional testing is needed for study purposes, using a new blood sample. 3. The additional testing is done to follow the rules of the study. 4. It is common for HIV prevention studies to do additional testing in this situation. 5. It is unusual for the additional testing to show a different result. 6. We expect these additional results to be available [INSERT TIME FRAME].
Sample 1 Western blot negative or indeterminate **AND** HIV viral load negative (below limit of detection)	HIV-uninfected	1. Test results show 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	1. Test results show that you **may be** infected with HIV. 2. Sometimes, HIV test results are not clearly positive or negative. 3. Additional testing is needed until we know your status clearly. 4. Today, you will have [INSERT TESTS RECOMMENDED BY NL] 5. The additional testing will show whether you are infected with HIV or not.
Sample 2 Western blot positive	HIV-infected	1. Test results confirm that you **are** infected with HIV. 2. The additional testing was done for study purposes.
Sample 2 Western blot negative or indeterminate	HIV status not clear	1. Test results indicate that you **may be** infected with HIV. 2. Sometimes, HIV test results are not clearly positive or negative. 3. Additional testing is needed. 4. The additional testing may show whether you are infected with HIV or not.

* For sites <u>not</u> utilizing fingerstick rapid testing: If a participant consented to PBMC collection, after her first dual positive rapid tests, additional blood will be collected on that same day for PBMC and Sample 2 specimens (including Western Blot, CD4+ count, HIV RNA PCR, and plasma archive). Staff should explain to the participant that the additional blood collection and testing is done to follow the rules of the study. Provide counseling messages #3-6 above "FOR SITES DOING TWO RAPID TESTS: Two rapid tests positive."

Note, when the participant returns to obtain Sample 1 and Sample 2 Western Blot results, if both are positive, follow guidance above for "Sample 2 Western Blot Positive" results. If either of these samples are negative or indeterminate, inform participant that additional testing is needed and the additional testing may show whether she is infected with HIV or not.

12.1.1 Risk Reduction Counseling

Risk reduction counseling is required per protocol at each scheduled visit. Client-centered approaches should 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.

Section 12.1.2 below provides further details on specific sexual risk behaviors and related risk reduction approaches that can be discussed with the participant if she is engaging in such practices.

12.1.2 HIV Sexual Risk and Risk Reduction

The main way HIV is spread through sex is by **anal or vaginal sex without condoms** (see table 12-2 below).

All women in MTN-003 will be experienced and familiar with vaginal sex, but some may not be familiar with the term, the risk, or the practice of anal sex. Below is some information that may help counselors provide factual information and counseling to the participant concerning anal sex, as appropriate.

At the initial HIV and risk reduction counseling session, the counselor should probe about the type of sexual risk behavior the women are engaging in, and, specifically enquire about anal sex, and clarify what is meant by anal sex (given potential lack of familiarity with the term). If women do not report engaging in this behavior, no further counseling on this topic is needed. If they report a history of anal sex, the counselors should probe the reasons/motivations for this, and explore whether it is consensual or not. If it is coercive, women should be counseled appropriately, and then regardless of the reason/motivation, counselors should provide risk reduction counseling according to the guidelines below.

What is anal sex and who does it:
For purpose of this protocol, anal sex is defined as the insertion of a man's penis into the woman's anus. Although anal sex is often thought of as an activity that only same-sex male couples engage in, many opposite-sex couples engage in it too. Note that anal sex is different than vaginal sex from behind, and counselors should clarify this with participants if necessary.

It is thought that about 10 percent of heterosexual couples have anal sex as a more regular feature of their lovemaking. In absolute numbers, more heterosexual couples have anal sex than homosexual couples, because more people are heterosexual. It is important to remember that while some people find these activities unnatural or inappropriate, others may find them stimulating, exciting, and a normal part of their sexual intimacy. Thus counseling around anal sex should, like all other topics, be approached in a neutral, non-judgmental way.

Anal sex risk and risk reduction:
The rectum is a very delicate part of the body. Anal sex can easily tear the skin, and it can be painful for the receptive partner (the woman). For women, unprotected anal sex with a man involves higher risk of HIV transmission than unprotected vaginal sex. Whether it is vaginal or anal sex, participants should be counseled to use condoms to prevent passing bodily fluids, and reduce their risk of HIV infection.

Anal sex in the context of microbicide trials and MTN-003:
The following facts may be useful for the counselor when discussing anal sex with a participant:

- Anal sex is <u>not</u> exclusionary in MTN-003.
- For women in the vaginal group, the <u>gel should ONLY be applied vaginally.</u>
- In the context of the MTN-003 study, anal sex should be discouraged, because, at least for women in the vaginal arm, it is not known if the gel, even if effective, can protect from HIV through anal sex.
- If a participant reports anal sex, explore reason(s) for her engaging in this activity and strategize based on her reason(s).
- If anal sex cannot be avoided, emphasize risk reduction via condom use.

- Note that in MTN-003, the use of lubricants for vaginal or anal sex should be discouraged. However, if a participant expresses that anal sex can not be avoided and it is painful/uncomfortable, counselors could recommend use of a water-based lubricant for use during anal sex only.

The table below outlines a range of sexual activities and their levels of risk for HIV and other STD infection. The counselor can use the information in the table to discuss risk reduction options, and the obstacles that may be associated with them, with the participant.

Table 12-2: HIV and STD Sexual Risk and Risk Reduction

Sexual Activity	**Bodily Fluids Involved**	**Risk For HIV /STD Infection**	**Risk reduction options for women**
Holding hands	None	None	
Social Kissing	None	None	
Masturbation	Vaginal fluid/semen	None	
Deep Kissing	Saliva	Low	
Thigh sex	Vaginal fluid/semen	Low	
Mutual masturbation	Vaginal fluid/semen	Low	
Oral sex	Saliva/vaginal fluid/semen/blood	Low (for HIV) to high (for some STDs)	Use male condom; dental dams; abstinence
Vaginal sex	Vaginal fluid/semen/blood	High	Use a condom; get both partners tested and practice mutual monogamy, abstinence
Anal sex	Semen/blood	Very High	If possible, avoid this practice (while participating in MTN-003); use a condom; get both partners tested and practice mutual monogamy, abstinence

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 visit. 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. If the participant would like to practice inserting an empty applicator, these can be obtained from the site pharmacy by written request, which should include the PTID. 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. **Specifically, site pharmacy staff should not count additional gel applicators or tablets used at the enrollment visit in the "expected to be returned" product count when completing the Unused Product Returns Slip – version 2.** In this situation, staff must also ensure the participant still has the minimum quantity of product necessary for daily use until her next scheduled 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 Study Product Adherence Counseling -- Enrollment

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 of the 10 key messages listed below. After the enrollment visit, the 10 key messages will not be routinely covered by the counselor in the adherence counseling sessions. Rather, the pharmacist, or other designated staff, will review the 10 key messages with the participant on an as-needed basis separate from the counseling session (see section 12.5).

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, as well as 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, adherence counseling should focus on exploring participant's experiences with product use, including what makes it easier or harder for her to use the study product. These sessions should NOT focus on product counts, reinforcement of the 10 key messages, reasons for missed doses, or obtaining perfect adherence. Counselors should NOT review product counts on the Unused Product Returns Slip – version 2 prior to the counseling session or probe about discrepancies in product counts versus participant self-report. While product use instructions (10 key messages) will not be routinely reviewed during the adherence counseling session, staff should always address immediately any misinformation shared by the participant (whether in the counseling session, with the pharmacist, or with the clinician).

During follow-up, adherence counseling should always occur after completion of ACASI and administration of the behavioral CRF(s), as required. Sites may choose to conduct adherence counseling prior to completion of clinical/lab assessments to improve visit flow. Note that in this situation, some participants may receive adherence counseling, but may subsequently be put on product hold during the visit and not receive product.

Detailed guidance regarding adherence counseling during follow-up is provided in Appendix 12-7, the VOICE Adherence Support Program (VASP) Counseling Manual. The Follow-up Adherence Counseling Worksheet shown in Section Appendix 12-5 should be used to document the adherence counseling *after* closing the session. If needed, staff can take brief notes during the counseling session, but should always show the participant what they are writing. The formatting of the worksheet may be tailored to individual site needs; however, the content of worksheet should not be modified at any site.

12.5 Product Use Instructions — Follow-up

With the implementation of VASP, the review of product use instructions (10 key messages) during follow-up will be transitioned out of the adherence counseling session. Pharmacists, or other designated staff, should review product-use instructions on an as-needed basis throughout study follow-up, preferably at the time of product dispensation. At a minimum, staff should check-in with participants to see if any further product use instructions are warranted, review at least one of the key messages, and document that this was done. Even if a participant does not specifically report problem/issues, staff can review any messages per their discretion. This guidance should be provided only after completion of ACASI and administration of the behavioral CRF(s), as required.

Optional information sheets containing the 10 key messages will be provided to each site (also available on the MTN website), as both a reference and a visual-aid for providing these instructions to participants. Sites can also choose to post these messages in the pharmacy and/or waiting area for participant reference, keeping in mind that messages may need to be translated.

Importantly, provision of any product use instructions should be adequately documented. A sample product use instruction checklist is available on the MTN website and in Appendix 12-6. Alternatively, sites may choose to document this information on site-specific forms or chart notes. An optional comments section is available on the sample checklist to document additional details as needed. If information relevant to clinical management, safety, or study participation is discovered during discussions with the participant, staff are asked to document the issue in the comments section, and inform clinicians of these issues. If sites choose not to use this checklist, they should ensure site-specific procedures are in place to document and communicate any relevant information between pharmacy and clinic staff (e.g. note to file, action log, communication log). Sites should specify in site-specific SOPs when product use instructions will be provided, staff responsibilities for provision of instructions (e.g. clinical or pharmacy staff), documentation of instructions, where documentation will be filed, as well as procedures for communication of relevant information between pharmacy and clinic staff.

Section Appendix 12-1
Sample 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

Additional Notes:

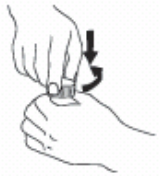
Section Appendix 12-2
Sample Contraception Counseling Flowsheet

PTID: Page:

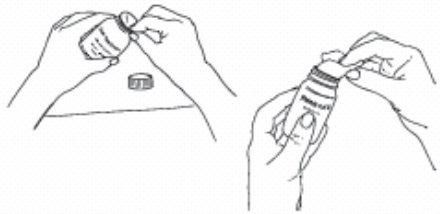
Visit Date			
Visit Code			
Review participant's reproductive history documentation and previous entries on this flow sheet to inform and guide contraceptive counseling provided at each visit.			
Current contraceptive method			
Contraceptive issues/questions/ concerns discussed at this visit			
Issues 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			

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.



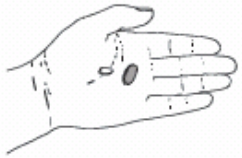
3. The first time each bottle is opened, there will be a seal covering the bottle. Remove and discard this seal. Inside the smaller bottle, there will be cotton wool. Remove and discard this cotton wool.

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.

5. When taking tablets each day, first open one bottle. Remove one tablet from this bottle.

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

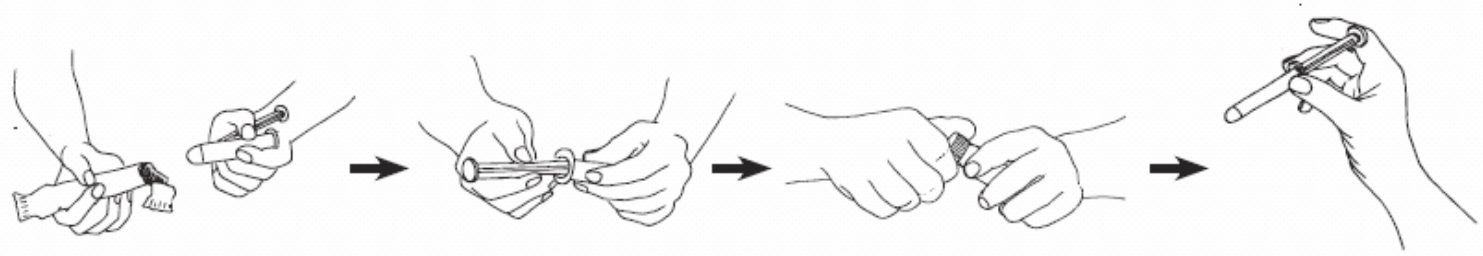
7. Next, do the same to remove one tablet from the other bottle.



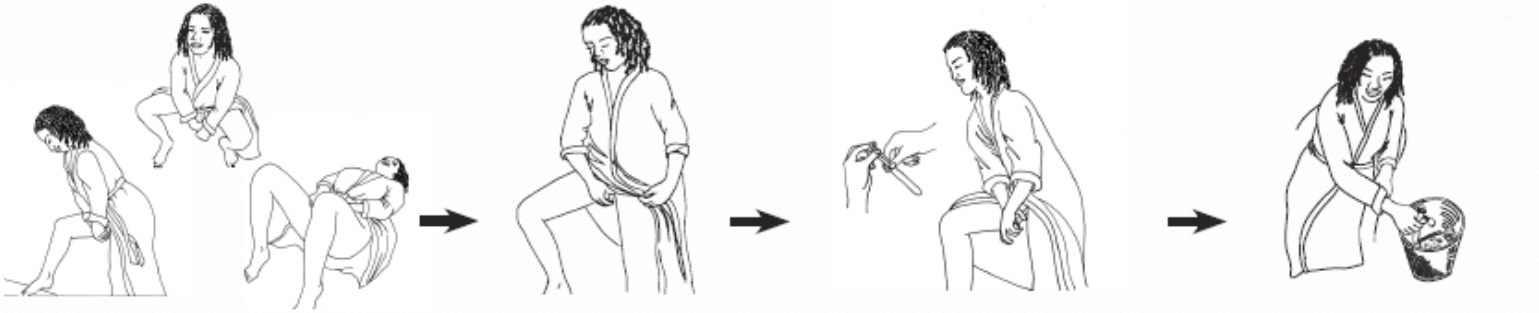
8. Now you will have one lighter tablet and one darker tablet taken from the two bottles.

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.

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:**

❒ **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

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?

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).

_____

_____

_____

_____

❒ **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.**

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.

❒ **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.**

How might you plan to do this? Where do you think you will keep your supplies?

_____

_____

_____

_____

PTID:	Visit Date:

❒ **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.**

PTID:	Visit Date:

Additional Counselors Notes:

Section Appendix 12-5
Follow-up Adherence Counseling Worksheet

PTID:	**Visit Code:**

1. WELCOME: Greet and thank participant and establish rapport.

2. FRAME: Explain the purpose of discussion and seek permission.

3. EXPLORE: The context (experiences) in which the participant feels it is easiest and hardest to use the study product. Check in on how things went with the goals set at the last session; reinforce efforts and move on to exploring ease and difficulty <u>now</u>.

CONTEXT (EXPERIENCES)	
… made it feel easier…	*… made it seem difficult …*

CONTEXT AROUND EXPERIENCES WITH PRODUCT: REGARDLESS OF ACTUAL PRODUCT USE

4. SUMMARIZE: The context (experiences) in which product feels easiest to use/hardest to use for this participant.

5. IDENTIFY NEEDS: Help the participant to identify her specific adherence needs given the context explored. What does this participant feel she needs in order for adherence to be as manageable as possible? (Keep the focus on making use *easier*, rather than *perfect*).

<u>Adherence Related NEEDS:</u>

PTID:	Visit Code:

6. STRATEGIZE: Explore new strategies or continued use of established ones to address the needs identified.

STRATEGIES:

7. NEGOTIATE: A goal that the participant identifies. Ask the participant what she might be willing to try or continue to do between now and the next session (Goal).

GOAL

8. CLOSE THE SESSION: Summarize what was discussed; thank the participant for talking with you and contributing to the study; document the session (after participant leaves the room).

CONTEXT → ADHERENCE RELATED NEEDS → STRATEGIES → GOAL

Please show participant what you are writing if you write notes during the session

Section Appendix 12-6
Sample Product Use Instruction Checklist

PTID:	Date:	Visit Code:

Instructions: *Pharmacists, or other designated staff, are to use this checklist for documentation of any product use instructions provided to participants during VOICE follow-up visits. Note that product use instructions should only be provided after completion of ACASI and administration of the behavioral CRF(s), as required (MBA, OPA, or VPA). Pharmacists, or other designated staff, should notify clinic staff if the checklist contains documentation relevant to the participant's clinical management, safety, or study participation.*

The following product use instructions were reviewed with the participant *(check all that apply): Note: Instructions can be reviewed on an as-needed basis. At a minimum, at least one item below should be reviewed.*

- ❒ Use the study product every day, around the same time of day
- ❒ Missed dose instructions
- ❒ Keep study product in your possession
- ❒ Product storage instructions
- ❒ Contact clinic if you are going to run out of study product
- ❒ Take study product with you on trips away from home
- ❒ Do not share study product
- ❒ Issues/problems taking the tablets/inserting the gel
- ❒ Product being stolen/taken from her or lost
- ❒ Bring all remaining unused product/empty bottles to visits
- ❒ Contact clinic with any problems between visits
- ❒ Use only the study product assigned to you
- ❒ Product expiry instructions/guidance
- ❒ Other *(describe in comments below)*

Comments *(optional)*:

Pharmacist or Designated Staff Initials/Date: _____

Section Appendix 12-7
VOICE Adherence Strengthening Program (VASP) Counseling Manual

VOICE Adherence Strengthening Program (VASP) Adherence Counseling Manual

Introduction

The **VOICE Adherence Strengthening Program (VASP)** was developed based on Next-Step-Counseling and other participant-centered approaches for behavior change. While several aspects of the original VOICE adherence approach are retained, the spirit in which the counseling is conducted and the manner in which adherence is understood may be a dramatic difference for some counselors. The goal of VASP is to create a supportive environment where participants can share their ***experience*** with the product while recognizing that product use is ultimately a choice. There are 8 steps involved in the VASP discussion about experiences with the study products, which are detailed sequentially in this guide, providing the goals, critical components, and illustrative examples of each step.

Several aspects of the original VOICE adherence counseling approach are retained and bolstered to create VASP. Both promote a client-centered approach, the use of open-ended questions, and the importance of building rapport with the participant. Adequate documentation and the review of action plans from previous sessions are also important aspects of both approaches, to ensure continuity throughout the duration of a participant's time in the VOICE study.

In contrast, VASP eliminates or modifies several aspects of the current counseling approach, which we have understood to be counterproductive. These are outlined in the table below.

Key Revisions to Adherence Counseling Approach

Previous Approach	VASP
Used product count from pharmacists to inform the counseling session; reconciled product count and self-reported adherence.	Counselors will ***NOT*** review product count prior to counseling session or probe about discrepancies in product count versus self report.
Asked the participant how often she had been able to use the product and then based counseling on reported level of adherence.	Counseling will focus on participant's ***experiences*** using the product, and what makes using product easier or harder, regardless of how much she used it.
Adherence plan/strategies based on overcoming ***barriers*** to product use.	Adherence plan/strategies based on addressing adherence-related ***needs***.
Used reported adherence to determine the focus of the session (i.e. page 2 of the counseling worksheet options).	All sessions will follow the same 8 steps, regardless of how much the participant has been using the study product.
Reinforcement of product use instructions (10 key messages) by the adherence counselor.	Product use instructions (10 key messages) will be reviewed by the pharmacist* as needed.
Positive reinforcement of good adherence.	Maintain a neutral counseling approach.
Goals focused on perfect adherence.	Goals focused on making product use manageable.

**Product use instructions may be provided by a study staff member other than the site pharmacist, per site SOP.*

Steps of VOICE Adherence Strengthening Program (VASP)

1 **WELCOME**
Greet/Rapport; Thank participant; Check-in

2 **FRAME**
Explain purpose of discussion;
Seek permission to continue discussion.

3 **EXPLORE**
Explore product use experiences (facilitators/challenges);
Discuss efforts on strategies from last session.

4 **SUMMARIZE**
Summarize Context/Experiences

5 **IDENTIFY NEEDS**
Explore needs for adherence given experiences;
What would make it easier?

6 **STRATEGIZE**
Explore how participant
could increase ease/comfort/efficacy.

7 **NEGOTIATE**
Agree on a goal identified by the participant.

8 **CLOSE**
Summarize; Thank participant, Document

GOAL: Create a comfortable environment to talk about experiences with the product

CLIMATE: Supportive, non-judgmental, neutral, reinforcing of open discussion/efforts, avoidance of "fixing," recognition of limited role, and emphasis on participant as a whole person.

METHOD: Exploration of context (experiences, thoughts, beliefs, feelings) to identify needs and promote movement towards building a context that supports product use.

IMPLICIT ASSUMPTION: Participants choose whether or not, or how much, to use the study product. We cannot make them use it, but can support open frank discussions about it.

STEP 1: WELCOME: Thank participant and establish rapport

Goal: Welcome and thank the participant for their contributions to the study (empower). Note that if you've already had interactions with this participant during this visit, the goal of Step 1 is to recognize her contributions to today's visit and in the study more generally.

Critical Components:

- Specifically recognize and appreciate the contributions the participant has made (for example, today's visit in terms of length, completing measures, procedures or more generally in terms of months on study or other ways this individual contributes her time and efforts to this study).
- Emphasize genuine observations about personal contributions the participant has made/is making, and thus empower the participant to see the study as her study, something not possible without her specific efforts. These efforts are regardless of her actual product use; that she is there, has spent time in the waiting room, is speaking with you now, has undergone study procedures; these are all visible contributions that should be recognized.
- Balance the interaction between the counselor and participant through conversations that engage the participant in her contributions to this study (contributions that are not linked specifically to product use).

Examples:

Before we talk about how you have been doing with the {gel/ tablets} I just want to stop and thank you for coming in today and waiting all this time. You do so much for this study and it would not be at all possible without your contribution. No matter what is going on with {tablet taking/gel use} the contribution you make deserves recognition- so, thank you. Thank you for this.

You have been here several hours and I want to stop a moment to tell you that without your being here, without your patience with this process….we would not be able to do this study at all, we would not be able to answer a very important question about whether or not HIV could be prevented with tablets or gel. You make many contributions to this study, and showing up here today and talking with me is a really important one. Thank you.

We've talked about this before, but I think it is worth recognizing every time you come in…you being here today is a great contribution you make to this study. I want to thank you for this- I see how hard it is to be here so long and the sacrifices you make to do this. Your efforts are very much recognized and appreciated by all of us.

STEP 2: FRAME: Explain the purpose of discussion.

Goal: Invite the participant to join the discussion by explaining what you want to talk about, framing it as important, presenting yourself as open, and seeking her permission to continue.

Critical Components:

- Explain what you're going to talk about and why.
- Get permission to proceed.

Examples:

I would like to take just a few minutes to talk with you about your experiences with the study {gel/tablets}. Would that be OK with you?

At each visit a counselor will talk with you about your experiences with the study {gel/tablets}. This is because we recognize that using the study {gel/tablets} each day can be difficult and even when people manage to use them, it can be a burden. Part of this study is to better understand this process. So checking in with everyone about this part of their participation in the study is very important. May we spend a few minutes talking about what your experiences have been?

I know we have spoken together in the past about your experiences with the study {gel/tablets}. I will check in with you about this at every visit, because sometimes things change or new situations come up when it may feel easier or harder to use the study {gel/tablets}. These are all important for the study researchers to learn about- what it is really like to try to use the study products. Even if things have not changed for you, I am hoping we could just spend a few minutes discussing your experiences with the study {gel/tablets} over the last X month(s)? Is that OK with you?

STEP 2

IS intended to be…	IS NOT intended to be…
A sincere invitation	A long explanation
An opening to a frank conversation	Read from a sheet
An opportunity for the participant to exercise choice	Non-responsive
Genuine	(participants can say, "No")

STEP 3: EXPLORE: Discuss the context (experiences) in which the participant feels it is easiest and hardest to use the study product (check-in on previous agreement).

Goal: Establish a shared understanding of the specific context in which this participant experiences study {gel/tablet} use. Elicit factors that facilitate ease of product use first; then factors that present challenges to product use. (Note: For month 2 visits and beyond, first check in on how things went with the goal she set at the last visit. Reinforce effort(s) and move conversation to exploration of how things are going now.)

Critical Components:

- Elicit (ask about) the **context** in which she negotiates, manages, or experiences product use. This discussion is independent of the participant's level of product adherence.
- Elicit (ask about) **facilitators** of product use (times, situations, factors that make it feel easy to use the product in a given situation, generally, or over time).
- Elicit (ask about) **challenges** to product use (times, situations, factors that make it feel difficult to use the product in a given situation, generally, or over time).
- Establish a conversation about facilitators and challenges regardless of actual level of product use. Regardless of actual use or non-use of the products, one can still reflect on ease and difficulty.
- Counselors may need to help participants move away from focusing exclusively on how much they used the product; (e.g., *Thank you for sharing that with me, but I am hoping we can talk about what your experiences with the study {gel/tablets} have been like, whether you use it consistently or not. Things that make it easy and not so easy to work study gel/tablets into your life*).
- The critical aspect of this conversation is to position adherence as (1) a choice; (2) a behavior that is influenced by many things; and (3) as needing to fit *into* the participant's life (versus needing to work one's life around adherence). The context of one's life is first and foremost, and adherence to study product is seen as a behavior that exists in relation to other things going on in life. Adherence is "situated" within the larger social, cultural, emotional, and situational/circumstantial factors that create the participant's daily life.

Examples:

In thinking about the study {gel/tablets}, what have your experiences with using the {gel/tablets} been? What are the times, situations, or things that have made using the {gel/tablets} feel easy, made it fit in your life? What are the times, situations, or things that have made using the {gel/tablets} feel more difficult, less easy to manage?

Examples:

Think a moment about your experiences with the study {gel/tablets}. Not about whether or not or how much or how little you used them, but just about what it has been like for you. Can you share with me what kinds of things, situations, or feelings make using the {gel/tablets} feel like something that is easy to do…that just works well or fits in your life? What about things or times when it feels like {this gel/these tablets} are a difficult to use/take for you- times when it just feels harder to do?

STEP 3

IS intended to …	**IS NOT intended to …**
Explore/elicit context	Find and "fix" barriers
Frame product use as part of one's life	Identify times when the participant missed taking study product
Move away from rates of use	Require or suggest movement to action
Move towards experiences with product use	Push beyond what the participant is comfortable sharing

STEP 4: SUMMARIZE: Summarize the context (experiences) in which product feels easiest to use/hardest to use for this participant.

Goal: Validate and confirm participant's experiences by checking in with them about your understanding of facilitating and challenging factors.

Critical Components:

- Demonstrate active listening and reflection.
- Promote the feeling of being "heard" on the part of the participant.
- Provide a summary and elicit participant's reactions to your summary.

Examples:

What I hear you saying is that these things {explain} make it easier while these {list} make it harder for you. Does that sound right to you?

It sounds like you feel that your motivation to use the study {gel/tablets} comes from wanting to contribute to the study and find new ways for women to protect themselves from HIV. You don't know about times when it feels difficult right now. Does that feel like an accurate summary?

If I am hearing you correctly, you feel that not a lot has changed since we last explored your experiences with the study {gel/tablets} and that you continue to feel it is easy for you because you use it with breakfast. The only time it feels more difficult is when there is no breakfast and things get changed around with your day. Is that right?

So, right now there are few or no times when it feels easy because it is difficult when your husband is home and he has been home all month. Did I understand you correctly?

STEP 4

IS intended to …	**IS NOT intended to …**
Demonstrate that you have been listening	Suggest possible solutions or actions
Help the participant feel heard	Judge perceived ease or difficulty
Emphasize your interest in understanding the participant's context	Turn challenges into "barriers to overcome"
	Force compliance

STEP 5: IDENTIFY: Help the participant to identify her specific adherence needs given the context explored. What does this participant feel she needs in order for adherence to be as manageable as possible? (Keep the focus on making use *easier*, rather than on making use *perfect.*)

Goal: Work with participants to identify (or name) what would need to happen for product use to be manageable, slightly easier to do, or for current sense of ease of product use to be maintained or sustained over time. **WHAT** are this participant's underlying, core adherence-related requirements or needs? *In order for this to feel like it fits well in her life,* **WHAT** *would need to happen*?

Critical Components:

- Help the participant to identify relevant needs for facilitating, supporting, or developing high commitment, motivation, and skills towards study product {gel/tablets} use by focusing on what would make study product use as easy/manageable as possible for this participant.
- Empower problem solving: Emphasize that having personal needs or requirements are normal and understandable (e.g., in response to a participant's report of what would need to be in place for things to feel easier, the counselor may say, "*That is completely understandable,*" or, "*That sounds very reasonable to me,*" or, *"Other participants have shared the same concerns".*) If one can identify what they need for adherence to feel manageable and believe that this is a reasonable need, adherence can feel more like a behavior one owns and can accomplish, if desired.

Examples:

What do you think would need to happen for {gel/tablet} use to feel just a little more manageable in your life? What would need to change or be different in that picture?

What would need to be different for it to feel easier to use the study {gel/tablets} in that situation you described as being difficult?

What would need to happen for you to continue with those feelings that using the {gel/tablets} is actually pretty easy for you most of the time? What would really keep that going?

STEP 5

IS intended to …	**IS NOT intended to …**
Let the participant identify adherence-related needs	Tell the participant what their needs are
Focus on needs before actual adherence-strategies	Fix barriers or address needs
Empower participants	

Examples of adherence-related NEEDS

I would need to have more privacy
I would need to feel better supported
I would need to feel like this is not going to hurt me in some way
I would need to have my husband's support
I would need to know that this will not hurt me when I am in menses
I would need to better understand why I would do this when I am not having sex
I would need to remember better
I would need my schedule to stay the same
I would need to have it with me
I would need to care more about this when so much else is going on

*Nothing - it is already easy for me, it is a habit, I just do it**

It is a habit*
(Examples)

Counselor*: What would need to happen for you to keep feeling it is easy for you?*
Participant*: Nothing- it is already easy for me, it is a habit, I just do it.*

"Relapse (lapse) Prevention"
Counselor*: Is there anything that might get in the way of that habit that we could discuss together?*

"Maintenance"
Counselor*: There are so many people that struggle with using the study {gel/tablets}, can you share with me what it is that you do that makes it feel so manageable for you?*

"Reframe 'habit' or strategy into the need it satisfies"
Counselor: *It sounds to me like your habit, you using the study {gel/tablets} right after breakfast, helps to make it feel easy because you have worked the study {gel/tablets} into your life…into something that you already do each day. What makes it easier for you is having it be part of your normal life. Does that sound right?*

STEP 6: STRATEGIZE: Explore new strategies or continued use of established ones to address needs identified.

Goal: Work with participants to have them identify possible new strategies to address their adherence-related needs, or to continue to use established strategies that have been effective in increasing ease of study {gel/tablets} use in the past. **HOW** will the participant work towards satisfying their adherence-related needs?

Critical Components:

- Identify several strategies that the participant may use or currently does use to address her adherence-related needs.
- Empower problem solving: First ask the participants to identify strategies, then offer suggestions that are participant-specific (reflecting *this* participant's context and needs) only after the participant has been provided the opportunity to explore their own suggestions.

Examples:

So you mentioned that something that would make it easier is having the privacy you need, how could you see that happening?

One of the things that would make it feel more manageable to you would be to be able to have some kind of reminder of the time you would like to use the study {gel/tablets}. How could you see that happening?

You feel that needing to have the {gel/tablets} fit into you daily routine is important and something you do by taking the {gel/tablets} with dinner each evening. Are there other things that help to have the {gel/tablets} fit in your life?

We have talked several times about you feeling that using the study {gel/tablets} is easiest for you when you take it at the same time each day, have a reminder of the time, and remind yourself of why you are doing all this. By using the {gel/tablets} after your tv/radio program, you have linked it with something you like to do most days, that happens at the time you want to use it, and leaves you in the kind of mood that helps you feel good about what you are doing. Is there anything else we can discuss together about making the {gel/tablets} as easy as possible to use for you?

STEP 6

IS intended to …	**IS NOT intended to …**
Encourage the participant to draw from her own resources to identify potential strategies to address adherence-related needs	Identify new strategies if there are current ones in place that are perceived to be effective
Offer several possible things for participants to consider as ways to address adherence related needs	Push participants towards "our" strategies

STEP 7: NEGOTIATE: A goal identified by the participant.

Goal: Create a "goal" by working with the participant to help her to identify a strategy or strategies that she is willing to try or continue to use between now and the next time you meet that feels *achievable and realistic to her*.

Critical Components:

- Help the participants to identify a strategy (or strategies) that becomes a goal or a step to accomplish between visits. This may be something the participant already does or is something new.
- Support the selection of a goal that is achievable. It's critical that the participant feels progress and success, which may involve the selection of a "small" step.
- The goal is not necessarily trying something new or committing to trying a study product use strategy at all. A participant may simply set a goal to come back in to talk with you, to remain open to discussing experiences, or to just observe her experiences over the next few weeks. These are all very good goals for participants who are unsure about challenges, needs, or strategies. It's better to respect and work with their uncertainty then to suggest product use strategies that may be a poor fit with where the participant is presently with her product use. By focusing instead on her engagement in the discussion, commitment towards exploring adherence, or ownership of this aspect of her participation in the study, overall engagement is fostered, which ultimately is a critical goal.

Examples:

Of the things we just discussed, is there one or some of these that you would be willing to try between now and the next time we meet?

Would you be willing to continue with the strategies you identified {summarize needs and current strategies} between now and the next time we meet?

Given that you're not really sure what might help to make {gel/tablet} use easier for you right now, maybe just trying to be aware of what using the {gel/tablets} is like for you- what your feelings and thoughts are around it when it is actually happening- would be most useful right now. Is that something you would be willing to do between now and the next time we meet?

You explained that you need privacy to use the {gel/tablets}, and we talked about some ways you might be able to have more privacy. Right now, you don't feel like any of those really fit for you. I wonder if a good goal for us is to just keep exploring. Would you be willing to set a goal with me to come in again and explore some more next study visit?

STEP 7

IS intended to …	IS NOT intended to …
Identify a concrete, realistic, accomplishable goal	Assign tasks or strategies that are not reflective of participant context, needs, or engagement
Provide participants with the opportunity to experience progress and success around experiences with product use	Identify strategies related to actual use of product or increasing rate of adherence, per se (strategies should reflect increasing one's comfort, ease, and confidence around product use)

STEP 8: CLOSE THE SESSIONS: Summarize what was discussed; thank the participant for engaging in the discussion and contributing to the study; document the session.

Goal: Provide a summary of what was discussed (context, needs, strategies, goals). Express appreciation for the participant's engagement in this conversation/exploration as an important contribution to the study. After participant leaves, document or finalize documentation of the session.

Critical Components:

- Model, empower, and celebrate problem-solving around product use by providing a summary of the discussion and thank the participant.
- A thorough summary will include brief comments on:

  (1) the **context** that "situates" one's (2) **needs** for fitting product use most easily into her life, and the (3) new or current **strategies** focused on increasing or sustaining ease of use that were discussed, that then led to a (4) **goal** to do, try, or continue to use a strategy (strategies) between now and the next visit.
- Document the session on the worksheet so that the next counseling visit can reflect on the strategy (strategies) the participant said she would consider. This will provide continuity for the participant, even if she meets with another counselor at the next visit. Subsequent sessions may be shorter, if participants mention that the context has not really changed, or that previous strategies continue to "work" well. Each step of VASP is still briefly touched upon, but by having documentation of previous sessions and reviewing these before the participant visit, a sense of history can ease the discussion. Participants should always have some goal from the previous visit and this must be well documented in order for the next visit to appropriately reflect on potential progress towards that goal.

Examples:

We talked about how using the study {gel/tablets} seemed to be easy when your schedule did not change and harder when visitors are staying with you.

You noticed that one of the things that seems to make it easier for you to use the study {gel/tablets} was to have privacy and to have some time in your day that is just for you. Using the study product after your tv/radio program helps with that because it is your time and people in your home know that it is a time you take for yourself.

One thing you are interested in doing is to keep using this strategy because it really works for you. Another thing we talked about is using the {gel/tablets} when you are the first one awake on the weekend because your tv/radio program is not on over the weekend and you are often the first one up. That is another time when you have some moments to yourself and have privacy.

I want to thank you for speaking so openly with me about your experiences. Your contributions to this study are recognized and appreciated. Thank you.

MAIN PRINCIPLES

Client-Centered

The participant is the expert on her life and behaviors.

Comprehensive (Multi-targeted)

Providing accurate information is necessary but insufficient to produce behavior change or promote participant engagement in discussions about product use. Motivation (personal and social) and skills are also critical to help produce change.

Counselor-Guided

The counselor guides the discussion through questioning, and does *not* do most of the 'talking'. The participant should have the majority of 'talk time' in any given session.

Context-Driven

The counseling session explores the context in which one negotiates product use. It is not focused on events when the product was not taken, or specifically on barriers. The focus is on the aspects of product use that facilitate or challenge the ease with which one experiences product use (or non-use) in their daily life.

Genuine

The counselor maintains a genuine interest in the participant and reflects that interest through exploration of the participant's experiences. Counselors seek to remain engaged and authentic (real, honest, present, and attentive) throughout the conversation.

Individualized

The counseling for product use is individually tailored to the levels of engagement and product use behaviors of a given participant at a given point in time.

Neutral (In Stance)

The counselor maintains a supportive but neutral stance throughout the session to convey acceptance of both the participant and her disclosures of positive and negative aspects of product use.

Recognizes Limited Role

The counselors recognize that their impact is in the immediate session and that they cannot "make" participants do anything. They can, however, ensure that a safe environment is consistently provided for participants to openly discuss product use.

COUNSELOR SKILLS

Active listening

Active listening (or attending) refers to the counselor's ability to communicate listening through frequent and varied eye contact, facial expressions and other forms of non-verbal communication. This includes sitting in a relaxed posture, leaning forward occasionally, and using natural hand and arm movements that are responsive and encouraging. Counselors need also to be aware of non-verbal communications in the participant's demeanor, since non-verbal cues are important forms of communication.

Open-ended questions

Open-ended questions are those questions that are not easily answered with a one-word response ("yes" or "no") and do not assert the counselor's values or objectives. Counselors should use them when they are seeking information about the context in which product use occurs or when exploring attitude, culture, economic and/or social factors that may play a role in product use. Open-ended questions invite further disclosure and help to build rapport and trust. What the counselor asks and how it is asked can also demonstrate positive regard for the participant and a genuine interest in knowing how the participant feels. An example of a closed ended question would be: "Is it easy to insert your gel daily?" (Answer: Yes or No.) An open-ended approach would be: "What is your experience with inserting gel daily? What makes it easier . . . and what makes it more challenging?"

Pausing

Pausing provides opportunities for participants and counselors to digest material and to make room for feelings or thoughts to emerge. Giving the participant time to "experience the moment" by allowing silence to happen is a sign of respect for the power of the participant's thoughts and feelings. Sometimes counselor's discomfort with silence can interrupt the participant's process. Remember: *Silence is also a form of communication.*

Paraphrasing

Paraphrasing refers to rewording the content of what the participant has said in similar but fewer words. This can help the counselor clarify the basic message expressed in the verbal content of the participant's communication. Paraphrasing neither expands nor builds on the topic, but is a way to help the participant feel heard and build rapport. A participant may say that her brother-in-law is visiting and he's shifted much of the routine of the family. After her detailed explanation of how this occurs, the counselor 'paraphrases' with a short sentence. "Since he has moved in, things that were predictable each day are not predictable anymore." Note that paraphrasing does not try to reflect back the participant's exact words or expressions and is more like summarizing (each explained below) but on a smaller scale. It is a good practice with paraphrasing, or summarizing, to either pause (see below) for several seconds to allow for a reaction from the participant, or elicit (ask) the participant specifically if the paraphrase feels accurate "Am I understanding correctly?"

Summarizing

Summarizing refers to the technique of highlighting for the participant the most important aspects of the session that have been discussed. For the VASP, and other approaches drawing

from Next Step Counseling, summarizing the context, needs, strategies, and goals is a critical part of modeling and empowering problem-solving.

Reflective listening statements

Reflective listening statements refer to listening carefully to what a participant is sharing or expressing and then "reflecting" back to them something they said that feels important. These statements do *not* offer an interpretation of what was shared, nor are they just "repeating back" everything the participant says. Rather they are short statements that reflect some important aspect of what was said using the same language that the participant used. Using the participant's own words or expressions conveys not only that you are actively listening, but also hearing the reflection can help participant's clarify their feelings and thoughts. Counselors often use reflective statements in situations where they hear something meaningful in what the participant says, but the participant doesn't appear to have fully appreciated it. For example, a participant explains that her days consist of taking care of everyone else in the family and has said this in a very casual way, moving quickly to another topic. The counselor may simply reflect back, "Every day it's the same, taking care of others," and follow this with silence to allow the participant to process the observation and respond.

Reframing

Reframing refers to offering an alternative way of looking at something that the participant has just said, usually one that is more constructive and positive. For example, where a participant might say, "I get so frustrated with myself because I often miss my tablets on the weekend," a counselor may reframe this towards a productive strengths-based discussion by saying, "Which also means that most of the time you do take your tablets. Yes?"

Third-personing

Third-personing refers to a counselor noting what "others" have done, experienced, or found helpful. The counselor refers to someone outside the session (other participants he or she have worked with, etc.) as a way to normalize the participant's experiences. For example, "Many other participants have shared similar concerns with me," or suggest alternative ways of thinking about or doing things based on the shared experiences of others (e.g., "I have worked with a few participants struggling with this, and they have found some interesting approaches to deal with it. Obviously, everyone is different, but would you be interested in hearing about what worked for them?")

Process comments

Process comments are observations a counselor shares about what is going on in the session itself. This could be something the counselor has observed about the exchange, discussion, or process of communication between the counselor and participant, that is typically (but not necessarily) followed with a question (eliciting) about the observation. If, for example, your participant was suddenly looking at their watch, a good process comment could be: "I see you're looking at your watch . . . do you have concerns about how long our session is taking?" If the participant suddenly crossed her arms and looked away, you could ask, "Your body looks tense right now, I'd like to take a moment and check in with you . . . How are you feeling right now?" When a discussion feels "stuck," consider whether or not there is a process comment that might help to move the discussion forward.

Elicit-Provide-Elicit

Elicit-Provide-Elicit is a strategy from Motivational Interviewing that involves asking the participant to explore some aspect of a feeling, experience, or behavior (eliciting information from the participant); providing the participant with relevant information about what she has shared (the counselor shares knowledge or expertise he or she has on the issue in a supportive manner); and then again asking the participant to share what she makes of the information (given what the counselor has shared, what does the participant make of that information, how does it fit or not fit with the participant's sense of things). This is a marked difference from simply giving the participant information and then moving on to some other topic area. The elicit-provide-elicit approach offers greater opportunity to build consensus and keep the session participant-centered. An example of elicit-provide-elicit would be to ask about experiences, provide information to correct mis-information and then elicit reactions. The counselor may ask about experiences with the study product (elicit) and hear in the participants discourse that the participant believes that if she misses her "dose time" by 15 minutes she should skip the dose. The counselor then provides information about dose times and windows (provide), and then asks the participant how they feel about that new information (elicit).

Ventilation and Validation

Ventilation (venting) refers to 'getting something off your chest.' When someone has complaints about something or someone, it can be helpful at times, and when used constructively, to 'vent' or verbalize feelings and frustration. Validation is when the participant's frustration is recognized by the counselor as valid, understandable, and within reason. By allowing the frustration to be legitimate and a reasonable understandable response, the pressure and discomfort in experiencing the frustration can be reduced. In this regard, it is most important for the counselor to validate feelings and not the content or specifics of the events attributed to causing the frustration. For example, a counselor may reply to venting about wait times for the visit by saying, "It is perfectly reasonable to feel frustrated about waiting so long." Or, "That does sound really taxing." Note that the counselor is not trying to reduce the frustration by saying it is inappropriate or by providing excuses for the event (the long wait time). Instead the counselor simply recognizes that the feelings are legitimate without placing or necessarily taking on blame for the feelings.

Follow-up Adherence Counseling Worksheet

PTID:	Visit Code:

❒ **1. WELCOME: Greet and thank participant and establish rapport.**

❒ **2. FRAME: Explain the purpose of discussion and seek permission.**

❒ **3. EXPLORE: The context (experiences) in which the participant feels it is easiest and hardest to use the study product. Check in on how things went with the goals set at the last session; reinforce efforts and move on to exploring ease and difficulty <u>now</u>.**

CONTEXT (EXPERIENCES)	
… made it feel easier…	*… made it seem difficult …*

CONTEXT AROUND EXPERIENCES WITH PRODUCT: REGARDLESS OF ACTUAL PRODUCT USE

❒ **4. SUMMARIZE: The context (experiences) in which product feels easiest to use/hardest to use for this participant.**

❒ **5. IDENTIFY NEEDS: Help the participant to identify her specific adherence needs given the context explored. What does this participant feel she needs in order for adherence to be as manageable as possible? (Keep the focus on making use *easier*, rather than *perfect*).**

<u>Adherence Related NEEDS:</u>

PTID:	Visit Code:

❒ **6. STRATEGIZE: Explore new strategies or continued use of established ones to address the needs identified.**

STRATEGIES:

❒ **7. NEGOTIATE: A goal that the participant identifies. Ask the participant what she might be willing to try or continue to do between now and the next session (Goal).**

GOAL

❒ **8. CLOSE THE SESSION: Summarize what was discussed; thank the participant for talking with you and contributing to the study; document the session (after participant leaves the room).**

CONTEXT → ADHERENCE RELATED NEEDS → STRATEGIES → GOAL

Please show participant what you are writing if you write notes during the session