Section 12. Counseling Considerations

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This section contains guidance on the following types of counseling provided in MTN-025:

- HIV pre- and post-test counseling
- HIV risk-reduction and vaginal ring adherence counseling (referred to as "HIV Prevention Options Counseling")
- Anal sex counseling
- Contraceptive counseling
- Month 3 Counseling Considerations
- Counseling on hair collection

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, support, motivation, skills-building, and/or referrals. Participants should be collaborators in the counseling sessions, which should be treated as a time for study staff and participants to exchange information with one another. Participants' experiences and needs are likely to change over time, so it is important to create an environment where they feel comfortable and encouraged to share openly with study staff. The content and focus of counseling discussions should responsively change over time, so

specific content to cover or skills to emphasize are not standardized for many of the counseling conversations that will take place. Rather, the *process* for these discussions is standardized to allow for appropriate tailoring and targeting to an individual participant's needs at a given point in time.

All counseling and referrals should be documented in participant study records per site SOPs. Proper documentation may be achieved through the use of counseling checklists/worksheets, and/or chart notes. Sample worksheets are available on the MTN website for HIV pre- and post-test, HIV prevention options, and contraceptive counseling. To support continuity in the ongoing client-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform subsequent counseling sessions. Sites are encouraged to use flags or alert notes in participant study charts to highlight issues requiring follow-up at subsequent visits or issues that need to be addressed by study team members outside of the counseling sessions (e.g. referral for clinical issues). Additional documentation requirements and tips are included for each type of counseling described below.

12.1 HIV Pre- and Post-test Counseling

HIV testing is required at all scheduled study visits. HIV pre-test and post-test counseling is therefore required at these visits as well. Sites are required to develop and follow SOPs for HIV counseling and testing. All HIV pre- and post-test counseling should be provided in accordance with local counseling standards and study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithm in protocol Appendices II and III. Client-centered approaches should be used to assess participant knowledge of relevant information, dispel misconceptions, ensure participant readiness for HIV testing, and confirm participant understanding of test results. Information should be provided in a manner that is respectful and interactive. Referrals should be provided when indicated.

At all participant visits, starting at screening, two rapid HIV tests will be conducted. Counseling messages following rapid HIV test results are provided in Table 12-1.

Table 12-1

Counseling Messages following Rapid HIV Test Results

Test Result	Counseling Message
Two negative Rapid tests	1. Test results indicate that you **are not infected** with HIV.
Two positive Rapid tests	1. Test results indicate that you **are infected** with HIV. **If at screening or enrollment:** 1. You are not eligible for MTN-025. ***Note:*** *Additional post-test counseling and referrals should be provided. Confirmatory testing may be provided as a service, per site discretion, but is not required per protocol. If testing will not be done, skip the rest of these messages* 2. If you choose, 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. The additional testing is done to give you information about your health and is not part of the study. 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. **If during follow-up:** 1. Additional testing will be done today to confirm this result. 2. The testing will be done from a new blood sample and can be conducted today in our lab. 3. It is common for HIV prevention studies to do additional testing for study purposes in this situation. 4. It is unusual for the additional testing to show a different result. 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.
One positive Rapid test, one negative Rapid test	1. Test results **are unclear**. 2. Additional testing is needed to determine your HIV status. 3. The testing will be done from a new blood sample and can be conducted today in our lab. 4. 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.

Depending on the results of the rapid HIV tests, Geenius confirmatory testing may be required. If Geenius confirmatory testing is going to be conducted, counselors should explain this testing, what it is for, and how it will be conducted when giving the rapid test results, as indicated in Table 12-1. Table 12-2 contains post-test counseling messages to provide to participants once the results of the Geenius confirmatory testing are known.

Table 12-2
Interpretation of HIV Tests Results Following Geenius Confirmatory Testing

Test Result	Status	Counseling Message
Two positive Rapid tests → Geenius positive	HIV-infected	1. Test results indicate that you **are infected** with HIV. 2. [Provide post-test counseling and referrals for HIV-infected participants as per site SOPs.]
Two positive Rapid tests → Geenius negative, HIV-1 indeterminate or other*	HIV status not clear	1. Although the HIV rapid tests we ran indicated that you are infected with HIV, the additional tests now indicate unclear results. 2. Further testing is needed to determine your HIV status. 3. The additional testing may show whether you are infected with HIV or not. No more blood needs to be taken at this time; we will use samples we have already collected. 4. You may need to give blood for testing at future visits for your status to be known. 5. We expect these additional results to be available [INSERT TIME FRAME – for Gene Xpert sites, probably 1-3 hours and for non-Gene Xpert sites, up to 2 weeks].
One positive Rapid test, one negative Rapid test → Geenius negative, HIV-1 indeterminate or other*	HIV status not clear	1. Test results **are unclear**. 2. Further testing is needed to determine your HIV status. **If at screening or enrollment:** 1. [Sites to perform additional testing and associated counseling per local standards of care (as outlined in SOPs) and as directed by the LC.] 2. You are not eligible for MTN-025 enrollment until your final HIV status is confirmed. **If during follow-up:** 1. The additional testing may show whether you are infected with HIV or not. No more blood needs to be taken at this time; we will use samples we have already collected. 2. You may need to give blood for testing at future visits for your status to be known. 3. We expect these additional results to be available [INSERT TIME FRAME – for Gene Xpert sites, probably 2-3 hours and for non-Gene Xpert sites, up to 2 weeks].
One positive Rapid test, one negative Rapid test → Geenius HIV-1 positive	HIV infected	1. Test results indicate you **are infected** with HIV. 2. [Provide additional post-test counseling and referrals for HIV infected participants as per site SOPs.] ***Note:*** *If at enrollment visit, participant is not eligible for MTN-025 enrollment.*

*Same counseling message for Geenius results of HIV-2 positive; HIV-2 indeterminate; HIV-2 positive with HIV-1 cross reactivity; HIV untypable

Additional results interpretations and counseling messages for the rare cases when a second Geenius test and HIV RNA viral load testing is required are provided in Table 12-3. These informational resources should be referenced as needed when providing pre-test and post-counseling. Stand-alone reference sheets of the counseling messages can be found in the Study Implementation section of the HOPE website. Additional information on HIV testing during screening and follow-up is provided in Section 13 of this manual.

Table 12-3
Interpretation of Additional HIV Tests Performed During Follow-up
Per Protocol Appendix III

Test Result	Status	Counseling Message
Additional Testing – Counseling Message Given at a future interim visit		
Geenius negative or HIV-1 indeterminate* → HIV-1 viral load negative (below limit of detection)	HIV-uninfected	1. Test results show that you **are not infected** with HIV.
Geenius negative or HIV-1 indeterminate* → HIV-1 viral load positive (at or above limit of detection)	HIV infected	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.
Geenius HIV-1 positive→ HIV-1 viral load positive (at or above limit of detection)	HIV-infected	1. Test results show that you **are infected** with HIV. 2. [Provide post-test counseling and referrals or follow-up on referrals previously provided as per site SOPs.]

*If Geenius results are HIV-2 positive; HIV-2 indeterminate; HIV-2 positive with HIV-1 cross reactivity; HIV untypable, HIV-1 viral load (Abbott M2000, Roche TaqMan or Gene Xpert) should not be performed. Please consult the MTN LC for guidance to confirm HIV-2 infection and for additional counseling messages, as needed.

Should you receive a result that is not outlined in one of the tables above, counsel the participant that her results are unclear and additional testing may be required. Contact the MTN Laboratory Center for guidance and additional counseling messages, as needed.

12.1.1 Documentation of HIV pre- and post-test counseling

HIV pre- and post-test counseling 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 counseling checklists, worksheets, and other tools, as desired. At a minimum, documentation should include questions that arise during the counseling session, the participant's acknowledgement of testing readiness, confirmation that the participant understood the results that were presented to her, and any referrals that may have been provided. During study visits when both rapid tests and Geenius confirmatory testing are conducted, testing readiness and understanding of results must be documented for *each* test. Sample HIV counseling worksheets are available on the study implementation tools section of the MTN-025 website.

12.2 HIV risk-reduction and protocol adherence counseling

HOPE participants will receive HIV risk reduction counseling at every visit beginning with the screening visit. At visits where the vaginal ring will be offered as an HIV prevention option (enrollment and all follow-up visits before PUEV), protocol adherence counseling, including vaginal ring adherence counseling as appropriate, will also be provided. At visits where both risk-reduction and adherence counseling are required, they will be incorporated into a single session referred to as "HIV Prevention Options Counseling". An HIV prevention options counseling session will also occur at PUEV, where it will focus on providing available residual drug data to participants and developing effective risk reduction plans once the dapivirine ring is no longer accessible. See Figure 1 for an illustration of the different types of counseling sessions HIV risk reduction counseling will be provided throughout study follow-up.

Figure 12.1: HIV Risk Reduction Counseling Sessions

Whenever possible, counseling sessions should offer skills-building to the participant, e.g., on how to use male condoms, how to discuss sensitive issues with partners and other influential persons. Condoms should always be offered as part of HIV risk-reduction and/or HIV prevention options counseling sessions as well.

12.2.1 HIV risk-reduction counseling at screening

HIV risk-reduction counseling is required at all HOPE screening visits. This session may be incorporated into HIV pre- or post-test counseling, as specified in site SOPs,

or may occur as a stand-alone session. Risk reduction counseling sessions should start with an assessment of recent risk behavior during which counselors should ask open-ended questions, actively listen to participant responses, and probe as needed for further information. As with all counseling sessions, efforts should be made to create a neutral and non-judgmental environment so the participant feels comfortable sharing her risk behaviors. Ideally, the counselor will guide the participant in self-identifying her risk factors, though if it seems that the participant is struggling with identifying experiences or behaviors that could potentially expose her to HIV, the counselor can help point out these risks.

Once potential risks have been identified, the conversation should progress to a discussion of possible risk reduction strategies and, eventually, to the development of an individualized risk reduction plan. When exploring risk reduction strategies, the counselor should first ask what the participant's experience with risk reduction strategies has been since her last ASPIRE visit. Counselors might want to ask what strategies the participant tried, what worked or didn't work, and what facilitators or barriers she encountered when trying to implement her risk reduction plan. Building off of this information, the counselor can then correct any misinformation and/or review additional HIV risk reduction strategies by referencing the HIV Prevention Options factsheet available on the MTN website. This is a good point in the session to review the ASPIRE and Ring Study results and to remind the participant that if she is eligible to join HOPE, she will also have access to the dapivirine ring and may choose to use it for HIV prevention in addition to the other strategies discussed during this session.

The final step in the risk reduction counseling at screening is to develop a risk reduction plan for the participant to use after her screening visit. Risk reduction plans should be participant-driven and responsive to the participant's unique HIV risks and life circumstances. Risk reduction plans should be practical, yet challenge the participant toward risk reduction. For participants whose risk reduction barriers are significant, risk reduction plans may need focus on very small, incremental, and achievable steps. When helping a participant develop her risk reduction plan, remember:

- Successful strategies should be continued;
- Additional strategies may be identified to achieve further risk reduction;
- Alternative strategies may be identified if current strategies are not feasible or being successful.

HIV counseling for partners should always be offered, either as an individual session or as a couple's session. Some suggestions on how to conduct a couple's counseling session are provided below.

Table 12-4 below provides some examples of risk reduction (RR) conversations which can be used at pre- or post-test HIV counseling after providing necessary information about the HIV-test.

Table 12-4
Examples of Risk Reduction Conversations

	INDIVIDUAL	COUPLES
Check in on recent experiences (previous RR plan)	*Over the last month, what have your experiences around protecting your sexual health been? [How did things go with your RR plan from last visit?] Do you feel comfortable enough to tell me what kinds of sex you currently engage in? {inquire about vaginal sex and anal sex}*	*Over the last month, what has it been like for you both in terms of protecting each other's sexual health? [How did things go with the RR plan from last visit?] Do you feel comfortable enough to share with me the kinds of sex you engage in. {inquire about vaginal sex and anal sex}*
Ask about prevention strategies	*What are you doing now, or thinking of doing, to protect yourself sexually?*	*What are some of the things you are doing or thinking about doing to reduce your risks of getting HIV?*
Provide permission	*A lot of people find it difficult to use strategies to protect their sexual health in different kinds of situations.*	*A lot of couples find it difficult to use strategies to protect their sexual health in different kinds of situations.*
Ask about situations, conditions, or factors that increase risk of HIV exposure	*What are the situations, conditions or other things that make protecting yourself really hard to do?*	*What are the situations, conditions or other things that make protecting yourself or each other difficult to do?*
Discuss continuing with strategies in place and/or adopting new strategies	*What would need to happen for your sexual health to be better protected? How can you see that happening?*	*I would like to ask each of you to share what you think would need to happen for your sexual health to be better protected.*
Identify plan	*Summarize needs and strategies discussed. Ask participant if the strategy (strategies) identified (existing or new) is something she is willing to continue with or try before the next visit.*	*Summarize each partner's needs and suggestions. Work towards identifying one or more strategies noted that would offer a compromise (if needed) or a well-matched approach. Continue this process until an agreement to continue with or adopt a new approach is found. Encourage the couple to identify this; do not prescribe.*
Build information, motivation, and skills around the strategy (strategies) as needed	*Discuss strategy and provide skills building as needed.*	*Discuss strategy and provide skills building as needed.*
Set a goal for next visit	*Confirm plan.*	*Confirm plan.*

12.2.2 HIV prevention options counseling

An HIV prevention options counseling session will occur at Enrollment, months 1, 2, 3, 6, and 9 of study follow-up, as well as the PUEV visit. Only counselors who are certified (see Section 12.2.5 for details on the certification process) may conduct the HIV prevention options counseling. While any certified counselor can conduct Options Counseling, site teams should be thoughtful about their pairing of counselors to participants. Sites are *strongly encouraged* to have participants see the same counselor at each study visit, if at all possible. Site teams might consider factors such as counselor age, sex, communication style, and participant requests when pairing counselors with participants. In addition, in order to promote an open and neutral environment, staff conducting the Options counseling must be different than those who conduct other behavioral procedures during the visit (e.g. administration of

behavioral questionnaires, qualitative interviews, etc.). Ideally, a different cadre of staff should conduct the Options counseling and behavioral assessments.

Detailed guidance regarding the HIV prevention options counseling at enrollment and during follow-up is provided in the manual titled "Options in HIV Prevention: A Client-Centered Counseling Approach for The HOPE Study (MTN-025)" available on the HOPE website. A flipchart and counselor Q&A document covering common questions have also been developed for use during the HIV prevention options counseling session and are available online on the MTN-025 website.

For participants on a product hold or permanent discontinuation, HIV prevention options counseling sessions can be tailored, as needed (e.g. to discussions of risk reduction and retention only), and the HIV prevention options counseling flipchart may or may not be used, depending on the exact circumstances. However, residual drug information should always be shared, if available, using the relevant pages of the counseling flipchart, regardless of whether the participant is on product hold or permanent discontinuation. 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 12-3.

12.2.2.1 HIV prevention options counseling at enrollment

The purpose of the HIV prevention options counseling at enrollment is to orient the participant to the purpose and content of these sessions in HOPE, to help her make an informed decision about accepting or not accepting the ring as an HIV prevention method, to discuss other HIV prevention strategies (building upon the risk reduction counseling provided during the screening visit), and reinforce the importance of accurate reporting of adherence to study product use to the overall goals of the study. 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.

12.2.2.2 Follow-up HIV prevention options counseling

At the month 1, 2, 3, 6 and 9 follow-up visits, as well as PUEV, HIV prevention options counseling will focus on the HIV risk reduction plans developed at the previous session, including an exploration of how the participant is doing with ring use and/or other HIV prevention methods she selected to try. The conversation should include a discussion of what went well or did not go well, how the participant is feeling about her HIV prevention approach(es), and what the participant would like her HIV risk reduction plan to look like for the coming month(s), including her desire to start or continue using the ring as part of her HIV prevention strategy (if relevant). Counseling sessions should include a check-in about facilitating attendance to study visits. Informational support, such as a review of the Vaginal Ring Insertion Instructions/Important Information sheet or the HIV Prevention Options factsheet (See Appendix 12-2), should also be incorporated, as needed.

During follow-up, it is recommended that Options counseling occur after completion of ACASI 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 Options

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.

12.2.2.3 Receipt and Interpretation of Residual Drug Information

Starting at Month 3, HIV prevention options counseling will also include feedback on residual drug data. The table below presents a summary of what residual drug information will be available at respective study visits:

Table 12-5
Counseling Sessions with Residual Drug Feedback

Counseling Session	Residual Drug Data Available
Month 3	First Month of Use (i.e., ring dispensed at enrollment and collected at Month 1 visit)
Month 6	Rings from Months 2-3
Month 9	Rings from Months 4-6
Month 12 (PUEV)	Rings from Months 7-9

Residual drug data will be posted for sites to retrieve and download on a secure site-specific MTN-025 ATLAS webpage. Residual drug level results will be provided to sites in a report from SCHARP that will include the study PTID and results for any rings that are available at that time. Residual drug level results will be categorized into groups based on estimated use of the ring. Results are provided in four categories represented by a number on a scale: 0, 1, 2, 3; where "0" reflects probable low or no use/no HIV protection and "3" reflects probable high use/high HIV protection. Residual drug results will account for the length of time the participant had access to the ring, but counselors should remember that because the dapivirine ring is still an investigational product, it is not possible to say with absolute certainty what level of drug release is necessary to achieve HIV protection. Additionally, residual drug testing provides an estimate of ring use and, like all lab tests, is not 100% accurate. Finally, it is important to recognize that sometimes women may not use the ring all the time but still get good levels of protection, specifically if they use it when most at risk; depending on how and when a participant used the ring, any results in categories 1-3 could represent achieving adequate protection from HIV-1 based on her needs and circumstances. Because of these factors, residual drug feedback should be used to open a conversation with the participant, but counseling sessions should emphasize the importance of the participant's reported experience and regard her as the most reliable source of this information. Ultimately, only the participant knows how and when she used the ring throughout each month. See also Operational Guidance documents #1 and #2 for detailed information about residual drug result testing and counseling.

It is anticipated that residual drug results will be available on the schedule in table 12-5. In the event that results are not available, the visit should proceed as originally scheduled and the participant should be counseled that she will be contacted when this information is available. Note that various factors may contribute to RD results not being available at the time of a participant's scheduled visit, including but not limited to: shipping delays, visits being scheduled earlier than anticipated, issues with processing/testing of rings, outstanding QCs on ring related CRFs (e.g. Vaginal Ring

Tracking Log) or LDMS queries, or failure to recognize that updated RD reports are available on Atlas. In order to identify and resolve any issues with delays in RD reports, sites are requested to notify the MTN-025 management team whenever results are not available per the schedule reflected in table 12-5. The participant PTID, ring code, date of ring return, date ring shipped to Parexel, and date of scheduled visit at which results were not available should be provided in this notification.

In some cases, residual drug data may be available earlier than listed (e.g., rings returned at Months 1 and 2 may sometimes be available by the Month 3 counseling session). All available results at the time of the visit should be provided to participants during their Options counseling session. Counselors are also encouraged to make use of residual drug feedback visual tools available on the MTN-025 website (Residual Drug Feedback Over Time and Residual Drug Feedback Timeline) to support participants in understanding the information and its timing. Note that while it is up to the discretion of each counselor whether to use these tools during the Options counseling session, it is required that the Residual Drug Feedback Over Time tool be kept up to date and filed in the participant binder.

At PUEV/SEV, counselors should offer participants the opportunity to receive the residual drug feedback from the rings she returns at PUEV (i.e. rings used during the period from Month 9 through PUEV). In the event that a participant would like to receive this feedback, post-study contact can be made in order to provide her with this information. This procedure falls under the provision of lab results, is not required, and should only be documented in chart notes and, if desired, on the Residual Drug Feedback Over Time Supplement, which is available for download on the MTN-025 website. No CRF updates or completion is required for this procedure.

12.2.3 HIV risk-reduction counseling Study Exit/Termination Visit

Much like previous risk reduction discussions, HIV risk-reduction counseling at Study Exit/Termination should focus on helping the participant identify her individual HIV risk factors, explore experiences implementing her chosen risk reduction strategies since her last visit, and develop a risk reduction plan moving forward. During the Study Exit/Termination Visit risk reduction session, counselors should review the process and potential timelines for dapivirine ring licensure and roll-out so participants have a better understanding of the factors that might determine if/when the dapivirine ring might be available in their communities. Counselors should work with participants to develop risk reduction plans that are effective and achievable once study-provided support, including ring access, is no longer available. Referrals to community resources should be made, as appropriate.

12.2.4 Documentation of HIV risk-reduction and HIV Prevention Options Counseling

HIV risk-reduction and HIV prevention options 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 counseling checklists, worksheets, and other tools, as desired. An example of an HIV Prevention Options Counseling Worksheet is available for download on the MTN-025 website.

Ideally, documentation of the counseling discussion would take place *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. Counseling notes do NOT need to summarize the procedural aspects of the counseling approach, which are the

same across participants. Signing off on the risk reduction and/or HIV prevention options 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.

12.2.5 Quality Assurance and Mentorship for HIV Prevention Options Counselors

To ensure fidelity to the counseling approach in HOPE, each staff member who will be responsible for conducting HIV prevention options counseling in MTN-025 will be required to become certified prior to seeing study participants. This will be accomplished through the conduct of mock counseling sessions in English with a peer on site. To become certified, each counselor must complete three mock sessions that meet or exceed pre-established fidelity criteria, as defined and evaluated by the Behavioral Research Team at the HIV Center for Clinical and Behavioral Studies at Columbia University. At least one counselor must be certified prior to site activation for HOPE. Six videos of mock counseling sessions have been produced for training purposes and are available to viewing at: https://www.youtube.com/playlist?list=PLSxFFM-6EltKigi_lAAs9R2O3XRW5Ct1g.

The following scenarios are covered in these demonstration videos:

1. Visit 1, Yes to Ring: The participant accepts the dapivirine ring as part of her HIV prevention strategy
2. Visit 1, No to Ring: The participant does not accept the dapivirine ring and chooses other HIV prevention methods
3. Follow up visit, Drug Level 0: The counselor and participant discuss the residual drug feedback from the participant's first returned ring, which is categorized as a 0, indicating that a low level of drug was released into her body and, therefore, a low level of HIV protection was provided by the ring.
4. Follow up visit, Drug Level 2: The counselor and participant discuss residual drug feedback from a participant's returned ring, which indicates residual drug level of 2. The counselor and participant discuss how ring removals impact residual drug levels and possible levels of HIV protection provided by the ring. .
5. Follow up visit, Drug Level 3: The counselor and participant discuss residual drug feedback from the participant's first returned ring, which is categorized as a 3. They discuss the participant's reactions to these results and the fact that she is likely achieving a high level of HIV protection was from the ring.
6. Follow-up visit, Drug Level 1, participant insists she used the ring: The counselor and participant discuss residual drug feedback for the participant, categorized as a 1. The participant is confused and insists she is using the ring consistently. The counselor uses a client-centered approach to explore the participant's reactions to her results and what they mean and help her think through an HIV prevention plan for the coming month(s).

Sites may use these videos during their initial training and are also encouraged to reference them periodically throughout study implementation.

Once certified, counselors may begin seeing participants at their HOPE study visits. Ongoing fidelity monitoring will take place throughout the trial by a systematic review of audio-recorded counseling sessions. Participants should be informed of these audio recordings for quality assurance purposes verbally or through the administration of a site-specific information sheet or ICF, per local IRB requirements. All HIV prevention options counselling sessions will be digitally recorded and, after each interview, audio files will be uploaded to SCHARP's Atlas website. Additional

details regarding how to record and upload counseling sessions can be found in the counseling manual, "Options in HIV Prevention: A Client-Centered Counseling Approach for The HOPE Study (MTN-025)" available on the HOPE website. Columbia's behavioral researchers will create a small team of staff to listen to and rate sessions in each of the HOPE study languages. Once counselors begin seeing study participants, their first 5 Enrollment Visits and first 3 Follow-up Visits will be reviewed. Subsequently, one in 10 sessions will be reviewed and rated. Completed rating forms will be sent to the counselor who completed the session.

Using information gleaned from the counseling recordings, the Columbia team will convene monthly coaching calls in order to provide mentorship to the counselors at each site. Coaching calls may contain counselors from multiple sites and will involve feedback from the session ratings, discussion of challenges in delivering the counseling, and live review of recorded counseling sessions. Coaching calls that include review of non-English language sessions will also include the staff member at Columbia who rates the sessions in that language. These calls are not intended to be punitive in nature, but rather are designed to build capacity of counseling staff and improve the quality of the counseling at site.

12.3 Product Use Instructions

12.3.1 Participant Instructions for Ring Insertion and Removal

During the first visit in which a participant is receiving a vaginal ring, the staff member providing the participant with the ring should also review detailed instructions regarding vaginal ring insertion and removal. To assist with this task, staff should utilize the Vaginal Ring Insertion Instructions/Important Information sheet (see Appendix 12-2).

Note that the 'Important Information' sheet highlights key information for correct ring use, and should be supplemented with additional information provided verbally to participants as needed. For example, additional rationale for the 'avoid' message may be provided to encourage healthy vaginal practices. Study staff can explain that douching, vaginal devices, and other vaginal practices that involve using detergents and soaps inside the vagina are discouraged because they may impact the effectiveness of the ring (if the participant is an acceptor) and because they may have a negative impact on vaginal health. Or, as another example, further rationale may be provided about why we ask that participant not share their rings. Staff are encouraged to reference other study resources such as the study factsheets and counseling Q&A document for help with addressing participant questions.

The ring insertion instructions/important information sheet should also be translated into local languages and approved by local IRBs so that it may be provided to participants to take home, if desired. While reviewing these instructions with participants, staff should also use visual aids and pelvic models (if available) to help explain ring insertion and removal.

Participant Instructions for Ring Insertion: Review steps in Appendix 12-2

Participant Instructions for Ring Removal (provide verbally to participants):

1. Before removing the ring, wash and dry your hands.

2. Choose a comfortable position (can reference ring insertion instructions for illustrations of different positions).
3. Put a finger into your vagina and hook it through the ring.
4. Gently pull down and forward to remove the ring.
5. 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, continue to steps 6-9.
6. Place the used ring in the bag provided by clinic staff or other suitable container if the bag is not available.
7. Wash your hands.
8. Place used ring and container in a safe and private area out of reach of children or other occupants of the home.
9. Bring any used ring (in its container) with you to the clinic during your next study visit.

During the review of ring instructions starting at Month 3, staff members should explain that the HOPE study will also track the order in which rings were used. This will be done by numbering each ring and a corresponding return bag with the same numeric code. At any visit when a participant is returning a ring or rings not inserted in the vagina, she should place the ring in its matching return bag. Participants should be asked to make their best effort to complete this task, but should not be penalized for non-compliance with this request. Additional details about tracking the order of used rings can be found in SSP Section 9.2.2 as well as the MTN Pharmacy Manual (information for pharmacists),

12.3.2 First Product Use

After providing product insertion instructions and answering any questions the participant may have, study staff will ask the participant if she is ready to try inserting the VR herself. Insertion should be performed in a private space, with study staff standing by in case the participant requests guidance or technical assistance.

Difficulties in inserting the study VR are expected to be rare. For participants who have difficulty, study staff should provide further information and guidance to address the difficulty encountered. This should be flagged within chart notes or the alert logs in the participant binder for active follow-up at subsequent visits. After guidance is provided, the participant should try again to insert the study VR at the enrollment visit. If she is unable, study staff may insert the VR for the participant.

After the VR 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 participant study documents so the information is easily available for reference at study follow-up visits.

12.3.3 Clinician Instructions for Checking Ring Placement

Digit exams to check ring placement are only required if indicated throughout study follow-up (e.g. the participant expresses discomfort after inserting the ring and wants reassurance that it has been placed correctly).

As needed, the following is the procedure that should be used to verify ring placement:

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

After correct placement is confirmed, staff may ask the participant if she would like to feel the position of her ring. This will help ensure that she understands what correct placement feels like, should she need to check this between study visits. This instruction may be repeated at any visit, as needed.

12.4 Anal Intercourse Counseling

The main way HIV is spread sexually is by **anal or vaginal sex without condoms** with an HIV-infected person (see table 12-3 below). All women in MTN-025 will be experienced and familiar with vaginal sex and should have received anal sex education during ASPIRE study participation. Still, it may be necessary to review the following information about anal sex with HOPE participants:

Definition of heterosexual anal sex:
Anal sex is when the man puts his penis into a woman's anus or rectum. This is different from having vaginal sex "from behind," where the penis is inserted into the vagina.

Many heterosexual couples have tried anal sex, and some enjoy anal sex as a regular feature of their lovemaking. Regardless of whether or not counsellors are familiar with the practice, all discussions concerning anal sex should, like all topics, be approached in a neutral, non-judgmental way. If counselors anticipate being uncomfortable with conversations about anal sex, it is recommended they speak to their supervisor and/or other counselors.

Anal sex risk and risk reduction:
In terms of risk for HIV-infection, unprotected anal sex is riskier for women than unprotected vaginal sex. This has to do with the potential for damage to the rectum, allowing for greater opportunity for the passing of HIV through bodily fluids. Ways to manage risk with anal sex include using condoms, which is easier to do with the use of extra lubrication (using lubricants you can buy in a store).

Anal sex in the context of MTN-025:
The following facts may be useful when discussing anal sex with a participant:

- Anal sex is <u>not</u> exclusionary in MTN-025.
- The vaginal ring (VR) <u>should ONLY be inserted vaginally.</u>
- It is not known if the VR, even if effective for vaginal sex, can protect from HIV transmission through anal sex. Because of this, we ask for open reporting of anal sex practices throughout the duration of the study.

If the participant seroconverts, this will help the research team understand if this could have been due to practices that may not be protected through VR use.

- For all participants who report having anal sex, suggest strategies for risk reduction (e.g. condom use, reduction in number of partners, replacing some anal sex with less risky behaviors for anal sex) and support risk reduction strategies already in place.

Table 12-6 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 combined with HIV prevention options counseling manual and HIV prevention options factsheet to discuss risk reduction options, and the obstacles that may be associated with them, with the participant.

Table 12-6
HIV and STI Sexual Risk and Risk Reduction

Sexual Activity	Bodily Fluids Involved	Risk for HIV /STD Infection	Risk reduction options for women
Holding hands	None	None	These activities can be a viable alternative to higher risk behaviors.
Kissing	Saliva	None	
Masturbation	Vaginal fluid/semen	None	
Thigh sex	Vaginal fluid/semen	Low/negligible	
Mutual masturbation	Vaginal fluid/semen	Low/negligible	
Oral sex	Saliva/vaginal fluid/semen/blood	Condomless: Low (for HIV) to high (for some STIs) With Condom: Low	Use male condom; dental dams; abstinence; this can be a viable alternative to higher risk behaviors
Vaginal sex	Vaginal fluid/semen/blood	Condomless: High With Condom: Low	Use a condom; use dapivirine ring; get both partners tested and practice mutual monogamy; adopt alternative sexual behaviors; abstinence
Anal sex	Semen/blood	Condomless: Very High With Condom: Low	Use a condom; get both partners tested and practice mutual monogamy; adopt alternative sexual behaviors, abstinence

Anal Sex Counseling Guide and Fact Sheet:

To help facilitate participant education and counseling about anal sex, two resources have been developed for use in HOPE:

- Counseling Guide: This guide is intended for staff use only. It does not require translation or IRB approval prior to implementation.
- Factsheet: This information booklet is for use with participants either in the clinic or to take home. Site teams must translate and obtain IRB approval for the booklet prior to its distribution.

Use of these materials is left up to the sites, who may choose to use one, both, or neither of these resources. Both references can be found on the MTN-025 website on the Study Implementation Materials page (http://www.mtnstopshiv.org/node/3672). Microsoft Word versions of the Counseling Guide and Factsheet are available upon request from FHI 360 for any sites wishing to make site-specific modifications.

12.5 Contraception Considerations

To be eligible for MTN-025, potential participants must report use of an effective method of contraception at enrollment and intent to use an effective method for the duration of study participation. Effective methods include hormonal methods (other than contraceptive vaginal rings), IUDs, and sterilization of the participant.

To optimize access and consistent use of contraception, all sites should provide as many methods as possible to study participants on site. Sites that are not currently able to provide implants and IUDs are encouraged to build capacity to provide these methods as early as possible during the period of study implementation; while such capacity is being established, strong referral mechanisms must be maintained to ensure participant access to these methods.

All sites should offer emergency contraception to study participants when applicable. The term emergency contraception refers to back-up methods for contraceptive emergencies which can be used within the first few days after unprotected intercourse to prevent unwanted pregnancy. The WHO-recommends two methods of emergency contraception: emergency contraceptive pills and copper bearing IUDs. Please see the WHO Fact Sheet re-printed in Section Appendix 12-1 for more information on emergency contraception. Site staff are encouraged to incorporate information about emergency contraception into the monthly contraceptive counseling sessions in HOPE to increase participant understanding of how emergency contraception works and its availability at the clinical research site.

12.5.1 Contraceptive Counseling

Contraceptive counseling is required at all scheduled study visits until the Study Exit/Termination visit, when it is provided if indicated or if per local standard of care. 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/

For participants who become infected with HIV, further guidance is available in FHI 360's toolkit for Increasing Access to Contraception for Clients with HIV, which is available at http://www.fhi360.org/resource/increasing-access-contraception-clients-hiv-toolkit.

Study staff who provide contraceptive counseling should be trained to do so per local practice standards and should also be trained on MTN-025 protocol specifications related to contraception. Note that for MTN-025, effective methods include:

- Hormonal methods (except contraceptive rings)
- Intrauterine device (IUD)
- Sterilization (of participant, as defined in site SOPs)

Male and female condoms should be used in conjunction with one of the other methods mentioned above and are not, by themselves, considered effective contraceptive methods for MTN-025. Dual protection (hormonal contraception with condoms) should be encouraged generally. For participants who initiate hormonal contraceptives during the study, dual protection for the first month should be further emphasized, as hormonal contraceptives as may take a few weeks to become fully protective.

All contraceptive 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. 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.

At screening and enrollment visits, contraceptive counseling should be provided in the context of the study eligibility criteria related to pregnancy intentions and willingness to use an effective contraceptive method. Counseling provided at these visits should therefore explain which methods are acceptable for study purposes and emphasize that women who cannot commit to use of these methods for duration of study participation should not enroll.

At follow-up visits, client-centered counseling should be offered. 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 and supportive. For participants with issues or problems with their current method, counseling sessions during follow-up include discussion of the specific problems encountered and identify potential strategies to address these, which may include switching methods.

Women may choose to discontinue contraception during follow-up. These participants can remain in the study and continue using study product. Contraceptive counseling should still be provided at each scheduled visit. During these sessions, the possibility of resuming contraceptive use should be re-visited periodically to determine whether the participant's circumstances may have changed.

12.6 Month 3 Counseling Considerations

After the month 3 follow-up visit, participants will transition from a monthly to a quarterly visit schedule. Additional guidance about this schedule shift may need to be incorporated into the HOPE counseling sessions that occur at the month 3 visit.

12.6.1 Month 3 HIV Prevention Options Counseling Considerations

During the month 3 HIV prevention options counseling session, risk reduction plans should take into account that it may be three months before the participant returns to the clinic for her next visit. The participant should be encouraged to think through upcoming plans, events, or circumstances in the next three months that may challenge or facilitate her risk reduction plans. Additional condoms should be provided at quarterly visits beginning at month 3, as desired by the participant.

Possible topics for discussion might include:

- Where the participant will store her unused rings and used rings post-removal
- Why it is important to change the ring on time each month and how the participant will remember when it is time to change her ring
    - See also SSP section 6.4.2 Considerations for Interim Contacts During Quarterly Follow-up Schedule
- The importance of not sharing rings with friends or family members
- Any questions or concerns the participant has about having extra rings in her possession
- Alternatives to accepting additional rings at this visit, as needed (namely, that participants have the option to return to the clinic each month to pick up a new ring if she feels uncomfortable having a supply of two unused rings in her home)
    - See also SSP section 6.4.1 Visits to Pick Up Rings During Quarterly Follow-up Schedule

The counselor should flag any issues that arise during the counseling session that might be important for the staff member providing the ring(s) later in the visit to follow up on.

Staff responsible for providing the rings to the participant should review the process for removing rings and storing in the appropriate used ring bag (i.e. in numerical order, see section 12.3.1 above). Staff should emphasize that while we are asking the participant to track the order in which she uses the rings to the best of her abilities, we expect that this may not always be possible, and she will not be penalized for her inability to do.

Participants will also be asked at their subsequent visit to rate how well she felt she was able to use each ring and how many days each ring was removed. The purpose of collecting this information is to better understand how much dapivirine is released from the rings. Again, we ask participants to do the best they can to report accurate information about use of each ring, but they will not be penalized if they cannot recall exact use. Should the participant wish to use tools to help her remember this information (e.g. making a note in her diary or on a calendar), this is acceptable, however, these tools will not be collected or stored in the participant record nor are they expected to be routinely implemented across study participants.

As month 3 may be the first time a participant is receiving multiple rings, participants should be reminded and discouraged from sharing vaginal rings with others.

12.6.2 Month 3 Contraceptive/Clinical Counseling Considerations

At the month 3 visit, study staff should pay special attention to the contraceptive method the participant is using and when her next dose is due. If she will be due for contraception provision prior to her next scheduled study visit, staff should work with her to arrange for contraceptive coverage, either by scheduling an appointment at the clinic, providing additional coverage at the current visit (e.g. extra packs of oral contraceptive pills or condoms), or making sure she can access family planning services through the public sector, if that is where she prefers to receive her contraceptive method.

Study staff should also have a conversation with participants at their month 3 visit about what to do in the case of a suspected pregnancy in between study visits. Participants should be encouraged to contact the study clinic any time they have a suspected or confirmed pregnancy and should be invited to the clinic for a confirmatory test any time. Staff should reassure participants that continued product use is ok unless or until a positive pregnancy test is received.

In the same respect, study staff should have a conversation with participants about what to do if she suspects HIV infection between study visits. Participant should be counseled on what the signs and symptoms of acute HIV are, and encouraged to contact the clinic if she suspects HIV infection, and invited to the clinic for HIV testing at any point per clinician discretion.

12.7 Counseling on Hair Collection Procedures

Starting at a participant's Month 1 visit, hair samples will be collected from all participants. Hair collection is required per protocol unless the participant declines. As this procedure is new for participants (i.e. was not previously done in ASPIRE), some guidance on counseling about this sample collection is provided below. It is recommended that staff review these points with participants when she first has hair collected (month 1) and then as needed throughout study follow-up. Staff should also make use of hair collection visual tools, which are available on the MTN-025 website.

Counseling Messages:

- As part of HOPE, we are asking for your permission to cut a small sample of hair from your head to check the amount of dapivirine in this hair sample.
    - Note: For participants who have never had exposure to dapivirine, e.g. those who have always declined the ring, hair samples will be used as negative controls (samples known not to contain dapivirine so we can compare to samples which contain dapivirine)
- Medicines go into many places in the body, for example into your blood, tissue, and your hair.
- The amount of dapivirine found inside the hair sample may provide a better idea of how much dapivirine was released from the ring into your body over a long period of time.
- Hair sample testing has been part of many other studies throughout Africa and the world, and is being done in HOPE as another possible way to help researchers understand how much dapivirine is needed to prevent HIV infection.

- We will collect about 50-hairs from your head. Of note, we all lose about 100 strands from our scalp daily (that amount of hair falls out or is brushed out).
- Cutting this small amount of hair from your head will not disrupt your hairstyle and will not affect the normal new growth of your hair.
- We store the hair samples safely, ship them to a laboratory, cut them up into small pieces and dissolve the entire sample into a liquid. That liquid is then injected into a machine to measure the amount of study medication. The hair sample is completely dissolved so there is none remaining.
- If there is hair collected that is not analyzed, those hair samples will be completely destroyed at the end of the study by dissolving the hair into a liquid and then disposing of the liquid.
- No one but study investigators will have access to the hair samples and they will be kept safe at all times in a secured laboratory. The laboratory will not have access to any names or any identifying information for the people from whom hair was collected.
- As with any study procedure, collection of hair samples is voluntary. If you choose not to provide a hair sample, this will not affect your participation in HOPE.

World Health Organization

Emergency contraception

Key facts

- Emergency contraception can prevent most pregnancies when taken after intercourse.
- Emergency contraception can be used following unprotected intercourse, contraceptive failure, incorrect use of contraceptives, or in cases of sexual assault.
- There are two methods of emergency contraception: emergency contraceptive pills (ECPs) and copper-bearing intrauterine devices (IUDs).
- When inserted within five days of unprotected intercourse, a copper-bearing IUD is the most effective form of emergency contraception available.
- The emergency contraceptive pill regimen recommended by WHO is one dose of levonorgestrel 1.5 mg, taken within five days (120 hours) of unprotected intercourse.

Emergency contraception, or post-coital contraception, refers to methods of contraception that can be used to prevent pregnancy in the first few days after intercourse. It is intended for emergency use following unprotected intercourse, contraceptive failure or misuse (such as forgotten pills or torn condoms), rape or coerced sex.

Emergency contraception is effective only in the first few days following intercourse before the ovum is released from the ovary and before the sperm fertilizes the ovum. Emergency contraceptive pills cannot interrupt an established pregnancy or harm a developing embryo.

Who needs emergency contraception?

Any woman of reproductive age may need emergency contraception at some point to avoid an unwanted pregnancy.

In what situations should emergency contraception be used?

Emergency contraception can be used in a number of situations following sexual intercourse.

- When no contraceptive has been used.
- When there is a contraceptive failure or incorrect use, including:
    - condom breakage, slippage, or incorrect use;
    - three or more consecutively missed combined oral contraceptive pills;
    - the progestogen-only pill (minipill) taken more than three hours late (or more than 12 hours late if taking a 0.75mg desogestrel-containing pill);
    - norethisterone enanthate (NET-EN) progestogen-only injection taken more than two weeks late;
    - depot-medroxyprogesterone acetate (DMPA) progestogen-only injection taken more than four weeks late;
    - the combined estrogen-plus-progestogen monthly injection taken more than seven days late;
    - dislodgment, delay in placing, or early removal of a contraceptive hormonal ring or skin patch;
    - dislodgment, breakage, tearing, or early removal of a diaphragm or cervical cap;
    - failed withdrawal (e.g. ejaculation in the vagina or on external genitalia);

    - failure of a spermicide tablet or film to melt before intercourse;
    - miscalculation of the periodic abstinence method, or failure to abstain or use a barrier method on the fertile days of the cycle;
    - expulsion of an intrauterine contraceptive device (IUD) or hormonal contraceptive implant.
- In cases of sexual assault when the woman was not protected by an effective contraceptive method.

Methods of emergency contraception

There are two methods of emergency contraception:

- emergency contraception pills (ECPs)
- copper-bearing intrauterine devices (IUDs).

1. Emergency contraception pills

WHO recommends levonorgestrel for emergency contraceptive pill use. Ideally, this progestogen-only method should be taken as a single dose (1.5 mg) within five days (120 hours) of unprotected intercourse. Alternatively, a woman can take the levonorgestrel in two doses (0.75 mg each; 12 hours apart).

Mode of action

Levonorgestrel emergency contraceptive pills prevent pregnancy by preventing or delaying ovulation. They may also work to prevent fertilization of an egg by affecting the cervical mucus or the ability of sperm to bind to the egg.

Levonorgestrel emergency contraceptive pills are not effective once the process of implantation has begun, and they will not cause abortion.

Effectiveness

Based on reports from nine studies including 10 500 women, the WHO-recommended levonorgestrel regimen is 52–94% effective in preventing pregnancy. The regimen is more effective the sooner after intercourse it is taken.

Safety

Levonorgestrel-alone emergency contraception pills are very safe and do not cause abortion or harm future fertility. Side-effects are uncommon and generally mild.

Medical eligibility criteria and contraindications

Emergency contraceptive pills prevent pregnancy. They should not be given to a woman who already has a confirmed pregnancy. However, if a woman inadvertently takes the pills after she becomes pregnant, the available evidence suggests that the pills will not harm either the mother or her fetus.

Emergency contraceptive pills are for emergency use only and are not appropriate for regular use as an ongoing contraceptive method because of the higher possibility of failure compared with non-emergency contraceptives. In addition, frequent use of emergency contraception can

result in side-effects such as menstrual irregularities, although their repeated use poses no known health risks.

There are no medical contraindications to the use of levonorgestrel emergency contraception pills.

2. Copper-bearing intrauterine devices (IUDs)

WHO recommends that a copper-bearing IUD, as an emergency contraceptive, be inserted within five days of unprotected intercourse. This may be an ideal emergency contraceptive for a woman who is hoping for an ongoing, highly effective contraceptive method.

Mode of action

As emergency contraception, the copper-bearing IUD primarily prevents fertilization by causing a chemical change that damages sperm and egg before they can meet.

Effectiveness

When inserted within five days of unprotected intercourse, a copper-bearing IUD is over 99% effective in preventing pregnancy. This is the most effective form of emergency contraception available. Once inserted, the woman can continue to use the IUD as an ongoing method of contraception, and she may choose to change to another contraceptive method in the future.

Safety

A copper-bearing IUD is a very safe form of emergency contraception. The risks of infection, expulsion or perforation are low.

Medical eligibility criteria and contraindications

The only situation in which a copper-bearing IUD should never be used as emergency contraception is if a woman is already pregnant. There are other contraindications to using a copper-bearing IUD as ongoing contraception, which also should be considered before its use as emergency contraception. For more information, please refer to the *WHO Medical eligibility criteria for contraceptive use.*

WHO response

WHO's activities on emergency contraception form part of its work to provide access to high-quality services for family planning, particularly for the most vulnerable populations. This work is shaped by the WHO Global Reproductive Health Strategy.

In addition, through the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), research is carried out that aims to provide the widest range of safe and effective family planning methods, as well as clinical research into novel methods or uses.

WHO reaffirms its commitment to keeping emerging evidence under close review through its Continuous Identification of Research Evidence (CIRE) system.

VAGINAL RING INSERTION INSTRUCTIONS

Wash your hands with soap and dry them on a clean cloth.

Get in the position that is most comfortable for you to insert the ring.

Hold and press the sides of the ring together. You may find it easier to insert the ring if you twist it into the shape of the number 8.

Use your other hand to hold open the folds of skin around your vagina.

Place the tip of the ring in the vaginal opening and then use your finger to push the folded ring gently into your vagina.

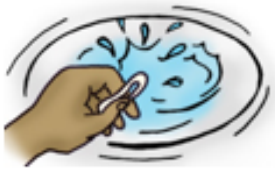
Push it up towards your lower back as far as you can. If the ring feels uncomfortable, it is probably not inserted far enough into your vagina. Use your finger to push the ring up as far as you can into your vagina.

The ring should now be in your upper vagina. Wash your hands when you are done. If you have trouble, contact the clinic or come in for assistance.

IMPORTANT INFORMATION

Leave ring inserted, all day, every day: The ring should be kept inserted at all times including menses, bathing, and sex.

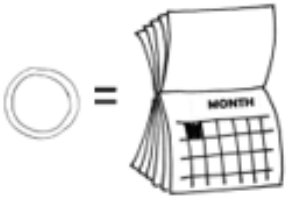
If the ring falls or is taken out:



Somewhere clean: Try to reinsert the ring as soon as possible. Rinse the ring in clean water and follow the insertion instructions on the other side.

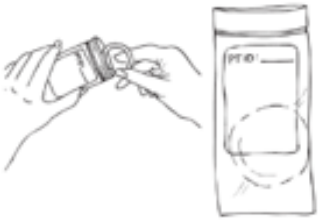
Somewhere dirty (such as the toilet or the ground)**:** Do NOT reinsert the ring. Instead, place it in the bag provided to you and contact the clinic as soon as possible.

Replace: After about 4 weeks, the ring should be removed and replaced with a new ring.



Avoid: Women should always avoid using douches, soaps, detergents, and herbs inside the vagina. When using the ring, use of other vaginal devices is also discouraged. Some vaginal products such as condoms, lubricants, and tampons are okay to use. Talk to study staff before using any vaginal products.

Do not Share: Do not share your ring with other women.



Storage: Used and dirty rings should always be stored sealed in the white bag provided to you. Store unused rings in their packaging until needed for use. Do not store used or unused rings in the refrigerator or in direct sunlight. Store out of reach of children and pets.

Transport: Always bring all used and unused rings with you to the clinic. During transport, keep your rings with you at all times to avoid loss.

Questions or Concerns: The study staff is here to help and support you. Please contact us between visits with any questions or concerns.

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Section Appendix 12-3
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 risk reduction and HIV prevention options 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.