Section 12. Counseling Considerations

Table of Contents

12.1 HIV and Risk Reduction Counseling
  12.1.1 Anal Intercourse
12.2 Contraceptive Considerations
  12.2.1 Contraceptive Counseling
12.3 Product Use Instructions and First Product Use
  12.3.1 Participant Instructions For Ring Insertion and Removal
  12.3.2 First Product Use and Attempt to Remove and Reinsert VR
  12.3.3 Clinician Instructions for Checking Ring Placement
12.4 Enrollment Adherence Counseling (Ring-use Education Session)
12.5 Follow-up Adherence Counseling

Table 12-1 Interpretation of HIV Tests Performed During Screening & Enrollment Visits
Table 12-2 Interpretation of HIV Tests Performed During Follow-up
Table 12-3 Examples of Risk Reduction Conversations
Table 12-4 HIV and STI Sexual Risk and Risk Reduction
Appendix 12-1 WHO Fact Sheet on Emergency Contraception
Appendix 12-2 Vaginal Ring Insertion Instructions/Important Information
Appendix 12-3 Counselor Reference for Ring Use Education at Enrollment
Appendix 12-4 Counselor Reference for Follow-Up Adherence Counseling
Appendix 12-5 ASPIRE Counseling and Education Manual

This section contains guidance on the following types of counseling provided in MTN-020: HIV counseling, risk reduction counseling, contraceptive counseling, study product adherence counseling and visit retention counseling.

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' needs are likely to change over time; thus the content and focus of counseling discussions should also responsively change over time. Because of this, specific content to cover or skills to emphasize are not standardized. Rather, the process for these discussions is 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, Risk Reduction, 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.

12.1 HIV and Risk Reduction Counseling

HIV testing is required at all scheduled study visits. HIV pre-test, post-test, and risk reduction counseling is therefore required at these visits as well, as is condom provision. Condom provision is understood to mean that condoms are offered to participants at each visit even though participants are under no obligation to accept

this offer and may decline study-provided condoms at any time and for any reason. Referrals should be provided when indicated. Sites are required to develop and follow SOPs for HIV pre- and post-test counseling as well as HIV risk reduction counseling.

All HIV counseling should be provided in accordance with local counseling standards and study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithm in protocol Appendices II and III. Additional information on HIV testing during screening and follow-up is provided in Section 13 of this manual; further information on interpretation of screening and follow-up test results is provided in Table 12-1 and 12-2 below. 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 ASPIRE website.

Table 12-1
Interpretation of HIV Tests Performed During Screening and at Enrollment Visit
Per Protocol Appendix II

Test Result	Status	Counseling Message
Two negative Rapid tests	HIV-uninfected	1. Test results indicate that you **are not infected** with HIV.
Two positive Rapid tests	HIV-infected	1. Test results indicate that you **are infected** with HIV. 2. [Provide additional post-test counseling and referrals for HIV-infected participants as per site SOPs.] 3. Participant is not eligible for MTN-020 enrollment.
One positive Rapid test, one negative Rapid test	HIV status not clear	1. Test results **are unclear**. 2. [Sites to perform additional testing and associated counseling per local standards of care (as outlined in SOPs) and as directed by the NL.] 3. Participant is not eligible for MTN-020 enrollment at this time.

Table 12-2
Interpretation of HIV Tests Performed During Follow-up
Per Protocol Appendix III

Test Result	Status	Counseling Message
Two negative Rapid tests	HIV-uninfected	1. Test results show that you **are not infected** with HIV.
Two positive Rapid tests	HIV-infected	1. Test results show that you **are infected** with HIV. 2. [Provide post-test counseling and referrals for HIV-infected participants as per site SOPs.] 3. Additional testing is needed for study purposes and to see how your body is responding to the virus. This additional testing will be done from a new blood sample**.** 4. The additional testing is done to follow the rules of the study, even though this may differ from your country's HIV testing algorithm. 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. 7. We expect these additional results to be available [INSERT TIME FRAME].
One positive Rapid test, one negative Rapid test	HIV status not clear	1. Test results **are unclear**. 2. Further testing is needed to determine your HIV status. 3. The additional testing may show whether you are infected with HIV or not. This additional testing will be done from a new blood sample**.** 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].
Western blot positive	HIV-infected	1. These test results confirm that you **are infected** with HIV. 2. [Follow-up on HIV care referral uptake per site SOPs]
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.
Western blot negative or indeterminate **AND** HIV viral load positive (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 Network Lab]*. 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.

Client-centered approaches should be used to assess participant knowledge of relevant information, dispel misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results. Information should be

provided in a manner that is respectful and interactive. If the site SOP includes an assessment of recent risk behavior, efforts to make these assessments neutral and non-judgmental should be made. 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 strengths and barriers change over time (e.g., due to a partner change), risk reduction plans may need to change over time. Importantly, all risk reduction plans should be agreed upon by the participant and should be documented in the participant's study records, with a copy made available to the participant if she wishes.

At each counseling session, prevention strategies and risk factors should be used to lead to a risk reduction plan. These plans will be reviewed at subsequent sessions and discussed with the participant to determine:

- What was her experience since her last session?
- How did the strategies in the risk reduction plan from last visit work or not work for her?

Counselors use this opportunity to reinforce effort, not outcomes, and to frame the current discussion as an opportunity to continue exploring protecting one's sexual health.

Risk reduction plans identified and agreed upon with the participant at the current session should then build on experience since the last session:

- Successful strategies should be continued;
- Additional strategies may be identified to achieve further risk reduction;
- Alternative strategies may be identified if strategies tried since the last session were not successful.

Risk reduction counseling sessions should also offer skills-building to the participant when indicated, e.g., on how to use male condoms, how to discuss sensitive issues with partners and other influential persons. HIV counseling for partners should always be offered, either as an individual session or as a couple's session. Some suggestions on how to conduct a couple's counseling session are provided below. Additional training resources on couple's counseling can be found on the MTN website under *Resources and Links.*

Table 12-3 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 12-3
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.*

12.1.1 Anal Intercourse

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-020 will be experienced and familiar with vaginal sex. Because anal sex may be a term participants have not heard before, a definition of it is provided below.

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-020:
The following facts may be useful when discussing anal sex with a participant:

- Anal sex is <u>not</u> exclusionary in MTN-020.
- 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.
- Note that in MTN-020, we ask participant not to use lubricants for vaginal sex.

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 12-4: 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; 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 ASPIRE:

- 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-020 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.

12.2 Contraception Considerations

To be eligible for MTN-020, 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, 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 ASPIRE to increase participant understanding of how emergency contraception works and its availability at the clinical research site.

Contraceptive methods used by study participants will be recorded on the Concomitant Medications Log CRF, and on the Baseline Family Planning CRF (enrollment) or the Family Planning CRF (follow-up). Note the instructions on the back of the CRFs regarding start/stop dates for contraceptives. Side effects related to contraception at baseline should be documented on the Pre-existing Conditions case report form. Side effects reported during follow-up should be recorded on the Adverse Experience Log and Grade 1 Adverse Experience Log, as applicable.

12.2.1 Contraceptive Counseling

Contraceptive counseling is required at all scheduled study visits until the Product Use End Visit. Per protocol, it is provided if indicated or if per local standard of care at the PUEV and Study Exit Visits. All contraceptive counseling should be provided in accordance with local counseling standards, site-specific SOPs, and World Health Organization (WHO) guidance, which is available in the following resources:

- Medical Eligibility Criteria for Contraceptive Use (Fourth edition, 2009)
- Family Planning: A Global Handbook for Providers (WHO/USAID/Johns Hopkins Bloomberg School of Public Health, 2011)

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-020 protocol specifications related to contraception. Note that for MTN-020, 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-020. 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.

12.3 Product Use Instructions and First Product Use

12.3.1 Participant Instructions For Ring Insertion and Removal

During the enrollment visit, participants will be provided with detailed instructions regarding vaginal ring insertion and removal. Vaginal Ring Insertion Instructions (see Appendix 12-2) should be translated into local languages and approved by local IRBs so that they may be provided to participants. Staff should actively review these instructions with participants, and 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.

In addition to receiving ring insertion and removal instructions, staff should provide ring use counseling as outlined in section 12.4. This can be done before or after first product use where participants insert, remove and reinsert the VR (section 12.3.2).

12.3.2 First Product Use and Attempt to Remove and Reinsert VR

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. At the Enrollment Visit and Month 1 visit only, study staff are required to confirm proper placement of the VR by a digital examination (see Section 12.3.3). For all other follow-up visits, this procedure should be done only if indicated (i.e. the participant is having discomfort potentially due to improper VR placement). For participants who have difficulty or who have inserted the ring incorrectly, 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.

At the enrollment visit only, staff should also confirm that the participant is able to remove and reinsert the VR. This is to encourage comfort with removal procedures, and additional practice in case the VR is removed or accidentally falls out prior to her next clinic visit.

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

At the enrollment visit, following insertion of the VR, the study clinician should check placement of the VR, regardless of who inserted it, to confirm correct placement. 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.

At the Enrollment visit, after correct placement is confirmed, staff should ask the participant 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 Enrollment Adherence Counseling (Ring-use Education Session)

At enrollment, all participants should engage in an education session with the designated study team member. This session will provide important information about the ring and aspects of ring-use that the study is requesting. Per site discretion, this session can occur before or after randomization. Detailed guidance regarding education/adherence counseling during enrollment is provided in Appendix 12-5, the ASPIRE Counseling and Education Manual. Additionally, a "Counselor Reference for Ring Use Education at Enrollment" (Appendix 12-3) is provided as a tool staff can reference during the session. The education/adherence counseling session should be fully documented per site-specific SOPs for source documentation.

12.5 Follow-up Adherence Counseling

Study product adherence counseling is required at all scheduled follow-up visits (unless the participant is on a product hold or permanent discontinuation in which case the session can be tailored to discussions of retention only). At follow-up visits, adherence counseling should focus on exploring participant's experiences with ring use, including what makes it easier or harder for her to use the study product as recommended. Discussion of experiences is framed as an opportunity to gain an understanding from participants of how well this ring may "fit" into the daily and sexual lives of women using it. With that, it is important to gain a sense of what seems to help it be a good "fit" and what seems to make it a poor "fit." Additionally, as the ability to come to the clinic for scheduled visits is directly related to product use, these counseling sessions should also include a check-in about facilitating attendance to study visits.

Staff can review the "Vaginal Ring Insertion Instructions"/"Important Information" as needed during follow-up visits (Appendix 12-2). It is recommended that this information be reviewed more often for participants new to the study (i.e. at Month 1). As a participant becomes more experienced with ring use, time spent on this information can be tailored to suit participant needs.

During follow-up, it is recommended that adherence counseling occur after completion of ACASI and administration of the behavioral CRF(s). In order to

promote an open and neutral environment, staff conducting the adherence counseling should ideally be different than those who conduct the adherence assessment questionnaires (Ring Adherence CRF). While staff may have information on participant report of non-use, previous missed visits, and data from the Month 3 Ring Worries CRF, this information should not drive or be the sole basis for the counseling session.

It is recommended that adherence counseling be completed as early as possible in the visit so that participants are not fatigued and are more receptive to counseling. 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.

The "Counselor Reference for Follow-up Adherence Counseling" (Appendix 12-4) is provided as a tool staff can reference during the session if needed. Chart notes and/or other source documents as specified in site SOPs should be used to document the adherence counseling, ideally *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.

Detailed guidance regarding adherence counseling during follow-up is provided in Appendix 12-5, the ASPIRE Counseling and Education Manual.

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.

Section Appendix 12-2
Vaginal Ring Insertion Instructions/Important Information

VAGINAL RING INSERTION INSTRUCTIONS

1

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

2

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

3

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.

4

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

5

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

6

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.

7

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

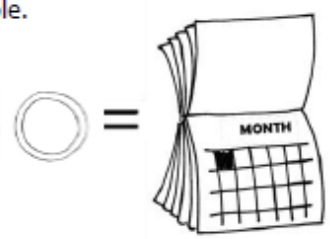
Leave ring inserted, all day, every day: The ring should be kept inserted at all times including menses, bathing, and sex.

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.

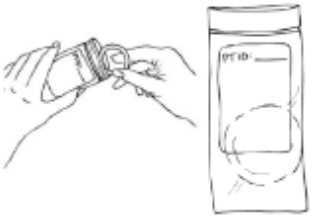
Somewhere dirty (such as the toilet or the ground): Do NOT reinsert the ring. Instead, place it in the bag provided to you and contact the clinic as soon as possible.

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



Avoid: Other than the ring, avoid using any vaginal products or devices (with the exception of tampons during menses, and male and female condoms).

Do not Share: Insert only the ring assigned to you and do not share your ring with other women.



Storage: Used and dirty rings should be stored in the bag provided to you. If you have been provided with an additional ring, store it in the packaging until needed for use.

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.

Counselor Reference for Ring Use Education at Enrollment

LEAVE THE RING INSERTED

The ring should be left inserted all day, every day, including during menses, bathing, and sex.

- Previous studies have shown that it is not harmful to leave the ring inserted during any of these activities.
- If you have concerns that the ring has slipped out, you can always use your finger to check that it is still inserted. It is uncommon for the ring to slip out, but this may happen.
- The ring will not block your menstrual flow.
- If you have discomfort, or if your partner tells you he can feel the ring during sexual activity, check the placement of the ring. Wash your hands, and try to gently push the ring further into your vagina. It's impossible for the ring to be pushed too far up or get lost inside the body. Even if you or your partner may be able to feel it, it is safe to leave it inserted during sex.
- If you experience discomfort that cannot be resolved by moving the ring further up in the vagina, contact the clinic as soon as possible.
- If you have difficulties using the ring as directed, it is also important that you share these experiences with site staff. Knowing when women were able to use the ring and when they were not is also very important for knowing whether these products are safe/effective for HIV prevention.

IF THE RING FALLS OR IS TAKEN OUT

Somewhere clean: Rinse the ring and try to reinsert it as soon as possible. Somewhere dirty: DO NOT reinsert. Put it in the bag provided and contact the clinic.

- Do not use soap or hot water to clean the ring; rinse only in clean water which is at room temperature or cool before reinsertion.
- If the ring falls out somewhere that is unsanitary, it is okay not to retrieve the ring. Contact or return to clinic to get a new ring.
- Do not rinse the ring unless it will be reinserted into your vagina

REPLACE

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

- This will typically occur at your scheduled clinic visits.
- If you cannot make it to the clinic for your visit, contact the clinic to be rescheduled and do not remove the ring.
- If you anticipate being away and unable to make a visit, tell study staff in advance and they may be able to provide you with an extra ring.
- If the ring is used for more than 4 weeks (28 days), contact the clinic to get a new ring as soon as possible.
- For participants who receive more than one ring: work with participant to determine when she will need to replace the ring and potential reminder methods.

AVOID

Other than the ring, using any vaginal products and devices (other than male and female condoms) is discouraged.

- This includes lubricants for sex, diaphragms, douching products, items used to dry the vagina, as well as vaginally applied medications. If you cannot avoid these, please let us know so we can keep track of how the ring works in this situation. Use of tampons during menses is permitted.
- The reason all participants are asked not to use products in their vagina is because the ring may work differently when different products are present or vaginal products could irritate the vagina leading to higher risk of infection or vaginal adverse events. This could lead to wrong conclusions from this research.

DO NOT SHARE

Insert only the ring assigned to you and do not share your ring with other women.

- If participants do not use the ring assigned to them, it will make it difficult for researchers to learn if the ring helps prevent HIV infection.
- Women who are not in the study should not use the ring, as they do not have the proper medical care to determine if the ring is safe for them. For example, they do not have regular HIV or pregnancy testing.

STORAGE

Used and dirty rings should be stored in the bag provided to you. If you have been provided with an additional ring, store it in the packaging until needed for use.

- If you do not have the bag provided, you may use another bag or container available to store your used ring.
- Store used and unused rings in a private area out of reach of children.

TRANSPORT

Always bring all rings in your possession (used and unused) with you to the clinic. During transport, keep your rings with you at all times to avoid loss .

- Because this is an investigational study product, it is important to collect and properly dispose of all rings.

QUESTIONS OR CONCERNS

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

- If you have discomfort with the ring or any medical problems.
- If you need another ring, or have questions about any of the information provided to you.
- If the ring comes out or you take it out and have concerns about reinserting it or any difficulties putting it back in.
- If you have problems with your partner, relatives, or other people, that are related to your study participation or they have any questions.

Remember to use visual aids, such as a sample rings, pelvic models (if available), diagrammatic representations, bags for used ring collection, factsheets, and illustrations, as needed to help ensure participant understanding. Participants should be encouraged to ask questions and raise issues or problems at any time.

Section Appendix 12-4

Counselor Reference for Follow-up Adherence Counseling

1. WELCOME AND FRAME

Greet and thank participant to establish rapport. Recognize her specific efforts, regardless of product use, and explain the purpose of the discussion. Seek permission to continue.

"Welcome back to the clinic, it's nice to see you. Thank-you for… "
"We appreciate…I am hoping we can spend a few minutes discussing…is that ok with you?"

2. EXPLORE

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 regardless of the actual level of product use.

"At our last visit when we talked about using the study product, you said…"
"Can you tell me about some of the times, situations, or things that have made ring use feel easy?"
"What are the things that have made using the ring feel more difficult?"

3. IDENTIFY NEEDS

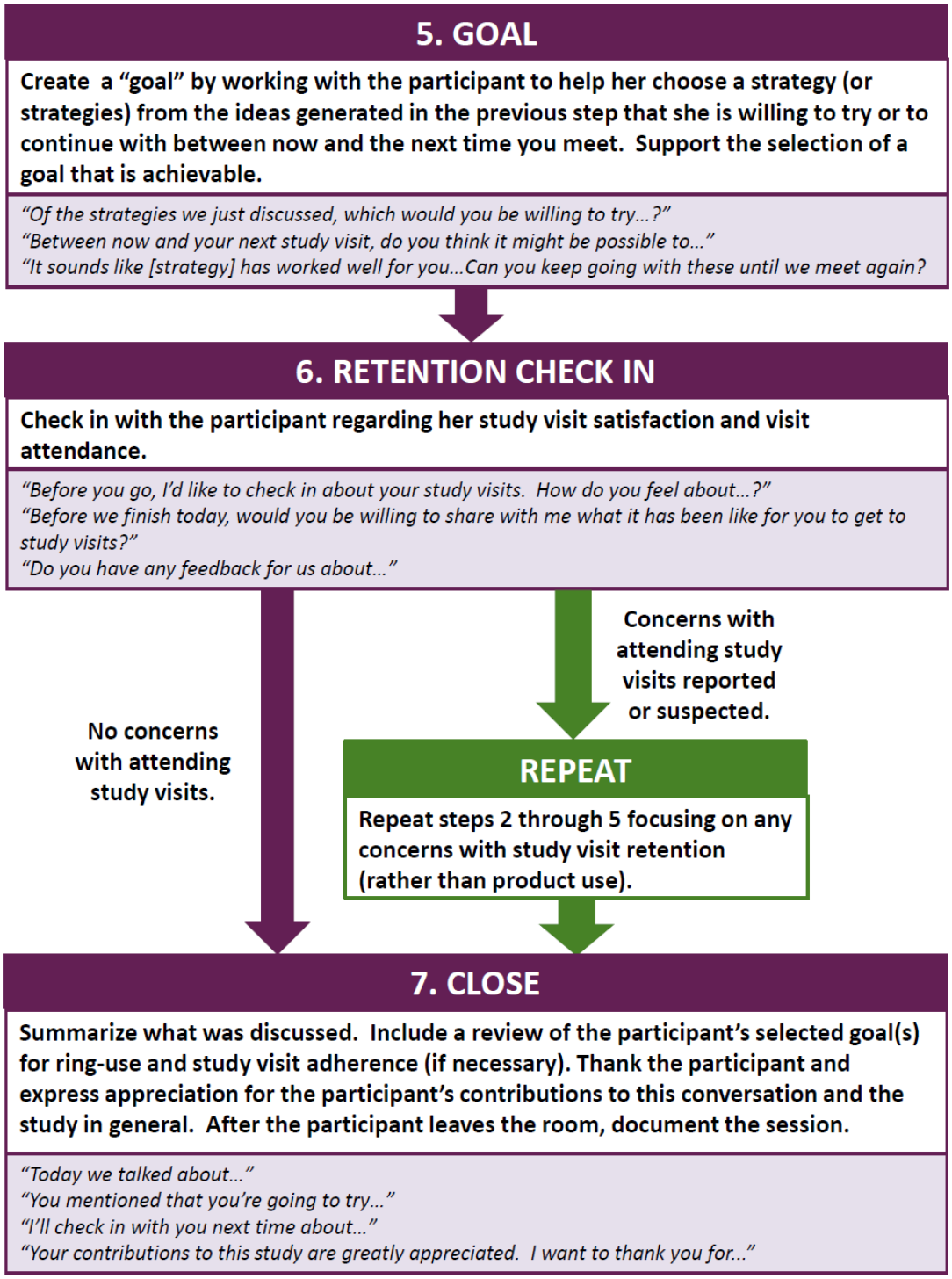
Work with participant to identify what she would need for ring use to be manageable, slightly easier to do, or for current ease of ring use to be maintained or sustained over time. Empower problem solving.

"What do you think you would need in order for…?"
"In the difficult situation you described, what do you feel would need to change to…?"
"What would you need to continue feeling that using the ring is easy for you…?"

4. STRATEGIZE

Work with the participant to identify possible new strategies to address adherence-related needs, or focus on continuing to use established strategies that have been effective in increasing ease of ring use in the past.

"You mentioned that you need…how could you see that happening?"
"One of the things you said makes ring use easy is…what are some way to ensure that continues?"


5. GOAL
Create a "goal" by working with the participant to help her choose a strategy (or strategies) from the ideas generated in the previous step that she is willing to try or to continue with between now and the next time you meet. Support the selection of a goal that is achievable.
"Of the strategies we just discussed, which would you be willing to try…?"
"Between now and your next study visit, do you think it might be possible to…"
"It sounds like [strategy] has worked well for you…Can you keep going with these until we meet again?
6. RETENTION CHECK IN
Check in with the participant regarding her study visit satisfaction and visit attendance.
"Before you go, I'd like to check in about your study visits. How do you feel about…?"
"Before we finish today, would you be willing to share with me what it has been like for you to get to study visits?"
"Do you have any feedback for us about…"
Concerns with attending study visits reported or suspected.
No concerns with attending study visits.
REPEAT
Repeat steps 2 through 5 focusing on any concerns with study visit retention (rather than product use).
7. CLOSE
Summarize what was discussed. Include a review of the participant's selected goal(s) for ring-use and study visit adherence (if necessary). Thank the participant and express appreciation for the participant's contributions to this conversation and the study in general. After the participant leaves the room, document the session.
"Today we talked about…"
"You mentioned that you're going to try…"
"I'll check in with you next time about…"
"Your contributions to this study are greatly appreciated. I want to thank you for…"