MTN-026
Counseling Considerations

Overview

- HIV Pre/Post Test
- HIV and STI Risk Reduction
- Contraceptive (♀)
- Product Use Instructions
- Protocol Adherence
- Additional Counseling Materials

HIV Pre- and Post-Test Counseling

- HIV testing is required at :
  - Screening
  - Enrollment
  - Visit 7
  - Visit 16
  - Other visits if clinically indicated

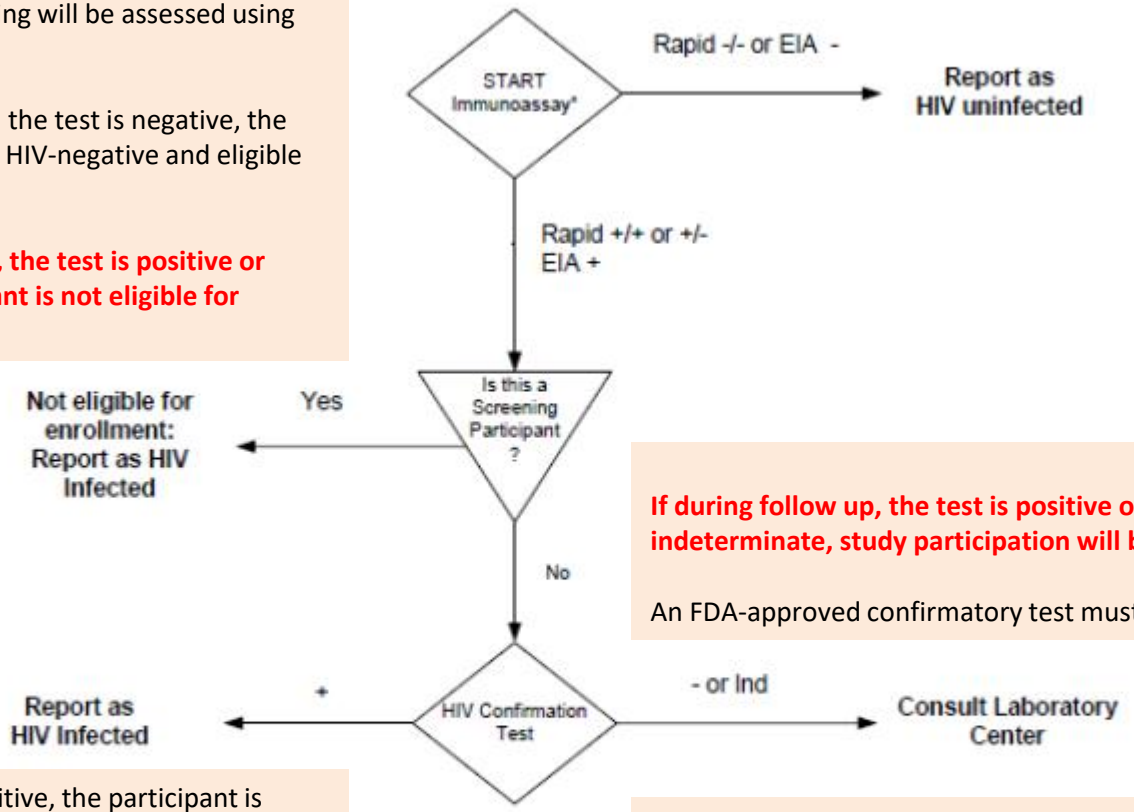
HIV pre-test and post-test is provided in conjunction with HIV testing

APPENDIX II: ALGORITHM FOR HIV ANTIBODY TESTING FOR SCREENING AND FOLLOW-UP

HIV infection status at screening will be assessed using an FDA-approved HIV test

If at Screening or Enrollment, the test is negative, the participant will be considered HIV-negative and eligible enrollment.

If at Screening or Enrollment, the test is positive or indeterminate , this participant is not eligible for enrollment.



If during follow up, the test is positive or indeterminate, study participation will be discontinued.

An FDA-approved confirmatory test must be performed.

If the confirmatory test is positive, the participant is considered HIV-positive.

If the confirmatory test is negative or indeterminate, contact the LC for guidance. Additional testing is required.

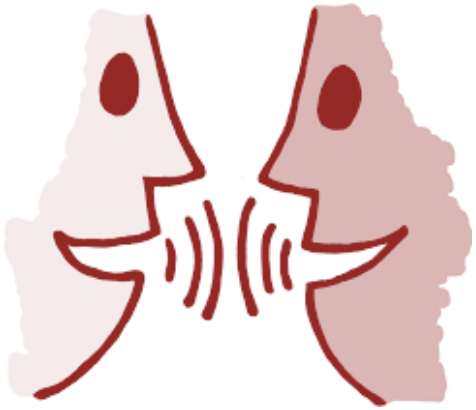
*CLIA certified labs may perform 1 rapid test
Ind: Indeterminate test results
EIA: Enzyme Immunoassay

In the event of an HIV positive result…

- Refer participants to local care and treatment services
- Provide additional counseling and other support services, as needed
- Discontinue follow-up visits and terminate participant from the study
- Offer additional laboratory testing (HIV RNA and HIV drug resistance testing) at the discretion of IoR and MTN LC

STI/HIV Risk Reduction Counseling

- Utilize Participant-Centered Approaches
- Non-judgmental
- Collaborative partnership
- Respectful of the participants' ability to choose
- Encompasses more listening and eliciting than telling
- Tailored to participants' needs which change over time



STI/HIV Risk Reduction Counseling

- Assess knowledge of relevant information
- Ensure readiness for HIV testing and understanding of test results
- Dispel any misconceptions
- Re-emphasize confidentiality
- Emphasize risk-reduction (identification of risk factors/barriers to risk reduction and strategies/action plans to try to address)
- Offer skills building (e.g. how to use condoms, discuss sensitive issues with partners/others)

- Worksheet provides an overview of the minimum requirements expected for each HIV testing and risk reduction counseling session
- Required at Screening, Enrollment, Visit 7, and Visit 16
- Assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, ensure participant understanding of test results
- Guides the participant in identifying risk factors, barriers to risk reduction and developing strategies and action plans to reduce/eliminate risk

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HIV Pre/Post Test and Risk Reduction Counseling Worksheet

PTID:	**Visit Date:**
Visit Code:	**Staff Initials:**

Instructions: Notes documenting counseling discussions should be recorded. Include any questions raised about HIV and HIV testing discussed with the participant. Document the participant's personal risk factors for HIV exposure, experiences with the risk reduction strategies employed since the last visit, any barriers to risk reduction, and a risk reduction plan for the coming month. Include documentation of participant understanding of HIV test results and next steps.

General

- Greet client and establish rapport
- Review purpose and nature of today's session
- Emphasize confidentiality
- Address any immediate issues or concerns
- HIV Education and Pre-Test Counseling
- Review difference between HIV and AIDS
- Review modes of HIV transmission and methods of prevention
- Review HIV tests to be done today and tests to be done if today's tests indicate possible infection
- Review window period and how it may affect test results
- Correct any misconceptions or myths
- Verify readiness for testing
- Risk Reduction Counseling

Use open-ended questions to assess client's HIV risk factors

- Discuss whether risk factors have changed since the last visit
- Probe on factors associated with higher versus lower risk (e.g., what was different about the times when you were able to use a condom compared to times when you were not?)
- Discuss previous month's risk reduction plan and develop risk reduction strategies with the participant moving forward
- HIV Post-Test Counseling

Provide and explain test results, per protocol appendix II

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

Counseling Notes:

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HIV/STI Risk Reduction Counseling Considerations

- Will you incorporate risk-reduction counseling before or after the test results are given?
- Will the same person conduct pre- and post-test and risk reduction counseling?
- What kinds of questions might you ask to assess participant understanding?
- How will you avoid repetition during follow up counseling sessions?

Contraceptive Counseling

- Required at Screening and Enrollment; other visits if indicated
- Intended to assess eligibility criteria (per participant report)
- Provide rationale for contraceptive requirement and obtain accurate information about use
- Confirms pregnancy intentions and willingness to use an effective contraceptive method
- Discuss which methods are acceptable for study purposes and emphasize that women who cannot commit to using one of these methods for the duration of the study should not enroll

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Contraceptive Counseling Worksheet

PTID:	Visit Date:
Visit Code:	Staff Initials:

Instructions: Review participant's reproductive history documentation and previous entries in this worksheet to inform and guide contraceptive counseling. Contraceptive counseling is required at Screening and Enrollment; and then if indicated throughout study follow-up.

Current contraceptive method:

_____
_____
_____

Contraceptive information/issues/questions/ concerns discussed at this visit:

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_____
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_____
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Issues to follow up at next visit:

_____
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_____
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_____

Scheduled date of next contraceptive prescription/injection (or NA):

_____

In the event of a positive pregnancy test result…

- Participant will be referred to local health care services and may return to the research clinic for additional counseling, as needed
- Follow-up visits will be discontinued and the participant will be terminated from the study
- Optional Procedure:
  - Participants who become pregnant while on study product may be offered enrollment in MTN-016*

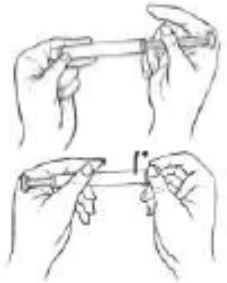
Product Use Counseling

- Product use instructions should be reviewed at Visit 3 and during Visits 7-13
- Provide copy of illustrated instructions to each participant in the event participant is unable to attend a clinic visit and rectal gel is inserted at home
  - Page 1: General Use Instructions
  - Page 2: Key Messages
- For participants who have difficulty inserting the gel, study staff should provide further information and guidance to address the difficulty encountered.
  - After guidance is provided, the participant should try again to insert the gel. If unable, study staff may insert the gel for the participant.

MTN-026 Gel Use Instructions

Tear open the wrapper.

Remove the applicator and plunger. The applicator is prefilled with gel.

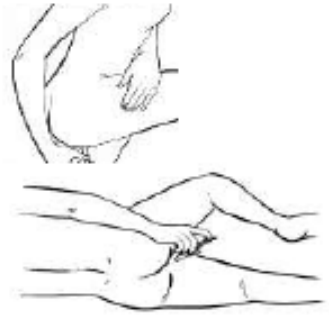


Place the small end of the plunger in the hole at the back end of the applicator barrel (opposite the blue cap).

Remove the blue cap from the end of the barrel.

Tear open the lubricant packet provided by the study staff and apply to the applicator barrel.

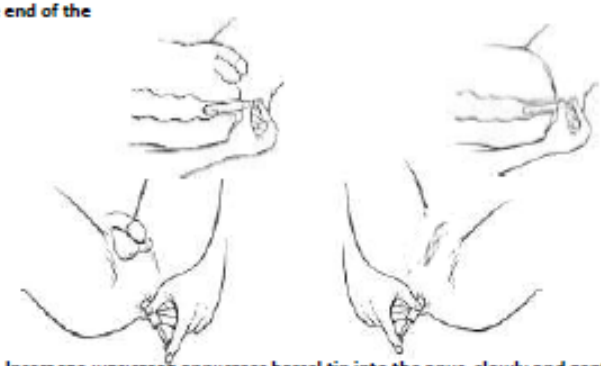
Hold the applicator with your thumb and middle finger on the applicator about halfway along the applicator barrel.



Choose a comfortable position for inserting the applicator (e.g. standing, lying on your side, or on your back)

If you are standing: Separate your legs while kneeling or squatting to allow good access to your anus. Use one hand to guide in the applicator tip by reaching around/ behind you.

If you are lying on your back: Lie on your back with one knee bent. This should allow good access to your anus from below.



Insert the lubricated applicator barrel tip into the anus, slowly and gently.

Once the tip is inserted into anus, gently slide the applicator further into the rectum until your thumb and middle finger touch your body (about halfway along the applicator or 2–3 inches).

While holding the applicator in place with your middle finger and thumb, use your index finger to push the plunger all the way into the applicator barrel. Push the plunger until it stops.

After the plunger has been pushed all the way into the applicator barrel, gently slide the applicator out of the anus.

Dispose of the wrapper, applicator and blue cap.

MTN-026 Gel Use Instructions

While in the clinic, you will be asked to insert one dose of gel (one applicator) into your rectum.

- You will also be given one applicator to take home with you just in case you are unable to come to the clinic for one of your scheduled visits.
- If you need to insert a dose at home, insert one dose (one applicator) into your rectum at the same time of the day that all other daily doses were inserted.
- It is important that you don't miss any doses. If you miss any doses, please contact study staff.

Avoid practices that could cause discomfort or any additional side effects.

- Do not insert the applicator without lubricant. Inserting a dry applicator may cause discomfort.
- Do not force the applicator into the rectum.
- Do not wash or wipe off the applicator prior to insertion.
- **Please remember you are asked to refrain from engaging in sexual activity for seven consecutive days while you are using the study gel.**
- **You are also asked not to have sex 72 hours prior to each of your scheduled visits. See the Information Booklet for a detailed list of these times. If you do engage in sex at any time during the study, please be sure to use a condom.**

Keep the gel applicator in your possession at all times.

- Do not share your gel applicator with other people. It is important that you only use the gel assigned to you.
- Store at room temperature in a safe, cool, dry place.
- Keep the gel applicator out of reach of children.
- Keep the gel applicator in its original wrapper until it is time to use (if necessary).
- Do not remove labels from the applicator overwrap.
- Do not use the gel if the wrapper is open or seems broken or any part of the applicator is missing. If you notice a problem with the applicator, please bring the gel back to the clinic and give it to clinic staff.
- If you do not use your gel applicator at home, please bring the unused applicator and lubricant back to the clinic at your next clinic visit.

The study staff is here to help and support you. Please contact study staff if you have:

- Any questions or concerns.
- Problems using the gel.
- New symptoms or worsening of any continuing medical symptoms.

Protocol Adherence Counseling

- Required at every scheduled study visit, per protocol; content may be targeted towards participants' need, given frequency of the sessions
- 2-Page worksheet provided to aid in provision of counseling
  - Page 1 (Reviewed at every visit)
  - Page 2 (Reviewed at Visit 3 and/or Visits 7-13)

Protocol Adherence Counseling Worksheet

PTID:	Visit Date:
Visit Code:	Staff Initials:

Note: Given the frequency of the study visits, protocol counseling should be targeted per participant's needs; not all items on this worksheet are required to be reviewed at all visits. However, at every study visit, elements listed on page 1 of this worksheet should be reviewed with the participant.

❒ **Provide guidance on study requirements including prohibited practices, products and/or medications**

- ❒ Present to the study visits as scheduled.
- ❒ Contact study clinic staff if there are any questions and/or to report any issues with study product.
- ❒ Inform study staff of all medications taken during the study
- ❒ Do not take part in other research studies involving drugs, medical devices, vaccines, or genital or rectal products for the duration of study participation
- ❒ Refrain from using the following products during study participation: Heparin, including Lovenox®; Warfarin; Plavix®; hormone therapy (tablet, injectable or gel form); Aspirin (greater than 81mg); NSAIDS or any other drugs that increase the likelihood of bleeding; and CYP3A inhibitors and inducers.

  NOTE: If participant reports use of the following products, study product must be permanently discontinued:

  - Heparin
  - Lovenox®
  - Warfarin
  - Plavix® (clopidogrel bisulfate)
  - Hormone therapy in tablet, injectable, or gel form

- ❒ All Participants: Refrain from engaging in the following activities 72 hours prior to each scheduled visit and while using study product:
  - ❒ Using non-study products in the rectum and/or vagina
- ❒ Male participants: Abstain from engaging in the following sexual activities 72 hours after biopsy collection:
  - ❒ Receptive anal intercourse, oral anogenital stimulation, stimulation via fingers and rectal insertion of sex toys
- ❒ Female participants: Abstain from engaging in the following activities 7 days following biopsy collection:

Inserting anything in the vagina and rectum, sexual activities including RAI, penile-vaginal intercourse, receptive oral anogenital stimulation, vaginal or rectal stimulation via fingers, and vaginal or rectal insertion of sex toys
Comments:

- Page 1 of 2
- Reviewed at every visit
- Focuses on explaining prohibited medications and practices participants should refrain from engaging in during the course of study participation

Protocol Adherence Counseling Worksheet, cont'd

- Page 2 of 2
- Reviewed at Visit 3 and/or Visits 7-13
- Focuses on product administration and direct observed dosing procedures

PTID:	Visit Date:
Visit Code:	Staff Initials:

❒ **At Visit 3 and Visits 7-13, provide product adherence counseling**

- ❒ **At Visit 3:**
  - ❒ Explain to participant that clinic staff will be administering the gel.
  - ❒ Explain the process for gel administration
  - ❒ If there is any discomfort while inserting the gel, participant should immediately inform study staff.
- ❒ **At Visits 7-13 (directly observed or staff-administered):**
  - ❒ Review product use instructions with participant
  - ❒ Inform participant dose administration will be directly observed or explain the process for gel administration
  - ❒ Encourage the participant to ask any questions he/she may have about gel insertion
  - ❒ If there is any discomfort while inserting the gel, participant should immediately inform study staff.
- ❒ **At Visit 7:**
  - ❒ Provide participant with one additional pre-filled applicator of study product
  - ❒ Explain to participant the purpose of this extra applicator
  - ❒ Review with participant product use instructions and provide a copy of the Product Use Instructions sheet
  - ❒ Provide participant an appointment card with space to record date and time of dose administration.
  - ❒ Instruct participant to return unused applicator at Visit 13

Comments:

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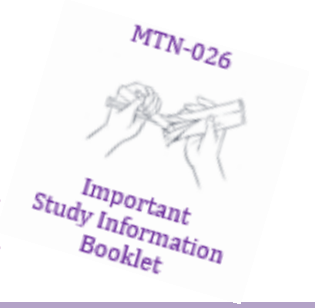
Important Informational Booklet



- Reference the 'Prohibited Activities and Products' section of the MTN-026 Important Study Information Booklet available on the MTN-026 webpage

- Review the list of prohibited medications, products and practices participants should refrain from engaging in or using during study participation

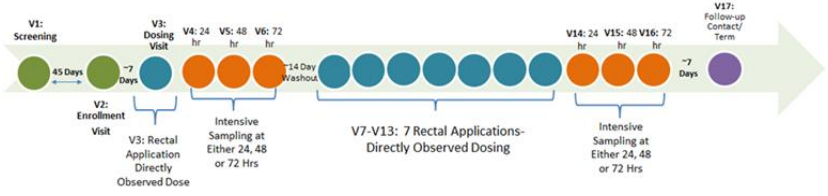
- Document provision and review of booklet in chart notes or visit checklist

Important Information:

Researchers are conducting this study to see if an investigational drug called dapivirine is safe when used rectally. Dapivirine works to prevent HIV from making copies of itself, thus stopping the spread of HIV in the body. You will be asked to insert a gel containing either dapivirine or a placebo into your rectum approximately 8 times over the course of the study. First, study staff will administer a single dose of the gel. Then, following a minimum two-week washout period, you or study staff will administer daily rectal doses of study gel for 7 consecutive days under direct observation in the clinic. Researchers are also interested in learning more about how this study drug enters and exits the body.

Your participation is voluntary; you do not have to join or remain in the study if you do not want to.

You will have a total of 16 visits and one follow-up contact (by phone or in person). Most visits will last about [**site to insert**]. Some visits will last longer because you will be asked to provide samples of blood, rectal fluid and tissue. Women are also asked to provide vaginal fluid and cervical tissue.



Study participation is expected to last 40 days. If you join, you will be randomly placed into 1 of 2 rectal gel study groups; one group will receive a placebo gel, which does not contain any study drug. The other group will receive gel containing dapivirine. No matter which group you are in, please remember that we do not know if this gel will protect you from getting HIV nor is this study testing whether the gel will prevent HIV. There are two known ways to prevent HIV: using condoms and/or an oral pre-exposure prophylaxis (PrEP). Study staff can tell you more about these

Prohibited Activities and Products:

You cannot join this study if you are currently or have recently taken part in another study of drugs, medical devices, genital and rectal products or vaccines. Please tell the study staff about studies you may have recently participated in, you are currently taking part in or are thinking of taking part in. You should also inform study staff of all medications you are taking or may take during the study. This is very important for your safety. Engaging in these practices or using any of the above products while in the study may make the gel work differently. These products and practices could irritate the rectum or vagina and increase the risk of side effects.

While in the study, you will be asked to avoid the following practices and medications for the entire duration of study participation:

- Using Heparin, including Lovenox®, Warfarin, Plavix®, hormone-replacement therapy (tablet, injectable or gel form), Aspirin (greater than 81mg), NSAIDS or any other drugs that increase the likelihood of bleeding and CYP3A inhibitors and inducers (study staff will explain what these are in more detail)

All participants are asked to abstain from using rectal and/or vaginal non-study products **72 hours prior to each of your scheduled visits** and **during product use period.**

Male participants are also asked to avoid the following sexual activities for **72 hours after** biopsies are collected:

- Receptive sexual activity (anal sex, oral anogenital stimulation, rectal stimulation via fingers or the rectal use of sex toys)

Female participants are asked to avoid the following sexual activities for **7 days after** biopsies are collected:

- Receptive anal intercourse, penile-vaginal intercourse, receptive oral anogenital stimulation, vaginal or rectal stimulation via fingers, and vaginal or rectal insertion of sex toys

Documentation

- All counseling activities (including but not limited to participant questions, risk reduction strategies, action plans, etc.) should also be recorded on the worksheet and/or in chart notes to support review and appropriate follow up at subsequent visits
- Documentation should be sufficient and detailed enough to inform and guide subsequent counseling sessions
- Be sure to engage in the discussion rather than focusing on taking notes
- Summarize the session once, complete

Questions? Comments?