

MTN-017
Study Specific Training
Counseling Considerations

Overview

- Collection of Rectal Biopsies
- HIV Pre- and Post-Test
- STI/HIV Risk Reduction
- Product Use Instructions
- Product Use Adherence*
- Protocol Adherence

*Note: Product Use Adherence Counseling will be covered in separate training

Counseling on Collection of Rectal Biopsies

- When required?
 - Screening
 - Enrollment
 - Period End Visits

HIV Pre- and Post-Test Counseling

- When is HIV testing required?
 - Screening
 - Enrollment
 - Every visit except Initiate Periods 2 & 3
 - As clinically indicated
- HIV pre-test and post-test is provided in conjunction with a participant's HIV test; therefore, counseling is required at these visits as well

HIV Pre- and Post-Test Counseling Guidelines

- HIV Testing Algorithm in protocol Appendix II
- Participant-centered approaches:
 - assess participant knowledge of relevant information
 - dispel any misconceptions
 - ensure participant readiness for HIV testing
 - ensure participant understanding of test results
 - re-emphasize confidentiality

HIV and Risk Reduction Counseling Worksheet

PTID:

Visit Code:

General

- Greet client and establish rapport
- Review purpose and nature of today's session
- Discuss counseling objectives for the day as it pertains to the participant
- Emphasize confidentiality
- Address any immediate issues or concerns with regards to individual risk.

Introduce the participant to the session

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

Assess participant knowledge

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

Assess risk behaviors

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

Provide communication about what the test results mean

Documentation Instructions: *Notes documenting counseling discussions should be recorded below (continuing on the opposite side if needed). 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. Initial and date after each entry.*

Counseling Notes:

STI/HIV Risk Reduction Counseling

- At which visit is STI/HIV risk reduction counseling required?
- Please describe how risk reduction counseling will be done.



Provision of Product Use Instructions

Provision of Product Use and Adherence Counseling*

Product Use Counseling

- Required at Enrollment/Initiate and Mid Period visits.
- Regimen specific
- Key messages are outlined in SSP Section 6.3 and Product Use Instructions

PRODUCT USE INSTRUCTIONS COUNSELING WORKSHEET

Provided at Initiate and Mid-Period Visits

Accompanies the provision and verbal overview of the product use instructions

General overview of key important messages

Documentation of debrief regarding his/her first dose/insertion or simulation of first insertion of product

PTID:	Visit Date:
Visit Code:	Staff Initials:

Product Regimen (please check appropriate box):

Daily Tablet Daily Rectal Gel RAI Rectal Gel

Visit Type (please check appropriate box):

Initiate Period 1 Mid Period 1 Initiate Period 2 Mid Period 2

Initiate Period 3 Mid Period 3

Provide Product Use Instructions handout to the participant. Verbally review in detail the applicable product use instructions.

(Note: use of visual aids to ensure participant understanding of proper product use is encouraged e.g. sample tablet bottles, sample applicators)

Discuss key important information messages (located on the back of the applicable product use instructions). The following key messages were reviewed with the participant (check all that apply):

<input type="checkbox"/> Use the study product as instructed by study staff	<input type="checkbox"/> Report issues/problems taking the tablets/inserting the gel
<input type="checkbox"/> Missed dose instructions	<input type="checkbox"/> Bring all remaining unused product/empty bottles to visits
<input type="checkbox"/> Keep study product in your possession	<input type="checkbox"/> Contact clinic with any problems between visits
<input type="checkbox"/> Product storage instructions	<input type="checkbox"/> Use only the study product assigned to you
<input type="checkbox"/> Clinic contact information	<input type="checkbox"/> Other (describe in comments below)
<input type="checkbox"/> Do not share study product	

Discuss and assess expectations or concerns about adherence to product use. Debrief with participant about his/her first dose/insertion or simulation of first insertion of product experience:

(Probes: was he/she able to swallow the pill/insert the applicator? Did he/she have any difficulties? Does he/she have any questions? Does he/she have any concerns about swallowing or inserting product at home? Would he/she like any additional information or instructions?)

Comments:

PRODUCT USE INSTRUCTIONS: GEL

MTN-017 **Before and After Sex Gel Use Instructions**

1



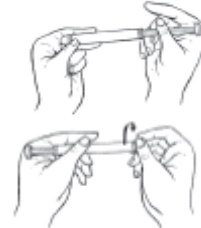
- Wash your hands with soap and water.

2



- Tear open the wrapper.
- Remove the applicator and plunger. The applicator is prefilled with gel.

3



- 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.

4



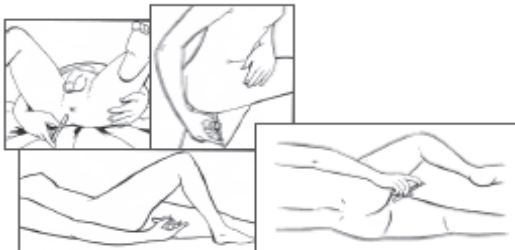
- Tear open the lubricant packet provided by the study staff and insert the applicator so the outside is covered with lubricant.

5



- Hold the applicator with your thumb and middle finger on the applicator about half-way along the applicator barrel.

6



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.

If you are lying on your side: One leg should be bent up toward the chest. Use one hand to guide in the applicator tip by reaching around behind you.

7



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).

8



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.

9



- Dispose of the wrapper, applicator and blue cap.

PRODUCT USE INSTRUCTIONS:

BEFORE AND AFTER SEX

1. Insert two separate doses of gel into the rectum when you anticipate having anal sex as per the instructions below

- Insert first dose (one applicator) into the rectum within 12 hours before you anticipate having anal sex
- Insert second dose (one applicator) into the rectum as soon as possible within 12 hours after you have anal sex

- If you insert one dose (one applicator) before you anticipate having anal sex, and sex does not happen, insert a second dose (one applicator) at any time up to 24 hours after you inserted the first dose

- If you did not or will not have sex during the entire week (7-days):

- Do not take more than 2 doses in a day (24-hour period) even if you have anal sex more than once

2. Avoid practices that could cause discomfort

- Do not insert the applicator without lubricant. Inserting a dry applicator may cause discomfort
- Do not force the applicator into the rectum
- Always practice safe sex. Use a condom when having any type of sex
- Rectal Biopsy/Fluid Subset Only: Do not insert anything in your rectum including gel for 72 hours after biopsies are taken.

3. Keep all gel applicators in your possession

- Do not remove labels from your cartons
- Keep the gel in a safe place
- Keep the gel out of reach of children
- Store at room temperature

4. Do not share your gel applicators with other people

- Use only the gel assigned to you

5. Return all remaining unused applicators to the study staff at your next visit

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

- Any question or concerns
- If your supply starts to run low
- Problems using the gel. Do not change how much you are taking or stop using the gel without first talking with study staff
- New symptoms or worsening of any continuing medical symptoms

No RAI in the preceding 6 days, participants should receive instructions to apply gel using the BAT 24 regimen on the 6-7th day or use 2 doses of product at least once per week on a day that is convenient for them (Per CM #02)

PRODUCT USE INSTRUCTIONS:

DAILY USE

1. Insert one dose of gel (one applicator) into the rectum

- Insert one dose around the same time each day
- It is important that you don't miss any doses
- If you forget a dose, insert the gel as soon as you remember
- If you forget a dose, and your next dose is due within 6 hours, skip the missed dose
- Do not take more than 1 dose in a day

2. Avoid practices that could cause discomfort

- Do not insert the applicator without lubricant. Inserting a dry applicator may cause discomfort
- Do not force the applicator into the rectum
- Do wash or wipe off the applicator
- Always practice safe sex. Use a condom when having any type of sex

- **Rectal Biopsy/Fluid Subset Only: Do not insert anything in your rectum including gel for 72 hours after biopsies are taken**

3. Keep all gel applicators in your possession

- Do not remove labels from your cartons
- Keep the gel in a safe place
- Keep the gel out of reach of children
- Store at room temperature
- Keep the gel in its original wrapper until it is time to use
- Do not use the gel if the wrapper is open or seems broken or any part of the applicator is missing

4. Used OR dirty gel applicators should be properly disposed of in the trash can or brought back to the clinic to be disposed of

5. Do not share your gel applicators with other people

- Use only the gel assigned to you
- Return all remaining unused applicators to the study staff at your next visit

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

- Any question or concerns
- If your supply starts to run low
- Problems using the gel. Do not change how much you are taking or stop using the gel without first talking with study staff
- New symptoms or worsening of any continuing medical symptoms

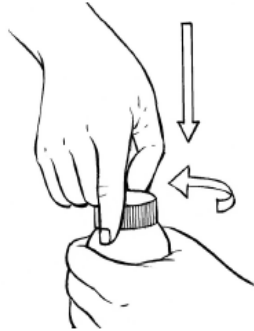
PRODUCT USE INSTRUCTIONS: TABLET

1



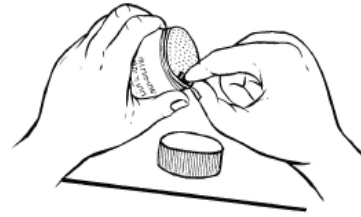
- Wash your hands with soap and water.

2



- Open the bottle by pushing the cap down while turning to the left.

3



- The first time the bottle is opened, there will be a seal covering the bottle.
- Remove and discard this seal.

4



- Inside the bottle, there will be a seal covering the bottle.
- See 21 November 2013 Official Memo**
- Remove and discard this seal.

5



- There is a sealed container inside the bottle that helps keep the tablets dry.
- Do not open this container, swallow it, or remove it from the bottle.

6



- Remove one tablet from the bottle when taking one tablet each day.

7



- After removing the tablet, close the bottle tightly by replacing the cap and turning it to the right.

8



- Put one tablet in your mouth and swallow it with water or other non-alcoholic beverage.

PRODUCT USE INSTRUCTIONS: TABLET

- **Take one dose (one tablet) by mouth every day**

- Take one dose at the same time each day
- It may be taken with or without a meal

- **It is important that you do not miss any doses**

- If you forget to take a dose, take one tablet as soon as you remember
- If you forget to take a dose, and your next dose is due within 6 hours, skip the missed dose
- Do not take more than 1 dose in a day

- **Keep all tablets in your possession**

- Do not remove labels from the bottle
- Keep the tablets in a safe place and out of the reach of children
- Store at room temperature
- Keep the tablets in its original container and keep the container tightly closed

- **Do not share your tablets with other people**

- Use only the tablets assigned to you
- Do not use the tablets if the seal of the bottle opening is broken or missing when taking the first dose.

- **Return remaining unused tablets to the study staff at your next visit**

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

- Any questions or concerns
- If your supply starts to run low
- Problems taking the tablets. Do not change how much you are taking or stop taking your pills without first talking with study staff
- New symptoms or worsening of any continuing medical symptoms

FIRST DOSE

VS.

**SIMULATION OF FIRST
DOSE**

First Dose at Start of Each Product Use Regimen

- All study participants will complete their first use or simulation of their first use at the study clinic during their Initiate Period Visits.
- Simulation of product use refers to inserting an empty applicator (an applicator without any gel) to allow participant to practice applicator insertion prior to leaving the clinic.

First Dose at Start of Each Product Use Regimen

- For participants initiating the daily rectal gel regimen:
 - First insertion could be insertion of first dose or simulated insertion, depending on participant's preference and level of comfort.
 - Participants can chose to do the first insertion either:
 - in a private space, with study staff standing by in case the participant requests guidance or technical assistance.
 - in a private space with direct staff observation of the gel insertion.

First Dose at Start of Each Product Use Regimen

- For participants initiating the RAI-associated rectal gel regimen:
 - First insertion should be simulated only.
 - Participant should be provided clear instructions that first use should occur around the time of sex.

First Dose at Start of Each Product Use Regimen

- For participants initiating the daily oral regimen:
 - First dose should be directly observed by study staff.
 - A private space is not required.
 - Study staff should remind the participant to leave the desiccant inside the bottles but discard the bottle seals.

Product Use Adherence Counseling

- Based on participant-centered strategies
- Aim: Reinforce the value of accurate reporting of adherence to study product use
- Purpose:
 - Gauge the participant's understanding of product use instructions
 - Assess the participant's confidence with using the study product
 - Identify potential obstacles to using the product and how they might overcome such challenges
 - Converge three adherence measures (product count, SMS, and PK result)
 - What, if anything, helped the participant to adhere to product use and whether these approaches might be helpful to the participant in the next period of the study

Refer to the [Participant Centered Product Adherence Counseling Manual](#) available on the MTN-017 Study Implementation Materials webpage under *Counseling Tools/Worksheets*.



Provision of Protocol Adherence Counseling

PROTOCOL ADHERENCE COUNSELING WORKSHEET

Required at Initiate and
Mid Period visits

Counsel the participant to
refrain from using
prohibited medications
and/or engaging in certain
practices during study
participation

Documentation of debrief
regarding practices or
medications participants are
asked to refrain from using or
engaging in

PTID:	Visit Date:
Visit Code:	Staff Initials:
Visit Type (please check appropriate box): <input type="checkbox"/> Initiate Period 1 <input type="checkbox"/> Mid Period 1 <input type="checkbox"/> Initiate Period 2 <input type="checkbox"/> Mid Period 2 <input type="checkbox"/> Initiate Period 3 <input type="checkbox"/> Mid Period 3	
<input type="checkbox"/> Provide guidance on prohibited practices, products or medications <input type="checkbox"/> Refrain engaging in receptive or insertive sexual activity with another MTN-017 study participant for the duration of the study <input type="checkbox"/> Use study-provided male condoms for the duration of the study for penetrative intercourse <input type="checkbox"/> Do not take part in other research studies involving drugs, medical devices, vaccines, or genital products for the duration of study participation <input type="checkbox"/> Refrain from using the following products during study participation: systemic immunomodulatory medications, Heparin, including Lovenox®, Warfarin, Plavix® (clopidogrel bisulfate), rectally-administered medications or products, containing N-9 or corticosteroids, or any investigational products unless otherwise permitted ▪ <i>Note: Use of lubricants, douches and/or enemas that do not contain N-9 or corticosteroids are permitted by the study. Information regarding the use of these products will be recorded at all scheduled clinic visits.</i> <input type="checkbox"/> Refrain from using NSAIDs, aspirin and/or other drugs that are associated with increased likelihood of bleeding for 72 hours prior to and following mucosal biopsies	
<input type="checkbox"/> Discuss and assess expectations or concerns about protocol adherence Comments: _____ _____ _____ _____ _____	

Protocol Adherence Counseling

- Protocol adherence counseling should also include:
 - Review of the participants' visit schedule
 - How to contact the clinic staff
 - How to use product
 - SMS (how to and when)
 - Adhere to protocol requirements (e.g. willing to use condoms, not to participate in other research study)

Documentation

- All counseling activities should be documented in chart notes and/or on counseling worksheets to allow for appropriate follow up at the next visit.



What are your questions?

Case Scenario

At the Enrollment visit, a participant was assigned the daily tablet regimen and demonstrated taking the daily tablet without issue. However, while at home, the participant reports having some difficulty swallowing the tablet. When he is finally able to swallow the tablet, he vomits.

How would you counsel this participant?

Case Scenario

A participant reports to the study nurse that one dose (one applicator) was inserted during the RAI associated rectal gel use regimen as s/he planned to have sex later that day. However, sex did not occur as planned.

How would you instruct this participant to use his/her next dose of gel?

Case Scenario

A participant, currently in the daily rectal gel regimen, mentions he forget to use one dose as he left the applicators at home while he traveled out of the city.

How should this participant be counseled?

Case Scenario

A participant, in the RAI associated rectal gel use regimen, reports he intends to have sex multiple times over the weekend. He asks if he should insert his required doses before and after each time he has sex?

How would you instruct him to use the gel?

Case Scenario

A participant reports having difficulty inserting the rectal gel applicator on his own. He asks if his partner can insert the study gel for him?

How would you counsel this participant?

Case Scenario

A participant, in the RAI associated rectal gel use regimen, tells the study nurse that he did not have sex in the week prior to his visit. As instructed, he inserted one dose in the evening of the 6th day. He then had sex within the 12 hours of inserting the first dose.

When should he be instructed to insert his next dose?

Case Scenario

A participant is assigned to the RAI associated rectal gel use regimen. Two weeks after the start of the period, he contacts the study nurse and reports that he stopped using the gel as instructed because it was too hard to remember using it when he wanted to have sex.

How would you counsel this participant?

Case Scenario

A participant, in the RAI-associated rectal gel use regimen, inserts one dose when he plans to have sex. However, sex dose not occur and a second dose of gel is not inserted. The next day, the participant has sex, without inserting a dose of gel prior to having sex.

When should the participant be instructed to insert his dose?