

## MTN 026 Single-Dose Behavioral Survey

### Table of Contents

Section:	Title:	Pages:
A	Overview of experiences with trial participation	2-3
B	Gel acceptability	4-5
C	Experiences using the product	6
D	Recommendations	7

PROGRAMMER: Logic checks are in *italics*. Skip patterns are in **CAPITALIZED BOLD**.

## SECTION A. Overview of experiences with trial participation

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We would like to understand your satisfaction with the clinical procedures that are part of this trial. Please answer the following statements as honestly as possible.

Use the following scale for all questions in Section A.

1	2	3	4	5
Completely Disagree	Disagree	Neutral	Agree	Completely Agree

### A1. Experiences of Participation

1. My experience of participating in the trial has corresponded well with the information I have received about the trial.
2. The clinic staff took their time in explaining the content of the trial.
3. Based on my experience, I would recommend to others that they participate in HIV prevention trials.
4. The clinic staff was interested in my experiences of the treatment in the trial.
5. The clinic staff has been interested in my experiences of the treatment in the trial.
6. Contact with the clinic staff has allowed me to receive better care than I would have received outside the trial.
7. I am receiving better healthcare because I am participating in a trial.
8. If a pharmaceutical company finances a trial, my desire to participate is lower compared with if it is healthcare/society conducting a trial.
9. I sensed expectation from the clinic staff that I would consent to participate in the trial.
10. I worry that participation in the trial can hurt me.
11. I worry that my participation in the trial carries a risk that I will receive lower quality treatment than I otherwise would have received.
12. I have regretted consenting to participate in the trial.

### A2. Clinic Procedures

1. I was fully informed through the course of the trial about what was going to happen.
2. I felt free to ask the staff questions I wanted to ask.
3. People here seem to really care about me.
4. People here really know what they are doing.
5. The clinic staff seemed to hurry me through too quickly.
6. The clinic staff used words that were hard to understand.
7. The clinician was too rough when performing the rectal exam.
8. I had a lot of pain during the rectal exam.
9. The rectal exam was more comfortable than I expected.
10. The rectal exam caused me great discomfort.
11. I was very anxious about having the rectal exam.
12. I was embarrassed by the rectal exam.
13. I look forward to the sessions I have with people here.

14. I was very satisfied with the care I received.

As part of this trial, you were asked to have a gel inserted during the clinic visit. Please answer the following gel insertion questions.

A3. Directly Observed Gel Application – use the following scale:

1	2	3	4	5
Completely Disagree	Disagree	Neutral	Agree	Completely Agree

1. I was treated respectfully during the gel insertion procedures.
2. I was fully informed about what was going to happen throughout the gel insertion procedure.
3. The clinic staff was too rough when inserting the gel.
4. I feel confident that the gel insertion was performed properly.
5. I had a lot of pain during the gel insertion.
6. The gel insertion was more comfortable than I expected.
7. The gel insertion caused me great discomfort.
8. I was very anxious about having the gel inserted by staff.
9. I was embarrassed by the gel insertion by staff.
10. I look forward to the sessions I have with people here.
11. I was very satisfied with the care I received.

**SECTION B. GEL ACCEPTABILITY**

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The following questions are about your **overall experience with the gel used in this trial.**

B1. Overall how easy or difficult was it to use the gel?

- 1. Very difficult
- 2. Difficult
- 3. Easy
- 4. Very easy

B2. Overall, how did it feel to have the gel inside you?

- 1. Very comfortable
- 2. Comfortable
- 3. Uncomfortable
- 4. Very uncomfortable

The following questions are about changes in your rectum that you may have experienced while using the gel.

B3. Did you have any problems using this product?

- 1. Yes (please specify: \_\_\_\_\_)
- 2. No

B4. Did you experience any leakage after you used the product?

- 1. None [SKIP TO B5]
- 2. Some [go to B4a]
- 3. A lot [go to B4a]

B4a. How soon did leakage occur after application?

- 1. Less than 15 minutes after application
- 2. 15-29 minutes after application
- 3. 30-44 minutes after application
- 4. 45 minutes to an hour after application
- 5. More than an hour after application

B4b. How much were you bothered by leakage?

- 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
- Not at all Very much

B5. Did you experience any soiling of your underwear or linens from the gel?

1. None [SKIP TO B6]
2. Some [go to B5a]
3. A lot [go to B5a]

B5a. What type of soiling did you experience? (check all that apply)

1. Gel
2. Stool
3. Blood
4. Other (specify)

B5b. How soon did soiling occur after application?

1. Less than 15 minutes after application
2. 15-29 minutes after application
3. 30-44 minutes after application
4. 45 minutes to an hour after application
5. More than an hour after application

B5c. How much were you bothered by soiling of underwear or linens from the gel?

- 1—— 2—— 3—— 4—— 5—— 6—— 7—— 8—— 9—— 10
- Not Very
- at all Much

B6. Did you experience any diarrhea after using the gel?

1. None [SKIP to B7]
2. Some
3. A lot

B6a. How soon did you experience diarrhea after using the gel?

1. Less than 15 minutes after application
2. 15-29 minutes after application
3. 30-44 minutes after application
4. 45 minutes to an hour after application
5. More than an hour after application

B7. Did you experience any other stomach or abdominal problems (such as cramps, bloating, gassiness or passing wind or urge to have a bowel movement) after using the gel?

1. None
2. Some
3. A lot

**SECTION C: EXPERIENCES USING THE PRODUCT**

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We would love to know your experiences applying the gel into your rectum.

C1. Overall, how much did you like the process of applying the gel?

0	1	2	3	4
Disliked very much	Disliked a little	Neither	Liked a little	Liked very much

C2. How easy was it to insert the gel?

0	1	2	3	4
Very difficult	Difficult	Neither	Easy	Very easy

C3. How pleasurable did the gel feel inside your rectum?

0	1	2	3	4
Very unpleasant	Unpleasant	Neutral	pleasant	Very pleasant

C4. Did you have any problems using the applicator to insert the gel rectally?

1. Yes
2. No [**If no, skip to D1**]

C5. What problems did you have with the applicator? \_\_\_\_\_

**SECTION D: RECOMMENDATIONS**

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Please help us understand how we could make the product more attractive to a person like you.

D1. Would you change anything about the applicator?

1. Yes
2. No [if No, SKIP to D3]

D2. What would you change about the applicator? \_\_\_\_\_

D3. Would you change anything about the consistency of the product (for example, how thick or thin it is)?

1. Yes
2. No [if No, SKIP to D5]

D4. What would you change about the consistency of the product? \_\_\_\_\_

D5. Would you change anything about how the product is packaged?

1. Yes
2. No [If No, SKIP to D7]

D6. What would you change about how the product is packaged? \_\_\_\_\_

D7. Would you recommend the applicator be...

1. Refillable
2. Disposable

D8. Do you have any other recommendations?

1. Yes (please explain: \_\_\_\_\_)
2. No

This is the end of the interview. Thank you for completing this questionnaire! Please click on 'Next' when you are ready to save your responses. After you do so, you will not be able to change your answers.