

MTN-026 EXIT Behavioral Survey

Table of Contents

Section:	Title:	Pages:
A	Psychosocial	2-3
B	Gel Acceptability	4-5
C	Experience Using the Product	6
D	Gel Problems	7-9
E	Satisfaction with Clinical Procedures	10
F	Rectal Douches	11
G	Additional Comments	12-13

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

SECTION A. PSYCHOSOCIAL

We would like to ask you about your everyday emotions and experiences. The questions in this scale ask you about your feelings and thoughts SINCE BEGINNING THIS TRIAL. In each case, please indicate your response by choosing how often you felt a certain way.

A1. Please use the following scale for each question.

0	1	2	3	4
Never	Almost Never	Sometimes	Fairly Often	Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?
2. In the last month, how often have you felt that you were unable to control the important things in your life?
3. In the last month, how often have you felt nervous and “stressed”?
4. In the last month, how often have you felt confident about your ability to handle your personal problems?
5. In the last month, how often have you felt that things were going your way?
6. In the last month, how often have you found that you could not cope with all the things that you had to do?
7. In the last month, how often have you been able to control irritations in your life?
8. In the last month, how often have you felt that you were on top of things?
9. In the last month, how often have you been angered because of things that were outside your control?
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

A2. How many participants do you personally know in the MTN-026 study?

_____ participant(s) **[IF A2=0, SKIP TO A4]**

A3. Of those **[import A2 response]** participants, how many are:

- a. Friends _____
- b. Family members _____
- c. Women you met through clinic _____
- d. Men you met through clinic _____
- e. Neighbors _____
- f. Other _____ *Please specify your relationship:* _____

The sum of responses for 3a-f must equal A2.

A4. Other than clinic staff, think of up to 5 close/important people that you have talked to about MTN-026 (this study) and list them below.

(List up to 5 people. If fewer than 5, leave rows blank. Please use only initials or a nickname/alias.)

- a. Person 1: _____
- b. Person 2: _____
- c. Person 3: _____
- d. Person 4: _____
- e. Person 5: _____
- f. Did not tell anybody [if A4 = f, Skip to B1]

PRE-SKIP: IF A4a-e ARE ALL BLANK, SKIP TO B1.

Please answer the following questions for each person listed.

A5. For each person named, please select the box that best applies

[Columns:]

- 1. Is this person male or female?
 - 1. Male
 - 2. Female
 - 3. Other, please specify: _____

- 2. What is each person's relationship to you?
 - 1. Husband or wife
 - 2. Sexual partner other than husband or wife
 - 3. Other family member (e.g., sister or mother)
 - 4. Someone you met during the trial
 - 5. Neighbor
 - 6. Friend
 - 7. Co-worker
 - 8. Other, please specify: _____

- 3. Have they participated in MTN-026?
 - 1. Yes
 - 2. No

- 4. What is each person's opinion about the gel?
 - 1. Liked the gel
 - 2. Disliked the gel
 - 3. No opinion
 - 4. Don't know

- 5. How did each person respond to your use of the gel?
 - 1. Encouraged me to use the gel
 - 2. Discouraged me from using the gel
 - 3. Did neither

SECTION B. GEL ACCEPTABILITY

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
3. A lot

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
3. A lot

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

1. Gel
2. Stool
3. Blood
4. Other (please 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
at all

Very
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

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 pleasant did the gel feel inside your rectum?

0	1	2	3	4
Very Unpleasant	Unpleasant	Neither	Pleasant	Very Pleasant

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

1. Yes
2. No {SKIP TO C6}

C5. What problems did you have with the applicator? _____

Now we would like to ask you about your experience with both the gel and male condoms.

C6. Overall, how much do you like male condoms?

1. Dislike very much
2. Dislike
3. Like
4. Like very much

If in the future a rectal gel was available that provided some protection against HIV, and it was similar to the one you will use in this study...

C7. Which would you prefer to use—the study gel, the male condom, or both?

1. Gel
2. Condom
3. Neither—I dislike both products
4. Both—I like both products equally

C8. What do you think your primary partner would prefer?

1. Gel
2. Condom
3. Neither—dislikes both products
4. Both—likes both products equally
5. Don't know
6. I don't have a primary partner

SECTION D. GEL PROBLEMS

Now we would like to ask you about any problems you experienced while using the gel.

D1. During the 7 days that you were asked to use the gel, how many days did you experience any physical discomfort because of the gel?

_____ day(s) **[IF D1=0, SKIP TO D3]**

D2. Overall, how much did the physical discomfort bother you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D3. During the 7 days that you were asked to use the gel, how many days did you experience any pain because of the gel?

_____ day(s) **[IF D3=0, SKIP TO D5]**

D4. Overall, how much did the pain bother you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D5. During the 7 days that you were asked to use the gel, how many days did you feel that the gel applicator was not inserted correctly?

_____ day(s) **[IF D5=0, SKIP TO D7]**

D6. Overall, how much did the gel applicator not being inserted correctly affect you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D7. During the 7 days that you were asked to use the gel, how many days did the gel cause you emotional discomfort such as worries, fears, guilt or any other unpleasant feelings?

_____ day(s) **[IF D7=0, SKIP TO D9]**

D8. Overall, how much did this emotional discomfort bother you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D9. During the 7 days that you were asked to use the gel, how many days did the gel interfere with your normal daily activities?

_____ day(s) **[IF D9=0, SKIP TO D11]**

D10. Overall, how much did this interference with daily activities bother you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D11. During the 7 days that you were asked to use the gel, how many days did you experience any constipation?

_____ day(s) **[IF D11=0, SKIP TO D13]**

D12. Overall, how much did the constipation bother you?

1. Not at all
2. A little
3. Somewhat
4. Very much

D13. Did you ever want to remove the gel during the 7-day trial?

1. Yes
2. No
3. I never tried to remove the gel

D14. Was there any other problem you had with the gel?

1. Yes, *please specify:* _____
2. No

D15. Were you able to attend all clinic visits over the 7 days of dosage?

1. Yes
2. No

D16. Did you use the extra applicator with gel given to you by study staff for use at home?

1. Yes
2. No

D17. What are your preferences about using the gel every day?

1. I prefer using it every day
2. I prefer not using it every day
3. I don't have a preference

D18. Overall, how much do you like the gel?

1. Dislike very much
2. Dislike
3. Like
4. Like very much

D19. How do you like the gel now compared to when you started the study?

1. I like it MORE now than when I started the study
2. I like it LESS now than when I started the study
3. I like it the SAME as when I first started
4. Not applicable, **I do not like** the gel

SECTION E. SATISFACTION WITH CLINICAL PROCEDURES

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 statements in E1 & E2.

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

E1. Overall impressions of study trial

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 staff seemed to hurry me through too quickly.
6. The staff used words that were hard to understand.
7. The clinic staff explained the procedures fully.
8. The clinician was too rough when performing the rectal exam.
9. The clinician was gentle when performing the rectal exam.
10. The clinician made the exam easy for me.
11. I had a lot of pain during the rectal exam.
12. The rectal exam was more comfortable than I expected.
13. The rectal exam caused me great discomfort.
14. I was very anxious about having the rectal exam.
15. I was embarrassed by the rectal exam.
16. I look forward to the sessions I have with people here.
17. I was very satisfied with the care I received.

E2. Directly Observed Study Product Application: As part of this trial, you were asked to have a gel inserted during the clinic visit. Please answer the following gel insertion questions.

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. I feel confident that the gel insertion was performed properly.
4. I had a lot of pain during the gel insertion.
5. The gel insertion was more comfortable than I expected.
6. The gel insertion caused me great discomfort.
7. I was very anxious about having the gel inserted by staff.
8. I was embarrassed that the staff would insert the gel.
9. I look forward to the sessions I have with people here.
10. I was very satisfied with the care I received.

SECTION G. ADDITIONAL COMMENTS

We are almost to the end of the interview.

Use the following scale for questions G1-G6.

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

G1. 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 clinician took his/her 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 has been interested in my experiences of the treatment in the trial.
5. The clinicians have 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 taken better care of within 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 the clinic staff expected 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.

G2. Informed Consent

1. I was provided with adequate time to read and ask questions about the informed consent form.
2. The informed consent form was confusing and difficult to understand.
3. Staff fully answered any questions I had about the informed consent form.
 - a. (Additional option: I did not have any questions about the informed consent.)
4. I have a clear understanding of what a clinical trial is.
5. Throughout the trial, I was worried about the potential side effects listed in the consent form.

G3. Participation

1. I was treated respectfully during all study procedures.
2. I was fully informed throughout the course of the trial about what was going to happen.
3. I had confidence in the staff performing the procedures.
4. My overall needs were met during my participation in the study.

G4. Facilities

1. The facilities (exam rooms, recreation areas, patient rooms) were clean.
2. I was provided with acceptable options to keep myself entertained during down time.

G5. Overall Impression and Future Participation

1. I believe that I will participate in a future clinical trial
2. The stipend I received for participation in this study was an acceptable amount for the time involved and the type and number of procedures I completed.
3. Overall, my participation in this study was a positive experience.
4. Based on my experience during this trial, I would recommend a friend or family member to participate in a trial.

G6. Patients' perceptions of aspects of the trial to be improved

1. I would have preferred more information about the trial prior to its commencement.
2. I would have preferred more information about the trial while it was in progress.
3. I would have liked more recognition for my efforts.
4. I would have liked to receive better medical care during the trial.
5. There should have been more financial incentives.
6. More social networks needed to be incorporated into the trial.
7. More education about HIV should have been incorporated into the trial.
8. The clinic procedures should have been performed less often.
9. The trial should have been shorter in duration.

G7. Is there anything that we haven't asked that you think we should have?

[Open response]

G8. Is there anything else you would like to tell us about your experience with the gel **since beginning this trial?**

[Open response]

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.