

MTN 039 Follow-up Visit 4
(Brief Visit-Specific WSI)

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SECTION A. Overview of experiences with trial participation

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

Use the following scale for all questions in Section A.

A1. Insert Application – use the following scale:

1	2	3	4
Completely Disagree	Disagree	Agree	Completely Agree

1. I felt comfortable using the insert at this study visit.
2. I had a lot of pain when the insert was administered.
3. Using the rectal insert was more comfortable than I expected.
4. Using the rectal insert caused me great discomfort.
5. I was very anxious about using the rectal insert.
6. I was very satisfied with the care I received.

SECTION B. RECTAL INSERT ACCEPTABILITY

B1. Overall, how easy or difficult was it to use the study product when inserted by clinic staff?

- Very difficult
- Difficult
- Easy
- Very easy

B2. How did it feel to have the insert inside you?

- Very comfortable
- Comfortable
- Uncomfortable
- Very uncomfortable

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

B3. Did you have any problems using the study insert after it was inserted?

- No
- Yes (please specify: _____)

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

- No **[IF NO, SKIP TO B5]**
- Yes

B4a. How soon did leakage occur after insertion?

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion

B4b. How much were you bothered by leakage?

1—2—3—4—5—6—7—8—9—10

Not
at all

Very
much

B5. Since your last study visit, have you experienced any soiling of your underwear or linens?

- No **[IF NO, SKIP TO B6]**
- Yes

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

- Stool
- Blood
- Other (Specify)

B5b. How soon did soiling occur after insertion of the insert?

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion

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

1—2—3—4—5—6—7—8—9—10

Not
at all

Very
much

B6. Since your last study visit, have you experienced any diarrhea?

- No **[IF NO, SKIP to B7]**
- Yes

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

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion
- It was not when I used the study insert

B7. Since your last study visit, have you experienced any other stomach or abdominal problems (such as cramps, bloating, gassiness or passing wind or urge to have a bowel movement)?

- No **[If no, skip to Section C]**
- Yes

B7a. How soon did you experience any stomach or abdominal problems after using the insert?

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion
- It was not when I used the study insert

SECTION C: EXPERIENCES USING THE INSERT

We would like to know your experiences applying the insert into your rectum.

C1. How much did you like the process of clinic staff applying the study insert into your rectum?

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

C2. How easy was it to have the staff insert the study product?

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

C3. How comfortable did the insert feel inside your rectum?

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

C4. Did you have any problems with the clinic staff inserting the study product into your rectum?

- Yes
- No **[IF NO, SKIP TO C5]**

C4a. What problems did you have? _____

Researchers are trying to develop alternatives to condoms and oral PrEP for the prevention of HIV transmission during intercourse.

C5. How likely would you be to use the insert that was provided to you during your study visit if found to provide some protection against HIV?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

C6. How likely would you be to use the insert if it were double the size?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

C7. How likely would you be to use the insert if it were half the size?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

SECTION D: RECOMMENDATIONS

D1. Would you change anything about your study visit?

- Yes
- No [**IF NO, SKIP TO D2**]

D1a. What would you change? _____

D2. Do you have any other recommendations?

- Yes (please explain: _____)
- 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.