MTN-039 Follow-Up Visit 8

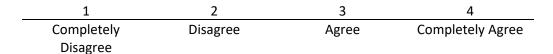
(Brief Visit-Specific CASI)

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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. Experiences of Participation

- 1. My experience 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 with the study product in the trial.
- 5. The clinic staff have been interested in my experiences during treatment in the trial.
- 6. I am taken better care of because I am participating in a trial.
- 7. If a pharmaceutical company finances a trial, my desire to participate is lower compared with if it is healthcare/society conducting a trial.
- **8.** I sensed expectation from the clinic staff that I would consent 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 physician 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.

Please answer the following questions.

A3. Insert Application – use the following scale:

1	2	3	4
Completely	Disagree	Agree	Completely Agree
Disagree			

- 1. I felt comfortable using the two inserts at this study visit.
- 2. I had a lot of pain having the study product inserted into my rectum.
- 3. Having the insert applied was more comfortable than I expected.
- 4. Having the insert applied caused me great discomfort.
- 5. I was very anxious about having the insert applied.

SECTION B. RECTAL INSERT ACCEPTABILITY

The following questions are about your **overall experience with the two inserts used at this study visit**.

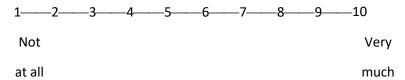
- B1. Overall, how easy or difficult was it to use the two inserts when applied by clinic staff?
 - Very difficult
 - Difficult
 - Easy
 - Very easy
- B2. How did it feel to have the two inserts inside you?
 - Very comfortable
 - Comfortable
 - Uncomfortable
 - Very uncomfortable

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

- B3. Did you have any problems using the two study inserts after they were administered?
 - No
 - Yes (please specify:_____)
- B4. Did you experience any leakage after you used the two study inserts?
 - No [IF NO, SKIP TO B5]
 - Yes

B4a. How soon did leakage occur after insertion of the **two study inserts**?

- 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?



- B5. Since your last study visit, have you experienced any soiling of your underwear or linens?
 - No [IF NO, SKIP TO B6]
 - Yes

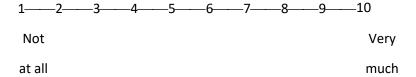
B5a. What type of soiling did you experience? (check all that apply)

- Stool
- Blood
- Other (Specify)

B5b. How soon did soiling occur after insertion of the two study inserts?

- 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 \underline{two} study inserts?



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 two study inserts?

- 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(s)

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 C1]
- Yes

B7a. How soon did you experience any stomach or abdominal problems after using the **two study inserts**?

- 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(s)

SECTION C: EXPERIENCES USING THE TWO INSERTS

We would like to know	v your experiences app	plying the <u>two stuc</u>	<mark>dy inserts</mark> into your re	ectum.
C1. How much did you rectum?	like the process of cli	nic staff inserting t	he study <u>two study i</u>	nserts into your
0	1	2	3	4
Disliked very much	Disliked a little	Neither	Liked a little	Liked very much
C2. How easy was it t	to have the staff insert	the two study ins	erts?	
0	1	2	3	4
Very Difficult	Difficult	Neither	Easy	Very Easy
C3. How pleasurable d	lid the <u>two study inse</u>	<u>rts</u> feel inside your	rectum?	
0	1	2	3	4
Very Pleasant	Pleasant	Neutral	Unpleasant	Very unpleasant
C4a. What problems d C5. How likely would		study inserts if it v	were double the amo	unt?
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
C6. How likely would y	ou be to use the two	study inserts if it w	vere half the amount	?
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

SECTION D: RECTAL MICROBICIDE INTENTIONS

Researchers are trying to develop alternatives to condoms and PrEP for the prevention of HIV transmission during intercourse. Microbicides could be one such alternative.

D1. If a rectal microbicion	de were available th	hat provided some pro	tection against H	IV, how likely would
you be to use it every ti	me you have anal i	ntercourse?		
0	1	2	3	4
0 Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
D2.If a rectal insert were			_	
to use it every time you	nave receptive an	ai intercourse with a s	teady sex partne	r:
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
D2 How likely woul	ld vou bo to uso a r	nisrahisida insart ayar	v timo vou bavo r	ocontivo anal
D3. How likely woul intercourse with a one-		nicrobicide insert ever	y time you have r	eceptive anai
	-			
0 Extremely Unlikely	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
D4. How likely woul	ld vou he to use a r	nicrobicide insert eve	ry time you have I	recentive anal
intercourse with other p	•		•	•
·	•	•		· ·
O System on a least tradition to	1	2 Neither	3 Likely	4 Extremely Likely
Extremely Unlikely	Unlikely	Neither	Likely	extremely likely
D5. How likely woul	d vou be to use a r	nicrobicide insert for i	receptive anal inte	ercourse if you were
using alcohol or drugs?	. ,			, , , , , , , , , , , , , , , , , , , ,
0	1	2	2	1
Extremely Unlikely		Neither	3 Likely	4 Extremely Likely
Extremely offinery	O'IIIICIY		Linely	Extremely Emery
D6. If a rectal micro	bicide were availak	ole that provided some	protection again	st HIV, and it came in
the form of a supposito	<u>ry</u> , how likely woul	d you be to use it ever	y time you have r	eceptive anal
intercourse?				
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
D7. If a rectal micro	bicide were availak	ole that provided some	protection again	st HIV. and it came in
the form of a gel, like c		·	-	
have receptive anal inte		•	•	. ,
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
				· · · · · · · · · · · · · · · · · · ·

	low likely would yo		ne you have rece	ptive anal intercourse?
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
D9. If a rectal micro the form of a <u>douche</u> , h		ole that provided some u be to use it every tin		
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
D10. How likely woul condoms?	d you be to use a n	nicrobicide insert on t	the occasions whe	en you don't use
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
application before havir	•	nicrobicide insert if yo 2	3	4
0	1	2	2	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
Twice as much a	•			
D13. If you have a stead 1. No [IF NO, 2. Yes	ly sexual partner, w	ould you want to use	a microbicide wit	hout their knowledge
1. No [IF NO,	SKIP TO D14] mstances would yo	ou use a microbicide w		
 No [IF NO, Yes D13a. Under what circu	SKIP TO D14] mstances would yo(text	ou use a microbicide w range 0-500) <i>(fill-in)</i>	ithout your stead	y partner's
 No [IF NO, Yes D13a. Under what circu knowledge? 	SKIP TO D14] mstances would yo(text	ou use a microbicide w range 0-500) <i>(fill-in)</i>	ithout your stead	y partner's

SECTION F: RECOMMENDATIONS

F1. Would you cha	nge anything about your participation in the study?
•	Yes
•	No [IF NO, SKIP TO F2]
F1a. What woul	d you change?
23. Do you have ar	y other recommendations?
1.	Yes (please explain:)
2.	No
	ne interview. Thank you for completing this questionnaire! Please click on 'Next' wher ve your responses. After you do so, you will not be able to change your answers.