

MTN-017

Follow-up Behavioral Questionnaire

9-11-12 version

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TEXT IN CAPITAL LETTERS SHOULD NOT BE PRESENTED TO THE PARTICIPANT.

FOR THE PURPOSES OF THIS QUESTIONNAIRE, CONDITION A IS THE TABLET CONDITION, CONDITION B IS THE DAILY GEL CONDITION, AND CONDITION C IS THE RECEPTIVE ANAL INTERCOURSE-ASSOCIATED GEL CONDITION. QUESTION NUMBERS ENDING WITH THE LETTERS A, B, OR C REFER SPECIFICALLY TO THE ABOVE CONDITIONS. QUESTIONS NUMBERS WITHOUT A LETTER REFER TO ALL CONDITIONS. WHEN ANSWER CHOICES FOR QUESTIONS IN EACH CONDITION ARE THE SAME, THEY ARE ONLY PRESENTED ONCE.

ALL QUESTIONS WILL HAVE A REFUSE TO ANSWER OPTION, EXCEPT FOR WRITE-IN RESPONSES, WHICH CAN BE SKIPPED.

[INCLUDE OPT-OUT PRACTICE SESSION]

SECTION A. LIKING THE PRODUCT

1A. Overall, how do you feel about the Truvada tablets you took recently?

1BC. Overall, how do you feel about the tenofovir gel you used recently?

1. Disliked very much
2. Disliked a little
3. Liked a little
4. Liked very much

2BC. Would you have preferred that the tenofovir gel be...?

1. Thicker, or less watery
2. Thinner, or more watery
3. No change

3BC. Would you have preferred to have...?

1. More tenofovir gel in the applicator
2. Less tenofovir gel in the applicator
3. No change

SECTION B. EASE OF USE

1A. Overall, how easy or difficult was it to swallow the Truvada tablet? [SKIP TO NEXT SECTION]

1BC. Overall, how easy or difficult was it to apply the tenofovir gel?

2BC. How easy or difficult was it to apply the tenofovir gel the first few times you ever applied it on your own (not in the clinic)? [ONLY ASK FOR FIRST GEL CONDITION]

3BC. How easy or difficult was it to apply the tenofovir gel the last few times you applied it on your own?

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

4. How much did you like the tenofovir gel applicator?

1. Disliked very much
2. Disliked a little
3. Liked a little
4. Liked very much

5. How frequently did some of the tenofovir gel come out of the applicator (accidentally or intentionally) before it was inserted into your rectum?

1. Never [SKIP TO Q7]
2. Infrequently
3. About half of the time
4. Frequently
5. Always

6. Please explain what happened when the tenofovir gel came out of the applicator before it was inserted into your rectum. Choose all that apply.

1. Tenofovir gel was applied to my partner's penis
2. Tenofovir gel was applied on the outside of my rectum as a lubricant
3. I pushed some tenofovir gel out of the applicator to lubricate the tip
4. I pushed some tenofovir gel out to remove air from the applicator
5. I pushed some tenofovir gel out of the applicator accidentally
6. Other (please specify): _____

7. Did you ever forget to remove the cap before inserting the applicator into your rectum?

1. Yes
2. No

Please indicate how much you were bothered by each of the following:

8. The size of the applicator
9. Opening the wrapper of the applicator

10. Having to assemble the applicator
11. Lack of lubrication on the tip
12. Finding a comfortable position to insert the applicator

1. Not at all
2. A little
3. A lot

12. Did you experience any pain or trauma caused by inserting the applicator?

1. None
2. Some
3. A lot

13. How easy or difficult would it be to carry this gel applicator around?

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

SECTION C. SEXUAL BEHAVIOR

The following questions refer to your sexual behavior during the past eight weeks that is, from [CASI: INSERT TODAY'S DATE EIGHT WEEKS AGO] until today. We understand this topic is very personal, but every answer is important for the study. All of your answers will be kept confidential. For questions that ask the number of times, if you are unsure just give your best guess.

First, let's take a minute to review some words so it is clear what we are asking.

[SCREEN TIPS WILL BE GENERATED FOR WORDS IN BOLD TO DISPLAY THEIR MEANINGS AND ALTERNATE PHRASES, AS PER THE FOLLOWING:]

Penis is the male sex organ. Some people call it "dick" or "cock." Men and transgender people can have penises.

Vagina is the female sex organ. Some people call it "pussy." Women and transgender people can have vaginas.

Rectum and anus are frequently called "butt" or "asshole."

Anal sex is when someone puts their penis in another person's rectum or anus; some people call this "butt fucking."

Receptive anal sex is when you are penetrated or are the "bottom."

Insertive anal sex is when you penetrate your partner or are the "top."

Vaginal sex is when someone puts their penis into a vagina; some people call this "fucking" or "screwing" or "having sex."

Oral sex is when people put their mouth or tongue on each other's sex organs, including the penis, vagina or anus. When someone puts their mouth on a man's penis, some people call this a "blow job" or "fellatio." When someone puts their mouth on another person's anus, some people call this "rimming." When someone puts their mouth on another person's vagina, some people call this "cunnilingus."

As you go through the following questions, these words will sometimes appear in **bold**. If you are not sure what a word in bold means, use the mouse to place the arrow or cursor on the bolded word to see its meaning.

In some cases, these questions may not specifically apply to you. At the end of this section, you will have a space to enter comments.

SEXUAL BEHAVIOR

First, we will ask you questions about your body.

1. Do you currently have a **penis**?

_____ 1 Yes [SKIP TO Q3]

_____ 2 No

2. Do you currently have a **vagina**?

_____ 1 Yes

_____ 2 No

Now we will ask you questions about your sexual history.

A. These questions refer to your behavior during the eight weeks in which you were asked to take the Truvada tablet every day.

B. These questions refer to your behavior during the eight weeks in which you were asked to use the tenofovir gel every day.

C. These questions refer to your behavior during the eight weeks in which you were asked to use the tenofovir gel with receptive anal sex.

3. During those eight weeks, how many people did you have **sex** with? (Sex can include anal sex, vaginal sex, oral sex, or anilingus).

[If Q3=1, ask 4.1. If Q3 > 1, ask 4.2.]

4.1. You said you had **sex** with *one* person in those eight weeks. Please indicate whether this person was a....

_____ 1 Man

_____ 2 Woman

_____ 3 Transgender man

_____ 4 Transgender woman

4.2. You said you had **sex** with [Q4] people in those eight weeks. Please indicate how many of these people were men, women, or transgender. Note that your answers must add up to [Q4].

_____ 1 Men

_____ 2 Women

_____ 3 Transgender man

_____ 4 Transgender woman

[SKIP PATTERNS WILL BE BASED ON ANSWERS TO ANATOMY AND PARTNER' S GENDER]

5. During those eight weeks, how many times did you have **vaginal sex**, when you put your **penis** into a partner's **vagina**? _____ [RANGE 0-1000]

6. Of the [Q5] times you had **vaginal sex**, how many times did you put your **penis** into a partner's **vagina** *without a condom*, even for a little while? _____

7. During those eight weeks, how many times did you have **insertive anal sex**, when you put your **penis** into a partner's **rectum**? _____

8. Of the [Q7] times you had **insertive anal sex**, how many times did you put your **penis** into a partner's rectum *without a condom*, even for a little while? _____

9. During those eight weeks, how many times did you have **receptive anal sex**, when a partner's penis was in your rectum? _____

10. Of the [Q9] times you had **receptive anal sex**, how many times was a partner's penis in your **rectum** *without a condom*, even for a little while? _____

Now we would like to ask you about oral sex:

11. During those eight weeks, how many times did you put your mouth on a partner's **penis**? _____

12. During those eight weeks, how many times did a partner put their mouth on your **penis**? _____

13. During those eight weeks, how many times did you put your mouth on a partner's **anus**? _____

14. During those eight weeks, how many times did a partner put their mouth on your **anus**? _____

15. During those eight weeks, how many times did you put your mouth on a partner's **vagina**? _____

16. During those eight weeks, how many times did a partner put their mouth on your **vagina**? _____

17. During those eight weeks, how many times did you have **vaginal sex**, when a partner's penis was in your vagina? _____

18. Of the [Q17] times you had **vaginal sex**, how many times was a partner's penis in your **vagina** *without a condom*, even for a little while? _____

The next two questions refer to exchanging sex for money or other goods or services. Remember, your answers are confidential and will not be viewed by clinic staff.

19. During those eight weeks, how many times did you receive money or other goods or services in exchange for sex? _____

20. During those eight weeks, how many times did you pay money or provide other goods or services in exchange for sex? _____

21. Please leave us any comments you have about this sexual behavior questionnaire, especially if you thought these questions did not apply to you:

SECTION D. ADHERENCE

1A. You were asked to take the Truvada tablet once a day for eight weeks. However, for different reasons, many people have difficulties taking a tablet every day. Thinking about your experience during those eight weeks, how many Truvada tablets did you miss?

Dropdown menu 0-60 [IF 0, SKIP TO NEXT SECTION, IF 1 OR ABOVE, SKIP TO Q4A].

1B. You were asked to insert the tenofovir gel in your rectum once a day for eight weeks. However, for different reasons, many people have difficulties applying the tenofovir gel every day. Thinking about your experience during those eight weeks, how many tenofovir gel applications did you miss?

0-60 [IF 0, SKIP TO NEXT SECTION, IF 1 OR ABOVE, SKIP TO Q4B].

1C. During this eight-week period you were asked to insert the tenofovir gel in your rectum before and after **receptive anal sex** or twice per seven-day period if you didn't have sex during that seven-day period. However, for different reasons, many people have difficulties doing this.

How many times did a partner put a penis in your rectum during those 8 weeks? _____

Of those times, how many times did you apply the tenofovir gel... [ANSWERS MUST SUM TO Q.D1C]

Within 12 hours before being penetrated AND within 12 hours after being penetrated? _____

Within 12 hours before being penetrated but NOT after _____

Within 12 hours after being penetrated but NOT before _____

I did not use the tenofovir gel before or after _____

2C. During those eight weeks, how many times did seven days go by in which you did NOT have sex? _____

3C. During those [Q.D2C] weeks, how many times did you apply the tenofovir gel at least twice per week? _____

4A. Which of the following prevented you from taking the Truvada tablet daily (check all that apply).

I forgot

I did not have the Truvada tablet with me

My sexual partner did not want me to take the Truvada tablet

I did not have the privacy needed to take the Truvada tablet

I did not like the Truvada tablet

The Truvada tablet made me feel ill

I was drinking or using drugs

There was a change in my regular routine

Other (specify _____)

4BC. Please check all that apply if any of the following reasons prevented you from using the tenofovir gel.

I forgot

I did not have the tenofovir gel with me

My sexual partner did not want me to use the tenofovir gel

- I did not have the privacy needed to use the tenofovir gel
- I did not like the tenofovir gel
- The tenofovir gel made me feel ill
- I was drinking or using drugs
- There was a change in my regular routine
- Other (specify _____)

5A. Did you ever give the Truvada tablets to another person?

- 1. Yes
- 2. No [GO TO NEXT SECTION]

6A. How many Truvada tablets did you give to another person? _____

7A. I gave the Truvada tablets to (check all that apply)

- 1. A family member
- 2. A friend
- 3. A partner
- 4. A person who wanted to buy it
- 5. A person who has HIV
- 6. Other (please specify: _____)

5BC. Did you ever give the tenofovir gel to another person?

- 1. Yes
- 2. No [GO TO NEXT SECTION]

6BC. How many tenofovir gel applicators did you give to another person? _____

7BC. I gave the tenofovir gel to (check all that apply)

- 1. A family member
- 2. A friend
- 3. A partner
- 4. A person who wanted to buy it
- 5. A person who has HIV
- 6. Other (please specify: _____)

SECTION E. DOUCHE AND LUBRICANT USE

[CASI PROGRAMMER: IF CONDITION A, SKIP THIS SECTION]

Now we would like to ask you some questions about other products you may have used during the recent period in which you were using the tenofovir gel.

1BC. Thinking about all of the times that you used the tenofovir gel prior to sex, how frequently did you douche or give yourself an enema less than 30 minutes before inserting the tenofovir gel?

1. Never
2. Infrequently
3. About half of the time
4. Frequently
5. Always

2BC. Did your douching practices change as a result of using the tenofovir gel?

1. No, I douched as frequently as I typically do
2. Yes, I douched less frequently than I typically do
3. Yes, I douched more frequently than I typically do
4. Not applicable, I never douche

3BC. Thinking about all of the times that you used the tenofovir gel prior to sex, how frequently did you use a sexual lubricant in addition to the tenofovir gel?

1. Never
2. Infrequently
3. About half of the time
4. Frequently
5. Always

4BC. Did your lubricant use change as a result of using the tenofovir gel?

1. No, I used as much lubricant as I typically use
2. Yes, I used less lubricant than I typically use
3. Yes, I used more lubricant than I typically use
4. Not applicable, I never use lubricant

SECTION F. EXPERIENCES USING THE PRODUCT

1A. Now we would like to ask you some questions about problems you may have experienced when taking the tablet. Did you experience any nausea after taking the Truvada tablet?

1. None
2. Some
3. A lot

2A. Did you experience any vomiting after taking the Truvada tablet?

1. None
2. Some
3. A lot

3A. Did you experience any dizziness after taking the Truvada tablet?

1. None
2. Some
3. A lot

4A. Did you experience any headaches after taking the Truvada tablet?

1. None
2. Some
3. A lot

5A. Did you experience a rash after taking the Truvada tablet?

1. None
2. Some
3. A lot

6A. Did you experience any diarrhea after taking the Truvada tablet?

1. None
2. Some
3. A lot

1BC. Now we would like to ask you some questions about problems you may have experienced when most recently using the tenofovir gel. Did you experience any leakage after applying the tenofovir gel?

1. None
2. Some
3. A lot

2BC. Did you experience any diarrhea after using the tenofovir gel?

1. None
2. Some
3. A lot

3BC. 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 tenofovir gel?

1. None
2. Some
3. A lot

4BC. After you inserted the gel in your rectum, did the tenofovir gel feel cold?

1. No [SKIP TO Q 6BC]
2. Yes

5BC. How much were you bothered by the tenofovir gel feeling cold?

1. Not at all
2. A little
3. A lot

6BC. Did the tenofovir gel feel sticky?

1. No [SKIP TO Q8]
2. Yes

7BC. How much were you bothered by the tenofovir gel feeling sticky?

1. Not at all
2. A little
3. A lot

8BC. Did the tenofovir gel burn or irritate your skin?

1. No
2. Yes

9A. During the eight weeks in which you were asked to take the Truvada tablet every day, how did it affect your sexual enjoyment?

1. My sexual enjoyment was not affected at all
2. I had less sexual enjoyment than usual
3. I had more sexual enjoyment than usual

9B. During the eight weeks in which you were asked to use the tenofovir gel every day, how did it affect your sexual enjoyment?

1. My sexual enjoyment was not affected at all
2. I had less sexual enjoyment than usual
3. I had more sexual enjoyment than usual

9C. During the eight weeks in which you were asked to use the tenofovir gel with receptive anal sex, how did it affect your sexual enjoyment?

1. My sexual enjoyment was not affected at all
2. I had less sexual enjoyment than usual
3. I had more sexual enjoyment than usual

10A. During the eight weeks in which you were asked to take the Truvada tablet every day, did any of your partners have a negative reaction?

1. No
2. Yes, (please specify:_____)

10B. During the eight weeks in which you were asked to use the tenofovir gel every day, did any of your partners have a negative reaction?

1. No
2. Yes, (please specify:_____)

10C. During the eight weeks in which you were asked to use the tenofovir gel with receptive anal sex, did any of your partners have a negative reaction?

1. No
2. Yes, (please specify:_____)

11A. During the eight weeks in which you were asked to take the Truvada tablet every day, did any of your partners have a positive reaction?

1. No
2. Yes, (please specify:_____)

11B. During the eight weeks in which you were asked to use the tenofovir gel every day, did any of your partners have a positive reaction?

1. No
2. Yes, (please specify:_____)

11C. During the eight weeks in which you were asked to use the tenofovir gel with receptive anal sex, did any of your partners have a positive reaction?

1. No
2. Yes, (please specify:_____)

SECTION G. LIKELIHOOD TO USE PRODUCT IN THE FUTURE

1A. Think about the positive and negative experiences you have had taking the Truvada tablet during the eight week study period. If this Truvada tablet, which provides some protection against HIV, were available to you, how likely would you be to take it every day?

1B. Think about the positive and negative experiences you have had using the tenofovir gel daily during the eight week study period. If this tenofovir gel were available and it provided some protection against HIV, how likely would you be to use it every day?

1C. Think about the positive and negative experiences you have had using the tenofovir gel during the eight week study period. If this tenofovir gel were available and it provided some protection against HIV, how likely would you be to use it before and after **receptive anal sex**? (Within 12 hours before and within 12 hours afterwards)

1. Very unlikely
2. Unlikely
3. Likely
4. Very likely

ONLY AFTER FINAL CONDITION:

2. You've had the chance to take a Truvada tablet every day, use the tenofovir gel every day, or use the tenofovir gel only when you have **receptive anal sex**. Which did you like the most?

3. You've had the chance to take a Truvada tablet every day, use the tenofovir gel every day, or use the tenofovir gel only when you have **receptive anal sex**. Which did you like the least?

- Taking the Truvada tablet every day
- Using the tenofovir gel every day
- Using the tenofovir gel with receptive anal sex

SECTION H. RECOMMENDATIONS

0A. Think about the positive and negative experiences you have had taking the Truvada tablet during the eight week study period.

0B. Think about the positive and negative experiences you have had using the tenofovir gel daily during the eight week study period.

0C. Think about the positive and negative experiences you have had using the tenofovir gel during the eight week study period.

1. What were the things you liked the most?

1. _____

2. _____

3. _____

2. What were the things you liked the least?

1. _____

2. _____

3. _____

ONLY AFTER FINAL CONDITION

SECTION I. FEEDBACK ON SMS DIARY

1. How did you feel about using the SMS text message system in this study?
 1. Disliked very much
 2. Disliked
 3. Liked
 4. Liked very much

2. Indicate how much you were bothered by the following aspects of the SMS text system:
 1. The time delay in between SMS text messages
 2. Having to text both a number and a letter
 3. The daily SMS text message reminders
 4. Having to use a password
 5. Having to erase the SMS session from my phone
 6. Receiving the instructions every session

Not at all
A little
A lot

3. How did you feel about the amount of the incentive?
 1. Too much
 2. Enough
 3. Too little

4. How concerned were you about privacy while using this system?
 1. Not concerned at all
 2. A little concerned
 3. Very concerned

5. How helpful was it when study staff provided you additional information via text message?
 1. Very helpful
 2. Helpful
 3. Somewhat helpful
 4. Not helpful
 5. Does not apply

Thank you for completing this questionnaire! Please notify the study staff that you are finished.

END OF QUESTIONNAIRE