

**MTN 035 Product Use End Visit Behavioral Survey
Rectal Douche**

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

SECTION A. PSYCHOSOCIAL

A1. First we would like to ask you about your everyday emotions and experiences. **Since you last completed this survey**, how often have you...

[Response options for 1=Never, 2=Almost never, 3=Sometimes, 4=Fairly often, 5=Very often]

- a. Been upset because of something that happened that you didn't expect?
- b. Felt nervous and "stressed out"?
- c. Found that you could not deal with all the things that you had to do?
- d. Gotten angry because of things that happened that were outside of your control?
- e. Felt that you had so many problems that you could not deal with them?
- f. Felt that you were able to successfully handle the important changes occurring in your life?
- g. Felt able to handle your personal problems?
- h. Felt that things were going your way?
- i. Been able to control hassles in your life?
- j. Felt that you were on top of things?
- k. Been able to control the way to spend your time?

SECTION B. Douche Use & Adherence

The following questions refer to your use of the study provided rectal douches/enemas over the past 4 weeks.

You were asked to insert the **study provided rectal douche/enema** in your rectum at least once a week during the past 4 weeks. However, for different reasons, people might have encountered difficulties using the douche/enema.

B0. Thinking about your experience during these past four weeks, in how many of the weeks did you miss a rectal enema/douche application?

1. 0 weeks
2. 1 week
3. 2 weeks
4. 3 weeks
5. 4 weeks **[SKIP TO B4B]**

During this 4-week period you were asked to insert the study douche/enema in your rectum before anal sex or to use it at least once in a seven-day period if you didn't have sex during that time. However, for different reasons, people might have difficulties doing this.

B1. How many times did a partner put a penis in your rectum during the past 4 weeks? _____

[IF B1 = 0, GO TO B4]

B2. **Of those [B1] times**, how many times did you use the study-provided rectal douche/enema BEFORE receptive anal sex?

(If you did not use the douche prior to anal sex, please enter '0').

__ time(s) **[IF 0, SKIP TO B3]**

B2a. Typically, how long before **receptive anal intercourse** did you use the study-provided **rectal douche**?

1. Less than 15 minutes
2. Between 15 minutes and 30 minutes
3. Between 30 minutes and 1 hour
4. Between 1 and 2 hours
5. Between 2 and 3 hours
6. Between 3 and 4 hours
7. 4 hours or more

B2b. Typically, how many study douches/enemas did you apply before each receptive anal sex occasion?

1. One enema **[GO TO B2e]**
2. Two enemas
3. Three enemas

4. Four enemas
5. Five or more enemas

B2c. [If B2b > 1] When you used multiple douches/enemas before receptive anal sex, how often did you rinse the tip with water before reinserting it?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

B2d. [If B2b > 1] When you used multiple douches/enemas before receptive anal sex, how often did you wash the tip with a soap or detergent before reinserting it?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

B2e. What motivated you to use the study provided **rectal douche/enema BEFORE receptive anal intercourse?** *Indicate all that apply*

1. To follow the study procedures
2. I usually use a douche/enema before receptive anal intercourse
3. I wanted to be clean
4. My sex partner suggested that I use a douche/enema before sex
5. Other, *please specify:* _____

B2f. [IF B2 ≠ B1] Which of the following prevented you from using the study provided rectal douche/enema before sex? (Check all that apply).

- I forgot
- I did not have the enema bottle with me
- I didn't have enough time to use the enema before anal sex
- My sexual partner did not want me to use the enema/douche
- I did not have the privacy needed to use the enema/douche
- I did not like the enema/douche
- The enema/douche made me feel ill
- I was drinking or using drugs
- There was a change in my regular routine
- I felt like people judged me for using a rectal douche
- Other, specify _____

B3. Of those [B1] times that a partner put a penis in your rectum over the past 4 weeks, how many times did you use the study-provided rectal douche AFTER receptive anal sex?

(If you did not use the douche AFTER anal sex, please enter '0'.)

__ time(s) [IF 0, SKIP TO B4]

B3a. Typically, how long after **receptive anal intercourse** did you use a study-provided **rectal douche**?

1. Less than 15 minutes
2. Between 15 minutes and 30 minutes
3. Between 30 minutes and 1 hour
4. Between 1 and 2 hours
5. Between 2 and 3 hours
6. Between 3 and 4 hours
7. 4 hours or more

B3b. Typically, how many douches/enemas did you apply after receptive anal sex?

1. One enema [GO TO B3e]
2. Two enemas
3. Three enemas
4. Four enemas
5. Five or more enemas

B3c. [If B3b > 1] When you used multiple douches/enemas after receptive anal sex, how often did you rinse the tip with water before reinserting it?

6. Never
7. Rarely
8. Sometimes
9. Often
10. Always

B3d. [If B3b > 1] When you used multiple douches/enemas after receptive anal sex, how often did you wash the tip with a soap or detergent before reinserting it?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

B3e. What made you use a **rectal douche/enema** AFTER **receptive anal intercourse**?
Indicate all that apply

1. I usually use a douche/enema after receptive anal intercourse
2. I wanted to be clean
3. My sex partner suggested that I use a douche/enema after sex
4. Other, *please specify:* _____

B4. During the past 4 weeks, how many times did seven days go by in which you did NOT have receptive anal sex? _____ [IF B4 = 0, GO TO B5]

B4a. During those [B4] weeks, how many times did you use the study provided rectal douche/enema at least once per week? _____

B4b. [IF B0=5 OR B4a ≠ B4] Which of the following prevented you from using the study provided rectal douche/enema? (Check all that apply).

- I forgot
- I did not have the enema bottle with me
- My sexual partner did not want me to use the enema/douche
- I did not have the privacy needed to use the enema/douche
- I did not like the enema/douche
- The enema/douche made me feel ill
- I was drinking or using drugs
- There was a change in my regular routine
- My work/school schedule got in the way
- I was worried about the long-term effects of the douche on my health
- I was worried my friends would find out that I was using a rectal douche
- I was worried my family would find out that I was using a rectal douche
- I was worried my sexual partners would find out I was using a rectal douche
- I felt like people judged me for using a rectal douche
- Other, specify _____

B5. Besides the study provided rectal douche/enema, did you use any other rectal products (e.g., douche/enema, suppository) over the past 4 weeks?

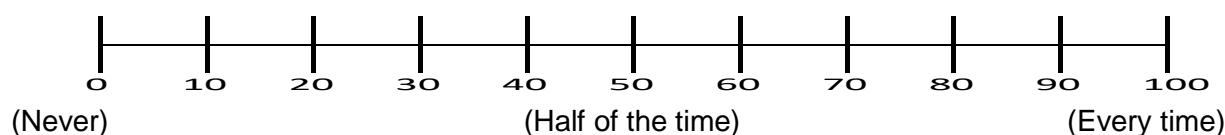
1. Yes
2. No [GO TO B6]

B5a. [If B5=1] Which of the following products did you use? (Check all that apply)

- Over-the-counter disposable enema product (e.g., Fleet[®])
- A vaginal douche (e.g., Summer's Eve[®]) in your rectum
- A non-disposable douche or enema bag system (neoprene or rubber bag, rubber hose, plastic clamp, and plastic or rubber nozzle)_____
- A shower head hose and nozzle
- A "sinker", a portable rubber or vinyl hose that attaches to a sink or bidet
- Re-useable bulb enema
- Suppositories (e.g., for hemorrhoids)
- Other (please specify:_____)

B5b. [IF B2 > 0 AND/OR B4a > 0] What percentage of time did you use another rectal douche/enema?

Visual Analog Scale:



B6. Typically, how far into your rectum did you insert the enema applicator?

1. up to 1 inch
2. between 1 and 2 inches
3. between 2 and 3 inches
4. more than 3 inches

B7. Where did you use a rectal douche?

1. Toilet
2. Shower/tub
3. Sink
4. Bidet
5. Bathroom floor
6. Other, *please specify:* _____

B8. What temperature do you prefer when douching?

1. Hot
2. Warm
3. Cool
4. No preference

B9. In what position did you prefer to use a rectal douche?

1. Kneeling
2. Laying on side
3. Standing
4. Squatting or seated over toilet/tub
5. Other, *please specify:* _____

B10. Which of the following did you use to fill the study enema/douche over the past 4 weeks?

(Check all that apply)

1. Tap water from the sink
2. Water provided by study team

3. Water from a public source (e.g., well)
4. Home-made solution (e.g., vinegar)
5. Store-bought product (e.g., vaginal douche, soap)

B11. How often did you need to apply lubricant before inserting the enema/douche bottle?

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

B12. When you use a rectal douche, how long does it usually take you before you have a bowel movement?

1. Occurs immediately
2. 1-5 minutes
3. More than 5 minutes

B13. Did you give the study enema/douche to another person to use?

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

B14. How many enemas/douches did you give to another person? _____

B15. I gave the enema/douche 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: _____)

B16. Why did you give the study enema/douche to [B15]?

SECTION C. Rectal Douche ACCEPTABILITY

The following questions are about your overall experience with the study douche/enema.

C1. Overall, how much did you like the rectal douche/enema used as part of this study?

1—2—3—4—5—6—7—8—9—10

Disliked

Liked

very much

very much

C1a. How much did you like how the rectal douche/enema felt inside your rectum immediately after inserting it?

1—2—3—4—5—6—7—8—9—10

Disliked

Liked

very much

very much

C1b. How much did you like how the rectal douche/enema felt inside your rectum 30 minutes after using it?

1—2—3—4—5—6—7—8—9—10

Disliked

Liked

very much

very much

C2. If it were available, how likely would you be to continue using the rectal douche/enema provided as part of this study?

1—2—3—4—5—6—7—8—9—10

Very

Very Likely

Unlikely

C3. How likely would you be to recommend the study provided rectal enema/douche to your friends?

1—2—3—4—5—6—7—8—9—10

Very

Very Likely

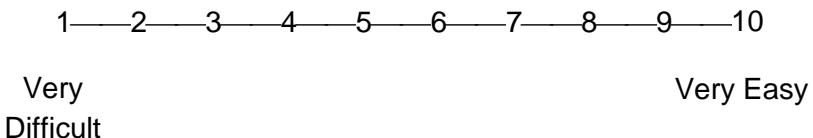
Unlikely

C4. Compared to other rectal douches/enemas that you may have used in the past, how satisfied were you with the rectal douche/enema used in this study?

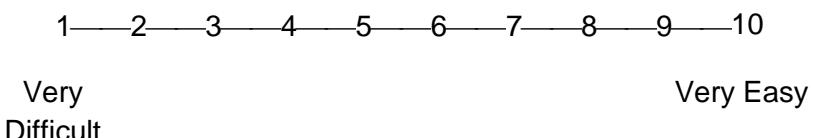
1. Very satisfied

2. Satisfied
3. Neutral
4. Dissatisfied
5. Very dissatisfied
6. I had never used a rectal douche/enema in the past

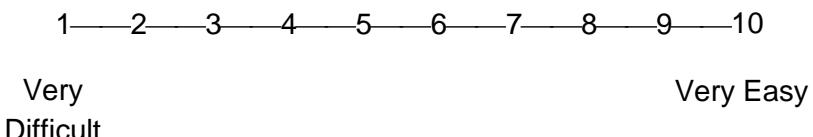
C5. [IF B2 > 0] **Overall**, how easy or difficult was it to use the rectal douche BEFORE having receptive anal sex?



C6. **Overall**, how easy or difficult was it to insert the rectal douche/enema?



C7. The **last time** you inserted the enema/douche into your rectum, how difficult or easy was it to insert?

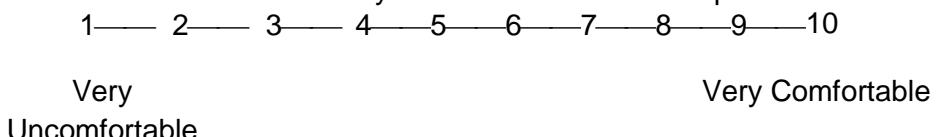


The following questions are about any changes that you may have experienced while using the study provided rectal douche/enema over the past 4 weeks.

C8. Did your douching practices change over the past 4 weeks?

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 had never douched before

C9. **Overall**, how did it feel to use the study douche/enema over the past 4 weeks?



C10. Please indicate how hard or easy it would be for you to do each of the following things.

[1] Very Easy to Do	[2] Fairly Easy	[3] Fairly Hard	[4] Very Hard to Do
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- a. To use the **rectal douche/enema** every time BEFORE having sex?
- b. To discuss your use of the **rectal douche/enema** with a sexual partner BEFORE having sex?
- c. To discuss your use of the rectal douche/enema with a sexual partner AFTER having sex?
- d. To use the **rectal douche/enema** while under the influence of alcohol or drugs?
- e. To keep the **rectal douche/enema** stored in a private location?
- f. To discretely dispose of the **rectal douche/enema** after use?

C11. How much did you like the packaging of the rectal douche/enema?

1—2—3—4—5—6—7—8—9—10

Disliked

Liked

very much

very much

C12. How easy would it be to carry the rectal douche/enema around if you needed to?

1—2—3—4—5—6—7—8—9—10

Extremely
difficult

Extremely
easy

SECTION D. DOUCHE PROBLEMS

Now we would like to ask you about any problems you experienced while using the study enema/douche over the past 4 weeks.

D0. Over the past 28 days, on how many days did you experience any physical discomfort because of the enema/douche?

_____ day(s) [IF D0=0, GO TO D1]

D0b. Overall, how much did the physical discomfort bother you?

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

D1. Did you experience any leakage or soiling after having expelled the water from the douche/enema?

1. None [GO TO D2]
2. Some
3. A lot

D1b. How much were you bothered by the leakage or soiling?

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

D2. After having expelled the water from the douche/enema, did you experience any unexpected diarrhea?

1. None [GO TO D3]
2. Some
3. A lot

D2b. How much were you bothered by the unexpected diarrhea?

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

D3. After having expelled the water from the douche/enema, did you experience any other unexpected stomach or abdominal problems (such as cramps, bloating, gassiness or passing wind or urge to have a bowel movement)?

1. None [GO TO D4]
2. Some
3. A lot

D3b. How much were you bothered by these stomach or abdominal problems?

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

D4. Over the past 28 days, on how many days did you experience any pain because of the enema/douche?

_____ day(s) **[IF D4=0, SKIP TO D5]**

D4b. Overall, how much did the pain bother you?

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

D5. Did the enema/douche cause you any emotional discomfort such as feeling worried, guilty or any other unpleasant feelings?

0. No [GO TO D6]
1. Yes

D5b. Overall, how much did this emotional discomfort bother you?

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

D6. During the four weeks in which you were asked to use the douche/enema, 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

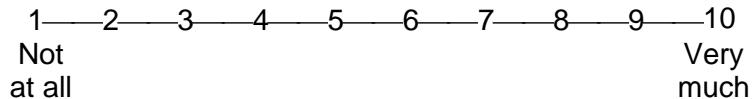
D7. **[IF B2 > 0]** Compared to prior times when you have had receptive anal sex, how different did you feel while having anal sex after using the **study enema/douche** before sex?

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

D8. **[IF B2 > 0]** How did the enema/douche affect your sexual pleasure?

1. Increased my sexual pleasure
2. Did not change my sexual pleasure
3. Decreased my sexual pleasure

D8b. How much were you bothered by having to wait a while to have sex after using the rectal enema/douche?



D9. [IF B2 > 0] How did the douche affect your sex partner's sexual pleasure?

1. Increased my partner's sexual pleasure
 2. Did not change my partner's sexual pleasure
 3. Decreased my partner's sexual pleasure
 4. Don't know

D10. Over the past 4 weeks, did any of your partners have a negative reaction regarding your use of the enema/douche?

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

D11. Over the past 4 weeks, did any of your partners have a positive reaction regarding your use of the enema/douche?

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

D12. Over the past 4 weeks, did you have an injury as a result of using the enema/douche?

1. Yes [IF NO, SKIP TO NEXT SECTION]
2. No

D13. How many times have you had an injury to the anus or rectum while douching in the past 28 days that you used the study product?

[If “0,” SKIP to NEXT SECTION]

D14. When injuries have occurred, what was the cause? *Indicate all that apply*

1. Problems with the bottle tip
 2. Position played a role
 4. Insufficient lubrication
 5. Water was too hot
 6. Other, *please specify:* _____

SECTION E. SEXUAL BEHAVIOR

First, we will ask you questions about your body.

E1. Do you currently have a penis?

1 Yes [SKIP TO E3]

2 No

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

1. Yes, I refuse to answer
2. No, I want to change my answer

E2. Do you currently have a vagina?

1 Yes

2 No

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

1. Yes, I refuse to answer
2. No, I want to change my answer

RECENT SEXUAL BEHAVIOR

E3. In the past 30 days, how many people have you had **sex** with? (Sex can include anal sex, vaginal sex, oral sex, or analingus).

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

1. Yes, I refuse to answer
2. No, I want to change my answer

[If E3=1, ask 4.1. If E3> 1, ask 4.2.]

E4.1. You said you had **sex** with one person in the past 30 days. Please indicate whether this person was a....

- 1 Man
- 2 Woman
- 3 Transgender man
- 4 Transgender woman

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

- 1. Yes, I refuse to answer
- 2. No, I want to change my answer

E4.2. You said you had **sex** with [E4] people in the past 30 days. 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

[IF REFUSE TO ANSWER, ask:]

You selected "Refuse to answer." If you do not answer this question, you may be asked questions about your sexual behavior that do not apply to you. Please confirm your answer.

- 1. Yes, I refuse to answer
- 2. No, I want to change my answer

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

E5. During the past 30 days, how many times did you have **vaginal sex**, when you put your **penis** into a partner's **vagina**? _____ [RANGE 0-900]

E6. Of the [E5] 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? _____

E7. During the past 30 days, how many times did you have **insertive anal sex**, when you put your **penis** into a partner's **rectum**? _____

E8. Of the [E7] 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? _____

E9 During the past 30 days, how many times did you have **receptive anal sex**, when a partner's penis was in your rectum? _____

E10. Of the [E9] 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:

E11. During the past 30 days, how many times did you put your mouth on a partner's **penis**?

E12. During the past 30 days, how many times did a partner put their mouth on your **penis**?

E13. During the past 30 days, how many times did you put your mouth on a partner's **anus**?

E14. During the past 30 days, how many times did a partner put their mouth on your **anus**?

E15. During the past 30 days, how many times did you put your mouth on a partner's **vagina**?

E16. During the past 30 days, how many times did a partner put their mouth on your **vagina**?

E17. During the past 30 days, how many times did you have **vaginal sex**, when a partner's penis was in your vagina? _____

E18. Of the [E17] 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.

E19. During the past 30 days, how many times did you receive money or other goods or services in exchange for sex? _____

E20. During the past 30 days, how many times did you pay money or provide other goods or services in exchange for sex? _____

E21. Please leave us any comments you have about this sexual behavior questionnaire,
especially if you thought these questions did not apply to you:

SECTION F. SUBSTANCE USE

The following questions refer to alcohol and drug use. Remember, your answers are confidential and will not be viewed by clinic staff.

F1. Now you will see a list of different drugs. During the last 30 days, how often have you used each of the following substances?

GO DOWN “A” COLUMN FIRST. IF “0” FOR ANY SUBSTANCES, SKIP B FOR THOSE PARTICULAR SUBSTANCES.

	[A] Number of times used in past 30 days	[B] Number of times used before or during sex in past 30 days [Only ask if A > 0]
a. Tobacco (cigarettes, cigars, chew, snuff, e-cigs)	______ times	______ times
b. Alcohol (beer, wine, liquor)	______ times	______ times
c. Marijuana/hashish/pot/weed/chamba	______ times	______ times
d. Synthetic Marijuana/K2/Spice	______ times	______ times
e. Ecstasy/MDMA	______ times	______ times
f. Crystal Meth/amphetamines/methamphetamines/speed/crank/ice/yaba	______ times	______ times
G. Ketamine/special K	______ times	______ times
H. GHB (Gamma hydroxybutyrate)	______ times	______ times
I. Other hallucinogens/LSD/mushrooms	______ times	______ times
J. Poppers/amyl nitrate/butyl nitrate	______ times	______ times
K. Crack	______ times	______ times
L. Cocaine (not crack)	______ times	______ times
M. Opium/Opioids (Heroin, Codeine, Vicodin, OxyContin)	______ times	______ times
N. Mandrax/Quaalude	______ times	______ times
O. Kratom	______ times	______ times
P. Khat	______ times	______ times
Q. Any other pharmaceutical drugs not prescribed to you by a physician	______ times	______ times
R. Other, <i>please specify:</i> _____	______ times	______ times

F2. [IF F1A_b>0] Thinking about the times you used alcohol during the last 30 days, how much did you typically use?

1. Too little to feel any effect
2. Enough to feel it a little
3. Enough to feel it a lot
4. Enough to get drunk
5. Enough to feel like you might pass out
6. Enough to pass out

SECTION G. Discussion with Social Network

G1. Have you talked about this study with anyone in your social network?

1. No
2. Yes (**GO TO G1B**)

G1a. Different circumstances may prevent people from discussing participation in the study with social networks. Thinking about your experience since you last completed the survey, please choose all the reasons that have made it difficult to talk about the study?

- Embarrassment
- Fear of Violence
- Potential Misunderstanding
- Don't think it's important
- Lack of Trust
- Stigmatization
- Shyness
- Awkwardness
- Fear of job loss
- Fear of losing housing
- Fear of criminalization

G1b. Who did you talk about it with? (Check all that apply)

- Friends
- Family
- Sex partners
- Coworkers
- Roommates
- Other _____

G2a. Have you talked about the rectal douche/enema used in this study with anyone in your social network?

- Yes
- No (**GO TO NEXT SECTION**)

G2b. Who did you talk about it with? (Check all that apply)

- Friends
- Family
- Sex partners
- Coworkers
- Roommates
- Other _____

G2c. How comfortable did you feel talking about the rectal enema/douche?

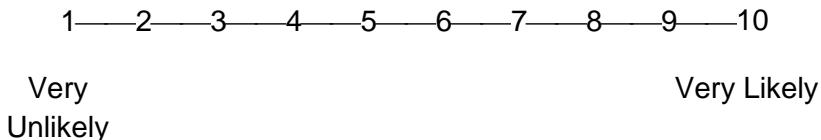
{NOTE: LIST FILLS BASED ON G2A answers}	Very Uncomfortable	Uncomfortable	Neutral	Comfortable	Very Comfortable
Friends					
Family					
Sex Partner					
Co-Workers					
Roommates					
Fill-in from #2					

G2d. How did they respond when you talked about the rectal enema/douche?

{NOTE: LIST FILLS BASED ON G2A answers}	Negatively	Somewhat Negatively	Neutral	Somewhat Positively	Positively	N/A
Friends						
Family						
Sex Partner						
Co-Workers						
Roommates						
Fill-in from #2						

SECTION H. RECOMMENDATIONS

H1. Think about the positive and negative experiences you have had using the rectal douche/enema during the past 4-week period. If this douche/enema was available and it provided some protection against HIV, how likely would you be to use it before receptive anal sex?



H2. What were the things you liked the most?

1. _____
 2. _____
 3. _____

H3. What were the things you liked the least?

1. _____
 2. _____
 3. _____

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

END OF QUESTIONNAIRE