

MTN 008 Follow-up Acceptability & Adherence Question by Question (QxQ) Instructions

Adherence

Q1. This question refers to whether the participant inserted the gel **any days** at home.

Q1a. This sub-question asks the **most important reason** why the participant did **not** insert the study gel at home.

Q2. This question asks the participant the **number** of days she inserted study gel at home.

Q3. This question asks the participant to list the number of study gel applicator she inserted **at home** each day since joining the study on her enrollment visit. Since this question only requests the count for applicators inserted at home, the participant should not include inserted at the clinic.

Q4. This question asks the participant to identify the **most important reason** why study gel was **not** inserted at home on day(s) in which it was not inserted.

Q5. This question asks the participant if on any days in which gel was inserted there were any instances when **less than** the full amount of study gel was inserted.

Q5a. This question asks the **number of days** in which less than the full amount of gel was inserted.

Q5b. This question asks the participant to identify **the most important reason** less than the full amount was inserted on those day(s).

Q6. This question asks the participant to **rate her ability**, since her enrollment visit, to insert the study gel as instructed.

Sexual Behavior

In these questions we ask about sex with both males (men and boys) and females (women and girls). In the definition of terms, sex with a male includes “boys” because the participant may interpret her current or previous sexual episodes to have been with a boy. For example, she may have a male partner aged 18 or younger that she considers to be a boy, or when considering lifetime sexual partners, she may include sex she had with a boy. Questions that refer only to “men” or “women” are meant to include any sex with a male (man or boy) or a female (woman or girl).

Q7. This question asks the participant the **number of times** she has had vaginal sex since her enrollment visit.

Q7a. This sub-question asks the participant to record the **number of times** she had vaginal sex each day since her enrollment visit. The participant must enter a number for each day, even if the response is “0”.

Q7b. This question asks the participant to record the **number of times** she had vaginal sex with a **condom each day** since her enrollment visit.

Q8. This question asks the participant to record the **number of times** she has had anal sex since her enrollment visit.

Q8a. This sub-question asks the participant to record the **number of times** she has had anal sex **each day** since her enrollment visit. The participant must enter a number for each day, even if the response is “0”.

Q8b. This sub-question asks the participant to record the number of times she had anal sex with a **condom each day** since her enrollment visit.

Q9. This question asks the participant the **number of times** she has **received** finger sex since her enrollment visit.

Q9a. This sub-question asks the participant to record the **number of times** she received finger sex each day since enrollment visit. The participant must enter a number for each day, even if the response is “0”.

MTN 008 Follow-up Acceptability & Adherence Question by Question (QxQ) Instructions

- Q10. This question asks the participant the **number of times** she gave oral sex since enrollment visit.
- Q11. This question asks the participant the **number of times** she received oral sex since enrollment visit.
- Q12. This question asks the participant the number of times she put something in her vagina for sexual stimulation since enrollment visit.
- Q13. This question asks the participant whether she has a main male partner. “Main male partner” refers to someone who the participant typically has sex with, may have an ongoing relationship with, and may consider one to be serious about. This individual may be a lover, spouse or boyfriend.
- Q13a. This sub-question asks the participant if the main male partner is the same person identified as her main male partner during her enrollment visit.
- Q13b. This sub-question asks if the participant told her main male partner she joined the study.
- Q14. This question asks how much the participant thinks her main male partner likes the study gel on a scale from 1-10, or NA if he does not know about the study gel.
- Q15. This question asks the participant how the use of study gel increased or decreased pleasure for her main male sex partner.
- Q16. This question asks the participant how the study gel increased or decreased sexual pleasure for her.

Gel Acceptability

The following questions are about the participant’s opinions of the study gel. For many questions, the responses are based on a **scale from 1 to 10 with 1 being lowest and 10 being highest**. The participant should select the number that most accurately corresponds to her feelings. If a participant is completely unequivocal or neutral about her attitude, she should select “5”. The questions refer to the participant’s experience using the gel since enrollment visit up until today.

- Q17. This question asks how much the participant likes the study gel overall.
- Q18. This question asks how much the participant likes the study gel color.
- Q19. This question asks how much the participant likes the taste of the study gel. There is a box to tick “NA” if the gel was not tasted.
- Q20. This question asks how much the participant likes the smell of the gel. There is a box to tick “NA” if the gel was not smelled.
- Q21. This question asks how much the participant likes the consistency (thickness or thinness) of the study gel.
- Q22. This question asks the participant how the study gel felt inside her vagina immediately after insertion.
- Q23. This question asks the participant if she liked how the gel felt 30 minutes after insertion.
- Q24. This question asks the participant to comment on the level of runniness of the gel. By ‘runny’, we mean whether the gel feels too liquid-like to the touch or in the vagina, or that it comes out (leaks or runs) from the vagina too much. .
- Q25. This question asks the participant if the gel feels sticky. By sticky, we mean clumpy and/or sticky, either to the touch or inside the vagina.
- Q26. This question refers to how often the gel leaked (if at all) from the participant’s vagina.

MTN 008 Follow-up Acceptability & Adherence Question by Question (QxQ) Instructions

Q26a. This question refers to the amount of gel leakage (if any) from the participant's vagina.

Q26b. This question asks the degree to which the participant is bothered by the gel leakage.

Q27. This question asks how often the gel applicator caused the participant any pain. By gel applicator, we mean the applicator itself that is used to insert the gel. By pain, we mean a dull or sharp feeling triggered by the sensory system.

Q28. This question asks how often the insertion of the gel applicator caused any other physical discomfort aside from pain. By other physical discomfort, we mean unpleasant sensations which the participant would not classify as pain.

Q29. This question asks how often the insertion of the gel applicator caused any mental or emotional discomfort such as worries, fears, guilt or other unpleasant feelings.

Q29a. This question asks on a scale from 1-10 how **bothersome** the mental/emotional discomfort was.

Q29b. This question asks on a scale from 1-10 how **intense** the mental/emotional discomfort was.

Q30. This question asks how often the **gel itself** caused any pain.

Q30a. This question refers to how **bothersome** the pain was for the participant.

Q30b. This question refers to the level of pain **intensity** experienced by the participant.

Q31. This question asks how often the gel itself caused any physical discomfort outside of pain.

Q31a. This question asks on a scale from 1-10 how **bothersome** this physical discomfort was.

Q31b. This question asks on a scale from 1-10 how **intense** this physical discomfort was.

Q32. This question asks how often the insertion of the gel caused any mental or emotional discomfort such as worries, fears, guilt or any other unpleasant feelings.

Q32a. This question asks on a scale from 1-10 how bothersome the mental or emotional discomfort was.

Q32b. This question asks on a scale from 1-10 how intense the mental or emotional discomfort was.

Q33. This question asks how comfortable the participant was with the insertion of the gel at home since enrollment visit as instructed by study staff.

Q34. This question asks which position was most comfortable for the participant to insert the gel.

Q35. This question asks the participant if worries about the gel increased, decreased or remained the same since her enrollment visit.

Willingness to Use the Gel in the Future

For many questions, the responses are based on a **scale from 1 to 10 with 1 being lowest and 10 being highest**. The participant should select the number that most accurately corresponds to her feelings. If a participant is completely unequivocal or neutral about her attitude, she should select "5". The questions refer to the participant's attitudes about using the gel in the future.

Q36. This question asks how generally worried (on a scale from 1-10) the participant is about getting HIV.

Q37. This question asks if the participant were using the gel when **not pregnant**, would she prefer to use the gel daily or before having sex.

MTN 008 Follow-up Acceptability & Adherence Question by Question (QxQ) Instructions

Q37a. This sub-question asks how likely the participant would be to use the gel **every time** before having sex on a scale from 1-10.

Q37b. This sub-question asks how likely the participant would be to use the gel **every day** on a scale from 1-10.

Q38. This question asks how important it is to the participant to prevent HIV when the participant is pregnant on a scale from 1-10.

Q39. This question asks the participant if in the future she was using the gel **when pregnant**, would she prefer to use it daily or before having sex (on a scale from 1-10).

Q40. This question asks the participant if in the future she was using the gel when breastfeeding, would she prefer to use the gel daily or before having sex (on a scale from 1-10).

Q40a. This sub-question asks the participant how likely on a scale from 1-10 the participant would be to use the gel **every time before having sex**.

Q40b. This sub-question asks the participant how likely on a scale from 1-10 the participant would be to use the gel **every day**.

Q41. This question asks if the gel is proven safe and effective in preventing HIV when used daily, would the participant **recommend the gel to a pregnant friend**.

Q42. This question asks if the gel was proven safe and effective in preventing HIV when used daily, would the participant **recommend it to a breastfeeding friend**.

Q43. This question asks if the gel was proven safe and effective in preventing HIV when used daily, would the participant **recommend it to a friend neither pregnant nor breastfeeding**.

Intravaginal Practices

The last set of questions is about things the participant may have inserted or put inside her vagina for various reasons since her enrollment visit. The participant should be sure to include things that she may have inserted today before the study visit.

Q44. This question asks the number of times the participant has **douched** since enrollment visit.

Q45. This question asks the number of times the participant put **personal or sexual lubricant** in her vagina since enrollment visit.

Q46. This question asks the number of times the participant put something in her vagina to make it **tighter or drier** for sex since enrollment visit.

Q47. This question asks the participant the number of times she put something in her vagina to **treat vaginal symptoms** or make it healthy since enrollment visit.

Q48. This question asks the participant the number of times she put something in her vagina for any other reason since enrollment visit.

Q49. This question asks the participant the number of times she put something in her vagina for **contraception** since enrollment visit.

Q50. This question asks the number of times the participant has put something in her vagina to **control bleeding** since enrollment visit.