

MTN 008 Baseline Behavioral & Acceptability Question by Question (QxQ) Instructions

Demographics

Q1. This question refers to the total number of years of education a participant has completed. If a partial year has been completed, please round up. For example, if a participant has completed a half-year, she should round up to the next full year.

Q2. This question refers to the participant's current sexual orientation. Even if the participant identifies with more than one response, please select the response that **best** or **most** describes the current situation. If a participant does not identify with any of the categories listed, select 'none of the above'.

Q3. This question refers to the total number of pregnancies in the participant's life. This figure should include the current pregnancy (if applicable) as well as all other pregnancies, whether they resulted in live births, still births, terminations/abortions, miscarriages or tubal pregnancies.

Q4. This question is meant to categorize the pregnancy outcomes per Question 3. Therefore, the categorization of pregnancy outcomes should match the total in Question 3 (or one minus Question 3 if currently pregnant).

Q5. This question refers to the number of (live) children the participant currently has, whether that child is over or under 18 of age. For pregnancy cohorts, do not include the child in utero. The participant may include children she might be taking care of but did not give birth to (i.e. relative's child, foster child, step child, etc).

Q6. This question refers to the participant's current employment status. If a participant is on maternity leave, employment may be included as long as the participant continues to resume the position after maternity leave, or intends to resume the position. If the participant is on maternity leave but does not intend to resume work full or part-time, select "not employed".

Q7. This question refers to the participant's school status. Similar to Question 6, if in school but temporarily on maternity leave, please select the response that best captures what her school status will be following maternity leave.

Q8. This question seeks to capture **all** the types of insurance the participant currently has. Therefore, the participant should select yes for all appropriate categories. If, however, the participant selects 'uninsured', she will not be able to select any additional categories as it is assumed they don't apply. If the participant has a type of insurance not described, tick yes for "other" and type a description in the space provided. If the participant is not sure how to categorize a type of insurance, tick other and describe it.

Q9. This question refers to the participant's current marital status. It should reflect the participant's legal marital status. If the participant does not identify with any of the selections, select 'Other, describe' and provide the preferred status categorization.

Q10. This question refers to the participant's current living situation. The participant should select the situation that **best** or **most** describes the current situation, as she will not be able to select more than one option.

Use of Alcohol and Drugs and Other Behaviors

Q11. This question refers to a participant's **typical** weekly alcohol consumption (measured in days where more than 1 drink was consumed) in a given week **prior to the current or most recent pregnancy**.

Q11a. This sub-question refers to the participant's weekly (measured in number of days where more than 1 drink was consumed) alcohol consumption **over the past 4 weeks while pregnant/ lactating**.

Q12. This question refers to whether a participant has ever, **over the course of her lifetime**, smoked, ingested via swallowing or inhaled a **recreational drug**. By recreational drug, we are referring to a drug procured and taken on one's own and without clinical prescription.

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Q12a. This sub-question refers to whether the participant has smoked, ingested or inhaled a recreational drug **in the past 12 months**.

Q13. This question refers to whether the participant has ever, **over the course of her lifetime**, injected (with a needle) a recreational drug. Similar to Question 12, a recreational drug refers to a drug procured and taken on one's own and without clinical prescription.

Q13a. This sub-question refers to whether the participant has injected (with a needle) a recreational drug **in the past 12 months**.

Q14. This question refers to whether the participant has ever **over the course of her lifetime** exchanged sex for food, drugs, shelter or money. This question is intended to assess if the participant has ever received a transaction [in the form of food, drugs, shelter or money] in exchange for sex. Sex can be any kind of sex: vaginal, anal, oral, finger, etc.

Q14a. This sub-question refers to whether the participant has exchanged sex for food, drugs, shelter or money **in the past 12 months**.

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).

Q15. This question refers to whether the participant has ever, **over the course of her lifetime**, had sex with a woman. **Any sex** is inclusive of all of the applicable previous descriptions in the introduction to this section: receiving oral sex, giving oral sex and/or finger sex. If any of these types of sex are unclear, press the left arrow to read their description at the introduction to this section.

Q15a. This sub-question refers to the participant's age when she **first** had **any sex** with a woman or girl. The answer should be in the form of an **age**.

Q15b. This sub-question refers to the **number of different women or girls** the participant has had **any sex** with **over the course of her lifetime**. If the exact number is not known, provide the best estimate.

Q15c. This sub-question refers to the number of **current female sexual partners** that the participant has.

Q16. This question refers to whether the participant has ever **in her lifetime** given or received oral sex from a **man or a woman (or boy or girl)**. If the answer to any one (or more) of these combinations is yes, the participant should check 'yes'.

Q17. This question refers to whether the participant has ever had vaginal sex with a man or boy. As described in the instructions, by vaginal sex, we mean when a man or boy puts his penis into the participant's vagina.

Q17a. This sub-question refers to the **age** at which the participant first had vaginal sex with a man or boy.

Q18. This question refers to whether the participant has ever had anal sex with a man or boy. By anal sex, we mean when a man or boy puts his penis into the participant's anus (or butt).

Q18a. This sub-question refers to the age that the participant first had anal sex with a man or boy.

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Q19. This question refers to the number of different men (or boys) the participant has had anal or vaginal sex within her lifetime. If the exact number is not known, provide the best estimate.

Q20. This question asks whether the participant currently 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 oneself serious about. This individual may be a lover, spouse or boyfriend.

Q20a. This sub-question asks whether the participant told the individual identified in Question 20 as the main male partner about joining this study.

Q20b. This sub-question asks whether the participant told the individual identified in Question 20 as the main male partner that the participant would be inserting gel daily in the study.

Q21. This question refers to the number of other male sexual partners the participant currently has. This number should **not** include the main male partner but it should capture any other male partners. Other male partners refer to other sexual partner(s) the participant has a sexual relationship with through engaging in sexual acts.

Q22. This question refers to whether any type of condom (male or female) during vaginal or anal sex has ever been used in the participant’s lifetime.

Recent Sexual Activity

Participant responses should include sex today prior to study visit. In all cases when the question refers to “vaginal sex”, we mean when a man or boy puts his penis into the participant’s vagina. In all cases when the question refers to “condom”, this may include a male or female condom.

Q23. This question asks the most recent date (month and year) of vaginal sex.

Q24. This question refers to the number of times the participant has had vaginal sex in the **past 4 weeks**.

Q24a. This question refers to the number of times the participant has had vaginal sex **with a condom** in the **past 4 weeks**.

Q24b. This question asks the participant to identify the **primary use** of the condom over the past 4 week period.

Q24c. This question asks the participant the number of times she has had vaginal sex the **week prior to study enrollment**.

Q24d. This question asks the participant the number of time she has had vaginal sex **with a condom** the week prior to study enrollment.

Q25. This question refers to the number of times the participant has had **anal sex** in the **past 4 weeks**. By anal sex, we mean when a man or boy puts his penis into the participant’s vagina. This definition applies to sub-questions as well.

Q25a. This sub-question refers to the number of times the participant has had anal sex with a **condom** in the **past 4 weeks**.

Q25b. This sub-question refers to the number of times the participant has had anal sex since the **week prior to study enrollment**.

Q25c. This question refers to the number of times the participant has had anal sex with a **condom** the week prior to study enrollment.

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Q26. This question refers to the number of times the participant has **given** oral sex in the **past 4 weeks**. By giving oral sex, we mean when the participant puts her mouth or tongue on her partner's penis, vagina, or anus (butt). This definition applies to sub-questions as well.

Q26a. This sub-question asks the number of times the participant has **given** oral sex since the **week prior to study enrollment**.

Q27. This question refers to the number of times the participant has **received** oral sex in the **past 4 weeks**. By receiving oral sex, we mean when a partner puts his/her mouth or tongue on the participant's vagina or anus (butt). This definition applies to sub-questions as well.

Q27a. This sub-question asks the number of times the participant has **received** oral sex since the **week prior to study enrollment**.

Q28. This question refers whether the participant has **ever** in her life put a dildo, vibrator or other sex toy in her vagina for sexual stimulation.

Q28a. This sub-question asks the **number of times** the participant has put something in her vagina for sexual stimulation in the **past 4 weeks**. By something, the question is referring to the items in Question 28: dildo, vibrator and/or other sex toy.

Q28b. This sub-question asks the **number of times** the participant has put something in her vagina for sexual stimulation since the **week prior to study enrollment**. This definition applies to sub-questions as well.

Q29. This question refers to whether the participant has **ever** in the course of her life had finger sex. By finger sex, we mean when a partner puts his/her finger(s) into the participant's vagina. This definition applies to sub-questions as well.

Q29a. This question refers to the **number of times** the participant has had finger sex in the **past 4 weeks**.

Q30. This question refers to whether the participant has **ever in her life** been diagnosed and/or treated for a sexually transmitted infection. By sexually transmitted infection, we mean infections transmitted by sexual behaviors such as vaginal sex, anal sex and oral sex. Some common examples are (but are not limited to) the following: Chlamydia, Gonorrhea, Hepatitis, Herpes, HPV, PID, Syphilis. A yeast infection (Candidiasis) is not considered to be an STI.

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".

Q31. This question refers to the participant's overall like or dislike of the study gel. This should include the participant's overall broad opinion.

Physical attributes of the study gel

Q32. This question refers to the participant's level of like or dislike of the study gel **color**, either prior to or following insertion.

Q33. This question refers to the participant's level of like or dislike of the gel's taste. If the participant did not taste the gel, she should tick the 'did not taste' box below and move to the next question.

Q34. This question refers to the participant's level of like or dislike of the smell of the gel. If the participant never smelled the gel, she should tick the 'did not smell' box and proceed to the next question.

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Q35. This question refers to the participant's level of like or dislike of the consistency or texture of the gel. Specifically, this could refer to how thick the gel feels (either to her touch, or when in her vagina), how thin the gel feels, or other texture related qualities.

Q36. This question refers to the participant's level of like or dislike of the feeling of the gel inside her vagina **immediately following insertion**.

Q37. This question refers to the participant's level of like or dislike of the feeling of the gel inside her vagina **30 minutes following insertion**.

Q38. 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. .

Q39. 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.

The next set of questions asks about the level of **bother** and level of **intensity of events, which may be experienced physically, emotionally or psychologically**. By **bother**, we mean **annoying or disturbed**. By **intense**, we mean **the degree** of (i.e. the degree of discomfort).

Q40. This question refers to the amount of gel leakage (if any) from the participant's vagina.

Q40a. This question asks the degree to which the participant is bothered by the gel leakage.

Q41. This question asks whether the insertion of 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.

Q41a. This question refers to the level to which the pain **bothered** the participant.

Q41b. This question refers the level of **intensity** experienced by the participant due to the pain.

Q42. This question asks if the insertion of the caused any **other physical discomfort** outside of pain. By other physical discomfort, we mean unpleasant sensations which the participant would not classify as pain.

Q42a. This question refers to the level to which the physical discomfort **bothered** the participant.

Q42b. This question refers the level of **intensity** experienced by the participant by the physical discomfort.

Q43. This question refers to emotional and/or mental discomfort the participant experienced due to the insertion of the gel applicator. Examples of emotional and/or mental discomfort are worries, fears, guilt, anxiousness, or other unpleasant feelings.

Q43a. This question refers to the level to which the emotional/mental discomfort **bothered** the participant.

Q43b. This question refers the level of **intensity** experienced by the participant by the emotional/mental discomfort.

Q44. This question asks the participant if the gel itself (and not the gel applicator) caused the participant any pain.

Q44a. This question refers to how **bothersome** the pain was for the participant.

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Q44b. This question refers the level of pain **intensity** experienced by the participant.

Q45. This question refers to the physical discomfort (other than pain) caused by the gel itself.

Q45a. This question refers to how **bothersome** the physical discomfort was for the participant.

Q45b. This question refers the level of **intensity** experienced by the participant due to the physical discomfort.

Q46. This question refers to the emotional and/or mental discomfort caused by the gel itself. Examples of emotional and/or mental discomfort are worries, fears, guilt, anxiousness, or other unpleasant feelings.

Q46a. This question refers to the level to which the emotional/mental discomfort **bothered** the participant.

Q46b. This question refers the level of **intensity** experienced by the participant by the emotional/mental discomfort.

Q47. This question refers to how worried the participant is about inserting the gel at home as instructed by the study over the next 5 days.

Intravaginal Practices

Q48. This question asks the participant if she has **ever in her life** put a douche in her vagina.

Q48a. This sub-question asks the **number of times** the participant has douched in the **past 4 weeks**.

Q48b. This question asks the participant to identify the **main** reason she douched.

Q48c. This question asks the participant the **number of times** she has douched since the week prior to study enrollment.

Q49. This question asks if the participant has **ever in her life** used personal or sexual **lubricant** in her vagina.

Q49a. This sub-question asks **how many times** the participant has put personal or sexual lubricant in her vagina in the **past 4 weeks**.

Q49b. This sub-question asks the participant the number of times she's put personal or sexual lubricant in her vagina since the week prior to study enrollment.

Q50. This question asks if the participant has **ever in her life** put something in her vagina to make it tighter or dryer for sex.

Q50a. This sub-question asks the number of times the participant has put something in her vagina to make it tighter or drier for sex in the **past 4 weeks**.

Q50b. This sub-question asks the number of times the participant has put something in her vagina to make it tighter or drier for sex since the **week prior to study enrollment**.

Q51. This question asks if the participant has **ever in her life** put something in her vagina to treat vaginal symptoms or make it healthy. An example of this would be the insertion of monistat for a yeast infection.

Q51a. This sub-question asks the participant the number of times she's put something in her vagina to treat vaginal symptoms or make it healthy over the past week.

Q51b. This sub-question asks the participant the number of times she put something in her vagina to treat vaginal symptoms or make it healthy since the week prior to study enrollment.

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Q52. This question asks if the participant ever put something in her vagina for contraception (to prevent pregnancy). Examples include a diaphragm, ring, cervical cap or female condom.

Q52a. This sub-question asks the participant the number of times she's put something in her vagina for contraception over the past 4 weeks.

Q52b. This sub-question asks the participant the number of times she put something in her vagina for contraception since the week prior to study enrollment.

Q53. This question asks if the participant has **ever in her life** put something in her vagina to control blood during her period, for example tampons or a menstrual cup.

Q53a. This sub-question asks the participant the number of times she's put something in her vagina to control bleeding over the past 4 weeks.

Q53b. This sub-question asks the participant the number of times she put something in her vagina to control bleeding since the week prior to study enrollment.