

MTN 008 Gel Use Experience (GUE) Form Question by Question (QxQ) Instructions

Q1. Gel applicator refers to the applicator that was used to insert the gel. And gel therefore includes only the gel and not the applicator itself. Describe verbatim if the gel or the applicator caused any kind of physical pain to the participant. Check the NA box if the gel applicator or gel caused no physical pain.

Q2. A verbatim description should be written if the insertion of gel applicator or gel itself caused any other physical discomfort. Otherwise, if the gel applicator or gel caused no other physical discomfort, the NA box should be checked.

Q3. A verbatim description should be written if the insertion of gel applicator or gel itself caused any other physical discomfort. Otherwise, if the gel applicator or gel caused no mental, psychological or emotional, the NA box should be checked.

Q4. This question has 4 sub-questions all of which are based on a scale from 1-10. 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".

Q5. This question should capture any other worries the participant may have experienced which were not captured in Question 4.

Q6. If the participant's main male sexual partner knows about the gel but does not have any worries, this should be recorded in the description section. The description section should only be left blank if one of the NA boxes is checked.

Q7. This question should capture participant feeling about the study gel over the course of the study (enrollment visit through now).

Q8. If every day is checked, remember to ask Question 8a and record the system the participant used to remember to insert the study gel daily.

Q9. This question should be administered regardless of whether the participant was or was not able to insert the study gel every day.

Q11. 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".

Q11a. The participants should describe why she did or did not insert the gel at the same time every day.

Q12. By circumstances, the participant can describe situations, examples, factors or any bits of information that provide detail surrounding why less than the full amount of study gel in the applicator was used. There should either be a description provided or the NA box should be checked.

Q13. By circumstances, the participant can describe situations, examples, factors or any bits of information that provide detail surrounding why more than 1 applicator of study gel was used per day. There should either be a description provided or the NA box should be checked.

Q14. This section should be completed by the Interviewer if either the participant has any additional feedback she would like to provide OR if she provided valuable feedback during the GUE that isn't captured elsewhere on the GUE form.