

Section 13. Behavioral Assessments

1. Overview

The behavioral assessments of the MTN-008 protocol will be collected via: 1) Web-based Computer Assisted Self-Interview (CASI) questionnaires; 2) A self-administered gel use log and 3) A short interviewer-administered questionnaire. Behavioral assessments will be captured through the Baseline Behavioral and Acceptability Questionnaire, completed at the Enrollment Visit (Day 0); the self-administered Home Dosing Log (Days 1 – 5), the Follow-up Acceptability and Adherence Questionnaire, completed at the Day 6 Clinic visit; and the Gel Use Experiences Questionnaire administered by a research staff member at the Day 6 Clinic Visit (see Table 1, below). CASI interviews and hard-copy Home Dosing Logs and GUE forms are source documentation and must be maintained in accordance with the guidelines for other study documentation.

2. Table 1: Behavioral Assessments: Timing and Mode of Administration, by Instrument

Instrument Name	Timing	Mode of Administration
Baseline Behavioral and Acceptability Questionnaire	Enrollment - Day 0	CASI
Home Dosing Log	Days 1-5	Self-administration
Follow-up Acceptability and Adherence Questionnaire	Day 6	CASI
Gel Use Experiences Questionnaire		Interviewer-administered, then entered into CASI computer

This section of the SSP contains information about the necessary preparation, equipment and process for participant completion of the Web-based Behavioral Assessments. The operations manual of the PC or laptop used for the CASI study computer should be consulted for hardware and software specifications, and instructions on how to use the computer (i.e., turning a computer on and off, etc.). Other questions should be directed to the MTN-008 CASI Instrument Troubleshooting email alias.

- For any problems with the Behavioral Assessments, either accessing them or completing them, or with the CASI study computer, notify the team by sending an email to the alias list <mtn008casi@mtnstopshiv.org>. A team of staff members (Corey Miller and Lynda McVarish at SCHARP; Karen Isaacs and Lisa Levy at FHI, and Elizabeth Montgomery and Ariane van der Straten at RTI International) will be available to assist and troubleshoot any problems with the Behavioral Assessments.

3. Equipment Requirements and Set-up

Each study site will have a desktop or laptop computer connected to the Web that is for use by the MTN-008 study participants. Select a location for the CASI study computer that is private (i.e. the screen should be out of sight of staff members or other participants while answers are being entered), but allows study staff to be nearby to answer questions or assess whether the participant is having technical problems. The location must have an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. The CASI study computer should be plugged into an AC power source. An external mouse should be connected to the computer. Each site is responsible for addressing issues of security,

privacy, background noise, lighting, ergonomics, and overall participant comfort in its site specific procedures. Staff members should be familiar with the use of the computer and the content of questionnaires, in case participants raise any questions.

3.1. Keyboard and Mouse Use

The CASI study computer will require a keyboard and an external mouse. To use the mouse, the following instructions are provided:

- To move the cursor, move mouse.
- To select an object, tap left button once. To unselect an object, tap left button again once.
- References in this SSP to ‘clicking’ on icons or other items displayed on the screen are meant to direct the user to press the left button.

4. Data Collection Instruments

4.1. Baseline Behavioral and Acceptability Questionnaire

The Baseline Behavioral and Acceptability Questionnaire will be administered at the Enrollment Visit. A staff member will access the following web page for the CASI Baseline Behavioral and Acceptability Questionnaire: www.scharp.org/MTN008baseline. The staff member will then double-enter the participant’s PTID to log in.

The staff member should provide instructions to participants for using both the keyboard and mouse, as well as moving from page to page to answer questions using the arrow buttons (not the browser). Initially, the participant will be presented with simple practice questions (e.g., “choose all that apply,” “indicate how many times,” “choose one of a fixed set of answers”). The staff member should verify participant's comfort with using the mouse and keyboard, and navigating through the questionnaire. The participant should be given time to complete the practice questions, with assistance as needed. Staff should ensure that participants understand how to answer questions by ticking boxes or entering numbers, and how to change invalid entries. Invalid entries are those that are not accepted by the program, either because they contradict information that the participant previously entered or because they are not permitted (e.g., numbers that are out of the possible range, or for example if a participant responded that she used the gel 10 days in the past 5 days). Staff should inform the participant that she can refuse to answer any question by ticking the “refuse to answer” button in the bottom corner of the screen. If the participant is unsure of her answer, she should be encouraged to make her best guess rather than to refuse. Participants should be informed that they may go back and change answers at any time, using the back arrow. Staff should then remind participants that they are available to answer any questions or assist with administration of the computer.

Once the practice questions have been successfully completed, the staff member will enter or select some key fields, including the participant’s PTID, visit code and date, the day of the week, and the participant’s study cohort/ group (pregnant 34-36 weeks, pregnant 37 – 39 weeks, or lactating). A confirmation screen will then come up for these key field data.

Following this, the participant should be left alone to complete the Baseline Behavioral and Acceptability Questionnaire. This questionnaire will measure study participant’s demographic characteristics, assess her frequency of different types of sexual behavior (vaginal/anal/oral/ finger), condom use per act (with/without), partner gender (male/female) and partner type (significant other/casual partner). It will also include questions on current and past use of vaginal products including douches, lubricants, medications, desiccants, tampons, and contraceptive methods. Participants will also be asked about their initial attitudes and feelings towards use of the study gel. At the end of the questionnaire, a message will

appear indicating to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

4.2 Home Dosing Log

At the Enrollment Visit, participants will be given a Home Dosing Log, and asked to record the time that they administer gel at home on Days 1-5. They will be asked to bring the Log when they return for their Day 6 Visit. A staff member will complete the PTID and the dates on the form prior to giving it to the participant. If and when the Home Dosing Log is returned on Day 6, the participant should be encouraged to reference it when completing the CASI Follow-up Questionnaire, and it should then be filed by staff in the participant file.

4.3 Follow-up Acceptability and Adherence Questionnaire

At the Day 6 Visit, the participant will complete a Follow-up Acceptability and Adherence Questionnaire using a Web-based questionnaire and following procedures similar to those utilized for the Baseline Questionnaire. At the appropriate time, a staff member will access the Web page for the Follow-up Acceptability and Adherence Questionnaire: www.ssharp.org/MTN008follow-up. The staff member will then double-enter the participant's ID, followed by visit code, date and the day of the week, the enrollment date and day of the week and the participant's study cohort/ group (pregnant 34-36 weeks, pregnant 37 – 39 weeks, or lactating). A confirmation screen will then come up for these key field data. Next, the participant will be left to answer the questionnaire on her own. The Follow-up Acceptability and Adherence Questionnaire will explore the experiences the participant had during the prior 6 days using the gel vaginally, including a record of the days she used the gel or not, and reasons for non-use, her sexual behavior (vaginal, anal, oral) and condom use, her likes and dislikes concerning the gel, the applicator, the application process, any changes she may have introduced in the volume used, any problems (e.g. leakage) she may have had, partner's reaction, sexual enjoyment, her willingness and likelihood of using a microbicide in the future and her use of other intravaginal products (douche, lubricant, dessicants, etc.) since the start of the study. At the end of this section, a message will appear indicating to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

4.4 Gel Use Experiences (GUE) Questionnaire

Immediately following the Follow-up Acceptability and Adherence Questionnaire, a staff member will administer the GUE Questionnaire to the participant. This questionnaire will explore, through structured and open-ended questions, the participant's overall experiences and feelings using the gel during the trial, including any physical, mental or emotional concerns or experiences she encountered or she perceived in her partner; her experiences using the prescribed amount of gel, and using it at the same time every day, and other worries, likes or dislikes. The staff member should explain that a few additional questions are being asked in person to more thoroughly explore the participant's feelings, and that her responses will be entered into the computer after her visit. The interviewer should endeavor to record open-ended responses verbatim, as provided by the participant. However, the essence and key points may be summarized by the interviewer for lengthy responses. When writing and entering these data, direct quotations from the participant should be indicated with quotation marks to distinguish them from interviewer summaries. The interviewer should probe to get more specific and detailed information in response to each question, and may write responses on the reverse side of the form, in the margins, or on additional sheets of paper if needed. For example, if a participant reports that insertion of the gel applicator was "difficult", probe to better understand what she means by difficult (i.e. painful, hard to find time, hard to physically reach). The participant may spontaneously raise comments or questions during the interview that are unrelated or not a response to the questions being asked. It is allowable, but not required, to probe on and record data

regarding these issues. At the end of the questionnaire, the study staff member should quickly review the form for completeness, thank the participant, and escort her to the next stage of her visit.

Ideally the questionnaire data should be entered into the CASI study computer that day. The designated staff member should open up the GUE Questionnaire on the web-based CASI system, accessible at the address: www.ssharp.org/MTN008gue. The participant ID, visit code date and the study participant's cohort/ group should be entered, along with initials of the interviewer and data entry staff member. Participant responses should then be entered into the system. All open-ended textual responses should be entered verbatim in **sentence case**. Following data entry, the staff member should write his/ her initials, date and "entered" on the GUE, and file the document in the participant file.

If any participant discontinues study participation early, or has a modified Day 6 Visit, she will be encouraged to respond to the Follow-up Acceptability and Adherence Questionnaire and the GUE Questionnaire at the time of her study discontinuation.

Again, for any technical problems accessing or using any of the questionnaires, contact the MTN-008 CASI Instrument Troubleshooting team at mtn008casi@mtnstopshiv.org.

4.5 Question by question Instructions

A question-by-question guide, that explains the purpose and intention of each question, has been developed as reference for the CASI questionnaires and the GUE. These guides are available on the MTN website (<http://www.mtnstopshiv.org>) under MTN 008> Study Implementation Materials. The question-by-question guides should be reviewed by staff prior to the enrollment of participant. The guides should be consulted if participants request assistance in the interpretation of a CASI question, or if staff members are unclear with the meaning of a GUE question.

5. Hard Copy Back-up

Hard copy versions of CASI questionnaires will not be distributed in this study. In the event of technical problems (i.e. server or power outage) that would preclude a participant's ability to complete the questionnaire online these data will be considered missed. If feasible, participants may complete the appropriate questionnaire at a later time when the system is functioning, and these unique circumstances should be documented in the Chart Notes. The study team may distribute hard copy versions of the CASI questionnaires at a later date if persistent technical problems occur.

6. Staff Training

Prior to participant enrollments, all staff who will be assisting participants with CASI or administering the GUE must complete at least 2 practice sessions for each instrument.

For testing please access questionnaires through the websites indicated above. The following test PTIDs should be used:

PITT TEST PTIDs

999-0001-7-1
999-0002-2-1
999-0003-0-1
999-0004-6-1
999-0005-8-1

UAB TEST PTIDs

999-0006-5-1

999-0007-3-1

999-0008-4-1

999-0009-1-1

999-0010-8-1

Upon completion of testing, an email should be sent to the MTN 008 CASI alias list: mtn008casi@mtnstopshiv.org indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered.

Section Appendix 13-1

QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS

- Prior to starting a questionnaire, make sure that the computer, internet connection, keyboard and mouse are connected and working properly.
- Make sure that the participant is comfortable and has privacy to assure the confidentiality of her responses.

- Start the questionnaire by typing the Web address to the corresponding Behavioral Assessment:
 - 1 Baseline Behavioral and Acceptability Questionnaire (Enrollment Visit)
www.ssharp.org/MTN008baseline
 - 2 Follow-up Acceptability and Adherence Questionnaire (Day 6 Visit)
www.ssharp.org/MTN008follow-up
 - 3 Gel Use Questionnaire (Day 6 Visit)
www.ssharp.org/MTN008gue

- Make sure that the participant is comfortable with using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant ID to enter the questionnaire.

- Allow participant to complete the practice questions (Day 0 only).
- Assist the participant as needed.

- • Enter or select: PTID, visit code, date and day of the week, participant study cohort. At follow-up the enrollment date and day of the week will also need to be entered.
- Instruct the participant that when she reaches the end of the survey, she will see a screen that says "Thanks, you have finished this questionnaire." The participant is not finished until she reaches this end screen. At that point the participant should leave the computer as it is and notify a staff member.

- If, for any reason, the participant cannot complete the questionnaire, the questionnaire may be closed. If the participant is able to return to it at another time, the questionnaire can be restarted by going back to the appropriate Web page and entering the participant's ID.