

## Section 16. Week 21 In-Depth Interviews

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This section provides information on requirements and procedures for conducting, transcribing, translating, and managing data for week 21 in-depth interviews in MTN 001.

### 16.1 Introduction

Qualitative data collection (in-depth interviews) will be conducted with a random sample of approximately **forty** randomly selected participants total at five sites participating in this study activity to explore use of study drugs and male condoms during the trial.

Interviews will be conducted by a trained study interviewer using a semi-structured interview guide that has been prepared to collect data on:

- Challenges to use of study products
- Perceived benefits of use
- Preferences between oral and vaginal formulations
- Preferences between a single and dual use regimen
- Partner knowledge of study participation and reaction to product use
- Who knew that they had access to anti-retroviral drugs
- Whether they were ever asked to share (or sell) the product or if someone tried to take it away from them

These in-depth interviews directed by the structured interview guide will provide an opportunity to explore the adherence and acceptability research objectives in greater depth. Interviews will be conducted in a designated private space just before the participants leave the clinic.

### 16.2 Target number of participants

The Statistical Center for HIV/AIDS Research and Prevention (SCHARP) will generate and maintain the study randomization scheme, randomly selecting a total of about **forty** participants at five participating sites to complete the week 21 in-depth interviews. Site clinic staff will inform participants if they have been randomized to the 21-Week In-Depth Interviews during the randomization process (see Section 4.2.7). The MTN 001 Randomization Envelopes will contain a two-part no carbon required (NCR) Randomization Document that will indicate whether the participant has been randomly assigned to complete the in-depth interview at Week 21. Each site should develop a procedure through which they can easily identify the participants randomized to the Week 21 interviews. For example, a site might choose to place a yellow sticker on the front of each of the study notebooks of participants who have been randomized to complete the week 21 in-depth interview, so that these participants can be identified when they return for their week 21 visit. These participants will be asked, during the informed consent process, to consent to the in-depth interview (SSP section 16.4.2). At the 20-week study visit, site clinic staff should remind participants who consented to the in-depth interview that they will complete this interview at their next study visit.

Participants who are asked, but do not consent to the in-depth interview, will not complete the interview. In addition, participants who meet the criteria for replacement (SSP section 4.2.7.1) will not participate in the in-depth interviews. If a participant is randomized to the in-depth interview at enrollment, but subsequently meets the criteria for replacement, she will not complete the in-depth interview; rather, the participant enrolled to replace her will receive the same randomization assignments and will complete the in-depth interview in lieu of the original participant.

### **16.3 Differential Adherence**

The purpose of the in-depth interviews is to collect qualitative data on participants who represent differing levels of adherence to study product (i.e., participants who report better adherence to study gel than study tablets, or vice-versa, or participants who report low or high adherence to both study gel and study tablets). In the event that the participants who are randomized to and complete the in-depth interviews do not represent differing levels of adherence, site staff, with input from the behavioral researchers, may select up to two additional study participants (who report differential study product adherence or who they believe would be good informants about product adherence) to complete the in-depth interview.

#### **16.3.1 Identification of participants reporting differential adherence and/or participants who may be good informants about product adherence**

SCHARP will periodically send the behavioral researchers at RTI a listing of the adherence data reported by the participants randomized to the in-depth interviews (as documented on the Case Report Forms). The behavioral researchers will review this listing and assess whether or not the data represent different levels of adherence to study products. In the event that the randomized participants at each participating site do not represent different levels of adherence to study products, the behavioral research team will work with the site to identify **up to two** additional participants to complete the week 21 in-depth interviews. These additional participants may be chosen based on differential reporting of adherence to study products (as documented on the Case Report Forms). They may also be chosen if they are identified by site staff as excellent informants (based on specific experiences they may have had using study product(s) or other comments they may have shared with site staff during study visits). If additional participants are needed for the in-depth interview, and if a site identifies a participant that may be a good candidate to participate in the interview (i.e., a participant that represents atypical adherence to study product, or a participant likely to be an excellent informant on study product experiences), the rationale will be communicated and discussed with the behavioral researchers. Participants whom study staff and behavioral researchers have identified as eligible and good candidates for the week-21 in-depth interview may be asked by site staff at the 20-week study visit if they would be willing to complete the in-depth interview at their next study visit. Those participants who are asked and who have consented to the in-depth interviews will complete the interviews at their respective 21-Week study visit.

### **16.4 Data Collection**

During the 21-Week in-depth interview process, the conversation will be recorded to ensure that all participant-provided information has been collected appropriately. In addition to recording of the interview, the interviewer will take notes on his/hers observations during the interview. Therefore, the interview data will consist of voice files, text files of the interview transcripts, and interviewer observational notes.

#### **16.4.1 General Preparation Prior to Interview: Checklists**

In preparation for the interview, assemble and bring all necessary items to the interview room, including:

- Interview guide
- Digital tape recorder with a 128MB memory stick, a spare 8MB memory stick, and spare batteries
- Notebook, pencils and/or pens
- Clock or watch to time the interview
- Register, re-imburement log and vouchers/cash [site specific]

To ensure the interview is successful, it is important to prepare prior to the study visit by:

- Preparing the private and confidential room where the interview will be conducted, including arranging the furniture, placing a “Do Not Disturb” sign on the door, and ensuring that all materials are available.
- Check the battery life meter on the digital recorder and make sure you have a full dark colored bar. For each interview, use new batteries just to be sure. Old batteries can be used for transcription.
- Make sure that you are familiar with the way your digital recorder works. Test it and practice recording until you are confident about how to use it correctly (see section 16.4.5).
- Be aware of ambient noise, such as fans, street noise, etc. Place the recorder where it can record the participant’s voice clearly, while still being monitored by the facilitating team. You should test the sound quality in advance.
- Be on time for the interview. It is very important to respect participants’ time.

#### **16.4.2 Reiterating Informed Consent**

As part of the enrollment informed consent process, participants will provide consent to participate in a recorded in-depth interview. Before the interview, it is important to review with the participant the information regarding the interviews that was provided to her during the enrollment process. Also, it is important to remind participants that every effort will be made to keep confidential all information that she provides in the interview. Please note that all participants assigned to complete the in-depth interview, whether through randomization or site selection, must sign an informed consent form before they participate in the in-depth interview.

#### **16.4.3 Style of Interviewing**

Below are some general tips to keep in mind when interviewing:

- Build rapport. Start with an informal chat on a topic that will be of interest to the participant. For example, try to link the MTN-001 trial with issues/events in the community.
- Motivate the participant to tell her story by showing sincere interest in what she is sharing through eye contact and probing. Silence can also be helpful (see section 13.5 for interviewing techniques).

- Remain non-judgmental. Show understanding but do not show approval or disapproval, or share your own personal experiences. Show respect, acceptance and emotional support through empathetic tone of voice, gestures, responsive facial expression, nods, etc. Use expressions such as “I see” and “that’s interesting,” which show that the interviewer is paying attention without suggesting agreement or disagreement.
- Do not interrupt the participant. Sometimes interviewers are so determined to get their point across that they interrupt and speak "over" the respondent. This is not only inappropriate behavior for the interviewer, but when individuals speak simultaneously the voice recording is unclear and valuable information may be lost as a result.
- A good interviewer listens attentively to every word and sentence, observes gestures, symbols, pauses, and emotions. Take record of all these.
- There are no desirable or undesirable answers. Your manner should reflect great interest and compassion and this will encourage participants to share deeply their experiences.
- “Difficult” questions should be asked when you sense that the conversation is relaxed and you have won the trust of the participant. The questions in the guides are arranged in a progressive order, from the general ones to the more specific.
- Be especially sensitive to the effect the conversation may be having on the participant and how comfortable you are yourself in handling these questions, especially when discussing sexual issues.
- “Difficult” questions can be asked repeatedly in different ways at different points during the interview.
- Sometimes qualitative interviews can bring out strong emotions in a participant. The interviewer can change the topic, stop the interview to allow her to vent her emotions and/or shift to a neutral topic.
- Sometimes participants give answers that they think we want to hear or that they think are expected by the trial, e.g. used condoms all the time. The interviewer can ask participants how easy it is to practice some public health messages or can make a note about her observations and why.
- Be flexible yet focused; keep the dialogue focused. The participant may ask the question even before it is time to discuss it on the guide. The interviewer should judge for herself whether to go along and exhaust the question or to follow it up later.
- The participant may also give another meaning to the question. The interviewer should be flexible enough to encourage new perspectives and experiences while at the same time maintaining focus in the discussion.
- If the participant begins discussing something irrelevant, the interviewer should try to redirect the discussion to the appropriate topic.
- Closing the discussion can be difficult once the participant is relaxed and trusting. Be sure to thank the participant for her willingness to share her experiences and once more assure her of confidentiality.
- Sometimes the conversation may continue off record and important information related to the questions may be disclosed. Take note of this information and ask the participants if you may include these in your formal notes.

#### 16.4.4 Digital recording and managing voice files

This sub-section describes how to use the digital recorder and manage the voice files that it creates from the interview recordings. The 2 US sites will use a Sony ICD-SX68 Stick Recorder with transcription capacity (*Note: US sites will receive individualized training to learn how to use the built in transcription software*) and African sites will use a Sony ICD-SX68 without transcription capacity to record the interviews. The recorders come with a 158MB Memory stick which holds about 185 hours of recording time. Please carefully review the ‘Operating Instructions’ manual for the digital recorder to familiarize yourself with it. After review of the manual, site staff should install the IC recorder software CD on the computer where voice files will be transferred.

Figure 16-1: Sony ICD- SX68DR9 Memory Stick Digital Voice Recorder



#### 16.4.5 Recording Preparation Prior to Interview

Site counselors should practice using the recorder with colleagues to familiarize themselves with all aspects of recording, downloading, saving, labeling, transferring, and transcribing digital recordings. We cannot replace an interview that has been successfully carried out but the recording is lost, damaged, or inaudible.

Make sure to set the clock for the recorder to the current date and time (see page 17-18 of Operating Instructions manual). That way, the default label assigned to a voice file will include the actual interview date in “yyyy\_mm\_dd” format (i.e., 2005\_03\_26) when downloaded onto a computer after the interview, which will allow for the files to be arranged in chronological order, making it easy to locate files of interest.

Make sure to set the recording level to “MANUAL”. Hold down the menu button and select the REC LEVEL menu option, use the forward and backwards buttons to select “MANUAL” (see pg 25-26 of the Operating Instructions manual).

#### 16.4.6 Recording the interview

To start recording an interview press and hold the “REC/ PAUSE” button, speak into the microphone and adjust the recording volume as needed, press the “REC/PAUSE” button (the operation indicator lights in red and “REC” will be displayed). To pause a recording, press “REC/PAUSE”, to end a recording, press “STOP”. Each time you start to record an interview and then press the stop button, a separate voice file is made. To avoid having several voice files for the one interview, it is recommended that the “REC/PAUSE” button be used to pause and resume the interview, and press the “STOP” button when finishing the interview.

The Sony ICD-SX68 Memory Stick Recorder is organized into five folders (FOLDER01 to FOLDER05). Each file created is assigned to these folders in a chronological order, or the user can specify a folder.

#### 16.4.7 Procedures Following the Interview

As soon as you stop the recording, your digital voice recorder creates a sound file with a unique identity with date and time.

Transfer of interview data from the recorder to a computer should happen immediately after the interview. *Note: specific data transfer training will be provided to all sites*

- Connect the recorder to the computer using the USB connecting cable.
- Start the Digital Voice Editor (which should have been installed in advance from the CD that comes with the recorder package).
- The Voice Editor’s main window will pop up, showing the folders and file names for the Memory Stick recorder and the computer.
- In the PC section (on the right), open the destination folder (“original downloads”), where the files are to be transferred.
- In the Memory Stick section (on the left), open the folder of interest, select the files to be transferred, and drag and drop them into the destination folder on the PC side.
- After the files have been transferred, they should appear in the destination folder.
- Check the downloaded files. To listen to a voice file double-click on the file, and it will start to play. You can move the cursor on the playtime toolbar to listen to particular portions of the interview. You can take note of the time on the counter to listen to an interview section of interest later e.g. 1:20:06 to 1:35:45.
- Create a new folder on your PC called “voice files-transcription.” Copy the files that you have saved successfully in the “original downloads” folder and save them in the “voice files-transcription” folder. This will be the copy of the recording that you will work with. Do not use the master file in “original downloads.”
- All the voice files in the “voice files-transcription” folder should be relabeled from the default format to follow the following format: Study Staff ID, Clinic name, number of voice files per discussion/interview, date of interview (YYYYMMDD) - e.g. SSCase 1of1 20080723. SS is the staff ID of the note-taker. We hope the file naming format will help the site staff and other MTN-001 collaborators easily identify the files. Sites are free to add other pieces of information that maybe useful in the file name e.g. initials of note taker, etc.
- Once the download is verified you can clear the memory stick of old files so that it will not get prematurely filled up during the next interview. Voice files can be selected, copied or deleted on the E: drive (for the voice recorder) using Windows File Manager.

When the voice files are first downloaded onto a computer, they have “\*.msv” as the file extension. Create a folder named “original downloads.” This is your ‘Master tape’ of the interview. Do not change these files in any way (e.g., do not re-label). The voice files in this folder will serve as the original source of interview data and as a backup in case any of the data are lost or damaged in the future; for example, while it is being relabeled, transmitted, or analyzed. If the recorder’s date and time have been set correctly, as described above, the files should be automatically organized in chronological order.

#### **16.4.8 Backup, storage and transmission of voice files**

After the files have been set up in the computer, make two CDs of the voice-files. The first will be the original copy of the interview data in the “original downloads” folder and in the “voice files-transcription” folder, and stored in a locked file cabinet or drawer until all interviews are completed and all CDs can be securely mailed to the social science coordinator at RTI International. The second copy will serve as a backup of the original downloads, and should be stored in a locked file cabinet or drawer in the “back up voice files-transcription” folder.

### **16.5 Data Collation and Management**

For the In-Depth interviews data collection, data is defined as the electronic (digital recording and computer files) and manual (interviewers note, transcriptions) copies of all information collected during the interview. The final research output of these data will be written text in reports and paper publications.

#### **16.5.1 Transcriptions**

A transcript or transcription is a word-for-word written copy of a voice recorded interview. Transcribing a recording of interviews (in the language of the original interview) is necessary in order to consider and compare what participants say in their interviews. In a face-to-face interview the interviewer can observe non-verbal communication such as hand, face and body gestures. The original audio recording is the most accurate reproduction of the interview; however, one can only listen to the tone of speech but not the non-verbal gestures. Transcriptions accompanied by summaries and observational notes from of the interview provide an objective representation of the interview or discussion.

A typed interview transcript serves as a written record of every word spoken by participants and it can be made accessible for analysis. A transcript provides the means to search for specific words and phrases mentioned in the interview using word processing or specialized qualitative data analysis software.

Here are general instructions about transcribing interviews:

- We recommend that you start to transcribe the interview recordings as soon as possible after the interview.
- You may wish to first listen to parts of the recording or in its entirety once before you start transcribing to become familiar with the voices and content.
- Write down unique identification particulars of the transcription at the top of the first page: time started; time finished; venue of interview; transcriber; translator; and date(s) of transcription and translation.

- Listen to the recording carefully, one phrase or portion at a time, and transcribe verbatim, including all words, in the language of interview. Abbreviations should be kept the way they were said, such as “I’d” and “we’ve.” Do not summarize thoughts or ideas. Do not change from the first person to the third person, i.e. if a participant said “I like it because” do not transcribe as “she likes it because...”
- Sounds, crutch words or incomplete words such as Um,” “Er” or “Ahh...” after single words in a row do not need to be transcribed if it makes reading difficult, unless it is an important part of the narrator’s speech pattern.
- Interviewers use feedback words and sounds such as “uh huh,” “yes” and “hmm” to engage with the interviewee, but they can make transcripts difficult to read. Use your judgment when to leave these out.
- Do not revise the speaker’s words to force them into standard written prose. Leave untouched any sentence fragments, run-on sentences, and incorrect grammar. Commas and dashes may be used to reflect pauses in the spoken words.
- Use the jargon, idioms and metaphors that participants used in the interview; this enriches the data.
- Insert observations about non-verbal communication or the tone of voice of the speakers from the notes taken during interview or the transcription using [square brackets] to give it more depth and feeling e.g. [participant A standing and shouting]; [participant laughing]; [I think participant A misunderstood the question].
- Also include in [square brackets] explanations about why the interview was interrupted or why the recorder was turned off e.g., [Interview interrupted by a child crying].
- Identify inaudible portions of the recording. If one word is inaudible, indicate the gap with a “\_”. When multiple words are inaudible, insert “\_+” or estimate the elapsed time using the indicator “.... # seconds”.
- Place two question marks before and after a word or phrase where you are not sure e.g., “??the partner always laughs??” The interviewer needs to pay extra attention that there is minimal interference with the sound quality during the interview.
- Indicate the end or break of a recording in capital letters, e.g., END 1of2; BEGIN 2of2; END OF INTERVIEW.
- The goal is to create a transcript that is both accurate and understandable to the reader. It need not include every utterance or describe every background noise, but it should reproduce as closely as possible the speaker's words. It should also be consistent in style and level of detail throughout.
- After an interview voice recording is transcribed, it is critical that the transcriber and a second person (the interviewer, if different to the subscriber) read through it for accuracy. In particular, the interviewer should check that cultural words or vocabulary of the participants were transcribed properly and try to fill in anything that was found to be unclear during transcribing.

### 16.5.2 Translations

Interviews will be conducted in the language that participants are comfortable with. Each site is responsible for all translation activities, or for contracting out for translation services.

After a non-English interview has been carried out, we recommend the following:

- Transcribe verbatim the interview in the original language following the transcription guidelines above. Then, translate the transcript into English under the passage for each speaker.

- Where jargon, idioms and metaphors have been used by participants in the interview try to translate these as directly as possible in order to maintain their original meaning. For example, if participants talk about “small houses” translate this as “small houses” not as some other term. Explanations to outside readers can be written in brackets. Cultural terms that do not have easy translations may be written in the local language and explained through notes written in square brackets, i.e. ukusoma [thigh sex]
- Team members can figure out what works best for them, whether the person who did transcription also translates the document or someone else.

The transcriptions should include all observer notes and feedback notes from the participants. Please note that a certified translator must carry out all translations and that written certification of the translation must be obtained. A copy of the transcript, translated copy, and written certification of the translation must be sent to the RTI International office in San Francisco (see Section 16.4.8 for shipping address) no longer than four weeks after the last interview is completed.

### 16.5.3 Data Management and Storage

Correct handling, filing and storage of all paper and electronic files and CDs containing study data are important for organizational purposes, quality assurance, monitoring, and the protection of participant confidentiality. The interview data will be in the form of:

- Enrollment data (with Participant ID number so that we can match their information with the trial data during the analysis).
- Transcripts and translations accompanied by interview notes, filed by interview type. e.g. PTID\_date of interview\_name of interviewer

The main components of the data management system are:

- To protect participant’s confidentiality, use PTIDs on interview data (forms, voice files and transcripts) so that the data are not directly linked to the participant’s name or other personal identifiers. Also, store interview materials separate from documents bearing participant’s identifiers such as informed consent form, and locator forms.
- Storage of paper documents (in the participants file) and CD backups in locked file cabinets and electronic documents on password-protected, secure computers at the project offices for the study sites.
- Access to the study data only by designated study staff.
- Routine backup and transfer of data to RTI. Ensure that you backup your work on a daily basis.

### 16.5.4 Electronic files

All electronic study data, documents and voice recordings should be routinely backed up as follows:

- Electronic study files should be automatically backed up each day on the office server.
- Staff should make CD backups of interview recordings and other study documents at least once a week.

### 16.5.5 Data storage

All study material will be completed, checked and filed at each research site. All qualitative back-up data will be kept at the sites throughout and after completion of the data collection. Per protocol sites are required to maintain all records for two years after the study. (see section 3 for data storage requirements following completion of the study). Records will be destroyed after the two year period. Records may not be destroyed without written permission from the MTN-001 protocol team chair.

### 16.6 Data tracking

This qualitative study falls under the administrative structure of the MTN-001 Trial. The sites responsibilities are outlined in the MTN-001 Protocol and MTN 001 SSP Manual.

#### 16.6.1 Site Investigator responsibilities

- Conduct the study in accordance with the relevant current protocol and recommend amendments where necessary.
- Ensure that all study staff follow ethical procedures as approved by the IRB.
- Maintain adequate and accurate records at the study site in accordance with this protocol and make those records available for inspection to study monitors and auditors.0.

#### 16.6.2 Data monitoring

Data monitoring activities include:

- After each interview, site staff will carefully review all interview data and participant files for any anomalies.
- The interviewer will make a written report of any anomalies.
- Transcriptions will be checked by a researcher other than the original transcriber before it is transmitted to the social science coordinator. During the analysis any passage of interest will also have the translation verified against the corresponding excerpt in the transcript of the original language of the interview.

#### 16.6.3 Sending Data

When all materials (voice files, summary notes and transcripts) are completed (and no longer than 4 weeks after the completion of the last in-depth interview), each site should securely mail (with the ability to track progress or delivery confirmation) all materials to the Qualitative Data Coordinator at RTI International:

Alexandra Minnis  
Women's Global Health Imperative  
RTI International  
114 Sansome St, Suite 500  
San Francisco, CA, 94104 USA  
Phone: 415-848-1323  
Email: aminnis@rti.org

Please package all materials carefully (for example, each CD should be protected by a case). **Please also be sure to include a log of the all files/materials included in the package. (See Appendix 16-2 for check-list of materials to include).**

**Section Appendix 16-1**  
**In-depth Interview Questionnaire**

Hello, my name is [FACILITATOR]. I would like to congratulate you for completing the study, and today I would like to discuss your experiences with being in the Tenofovir study. I would like to hear your views and learn about any problems and difficulties as well the positive experiences you have had with the study products. Everything you say is important to our research and will help us to better understand women's experiences using Tenofovir in the trial. Please feel free to speak openly and use any language or words you are most comfortable using. There are no right or wrong answers. Your name will not be written anywhere, which means that no one will know it was you who said something.

Since this discussion is very important to us, I would like to record it, with your permission just to make sure that I do not miss any important things that we will discuss today, and I will also be taking notes while we talk (*confirm their consent*). The tapes and notes will be kept private and safe, your name will not be used and the documents will be destroyed when the trial is finished. The discussion will take a little over one half-hour. Do you have any questions before we start?

**A: Study Experiences (3-5 minutes)**

1. What are some of the reasons that you joined the study?  
[PROBE: getting tested for HIV; learn more about HIV prevention; compensation of the study; curiosity/experience; free medical exam; etc]
2. What are some of the reasons you stayed until the end?  
[PROBE: What did you like about the study?  
PROBE: What did you dislike about the study?]

**B. Study product experience and use (10 minutes)**

3. Please tell me about your experience using the gel and applicator.  
[PROBE: What are the things you liked about the gel?  
PROBE: What are the things you disliked about the gel?  
PROBE: How did you feel about using the applicator?]
4. Please tell me about your experience taking the tablets?  
[PROBE: What are the things you liked about the tablets?  
PROBE: What are the things you disliked about the tablets?]
5. Please tell me about your experience using the gel together with the tablets.  
[PROBE: What are the things you liked about using the gel and tablets together?

**PROBE:** What are the things you disliked about using the gel and tablets together?]

6. In some instances women prefer using the gel, in other instances women prefer taking the tablets, and in other instances women prefer using the gel and tablets together. Please tell me about instances when you preferred using the gel or preferred taking the tablets?

[**PROBE:** Tell me about the instances when you preferred using only the tablets.

Why did you prefer using only the tablets, and not the gel?

**PROBE:** Tell me about the instances when you preferred using only the gel. Why did you prefer using only the gel, and not the tablets?

**PROBE:** Tell me about the instances when you preferred taking the tablets and gel together. Why did you prefer using the gel and tablets together?]

### **C. Product adherence (7-10 minutes)**

7. For some women it is not easy to use gel every day; yet for others it is easy. What was your experience?

[**PROBE:** Some women were not able to apply the gel everyday. What do you think could be some of the reasons that made it difficult for them to use the gel everyday? What made it difficult for you to use the gel every day

**PROBE:** Some women were able to use the gel everyday. What do you think could be some of the reasons that made it easy for them to use the gel everyday? What made it easy for you to use the gel every day?

**PROBE:** Can you think of a time where you thought it would be very difficult to use the gel, but you were still able to use it? If yes, can you tell me more about it?

**PROBE:** What do you think would make it easier for you to use gel every day?

**PROBE:** What were some of the things that did help you to use the gel?

**PROBE:** What were some of the things that helped you to remember to use the gel? (Would a timer have helped, a friend, a partner?)]

8. For some women it is not easy to take the tablets every day; yet for others it is easy. What was your experience?

[**PROBE:** Some women were not able to take the tablets everyday. What do you think could be some of the reasons that made it difficult for them to take the tablets everyday? What made it difficult for you to take the tablets every day?

**PROBE:** Some women were able to take the tablets everyday. What do you think could be some of the reasons that made it easy for them to take the tablets everyday? What made it easy for you to take the tablets every day?

**PROBE:** Can you think of a time where you thought it would be very difficult to take the tablets, but you were still able to use it? If yes, can you tell me more about it?

**PROBE:** What do you think would make it easier for you to take the tablets every day?

**PROBE:** What were some of the things that did help you to take the tablets?

**PROBE:** What were some of the things that helped you to remember to take the tablets? (Would a timer have helped, a friend, a partner?)]

#### **D. Partners and relationship issues (5-7 minutes)**

9. Please describe what information you shared with your partner on your trial participation and gel/tablet use? (*when I say partner I mean your husband, or someone who you consider to be your primary male sexual partner*)

[**PROBE:** What did you tell your partner about your participation in the trial? How did your partner react?

**PROBE:** How did your partner learn that you were using the gel the first time? How did he react?

**PROBE:** How did your partner feel about you using the gel?

**PROBE:** How did your partner learn that you were taking the tablets? How did he react?]

**PROBE:** How did your partner feel about you taking the tablets?]

10. Sometimes it is possible to use the gel and/or tablets without your partner noticing. What has been your experience?

[**PROBE:** Tell me about the times when you told your partner that you were using the gel. What are some of the reasons you told him? How often did you tell him?

**PROBE:** Tell me about the times when you told your partner that you were taking the tablets. What are some of the reasons you told him? How often did you tell him?

**PROBE:** Have you ever used the gel without your partner knowing? What were the reasons that you did not tell him?

**PROBE:** Have you ever taken the tablets without your partner knowing? What were

the reasons that you did not tell him?]

**PROBE:** What would happen if you tried to use the gel and/or tablets without your partner knowing? How would your partner react if he found out you were taking the tablets and/or gel without him knowing?]

11. Do you think it is important for male partners to be involved in the decision to use the gel and/or tablets?

[**PROBE:** What are some of the reasons? How can male partners be more engaged and empathetic about their partner's use? Do you think your partner could help you with using the product every day?]

### **E. Product Sharing (5-7 minutes)**

12. Who knew that you were taking tablets and gel provided by the study?

[**PROBE:** husband/primary partner, family members, neighbours, clients, community members

**PROBE:** how did they find out?

**PROBE:** Did you want people to know or would you prefer that only you (or you and your partner) know?]

13. Sometimes family members or friends ask participants in the study to share some of their gel and/or tablets. Tell me about your experience sharing or someone taking away your study products.

[**PROBE:** Tell me about the times that you shared your gel and/or tablets. What are some of the reasons that you shared your study gel and/or tablets?

**PROBE:** Tell me about the times that someone took your gel and/or tablets without your permission. How did it happen? What are some of the reasons that the other person took your gel and/or tablets without your permission?]

### **G. Conclusion**

14. We do not yet know if the tablets or gel will prevent HIV infection. But thinking ahead to the future, if they are proven to prevent infection, would you use the gel or tablets?

***A.E. reporting script:*** If the patient has mentioned anything at all that qualifies as an A.E., you are required to ensure that she has reported it, and double check in her file. Here are some guidelines for what you might say

During our interview you mentioned \_\_\_\_ (specify A.E.). At the time did you tell clinic staff about (specify A.E.)?

*If she says yes:* Before you go, I am just going to double check that (specify A.E.) was recorded in your file.

*If she says no:* For your health and safety, we need to make sure that this is recorded in your file. Before you go, we need to fill out a form to ensure that it has been recorded. Is that okay?

*Ask if there are questions or comments on anything about the study or this discussion. Address any outstanding questions/comments that you may have postponed to the end of the discussion.*

Thank you for your time and information.

**Section Appendix 16-2**  
Checklist of Required Materials

- ø **Name of Interviewer, Date of Interview, Location of Interview**
- ø **CD of electronic voice file (US sites only)**
- ø **English translation of interview transcript (international sites only)**
- ø **Certification of official translation (international sites only)**
- ø **Summary notes from interview (if any)**