Section 17. HOPE Qualitative Component

This section describes study-specific procedures for the HOPE qualitative component. This component will be conducted at the Emavundleni, WRHI, Isipingo, Seke South, Kampala, and Lilongwe sites. These sites must maintain this section of the Study-Specific Procedures (SSP) Manual in its entirety. All other HOPE sites not participating in the qualitative component are not required to maintain this section of the manual. For clarity of documentation, however, all sites should maintain a reference copy of Version 1.0 of this page (17-1) in their SSP manuals.

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17.1 Introduction

This section specifies the sources of procedural information available to HOPE qualitative staff, the responsibilities of HOPE Investigators of Record (IoRs), and the process by which each study site is approved to begin implementation of the HOPE qualitative component.

Study implementation questions regarding the qualitative component that are not answered by the protocol or this manual should be directed to the MTN-025 Qualitative Management Team (QMT). This group consists of representatives of the MTN Coordinating and Operations Center (CORE-FHI 360), RTI International (which acts as the qualitative data center), and the Protocol Chairs. This group can be reached using the following email address: mtn025qmt@mtnstopshiv.org

There is not a separate activation process for the qualitative component of HOPE. However, prior to undertaking any study procedures, each site must receive notification of completion of all items on the HOPE Qualitative Component Readiness Checklist from FHI 360.

17.2 Documentation Requirements

Essential documents pertaining to the qualitative component, e.g. IRB correspondence, should be filed in accordance with site specific procedures for other HOPE Essential Documents. Study sites must maintain adequate and accurate participant file records containing all information pertinent to participation in the HOPE qualitative component, for each study participant.

17.2.1 Participant File Contents

In addition to the file elements outlined in SSP Section 3, files for those participating in the qualitative component should contain:

- Documentation that the participant met the eligibility criteria to participate in the selected qualitative interview.
- A record of the participant's systematic or purposive selection to receive either a single in-depth interview (IDI) or serial IDIs. For purposive selection, documentation of approval from the QMT should be filed (see 17.3.2).
- A record of all contacts, and attempted contacts, with the participant.
- A record of all qualitative research-related activities that take place during the conduct of the study.
  - Notes recorded on interview guides, separate sheets, and/or additional materials used for in-depth interviews (IDIs; either single or serial) are filed in the participant file.
- Referrals made (including for social harms or adverse events reported) as a result of information gathered during qualitative interviewing.
- Documentation of any deviation from procedures outlined in HOPE protocol, SSP, or the site Qualitative Component SOP.

17.2.2 Source Documentation

For the qualitative component of HOPE, participant files contain the following source documents:

- **Qualitative IDI notes, associated tools and transcripts:** IDI notes, taken during qualitative data collection, including those made on any associated tools, are source documents and must be kept in the participant file per the site Qualitative Component SOP. Final versions of the English-translated transcriptions of audio files, and final debrief reports are also considered to be source documentation and must be kept in the participant file.
- **Visit Checklists:** The *Study Implementation Materials* section of the MTN-025 website contains examples of tools to fulfill the requirement of documenting all study activities that take place at each IDI with study participants. Checklists used for IDIs should be filed with the participant files. If the visit procedures deviate from what is outlined in the checklist, documentation of this should be in the comments section at the bottom of the checklist or in chart notes.
- **Chart notes:** Chart notes should be used to document contact attempts (unless other site-specific tools exist for this), as well as any other visit information not otherwise captured through other sources.
- **Audio CD of IDIs**: Audio file recordings are also considered to be source documentation for these interviews and must be kept in the participant file. Further details on the storage of these recordings is provided in Section 17.8.

17.2.3 Record Retention Requirements

Please refer to Section 3.8 of this manual. The documents for HOPE qualitative component must be maintained (at least) for the same timeframe as those for the HOPE study. No documents may be destroyed without written permission from DAIDS.

17.3 Participant Accrual

This section provides information on requirements and procedures for approaching participants for participation in the qualitative component. Informed consent considerations are provided in Section 17.4.

17.3.1 Study Accrual Plan and Site-Specific Accrual Targets

Approximately 18 participants per site are targeted to be included in the qualitative component, prior to the conclusion of the HOPE study (Table 17-1). This is anticipated to take place over a period of approximately 1 year (about 12 months), but will ultimately depend on the overall schedule of the HOPE study.

Table 17-1. Summary of Target Sample Size and Interviews, by Data Collection Type

Type of Qualitative Data Collection	# of Women per Site	# of Interviews per Site
Serial IDI (TOTAL)	~12*	30
Acceptor	***~6***	*~18 (3 per ppt)*
Non-acceptor/Product Switcher	***~6***	*~12 (2 per ppt)*
Single IDI (interesting cases)	≥3**	≥3
Single IDI (study decliner population)	~3***	~3
Total Per Site	**~18**	**~36**

*Serial IDIs will be systematically selected based on whether the participant accepts or declines a vaginal ring at enrollment.
**Interesting cases will be selected in consultation with the qualitative management team based on participant experiences during the trial.
***Recruited from those who express disinterest (during recruitment, screening or prior to enrolment) in being enrolled in HOPE

17.3.2 Accrual by Interview Type

Women selected for participation in the qualitative component will participate in one of three data collection activities, outlined below.

Serial IDIs: Approximately 12 participants from each qualitative site will be selected for serial IDIs in HOPE, six product acceptors and six non-acceptors/product switchers.

Acceptors: A participant who accepts study product at enrollment may be approached to participate in Serial IDIs as an "acceptor." Each acceptor will have three IDIs and qualitative staff should follow the interview schedule for acceptors outlined in section 17.5.1. Sites should outline details about accrual pace of acceptors in a qualitative recruitment SOP (e.g. "The site will recruit approximately one acceptor each month until accrual is complete.")

Non-Acceptors: A participant who does not accept study product at enrollment may be approached to participate in Serial IDIs as a "non-acceptor." Each non-acceptor will have two IDIs and qualitative staff should follow the interview schedule for non-acceptors outlined in section 17.5.1.

Product Switchers: If needed, sites may supplement their non-acceptor accrual with "product switchers". For the purposes of qualitative accrual, product switchers are those participants who accept study product at enrollment, but later decline to use the ring. Product switchers may have two or three IDIs depending on their individual circumstances. Qualitative staff should follow the guidance provided in section 17.5.1 and should contact the QMT with any questions about follow-up schedules. Sites should outline details about accrual pace of non-acceptors and product switchers in a qualitative recruitment SOP (e.g. "The site will recruit approximately one non-acceptor or product switcher each month until accrual is complete.") If a site is unable to complete accrual into the non-acceptor component even after enrolling product switchers, the site may increase the number of interesting cases interviewed in consultation with the QMT to fulfill overall accrual numbers.

Single "Interesting Case" IDIs: At least 3 single IDIs will be conducted at each site with "interesting case" participants. This group will be made up of special cases identified by site staff in consultation with the QMT and may include participants who have seroconverted, experienced ring expulsions or other challenges, had difficulty coming to study visits, or

admit to product sharing. Other interesting cases might include women who have suffered social harms as a result of ring use or study participation, or have indicated some social benefit. Other participants with unique experiences to share with the study team can also be included. Interesting cases should be selected over the duration of the trial (early, mid-point, late) after the interesting experience or event has taken place. Approval from the QMT should be obtained prior to conduct of any single IDI. However, in cases where this is not possible (e.g. a participant is withdrawing from the study and the interview needs to be scheduled quickly), notification of the QMT can occur after the interview.

To request approval to conduct a single IDI, site staff (as outlined in Qualitative Component SOP) should email the QMT and include the PTID and a short description detailing the reason for requesting an interesting case IDI. A copy of the e-mail and the QMT's response should be kept on file in the participant's chart.

If there is not good representation of participants whose product use preferences change over time in the serial IDI group, additional interesting cases may be selected toward the end of the study to capture information about this topic.

Decliner IDIs: Approximately three participants who decline enrollment into HOPE will be recruited for a single IDI in HOPE. Sites should recruit the first person who expresses disinterest in participating in HOPE; if that person declines to be interviewed, recruitment should continue in order of those who express disinterest in HOPE until the first decliner IDI position is filled. Before recruiting the remaining decliners, the MTN-025 QMT will review the debrief report of the first decliner and provide feedback to the site. After notification from MTN-025 QMT, the site can recruit the second and third decliners at a rate of no more than one decliner per week.

Qualitative staff should be prepared to interview participants anywhere (in the field during outreach, in their home, etc) in order to capture varied group of decliners (not just those willing to come to the clinic).

Sites should outline details of their recruitment plan in their Qualitative Component SOP.

17.3.3 Eligibility Criteria

Eligibility for the specific interview type to which a person participates is contingent upon meeting the criteria described below.

- Serial IDI: Participant is enrolled in HOPE, verbally confirms her willingness to participate in the IDI, and is HIV-negative at the time of her first interview. Ideally, SIDI participants will not have participated in MTN-032. If a site has a participant they would like to accrue for SIDIs who was enrolled in MTN-032, they should contact the QMT with a brief rationale and wait to feedback before approaching the participant for an IDI. Note: Enrollment is capped at 6 acceptors and 6 non-acceptors or product switchers at each site, so recruitment into each SIDI group should cease once these targets are met.
- Single "Interesting Case" IDI: Participant is enrolled in HOPE, verbally confirms her willingness to participate in the IDI, and has a unique experience or event to share, as determined by the site team in conjunction with the QMT.
- Single Decliner IDI: Participant is enrolled in the HOPE Decliner Population and verbally confirms her willingness to participate in the IDI. Note: After the first decliner IDI is completed, the site must receive approval from QMT before selecting the second and third participants to interview.

Participants may be excluded from any type of qualitative interviews if they have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make qualitative IDI participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives.

Note: For serial IDI participants, the most recent study HIV test results can be used to determine HIV-negative status. For example, if the first serial IDI interview is scheduled before her HOPE Month 2 visit, the HIV test results from Month 1 can be used for eligibility determination. If the first interview is done on/after HOPE Month 2 visit, the Month 2 HIV test results should be used.

17.3.4 Qualitative Component Participation Logs

Data about participation in the qualitative component will not be recorded on the site's HOPE Screening and Enrollment Log. However, it is necessary for sites to maintain a comprehensive record of all participants who are pre-selected, those who participate in the qualitative component, and reasons for non-participation. This should be recorded on the Qualitative Participation Log (QPL).

An entry in the QPL should be completed for each participant selected by site staff to participate in the qualitative component. This log will include HOPE PTID, whether participant was eligible, whether she agreed to participate, interview date(s), and reason for refusal (if applicable). A Qualitative Component Participation Log Template is available on the HOPE website.

Note: Product switchers recruited to supplement non-acceptor accrual targets may be recorded in the Non-Acceptor section of the QPL with the notation "PS" after their PTID. Some of these participants may have three interviews instead of two, depending on whether they receive residual drug feedback. More information is available in section 17.5.1.

Table 17-3: Sample Qualitative Component Participation Log (QPL)

PTID	HOPE/ Decliner Enrollment Date	I&D	Eligible or reason for ineligibility	Agreed to participate or reason for refusal	Interview 1 Date	I&D	Interview 2 Date	I&D	Interview 3 Date	I&D	Comments
SERIAL IDIs											
Acceptor											
Non-Acceptor											

17.3.5 Qualitative Component Progress Reports

Sites should report the cumulative number of participants interviewed through the 15th of each month to the QMT, along with other key progress indicators. More frequent reporting requests may be made by the QMT, if deemed necessary. The person responsible for this report should be described in the site Qualitative Component SOP. The template for reporting these statistics is available on the HOPE website under *MTN-025 Qualitative.*

17.4 Informed Consent

Informed Consent for participation in the Qualitative Component is embedded within the HOPE Enrollment ICF and the HOPE Decliner Screening and Enrollment ICF. Please see Section 5 of this manual.

Key elements of informed consent should be reviewed with participants, as needed, prior to the first interview, and willingness to continue with the interview should be confirmed. This review/confirmation can be documented on visit checklists (and chart notes as needed).

17.5 Visit Scheduling

This section provides information on visit scheduling for single and serial IDIs in HOPE.

17.5.1 Serial In-Depth Interviews (IDIs)

Acceptors and Non-Acceptors: Participants systematically selected to participate as acceptors or non-acceptors in serial IDIs should be informed of their selection prior to their one month follow-up visit so the first interview can take place during the Month 1 visit, if possible. If the participant is not able to complete the IDI during her Month 1 visit or she misses the visit for any reason, the first IDI may take place at an interim visit or at the Month 2 visit instead. If the participant has still not been interviewed by the end of her Month 2 visit window, sites should seek QMT guidance on whether or not to interview the participant or select a replacement.

For serial IDI participants who are product acceptors, a second, shorter IDI called the Drug Feedback IDI (DF-IDI) will be conducted and will focus primarily on the participant's reactions to receiving residual drug feedback during the HIV Prevention Options Counseling session. This interview should take place at or as soon as possible after the participant's Month 3 study visit. If the participant does not receive residual drug feedback at Month 3 or is unable to complete the interview during the Month 3 visit window, the interview may be conducted at the Month 6 study visit or any time during the Month 6 visit window instead. If, by the end of a participant's Month 6 visit window, she has not received residual drug feedback or has been unable to complete the drug feedback interview for any reason (e.g. is lost to follow-up or has withdrawn or been terminated from the study), the QMT may decide to replace this participant with someone new.

The final interview (SIDI2) for all acceptor and non-acceptor/product switcher IDI participants should be on or around the PUEV visit for HOPE and must take place before the participant is terminated from the study.

Interview Modality	**Timing**
Serial IDI1 (SIDI1)	Month 1 visit
Drug Feedback IDI (DF-IDI)	Month 3 visit
Serial IDI2 (SIDI2)	PUEV

Product Switchers: Product switchers should be counted toward a site's non-acceptor accrual target, but the schedule of interviews for product switchers is slightly different. If a site wishes to recruit a product switcher, they should approach her to complete an interview as soon as she switches (i.e. is identified as a participant who accepted study product at enrollment, but later declined). For the first interview, site staff should use the SIDI1 guide. If the participant joins the qualitative component as a product switcher and receives/has received residual drug feedback as part of her HIV Prevention Options Counseling, she should also receive a DF-IDI during the relevant visit window for which she received the drug feedback counseling. If the participant is unable to complete the interview during this time, the interview may be conducted at the next study visit or any time during that visit window instead. All product switchers, regardless of when they are recruited for qualitative interviews, should have a final IDI on or around the PUEV visit for HOPE. Note that IDIs for product switchers should occur at least one month apart and all IDIs must take place before the participant is terminated from the study.

Interview Modality	**Timing**
Serial IDI1 (SIDI1)	As soon as possible after recruitment
Drug Feedback IDI (DF-IDI)	During the visit window when RD feedback was given
Serial IDI2 (SIDI2)	PUEV

It is recommended that, if possible, the same HOPE interviewer be used for all serial IDIs with a participant in order to encourage greater rapport with the participant. Prior to the scheduled interview, study staff should contact the participant to remind them of the visit. The process for doing this should be described in the site Qualitative Component SOP.

17.5.2 Single IDI

Participants who are selected for a single IDI from the Decliner Population may be interviewed on the same day they are enrolled or may schedule a separate visit to complete the IDI. If a separate visit is scheduled, it should take place as soon as possible after enrollment and prior to the participant being terminated from the Decliner protocol.

Participants who are selected as "Interesting Cases" for a single IDI should be interviewed as soon as possible following their selection. Participants who are being interviewed because they have decided to withdraw consent from HOPE should be approached about willingness to participate in a single IDI before the participant is terminated. If the participant agrees, it should be documented clearly in the chart notes that the participant is withdrawing consent, but is agreeing to participate in one final interview and when this interview will occur. If the participant declines, this should be documented and she should not be pursued further. As with all IDIs, interesting case interviews must be completed prior to termination from the study.

Interview Modality	**Timing**
Decliner IDI (DIDI)	Same day as enrolled in decliner population or soon thereafter
Interesting Cases IDI (CIDI)	Soon as possible after selection and approval

17.5.3 Split Interviews

If a serial or single IDI participant is not able to complete an interview in one day, she may be rescheduled to come back and complete the rest of the interview on another day. In the event that this occurs, the circumstances should be noted in the chart notes, the interview debriefing report and a comment included on the QPL.

17.6 Visit Procedures

This section provides guidance on procedures for single and serial IDIs.

17.6.1 Preparing for the Interview

Before each interview, the following should occur:

- Ensure a signed copy of the Enrollment Informed Consent Form or Decliner Screening and Enrollment ICF is on file and that the participant consented to participate in IDIs (if the ICF contains specific check boxes for these procedures).
- Ensure the correct version of the IDI guide and any other supplemental tools are ready for use.
- Ensure the audio-recorder and interviewing space are ready.
- If a second serial IDI, review the debriefing report, notes and/ or transcripts from the previous IDI(s).
- Contact the participant(s) to remind them of the visit at least one day before the interview.

17.6.2 In-Depth Interview Procedures

The qualitative section of the MTN-025 website contains examples of checklists detailing the protocol-specified procedures that must be completed at HOPE qualitative study visits. These checklists should be modified as needed, then reviewed by the MTN CORE (FHI 360) for approval prior to implementation.

The IDIs will be conducted in private meeting rooms that are quiet enough for audio-recording. The IDIs should be located in a confidential private location that allows for neutrality, which may be at the clinic, or another venue preferred by the participant. If requested or preferred by the participant, the IDI can be arranged at the participant's home, or at a different outside location if she has provided consent for off-site visits. If conducted at the clinic, it is recommended to avoid the use of exam rooms to allow for a more comfortable discussion space. Please refer to Section 17.4 for the informed consent procedures for IDI.

The IDI will follow an IDI guide, but will allow for iteration, probing and digression on relevant themes. The interviewer may start the discussion with an ice-breaker to increase rapport as well as understanding of the context of participants' lives (e.g. asking about her home life, work, activities, family, friends). IDIs will be audio-recorded and later transcribed and translated by site staff or outsourced to a transcription/ translation agency. Ideally a note-taker will be present to take notes during the session, but if only an interviewer is available, the IDI may still go on, and the interviewer will take brief notes as the interview is ongoing.

Immediately following each IDI and on the same day as the interview, the interviewer should expand their notes and complete a debriefing report using the appropriate template for that interview type.

Further description of the management of the audio-files, interview notes, debriefing reports, visit checklists and transcripts of the IDIs is described in Section 17.8.

17.6.3 Procedures for Serial IDI Participants who Permanently Discontinue Study Product or Withdraw Consent

Serial IDI participants may permanently discontinue study product for clinical reasons and/or choose to terminate study participation early at any point during the trial. If permanent discontinuation takes place prior to a participant's final interview, she will continue to be considered a serial IDI participant, but the next interview should be moved up from its originally scheduled date to instead take place as close as possible to the participant's final product use experience. For participants who choose to terminate early, staff members should ask if the participant is willing to conduct a final interview prior to her termination from the study. If she consents, the interview may be conducted as long as the participant's willingness to participate is fully documented in her chart notes. In both of these scenarios, the SIDI2 guide should be used to guide the interview.

17.6.4 Reporting of Social Harms, Adverse Events, or Protocol Deviations

If any social harms (SH), adverse events (AEs), or protocol deviations (PDs) are reported by participants during qualitative interviews, interview staff should refer the issue to HOPE clinic/counseling staff as soon as possible and not more than 24 hours later to document and handle the AE, SH, or PD. If the issue is ongoing, ideally follow-up should occur after the interview is complete. However, if the issue is historical/resolved at the time of the interview, follow-up may occur at the next scheduled visit, per the discretion of the IoR. The site specific procedure for referring and documenting these occurrences should be outlined in the site Qualitative Component SOP.

Although the interviewer is required to share information about these events with other appropriate HOPE staff, she should aim to maintain a sense of trust, discretion and rapport with the participant by explaining this referral. Some sample language is provided below:

- *Thank you for sharing that issue with me. I want to reassure you that our conversations today will be kept private, but since this relates to your health, I need to pass this information along to [the nurse/doctor] so that they can follow-up with you [after our interview, during your next visit] and ensure you're okay. Are you okay with that?*
- *I appreciate your willingness to open up to me about that. I'm going to make a note for [the nurse/doctor, the counselor] to check in with you about that [after our interview, during your next visit] to make sure you're okay and all the necessary information is captured. This is the only part of our conversation I will share with them. Are you okay with that?*

Interviewers may also identify misunderstanding of key concepts that relate to study participant/informed consent during the interview (e.g. required study procedures, confidentiality). While interviewers should probe to fully understand the issue, they should avoid departures into counseling or health education during the interview. Instead, it is recommended that interviewers summarize any concerns on the debrief report, so that designated staff may determine appropriate follow-up—for example, general review of key concepts may be addressed as part of ongoing informed consent, or during group/waiting room education sessions.

17.7 Data Collection Procedures

Only data collection issues unique to the qualitative data are covered in this section. For more information on HOPE data collection procedures, see Section 14 of this manual.

For questions about this section or about general data collection policies, procedures, or materials for the HOPE qualitative component, please email the data management team at RTI (MTN025@rti.org).

All interviewer-administered guides should be administered in the preferred language of the participant. This may be different than the language she provided informed consent in, as long as fluency is confirmed/documented in both languages (e.g. on the IC coversheet and/or chart notes). Any deviation from this should be documented in the participant chart notes. Visit checklists should be used to guide the order of procedures for each IDI.

To maintain neutrality and promote an open/free environment, interviewers should be independent from (i.e. not involved in) any study procedures that will be discussed during the IDI.

17.7.1 Visit Codes

Visit codes will not be used for HOPE qualitative data collection activities. If a participant comes for her interview as an interim visit, a HOPE visit code will not be assigned unless a CRF is completed and faxed to SCHARP for other reasons (e.g. an AE or SH is reported).

17.7.2 Interview Guides and Materials: Supply and Storage

All guides and supplemental materials needed for the qualitative component of HOPE will be electronically supplied by RTI and should be printed locally. These materials will also be posted to the HOPE website under *Study Implementation Materials.* The site is responsible for maintaining an adequate supply of the current version of these documents in all languages. One copy of previous versions of guides and materials should be maintained in an archive, and all other copies destroyed. Procedures for form storage should be detailed in each site's Qualitative Component SOP.

17.8 Qualitative Data Management

As a condition for initiation of the qualitative component, each study site must establish procedures for data management that should be described in the Qualitative Component SOP. The SOP minimally should contain the following elements:

- Data collection, data back-up, transcription/translation procedures, and transmission procedures. This section should also include timeframes, and mechanisms for identifying when documents have been transmitted
- Procedures and timeline for resolving data quality control notes from RTI on both debriefing reports and transcripts
- Storage locations for blank guides
- Storage locations for documents identified by participant names or other personal identifiers
- Confidentiality protections, including the procedure for destroying audio files
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

HOPE qualitative data will be captured from the IDIs given at the site through audio recording and note-taking.

Audio Files

Following the interview or discussion, the audio file should be copied onto a password protected hard drive of a computer at the site, and saved onto a CD as source documentation of the interview. The CD should be labeled with the PTID and filed in the participant's file. Sites should upload the audio file on the same day as the interview to a secure (encrypted) FTP server* for RTI to receive as back-up (see Appendix 17-2 for FTP instructions).

Audio files of IDIs will be destroyed following finalization of transcripts (transcript finalization process described below), only after notification by RTI. The destruction process will be the responsibility of the IoR or his/ her designee and should be specified in the site Qualitative Component SOP. If required, sites may invite members of their community/CAB to observe the destruction. Once complete, destruction should be documented in the study files and confirmed via email with the data center (RTI).

Interview Notes

When an IDI is conducted, notes should be taken during each session to capture non-verbal communication and supplement the audio recording (or replace, if recording doesn't work or is refused). If the audio recording did not work, the interviewer will review the guide and expand the notes they have taken during the discussion to serve as an alternate transcript and a protocol deviation should be reported via a PD CRF for missing source documentation. Interview notes will be maintained by the sites, filed in the participant files.

Debriefing Reports

On the same day as the IDI, the interviewer should complete a Debriefing Report (DR) (using the appropriate template for that interview type),which will list basic information about the session and provide a summary report of the interview that can be used in "real time." After initial completion, DRs should undergo a site level quality review during which, at a minimum, all staff members who were present at the interview review the report for accuracy and completeness. A DR template will be provided by RTI, and is also available on the HOPE website under *MTN-025 Qualitative*.

- At RTI, the report will be read and reviewed by data team members and queries will be made on the report using MS Word's comment feature within **one week** of receipt of the file. The following are examples of queries:
  - Problems such as typos that lead to ambiguous meaning (e.g. "sore the medication" vs. "store the medication"), confusing terms or missing /potentially incorrect data
  - Sentences that are unclear
  - Clarification of local terminology or context

* An encrypted FTP is set by RTI's IT department. FTP use is account, username, and password protected with only designated team members from RTI and the site given access. The encrypted FTP site tracks user activity and file uploads making it easy to manage precisely by whom and when new files are updated, what changes are made, and what versions are most current.

- Within **one week**, the site is asked to correct or clarify any problems identified in the report directly in the report text using track changes and confirm the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query within the comment bubble.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated data team member reviews the corrected areas and deems the issue resolved or further follows up with the site until all necessary changes are made on the report.
- Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles and email the final clean report to the Qualitative Team. This final version of the DR should be printed and filed in the participant chart.

17.8.1 Transcription-Translation

The site staff will conduct the translation-transcription process per their site Qualitative Component SOP. All transcripts will be simultaneously transcribed and translated (when conducted in a local language) and written up in English unless there are unique local language sayings that should be preserved. These sayings can be kept in the local language with explanatory notes provided in brackets to explain their meanings. All expanded notes will be written in English. An example of a formatted transcript is available in Appendix 17-3. When translating the audio files into English, staff should follow their site's Translation SOP or outline any variations from this in the HOPE Qualitative SOP. Qualitative transcripts clearly documents who was responsible for the translation. Once all queries from RTI are resolved, the translator will type their name and date to the statement at the top of the transcript certifying the transcript is an accurate depiction of the audio file.

Additional quality checks of the transcription/translation should be performed at the site as described in the Qualitative Component SOP. This will include having a second staff member (i.e. one who did not translate the interview) who is fluent in the local language listen to the entire audio file while reading the English transcript. The quality of at least the first three transcripts per transcriber/translator will be checked in this manner to determine that the quality of translation is sufficient. These reviews will be continued until the quality is deemed acceptable for each transcriber.

Following this determination, quality checks will include listening to at least three 5 minute spots in the audio file as compared to the transcript. The text of each transcript will still be reviewed in its entirety even if the entire audio file is not reviewed. This process should be described in the Qualitative Component SOP.

If at any time the site coordinator decides that the direct transcription from audio to English transcript is not consistently of high quality, he/she should consult the MTN-025 Management Team to determine the corrective action, which may involve a temporary or permanent switch from a 1-step to a 2-step transcription/translation process for that translator.

Interviewing Quality Control Process

In addition to quality checks of the transcription, sites should also conduct in-depth reviews of the first 2 transcripts from each interviewer to provide feedback on moderating and interviewing techniques (e.g. adequacy of probing, appropriate linking of topics, fidelity to the guide, etc.) The feedback will serve to provide additional training to the interviewers and also to improve on the quality of the data collected.

After this site level QC process, the English language transcript will be uploaded to FTP site for RTI to review. Site teams should send English language transcripts to RTI as they become available (ideally one or two at a time, rather than as a large batch). RTI should receive an

English language transcript within **one month** of the interview date. Site teams should communicate with RTI if delays are anticipated. Transcripts will then undergo a similar QC process to that of the debriefing reports:

- Each transcript will be reviewed by a member of RTI's data team and queries will be made on the transcript using comment bubbles (or track changes for smaller/straightforward typos). The QC may include the identification of the following:
    - Problems such as typos that lead to ambiguous meaning, confusing terms or missing /potentially incorrect data
    - Issues identified by the protocol team requiring follow up, additional probing, or discussion with the interviewers. This could include general findings related to discussion facilitation techniques or specific issues that should be teased apart further in future IDIs.
    - RTI-reviewed transcripts will be emailed to the site within **approximately two weeks** of transcript receipt.
    - The site must then respond to all comments within **two weeks** of receipt of the reviewed transcript. Responses will be made either through changes directly in the transcript using track changes or through using the comment box in the reviewing mode of MS Word, when in-text changes are unable to be made. When changes in the text reflect content that was not spoken verbatim by the participant or interviewer, they will be inserted in [brackets].
    - After the revised transcript is received by RTI, a designated staff member will review the corrected areas and deem the issue resolved or else will follow up with the site until all necessary changes are made.
    - Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles, and finalize the transcript. RTI will notify sites of this finalization status via email and upload final transcripts to FTP site.

As mentioned above, audio files of IDIs are considered source documentation and will NOT be destroyed until directed by DAIDS following study completion. The destruction process will be the responsibility of the site Investigator or his/ her designee and should be specified in the site Data Management SOP. If required, sites may invite members of their community/CAB to observe the destruction. Once complete, destruction should be documented in the study files and confirmed via email with the data center (RTI).

The participant's final English transcript, and the final local language transcript (if applicable) must all be stored in the participant's file, or per site Qualitative Component SOP.

During the transcript QC process (outlined above), issues identified by the protocol team requiring follow up, additional probing, or discussion in subsequent interviews (if applicable) should be noted on the debriefing form. This could include general findings related to IDI facilitation techniques or specific issues that should be teased apart further in future IDIs.

17.8.2 File Naming Conventions

All data files should be named according to a standard naming format. The name should include the interview mode, followed by the PTID, data type (audio file, debrief report, transcript), and the date the discussion was conducted.
Interview Modes:

- CIDI for interesting cases IDI
- DIDI for decliner IDI

- SIDI for serial IDI with an A for acceptor or N for non-acceptor or NPS for non-acceptor product switcher (SIDI1A, SIDI1N, SIDI1NPS and SIDI2A, SIDI2N, SIDI2NPS) and
    - NOTE: For SIDI2, there are two interview guides (Acceptors and Non-Acceptors) and the guide used depends on the participant's ring choices *in the 3 months prior to her SIDI2*, not on her choice at enrollment. However, a participant who joined the qualitative component as an acceptor will ALWAYS be considered an acceptor for filename purposes, a non-acceptor will ALWAYS be labeled as a non-acceptor, a product switcher with ALWAYS be considered a product-switcher. This way, data filenames remain consistent across all serial interviews.
        - Example: A participant enrolled in the qualitative component as an acceptor decides to stop using the ring five months before study end and never accepts another ring before her PUEV visit. At PUEV an IDI is conducted using the non-acceptor guide and interview is labeled SIDI2A. On the debrief report and transcript, site will note which interview guide was used.
- DF-IDI for Drug Feedback IDI

Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. For the first iteration of the file that is sent to RTI for review, there is no need to include the editor's initials. It is only upon subsequent review (QCing) that this occurs.

For example, when reviewed for the first time, "SIDI1A_325-40008-1_Transcript_18JUL16" would become "SIDI1A_325-40008-1_Transcript_18JUL16_CM" and "SIDI1A_325-400081_Transcript_18JUL16_CM_NM" for the second revision. Once the document is finalized, all initials will be removed from the name and replaced with the word "FINAL" and become "SIDI1A_325-400081_Transcript_18JUL16_FINAL."

Staff Training: Site staff who collect data on the guides, enter data onto the debriefing reports, and transfer data to RTI will be instructed and in communication with RTI as described above in the staff training section.

17.8.3 Data Tracking

A Qualitative Data Tracking Log will be completed by RTI to maintain record of each audio file, debriefing report, and transcript that is submitted along with details regarding the submission date, query status, and finalization date. Sites will need to develop and outline their own tracking mechanism in the Qualitative Component SOP.

- **Maintain Confidentiality.** Respect confidentiality at all times. Be careful not to comment to other family members or neighbors about anything that you learned during the interview. This is especially important when interviewing participants about their sexual behaviors and intimate relationships.

- **Remaining Neutral.** It is especially important to be on guard against asking leading questions and influencing responses. Leading questions are those that imply a value judgment on your part. This can bias the responses that you will obtain because if the participant disagrees with you, they may be reluctant to state it.
    - *Biased question: "I know that most smart people in this community always use condoms, don't they?"*
    - *Better phrasing: "I have heard some people in this community say that most smart people use a condom, and others say that they know smart people who don't use condoms. What do you think?"*

- **Probe for Depth.** As much as possible ask follow up questions and probe for a deeper understanding of what the participant is saying. Examples of probing phrases might be: "Why?" "How did you feel when that happened?" "What did you do next?" "What do you think?" "What happened then?" "Can you tell me more?" "Could you describe X? I'm not sure I understand." Such probing also may require extra patience on the part of the interviewer.
    - *Example: Can you tell me more about why you didn't feel you could ask him to use a condom?*

- **If Uncertain, Verify Responses.** When you want to be sure that you have heard clearly what the participant said or that the information is accurate. You may ask them to repeat their response, or sometimes better, you can reflect the answer back to the participant.
    - *Example of reflecting back: So you told him that you think it's a sign of being responsible if you avoid sex while drinking?*

- **Do Not Respond to Questions.** If the participant asks you questions that are the focus of the interview, do not answer them. Your answers might influence how the participant will answer the rest of the questions. Instead, turn the question around and ask them what they think.
    - *Example: Well, I was hoping you could help me understand what people in this community say about how you get infected with the HIV virus.*

- **Be Patient.** It is not necessary to be asking questions every minute. Creating pauses and allowing silence can permit the participant to think more deeply about the topic. Don't be afraid to wait quietly while they think about a response or further probe, but be reassuring in your body language so the participant knows are genuinely interested in what she/he has to say.

- **Do Not Interrupt Participant's Work.** The participant is doing a favor to engage in a discussion and share her experience. If the participant must interrupt the interview to attend to a child, a customer, a neighbor, use this time productively to review your notes and think about what else you would like to ask and probe further upon.

† The Qualitative Interview Techniques section is adapted from the following reference: Mack, Natasha, Cynthia Woodsong, Kathleen MacQueen, Greg Guest and Emily Namey. Qualitative Research Methods: A Data Collector's Field Guide. RTP, NC: Family Health International, 2005.

- **Handle Time Wisely.** Always note the time when the interview begins and ends. As you begin the interview, evaluate how much time you may have with this participant and what are realistic goals for asking questions from the interview guide. Ideally, the interview will flow like a conversation rather than a series of questions and answers.

- **Be Truthful.** In obtaining informed consent or in responding to questions from participants during the interview, provide brief, truthful answers about the objectives of the study, the likely benefit to her or the community.

- **Moderate Tone of Voice.** During the interview, use a calm, moderate, friendly tone of voice.

- **Monitor Body Language.** Be sensitive to your participant's body language and aware of your own. Avoid body language that may send the signal that participants are giving "correct" or "incorrect" answers. Try not to appear closed off or like the participant is wasting your time.

Appendix 17-2: File Transfer Protocol Instructions

Enter the FTP site through https://ftp.rti.org (note if typing manually you must include the https://)

Each site will have a Username as follows:

MTN025-DTHF
MTN025-MRC
MTN025-MU-JHU
MTN025-UNC-Lilongwe
MTN025-UZ-UCSF
MTN025-WRHI

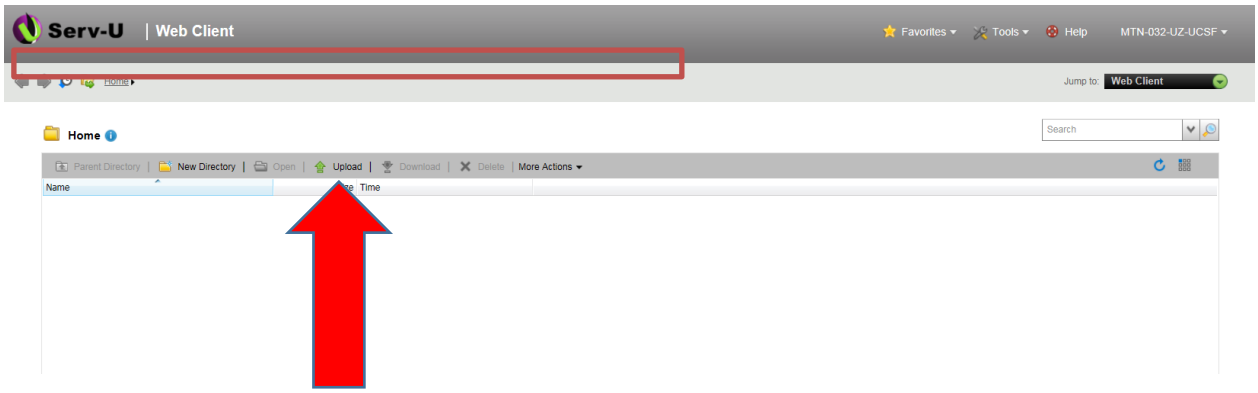
Passwords will be provided separately.

REMINDER: The FTP site is not meant to serve as a file storage location, it is **meant for transferring documents only**. Once you receive files from RTI, **delete those files from the FTP folder**. Only documents that are newly uploaded and waiting for RTI should be in the appropriate folders.

OPTION A: Web Client (good for uploading single smaller files)

When presented with "Client Options", please choose "Web Client" and then "OK, Continue"

The following window will appear.



To transfer a file from one's local computer folders to the FTP site:

- Navigate to the folder that corresponds to the file you would like to upload by double clicking on that folder (i.e. Upload the audio files in the Audio File folder). Click upload.
- A window will pop up and then click on "Browse." Navigate to the file you wish to upload and then click "Upload."
- If you have more documents to upload then please follow the previous instruction. If not, click on the "Close.". You will see the file(s) you have uploaded listed in the folder.

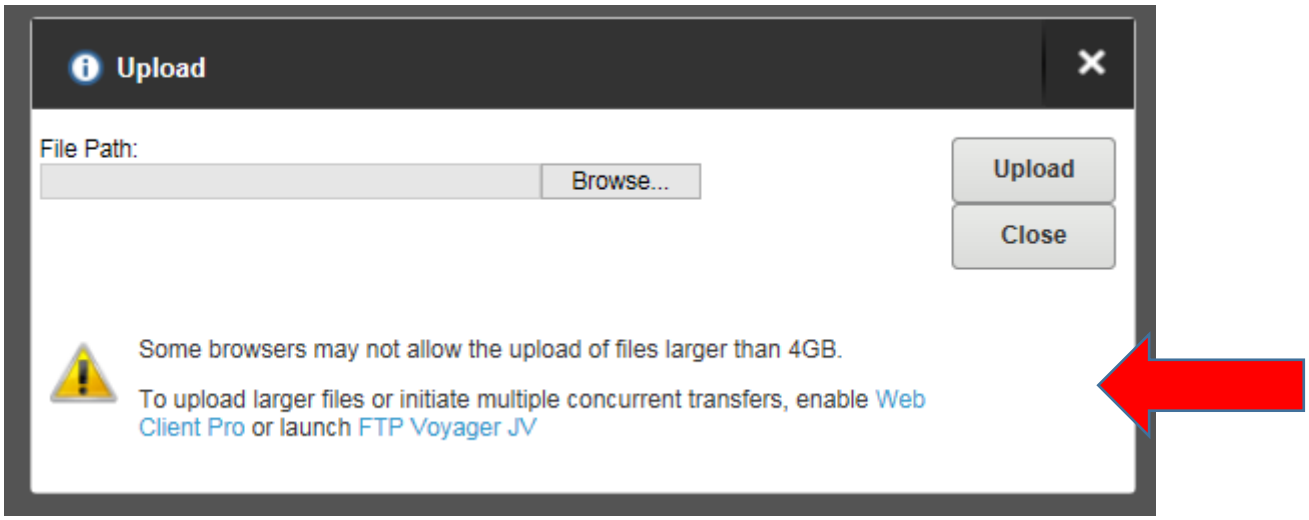
Note that when you transfer a file, it doesn't become removed from your local files, but rather a copy of it is made on the FTP server.

To download a file from the FTP site: Open up the appropriate folder. Put your cursor on the file you wish to open. Right click and select "Download." The file will be downloaded to your computer and you can open it.

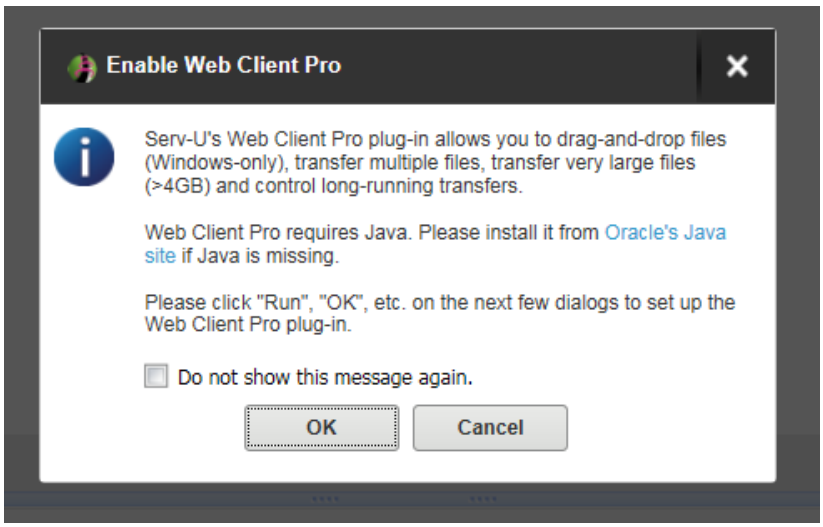
To save an updated file on the FTP site: when a file on the FTP site is opened and changes are made, the file must be saved to the user's local computer and then be transferred onto the FTP site. Please add initials as per SSP instructions to the end of the file name to distinguish one version from another (mostly relevant for QC'ing transcripts and debriefing reports.)

OPTION B: Web Client PRO (good for uploading larger or multiple files)

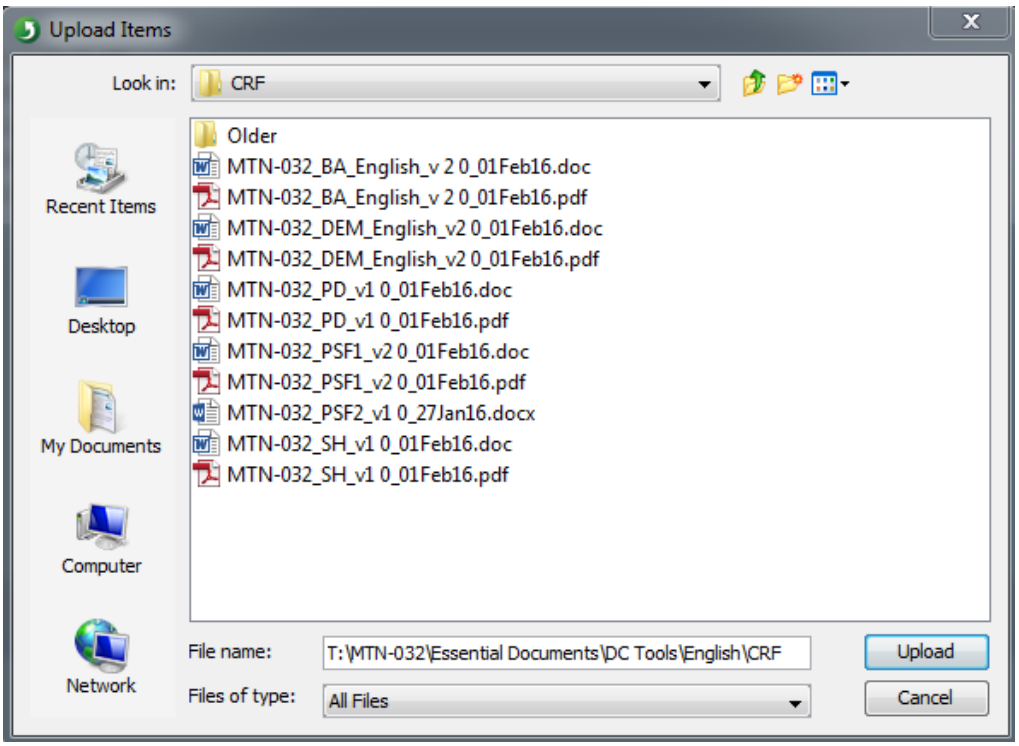
To transfer *multiple* files from one's local computer folders to the FTP site: Must use Web Client Pro or FTP Voyager JV.



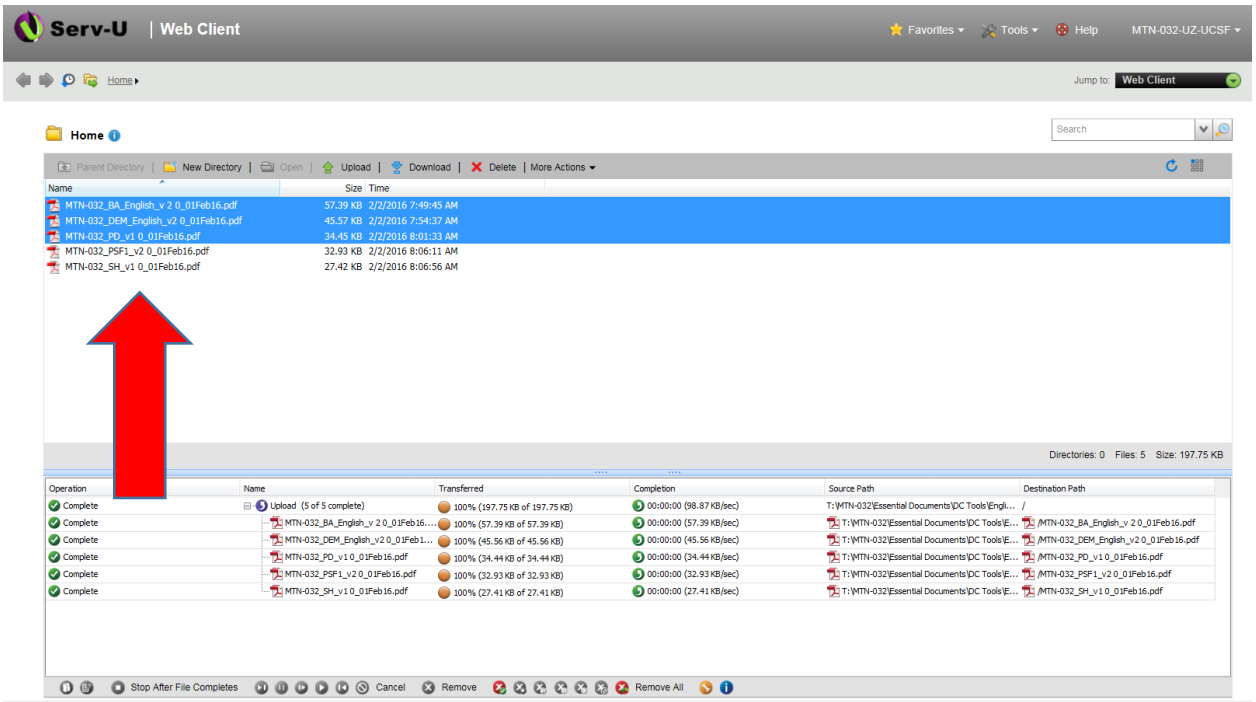
This pop up window will appear; you must have Java installed and be using Internet Explorer or Firefox.



Once you run Web Client Pro, then you can click “Upload” and this window will appear, allowing you to choose multiple files at once:



You will also be able to select multiple items for download using Web Client Pro.



Appendix 17-3: Example Formatted Transcript

Filename: SIDI2A_325-100015_Transcript_28Nov12

NOTE: This is for a participant who enrolled in the qualitatative component as an acceptor but sometime before her last 3 months in the study she stopped accepting a ring, therefore the non-acceptor SIDI2 guide was used. Her filename remains SIDI2A, however, in the transcript heading, the guide used will be noted as non-accceptor.

Transcript Sample:

Participant ID: 325-100015/ **Interview Mode:** Serial IDI 2/ **Interview Date**: 28 November 2012/ **Month in Study:** 6 / **Recent Visit #**: 6 / **Acceptor/Non-Acceptor/Product Switcher**: Acceptor / **Guide Used**: SIDI2 Non-Acceptor Guide **/ Clinical Site**: MRC Isipingo / **Audio File Name**: SIDI2A_325-10001-5_Audio File_28NOV12.WMA/ **Audio Recording Length**: 45m:11s/ **Interviewer Name(s)**: Funeka Vilakazi/ **Transcriber**: Hlamalani Rikhotso / **Translator**: Khosi Mbuli/ **Interview Language**: IsiZulu & English

I, [*Translator name***], certify on [***Date***], that this transcript is an accurate and complete representation of the original audio file. (***Complete this sentence by typing in the required information once RTI notifies site that all queries have been resolved***)**

Interview Text:

1. I: How is living in the new house?
2. *R: It's alright, but it is boring.*
3. I: Why?
4. *R: Everything is far away.*
5. I: Like?
6. *R: The shops, and the ATM [automatic teller machine] and most of the things are far away. If you do not have money you suffer [Laughing].*
7. I: Do you take taxis when you go to withdraw?
8. *R: I do not have money for the taxi. If I have money I can buy bread because there is a spaza shop [an informal shop operating from home]. A car is a necessity and we need to have it. It is allright at least I have my own space and privacy [Laughing].*
9. I: It is better. I was thinking about you and how the situation is in your new home? Are the children still there?

Formatting Tips:

- Use consistent Times New Roman or similar, 11 or 12 point font and 1.15 spacing.
- Header within document includes: Participant ID, Interview Mode, Interview Date, Month in Study, Visit Number, Acceptor/Non-Acceptor/Product Switcher, Guide Used, Clinical Site, Audio File Name, Audio Recording Length, Interviewer Name, Transcriber Name, Translator Name, Interview Language
- After header, label next section "**Interview Text**:" insert a hard return and begin transcribing the content of the audio file verbatim.
- Use "I:" before Interviewer remarks and "R:" before respondent remarks. *Italicize all respondent remarks*.
- Auto-number the transcript by paragraph so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number
- Replace all references to individual names or other identifying data with pseudonyms
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Long pauses can be represented by use of an ellipsis "…"
- Insert a footer with page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors
- Filename should follow instructions described above in section 17.8.2

Appendix 17-4: Qualitative Data Flowchart