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ACT Consortium Guidance:

Qualitative Research Protocol Template with example Tools and SOPs


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| This protocol template with example study documents and SOPs was prepared by ACT Consortium Social Scientists Clare Chandler and Joanna Reynolds with examples drawn from Sarah Staedke and her study team in Uganda ([www.actconsortium.org/PRIME](http://www.actconsortium.org/PRIME)), Lindsay Mangham and her study teams in Cameroon ([www.actconsortium.org/REACTCameroon](http://www.actconsortium.org/REACTCameroon)) and Nigeria ([www.actconsortium.org/REACTNigeria](http://www.actconsortium.org/REACTNigeria)), and Peter Mangesho and team in Tanzania ([www.actconsortium.org/InterACT](http://www.actconsortium.org/InterACT)).Please refer to the ACT Consortium Guidance document, Qualitative Methods for International Health Intervention Research, for more detail on approaches and methods of qualitative work.Suggested citation: Chandler, C.I.R., and Reynolds, J. (2013) ACT Consortium Guidance: Qualitative Methods Protocol Template with example Tools and SOPs. Available at [www.actconsortium.org/qualitativemethodsguidance](http://www.actconsortium.org/qualitativemethodsguidance) |

Study Title

**Names and institutions of principal investigators**

**Names and institutions of co-investigators**

**Names and acronyms of institutional review boards**

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# Background and Rationale

*Provide background information to put your study into wider social and scientific context:* *what is the situation on the ground in your study area and in what ways will your research contribute to furthering understanding of this situation. The background section should provide a justification for doing your study – set out what is already known/understood/interpreted related to your study topic and what/why new aspects need to be understood.*

# Conceptual Framework

*What is your theoretical perspective and framing for this study? Explain why the approach you propose to take will be most suitable to answering the gaps outlined in the background section.*

E.g. ‘In the PROCESS study, we adopt a theory-driven approach to our evaluation, aiming to understand what the PRIME intervention was and what it did, and aiming to contribute to broader discussions of how quality of care may be changed in similar contexts. It has been argued that carrying out theory-driven evaluations, including realist evaluation and the theory-of-change approach, is a way forward for opening the ‘black box’ and exploring the modes of effects of complex interventions (References), including within randomised controlled trials (reference). There is much variation in the concerns and methods used by those adopting a theory-driven evaluation approach (references), although most propose to explicate a theory or model of the programme/intervention and use this to guide and strengthen evaluation questions and analysis (reference). We set out to understand the PRIME intervention and its actions by mapping out the intended intervention programme and contrasting this with the realities of implementation in practice and local interpretations of intervention effects, as well as interpreting contextual influences and attempting to assess impact within and outside of the intended consequences of the intervention.’

*Conceptual frameworks are often include a visual representation, depicting the chronology of the study or expected relationships between different actors in the study landscape.*

E.g. Figure 1. Framework for ACT PROCESS study (www.actconsortium.org/PROCESS)

**Development of logic model**

Description and mapping

*Logic Model*

**Mechanisms evaluation**

Testing hypotheses and understanding interpretation

**Impact Evaluation**

Understanding of depth and breadth of impact

**Implementation evaluation**

Documentation of what was implemented

*Evaluation Model*

**Context Evaluation**

Understanding of context of implementation

# Aim

* *Be succinct – you can elaborate more below in the objectives section. Here, one overall aim of the research should be specified.*
* E.g. *‘*The PROCESS study aims to evaluate the implementation, mechanisms of change and context of the PRIME intervention at health centres in rural Uganda to inform interpretation of outcomes in the main cluster-randomised trial.’

# Objectives

* *List the separate strands of your investigation*
* *e.g. ‘*To develop a comprehensive logic model of the PRIME intervention, mapping components of the intervention through to their intended effects and outcomes.’
* *and ‘*To capture broader expected and unexpected impacts of the intervention and trial activities in communities, public health centres, and at private providers’

# Study Setting

*Describe the local context of the study. For example, what are the local governmental or organisational structures, politics, economics etc and how will your activities fit in with these during and after the study? What other studies or activities are happening in the study site and how will your work relate to those activities?*

# Study design

*Given an overview of the design of the study.*

E.g. ‘The PROCESS study is a mixed-method evaluation. Figure 1 depicts our framework for the evaluation activities. Our focus in this study is on documenting the PRIME intervention, understanding the mechanisms involved in the PRIME intervention in practice, and describing the context of the PRIME intervention and evaluation. The majority of impact evaluation activities are being carried out under the PRIME trial’

*There may be different approaches to tackling each of the objectives listed. If so, the design of the study can be divided into headings according to each objective.*

# Field Methods

*How are you going to carry out the research? What specific tools and activities will you undertake? Complete a section for each field work activity. Examples for in-depth interviews, focus group discussions and direct observations are below.*

## In-depth interviews

### Purpose

*Include a summary of the reasons for using this particular method for this study.*

E.g. ‘We plan to conduct in-depth interviews (IDIs) with health workers who received the intervention one year after roll-out. The purpose of the IDIs is to collect information on how the intervention was, or was not, enacted / adopted / resisted / adapted in practice. The interviews will explore the expected and unexpected impacts of the HFI and will explicitly aim to discuss perceptions of relevance as well as capture contextual issues that may have shaped interaction with, uptake of and impact of the intervention. IDIs are an appropriate method to understand these issues because they enable narratives of individuals to be elicited (reference), such that the interviewer can explore what was meaningful to individuals who were expected to respond to the intervention’s implementation.’

### Participants

*Who will be the interview respondents? Include sub-groups expected to differ in response according to conceptual framework.*

E.g. ‘Health workers from the intervention arm of the trial will be selected to participate by convenience sampling. We plan to complete up to 10 IDIs with health workers stationed at each of the intervention health centers.

#### Inclusion criteria

* *List criteria for eligibility for the study and justify rationale*
* E.g. ‘any health worker who has worked at the health centre since the time of the intervention and is a paid member of the health centre staff team will be eligible to participate.’

#### Exclusion criteria

* *List criteria for ineligibility for the study and justify rationale*
* E.g. ‘Volunteers will not be eligible to participate in the in-depth interviews because they were not the target of the intervention.’

### Sample size

*E.g. Number of respondents to be interviewed. Include a sampling matrix if relevant (see example for focus groups on page 2). Include a range, or maximum number if the process is to be iterative and exact number of participants is unclear. Some idea of numbers is helpful for review panels and for fieldwork planning but it is often not possible to give precise numbers until the fieldwork is underway.*

E.g. ‘We will conduct up to 25 IDIs with different target populations including implementers of the intervention (up to 5 interviews), health workers in the intervention arm (10 interviews), and key local and district stakeholders (up to 10 interviews).’

### Sample Selection

*How will you select your participants (e.g. randomly, snowball, convenience, purposive sampling) and from where? What is the rationale for this sampling strategy?*

### Permission and invitation

*Give details of those persons and organisations from whom you need to seek permission to carry out the interviews and how participants will be identified and invited to participate. This section should be expanded in detail into an SOP. An example is provided as* SOP 1. Approaching and inviting participants to interviews*. This may require study logs which should be prepared in conjunction with the protocol preparation, exemplified as* Appendix A. Health facility log *and* Appendix B. Health worker log*.*

### Consent process

*Give details of what information will be given to participants prior to participation. It is important to give the participant time to think about the study and what participation will mean for the individual. Consent is therefore sometimes requested prior to the date of the event, but most often at the time of the interview. An example information sheet can be found as* Appendix C *and an example consent form as* Appendix D*. Ensure that you have a separate mark on the consent form for inclusion of anonymous quotes in reports and manuscripts. The consent process should be detailed in an SOP, e.g.* SOP 2*.* Giving information and getting consent (interviews)

E.g. ‘Study personnel, including a translator if necessary, will seek informed consent from potential study participants for participation in the IDIs. The informed consent discussion will be conducted with potential participants at a convenient location (health center, office, residence) and in a language that the participant is most comfortable with, using a translator if necessary. If the potential participant cannot read, an impartial witness will be present during the entire consent process. After providing information answering any queries, the participant will be asked if they can give their written consent using consent form (reference)’

### Organising the interview

*Describe the characteristics of the location to be sought by the interviewer for the interview to take place, such as a private place outside of the health facility, and what equipment and materials will be needed. This should be expanded into an SOP, e.g.* SOP 3. Organising the interview.

### Introduction to the interview

*Describe the process of revision of information and gaining consent, if relevant, at the start of the interview. Make sure to include description of any incentives to be provided for participants.*

**Eg. ‘**Information about the objective of the interview and overall study will be provided to each participant at the commencement of each session. Confidentiality and anonymity will be explained. Each participant will be asked if s/he consents to be interviewed and for the interview to be recorded using a digital tape recorder. The participant will be informed that no incentive will be provided other than refreshments unless the participant travels to the interview, in which case transport will be refunded.’

### Topic guide, e.g. interview with health workers

*Include a draft of the topic guide(s) as appendices, e.g.* Appendix E*. Describe how the topic guide will be followed and the roles of different team members, e.g. the interviewer and note taker. This should be expanded into an SOP, together with the subsequent two sections, e.g.* SOP 4. Carrying out the interview*.*

### Recording interviews

*Provide details of how interviews will be recorded, for example note taking or tape recording. Justify the use of the method(s) chosen.*

**Eg. ‘**During each interview, the topic guide will be followed. A tape recording will be made of the interview and the field worker will make notes of the responses and non-verbal behaviour during the interview as well as notes about the setting and atmosphere of the interview.’

### Contact summary forms

*Describe methods for capturing a summary of each interview and when this will be done. The interviewer should be responsible for completing a contact summary form, with input from the note taker”. An example contact summary form can be found as* Appendix F*. Details of how this will be recorded and communicated should be given.*

**Eg. ‘**On completion of the interview, the interviewer and note-taker will meet to discuss the findings of the interview. The contact summary form will be completed immediately by hand and typed into a computer file, labelled with the identity number of the interviewee, and stored with the audio file. Contact summaries will be circulated to investigators weekly.’

### Team debriefing sessions

*Provide details of how the team will monitor progress and assess whether new questions need to be added, questions altered or whether saturation has been reached. This can be achieved through regular team debriefing sessions. An example debriefing form can be found as* Appendix G *and an example SOP for team debriefings found as* SOP 5. Carrying out team debriefings (interviews).

**Eg. ‘**Daily debriefing sessions will occur with all field workers and weekly meetings with the study investigators. Contact summaries will be used for reference during the meetings, and a further Debriefing Meeting Form will be completed. The purpose of the debriefing meetings are:

* For field staff to update each other on progress with data collection
* For field staff to discuss key findings from data collection so far, including differences and similarities
* For field staff and study investigators to discuss how these preliminary findings might feed into intervention design
* For field staff to discuss any problems/changes with the topic guides
* For field staff to get an idea of whether new ideas are still emerging or if saturation has been reached on key topics
* To provide a daily/weekly record of proceedings.’

## Focus Group Discussions

### Purpose

*Include a summary of the reasons for using this particular method for this study.*

### Participants

*Who will be participating in the focus group discussions? Include sub-groups expected to differ in response according to conceptual framework.*

**E.g.** ‘As outlined in , FGDs involving community members will be stratified into different target groups who may have different responses to the topics of interest and who may be more likely to discuss topics openly together than if groups were mixed. FGDs involving primary caregivers will be divided into groups of younger caregivers (usually women) vs. older caregivers, while those with heads of household will be divided into groups by gender (males vs. females). Because of the focus on access to health care, these community focus groups will also be divided into parishes where health facilities are present and parishes with no health facilities. All sub-counties will be covered. FGDs involving health care workers will be divided into groups by cadre (lower vs. mid) and will cover the different levels of health facility in the sub-district. FGDs will be held until no new information is gained, which will determine the total number of FGDs conducted.

Table 1 Target populations

|  |  |  |
| --- | --- | --- |
| **Target group** | **Definitions** | **FGD characteristics** |
| Primary caregivers | Person primarily responsible for daily care of young children (generally female) | Groups to be stratified into younger caregivers (< 30 years) vs. older caregivers (> 30 years)Each sub-countyParishes with vs without health facilities |
| Heads of households | Decision-makers and resource controllers for households with young children  | Groups to be stratified by gender (males vs. females)Each sub-countyParishes with vs without health facilities |
| Health care worker | Person providing health care at a public health facility | Groups to be stratified by level of health centre (HC II, III or IV) and by cadres of health workers: lower cadres (nursing assistants, lab assistants, volunteers, etc) vs. mid cadres (registered nurses, midwives, lab technicians, clinical officers, etc) |

####  Inclusion criteria

* *List criteria for eligibility for the study and justify rationale*

####  Exclusion criteria

* *List criteria for ineligibility for the study and justify rationale*

### Sample size

*State the number of focus groups and number of participants per focus group, with justification reflecting the methodology and sampling strategy. Include a sampling matrix if possible, like the example given below.*

**E.g.** Five FGDs with PCGs and five FGDs with HHHs will be held. These will cover the sub-groups identified in . One focus group with each PCGs and HHHs will be held in each sub-county. Across the sub-counties, half of the parishes will have health facilities within the parish and half no health facility. Amongst the PCG focus groups, three will be held with mothers over 30 years and two with mothers under 30 years. Amongst the HHH focus groups, three will be held with men and two with women. See matrix for distribution of the 10 focus group discussions across these categories.

Table 2. Sampling matrix for community FGDs

|  |  |
| --- | --- |
| PRIMARY CARE GIVERS | HOUSE HOLD HEADS |
| <30 years | >30 years | Female | Male |
| SC1\* | SC2 | SC3 | SC4 | SC5 | SC1 | SC2 | SC3 | SC4 | SC5 |
| PHC | PHNC | PHC | PHNC | PHC | PHNC | PHC | PHNC | PHC | PHNC |
| *FGD1* | *FGD2* | *FGD3* | *FGD4* | *FGD5* | *FGD6* | *FGD7* | *FGD8* | *FGD9* | *FGD10* |

\*SC refers to sub-county. Numbers will be randomly allocated to sub-counties in West Budama North

\*\*PHC refers to parishes with health centres. PNHC refers to parishes with no health centres.

### Sample Selection

*How will you select your participants (e.g. randomly, snowball, convenience, purposive sampling) and from where? What is the rationale for this sampling strategy? The rationale should reflect the methodological and theoretical framework for the study.*

**E.g.** Each sub-county will be randomly allocated a number from 1 to 5 and inserted into the matrix above. Parishes within each sub-county that have health facilities or don’t have health facilities will be listed, according to the allocation in the matrix. Two parishes will be randomly selected from this list of parishes to hold the PCG and the HHH focus groups.

Adult male and adult female community members will be selected by advertising prior to the date of the focus group. Villages will be selected randomly from a list of numbers representing eligible villages – according to the inclusion and exclusion criteria - through pulling the numbers from a hat.

### Topic guide for community FGDs

*Outline the process for introducing the study to participants and warming them up, as well as the key topics and questions to be addressed along with appropriate prompts. When developing the topic guide, consider the key areas to be explored, how best to ask these questions, the order in which they should be asked (ideally), and timing. Ensure that the questions are sufficiently open and not leading. See* Appendix H – Example FGD topic guide*.*

### Enrolment form

*Give details of how focus group participant details will be collected and when. See* Appendix I – Example FGD enrolment form*.*

**E.g.** Participants will be invited to sit in the group when they arrive. The note taker will ask each participant for demographic details one at a time, in a quiet voice to enable the participant to feel comfortable with answering personal questions, such as age.

### Permission and invitation

*Give details of those persons and organisations from whom you need to seek permission to carry out the focus groups discussions, and how participants will be contacted and invited to participate. See* SOP 6 – Approaching and inviting participants to FGDs *and also* Appendix J – FGD Recruitment log.

### Introduction and consent

*What information will be given to participants prior to the focus group discussion? How will informed consent be gained (written/verbal)? Refer to* Appendix D – Example consent form *and* SOP 7 – Giving information and getting consent (FGDs).

**E.g.** Information about the objective of the focus group and the overall study will be provided to each focus group. Confidentiality and anonymity will be assured and ground rules will be discussed with each group, posting the agreed rules on the flip chart or wall if participants are literate. Each participant will be asked if they consent to participate and for the focus group to be recorded using a tape recorder. No incentive will be provided, other than refreshments unless the participants have travelled to the interview, in which case transportation costs will be refunded.

### Set-up

*Describe the setting for the focus groups and how the research team will be seated. See* SOP 8 – Setting up the focus group discussion.

**E.g.** Each focus group will take place in a meeting area identified by local councillor. The meeting area will be enclosed for privacy if possible. The most appropriate time for the discussion will be elicited from the local councillor. If potential participants refuse on the day, this will be recorded in the study log. The researchers will be positioned within a circle with the respondents and a flip chart for ground rules will be within the circle if the group is literate.

### Conducting the FGDs

*Describe how the discussion will be structured, the roles of each research team member, and the methods used by the moderator to guide the discussion and manage group dynamics. This section should also address issues such as checking participants’ consent and formulating any ground rules at the beginning of the session. This should be expanded into an SOP; see* SOP 9 – Carrying out the focus group discussion.

### Recording interviews

*How will focus group discussions be recorded, for example note taking or tape recording? Justify the use of the method(s) chosen. Consider using more than one method if possible, for completeness and as a safeguard against technical problems with recording. For an example form for the note-taker, see* Appendix J – Example FGD note-taker form*.*

**E.g.** A note taking form will be used for all focus group discussions and will be completed by a separate note taker. In addition, a tape recording will be made of the discussion. Each participant will be given an ID number by the note taker who will draw a map of participants and record which participant made which contributions, to match up with the transcript of the focus group afterwards. The note taker will also make notes of the non-verbal behaviour during the interview as well as notes about the setting and atmosphere of the interview. During each focus group, the topic guide will be followed by the facilitator.

### Contact summary forms

*How will focus group discussions be summarised in a systematic way for the benefit of study investigators as well as for field staff reflection and records? See* Appendix K – Contact summary form – FGDs*.*

**E.g.** On completion of the focus group discussion, the facilitator and note-taker should meet to discuss the findings of the interview. The facilitator should be responsible for completing a contact summary form, with input from the note taker.

### Team debriefing sessions

*How frequently will those collecting data meet with each other and the study investigators to give feedback on the progress so far? Design a tool to capture the information and opinions discussed at the debriefing sessions to be shared with other investigators, and to monitor progress. See* Appendix L – Example team debriefing minutes form – FGDs*, and* SOP 10 – Carrying out team debriefings, (FGDs)*.*

**E.g.** Daily debriefing sessions will occur with all field workers and weekly meetings with the study investigators. Contact summaries will be used for reference during the meetings, and a further Debriefing Meeting Form will be completed. The aims of the debriefing meetings are:

* For field staff to update each other on progress with data collection
* For field staff to discuss key findings from data collection so far, including differences and similarities
* For field staff and study investigators to discuss how these preliminary findings might feed into intervention design
* For field staff to discuss any problems/changes with the topic guides
* For field staff to get an idea of whether new ideas are still emerging or if saturation has been reached on key topics
* To provide a daily/weekly record of proceedings

## Direct observations

### Purpose

*Include a summary of the reasons for using this particular method for this study.*

E.g. ‘A period of 3 months will be spent in a brief period of ethnographic fieldwork. Ethnography alongside intervention trials has been found to be valuable in revealing insights that may be hard for implementers and recipients of interventions to articulate or pinpoint due to their familiarity with their daily practice, and in showing how these activities are played out in social and wider contexts ([Evans & Lambert, 2008](#_ENREF_4)).’

### Participants

*Who will be the focus of observation? Include all potential participants but also acknowledge that, for unstructured observation, it is not always possible to anticipate actors who become of interest prior to fieldwork.*

E.g. ‘Members of the qualitative study team will spend time observing the implementation of the intervention activities, following the actors involved – members of the research team and others supporting the implementation, as well as the objects such as drugs, tests, paper and equipment ([Latour, 2007](#_ENREF_7)). This will involve observing and taking notes to describe activities, interactions and discourses relating to the intervention as it is enacted ([Spradley, 1980](#_ENREF_17)). It will also involve informal interviews with implementers and those in proximity to the intervention ([Spradley, 1979](#_ENREF_16)). Although the likely participants to be observed can be identified in advance, there may be others who are important to include as the study progresses but who are not anticipated *a priori* to be part of the picture of implementation of the intervention.’

### Sample size / Study duration

*For structured observations it may be possible to set out in advance the number of participants who will be observed, such as the number of doctor-patient dyads to be observed. For unstructured observations, it is more typical to estimate the length of time during which observations will be made.*

### Sample Selection

*How will you decide who to observe? What is the rationale for this sampling strategy?*

### Permission and invitation

*Give details of those persons and organisations from whom you need to seek permission to carry out the observations and how participants will be identified and invited to participate. This section could be expanded in detail into an SOP, particularly if to be carried out by a field team.*

### Consent process

*Give details of what information will be given to participants prior to participation.*

E.g. ‘Study personnel will seek written informed consent from each member of the implementation team in advance of observations and informal interviews. The nature and purpose of the research will be explained and participants will be free to withdraw from being observed at any time during the ethnography. If others who are in proximity to the intervention seem likely to become ‘informants’, i.e. observed and informally interviewed during the fieldwork, they will be informed about the study, invited to participate and asked to provide written consent on acceptance to participate (reference).

### Observation procedures

*Paint a picture of the process of observation*.

E.g. ‘Ethnographic observation will involve field workers in the qualitative study team following the activities of those implementing and interacting with the intervention activities. The field worker will attempt to capture in field notes a detailed description of activities relating to the intervention, how these are explained and interpreted by different actors, how different physical objects and reified concepts are used, referred to and employed to enact the intervention in practice. The fieldworker will principally be observing activities and interactions, but will also ask questions for clarification and will ask different actors about their practices, seeking to bring to light logics, concerns, classifications, processes and meanings that emerge from the intervention activities. ‘

### Recording observations

*Provide details of how observations will be recorded, for example note taking or tape recording. Justify the use of the method(s) chosen.*

**Eg.** ‘Discussions and informal interviews will be recorded manually in field notes, or, if an informant is likely to provide more detailed information and partake in a lengthy discussion, the field worker will ask to digitally record the interview for later transcription. From these observations, the researcher will attempt to produce a thick description of the intervention activities in the physical and social spaces that they employ ([Geertz, 1973](#_ENREF_5)).’

*If carrying out structured observations, include a draft of the observation guide(s) as appendices, e.g. Appendix N. Describe how the observation guide will be followed and the roles of different team members, e.g. there will be multiple observers, how they will cross-check for consistency between their observations and note taking. This could be expanded into an SOP.*

E.g. ‘Structured observation will be carried out with drug sellers, including pharmacists and informal drug sellers. The observation guide (Appendix N) will be used to record data in a systematic format, including verbal and physical communications and transactions with clients and unstructured fieldnotes to reflect on the relationship between those observed as well as the role of the researcher’.

### Team debriefing sessions

*Provide details of how the team will monitor progress and assess whether new questions need to be added, questions altered or whether saturation has been reached. This can be achieved through regular team debriefing sessions, as described for the IDIs and FGDs above.*

# Data Management and Analysis

## Data handling and data entry

### File Names

*How will participants/ focus groups/ documents containing notes and transcripts be labelled? It could also be useful to detail how individual participants will be referred to during the FGD to enable identification of different voices in the recordings and transcripts.*

**E.g.** Each interview or focus group will be allocated a unique identifying number. This will be written on the interview/focus group form, in notes taken, and will be used to name audio files and transcript documents. The format for naming files will follow , e.g. IDIFCH04; FGDVL09.

Table 3 Labelling files

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Type of data collection* | *Gender of respondent/group* | *Type of respondent/group* | *District**(transmission)* | *Number of interview/FGD* |
| IDI | MF | C=*clinical officer*N=*nursing officer/enrolled nurse*A=*aide* | HL | 01-12 |
| FGD | MFV= *village leader* | - | HL | 01-10 |

**Eg.** Although FGD participants will introduce themselves and be referred to in the discussion by their first name, they will also each be assigned a number by the note-taker to facilitate identification of different voices when transcribing and referencing quotations. The numbers will be assigned based on seating arrangements, and will reflect the file name assigned to the FGD, followed by their sequential number from the ordering of the group, for example FGDMH02/04.

### During field work

*Describe how data will be stored and confidentiality maintained in the field. All forms of data – recordings, transcripts, contact summary forms etc – should be addressed.*

**Eg.** All notes and audio files will be kept on the person of the field worker at all times or in a locked vehicle or room. Participants and non-participants will not be allowed to view the notes at any time and content of discussions and interviews will not be revealed to anyone else.

#### Interviews

*Describe how names of interviewees will be kept confidential in the field.*

**Eg**. Names of interviewees will not be used at any stage of the data collection process. Pre-determined identification numbers will be used on data collection form (topic guide and notes); Audio recordings will not start until the interviewee has given consent and will not record their name.

#### FGDs

*Describe how names of FGD participants will be kept confidential in the field.*

**Eg**. First names may be used during FGDs to refer to participants during the discussion and to enter demographic data in the field. However, notes will be taken using participant numbers as described above, and defined by a map of the group. All recorded and written records will only display the participant numbers and not individual names.

#### Observations

*Describe how names of observation participants will be kept confidential in the field.*

**Eg**. The researcher will generate a code or employ a pseudonym for each participant for use in all fieldnotes and computer based records. The names of individuals will not be noted at any time.

### After the field

*Describe how data will be stored and managed after data collection events, to ensure confidentiality is maintained.*

**Eg. ‘**Short summaries of fieldwork observations and of each interview will be typed into Word and shared only within the research team on a frequent basis. Researchers will type their detailed field notes directly into NVivo for coding at the end of each day or the next day. These field notes will be in English unless discussions had been held in other languages, in which case translation will occur as detailed for the in-depth interviews, below. All paper and soft copies of field notes, audio files, contact summary form, enrolment forms, consent forms and any other notes will be kept securely and if in digital format will be on a password protected computer, backed up regularly and only shared within the study team.’

### Transcription and Translation

#### Quantitative

*Describe the strategy for handling and entering any quantitative data, such as demographic details of participants.*

**Eg.** A data entry interface will be created for all quantitative data such as demographic details, in Excel. This will be double entered at the research offices. Data will then imported into NVivo as a new casebook. The relevant transcript and audio files will be linked to each case in the casebook.

#### Transcription

*Describe the chosen approach to transcription, which should reflect the study’s theoretical and methodological approaches. Define how much detail will be recorded in the transcription (for example any non-verbal communication, background noise etc), give clear explanations of any terminology such as ‘verbatim’ and indicate how the transcription will be laid out in a text document and any notations systems to be used. Also describe the process for checking and refining transcripts. Design an SOP to guide transcription eg* SOP 11 - Transcribing.

**Eg.** Audio recordings will be listened to carefully and then transcribed into Word in the language of the interview and then translated ready for exporting to NVivo (QSR International, Cambridge, MA) qualitative data management software for coding and analysis. All typed records will be kept in password protected computer hard drives and in a password-protected back-up drive. A standardised layout will be applied to all transcripts to facilitate the comparison of data at the analysis stage.([McLellan-Lemal, 2008](#_ENREF_9)) This will include a summary of quantitative data to describe the participant’s demographic characteristics, the location and other key information to situate the interview. Transcribers will be familiar with the theoretical perspectives of the study and will ensure this is reflected in the approach to transcription.([Davidson, 2009](#_ENREF_2)) For this study, the transcription method will reflect the interpretative approach underpinning the qualitative research, striving to convey as fully as possible the experiences and representations of the participants.([Roberts, 2007](#_ENREF_14)) This will include word-for-word transcription, recording all hesitations, pauses, utterances, cross-talking and incomplete sentences. An agreed set of notations will be applied to indicate these (see SOP). Major interruptions by other people or telephones will be recorded to contextualise any breaks in speech or repetitions. However, minor interruptions will not be recorded in order to ensure the flow of the transcript supports interpretation and analysis.([McLellan-Lemal, 2008](#_ENREF_9)) The transcription will be proof-read against the audio file by both the transcriber and a supervising member of the research team to check for accuracy, identify any missed or misheard words and to clarify any areas of confusion or unclear terminology.([Witcher, 2010](#_ENREF_18)) All queries and changes will be made using MS Word’s track changes tool. An agreed cleaned version of the transcription will be created, ready for translation.

#### Translation

*Describe the chosen approach to translation, which should reflect the study’s theoretical and methodological approaches. Define how the translation will be structured and laid out, and how any local or official terminology will be reported if no direct translation is available. Describe the process for checking translations. Indicate whether back translation will be carried out (if appropriate), how this will be done and how any discrepancies in text will be handled. Design an SOP to guide translation eg* SOP 12 – Translation.*.*

**Eg.** This study recognises the role of translation in constructing knowledge, and the role of translators as active agents in the research process.([Regmi et al., 2010](#_ENREF_13)) As such, translators will be familiar with the theoretical perspective of the research as well as its objectives. Translation will take a meaning-based approach from the original language into English. The translator will attempt to convey the meaning of the source language within the natural grammar of the target language – English. In addition, clarifications will be made in brackets, in order to capture and interpret for the reader meaningful elements of the source material, and the way the elements combine to form the meaning of the text as a whole. These clarifications will repackage the original narratives and utterances into words, grammar and idioms peculiar to the target language (English) ([Downing & Bogoslaw, 2003](#_ENREF_3)). Quality criteria for the translations will be comprehensibility (especially relating to culture-specific concepts), appropriateness (in content and approach) and accuracy (faithful to the source text and key facts) ([Downing & Bogoslaw, 2003](#_ENREF_3)). The original text will remain in the document, with the translation made beneath each short section of 4-5 lines. Sections of text will be double-checked for fidelity and appropriate communication of meaning by another member of the field team.

#### Cross-checking

*Describe how transcription and translation documents will be checked and revised by members of the research team prior to data analysis.*

**Eg.** Each transcript, and then each translation, will be checked by the team leader by listening to sections of the recordings and cross-checking the transcription, or reading sections of translations and cross-checking these with the original language texts. If errors are identified the entire file will be sent back for re-transcription or re-translation and the cycle of cross-checking will recur. If minor errors occur or in cases where transcription or meaning is unclear, the team leader will discuss with the person who carried out the interview/FGD to agree on a transcription or translation. If a clear transcription/translation cannot be agreed, or if the speech or phrase is ambiguous, two ore more options for interpreting the speech will be offered in the final transcription/translation.

## Data analysis

### Methods

*Describe the methods chosen to analyse the data, in reflection of the theoretical and methodological perspectives of the study. The methods should give an overview of how data will be coded and developed into meaningful themes and constructs from which theoretical narratives can be drawn. There should also be detail about how many people will be involved in the data coding and analysis, and if more than one, how multiple coding strategies will be negotiated and synthesised. An SOP should be developed to guide the whole data analysis process, for example see* SOP 13 – Data analysis and coding*.*

**Eg.** Field notes will be coded on a daily basis, as they are entered into NVivo. This will enable ongoing analysis and reflection on the purposes and findings of the research. This coding will group the descriptions of observations and informal conversations into themes. Alongside this coding, a reflective analytical diary will be kept, to draw out and justify emerging themes and lines of enquiry through the fieldwork process. Transcripts will be coded line-by-line, and then later developing themes and theoretical constructs by grouping the base coding together.([Auerbach & Silverstein, 2003](#_ENREF_1)) This method borrows from the iterative approach of grounded theory. A coding template will be developed from a few of the early transcripts, and will be used to code later transcripts in an on-going process as data is collected. As more transcripts are coded, the template will be further refined to reflect any new emerging ideas or themes. On-going analysis will be characterised by frequently going back to the original transcripts to ensure text is coded within context. Coding will be carried out using qualitative data analysis software, NVivo (QSR International, Cambridge, MA). Following the coding process, themes and theoretical constructs will be developed from both the field notes and the interview transcripts. This analytical process will attempt to situate the practices and perceptions of the intervention in the wider networks in which they are embedded, giving attention to cultural, historical, political and economic contexts ([Singer & Baer, 1995](#_ENREF_15)). The analysis will be carried out with reference to wider bodies of literature and theory regarding these particular intervention types as well as theories relating to the everyday work of public health as enacted by the different actors involved in this intervention.([Lock & Nguyen, 2010](#_ENREF_8))

### Organising the data

*Describe the practical processes of storing and managing the data, indicating any software to be used for this purpose.*

**Eg.** Data files will be imported into new QSR NVivo project, where all transcriptions, contact summaries and audio files will be filed.

### Quantitative data

*Describe the methods to manage and analyse any quantitative data such as demographic details.*

**Eg.** Quantitative data will be double entered into an Excel spreadsheet and then imported into NVivo as a new casebook, to be linked with the relevant transcript and audio files. Descriptive statistical analysis will also be performed on the data in Excel.

### Initial coding

*Describe how the qualitative data will be coded at the initial stage, detailing whether a pre-determined coding framework will be used, or whether codes will be generated empirically from the data. This is particularly important for team-based coding. See* SOP 13 – Data analysis and coding.

**Eg.** A selection of two or three transcripts will be chosen at random for each sub-group (FGDs with sub-group 1, FGDs with sub-group 2, FGDs with sub-group 3 and IDIs with staff). These transcripts will be used to generate a coding template for the remaining data. Different coding structures should be developed for each sub-group.

Coding will be conducted by reading the data line by line, trying to identify the underlying meaning or concepts behind the statement. Each line, or few lines, will be labelled according to the idea(s) in the transcript, using a short title, and used to create a new tree node in NVivo. When the same idea appears again, this will be coded to the same node, creating a list of repeating ideas. As coding develops and themes emerge, nodes will be arranged in groups under a parent node labelled with the theme. Beyond this, themes may be collated into broader groups representing theoretical constructs, again as labelled parent nodes. When creating theoretical constructs, memos will be made to describe the rationale behind creating the construct.

### Creating a coding template

*If initial coding has been developed from a few examples of the raw data, a coding template should be developed early on to guide the coding of the rest of the data. Describe how this will be developed. This is particularly important for team-based coding.*

**Eg.** After the initial coding has been completed on the sample of transcripts the lead investigator will discuss with the team the emerging coding structure, to decide which nodes and structures are most appropriate for the data and to create an initial coding template.

### Coding

*Describe how the coding template will be used to code the remaining data, including stating the procedure for identifying and adding new codes, or refining existing codes. This is particularly important for team-based coding.*

**Eg.** The coding template will be used to continue coding the rest of the transcripts. The template will be updated as new ideas, themes and theoretical constructs emerge. Periodically, the nodes and groupings developed will be explored and moved around through discussion with the research team and recourse to literature relating to the themes emerging. Codes will be revisited regularly to ensure their positioning reflects the revised coding template. Once all transcripts have been coded, the coding tree containing repeating ideanodes, theme nodes and some theoretical constructnodes will be finalised.

### Development of theoretical constructs and narratives

*Describe how the coded documents will be examined and arranged to develop theoretical constructs and drawn together as coherent narratives. Also describe how the narratives will be related to existing literature and the theoretical framework of the study, to develop conclusions.*

**Eg.** The fully coded project will be explored for theoretical constructs by the ACT Consortium social scientist in conjunction with the research team. This will include the running of queries, looking at any differences in the concepts emerging according to sub-groups, and different characteristics of participants.

The ACT Consortium social scientist, with input from the research team, will develop a narrative bridging the original research concerns with the participants’ subjective experiences. The aim of the theoretical narrative will be to retell the participants’ stories in terms of the theoretical constructs. The findings will be related to wider theory and literature in the topic of interest. This will involve relating the findings to the original conceptual framework, which may be adjusted or replaced by a new framework based on the evidence from the study. Drawing from this narrative, the research questions for the study will be revisited and recommendations made.

# Ensuring ethics and quality in practice

## Ethics

*Include a statement about the ethical commitments of the researchers, how this will be maintained in the study and the ethical boards approving the study.*

**E.g.** The field team will be briefed in the ethical guidelines of the Association of Social Anthropologists and will place these priorities of protecting research participants, anticipating harms, avoiding undue intrusion, rights to confidentiality and anonymity, intellectual property rights and involvement in research ahead of other requirements, whether for their own gain or that of the research. The study has been approved by XX ethics committee, which requires annual renewal (number XX).

## Quality assurance

*Indicate what quality assurance measures will be put in place for each stage of the research study, with detail of how and when these will be monitored.*

**Eg.** Standard operating procedures (SOPs) will be written for all stages of the study, including recruitment, data collection and data analysis, and these will be used as the basis for quality assurance assessment protocols. The SOPs will be developed in conjunction with the field research team, and all members of the team will be trained on how to interpret and implement the SOPs throughout the study. The regular debriefing meetings and review of data collection forms by the field team and ACT Consortium Social Scientist should help to ensure that data collection processes are being conducted in an appropriate and consistent manner.

At least one assessment of quality assurance will be conducted during the data collection phase by a moderator who will be external to the field team, preferably a collaborator from a similar study in a neighbouring country. These assessments will use the SOPs as guidance against which to evaluate the practice of the research team in each stage of the research process including recruitment, data collection and data analysis. If any issues or concerns arise as a result of this, the moderator will take action as appropriate.

# Team roles

*Give a break-down of all of the key research team staff with brief job descriptions.*

**Eg.** Lead field social scientist – managing and overseeing recruitment and data collection in the field; input into data analysis and writing up stages.

ACT Consortium research fellow – designing and supervising the research study; responsible for monitoring progress of data collection; leading on data analysis and writing up.

Research Assistant 1 – identifying and recruiting participants; assisting with data collection; input into writing up.

Research Assistant 2 – identifying and recruiting participants; assisting with organisation of interviews/FGDs; assisting with transcribing and translation.

Transcriber/translator – primary responsibility for conducting transcription and translation of all relevant field documents.

## Data collection

*Identify which team members will be involved in data collection, doing what roles and under whose supervision.*

**Eg.** The lead field social scientist will act as the moderator for FDGs and interviewer in IDIs, and will have overall responsibility for the organisation of data collection, for monitoring the recruitment and data collection processes in line with the quality assurance protocol, and for holding team debriefings and feeding back to other members of the research team.

The research assistants will assist in the recruitment process, in arranging suitable times and locations for the FDGs/IDIs and for ensuring participants are able to attend the events. For the FDGs, one research assistant will act as note-taker and the other will act as coordinator, ensuring the organisation and arrangement of facilities at the FDG. Research assistants may take it in turns to act as note-taker and coordinator, as desired. Following the FDGs/IDIs, the lead field social scientist will be responsible for ensuring that the contact summary forms are completed immediately after data collection, and sent as soon as possible to the ACT Consortium research fellow.

## Data entry

*Who enters quantitative data? Who transcribes? Who translates? Who checks and edits?*

**Eg.** The transcriber will be responsible for transcribing each of the digital recordings immediately after each recording, checking it against the audio file, and presenting it to the lead field social scientist and research assistants for further checking and additional edits. The transcriber will also be responsible for translating the transcripts into English and for arranging review of the translations by other members of the research team. Where necessary, the research assistants will also be required to conduct transcription and translation of data. The lead field social scientist will have responsibility for checking and ensuring that transcription and translation are conducted appropriately, in line with the SOPs, and for sending them to the study investigator as soon as each one is completed and checked.

The transcriber and research assistants will be required to enter the data from each of the FDG/IDI enrolment forms, the FDG note-taker’s forms and the contact summary forms into Word or Excel documents (translating where appropriate). The research assistants should be responsible for taking minutes at the regular team debriefing sessions. The transcriber and research assistants will also collate and store appropriately the consent forms and other data collection materials as per the protocol.

## Data analysis

*Who is responsible for co-ordinating data analysis?* *If more than one person is coding, identify who will be responsible for collating and synthesising the multiple codings.*

**Eg.** The study investigator will take overall responsibility for the data analysis, but will consult with the research team at regular stages throughout the analysis phase to feed into the coding process.

# Time lines

*Include a timeline for data collection, entry and analysis milestones, including specific milestones for each team member. Give as much detail as possible; for example for data analysis, include:*

* *When coding of the initial transcripts will be completed and who sent to for checking and feedback, merging and agreement of template for coding*
* *When coding of the remaining transcripts according to template will be completed for each set of interviews/focus groups/observations.*
* *When analysis of codes for theoretical constructs will be completed*
* *When narrative and write-up will be completed.*

**Eg.**

| **Dates** | **Study phase** | **Activities** | **Who** |
| --- | --- | --- | --- |
| Beginning of first quarter, 2011 | Scoping & Preparation | * Meet field team
* Draft SOPs and topic guides
* Assess locations for data collection
* Consult with InterACT regarding recruitment and participants
 | * LFSS, ACT RF, RA1, RA2, TT
* LFSS, ACT RF, RA1, RA2,
 |
| Beginning/mid first quarter, 2011 | Training | * Conduct training with field team prior to data collection
* Revise and finalise SOPs.
* Pilot topic guides and revise.
 | * ACT RF
* LFSS, ACT RF, RA1, RA2,
 |
| Mid/end of first quarter to end of second quarter, 2011 | Data Collection | * Begin recruitment and data collection
* Transcribe and translate data as it is collected
* Regular team debriefings and feedback to wider research team
* Share data with ACT RF
* On-going coding and analysis of data
 | * LFSS, RA1, RA2
* TT
* LFSS, RA1, RA2, TT
* LFSS
* ACT RF
 |
| Mid second quarter to mid third quarter, 2011 | Data Analysis | * Continue coding
* Develop theoretical constructs and narratives
 | * ACT RF
* ACT RF
 |
| Mid third quarter to early fourth quarter, 2011 | Writing up | * Write up final report
* Write up publication(s)
 | * ACT RF, LFSS, RA1
* ACT RF, LFSS, RA1
 |

# Appendices: example tools

**Appendix A** - Example health facility log

**Appendix B** - Example health worker log

**Appendix C** - Example information sheet

**Appendix D** - Example consent form

**Appendix E** - Example IDI topic guide

**Appendix F** - Example contact summary form - IDIs

**Appendix G** - Example team debriefing minutes form - IDIs

**Appendix H** - Example FGD topic guide

**Appendix I** - Example FGD enrolment form

**Appendix J**  - Example FGD recruitment log

**Appendix K** - Example FGD note-taker form

**Appendix L** - Example contact summary form - FGDs

**Appendix M** - Example team debriefing minutes form – FGDs

**Appendix N** - Example structured observation form

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Health facility code** | **Date approached 1st (dd/mm/yy)** | **HW identified** | **Date to return (dd/mm/ yy)** | **Date approached 2nd (dd/mm/yy)** | **HW identified** | **Date to return (dd/mm/ yy)** | **Date approached 3rd (dd/mm/yy)** | **HW identified** | **Date COMPLETE (dd/mm/ yy)** | **No. of HWs** |
| 1 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 2 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 3 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 4 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 5 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 6 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 7 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 8 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |
| 9 |   |   | Yes | No |   |   | Yes | No |   |   | Yes | No |   |   |

Appendix A. Example Health Facility Log

Appendix B. Example Health Worker Log

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Health facility code** | **HCW Study ID** | **Position** | **Date visited 1st (dd/mm/ yy)** | **1st Reason** | **Date of rescheduled visit (dd/mm/ yy)** | **Date visited 2nd (dd/mm/ yy)** | **2nd Reason** | **Date of rescheduled visit (dd/mm/ yy)** | **Date visited 3rd (dd/mm/ yy)** | **3rd Reason** | **Enrolled**  | **Date complete (dd/mm/yy)** |
|   |   |   |   |  |  |   |  |  |   |  | Yes | No |   |
|   |   |   |   |   |   |   |   |   |   |   | Yes | No |   |
|   |   |   |   |   |   |   |   |   |   |   | Yes | No |   |
|   |   |   |   |   |   |   |   |   |   |   | Yes | No |   |
|   |   |   |   |   |   |   |   |   |   |   | Yes | No |   |
|  |  |  |  |  |  |  |  |  |  |  | Yes | No |  |
|  |  |  |  |  |  |  |  |  |  |  | Yes | No |  |
|  |  |  |  |  |  |  |  |  |  |  | Yes | No |  |
|  |  |  |  |  |  |  |  |  |  |  | Yes | No |  |

Appendix C. Example Information Sheet

|  |
| --- |
| **INFORMATION SHEET****In-depth interviews****Introduction**XXXX and colleagues from XXXX are conducting a study to evaluate activities that have been undertaken at government-run health facilities to improve the health of children in this area. We are interested in learning about the delivery of health care services in this area and how attempts to improve services are working in practice from the perspective of implementers, health workers, private drug shops, and local and district stakeholders. **Why is this study being done?**We would like to know more about how activities to improve health care have been implemented in this area. To do this, we are asking selected implementers, health workers, private drug shops, and local and district stakeholders questions about their perspective on the implementation and effects of this intervention. This information will help us understand how and why health facility improvement activities have affected the health of children in this area. **What will happen today if I take part in this study?**Today, we would like to ask you some questions about your perspective on the implementation and effects of intervention activities. We will take notes of the discussion and a recording will also be made using a digital voice recorder. After we ask these questions today, we will not ask you to do anything further. All information gathered will be treated as confidential by the study personnel, and records of the interviews will be kept securely in locked filing cabinets and offices. No personal identification information such as names will be used in any reports arising out of this research.**How long will the study last?**Today, the interview will last about 60-90 minutes, however the total duration of the study will be about 2 1/2 years**Can I stop being in the study?**You can decide to stop participating at any time. Just tell the project researcher right away if you wish to stop the interview.**What risks can I expect from being in the study?**Participation in any research study may involve a loss of privacy. Information you provide about your experiences and opinions will be recorded, but your name will not be used in any reports of the information provided. No quotes or other results arising from your participation in this study will be included in any reports, even anonymously, without your agreement. The information obtained from these interviews will only be used by the project researchers and will be locked at our project offices. We will do our best to make sure that the personal information gathered for this survey is kept private. **Are there benefits to taking part in the study?**There will be no direct benefit to you from participating in this study. However, the information that you provide will help researchers and policy-makers understand how best to improve health services in this area, especially in the treatment of malaria.**What other choices do I have if I do not take part in this study?**You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.  **What are the costs of taking part in this study? Will I be paid for taking part in this study?**There are no costs to you for taking part in this study. You will not be paid for taking part in this study. **What are my rights if I take part in this survey?**Taking part in this study is your choice. You may choose either to take part or not to take part in the survey. If you decide to take part in this study, you may change your mind at any time. No matter what decision you take, there will be no penalty to you in any way.**Who can answer my questions about the study?**You can talk to the researchers about any questions or concerns you have about this survey. Contact XXXX or other members XXXXX on telephone number XXX. If you have any questions, comments or concerns about taking part in this study, first talk to the researchers. If for any reason you do not wish to do this, or you still have concerns about doing so, you may contact XXXX Ethical Committee at telephone number XXXX.**Giving consent to participate in the study**You may keep this information sheet if you wish. Participation in this survey is voluntary. You have the right to decline to participate in the study, or to withdraw from it at any point without penalty. If you do not wish to participate in the study, you should inform the researcher now. If you do wish to participate in this survey, you should tell the researcher now, or at the time of the interview if this is to take place in the future. If you do not agree to quotes or other results arising from your participation in the study being included, even anonymously, in any reports about the study, please tell the researcher now.  |

Appendix D. Example Consent Form

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CONSENT FORM**Study Title: XXXXHead of Research: XXX* The study has been explained to me in a language that I comprehend. All the questions I had about the study have been answered. I understand what will happen during the interview and what is expected of me.
* I have been informed that it is my right to refuse to take part in the interview today and that if I choose to refuse I do not have to give a reason, and that it will not prejudice the care that I can expect to receive now, or in the future.
* I have been informed that anything I say during the interview today will remain completely confidential: my name will not be used nor any other information that could be used to identify me.
* I am aware that due to the nature of the interview topic, my HIV status may be revealed to the interviewer and research team.
* It has been explained that sometimes the researchers find it helpful to use my own words when writing up the findings of this research. I understand that any use of my words would be completely anonymous (without my name). I have been told that I can decide whether I permit my words to be used in this way.

 Circle response:

|  |  |  |
| --- | --- | --- |
| I agree to take part in the study:  | Yes | No |
| I agree that my own words may be used anonymously in the report  | Yes | No |

**Signature of participant:**

|  |  |  |
| --- | --- | --- |
| **NAME**(in capital letters) | **SIGNATURE OR THUMB PRINT** | **DATE OF SIGNATURE**(in DD/MM/YYYY) |
|  |  |  |

 **If a thumb print is provided, signature of witness:**

|  |  |  |
| --- | --- | --- |
| **NAME**(in capital letters) | **SIGNATURE** | **DATE OF SIGNATURE**(in DD/MM/YYYY) |
|  |  |  |

Tick box if participant refuses to have witness present **Signature of study staff taking consent:**I have discussed the study with the respondent named above, in a language he/she can comprehend.I believe he/she has understood my explanation and agrees to take part in the interview.

|  |  |  |
| --- | --- | --- |
| **NAME**(in capital letters) | **SIGNATURE** | **DATE OF SIGNATURE**(in DD/MM/YYYY) |
|  |  |  |

 |

Appendix E. Example IDI Topic Guide

|  |
| --- |
| Participant IDNO |\_\_|\_\_|\_\_|\_\_| Gender Male / Female Researcher Initials |\_\_|\_\_|\_\_|Health facility number |\_\_|\_\_| Date |\_\_|\_\_/\_\_|\_\_/\_\_|\_\_| **Introduction**I am \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* General purpose of the study
* Aims of the interview and expected duration
* Who is involved in the process (other participants)
* Why the participant’s cooperation is important
* What will happen with the collected information and how the participant/target group will benefit
* Any questions?
* Consent

**Warm up [demographic & work history]**Can I ask some details about you and your job?Job Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Highest Educational Grade attained \_\_\_ \_\_ Year of graduation\_\_\_\_\_\_\_\_\_\_\_\_Years worked at this facility |\_\_|\_\_|yrs|\_\_|\_\_|mths Are you originally from this area/district? □ Yes □ NoHow old are you? □ Under 30yrs □ 30-40yrs □ Over 40yrs Do you have any children over 5yrs old? □ Yes □ NoDo you have any children under 5yrs old living with you now? □ Yes □ No**Now I am going to ask you some questions about your experiences as a provider in this facility.** |
| **Domain** | **Topic and Probes** |
| Aware of need to change? | What is your current practice with diagnosing malaria and prescribing antimalarials? Probes: what steps go into your usual diagnostic process and what factors affect whether each of these steps is completed? How do you decide which patients to give antimalarials to and how does this relate to what you know about district/MoH strategies for malaria control? Are you aware of any weaknesses in your current strategy for prescribing antimalarials? Probes: Do you think antimalarials should be prescribed any differently now that ACTs are becoming available? Have you tried to change your practice in antimalarial prescribing? |
| Perception of tests / culture | What tests do you have available for diagnosing malaria and other conditions? Probes: What are the strengths and limitations of these? What is your experience of working in facilities where microscopy (and other tests) are available? What do you think is the role of your clinical judgement when tests are available? Have you heard of RDTs (perceived strengths, limitations)?If RDTs were available to you, how might they fit with consultation and diagnostic process in practice?Probes: What problems could you foresee and what ways do you think these might be solved? (e.g. timing – who should conduct the test and what should happen whilst waiting for the result?) |
| Knowledge | Are you aware of guideline changes for antimalarial prescribing and malaria diagnosis? Prompt: Where did you receive this information? Do you trust the source of information and why/why not?What has been your experience of training in malaria diagnoses before you started working and during your career?Prompt: What do you think about what you have been taught at different stages? How does it relate to what you know now? |
| Supervision / Physical environment | What is your experience with supervision at this health facility? Prompt: Does anyone supervise how diagnoses are made at this health facility? What usually happens with routine supervision from the district: how frequent, who is supervisor, relationship with supervisor, what they ask, do they give any feedback? What is your experience with the way logistics of supplies work at the health facility?Prompt: What roles do different people play, is there an established system for: supply procurement, storage, monitoring? How do you think RDTs might fit with your current systems of logistics and supervision? Prompt: Can you suggest any ways that RDTs could be integrated with your work without creating extra work for you and your colleagues? |
| Social environment | In your opinion, what do patients (adults and children) expect from consultations when they attend here with fever?Prompt: Expectations for drugs, clinical or test-based diagnoses? Can you give examples of your own experiences of patient preferences? Do you think you would find it easier to change your practice (types of drugs or diagnostic methods) if patients had different demands? Prompt: How do you think patient demands or expectations might be changed? What strategies might be effective?What do you perceive are the expectations of your peers for the pattern of diagnoses and prescriptions from here?Prompt: What are their perceptions of the risk of malaria, risk of misdiagnosing malaria and other diseases? Do you agree with the opinions of your peers? How is your relationship with colleagues at this health facility- does this create any support/barriers if you wanted to change your diagnostic/treatment practice?Do you perceive there to be any rule-enforcers in your practice? Prompt: If something goes wrong (wrong diagnosis, treatment, dosage), who holds health workers responsible here? Is it patients, community leaders or supervisors?  |
| Promoting RDTs | What suggestions can you give for how to promote the use of RDTs for malaria diagnosis amongst prescribers like you and amongst community members?Prompt: Prescribers? Community? In some places where RDTs have been introduced, and the provider has been trained and understands a lot about when to use the RDT and what prescriptions to give based on the results, the provider sometimes still gives antimalarial drugs when the results of the RDT are negative. Can you comment why this might happen and how we can help to enable providers to follow the guidelines? |
| **Closing**Is there anything else you think is important in diagnosing malaria that we have not talked about? * Summarise
* Thank participant
* Provide extra information and contacts to participants
 |

Appendix F. Example IDI Contact Summary Form

|  |
| --- |
| **Contact summary form for each in-depth interview****IDI NO:** |\_\_|\_\_|\_\_|\_\_| **Facilitator Initials:** |\_\_|\_\_|\_\_|**Participant sub-group type** (*circle*): male/female **Participant title** (*circle*): DHMT leader/ supervisor **Audio file #:** |\_\_|\_\_|\_\_|\_\_| **Site number:** |\_\_|\_\_| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|**Today’s date:**  |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_| |
| 1. How would you describe the atmosphere and context of the interview?
2. What were the main points made by the respondent during this interview?
3. What new information did you gain through this interview compared to previous interviews?
4. Was there anything surprising to you personally? Or that made you think differently?
5. What messages did you take from this interview for intervention design?
6. Were there any problems with the topic guide (e.g. wording, order of topics, missing topics) you experienced in this interview?
 |

###

Appendix G. Example Team Debriefing Minutes Form - IDIs

|  |
| --- |
| **Team debriefing session minutes****Date:** |\_\_|\_\_/\_\_|\_\_/\_\_|\_\_|**List those present:** **Meeting chair:** **Interviews discussed:** IDI NOs: |\_\_|\_\_|\_\_|\_\_| to |\_\_|\_\_|\_\_|\_\_| **Participant sub-group types** (*state no*.): Male \_\_\_\_  Female \_\_\_\_ DHMT leader \_\_\_\_\_ Supervisor \_\_\_\_\_\_  |
| 1. Were all the interviews planned for this period completed? If not, what were the reasons for incompletion?
2. What were the main points made by the respondents during these interviews (keep a tally by each point for number of interviews identifying the same point)?
3. What information or ideas were new in these interviews compared with previous interviews (keep a tally by each point for number of interviews identifying the same point)?
4. Discuss the impact of the findings so far on intervention design and note ideas arising.
5. Going through each domain, are there still new ideas emerging of interest to the study objective? If no, consider whether saturation is complete (this may apply to one or more domain which could be removed from the topic guide for subsequent interviews. Only remove domains or terminate data collection after discussion with the study investigators).
6. Discuss any problems with the topic guides (e.g. wording, order of topics, missing topics) and make changes to the guides.
 |

Appendix H. Example FGD Topic Guide

|  |
| --- |
| **FGD IDNO** |\_\_|\_\_|\_\_|\_\_| **Facilitator Initials** |\_\_|\_\_|\_\_| **Note-taker Initials** |\_\_|\_\_|\_\_|**Participant sub-group:** (*circle*): Fathers/ Mothers/ community leaders **Audio file**: |\_\_|\_\_|\_\_| **Community number:** |\_\_|\_\_| **Date** |\_\_|\_\_/\_\_|\_\_/\_\_|\_\_| **Introduction**I am \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Facilitator)I am \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (note-taker)* Ask group to introduce themselves using first names
* Capture demographic details – using first name for discussion
* Explain general purpose of the study:
* *For FGD:* To understand the experiences of participants with diagnosing illnesses in this community
* *For overall study:* To see if there is any way for us to improve diagnosis in communities like this one
* Aims of the discussion and expected duration (1 hour)
* Who is involved in the process (other participants)
* Why the participants’ cooperation is important
* What will happen with the collected information and how the participant/target group will benefit
* Ask group to define their own ground rules, for example:
* Only one person talks at a time.
* It is important for us to hear everyone’s ideas and opinions. There are no right or wrong answers to questions – just ideas, experiences and opinions, which are all valuable.
* It is important for us to hear all sides of an issue – the positive and the negative.
* Confidentiality is assured. “What is shared in the room stays in the room.”
* Any questions?
* Check position and functioning of tape recorder
* Check for everyone’s consent to participate and be recorded
* Refreshments will be served after the discussion

**Now I am going to introduce some topics one at a time about your experiences when you are unwell, and I hope you can discuss them together.** |
| **Domain** | **Topic and Probes** |
| Common illnesses and sources of treatment | Can we talk about what kinds of illnesses you experience most commonly?Probe: Perception of malaria risk relative to other diseasesWhat do you do when you are ill with these conditions?Probe: Can you relate any recent experiences when you have had a fever: Where did you seek treatment (home, drug store, HF)? Is this similar to experiences in the rest of the group? What are the reasons for taking these steps?When you are ill, what are the methods that you can use to find out the cause?Probe: What do healers/health workers do when they make a diagnosis? What are the common reasons for fever? Do health workers rely on tests (list tests)?  |
| Perception of tests | Can you describe different tests for detecting illnesses?Probe: Can you explain how the different tests work, and how good they are? What are the good and bad things about different tests? What is the process for getting a test (timing, when receive treatment)When is it good to have tests, and when are tests not needed? |
| Perception of health workers | When you come to the health facility [CHW/health centre/hospital] have you ever had experiences when the health worker does not give you what you want?Probe: examinations, tests (and results), diagnosis, treatment type? What do you do if the health worker doesn’t give you what you wanted? Who are health workers responsible to (community, government, their families)?  |
| Perception of antimalarials | Have you heard of Coartem? What do you use Coartem for?Probe: symtoms/disease? Is it effective? Why do you think these new antimalarials are here (probe: source of antimalarials, trust in new/old antimalarials)? Are there any problems with using new or old antimalarial drugs (probe: adverse events, cost)? |
| Perception of IEC | How have you found out about changes in the recommended drug for malaria?Probe: Radio, health workers, NGOs. What sources are trust-worthy and why? Any contradictions?If health workers started using different kinds of tests for diagnosis, what sort of information should you in the community receive?Probe: Any at all, or trust doctors? Info about the test mechanism, effectiveness? What sources can be trusted to give accurate information about new medical technologies? If there was a new test for malaria (fever with parasites in the blood) and the test was always right, what would you think if you felt you had malaria but the test said ‘negative’ – no parasites? |
| **Closing**We are now approaching the end of our discussion. Is there anything else anyone would like to add about the kind of diagnosis and treatment you get from health facilities that we have not talked about? * Summarise
* Thank participants
* Provide extra information and contacts to participants

Collect participant demographic details |

Appendix I. Example FGD Enrolment Form

|  |
| --- |
| **FGD IDNO:**  |\_\_|\_\_|\_\_|\_\_| **Facilitator Initials:**  |\_\_|\_\_|\_\_| **Note-taker Initials:**  |\_\_|\_\_|\_\_|**Participant sub-group:** (*circle*): Fathers/ Mothers/ community leaders **Audio file**: |\_\_|\_\_|\_\_| **Community number:** |\_\_|\_\_| **Date** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|  |
| **ID** | **First name** | **Age** | **Community** | **Number Children <5** | **Last time child took an antimalarial** | **Last time visited a HF** | **Which HF?** |
| 1 |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |
| 11 |  |  |  |  |  |  |  |
| 12 |  |  |  |  |  |  |  |

Appendix J. Example recruitment log for FGDs

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Participant Name** | **M/F** | **Date Approached** | **Successful contact?** | **Eligibility for sub-group...** | **Interested?** | **Consent?** | **FGD arranged (date)** | **Contact No.** | **Location** |
| **A** | **B** | **C** |
| 1 |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |  |  |  |  |  |
| 11 |  |  |  |  |  |  |  |  |  |  |  |  |
| 12 |  |  |  |  |  |  |  |  |  |  |  |  |
| 13 |  |  |  |  |  |  |  |  |  |  |  |  |
| 14 |  |  |  |  |  |  |  |  |  |  |  |  |
| 15 |  |  |  |  |  |  |  |  |  |  |  |  |

Appendix K. Example FGD Note-Taker Form

|  |
| --- |
| **FGD Note taker form****FGD IDNO:**  |\_\_|\_\_|\_\_|\_\_| **Facilitator Initials:**  |\_\_|\_\_|\_\_| **Note-taker Initials**: |\_\_|\_\_|\_\_|**Participant sub-group:** (circle): Fathers /Mothers /Community leaders **Audio**: |\_\_|\_\_|\_\_| **Community number:** |\_\_|\_\_| **Date**: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_| **Time** start \_\_\_:\_\_\_ end \_\_\_:\_\_\_Meeting place description: *detail and description, e.g. size and accessibility, and how this could affect the discussion; interruptions during the discussion*Participants: *how many of those invited participated, description of demographics if not formally collecting this data*Seating diagram: Group dynamics: *general description – level of participation, dominant and passive participants, interest level, boredom, anxiety – and how these relate to the different topics discussed*Impressions and observations:Running notes (detailed notes following the discussion, as near verbatim as possible, including identification of all contributors): |

Appendix L. Example FGD Contact Summary Form

|  |
| --- |
| **FGD Contact summary form** (to be completed by facilitator in conjunction with note taker)**FGD IDNO** |\_\_|\_\_|\_\_|\_\_| **Facilitator Initials:**  |\_\_|\_\_|\_\_| **Note-taker Initials:**  |\_\_|\_\_|\_\_|**Participant sub-group type** (*circle*): Fathers/ Mothers/ Community leaders **Community number:**  |\_\_|\_\_| **Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_| **Today’s date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_| |
| 1. What were the main issues or themes that struck you during this focus group?
2. What new information did you gain through this focus group compared to previous focus groups in this study?
3. Was there anything surprising to you personally? Or that made you think differently about this research question?
4. What messages did you take from this focus group for intervention design?
5. How would you describe the general atmosphere and engagement of the focus group?
6. How would you describe the group dynamics? For example, were there dominant individuals (what was the result and what were their IDNOs)? Did all participants contribute? Did you feel there was pressure to adhere to dominant viewpoints (what topics)?
7. What else was important about this focus group?
8. Were there any problems with the topic guide (e.g. wording, order of topics, missing topics) you experienced in this focus group?
 |

Appendix M. Example Team Debriefing Minutes Form - FGDs

|  |
| --- |
| **Team debriefing session minutes****Date:** |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|**List those present:** **Meeting chair:** **FGDs discussed:** FGDs NOs: |\_\_|\_\_|\_\_|\_\_| to |\_\_|\_\_|\_\_|\_\_| **Participant sub-group types** (*state no*.): Male \_\_\_\_  Female \_\_\_\_ DHMT leader \_\_\_\_\_ Supervisor \_\_\_\_\_  |
| 1. Were all the FGDs planned for this period completed? If not, what were the reasons for incompletion?
2. What were the main points made by the respondents during these FGDs (*keep a tally by each point for number of discussions identifying the same point*)?
3. What information or ideas were new in these FGDs compared with previous FGDs, interviews and observations (*keep a tally by each point for number of discussions identifying the same point*)?
4. Discuss the impact of the findings so far on intervention design and note ideas arising.
5. Going through each domain, are there still new ideas emerging of interest to the study objective? If no, consider whether saturation is complete (*this may apply to one or more domain which could be removed from the topic guide for subsequent interviews. Only remove domains or terminate data collection after discussion with the study investigators*).
6. Discuss any problems with the topic guides (e.g. wording, order of topics, missing topics) or organisation/moderation of the FGDs and make changes to the guides or SOPs (*only make changes after discussion with the study investigators)*.
 |

Appendix N Example structured observation tool

*Complete only after gaining informed consent of drug seller and client.*

Client ID |\_\_\_|\_\_\_|\_\_\_|\_\_\_|\_\_\_|\_\_\_|Researcher Initials |\_\_\_|\_\_\_|\_\_\_|

Drug seller (DS)ID |\_\_\_|\_\_\_|\_\_\_| AUDIO No. |\_\_\_\_\_\_| ; |\_\_\_\_\_\_|

Date |\_\_\_|\_\_\_/\_\_\_|\_\_\_/\_\_\_|\_\_\_| Start time \_\_\_\_:\_\_\_\_ End time\_\_\_\_:\_\_\_\_\_

1. a. Record the initial interaction between the drug seller and client:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 b. Is client seeking medication for themselves □ or someone else □ (who\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)?

 c. Does client ask for a specific drug □ or consult the drug seller □?

 d. Does DS ask what drug the client wants □ or does DS enter a consultation with the client □?

2. a. Does DS ask if client already sought medical help elsewhere? □ Yes □ No

 b. Did client attend elsewhere before here? □ Yes □ No

 c. If Yes, where? □ Another drug seller (order\_\_\_\_\_\_\_\_\_name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 (and order) □ A private health facility (order\_\_\_\_\_\_name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ A public health facility (order\_\_\_\_\_\_\_name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ Other (order\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 d. If yes, does the client give an explanation for why they attended elsewhere first? □ Yes □ No

 Detail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. a. Does DS ask about patient symptoms? □ Yes □ No

 b. What symptoms does the client report?

 Fever □ Cough □ Vomit □ Diarrhoea □ Difficulty breathing □ Abdominal pain □ Headache □

 c. Client reported age and sex of patient: (years/ months/wks) |\_\_\_|\_\_\_|\_\_\_| / |\_\_\_|\_\_\_| / |\_\_\_|\_\_\_| □ Male □ Female

OR d. Researcher estimate of patient age and sex: □<12 months □< 5 years □< 15 years □>15 years

 □ Male □ Female

5. a. Does DS ask if patient has been tested for malaria? □ Yes □ No

 b. Has patient been tested for malaria? □ Yes □ No

 c. If yes, where? (name of facility\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_type of facility\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 d. Is there any discussion of malaria testing? Detail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 e. Does DS ask if patient has been diagnosed with malaria for this illness episode? □ Yes □ No

 f. Has patient been diagnosed with malaria for this illness episode? □ Yes □ No

 f. If yes, where? (name of facility\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_type of facility\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 g. Has patient been told to buy antimalarials by a health worker? □ Yes □ No

 h. If yes, where? (name of facility\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_type of facility\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 i. If yes, what type of antimalarial were they told to buy? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 j. Is there any discussion of the diagnostic process (doubts, reasons for following or ignoring

 advice)? □ Yes □ No Details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 k. Does DS offer to diagnose malaria with a test? □ Yes □ No (type of test \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 l. Does client ask for a malaria test? □ Yes □ No

 m. If yes (to k or l), what is the result? □ Positive □ Negative

6. a. Does DS ask if patient has already taken any medication? □ Yes □ No

 b. Does client report that patient has already taken any medication? □ Yes □ No

 c. If yes, what medication? Antimalarial □ Yes □ No. Type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Antibiotic □ Yes □ No. Type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Paracetamol □ Yes □ No

 Other □ Yes □ No. Type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 d. Does DS ask if patient has previously suffered adverse reactions with drugs? □ Yes □ No

 e. Details of any adverse reactions described by client:

 Drug \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reaction \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Drug \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reaction \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Drug \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reaction \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. a. Does DS recommend the patient buy antimalarials? □ Yes □ No

 b. If yes, what type? □ ALU □ Quinine □ SP □ Other

 c. Does DS recommend any other treatment? □ Yes □ No

 d. If yes, what type? □ Antibiotic \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 e. Does DS give any advice about taking the drug? □ Yes □ No

 f. If yes, is this: □ Dosage (what dose \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ Adherence (details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ Other (details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

8. a. Does DS refer the patient to a health facility?

 b. If yes, do they still sell a drug to the patient? □ Yes □ No

9. a. Does the client make a purchase? □ Yes □ No

 b. If yes, what does the client buy? □ Antimalarials (type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ Other drug (type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ Hygiene supply (e.g. soap, toothpaste\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ Food (detail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 □ Other (detail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 c. Does the drug seller reduce the price of the antimalarial during the interaction? □ Yes □ No

# SOP examples

**SOP 1** - Approaching and inviting participants to interviews

**SOP 2**  - Giving information and getting consent (interviews)

**SOP 3** - Organising the interview

**SOP 4** - Carrying out the interview

**SOP 5**  - Carrying out team debriefings (interviews)

**SOP 6** - Getting permission and inviting participants to focus groups

**SOP 7** - Giving information and getting consent (FGDs)

**SOP 8** - Organising the focus group discussion

**SOP 9**  - Carrying out the focus group discussion

**SOP 10** - Carrying out team debriefings (FGDs)

**SOP 11** - Transcribing

**SOP 12** - Translation

**SOP 13** - Data analysis and coding

SOP . Approaching and inviting participants to interviews

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| **SOP ID#:**  | **SOP TITLE: APPROACHING AND INVITING PARTICIPANTS TO INTERVIEWS** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
|  |  |  |

**I. PURPOSE.** To describe the procedures for approaching a health facility and identifying health care workers to participate in in-depth interviews.**II. RATIONALE.** We plan to conduct in-depth interviews with health workers in XXXXX in order to XXXX *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Information Sheet
* Health Facility Log
* Health Care Worker Log
* List of eligible public health facilities in area
* In-depth interview topic guide
* Notepad
* Pens
* Tape recorder
* Spare batteries
* Clip board

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Interviewers

**V. DEFINITIONS*** **Health facility (HF)**: In this SOP, a health care facility refers to a government-run, public health center (level II, III, or IV).
* **Health worker (HW):** In this SOP, a health care worker is anyone working at the health facility regardless of their salary and training status.
* **Interviewer:** member of the study team carrying out the in-depth interviews.
* **Health facility code index**: list of health facilities and study codes, kept confidentially.

**VI. PROCEDURES****A. Approaching the health facility*** Prior to the start of the survey, members of the study team will meet with local officials and community representatives to discuss the study and plans for the survey.
* A list of the eligible public health facilities is included as an attachment. Each team will be assigned to one health facility at a time.
* For the in-depth interview study, two interviewers will move together as a team; one will act as the interviewer, and the other as note-taker. The teams will move with local officials, such as the health inspector, as needed to identify the health facilities.
* The visit to the health facility should be recorded on the Health Facility Log by recording the health facility code (from the list), and the date first approached.
* Once the health facility has been identified, the interview team should approach the facility, introduce themselves and the team to the health facility staff, and attempt to locate the in-charge or other available health worker.
* If no HW is found, circle ‘No’ in the column labelled ‘HW identified’ on the Health Facility Log and attempt to find the best time to return. Record the date to return in the column labelled ‘Date to return’.
* Health facilities will be revisited up to a maximum of three times over a span of 4 weeks. The same procedures for completing the Health Facility Log should be followed for the second and third visits.
* If no HW is located at the first, second, or third visit to the facility, the interview team should record the date that the final visit was made in the column labelled ‘Date COMPLETE’ on the Health Facility Log.

**B. Introduction to the health care workers and completion of log forms*** If a HW is identified, circle ‘Yes’ on the Health Facility Log in the appropriate column, and record the date in the second-to-last column labelled ‘Date COMPLETE’.
* The interviewers should ask the HW how many HWs are stationed at the facility and record this number on the Health Facility Log in the final column labelled ‘Number of HWs’.
* Next, record the HW on the Health Worker Log, including the health facility code (from the HF code index), and the HW Study ID (assign the numbers sequentially beginning with ‘1’ for each HW enrolled into the study). We expect to enrol approximately 30 HWs into the study, so the HW Study IDs will run from 1 to about 30.
* Ask the HW what position they hold at the health facility and record this information on the Health Care Worker Log in the column labelled ‘Position’.
* Record the date that the HW was first visited (today’s date) in the column labelled ‘Date visited 1st’.
* Introduce the study to the health workers as outlined in the script below.

**Script for inviting potential health facility survey participants***“Hello. My name is.... and I work for the ACT Consortium project XXXX. We are conducting a study of XXXX. We would like to know more about XXXXX. To do this, we are asking selected health workers questions about their experiences with XXXX. We are interested in interviewing all available health workers stationed at this facility. Can we tell you more about the interviews now?** In general, the introductions, informed consent discussions, and interviews will be conducted in English; however, appropriate local languages should be used as needed to ensure that the health workers understand the conversations.
* If the HW appears interested, but does not currently have time to review the information sheet, in the column labelled ‘1st Reason’ record ‘B’ for ‘Come back later’ or ‘D’ for ‘Other’, schedule a date to return, and record the date in the Health Care Worker Log in the column labelled ‘Date of rescheduled visit’.
* If the HW is not interested, record ‘C’ for ‘Not interested’ in the Health Care Worker Log in the column labelled ‘1st Reason’, record the date that the final visit was made in the column labelled ‘Date Complete’, and circle ‘No’ in the column labelled ‘Enrolled’ in the Health Care Worker Log.
* If the HW is disinterested, or refuses to discuss the survey further, inform the study coordinator.
* HWs will be revisited up to a maximum of three times over a span of 4 weeks. If the HW is absent from the facility at a visit or indicates that they are not able to participate in the survey, the interview team should record the reasons that the HW was not available in the Health Care Worker Log in the column labelled ‘2nd Reason’ or ‘3rd Reason’ as appropriate.
* If the HW is not able to participate in the interview after 3 visits, circle ‘No’ in the second-to-last column labelled ‘Enrolled’ in the Health Care Worker Log, and record the date that the final visit was made in the column labelled ‘Date COMPLETE’.

**C. Reviewing the information sheet and obtaining verbal consent from HWs*** If the HW is agreeable, proceed with the information sheet and the consent process (**SOP 2**).
* If the HW declines to participate, circle ‘No’ on the Health Worker Log in the second-to last column labelled ‘Enrolled’. Record the date in the final column labelled ‘Date COMPLETE’.
* If the HW gives their consent to participate in the survey, circle ‘Yes’ on the Health Worker Log in the column labelled ‘Enrolled’. If the HW is able, proceed immediately with the interview. If the HW is not able to participate in the interview immediately, reschedule the interview and record the date in the Health Worker Log in the column labelled ‘Date of rescheduled visit’.
* When the interview is successfully completed, record the date in the column labelled ‘Date COMPLETE’.
* The same procedures should be followed for all HWs stationed at the health facility. Ideally, we would like to interview all HWs.

**VIII. ATTACHMENTS:*** Information Sheet
* Health Facility Log
* Health Worker Log
* List of eligible health facilities

**IX. DOCUMENTATION** XXXX Protocol |

SOP . Giving information and getting consent (interviews)

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| **SOP ID#:**  | **SOP TITLE: GIVING INFORMATION AND GETTING CONSENT (INTERVIEWS)** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
|  |  |  |

**I. PURPOSE.** To describe the procedures for giving information to potential participants, inviting them to participate in the study and getting their consent, as part of the recruitment process.**II. RATIONALE.** We plan to conduct in-depth interviews with health workers in XXXXX in order to XXXX (*Add summary of project and method rationale).***III. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Information Sheets (with copies translated into appropriate languages)
* Consent forms
* Health Facility Log
* Health Worker Log
* List of eligible public health facilities in area
* List of inclusion and exclusion criteria for participants
* SOP for identifying and approaching potential participants (**SOP 2**)
* Notepad
* Pens
* Clip board

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Interviewers
* Field recruitment staff

**V. DEFINITIONS*** **Health facility (HF)**: In this SOP, a health care facility refers to a government-run, public health center (level II, III, or IV).
* **Health facility code index**: list of health facilities and study codes, kept confidentially.
* **Health worker (HW):** In this SOP, a health care worker is anyone working at the health facility regardless of their salary and training status.
* **IDI:** in-depth interview
* **Interviewer:** member of the study team carrying out the in-depth interviews.

**VI. PROCEDURES****A. Giving information about the study*** Prior to commencing this SOP, the correct procedures for identifying and inviting HWs to participate in the study must have been followed (see **SOP 1**).
* If the HW has expressed interest in finding out about the study and potentially participating, explain to them that you will give them more detailed information about what participating in the study will involve, so they can choose whether or not they wish to participate.
* If the HW has *not* expressed interest, or states that they do not wish to find out more about the study as they are not interested in participating, thank them for their time and allow them to leave.
* Establish whether the HW wishes to read through the participant information sheet themselves (and which language is preferred) or whether they would prefer you to read through the sheet with them.
* If reading the information sheet to the HW, be sure to read slowly and clearly with sufficient pauses to make sure the HW is listening and understanding. If perceived necessary, briefly summarise the key points of the study and the nature of the participation using the script below, to ensure comprehension.
* If the HW is reading the information sheet themselves, when they have finished give a quick summary of the information, including key points about the nature of their participation and its consequences, to check comprehension (see script below).

**Script for summarising the study and nature of participating***“So to summarise, the aim of the study is to xxxx, and as health workers’ opinions on this topic are valuable we are inviting them to participate in an interview to discuss xxxx. If you wish to participate, you would be asked to attend x interview(s), which would last around xx minutes and, with your consent, would be tape recorded. The data from the interview would be kept confidential and your name would be anonymised. The benefits of participating are xxxx and the disadvantages are xxxx. Participation is voluntary and you can choose to withdraw at any time. If you have any further questions or complaints about the study you can contact xxxx on xxxx.”** Ask HW if they have any questions about the study or if there are any parts of the information sheet that they do not fully understand. Answer any questions or queries fully and check their comprehension of your answers.
* Reiterate that participation is voluntary, and should they consent to participate, they may withdraw from the study at any time.
* Ask the HW if they would like to keep a copy of the information sheet, and in which language. Give them the information sheet, as appropriate.

**B. Inviting participation*** Once the information sheet has been read through and/or explained, and all questions about the study have been answered, ask the HW if they wish to participate in the study.
* If the HW says ‘yes’, circle ‘Yes’ in the ‘Enrolled’ column on the Health Worker Log. Move onto section C, procedures for getting consent.
* If the HW says ‘no’, circle ‘No’ in the ‘Enrolled’ column on the Health Worker Log, and indicate the reason for not participating as ‘C’ for ‘not interested’ in the ‘1st reason’ column. Record the date in the final column labelled ‘Date COMPLETE’. Thank them for their time and allow them to leave.
* If the HW is unsure, record ‘B’ for ‘Come back later’ in the column titled ‘1st Reason’ on the Health Worker Log and arrange a date to return or contact them again. Record this date in the column “date of rescheduled visit”. Thank them for their time and allow them to leave.

 **C. Obtaining consent from participants*** Depending on the HW’s preference ask them to read through the consent form, or read it aloud to them in the appropriate language.
* Ask them whether they consent to each of the xx statements on the consent form.
* If they do consent, ask them to circle ‘yes’ next to each statement and to record their signature, printed name and the date in the appropriate area of the consent form.
* If they consent to participating in the study but not to one or more of the other statements, ask them to circle the correct response next to each statement and to record their signature, printed name and the date in the appropriate area of the consent form. Be sure to make note of to which statements – for example, the use of direct quotations – the HW *does not* consent.
* If the HW is not able to write their name or signature, the fieldworker should complete their printed name and date for them and ask them to give a thumb print in place of a signature.
* The fieldworker should then print and sign their name, and record the date in the appropriate area of the consent form.
* If the HW does not consent to participating in the study, ask whether they wish to have more time to think about it. If they answer yes, arrange a time and date to contact them again and record on the Health Worker Log, as ‘B’ for ‘Come back later’ and the arranged day and time.
* If the HW does not wish to think more about participation and is no longer interested, record ‘No’ in the Enrolled column of the Health Worker Log and the date under ‘Date COMPLETE’.
* For the HWs who agree to participate, ask whether they are available to complete the interview immediately. If so, move onto **SOP 3** and **SOP 4**, to organise and conduct the interview.
* If the HW is not able to participate in the interview immediately, reschedule the interview and record the date in the Health Worker Log in the column labelled ‘Date of rescheduled visit’.
* When the interview is successfully completed, record the date in the column labelled ‘Date COMPLETE’.
* The same procedures should be followed for all HWs stationed at the health facility. Ideally, we would like to interview all HWs.

**VIII. ATTACHMENTS:*** Information Sheet
* Health Facility Log
* Health Worker Log
* List of eligible health facilities

**IX. DOCUMENTATION** XXXX Protocol |

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| SOP 3. Organising the interview

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| **SOP ID#:**  | **SOP TITLE: ORGANISING THE INTERVIEW** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
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**I. PURPOSE.** To describe the procedures for organising interviews with HWs. **II. RATIONALE.** We plan to conduct in-depth interviews with health workers in XXXXX in order to XXXX (*Add summary of project and method rationale).***III. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Information Sheets (with copies translated into appropriate languages)
* Completed consent forms
* Health Facility Log
* Health Worker Log
* Interview topic guide
* Digital voice recorder
* Spare batteries
* Notepad
* Pens
* Clip board

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Interviewers
* Field recruitment staff

**V. DEFINITIONS*** **Health facility (HF)**: In this SOP, a health care facility refers to a government-run, public health center (level II, III, or IV).
* **Health facility code index**: list of health facilities and study codes, kept confidentially.
* **Health worker (HW):** In this SOP, a health care worker is anyone working at the health facility regardless of their salary and training status.
* **IDI:** in-depth interview
* **Interviewer:** member of the study team carrying out the in-depth interviews.

**VI. PROCEDURES****A. Organising a venue for the IDI*** The study team should work with local officials to identify appropriate venues for the IDIs. Ideally, venues should be away from the main health facility, easily accessible to participants, quiet, relatively private and free from distractions. Potential venues include school buildings, LC chairman’s house, community centres, church halls or a room at the research team’s office base.
* Arrangements should be made regarding the possibility of young children accompanying participants to the interview, to ensure they are cared for and do not cause too much disruption to the interview.
* Communicate the location of the venue to the participants at least 3 days before the scheduled interview and agree arrangements for reimbursement of transport costs.
* If possible, contact the participant again the day before the interview to remind them and to confirm that they are still able to attend.

**B. Arranging transport to the venue*** Participants will be responsible for arranging their own transport to the interview venue, but will be reimbursed for the cost at the end of the interview.
* Funds and documentation for reimbursing transport costs should be arranged in advance of the interviews.

**C. Arranging equipment and materials*** Prior to the interview, the interviewer (and other staff) should ensure they have all the necessary materials and equipment ready, including enrolment form, topic guide, contact summary form, note-taker’s form and copies of the participant information sheet and signed consent form. Equipment required includes digital voice recorder, spare batteries, note paper and pens.
* The equipment, particularly the voice recorder, should be tested before the interview to check that it is working and the interviewer is confident in using it.
* The interviewer (and note-taker, where appropriate) should seek to be at the interview venue half an hour before the scheduled interview time to arrange the equipment and set up the room.
* At the interview venue, the furniture (chairs and table) should be in a welcoming arrangement. The digital voice recorder should be placed centrally, in close proximity to both the interviewer and participant to record the interview successfully. and also suitable for recording the interview on the digital recorder.
* If a translator is to be used throughout the interview, arrangements on how the translation will be carried out should be agreed by the research team prior to any interviews being carried out, and recorded in an SOP (see **SOP x**).

**VIII. ATTACHMENTS:*** IDI Appointment schedule

**IX. DOCUMENTATION** XXXX Protocol |
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SOP . Carrying out the interview

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| **SOP ID#:**  | **SOP TITLE: CARRYING OUT THE INTERVIEW** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
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 **I. PURPOSE.** To provide all interviewer teams with a uniform and standard way of conducting in-depth interviews with all the selected interviewees in the study area. **II. RATIONALE.** An open-ended interview will be conducted to gather information about XXXXXX. The information gathered will help to XXXXX. **III. METHOD.** Face-to-face interviews will be conducted by the interviewer with every selected participant who consents to participate and a note-taker will record all the responses made by the participant. This will be a one-time only involvement of this health care provider. **V. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Binder containing:
1. Health facility log;
2. Health worker log;
3. Topic guide
* Notepad
* Clipboard
* Pens
* Audio recording device

**V. DEFINITIONS:*** **Topic guide:** The topic guide has a list of topics to be explored.
* **Code list**: This is the list of all identity codes used to identify the interviewee in coded language for confidentiality.

 **VI. Procedures*** When the consent form has been completed, inform the participant that you will begin an in-depth interview which will request them to express their own views or opinions about their individual training and supervision as well as the functioning of the facility where they work. Remind them about their voluntary participation in the voice recording.

 **A Sample introductory statement would go as follows:**

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| *“Now that we have completed the consent form, we will now ask you to express your own views and experiences about your work and role as a CMD. A note- taker will be writing down what you say for our records but these notes will be kept securely and your name will not be used anywhere. Your answers will be looked at together with those of other participants from different communities and you will not be identifiable in any reports that are published.**It is very important for us to hear your views and experiences because you have experience working here and can give us this insight. We hope you will have time to spend with us now to complete this. I am going to turn on the voice recorder now. Don’t forget, you can ask me to turn this off at any time.**Do you have any questions before we start?***”** |

**Turning on the voice recorder*** Turn on the voice recorder and show the participant the light indicating it is recording. Speak clearly and loudly enough for the recording and encourage the participant to do so too. Ask them to repeat any quiet statements but try to allow them to speak freely without fear of the recording.
* The interviewer will introduce the note taker to the respondent and will make the respondent aware that they will be working with the note-taker, for example in pausing the interview at regular intervals to ensure that all information gets recorded by the note-taker.

**Demographic details*** The demographic details of the participant should be asked and the detail completed in the table at the top of the topic guide. If the interviewer prefers, these questions can be completed at the end of the interview.
* Remember to label each page of the notes with the participant’s study ID so that you will be able to remember to whom it belongs.

**Following the topic guide*** The interviewer should follow the topic guide, but allow the pace to be set by the interviewee. They should follow-up all general statements made by the respondent with a probe, particularly bearing in mind the purpose of the research.
* The interviewer will follow the recommendations for seating position, asking good questions and active listening from the training.
* The interviewer should make brief notes on their topic guide that notes down the main items discussed during the interview (this is useful if topics are covered in advance by the respondent and for the contact summary).
* The note taker will write down all questions and responses given on blank sheets of paper, in verbatim (word for word) as far as possible as well as recording the exact questions asked by the interviewer and in the order they were asked.
* The note-taker will also write a summary of the context of the interview- the first page of the notes will be dedicated to this, with details of the immediate setting and atmosphere of the interview and of the surrounding people, activities and infrastructure.
* When the topic guide questions are finished, the interviewer will ask for any additional comments the participant would like to give and remind them that all the information given will be kept confidential. These will be recorded by the note taker at the end of the note pad in quote for “Unsolicited reactions”.
* Thank the participant and inform him/her that the interview is almost over.

**Closing the interview*** Check with your note taker through the rest of the participant questionnaire and ensure that all portions of the form are filled in properly.
* Thank the CMD and ask if he/she has any questions for you about the interview**.**
* Answer any questions that came up during the interview, which you may have deferred to the end.
* Conclude as follows:

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| *“That’s all the questions we had for you. Thank you for your patience and co-operation”; we truly appreciate this. We will be in touch should anything come up for which we might need your expert views on, and we will be available should you need to contact us for any reason related to this interview. Thanks again for every thing, have a good day/good evening.”* |

* Assure them again of your promised confidentiality and give them any additional information necessary, then invite them to leave.

**Completing the contact summary*** Before departing, or on arrival back at the field base, the interviewer and note-taker should meet to discuss the findings of the interview. The interviewer should be responsible for completing a contact summary form, with input from the note taker.
* Contact summaries should be attached with the other documents in the health worker survey before submission.

**IX. Attachments:** XXXX**X. Documentation:** XX Protocol |

SOP . Carrying out team debriefings (interviews)

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| **SOP ID#:**  | **SOP TITLE: CARRYING OUT TEAM DEBRIEFINGS (INTERVIEWS)** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
|  |  |  |

 **I. PURPOSE.** To provide research teams with guidance on how to conduct team debriefing meetings following data collection episodes. **II. RATIONALE.** We plan to conduct in-depth interviews with health workers in XXXXX in order to XXXX (*Add summary of project and method rationale).***III. SUPPLIES AND MATERIALS*** Record of all IDIs completed in specified period (Enrolment form)
* Record of all Contact Summary forms for IDIs in specified period
* IDI appointment schedule
* Debriefing minutes form
* Notepad
* Clipboard
* Pens

**V. DEFINITIONS:*** **HW:** health worker
* **IDI:** in-depth interview

 **VI. Procedures****A. Arranging debriefing meetings*** The project manager or lead investigator in the field should devise a regular schedule of debriefing meetings reflecting the frequency of IDIs being conducted. Debriefing meetings should be held approximately every 4 IDIs, or once a week, whichever is the sooner.
* The debriefing meeting schedule, including time and location of meetings, should be disseminated to all field team members and any revisions that are made should be communicated at the earliest possibility.
* It is the responsibility of all field team members to ensure that they are able to attend each debriefing meeting and to provide feedback.
* The project manager or lead investigator should ensure that all necessary documents from the specified time period are made available for the debriefing meeting (Enrolment Forms, Contact Summary Forms and IDI appointment schedule), and ideally available beforehand to enable the lead investigator to examine the documents.
* A member of the field team should be appointed minute-taker for each debriefing meeting, and be advised on how to capture all the information discussed in the meeting.
* A suitable venue should be arranged for each meeting that is easily accessible for all members of the research team.

**B. Conducting debriefing meetings*** The debriefing meetings should be chaired by the lead investigator in the field, and should be guided by the content of the Debriefing Minutes Form.
* A member of the field team designated to take minutes should record the details of the discussion on the Debriefing Minutes Form.
* The discussion in the meetings should address each of the IDIs conducted within the specified time period, with the field researchers inputting on their experiences and thoughts following the IDIs.
* The discussion of each IDI should be in conjunction with examination of the relevant Contact Summary Form and interviewers should be encouraged to reflect on their practice in each interview.
* The discussion should also address similarities and differences between interview data, what insights have arisen from the series of IDIs and how these compare to any previous data collected and the theoretical framework of the study.
* More practical issues such as problems with the topic guide, equipment or recruitment should also be addressed here, and any solutions identified should be recorded on the Debriefing Minutes Form and made into recommended action points.
* The discussion should also include the number of upcoming scheduled interviews, and this should be reflected upon in light of the sampling strategy and the emerging themes, for example if data saturation is beginning to occur.

**C. Feeding back from debriefing meetings*** The completed Debriefing Minutes Form should be disseminated to the wider research team as soon as possible after the meeting.
* If any action points have been recommended, for example for changes to the topic guide or recruitment process, these should be presented to the wider research team for consultation and agreement on action to be taken.
* Changes to the protocol, SOPs or interview topic guide should not be made without the agreement of the wider research team.
* The lead investigator in the field should be responsible for monitoring the progress of data collection in the field via consideration of all of the Debriefing Minutes Forms, and bring to the attention of the wider research team any concerns or observations as soon as they arise.

**IX. Attachments:** XXXX**X. Documentation:** XX Protocol |

**SOP 6. Approaching and inviting participants to FGDs**

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| **SOP ID#:**  | **SOP TITLE: APPROACHING AND INVITING PARTICIPANTS TO FGDS** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
|  |  |  |

**I. PURPOSE.** To describe the procedures for approaching participants of the InterACT study and also users of a HIV treatment facility to participate in focus group discussions**II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Information Sheet
* List of inclusion and exclusion criteria
* List of participants of the InterACT study
* List of people screened but not accepted for the InterACT study
* Recruitment protocol
* Recruitment log
* Notepad
* Pens
* Clip board

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Research assistants

**V. DEFINITIONS*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **HIV treatment centre:** for this SOP, this refers to the clinic located at Muheza District Hospital
* **Outpatients department:** for this SOP, this refers to the outpatients’ department at Muheza

Hospital * **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

**VI. PROCEDURES****A. Approaching potential participants** * Prior to the start of the survey, members of the study team will meet with local officials and community representatives to discuss the study and plans for the FGDs.
* For the identification of potential participants and inviting them to participate in the study, the two research assistants will work together. One will be responsible for approaching suitable people and talking about the study with them, and the other will be responsible for recording the relevant details on the Recruitment Log.
* When approaching people is to be done via telephone, the research assistant making the call will be responsible for both talking about the study and recording the details on the Recruitment Log.
* The participant list for the InterACT study will form the pool of people from which to recruit participants for sub-groups A and B (people already participating or who have participated in the InterACT study).
* The list of people screened for the InterACT study, but who did not consent to participate or who were not eligible to be included in the study will form the pool of people from which to recruit participants for sub-group C (non-participants of the InterACT study).
* To recruit people, the research assistants should work backwards from the most recent people recruited (or screened, unsuccessfully) for the InterACT study, until enough people have been recruited.
* Approaching people suitable for sub-groups A and B will primarily be done by telephone, using contact details supplied by the InterACT study team. Where contact cannot be made by telephone, participants for sub-group A will be approached at the HIV treatment centre when they attend to receive their treatment on a regular basis. Information about which days they are likely to attend can be obtained from staff working at the clinic.
* If contact cannot be made with a person suitable for sub-group B, the research assistant should move onto the next person on the list with a contact telephone number.
* Approaching people suitable for sub-group C should be done at the HIV treatment centre or over the telephone, depending on whether contact details are available.

**B. Introduction to the potential participants and completion of log forms*** If a potential participant is successfully identified and contact made (either in person or over the telephone), the following introductory script should be used:

**Script for inviting potential participants to FGDs***“Hello. My name is.... and I work for the ACT Consortium on a project connected to the InterACT study. We are conducting a study about people’s perceptions of taking antimalarial treatment at the same time as other medication. We would like to know more about how they feel about this. To do this, we want to organise some group discussions with people to ask them questions about malaria and malaria treatment, as well as their experiences participating in the InterACT study or being screened for it. Is this something you might be interested in? Can we tell you more about the group discussions now?”** The introductions and discussions about the study, as well as the consent procedures, should be conducted in Kiswahili, unless the potential participant wishes to converse in English or a local language.
* The second research assistant (or same one if using the telephone) should record the name of every person with whom contact is attempted on the Recruitment Log in the first column. They should then indicate the gender of the person in the column marked M/F, followed by the date of attempted contact in column three, and whether contact was successfully made in column four using either a tick or a cross. This should be done for every person with whom contact is attempted, whether successful or not.
* If the person appears interested and wishes to hear more about the study, the research assistant should use the list of inclusion and exclusion criteria to determine the person’s eligibility for the study (and for which particular sub-group), asking questions if necessary.
* If the person fulfils the eligibility criteria, this should be indicated on the Recruitment Log, by a tick in the correct column. If they do not fulfil the criteria for any sub-group, crosses should be placed in all columns and the person should be thanked for their time and informed that unfortunately, they are not eligible to participate.
* For those that are eligible, the research assistant should move on to talking through the participant information sheet and consent forms, following **SOP 7 – Giving information and getting consent (FGDs).**
* If the person indicates at any time that they are not interested in participating, this should be marked in the appropriate column on the Recruitment Log with a cross. The participant should then be thanked for their time.
* If contact cannot be made with a participant, two more attempts should be tried (on different days) either in person or over the telephone. If contact still hasn’t been made, this should be indicated on the Recruitment Log with a cross and the research assistant should move onto the next person down the list.

**VIII. ATTACHMENTS:*** Information Sheet
* Recruitment Log
* List of inclusion and exclusion criteria
* List of participants in the InterACT study
* List of people screened but unsuccessful for participation in the InterACT study.

**IX. DOCUMENTATION** XXXX Protocol |

**SOP 7. Giving information and getting consent (FGDs)**

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| **SOP ID#:**  | **SOP TITLE: GIVING INFORMATION AND GETTING CONSENT (FGDs)** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
|  |  |  |

**I. PURPOSE.** To describe the procedures for giving information to potential participants, inviting them to participate in the study and getting their consent, as part of the recruitment process.**II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Information Sheets (with copies translated into appropriate languages)
* Consent forms
* Recruitment Log
* List of inclusion and exclusion criteria for participants
* SOP for identifying and approaching potential participants (**SOP 6**)
* FGD Planner Log
* Notepad
* Pens
* Clip board

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Interviewers
* Field recruitment staff

**V. DEFINITIONS*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **HIV treatment centre:** for this SOP, this refers to the clinic located at Muheza District Hospital
* **Outpatients department:** for this SOP, this refers to the outpatients’ department at Muheza

Hospital * **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

**VI. PROCEDURES****A. Giving information about the study*** Prior to commencing this SOP, the correct procedures for identifying and inviting people to participate in the study must have been followed (see **SOP 6**).
* If the person has expressed interest in finding out about the study and potentially participating, explain to them that you will give them more detailed information about what participating in the study will involve, so they can choose whether or not they wish to participate.
* If the person has *not* expressed interest, or states that they do not wish to find out more about the study as they are not interested in participating, thank them for their time and allow them to leave. You should indicate that they are not interested in participating by placing a cross in the ‘Interested?’ column on the Recruitment Log.
* Establish whether the person wishes to read through the participant information sheet themselves (and which language is preferred) or whether they would prefer you to read through the sheet with them.
* If reading the information sheet to the person, be sure to read slowly and clearly with sufficient pauses to make sure they are understanding. If perceived necessary, briefly summarise the key points of the study and the nature of the participation using the script below, to ensure comprehension.
* If the person is reading the information sheet themselves, when they have finished give a quick summary of the information, including key points about the nature of their participation and its consequences, to check comprehension (see script below).

**Script for summarising the study and nature of participating***“So to summarise, the aim of the study is to xxxx, and we’re inviting people to come and discuss their opinions of taking antimalarial medication at the same time as other medication, in a group. If you wish to participate, you would be asked to attend one focus group discussion, which would last around 2 hours and, with your consent, would be tape recorded. The data from the group discussion would be kept confidential and your name would be anonymised. We would be able to reimburse your travel costs but there would be no other benefits to you. The disadvantages of participating are that you would be sharing your opinions with other people in the group. We will ask everyone to respect the confidentiality of what is discussed in the group but cannot guarantee this outside the discussion. Participation is voluntary and you can choose to withdraw at any time. If you have any further questions or complaints about the study you can contact xxxx on xxxx.”** For potential participants of sub-groups A and C it will be important to make them aware that it is possible their HIV status will be revealed within the group as the discussion is likely to cover taking antimalarial medication at the same time as ART. Make sure they understand that they will be placed in a discussion group only with other HIV-positive people.
* Ask the person if they have any questions about the study or if there are any parts of the information sheet that they do not fully understand. Answer any questions or queries fully and check their comprehension of your answers.
* Reiterate that participation is voluntary, and should they consent to participate, they may withdraw from the study at any time.
* Ask the person if they would like to keep a copy of the information sheet, and in which language. Give them the information sheet, as appropriate.

**B. Inviting participation*** Once the information sheet has been read through and/or explained, and all questions about the study have been answered, ask the person if they wish to participate in the study.
* If they say ‘yes’, place a tick in the ‘Interested?’ column of the Recruitment Log, and move onto section C, procedures for getting consent.
* If they say ‘no’, place a cross in the ‘Interested?’. Thank them for their time and allow them to leave.
* If the person is unsure and wishes to take more time to think about it, arrange a day and time to call them (for example in 3 days’ time) to discuss it further and see if they’re interested. Thank them for their time and allow them to leave.

 **C. Obtaining consent from participants*** Depending on the person’s preference ask them to read through the consent form, or read it aloud to them in the appropriate language.
* Ask them whether they consent to each of the xx statements on the consent form.
* If they do consent, ask them to circle ‘yes’ next to each statement and to record their signature, printed name and the date in the appropriate area of the consent form. Then put a tick into the ‘Consent’ column of the Recruitment Log.
* If the person does not consent, put a cross in the ‘Consent’ column of the Recruitment Log and thank them for their time.
* If they consent to participating in the study but not to one or more of the other statements, ask them to circle the correct response next to each statement and to record their signature, printed name and the date in the appropriate area of the consent form. Be sure to make note of to which statements – for example, the use of direct quotations – the person *does not* consent.
* If the person is not able to write their name or signature, the fieldworker should complete their printed name and date for them and ask them to give a thumb print in place of a signature. If they cannot do this, they should ask a witness to sign on their behalf in the appropriate place.
* The fieldworker should then print and sign their name, and record the date in the appropriate area of the consent form.
* For the people who agree to participate, take their contact telephone numbers and where they live, and record these details on the Recruitment Log.
* If there are no suitable FGDs already organised for the sub-group that the participant falls into, tell the participant that you will contact them by telephone in a few days to arrange a suitable time and location for the FGD.
* If there is already one (or more) FGD organised for the correct sub-group, ask the participant whether they would be able to attend the arranged date and time.
* If yes, record their availability for the FGD on the FGD planner log and give them the details of where and when to attend.
* If no, tell the participant that you will contact them by telephone in a few days to arrange a suitable time and location for the FGD.

**VIII. ATTACHMENTS:*** Information Sheet
* Consent Form
* Recruitment Log
* FGD planner log
* List of eligibility criteria
* Participant (and screening) lists from the InterACT study.

**IX. DOCUMENTATION** XXXX Protocol |

**SOP 8. Organising the focus group discussion**

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| **SOP ID#:**  | **SOP TITLE: ORGANISING THE FOCUS GROUP DISCUSSION** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
|  |  |  |

**I. PURPOSE.** To describe the procedures for organising focus group discussions with the three sub-groups of participants.**II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Information Sheets (with copies translated into appropriate languages)
* Consent forms
* FGD Planner Log
* Notepad
* Pens
* Clip board

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Interviewers
* Field recruitment staff

**V. DEFINITIONS*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion; a qualitative method to elicit opinions from a group of people, representing a quasi-naturalised social setting to facilitate participation.
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **Moderator:** the field team staff member who will facilitate the group discussion, ask questions and manage group dynamics. The moderator will also be responsible for setting ground rules and taking consent from the participants.
* **Note-taker:** the research assistant responsible for keeping record of all participants, where they sit, their demographic details, the key points of the discussion (including who said what).
* **Assistant:** the other research assistant who will be responsible for organising the venue and the layout of the room, will ensure all participants are informed of the date and location of the FGD, and will facilitate their transportation to the venue where possible. The assistant will also make sure that the digital recorder is working and located in a suitable place, and will organise refreshments for all participants at the end of the FGD.
* **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

**VI. PROCEDURES****A. Organising a schedule for FGDs*** Once recruitment has started, the field team should draw up a provisional list of dates for FGDs by sub-group; two FGDs per week is recommended. This should be recorded in the FGD Planner Log.
* As participants are enrolled in the study, the research assistants should determine their availability for the earliest provisional dates available. If they are available, their names should be added to the FGD Planner Log under the appropriate date.
* If they are not available, they should be added to the end of the FGD Planner Log and as new dates are arranged, they should be contacted to check availability.
* It is possible that dates will have to be rescheduled if insufficient people can attend.
* There should be a minimum of 10 participants signed up for each FGD date, to allow for two non-attenders on the day. There should be no fewer than eight participants attending each FGD, wherever possible.

**B. Selecting a venue for the FGD**: * The study team should work with local officials to identify appropriate venues for the FGDs. Ideally, a venue should be one that is easily accessible to all potential participants, is not controversial or threatening, should allow for privacy, and should be free from distractions. Potential venues include; schools, LC chairman's house, community centres, health care facilities, church halls, etc.
* Ideally, the FGDs should be conducted in central Muheza to facilitate accessibility for all potential participants.
* Preparations should be made to handle young children who may be brought to a FGD. Participants should be encouraged to leave children at home with childcare, but where possible a venue should be sought with an extra room or area outside where young children can be left under the care of the assistant.
* The venue should be communicated to the selected FGD participants in advance (at least 3 days prior to the FGD), and reminder telephone calls should be made the day before, wherever possible.

**C. Coordinating transport for all participants*** Each participant will be responsible for organizing his/her transport to the FGD; however, a transport refund will be given at the end of the FGD. Where transportation for individual participants is proving difficult, the research assistants can help to arrange transportation.
* The funds for transport reimbursement for the participants should be organized by the study personnel in coordination with study administrators at least 3 days before the FGD.
* All transportation reimbursements should be recorded by the research assistant on the appropriate Transportation Reimbursement Log, ensuring that each participant signs (or marks their thumbprint) to indicate they have received their money.

**D. Organizing equipment and materials*** Prior to the FGD, study personnel should review the necessary equipment and materials including tape recorders and tapes, extra batteries, paper, black pens, name tags, and flip chart. Additional materials should be ordered if necessary.
* The equipment should be tested prior to the FGD to ensure that it is functional.
* Name tags will bear the participants first names to facilitate the FGD discussion. Name tags should be prepared upon the participants’ arrival to the discussion to ensure that the name tag includes the name that they are most comfortable with.

**E. Organizing refreshments*** The FGD assistant should ensure that refreshments for FGD participants have been ordered and paid for. Generally, refreshments will include sodas, mineral water, and small snacks.

**F. Division of labour*** The moderator, note-taker, and assistant should be identified prior to each FGD. The two research assistants may rotate the responsibilities of note-taker and assistant if preferred.
* The moderator must be able to speak the language that the FGD participants are most comfortable with (usually Kiswahili).
* The note-taker will be responsible for bringing all equipment and materials to the FGD.
* The assistant will be responsible for organizing the venue and refreshments as outlined above. The assistant will also be responsible for reminding all FGD participants 1-2 days prior to the FGD.

**G. Preparations on the day of the FGD*** On the day of the FGD, the study team should arrive at least one hour before the discussion is scheduled to begin to organize the venue and ensure that the place is clean and appropriate for the function.
* Seats for all participants should be organized to ensure that everyone is comfortable and visible to the moderator, and to all the other participants.
* All materials should be in place ready for use i.e. pens, paper, name tags, batteries etc.
* The digital recorder should be re-tested to ensure that it is working, and should then be placed in a central place during the discussion to maximize the quality of the recording.

**VIII. ATTACHMENTS*** FGD Planner Log

**IX. DOCUMENTATION** XXXX Protocol |
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**SOP 9. Conducting the focus group discussion**

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| **SOP ID#:**  | **SOP TITLE: CONDUCTING THE FOCUS GROUP DISCUSSION** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
|  |  |  |

**I. PURPOSE.** To describe the procedures for conducting focus group discussions with the three sub-groups of participants.**II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Letter of permission
* Identification badge
* Information Sheets (with copies translated into appropriate languages)
* Consent forms
* FGD Planner Log
* FGD topic guide
* Note-taker form
* Enrolment form
* Contact summary form
* Digital recorder
* Spare batteries
* Name-tags with numbers
* Notepad
* Pens
* Clip board
* Whiteboard or large pieces of paper

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Interviewers
* Field recruitment staff

**V. DEFINITIONS*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion; a qualitative method to elicit opinions from a group of people, representing a quasi-naturalised social setting to facilitate participation.
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **Moderator:** the field team staff member who will facilitate the group discussion, ask questions and manage group dynamics. The moderator will also be responsible for setting ground rules and taking consent from the participants.
* **Note-taker:** the research assistant responsible for keeping record of all participants, where they sit, their demographic details, the key points of the discussion (including who said what).
* **Assistant:** the other research assistant who will be responsible for organising the venue and the layout of the room, will ensure all participants are informed of the date and location of the FGD, and will facilitate their transportation to the venue where possible. The assistant will also make sure that the digital recorder is working and located in a suitable place, and will organise refreshments for all participants at the end of the FGD.
* **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

**VI. REVIEW OF FGDs**1. **Role of moderator**
* The moderator should introduce themselves, the note taker and the study objectives. They should provide information about what participants can expect from the FGD and gain their consent to continue, making sure to gain everyone’s consent to be recorded.
* The moderator should then encourage the group to set their own ‘ground rules’ for the discussion (and use a list to prompt if necessary). If the group is literate, these rules should be written on a flip chart or black board. The rules should be referred to by the moderator if any member of the group transgresses, for example that ‘there are no right or wrong answers’. A key ground rule to highlight (or bring up if not mentioned) is confidentiality. Ask participants to agree to keep anything mentioned in the discussion confidential and not to discuss it with anyone else outside the group. This can be taken further by asking participants to quickly consider and discuss what this means, and the importance of keeping confidentiality among themselves.
* During the FGD, the moderator should guide the discussion by posing questions from the topic guide, or follow-on questions based on the emerging discussion. Questions should be open and should not lead the respondents to confirm the moderator’s view point.
* The moderator should show he/she is actively listening to all members of the group, to both the said and the unsaid. The moderator should listen for hidden meanings and be sure to clarify the messages.
* The moderator should show no judgment over the opinions or responses of group members, and emphasize that there are no ‘right’ or ‘wrong’ answers.
* It is important that the moderator balance the discussion, giving all participants a chance to speak, and not letting any one or more individuals dominate the conversation.
* Group answers to questions should be followed with probes to clarify comments, understand digressions, and evaluate the relationship between questions and digressions.
* At the end of the FGD, the moderator should open up the floor for questions, concerns or anything else relevant to the topic that has not yet been said. The FGD should be ended by thanking respondents for participating. The moderator and note-taker should remain alert during these questions as they may also be informative.
1. **Role of note-taker**
* The note-taker should record demographic details of each participant on the enrolment form as each participant arrives, seating and numbering them clockwise from the note-taker’s seat.
* As they go round each participant asking demographic information, they should write the participant’s first name on the name badge and their corresponding participant number, and give the name badge to the person to wear.
* The note-taker should start taking notes on the note-taker form, including the seating plan and context of the FGD. Additional notes to this form can be made throughout and after the focus group discussion.
* As far as possible, the note-taker should write down every single contribution, together with the ID number of the contributing participant, including verbal and non-verbal contributions, as close to verbatim as possible. All questions and probes by the moderator should also be recorded.
* The note-taker should record observations of non-verbal communication during FGDs including the sitting arrangements, laughter, and expressions.
* All responses noted down should be coupled with the identification number of the participant who uttered the response.
* The note-taker is also responsible for overseeing the digital-recording of the FGD, and must keep watch for when the batteries run out.
* It is important to capture as much of the FGD as possible in writing in case of technology failure, or poor quality recording.

**C. Role of assistant** * The assistant is responsible for hosting the FGD and ensuring minimal distraction for the participants and facilitator/note-taker team.
* The assistant should welcome and seat participants as they arrive in a clockwise direction from the seat of the note-taker.
* The assistant should give each participant a name-tag with their identification number if this system is deemed appropriate for the setting and participant group.
* The assistant is responsible for dealing with any participant(s) who may come late. In this case, if the introduction is complete and consent has been given by participants the latecomer will be politely turned away. If they arrive during the introduction the latecomer may join the group and other participants may be asked to summarise the introduction so far.
* The assistant is responsible for dealing with and catering for onlookers as well as people (like young children) who may come with the FGD participant(s),
* The assistant is responsible for making arrangements for refreshments.

**D. Dynamics of an FGD*** The moderator and participants should respect each idea and contribution.
* When experiences and comments are shared, the moderator should assess whether they are common or unique. In the case of a unique experience, the respondent should be given a chance to clarify or explain their position.
* Common ideas should be evaluated in the series of FGDs conducted to assess the prevalence of ideas and experiences.
* It is important to emphasize that there are no wrong answers in FGD.
* When an individual participant discusses their unique situation, the moderator should analyze the experience, picking an aspect of the experience to "throw back" to the group to see how their opinions compare.
* The moderator should focus on bringing all participants, even the quiet ones, on board with the discussion. Overly talkative participants should be silenced tastefully, if necessary (e.g. "Thank you very much. What does the group have to say about his/her opinion?" Thus, giving the group a chance to own the experience.)
* The experience of all participants is equally important, and it is the experience of the group, not of an individual, that is the aim of the FGD.
* Unique experience should be expected, and the "different gifts should be received". Incorporate jokes and proverbs, and be alert to answers that may come out of these. Ensure that these are recorded very carefully by the note-taker.
* The moderator must stay focused and not let the group derail the agenda.
* Watch for persistent questioners. They are leaders and may give insight into what else should be examined. The identification numbers of these characters should be specially noted.
* Also watch for "star", participants who are shining/loved/respected in the group. Learn to control them and use them in the discussion. The identification numbers of these characters should be specially noted.

**VII PROCEDURES****A. Conducting the FGDs*** As participants arrive, the note-taker should ask them their name, check it against the list of names on the FGD Planner Log, and then complete the enrolment form and their demographic details.
* The note-taker should check whether each participant has already signed a consent form (this should be indicated on the Recruitment Log). If they have not (there is a blank space in the ‘Consent’ column on the Recruitment Log), the note-taker should get a copy of the consent form, talk through it with the participant and then ask them if they consent to each of the statements. The note-taker should then ensure the consent form is signed by the participant (or with a thumb-print) and by themselves.
* The note-taker should then give the participant a badge with their first name and their participant number on it, and guide them to their seat.
* Once all the participants are seated, the note-taker should complete the seating plan on the note-taker form to record everyone’s seating positions.
* Whilst the note-taker is welcoming and enrolling the participants, the assistant should make sure all the equipment is set up and ready for use and that the refreshments are ready for after the discussion.
* Once all the participants have arrived, the moderator should welcome everybody and give a brief introduction to the discussion using the script below as a guide. All FGDs will be conducted in Kiswahili.

**Script for welcoming participants to the FGD***““Hello. My name is.... and I work for the ACT Consortium who carry out research about treating malaria.. Thank you very much for coming today. I am part of a team who are doing research to learn more about how people in Muheza think about malaria and malaria treatment, and their experiences of taking malaria treatment at the same time as other medication. We also would like to know a bit about people’s opinions of taking part in a clinical study like the InterACT study that has been taking place in Muheza hospital. The discussion will last for about an hour and a half, but maybe slightly more. I will be asking you questions and guiding the discussion; my colleague xx will be taking notes and my other colleague xx will be organising refreshments and reimbursements for your travel costs at the end of the discussion. We will take notes of the ideas discussed and, if you agree, a recording will be made of the discussion in order that we record what you say accurately. When you are being recorded, the light will be red. If you wish to say anything ‘off the record’ this is fine, please indicate to me or xx (note taker). The recording will only be used by the study team: no one else will hear your voice. It will be kept for 2 years for our records and will then be erased or destroyed. We are not writing down your names here and no one will be able to identify you in any reports arising out of this research. All records of this discussion will be kept securely. Is there anyone who is not happy to be recorded?**Let us begin by setting some ground rules.”** If any participants indicate that they are not happy to be recorded, the moderator should draw them aside and ask whether they are still interested in participating in the study. If yes, the moderator should inform the rest of the group that a recording will not be taken, but that the note-taker will take full notes of the discussion. The note-taker will then have to ensure that they take as full a report of the discussion as possible.
* The moderator should then invite the group to think about what ground rules they would like to have in place for the discussion to make it more enjoyable for everyone. The moderator should use the white board or large pieces of paper to write up participants’ suggestions for ground rules.
* If not mentioned by participants, the moderator should add the following rules:
	+ Turn mobile phones off
	+ Respect everyone’s opinions – there are no right or wrong answers
	+ Give everyone a chance to talk and do not interrupt or talk over someone
	+ Confidentiality must be maintained – do not repeat or discuss with anyone outside the group anything that is mentioned here.
* With regard to the final rule above, the moderator should spend a few minutes asking the participants to think carefully about why it is important not to repeat anything mentioned during the discussion outside the group.
* After the ground rules have been agreed, the moderator should begin the FGD using the topic guide.
* If/when latecomers arrive, the assistant should complete the enrolment form, give them a name badge and show them to a seat, as the note-taker will be recording the content of the discussion.
* Participants should be allowed to leave the discussion briefly for a toilet break, but the moderator should try to manage this so that no more than one participant is absent from the discussion at any one time.
* If participants wish to leave the group altogether, the moderator should ask them if they are happy for their contributions to be included in the research or whether they’d like to withdraw their contributions altogether. If the latter, this should be noted and at the data management and analysis stage, their comments should be removed from the transcripts as far as is feasible.
* At the end of the discussion, the moderator should thank the participants, remind them of how the information will be used and how confidentiality will be maintained by the research team, and then offer the participants refreshments and the opportunity to be reimbursed for travel expenses.
* The assistant should be ready to offer refreshments to each participant at the end of the discussion and then to give reimbursements.
* To reimburse travel expenses, the assistant should use the Travel Reimbursement Log form. They should complete the name of each participant, where they have travelled from, the mode of transport, whether they provided a receipt and the cost of transport. This should cover the return journey as well, if appropriate. The assistant should then give the cash sum to the participant and ask them to sign (or thumb-print) the form to indicate they have received the money.

**B. Immediately after the FGD*** Once all the participants have left, the moderator, note-taker and assistant should re-group for a debrief.
* The moderator will be responsible for completing the Contact Summary Form, with input from the note-taker and assistant where appropriate.
* The note-taker should ensure the digital recorder has been switched off and locked, so that data cannot be wiped from it.
* All data (the audit file, contact summary form, enrolment form, note-taker form and travel reimbursement log) should then be taken to the research office for storage and transcription and translation, in accordance with **SOPs 11 & 12. Transcrbing,** and **Translation.**

**VIII. ATTACHMENTS*** FGD Planner Log
* Travel Reimbursement Log
* Enrolment form
* Contact Summary form
* Note-taker’s form.

**IX. DOCUMENTATION** XXXX Protocol |
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SOP 10. Carrying out team debriefings (FGDs)

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| **SOP ID#:**  | **SOP TITLE: CARRYING OUT TEAM DEBRIEFINGS (FGDs)** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
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 **I. PURPOSE.** To provide research teams with guidance on how to conduct team debriefing meetings following data collection episodes. **II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Record of all FGDs completed in specified period (Enrolment forms)
* Record of all Contact Summary forms for FGDs in specified period
* FGD Planner Log
* Debriefing minutes form
* Notepad
* Clipboard
* Pens

**IV. DEFINITIONS:*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion; a qualitative method to elicit opinions from a group of people, representing a quasi-naturalised social setting to facilitate participation.
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **Moderator:** the field team staff member who will facilitate the group discussion, ask questions and manage group dynamics. The moderator will also be responsible for setting ground rules and taking consent from the participants.
* **Note-taker:** the research assistant responsible for keeping record of all participants, where they sit, their demographic details, the key points of the discussion (including who said what).
* **Assistant:** the other research assistant who will be responsible for organising the venue and the layout of the room, will ensure all participants are informed of the date and location of the FGD, and will facilitate their transportation to the venue where possible. The assistant will also make sure that the digital recorder is working and located in a suitable place, and will organise refreshments for all participants at the end of the FGD.
* **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

 **V. Procedures****A. Arranging debriefing meetings*** The project manager or lead investigator in the field should devise a regular schedule of debriefing meetings reflecting the frequency of FGDs being conducted. Debriefing meetings should be held approximately every 4 FGDs, or once a week, whichever is the sooner.
* The debriefing meeting schedule, including time and location of meetings, should be disseminated to all field team members and any revisions that are made should be communicated at the earliest possibility.
* It is the responsibility of all field team members to ensure that they are able to attend each debriefing meeting and to provide feedback.
* The project manager or lead investigator should ensure that all necessary documents from the specified time period are made available for the debriefing meeting (Enrolment Forms, Contact Summary Forms and FGD Planner Log), and ideally available beforehand to enable the lead investigator to examine the documents.
* A member of the field team should be appointed minute-taker for each debriefing meeting, and be advised on how to capture all the information discussed in the meeting.
* A suitable venue should be arranged for each meeting that is easily accessible for all members of the research team.

**B. Conducting debriefing meetings*** The debriefing meetings should be chaired by the lead investigator in the field, and should be guided by the content of the Debriefing Minutes Form.
* A member of the field team designated to take minutes should record the details of the discussion on the Debriefing Minutes Form.
* The discussion in the meetings should address each of the FGDs conducted within the specified time period, with the field researchers inputting on their experiences and thoughts following the FGDs.
* The discussion of each FGD should be in conjunction with examination of the relevant Contact Summary Form and the moderator and note-taker should be encouraged to reflect on their practice in each interview.
* The discussion should also address similarities and differences between data, what insights have arisen from the series of FGDs and how these compare to any previous data collected and the theoretical framework of the study.
* More practical issues such as problems with the topic guide, equipment or recruitment should also be addressed here, as well as any issues with moderation of FGDs and controlling group dynamics. Any solutions identified should be recorded on the Debriefing Minutes Form and made into recommended action points.
* The discussion should also include the number of upcoming scheduled FGDs, and this should be reflected upon in light of the sampling strategy and the emerging themes, for example if data saturation is beginning to occur.

**C. Feeding back from debriefing meetings*** The completed Debriefing Minutes Form should be disseminated to the wider research team as soon as possible after the meeting.
* If any action points have been recommended, for example for changes to the topic guide or recruitment process, these should be presented to the wider research team for consultation and agreement on action to be taken.
* Changes to the protocol, SOPs or FGD topic guide should not be made without the agreement of the wider research team.
* The lead investigator in the field should be responsible for monitoring the progress of data collection in the field via consideration of all of the Debriefing Minutes Forms, and bring to the attention of the wider research team any concerns or observations as soon as they arise.

**VI. Attachments:** * Debriefing minutes form

**VII. Documentation:** XX Protocol |

**SOP 11. Transcription**

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| **SOP ID#:**  | **SOP TITLE: TRANSCRIPTION** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
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**I. PURPOSE.** To describe the transcription of audio files of focus group discussions with the three sub-groups of participants.**II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Completed contact summary forms
* Audio files
* Completed enrolment forms
* Completed note-taker forms

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Transcriber/translator

**V. DEFINITIONS*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion; a qualitative method to elicit opinions from a group of people, representing a quasi-naturalised social setting to facilitate participation.
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **Transcriber/translator:** this person is responsible for transcribing and translating all the audio files from the FGDs and for ensuring that the files are checked by another member of the team for accuracy.
* **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

**VI. PROCEDURES**1. **Preparing documents**
* The transcriber/translator will be responsible for transcribing the discussions from the FGDs, recorded onto digital voice recorder.
* After each FGD, the audio file should be uploaded from the voice recorder onto the relevant computer software program and saved as a new file with the appropriate file name according to the file naming protocol.
* Each transcript should be typed into a new Word file directly from the audio file in the original language used during the FGD. The file should be saved using the appropriate file name, the same as the audio file.
* At the top of the transcript document should be the transcript table detailing the facilitator and note-taker names, date of the FGD, language of the interview, venue, date transcript completed, the ID number of the FGD, and the language that the transcript is in. See the example below:

|  |  |
| --- | --- |
| Identification Number (e.g. FGDA03)  | |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|  |
| Facilitator name:  |
| Note taker name:  |
| Date of FGD: (dd/mm/yyyy)  |
| Language of FGD:  |   |
| Venue:  |
| Date completed transcript: (dd/mm/yyyy)  |
| Start time of recording |   |
| End time of recordingLength of recording |
|  |

* Immediately after the transcript header table, the contact summary should be inserted prior to the start of the transcript itself.
* Recordings should be transcribed as soon as possible after the interview/group discussion, preferably within 24 hours.
1. **Transcription guidelines**
* The transcription should be done verbatim (every word captured exactly); all hesitations (umms, mmms, errrs), repetitions and incomplete sentences should be marked.
* Each new speaker should begin on a new line with their participant number (or ‘moderator’) at the beginning.
* Non-verbal occurrences including pauses (labelled short or long), laughter, exclamations or sounds of surprise, shock, disagreement, agreement should be marked in square brackets, eg [gasp of surprise] or [whole group laughs]. Any external interruptions should also be recorded in square brackets eg [telephone rings].
* Interruptions by another member of the group should be indicated with a ‘---‘ at the point of interruption in the interruptee’s speech and the beginning of the interrupter’s speech. The interrupter’s speech should begin with a lower case letter and be indented into the page. For example:

 Participant 4: I find the thought of taking more medication on top of my ART rather daunting and I’d prefer ---Participant 6: --- I don’t agree with that, it’s no more difficult for me.* Where more than one person is talking at once, the overlapping parts of speech should be contained within <<....>>. For example

  Participant 3: It’s when you go to the clinic and see a new nurse and have to explain your condition <<again to her, when you just want to say ‘I have malaria,>> please give me medication, it’s nothing to do with my HIV’Participant 1: <<absolutely, it’s so annoying>>* Any relevant annotations or observations from the note-taker’s form or contact summary form should be included in the appropriate place in the transcript within {...}. For example:

**{**Participants 4 and 5 look at each other and raise their eyebrows in an amused way}* If there are any words or sentences that are not clear or are inaudible, the transcriber should suggest what they think it is in italics followed by a ‘?’, and surrounded by ~...~, or write the word ‘inaudible’ in italics and surrounded by ~...~ if necessary. For example:

Participant 9: That’s never happened to me, I don’t think I’d worry too much if my daughter ~ *got sick*? ~.* If a comment cannot be attributed to a particular participant or group of participants, it should be labelled UNKNOWN, and where appropriate an estimate of the number of voices should be given, eg UNKNOWN (3 voices):.

**C. Checking transcriptions** * Once a transcription has been completed, the transcriber/translator should read through the transcription against the audio file to check for accuracy and completeness.
* The transcript should then be passed onto another member of the field team for checking and for verification of any unclear words or terminology.
* The transcriber/translator along with another member of the field team should then read through the transcript a third time to check whether there are any identifying details, and if so, to remove them or replace them with anonymous terms, for example names should be replaced with participant numbers or general descriptors such as “clinic nurse”, and place names should be replaced with a descriptor in “...” such as “local hospital”.
* Once transcripts have been checked and refined, they should be translated using the guidance in **SOP 12. Translation.**

**VIII. DOCUMENTATION** XXXX Protocol |
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**SOP 12. Translation**

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| **SOP ID#:**  | **SOP TITLE: TRANSLATION** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
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**I. PURPOSE.** To describe the translation of transcripts of focus group discussions with the three sub-groups of participants.**II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Transcripts of audio files.

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer
* Transcriber/translator

**V. DEFINITIONS*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion; a qualitative method to elicit opinions from a group of people, representing a quasi-naturalised social setting to facilitate participation.
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **Transcriber/translator:** this person is responsible for transcribing and translating all the audio files from the FGDs and for ensuring that the files are checked by another member of the team for accuracy.
* **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

**VI. PROCEDURES**1. **Translating**
* Audio files in Kiswahili will be transcribed in full on paper and then translated into English by the translator after transcribing has been completed.
* The original text will remain in the document, with the translation made beneath each short section of 4-5 lines. Sections of text will be double-checked for accuracy of translation by the interviewers who conducted the focus group or interview.
* For words that can have many meanings depending on the context in which the word is used or said, it is important that the translator writes all the possible meanings of the word/phrase in brackets and then the most appropriate meaning to the phrase that the respondent used is written out of bracket.
* Rather than word-for-word direct translation, or summarization, the translator will conduct meaning-based translation as outlined in the figure below:

 SOURCE LANGUAGE RECEPTOR LANGUAGEText to be translatedTranslationDiscover the meaningRe-express the meaning1. **Checking translations**
* The translated script will then be passed to a fluent English speaker who will check each of the scripts for legibility, accuracy and reproducibility.
* The checker will edit the translated transcript document. This can be done on the computer, using the ‘track changes’ function of Word, or can be done on paper, inserting any additional comments, using light green markers. All changes on the translated scripts should be made by drawing a single line through the incorrect word or phrase and then writing the correction above, if using paper, or by inserting a change under the ‘track changes’ function on the computer. Corrections made will bear the initials of the staff member correcting and date of correction.
* Both the final corrected script and the paper copy of the translated script should be filed.
* In the case of any difficult terms, phrases and corrections, the checker and translator will sit together and discuss, such that final and most appropriate translations are agreed upon.
* Only the final corrected translated transcript will be typed into the computer, if necessary. The translator will be responsible for typing the translated transcript into the computer.
* Translated transcriptions will be saved as new Word files, and labelledwith the FGD ID followed by the language that the transcript was translated into (usually English) e.g. ‘F101 E English’.

**VIII. DOCUMENTATION** XXXX Protocol |
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**SOP 13. Data coding and analysis**

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| **SOP ID#:**  | **SOP TITLE: DATA CODING AND ANALYSIS** |
| **Effective Date:**  | **Written by:**  |
| **Date Reviewed:** | **Approved by:** | **Approved Signature:** |
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**I. PURPOSE.** To describe the process of coding data transcripts and conducting data analysis.**II. RATIONALE.** We plan to conduct focus group discussions with three groups of patients in Muheza, Tanzania; HIV-positive people receiving anti-retroviral treatment and treatment for malaria; HIV-negative people receiving only treatment for malaria and HIV-positive people receiving only anti-retroviral treatment. This is to explore perceptions of malaria and malaria treatment, and to compare these between groups of people who do and do not currently take treatment for HIV. *Add summary of project and method rationale.***III. SUPPLIES AND MATERIALS*** Electronic files of translated transcripts
* NVivo software

**IV. TARGET AUDIENCE*** Investigators
* Project managers
* Study coordinators
* Project officer

**V. DEFINITIONS*** **ACT:** Artimesinin-combination therapy for treatment of malaria
* **ART:**  anti-retroviral therapy for treatment of HIV
* **FGD:** focus group discussion; a qualitative method to elicit opinions from a group of people, representing a quasi-naturalised social setting to facilitate participation.
* **Data analyst:** member of the research team responsible for coding and analysing the data.
* **InterACT:** clinical study currently underway in Muheza, Tanzania exploring safety and pharmacokinetic implications of taking ACT and ART concomitantly
* **Sub-group A:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-positive, receiving ART and ACT for malaria.
* **Sub-group B:** this is the sub-group of participants who represent people participating in the InterACT study, who are HIV-negative and receiving ACT for malaria.
* **Sub-group C:** this is the sub-group of participants who represent people not participating in the InterACT study, who are HIV-positive and receiving ART but no treatment for malaria.

**VI. PROCEDURES**1. **Managing quantitative data**
* Quantitative data from the FGD enrolment forms will be entered into an Excel spreadsheet by the data analyst, and will be double entered to verify accuracy.
* This data can then be uploaded into a new NVivo file as a casebook and can be linked to all the transcription and audio files.
1. **Managing qualitative data**
* All data files – the final edited versions of translated transcriptions, as Word documents, typed up contact summary forms, and the audio files – should be imported into a new QSR NVivo 8 workbook, where the files should be saved as ‘internals’.
* The new workbook should be saved with the name of the study, the date and the initials of the investigator working on it.
1. **Developing initial coding**
* Two or three transcripts should be selected at random to be used to develop an initial coding structure. The data analyst should begin to work slowly and carefully through each document, reading line by line to try to interpret the underlying meaning.
* For each line of text/sentence/sub-section of a sentence that carries meaning, the text will be highlighted and used to generate a new ‘tree node’ in the coding section. The ‘tree node’ can be labelled either using the *in vivo* text, or with a short description of the meaning or concept represented by the text.
* New ‘tree nodes’ should be developed for each new idea identified in the text. Repeating ideas can be coded using existing ‘tree nodes’. Names of ‘tree nodes’ can be modified to reflect the content as the coding progresses through the first few transcripts.
* It is important at this stage to generate codes (or ‘tree nodes’) from small units of empirical text, and to identify as many different ideas or units of meaning as possible.
* As the coding of the initial transcripts develops, tree nodes may be linked together under a new ‘parent node’ representing a common theme or idea.
* Once the first two or three transcripts have been coded in this way, with tree nodes grouped under parent ‘theme’ nodes where possible, the data analyst should create a new ‘memo’ to record what has been coded, and any reflections on that process.
1. **Creating a coding template**
* The series of parent and tree nodes developed through the initial coding should be saved and if appropriate, shared with other members of the research team to discuss the suitability of the codes.
* Following discussion and any revisions to the coding, the coding template will be finalised and saved.
* The coding template will then be used to code the remaining transcripts by the data analyst.
1. **Coding**
* As coding progresses, new categories, ideas or themes may emerge causing new nodes to be developed, existing ones to be modified or ‘parent nodes’ to be rearranged. Every time this occurs, the data analyst should create a new memo to describe what is being changed, why and to reflect upon this in light of the whole data analysis process.
* As coding progresses, parent nodes representing themes may be grouped together to represent emerging constructs, which will be labelled.
* Periodically, the coding structure and arrangement should be reviewed and discussed by members of the research team. Again, memos should be created to capture these discussions and any subsequent changes.
* Once all the transcripts have been coded, the coding structure, themes and any constructs will be finalised following discussion with the research team.
1. **Developing theoretical constructs and narratives**
* The fully coded project should be explored for theoretical constructs by the data analyst in conjunction with the research team. This will include the running of queries, looking at any differences in the concepts emerging according to sub-groups, and different characteristics of participants.
* The data analyst should then develop a narrative bridging the original research concerns with the participants’ subjective experiences. The aim of the theoretical narrative will be to retell the participants’ stories in terms of the theoretical constructs.
* The findings should be related to wider theory and literature in the topic of interest, documented in the literature review section of the protocol.
* This will involve relating the findings to the original conceptual framework, which may be adjusted or replaced by a new framework based on the evidence from the study. .
1. **Drawing conclusions**
* The data analyst should present a draft set of findings and conclusions, based on the data analysis and engagement with literature and the conceptual framework.
* This draft should be discussed with the wider research team, indicating where any revisions, clearer narrative links or more detail is required to justify the conclusions.
* Further conclusions or revised conclusions may be made as a result of the discussion.
* The discussion should also address how the conclusions can feed into recommendations to be made.
* Following the discussion, the data analyst should revise the draft findings, and write up the conclusions and recommendations.

**VII. DOCUMENTATION** XXXX Protocol |
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