ACT Consortium Guidance: Qualitative Methods for International Health Intervention Research

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Abbreviations

ACT	Artemesinin combination therapy
FGDs	Focus group discussions
HFs	Health facilities
HWs	Health workers
IDIs	In-depth interviews
SOP	Standard Operating Procedure
RDT	Rapid diagnostic test
QAS	Quality assessment and strengthening

Glossary

Analytic approach	A theoretical orientation to and set of techniques for conceptualising and interpreting data.
Coding	The practice of categorising data (e.g., sections of text from transcripts) by meanings or ideas, as they are interpreted by a researcher.
Conceptual framework	A theoretical framework or model describing the prior conceptualisation taken by a researcher of a particular phenomenon or issue. Often depicted graphically, a conceptual framework identifies factors that researchers believe may explain or influence the 'problem' to be studied, outlining hypothesised relationships between them.
Constructivism(ist)	An epistemological approach, or school of thought, which sees reality as multiply constructed, similar to interpretivism. But, whereas interpretivist researchers typically maintain analytic distance between their own and research subjects' beliefs as a matter of credibility, constructivist researchers recognise the shared or co-construction of meanings and explanations by both researchers and participants and may treat research activities as opportunities for change.
Epistemology	Epistemology is concerned with ways of knowing and learning about the world. Different epistemologies reflect different accepted ways that knowledge can and should be acquired. These epistemological positions reflect different ways of thinking about the nature of reality (ontology). In social research, some research is based on the premise that there is a social world which can be objectively observed and described in terms of sets of rules or laws, in a similar way to the natural sciences (positivism). Some other research is based on the premise that there is no single reality, there are multiple realities that are constructed by different groups, and learning about social worlds is an exercise in relativity and reflection on the position of the researcher in generating knowledge (constructivism).
Ethnography	A methodological approach to research that originated in the discipline of anthropology and aims to understand peoples' social worlds through immersion in their communities, using long term participant observation together with other methods such as interviews, often with the same individuals over time, and surveys informed by the ethnographer's observations. The product of this work is rich descriptions of the daily lives, relations, priorities and principles of different groups. The word 'ethnography' is also used to describe this product – usually in book form.

Field notes	A primary method of data collection in ethnographic research, field notes or diaries are a reflexive tool that researchers can use to record many types of informally-collected data. They are particularly used as a tool for participant observation where researchers seek to write 'thick descriptions' of what they are observing. Such unstructured notes allow the fieldworker to record what they are seeing, hearing and thinking, which may not be captured in structured methods or recordings. Such notes may include drawings of spaces, dynamics of a situation or the encounter with the researcher, connections made with previous observations or ideas and new ideas for inclusion in later fieldwork.
Formative research	Aims to understand an existing situation into which an intervention is to be introduced. Such research aims to understand the target 'problem' identified for an intervention, the local context and history and possible interventions that may meet the priorities of the intended target population. Formative research can be central to ensuring that an intervention is optimally designed.
Grounded theory	An approach to analysis which aims to develop emergent theories of social action through the identification of analytic categories and the relationships between them.
Interpretivism(ist)	An epistemological approach, or school of thought, which sees reality or the social world as not governed by regularities that hold law-like properties. Rather, the social world is seen to be governed by normative expectations and shared understandings which are mutable. Researchers explore and understand the social world through participants' and their own perspectives. Findings are accepted as being influenced by the researcher's perspectives and values, and as such researchers do not aim to conduct objective, value-free research. Instead, credibility is based on the researcher's reflection on their assumptions and role in the generation (reflexivity). Explanations are offered at the level of meaning, rather than cause.
Key-informants	People who possess expert knowledge about the group, topic or behaviour of interest to the researcher, for example community leaders, and who can provide insight on the nature of problems and give recommendations for solutions.
Logic model	An evaluation term used to describe the conceptual framework that explains the hypothesised mechanisms of effect of an intervention. Logic models are usually a graphical depiction of the logical relationships between the resources, activities, outputs and outcomes of an intervention which can be used to assess causal relationships between the elements in an evaluation.

Methods	A systematic or established procedure for carrying out fieldwork or analysis.
Methodology	The theoretical orientation underlying which method, set of methods or principles are applied to a research problem, within a particular discipline.
Normative	Relating to an ideal and shared cultural standard or model. Normative statements are value-laden and make claims about how things should be, and whether things are right or wrong. If sufficiently commonly-endorsed, social norms can become seen as 'common sense' and through socialisation, encourage or discourage specific types of behaviour or ways of thinking or talking.
Outcome evaluation	Quantitative outcome evaluations measure pre-specified outcomes that are intended to change as the result of an intervention. Qualitative outcome evaluations aim to understand the broader outcomes or impacts of an intervention, including unintended consequences. The latter often aim to offer explanations of why and how an intervention worked (or did not work) in terms of hypothesised versus actual mechanisms of effect.
Paradigm	A distinct set of beliefs or worldview that guide action consisting of ethics, epistemology, ontology (the nature of reality) and methodology.
Positivism(ist)	The epistemological approach, or school of thought, which sees reality and human behaviour as governed by law-like regularities. Phenomena are seen to be objectively observable, leading to facts which are seen as distinct from values. Methods developed for the natural sciences are seen as appropriate for social enquiry.
Process evaluation	Aims to understand the delivery and process of implementation of an intervention, comprehensively describing its components as received by the target audience and explaining unexpected results found in outcome evaluations.
Purposive or criterion-based sampling	A non-probability (non-statistical) approach to selection of research participants for small-scale qualitative research in which units are deliberately selected to reflect particular features of or groups within the sampled population. Unit features (socio-demographic characteristics, experiences, roles, behaviours, etc) are chosen to enable detailed exploration and understanding of the central themes and puzzles which the researcher wishes to study.
Quality assurance	Strategies to facilitate qualitative researchers to enact principles of quality at each stage of the research process, and to offer opportunities to demonstrate to external audiences the credibility of their research

Reflexivity	A continuous process of reflection on research and activities undertaken to collect and interpret data. Reflexivity involves examining one's assumptions and preconceptions, and how these affect research decisions, such as the selection and wording of questions and values placed on different types of data in the interpretation process. It also involves examining one's relationship to respondents, and how relationship dynamics affect responses to questions.
Saturation	Ideas expressed are repetitions of concepts identified in earlier work and no new themes emerge.
Stakeholders	People in decision-making positions, for example district health officers, who may provide information about existing structures, a historical perspective and perspectives on possibilities for change.
Theoretical perspective	A set of assumptions about reality that underlies the questions we ask and the kinds of answers we arrive at as a result.

INTRODUCTION TO THIS GUIDANCE DOCUMENT

Qualitative Research in the ACT Consortium

Qualitative research methods are increasingly in demand in the field of 'global health'. Often, they are used alongside, or embedded within, clinical trials to add deeper interpretations of the success – or otherwise – of interventions. This mounting appreciation of qualitative methods, and proximity to intervention research with established protocols to ensure standardisation and quality, has driven demand for guidance on conducting good quality qualitative research in these scenarios.

From our own experiences with conducting qualitative research within a group of projects investigating malaria diagnosis and treatment in ten countries in Africa and Asia, we have needed to respond to demands for demonstrating the quality of our research processes. As an international research consortium, we were furthermore challenged to cross spatial distances between senior investigators and field teams working in remote field sites as well as theoretical distances between researchers coming from different disciplines and educational backgrounds.

Faced with these needs and an absence of cohesive guidance to strengthen the quality of the type of qualitative work we were engaging in, we undertook substantive research on best practices and prepared guidance for our field teams to this aim. This document is a compendium of this guidance. It is not meant to be prescriptive, nor a collection of definitive 'lessons learned'. Rather, it is a description of what we did and our thinking behind it. Written by the Consortium's core social scientists (mainly anthropologists), the suggestions and templates are a result of reflections on the theoretical challenges of applying a meaning-centred approach in a set of projects that were related in a devolved, multi-team approach, characteristic of the way much global health research is conducted today. The research questions we were addressing represent a mix of public health research and practice perspectives alongside a more anthropological approach. The methods we present here are intended to be easily understood by to public health audiences, and we have incorporated values and languages used in public health research such as systematicity, transparency and the preference for work by teams over individuals.

It is our sincere hope that this experience may be useful to other groups engaging in large-scale qualitative international health interventions research.

About the ACT Consortium

Malaria is a leading cause of morbidity and mortality in many countries in Africa and in Asia. The wide-spread introduction of Artemisinin Combination Treatment (ACT) since the mid-2000s presented an opportunity to reduce this burden of malaria but, at this time, methods to effectively deliver treatment to those who most needed it remained unclear. Policy-makers were having to make major decisions on how best to deploy ACTs with little or no relevant evidence. We hoped to answer key questions on ACT delivery so that policy-makers would have the evidence they need.

Since 2007, the ACT Consortium has been developing and evaluating delivery mechanisms in a series of 25 projects to improve ACT access, targeting, safety and quality in endemic areas of Africa and Asia. Further details of us and our work can be found on our website: www.actconsortium.org

How to use this document

This guidance document covers theory and practical advice on qualitative methods in five chapters. Chapter 1 introduces the reader to some of the principles of social science that underlies qualitative research and three key stages of intervention design and evaluation which qualitative methods contributed to in the ACT Consortium. Chapter 2 discusses principles and practices for using three core qualitative research methods. Chapter 3 covers some practical issues relating to setting up a qualitative research project alongside or imbedded within an intervention. While this entire document is devoted to improving the quality of qualitative research in interventions, in Chapter 4, specific theory and methods for assuring on-going quality in qualitative research are discussed. Finally, approaches to analysis and writing-up of qualitative data in a team are discussed in Chapter 5. Qualitative research and social science theory terms which may be new to readers are ***highlighted in blue*** in the text; their definitions can be found in the Glossary at the beginning of this document.

Throughout the document we refer to specific experiences from planning and conducting qualitative research in ACT Consortium interventions. We also refer to examples of materials developed for this work and include extracts from these as boxes, tables and figures. The reader can find many more examples from ACT Consortium qualitative research, however, in the Supplementary Materials developed for and referred to **highlighted in orange** in this guide, available on the ACT Consortium website. These include:

1. ACTc Qualitative Research Protocol Template and Tools
2. ACTc Quality Assurance Monitoring for Qualitative Research Protocol Template
3. ACTc Qualitative Research Training materials (a folder including workshop Powerpoint presentations and handouts)

CHAPTER 1 Introduction to Qualitative Research

Chapter Outline

1.1 Why Do Qualitative Research?

All research seeks to make sense of the world using a particular set of methods, and all methods are underpinned by a particular set of theories or philosophical assumptions. To most fully understand a particular social phenomenon it can be helpful to look at it from many different angles, using a variety of quantitative and qualitative methods. As many researchers see it, quantity and quality are two sides of the same coin since, "behind every quantity there is a quality" (Sobo 2009). But what is it about qualitative methods in particular that make them increasingly in demand today in global health research?

There are probably two main, inter-related answers to this question. The first is that qualitative research can be valuable for studying *meaning*: what is important to people based on their knowledge and experience and why, since meaning influences social interactions on an individual and collective level –and these interactions ultimately influence health outcomes. In studying meaning, qualitative research is humanistic because it focuses on the personal, subjective, and experiential basis of knowledge and practice. It is also holistic because it seeks to situate the meaning of particular behaviours and ways of thinking about or doing things in a given context (Kielmann, Cataldo et al. 2011).

The second answer is that the interpretive and ***reflexive*** approach that qualitative research takes can reveal what is important about *processes*: of social behaviour, interventions and research methods themselves. According to an interpretive approach, the aim of qualitative research is to explain (e.g., an intervention's apparent success, or otherwise) rather than to merely describe (Kielmann, Cataldo et al. 2011). Further, by adopting a reflexive position to research as a social interaction, qualitative researchers are explicit about highlighting the interconnection between the nature of enquiry (e.g., how a survey question is asked) and the conclusions that are drawn, especially when the outcomes can only be understood through reference to that process (Walker and Dewar 2000).

These concepts will be discussed in more depth throughout this document; first, in this chapter, we introduce the reader to some social science principles and discuss the contributions that three particular types of qualitative research to ACT Consortium projects which are likely to apply more proudly to international health intervention research.

1.2 Social Science Principles Informing Qualitative Research

A central concern of qualitative enquiry is about theories of knowledge or ***epistemology***: how do we know what we know about the world? How does this relate to truth and evidence so that, as researchers, we can say something about the social phenomena we are studying, with confidence?

Most readers will be familiar with the theoretical perspective on knowledge common to the natural and quantitative sciences, described in epistemological terms as ***positivism***. This perspective sees reality and human behaviour as governed by law-like regularities. Developed out of a long tradition of empirical thought, this approach posits that all phenomena (including social behaviour) can be directly observed and measured through the scientific method. Phenomena are consistent across different contexts. Importantly, 'facts' and 'values' are considered to be distinct or separable. According to this approach, methods developed for the natural sciences are therefore appropriate for social enquiry and it is possible to carry out independent, objective and value-free social research.

The development of ideas now particularly associated with qualitative research can be traced through the late 18th to 20th Centuries (Snape and Spencer 2003) but the appreciation of qualitative methods as valid and appropriate to research gained potency in the 1970s, by which time positivism itself and the legitimacy of social research based on the scientific method began to be more widely debated. In particular, researchers were concerned about whether it is possible to 'control' variables in experimental research involving human subjects to achieve unambiguous results and whether emphasis on hypothesis testing neglects the importance of discovery through alternative understandings (Snape and Spencer 2003). By arguing for an interpretivist (meaning-centred) approach to knowledge generation, qualitative research came to be seen as a means to overcoming these limitations, aided by attempts by social researchers such as Glaser and Strauss (1967) to formalise their methods for wider acceptance by researchers in the natural sciences.

Interpretivism is the epistemological approach which sees the social world as not governed by regularities that hold law-like properties. Rather, inhabited by thinking people, the social world is governed by ***normative*** (values-based) expectations and shared understandings which are mutable (can change over time and across contexts). 'Facts' and 'values' are more difficult to distinguish, so, according to this approach, methods developed for the natural sciences, which do not consider values, are problematic and inappropriate for social enquiry. Social researchers instead explore and understand (interpret) the social world through participants' and their own perspectives. Findings are inevitably influenced by the researcher's perspectives and values, making it impossible to conduct objective, value-free research, but the researcher can declare and be transparent about his/her assumptions to gain credibility. Explanations can only be offered at the level of meaning, rather than definitive cause.

Post-modernism, critical theory, feminism, race research and participatory or 'action research' have since added to this discussion on knowledge, for example, by further questioning the notion of

objectivity with which qualitative researchers can truly offer a single authoritative account of other people (Snape and Spencer 2003, Sobo 2009).

Under a multi-method approach to operational research, some proponents argue that a helpful balance can be struck between philosophy (epistemology) and pragmatism, such that qualitative and quantitative techniques are viewed as part of a toolkit to be deployed in different contexts to address different research questions (Snape and Spencer 2003). The risk of divorcing techniques from their philosophical foundations in transdisciplinarity remains heavily debated, however. In this document, we discuss all chapters in relation to epistemology to encourage reflexivity as best practice in all stages and types of qualitative intervention research.

1.3 Who Does Qualitative Research?

In order to carry-out meaning-centred qualitative research with a reflexive focus on processes there are at least three inter-related characteristics that a qualitative researcher or research team collectively should possess. First, researchers should be very familiar with the study topic and the study context, in order to be able to pose the most relevant questions and situate all research findings (whether qualitative or quantitative) "within the fabric of daily life and the encompassing systems within which daily lives are lived" (Sobo 2009). People from the study area will have an inherent understanding of many aspects of the context which frame research topics. Knowledge of context can also be purposely gained, for example, using participative immersion, a principle activity of ***ethnography***, in which researchers spend substantial time becoming familiar with the culture under study. The purpose of becoming familiar with context is to overcome narrow or oversimplified understandings of others' 'culture', for example, as something "more than just ethnicity [...] [rather, one] that includes, for example, professional and organizational cultures, too" (Sobo 2009) or, at worst, as a set of inherently problematic 'beliefs' that can be straightforwardly exchanged for accurate knowledge using education (Good 1994). In fact, maintaining a focus on complexity in social phenomenon by spending time understanding context is a critical means to ensuring validity in qualitative research (Manderson 1998).

Training in the interpretivist and reflexive approaches is the second requirement for good qualitative research as it helps researchers better understand culture or context more "as a process than a thing" (Sobo 2009). By viewing 'beliefs' through an epistemological lens, they can be seen as constructed by history, people, politics and environments that are constantly changing in a totality of interconnected processes. Careful fieldwork that accounts for process and meaning can reveal how pre-existing ideas accommodate new ones, given the right social circumstances. Without awareness of social theory, researchers may simply apply qualitative methods as a set of unreflexive techniques like factory workers, which "virtually guarantees the superficiality of findings" (Sobo 2009).

Through intimate knowledge of context, qualitative research specifically seeks to explain social phenomena from an *emic* perspective that comes from insider cultural knowledge (rather than an external perspective) but these explanations also simultaneously acknowledge the perspective as socially constructed. Getting this balance right requires maintaining sufficient critical analytic distance, the third characteristic qualitative researchers should possess. Critical distance is needed, for example, to enable the distinction of values and norms, which are dynamic, from 'facts' or 'common sense' which are static and therefore not subject to change. In this, people from outside a

culture may be better placed to maintain a focus on this distinction because they are naturally making constant comparisons about their observations between at least two contexts (the one under study and their own).

Qualitative research therefore benefits from a team approach, with 'insiders' and 'outsiders' each contributing their interpretation of the social phenomena under study but, crucially, the best qualitative research is done when all team members are aware of and constantly use social theory to plan, conduct and reflect on research activities. Teamwork in qualitative research is discussed again in terms of research logistics in CHAPTER 3.

1.4 Qualitative Contributions to Intervention Research

Qualitative methods can be used to answer many types of research question and several resources exist to assist readers in selecting methods according to the type of question (Ritchie and Lewis 2003, Curatio and LSHTM 2011, Kielmann, Cataldo et al. 2011). In relation to international health interventions in particular, we highlight here key contributions that qualitative field research can make at three stages of intervention design and evaluation, namely: formative research, process evaluation and outcome evaluation, summarised below in Table 1. In the remainder of this chapter we discuss details of these, using examples from ACT Consortium projects.

The focus of qualitative research in the ACT Consortium was to gain an understanding of community, patient and health worker perceptions and behaviours in relation to malaria, its diagnosis and treatment in different settings. Studies of malaria perceptions and behaviours conducted over several decades in different (mostly African) settings were useful for hypothesising factors that could enhance or diminish effects of interventions to improve antimalarial delivery. However, perceptions and behaviours are dynamic, expected to vary between social groups and to affect and respond to change over time. Therefore, further data collection at the start of an intervention study was warranted in some settings to contribute to intervention design (***formative qualitative research***). Qualitative data was also collected to compare perceptions before and after an intervention or between intervention and control arms of a trial (***outcome evaluation***). In addition to forming and evaluating an intervention from an 'outcomes' viewpoint, intervention researchers sought to evaluate interventions from a 'process' viewpoint (***process evaluation***). For interventions of a complex nature such as ours which involved a change in behaviour of communities or providers, understanding the detail of components of an intervention actually delivered and received by participants was considered essential to interpret the impact of the intervention and to inform policy.

Table 1. Key stages of intervention research which qualitative methods can contribute to

Intervention stage	Qualitative research contribution
Formative research	In-depth qualitative methods can be used to understand the target problem and context of the intervention such as the particular perceptions, experiences and knowledge underlying provider and/or community behaviours in the study area, as well as structural barriers to change. This

	information can then be used to choose and refine intervention design. Qualitative methods can additionally be used to develop and pilot intervention content with its intended users. For qualitative evaluations, data collected at this stage can also be used as baseline data to compare with data collected during or after an intervention.
Process evaluation	Taking place during the trial, both qualitative and quantitative methods can be used to find out if the implementation of the trial is going as planned in the objectives. This entails assessment of the intervention in terms of its *fidelity, dose delivery, dose received, reach, recruitment* and documentation of the *context* of the trial. This is on-going and can therefore contribute to changes in the intervention during the trial as well as to an understanding of the effect of the intervention.
Outcome evaluation	Qualitative assessment of intervention outcomes, such as changes in health worker and community perceptions and behaviour, and the acceptability of intervention components to support assessments of causality. This may take place during and/or after an intervention and encompasses both intended and unintended consequences of interventions.

1.5 Formative Field Research

1.5.1 Honing understanding of the research problem and potential solutions

During intervention design, formative field research can complement information-gathering activities conducted in several domains including review of evidence on interventions and behaviour change theory in the literature (see, for example, our discussion elsewhere on intervention design and selected lessons learned from planning interventions in ACT Consortium work: "Designing health service interventions in low resource countries: lessons learnt" by Chandler et al available at www.actconsortium.org/publications.

Formative field research aims to understand the target problem, its context and/or possible solutions and it can be central to ensuring that an intervention is optimally designed (Power, Langhaug et al. 2004, Ulin, Robinson et al. 2005). Different methods are used, depending on the question to be answered, including quantitative surveys to identify determinants of the problem (Yoder 1997) and/or qualitative methods that try to capture locally-driven interpretations of the situation (Arhinful, Das et al. 1996, Manderson 1998, Nichter, Acuin et al. 2008). Quantitative approaches have the advantage of being relatively rapid, although these have limited capacity to bring out new understandings of a situation, often asking questions based on pre-determined topics which may exclude some relevant issues (Yoder 1997). Qualitative approaches such as ethnographic observation, in-depth interviews, and discussions with groups of people expected to be targeted by the intervention are open to unexpected findings, but require expertise and often more time for fieldwork and analysis.

In response to these limitations, various qualitative rapid appraisal approaches have been developed (Agyepong, Aryee et al. 1995, Trotter, Needle et al. 2001), with some success in contributing to intervention design (Manderson and Aaby 1992). Key informant interviewing with particularly knowledgeable and articulate individuals can be useful for this purpose (see Box 1 for an example topic guide of a key informant interview in ACT Consortium formative field research; examples of other types of formative research tools can be found in the Supplementary Materials document: **"ACTc Materials - Qualitative Research Field Tools"**). Participative 'needs analysis' exercises which engage intervention recipients to help researchers explore the diversity and complexity of needs and priorities of local actors can also be used (Cornwall and Jewkes 1995). In addition, these approaches can identify what is already being undertaken in the study area or what has been tried in the past to address the target problem, or a similar issue.

Still others argue that the anthropological 'sensibility' (theories and concepts, analytic approaches and anthropological imagination) necessary to generate the most informative baseline information about a problem to guide intervention design cannot possibly be collapsed into this abbreviated format (Manderson 1998). Such advocates argue that the target behaviours studied in formative field research must be situated in the local social, economic and cultural context which draw attention to the structural barriers to change (and therefore the difficulties of introducing and sustaining interventions), prompting calls for investment in qualitative research, above all, at this formative stage.

Formative field research comprised a significant phase in the design of ACT Consortium projects in terms of time and resources. This investment was considered valuable up front because the target behaviours were known to be 'difficult to change'. Existing studies showed that simple interventions to introduce new malaria drugs and diagnostic tools for malaria had had limited impact on uptake and adherence by health workers previously (Smith, Jones et al. 2009, Rao, Schellenberg et al. 2013). We felt it was important to understand current practices, including perceptions and enactment of care and treatment seeking, as well as local histories of previous and existing interventions, in order to design intervention packages with the potential to support change in specific contexts.

Box 1. Example topic guide of a key informant interview

Key informant interviews are often used to help an outsider to understand an issue or setting. Below is an example topic guide with community leaders used in ACT Consortium research to assist design of an intervention to introduce rapid diagnostic tests for malaria diagnosis.

Topic of interest	Question
Treatment seeking behaviour	What typically happens when you or your child is ill? What happened last time you/your child was ill – can you tell me the story?
Malaria knowledge & Practice	What is malaria? How do you know if you/your child has malaria? How do others usually describe malaria? What can you do and can you not do when you have malaria? How does malaria stop – and what do you do to stop it?
Perceptions of tests	How do you know that you have malaria? Last time you personally had malaria, what made you know that it was malaria? What are your experiences with tests for malaria – can you tell me about when/where you were tested and your experiences that time with the process and outcome? What do you know about getting a negative result for malaria from the lab – what should be done then?
Perception of antimalarials	How do you deal with a case of malaria? What did you do last time when you had malaria? Is this the same as for other people, or do others do something different? Why are there differences in what people do when they think they are having malaria? What do you know about the malaria drug known as Alu/Coartem? Have you heard anything about people using this drug, and their opinions of when and how it works? How does this compare with your own and others' previous experiences with malaria drugs?
Perception of health workers	What options do you have for getting help when you have malaria here? What can you tell me about the public health centre that is near to here – what are your experiences there? If you think you might have malaria, is this somewhere you would choose to go, or not to go? What experiences have you or others had there that makes you decide to use/not use that health centre so much?
Perception of IEC	Do you think that the methods for diagnosing and treating people with fever in this community should be changed? If so, who is responsible? What do you think would be effective in improving the way fevers are dealt with here? What other activities are going on here about malaria and fevers / improving access to health care – and what are your opinions of these (probe for what and who they involve, what and who are left out, what conflicts and opportunities have arisen etc)?

1.5.2 Use of conceptual frameworks

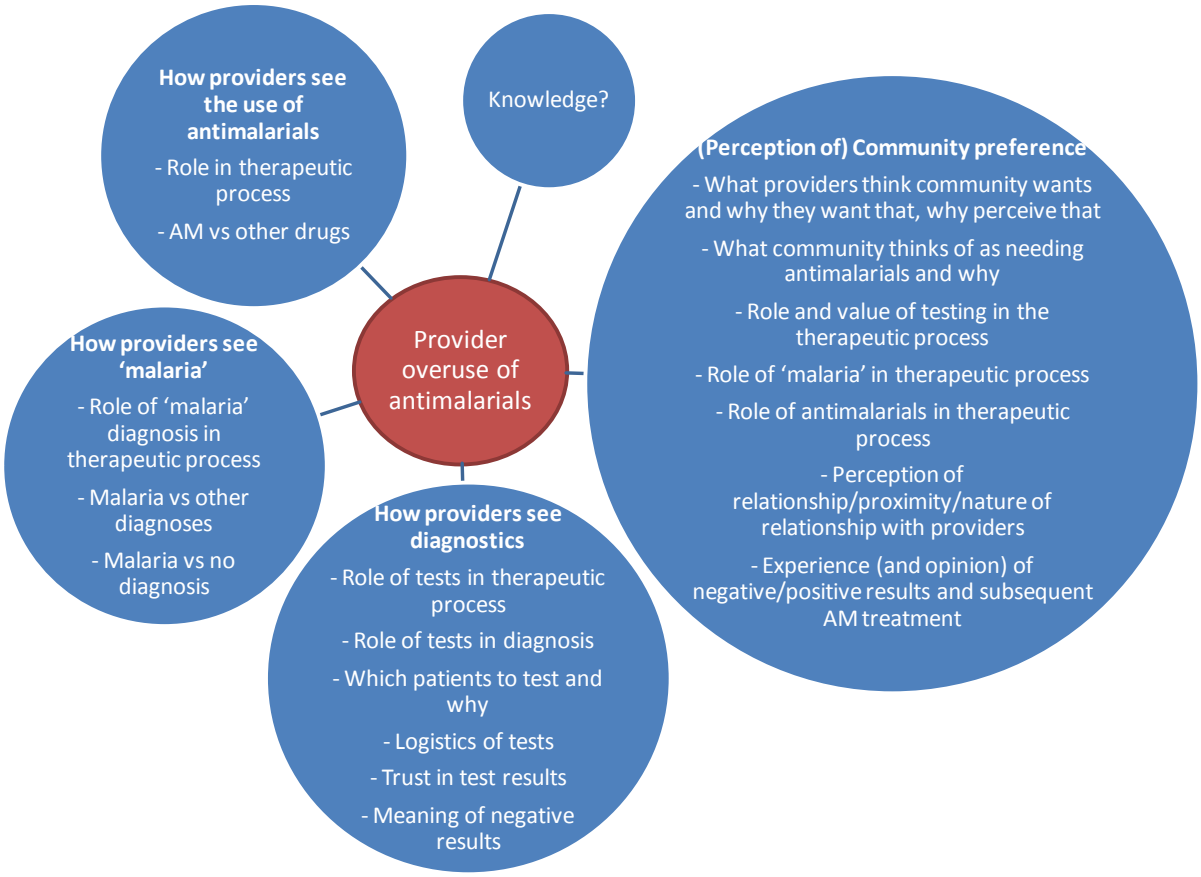
Even the most directly applied formative field research should be carefully conceptualized prior to undertaking fieldwork, in order to maximise the usefulness of the fieldwork. To assist in this, a ***conceptual framework*** may be developed which can be continually added to and refined during the analysis of the formative research and through the intervention design and even evaluation stages of the project. A conceptual framework attempts to depict factors that may explain or influence a 'problem' to be studied, outlining hypothesised relationships between them. The process of developing and documenting a conceptual framework can help a research team to be explicit about the factors presumed to shape the problem as they see it, and can be useful in highlighting the factors and relationships perceived to be most important (Robson 2011).

In ACT Consortium projects, we found the process of developing a conceptual framework was dynamic, drawing on reviews of literature and theory undertaken already, implicit hypotheses that underlay the project's logic and the experiences and perspectives of project field workers familiar with the study setting, local priorities and histories. See Box 2 for an example of a conceptual framework developed for ACT Consortium work in Cameroon (www.actconsortium.org/REACTCameroon). For us, conceptual framework development was most useful prior to undertaking formative research in order to identify important areas to collect information on, to guide methods and to develop data collection tools. In the analysis, we were able to test hypotheses set out in the conceptual frameworks and to build on these to depict revised conceptualisations of the existing situation, together with potential areas amenable to intervention.

At this point, analysis moved beyond the content of responses given in one context, to an interpretation of concepts being presented, relating these to wider, generalisable theories to ensure that interventions could be scalable. 'Middle range theories' have been proposed to extract findings that 'are sufficiently abstract to deal with different spheres of social behaviour and social structure, so that they transcend sheer description' (p68)(Merton 1967). Interventions based on these more generalisable theories can then be designed to be standardised at the level of general functions and processes while allowing the specific forms they take across contexts to be tailored to local conditions (Hawe, Shiell et al. 2004).

Box 2. Example of a conceptual framework developed to guide formative research

In Cameroon, the ACT Consortium research team recognised the importance of understanding local experiences of malaria treatment and diagnosis in order to design effective supporting interventions for the rational use of (anti-malarials, AM) including the introduction of new technologies such as rapid diagnostic tests. The team started by reviewing existing research about malaria and the use of medicines and diagnostics in Cameroon and elsewhere, hypothesising factors that may be applicable to the study setting. The team reflected on their theoretical orientation for this work, taking a meaning-based interpretative approach to understanding malaria, viewing it as a term with multiple meanings for different people and in different contexts. They drafted a conceptual framework for each specific research question to make explicit their expectations for what might be important, illustrated in diagram form, below. These hypotheses then helped to shape the topic guide domains for the data collection activities.



These initial conceptualisations shaped the team's interpretations of participant responses: they observed that clinicians enacted malaria as a "juggling" exercise, balancing the pathophysiology of the patient with patient desires and their own medical reputations, using tests and medicines for their therapeutic effects as symbols in the process of care, and rarely mentioning malaria parasites in their explanations of diagnostic decisions. Such enactments contrast sharply with evidence-based guidelines emerging from the WHO, which place the malaria parasite as the intended central driver of practice. Implications for intervention design are that if rapid diagnostic tests are to be widely, accurately and effectively utilised, careful attention must be paid to the values and priorities of both health workers and patients. The design of interventions followed this by attempting to support clinicians to continue to respond to the complex social context of their work within the changes of guidelines and new diagnostic tests.

Learn more at www.actconsortium.org/REACTCameroon

1.5.3 Participatory research for intervention content

After the design and logic of an intervention has been decided, qualitative research can contribute to the development of intervention materials to ensure that content, activities and materials are not only based on evidence and best practice but are also locally acceptable. A 'bottom-up' approach to the design of intervention materials explicitly recognises that target recipients are best placed to identify or refine content, messages, modes of delivery and visual details that are likely to be effective and acceptable to end users (Haaland 2001, Ajayi, Falade et al. 2008, Ajayi, Oladepo et al. 2009). Investment in this stage can also be considered valuable for the following reasons:

To ensure quality of intervention activities and materials and optimise the likelihood of effect;

To ensure consistency in intervention delivery in order that components are easily replicable;

To enable evaluation of the intended intervention through clear documentation of the activities, materials and procedures to be implemented.

Activities and materials developed for ACT Consortium interventions using formative research included training manuals for facilitated group learning, participatory dramas, peer education, supervisory visits, tools for referral of patients or requisition of supplies, posters and leaflets (see Box 3 for a description of our use of participatory research to design pharmacovigilance materials in Uganda; additional examples of intervention content development using qualitative methods can be found in the Supplementary Materials document: **"ACTc Materials - Qualitative Research Field Tools"**).

Given constraints in time and resources, we assessed draft intervention components in terms of immediately observable factors such as ease of delivery, whether the target audience was reached, how they responded and whether proximal outputs in the intervention logic model were achieved. Evaluation methods used included structured questionnaires, informal discussions and focus group discussions to elicit feedback from implementers, observers and the target audience. In some cases, several revisions to draft tools were made, followed by subsequent rounds of 'testing', feedback and revisions.

Box 3. Example of qualitative participatory research to design intervention materials

An ACT Consortium interdisciplinary research team in Uganda aimed to design a user-friendly form for non-clinicians to document adverse events after taking antimalarial drugs (www.actconsortium.org/drugsafetydatabase). The team held a series of participatory workshops with potential end-users of the adverse event form. After discussion of their own experiences and challenges with adverse event reporting, workshop participants were divided into small groups and asked to draft a simple reporting form, basing the layout on their own understanding of what it was important for the form to include. A local artist was briefed on principles for drawing pictures understandable to low-literacy audiences (Haaland, 2001), and drafted and refined sketches at the request of participants. Facilitators moved between the working groups to encourage participants to include essential data fields for pharmacovigilance within the form. Participants were asked to practice using their draft forms in role plays, and to make relevant adaptations. The facilitators allowed time to develop trust in their desire for participants' ideas and contributions in order to establish motivation and commitment towards the development of a good quality form. Participants were asked to pilot their forms with neighbours at home and to feedback on their experiences with suggestions for further revisions. A final version was pretested with a range of potential end-users, with slight amendments to refine the form until respondents had achieved scores of over 90% of form fields completed correctly, as has been described elsewhere. Source: (Davies, Chandler et al. 2012)

1.6 Process Evaluation

Many researchers and policy makers are now calling for ***process evaluations*** to be conducted, to provide a better understanding of the delivery of an intervention, by describing its components as actually received by the target audience and therefore delineating whether any success or failure of an intervention to achieve expected outcomes is attributable to the intervention itself or to the way it was implemented. The MRC's (2008) latest guidance on developing and evaluating complex interventions describes process evaluation as "highly valuable – providing insight into why an intervention fails unexpectedly or has unanticipated consequences, or why a successful intervention works and how it can be optimised. Process evaluation nested within a trial can also be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes. Process evaluations should be conducted to the same high methodological standards and reported just as thoroughly as evaluation of outcomes" (p12). Process evaluations can also help to distinguish between interventions that are inherently faulty (failure of intervention concept or theory) and those that are badly delivered (implementation failure) (Oakley, Strange et al. 2006). This form of evaluation is especially necessary in multi-site trials, where the 'same' intervention may be implemented and received in different ways.

1.6.1 Components and logic of process evaluation

Six types of measurement (or components) form a useful focus for process evaluation activities (Saunders, Evans et al. 2005) (Table 2).

Table 2. Definitions of components in a process evaluation

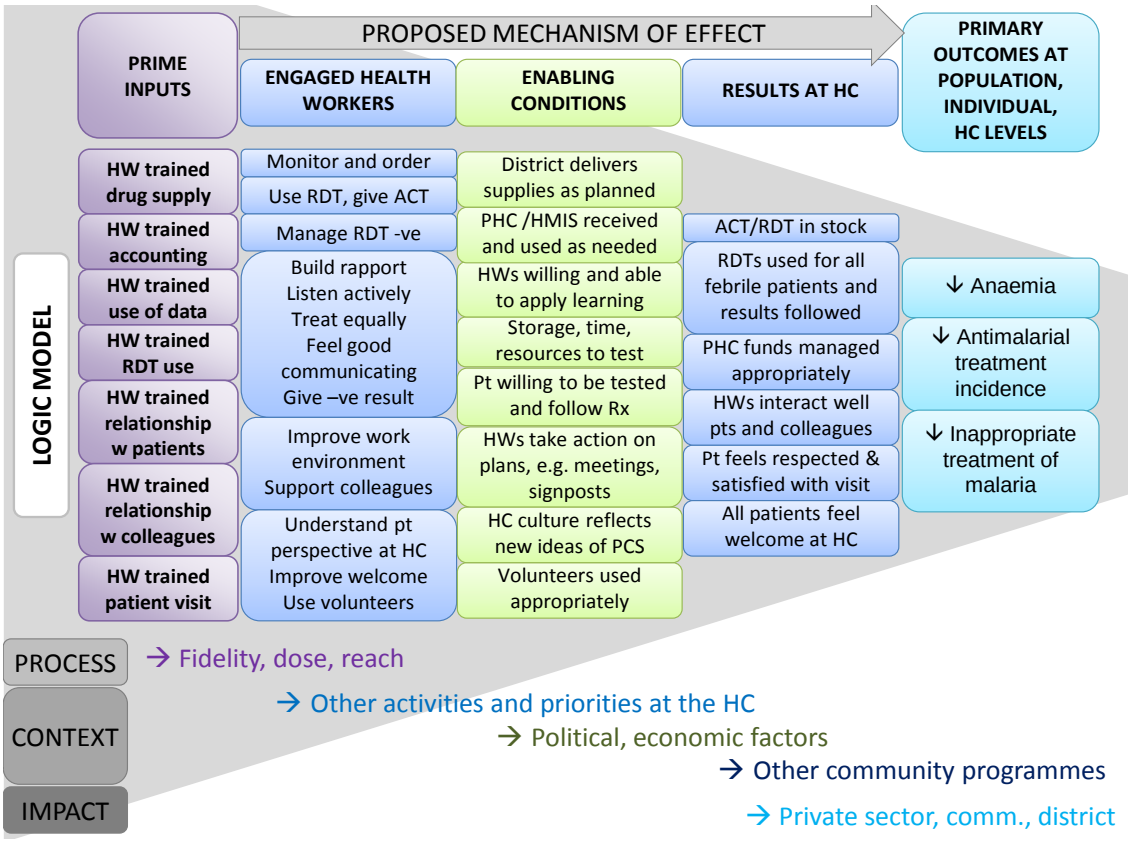
Evaluation component	*Definition*
Fidelity (quality)	The extent to which the intervention was implemented as planned
Dose delivered (completeness)	Amount or number of intended units of each intervention or

	component delivered or provided by interventionists
Dose received (exposure)	Extent to which participants actively engage with, interact with, are receptive to and/or use materials or recommended resources. Can include 'initial use' and 'continued use'
Reach (participation rate)	Proportion of the intended priority audience that participates in the intervention; often measured by attendance; includes documentation of barriers to participation
Recruitment	Procedures used to approach and attract participants at individual or organizational levels; includes maintenance of participant involvement in intervention
Context	Aspects of the environment that may influence intervention implementation or study outcomes; includes contamination

In order to direct these activities it can be useful to create a conceptual framework or ***logic model*** of the hypothesised process of change in the intervention in terms of inputs, predicted pathways of influences, and outcomes (Box 4, see also Wiseman et al 2012a&b for simplified logic models from ACT Consortium work) (Briss, Zaza et al. 2000, Wiseman, Mangham et al. 2012, Wiseman, Ogochukwu et al. 2012). Like conceptual frameworks in formative research, intervention logic models can be based on formative research, findings of previous interventions and behaviour change theory. The model may include both quantitative (e.g. number of a target group of patients receiving a correct drug) as well as qualitative measurements (e.g. changes in perception of patient pressure for specific drugs or tests). As well as forming a useful basis for a final outcome evaluation, as a network of hypotheses to be tested, the model can be explored in terms of the processes listed above. For example, if in an intervention which intended to show videos of clinical procedures hypothesised to improve skills using a specific pedagogy could not be shown to some participants because of power shortages, a process evaluation would identify that an incomplete 'dose' was delivered, and this should be taken into account in outcome analysis.

Box 4. Example of an intervention logic model developed to guide process evaluation

To develop a logic model for ACT Consortium the PRIME project in Uganda (www.actconsortium.org/PRIME), the research team reviewed the intended effects of each intervention component and attempted to depict the mechanisms by which each component was anticipated or assumed to 'work'. An understanding of the context of the situation into which the intervention components were to be delivered was helpful in considering potential 'conditions' that might affect uptake, interpretation and immediate outcomes of the intervention components. These were included as far as possible in the logic model. This is a simplified version of the logic model for the PRIME intervention, and expanded versions were useful for the evaluation of each component of the intervention and consideration of interacting effects.



Source: ACT PROCESS study, Uganda, building on the work of others (Huhman, Heitzler et al. 2004, Harris 2010). www.actconsortium.org/PROCESS

1.6.2 Process evaluation methods

Once the intended processes of change have been identified and made explicit in relation to measurable process evaluation components, a process evaluation can be planned, using a variety of methods. This may involve researchers conducting observations and informal qualitative interviews during the study, for example to create a 'social commentary' of the intervention, similar to methods described for formative research and outcome evaluations. Alternatively, or in addition, a series of reflexive documents can be kept by the fieldworkers and trainers to contribute towards a qualitative understanding of the process of the intervention.

An example of a method used to document external contextual influences on the delivery and outcome of an ACT Consortium intervention is given below in Box 5. For an example of an evaluation

protocol from an ACT Consortium project that combines process and outcome evaluation concepts, see the protocol for the PROCESS study (Chandler, Diliberto et al. 2013); or visit www.actconsortium.org/PROCESS.

Box 5. Example of a context awareness and documentation tool developed for process evaluation

Observations and comments to be recorded by fieldworkers at different points during the intervention, for each site

CONTEXT AFFECTING OUTCOME (i.e. outside factors affecting change in HW interpretations of RDT results: positive or negative)	DATE 1	DATE 2	DATE 3
Other interventions / research involving malaria			
Other training programmes for HF staff			
Other diagnostic tools available			
Management support (or not) for intervention work			
Community interventions regarding malaria, treatment seeking or empowerment before / during trial			
Level of supervision from district and involvement of supervisor in trial			
Messages from NGOs / government on radio / TV / newspapers			

1.6.3 Use of process evaluation results

The analysis of process evaluation data will depend upon the type of data collected; many of the qualitative data analysis methods described in CHAPTER 5 of this document would be relevant.

Regular review of process evaluation findings during the intervention can enable ongoing feedback to improve the intervention. On completion of the intervention, information on each component of the process evaluation can be brought together to provide a detailed description of the intervention process. This can be reported under the headings described above of *fidelity, dose delivered, dose received, reach, recruitment* and *context*, enabling an understanding of the components of the intervention that were most easy and difficult to deliver as well as information on the delivery and participation of individuals or groups of the target audience. In addition to a stand-alone report, data from the process evaluation can feed into data analysis in the outcome evaluation. Quantitatively, a measure of the dose delivered/received by each participant can be applied as explanatory variables in outcome analyses. Qualitatively, findings from the process evaluation may inform the design of questions and interpretation of results in outcome evaluation.

Some useful papers describing process evaluations are available (Power, Langhaug et al. 2004, Saunders, Evans et al. 2005, Berkowitz, Huhman et al. 2008) and examples from ACT Consortium work will be posted on the ACT Consortium website as they become available (www.actconsortium.org/publications).

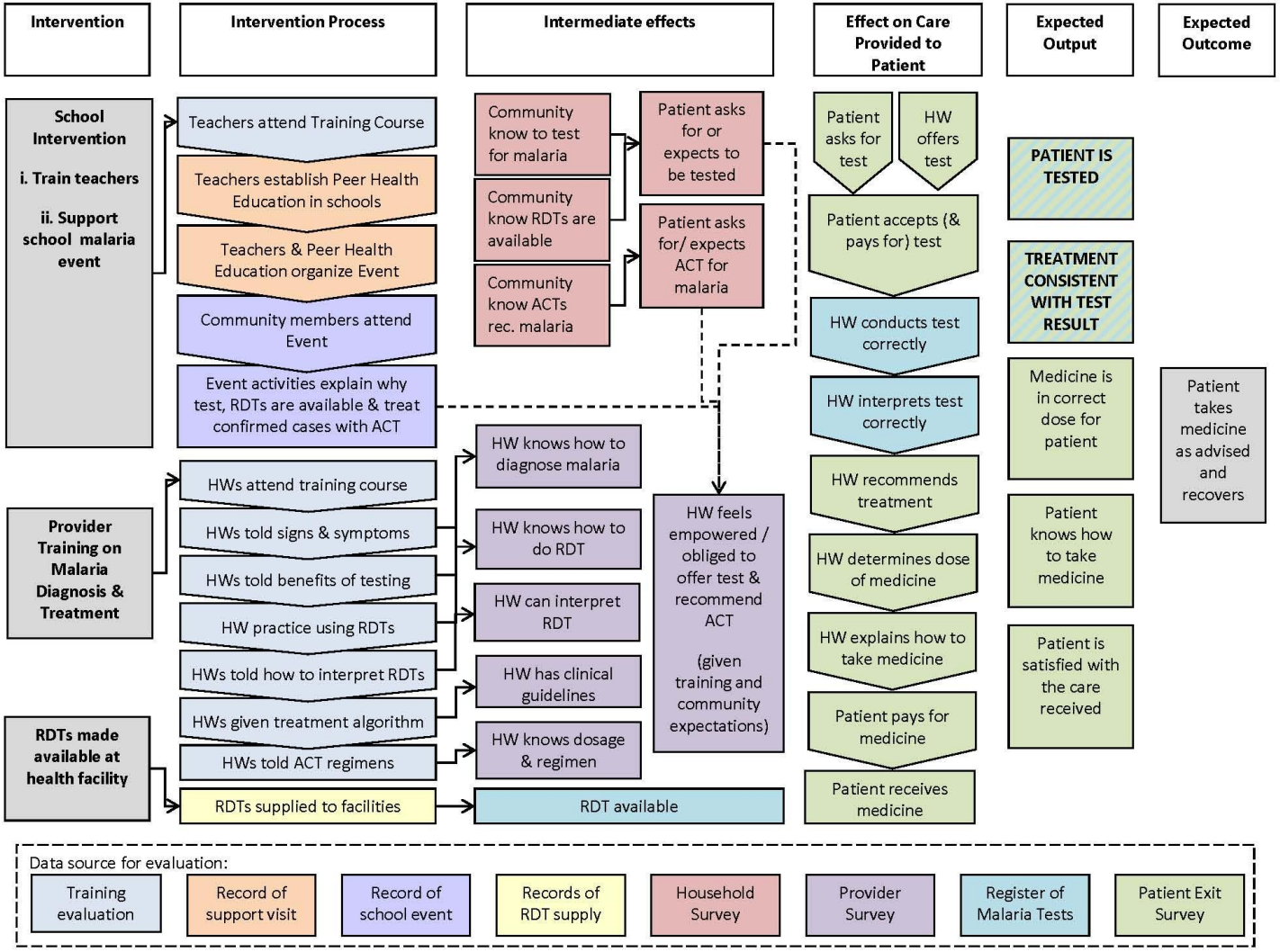
1.7 Outcome Evaluation

Qualitative methods can be used in outcome evaluations to support explanations of why and how an intervention worked (or did not work) (Pawson and Tilley 1997) as well as to capture and understand unintended consequences (Kleinman 2010). Using the intervention logic model to guide investigations, qualitative methods can be used to assess qualitative intervention outcomes such as changes in perceptions and behaviours of target audiences, to understand what an intervention was conceived as by its recipients and what meaning was ascribed to its processes, people and powers, and to compare this with its intended mechanism of effect. Outside of the logic model, it is important to purposefully attempt to capture unintended changes, unintended mechanisms that led to intended outcomes and resistance to change. Methods typically employed in qualitative evaluations include: (1) comparison between groups and time points in the nature of responses/discussions on behaviours/outcomes hypothesised to change due to the intervention, (2) asking participants to reflect on their experiences and interpretations of the intervention, and (3) a description of context from the perspectives of multiple actors both close to and far from the intervention's activities.

1.7.1 Components and logic of outcome evaluation

As with process evaluation, a logic model is important in informing the design of an outcome evaluation. The hypothesised or expected 'mechanisms of effect' of different components of an intervention on target groups and behaviours may have been made explicit in the intervention design, or it can be elaborated retrospectively by interviewing intervention staff. Both qualitative and quantitative evaluations can be guided by this model and the model can be revised in the light of evaluation findings. See Figure 1 for an example of a logic model used in outcome evaluation of ACT Consortium work.

Figure 1. Example of an intervention logic model developed to guide outcome evaluation



Source: ACT Consortium REACT project, Nigeria. See also (Wiseman, Ogochukwu et al. 2012) and www.actconsortium.org/REACTNigeria

The mechanisms of effect detailed in the logic model are likely to include one or more intermediate points or outcomes on a hypothesised 'causal pathway' to a primary intervention outcome. These intermediate outcomes can be, for example, qualitative perceptions that are targeted by an intervention component which first need to be addressed to change target behaviours (measured as primary outcomes). Qualitative methods can be used to explore differences in these intermediate and primary outcomes between before and after time points, or between intervention and control groups, allowing researchers to assess the plausibility of causality in hypothesised intervention mechanisms on primary outcomes.

The interpretation of individual intervention components, and meaning ascribed to intervention (and evaluation) activities is likely to affect intended mechanisms and, potentially, their effect on target behaviours. From the perspective of actors conceived as intervention 'recipients', the intervention (and evaluation) activities may not be conceptualised in the same way as implementers or researchers conceive them. The design of evaluation methods must allow for a reinterpretation by the researchers of what the intervention *is* or *becomes* in practice for different actors. In different settings, such as different health centres, the intended intervention and its components may be adopted wholesale, appropriated into other existing framings or practices, tolerated but not absorbed, actively resisted or simply terminated. Exploration of the experiences of those involved in the intervention can bring some of these possibilities to light, and provide insights into the consequences. An understanding of this therefore adds a more ***Interpretivist*** viewpoint rather than simply attempting to assess causality.

Realist evaluation approaches are now popular, although with limited worked examples, in understanding complex health interventions (Marchal, van Belle et al. 2012). Here, not only do researchers study intended vs. actual intervention mechanisms, but the types of people for whom interventions work is also assessed, recognising that the delivery and mechanism of an intervention may differ between different individuals or different contexts. Pawson and Tilley promote realist evaluation as essential for policy making because it asks not just 'does this programme work', but 'what works for whom in what circumstances and in what respects, and how?' (Pawson and Tilley 1997, Pawson and Tilley 2004). Outcome evaluation as described above can therefore be expanded, to look at what and how mechanisms work in different contexts and with different individuals. In ACT Consortium evaluations of intervention mechanisms, we were inspired by the premise of realist evaluation (Pawson 2003), but did not follow the methodology closely, preferring to view interventions from interpretativist and relational perspectives (Koivisto 2007, Sobo 2009). An example of this is the PROCESS study, carried out alongside the PRIME study as one of the ACT Consortium projects in Uganda (www.actconsortium.org/PRIME and www.actconsortium.org/PROCESS). Further details can be found in the published protocol, including an attempt to understand how the intervention was enacted (Chandler, Diliberto et al. 2013). Other approaches to evaluation with qualitative methods can be found in White & Phillips 2012 or at http://www.3ieimpact.org/en/evaluation/resources/ (White and Phillips 2012).

1.7.2 Outcome evaluation methods

To collect qualitative information on intermediate or primary outcomes, acceptability and context in an outcome evaluation, a range of standard qualitative data collection methods can be used (Table 3).

Table 3. Details of data collection methods by outcome evaluation objectives

Evaluation objective	Type of information	When/who	Methods of data collection
To understand intermediate and/or primary outcomes	Data on target behaviours or variables that are seen as proximal to target behaviours. These may include perceptions, attitudes, knowledge and practices of the target group.	Data collection usually takes place before and after an intervention, or in control and intervention groups for comparisons.	(Semi)structured questionnaires Structured observations IDIs FGDs
To understand how the intervention is interpreted	Data about participant experiences and interpretation of the intervention and its consequences; perspectives of those not targeted but affected by the intervention can also be collected.	Data collection can take place during or at the 'end' of an intervention.	(Semi)structured questionnaires IDIs FGDs Observations
To understand how context shapes the outcomes measured	Data about the context in which the intervention takes place. This includes the physical, social, political and economic context of each intervention site, encompassing long-term as well as short-term structures and activities (e.g. a description of NGO programmes in an area).	These data may be collected during the intervention (as for process evaluation), before or after and in all arms of the study.	Document review Context record Key-informant interviews Observations

Data may be collected for each evaluation component using separate methods, or methods can combine questions for these different at the same time. For example, in-depth interviews may provide data about perceptions and practices that can be compared between time points or groups as well as providing data about the experiences of participants during the intervention. These interviews could also contribute to an understanding of the context of intervention and control groups. See Box 6 for an example of an in-depth interview topic guide developed to evaluate changes in perceptions for an ACT Consortium project. Tools to support such research are included in the Supplementary Materials document: **"ACTc Qualitative Research Protocol Template and Tools"**.

Box 6. Example topic guide to understand the outcomes and processes of change for health workers receiving an ACT Consortium intervention that included RDT training and supervision (see also www.actconsortium.org/PROCESS)

Topic	Example questions
1. Your role at work	What does your usual day consist of at the health centre these days? What is the most important thing to you personally about doing this job? How do you feel about this job now? How has this changed over time?
2. Changes significant to you	Looking back over the past year, what do you think was the most significant change in the way you managed illness in your health centre? Why is this significant to you? What difference has this made now or will it make in the future?
3. Reflection on the intervention	The ACT Consortium project has carried out some activities at your health facility and others in this area since April 2011. Can you tell me about any that you have been involved with or that have affected you? *Probe for all aspects of the intervention they can recall, and what they remember about each (it may be different from the way we frame the intervention, but we want to hear their description of what it meant to them)* What impact has your involvement with this project had on you personally? *Probe for stories of consequences of being part of the intervention/evaluation – interactions with implementers/others, resources, practices, impacts on daily work, politics*
4. Reflection on training	What training did you attend with the ACT Consortium project since April last year? *Probe for a list of all components they can recall, in their own words.* How do you feel the ACT Consortium training you attended has impacted on your work? *Probe for stories of consequences of the training.* Was there anything that you learnt during the training that did not make sense to you once you got back to your everyday work? *Probe for stories.* Have you attended any other training courses or received any materials or tools from other organizations to help you do your job? *If yes, please list, and let us know what was most useful about each of those courses, materials or tools.*
5. Fever case management changes	Can you tell me about your experiences with the people who have visited you from the RDT programme since last year? *Probe for what their interactions with the intervention team consisted of and what mattered to them.* Can you tell me what were the most important things to you about these visits? *Probe for consequences – on malaria diagnosis practices and also anything that seems unrelated but is important to the respondent* Of what use has been this programme to you and your colleagues at your health centre? *What impact did it have on the health centre as a whole* Has your involvement in this programme had any impact on the relationship you have with your patients at your health centre? Were there any recommendations that the programme made which you have found it hard to put into practice? *Probe for any difficulties with mechanisms of doing the different types of tests available (pf/pan vs bioline, including loop vs dropper); how did these different methods affect your use of the tests (frequency/ inclination)* Can you make any recommendations for what could be improved about the RDT programme?

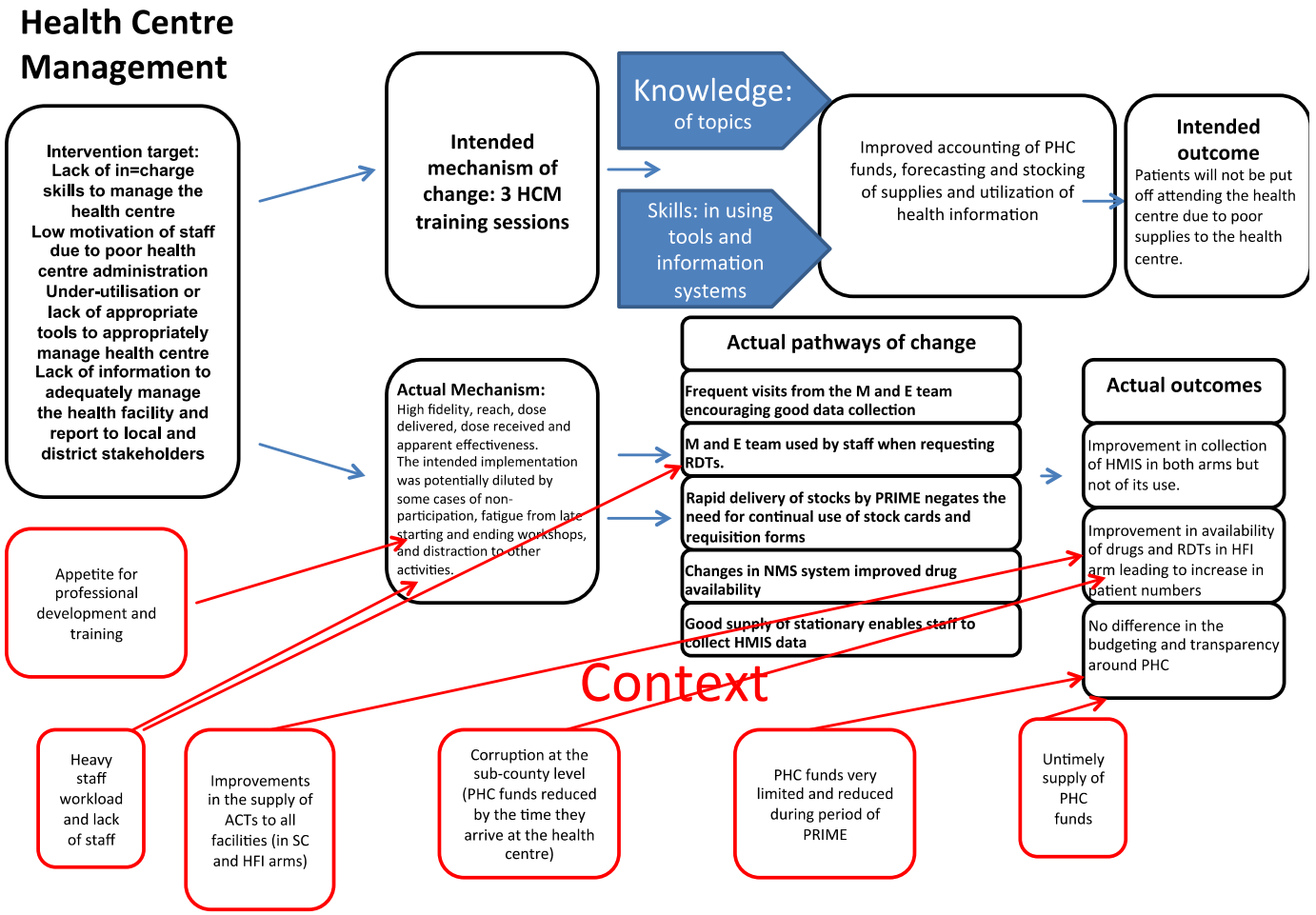
Topic guides for outcome evaluation may closely resemble topic guides from formative research – especially if formative research is used to form a 'baseline' for comparison in before-and-after studies. However, qualitative research is most useful for evaluation in understanding the process of change in a given context, and therefore questions that focus on what has happened, how and what actors, agendas and materials were involved, will be more informative for interpreting the intervention's effects. A 'most significant change' principle was applied in several ACT Consortium studies, which allows for an open question to be defined by the respondent in reference to changes in general. This enables the researcher to gain a sense of what has been important to respondents rather than taking the project's intervention as a starting point. This can be informative in seeing what other changes have occurred in the wider context of the intervention as well as getting a sense of the weight applied to the intervention in question. Of course, the perceived benefits for respondents of giving particularly positive responses about the intervention are possible if the interviewer is not careful to reinforce that although they are aligned with that project, they are interested in all and any changes of significance.

1.7.3 Use of outcome evaluation results

The evaluation methods described here should aid the interpretation of the overall study result by providing outcome measures of the impact of the intervention on intermediate or proxy perceptions or behaviours as well as by providing explanations for how the intervention worked. This will enable an assessment of how effective individual components of the intervention are in achieving the target behaviour change, identification of potential unexpected consequences of the intervention, and an interpretation of the context under which the intervention (or its components) may be most effective. Synthesis of evaluation findings comparing hypothesised and actual intervention effects can also be depicted using a revised intervention logic model, as in Figure 2. Following this overall approach, outcome evaluations should provide policy makers with evidence of 'what, where and how' to introduce interventions to achieve specific behaviour change targets on a broader scale.

There are many examples of studies that have used and described their methods for qualitative outcome evaluations (Eccles, McColl et al. 2002, Nazareth, Freemantle et al. 2002, Winch, Gilroy et al. 2008) and other examples from ACT Consortium work are available on the ACT Consortium website (www.actconsortium.org/projects).

Figure 2. Example of a logic model depicting the intended and actual mechanism of effect for an intervention component (health centre management) in ACT Consortium work



Abbreviations: HCM: health centre management, M and E: monitoring and evaluation, SC: standard care, HFI: health facility intervention, PHC: primary health care, HMIS: health management information system. *Source: PRIME study, Uganda (www.actconsortium.org/PRIME)*

CHAPTER 2 Qualitative Fieldwork Methods

CHAPTER 1 outlined key roles for qualitative methods in intervention research, including particular areas of enquiry for different research designs, with suggestions for possible research methods. This chapter describes *how* these key methods can be used. There is wide variation in the ways people collect and analyse qualitative data. Some options are described here but these are not exhaustive and therefore should only be considered a guide. If working in a consortium, comparability in methods between projects is desirable but the selection of methods and how they are implemented will naturally rely on the research objectives, skills and interests of individual research teams.

Three main qualitative research methods will be described in this chapter: in-depth interviews, focus group discussions and direct observations. For each method, the following topics are discussed: participant sampling, development of field work (data collection) tools, piloting of tools, preparation for data collection, data collection, data management and data analysis. These sections are followed by a detailed discussion of transcription and translation techniques for use with interview and discussion data. The chapter ends with a brief section discussing the importance of thinking through an analysis plan at the project design stage; CHAPTER 5 will cover qualitative data analysis in more depth. Field staff training on qualitative field work methods is discussed in CHAPTER 3.

Chapter Outline

2.1 In-Depth Interviews

In-depth or unstructured interviews are frequently used in qualitative research for researchers to understand research topics from respondents' points of view. In-depth interviews are designed to be open-ended and flexibly structured to enable respondents to discuss their point of view using their own language. Qualitative researchers view study of the construction of language itself as an opportunity to access meaning in recognition of the idea that knowledge of the social world is, at least partially, constructed by those who live within it, following an interpretive epistemological approach.

Two metaphors about interviewing are useful to illustrate social science debate about the construction of knowledge and, accordingly, how a researcher should behave in an interview: as a 'miner' or a 'traveller' (Legard, Keegan et al. 2003). In the miner metaphor, knowledge is seen as 'given', something that is a pre-existing phenomenon which, like buried metal, can be unearthed, extracted and uncontaminated. Through interviewing, the researcher digs nuggets of information out of a research subject's experience, unpolluted by leading questions or extraneous data told by the interviewee. Generally speaking, this is the ***positivist***'s perception of knowledge and is the approach commonly taken in structured interviewing in questionnaires or surveys when it is important to collect the same type of information from all respondents, systematically. In the traveller metaphor, the researcher is a traveller who is led on a journey by the research subject through stories. The researcher must interpret the meaning of the story as it is told in the research subject's own words, according to the ***interpretivist***'s perception of knowledge. This is the approach which is commonly taken in in-depth interviewing when the most relevant type of information to be collected in the interview may not be known from the outset. It is also the approach most commonly taken in ACT Consortium projects. If, through reciprocal conversation, the interviewer also leads the interviewee to new insights, both people's knowledge may be transformed during the journey, with the final interview product recognised as co-constructed by each (Mattingly 1998). This extension of the metaphor is the ***constructivist's*** perception of knowledge which is commonly taken in participatory or action research (Walker and Dewar 2000).

Structured interviews aim to systematically collect pre-specified information from each respondent. In in-depth interviews, the researcher sets the agenda for topics to be covered but allows the interviewee enough time to develop their own accounts of the issues important to them and to link their accounts to additional topics that the researcher might not have considered when designing the topic guide, not having gone through the same experiences as interviewees. The researcher can then follow-up on new topics that emerge. It is the interviewee's responses that determine the kinds of information produced about the topics and the relative importance of each kind of information discussed (Green and Thorogood 2004).

Given the unstructured nature of in-depth interviews, the interviewing and relationship facilitation skills of the researcher are very important to eliciting high quality data. Interviewer training is therefore important (see Section 3.2), as is in-depth knowledge of the context (such as through ethnographic-style immersion) to allow for the most comprehensive interpretation of data (Sobo 2009).

Information from in-depth interviews about the perceptions and priorities of respondents about research topics can feed into intervention design or evaluation interpretations.

2.1.1 Sampling

In-depth interviews with different groups of respondents for different purposes have been suggested in CHAPTER 1 of this guidance document. Respondents might be ***key-informants*** (people who possess expert knowledge about the group, topic or behaviour of interest, e.g., community leaders, and who can provide insight on the nature of problems and give recommendations for solutions); ***stakeholders*** (people in decision-making positions, e.g., district health officers, who may provide information about existing structures and possibilities for change); or the target group or beneficiaries of an intervention (e.g., community members or providers, who can provide an account of their perceptions and experiences).

Inclusion and exclusion criteria. The choice of respondents will depend on the research objective. For interviews with key-informants and stakeholders, it is important to include people with a wide range of backgrounds to avoid biased results and to enable analysis of varying perspectives and reveal underlying issues or problems. For target group interviews, the selection may be narrower, depending upon the stage of research. Formative research may require interviews with a range of individuals in order to conceptually refine an intervention focus. Process or outcome research is likely to include only those participants targeted (or anticipated to be affected) by the intervention. The first step in selection of participants is to identify criteria for inclusion and exclusion.

Identification of sub-groups. Participants for in-depth interviews are often selected through ***purposive or criterion-based sampling***. Specific sub-groups are identified for interview according to the research objective. For example, if researchers want to investigate how to improve the stocks and sales of a certain drug by retailers, the sample of participants chosen for in-depth interviews may include providers who stock the drug as well as providers who do not stock the drug, and privately-owned as well as government-sponsored retailers.

Sample size. Typically, 3-4 in-depth interviews are conducted with each sub-group to attempt to gain a consensus on responses to topics within sub-groups and to be able to identify differences between sub-groups. If consensus is not reached (saturation), further participants may be selected. However, differences are always likely to occur between individuals and the researcher may find that consensus is reached between sub-groups that were not previously defined (e.g. there may be more consensus between female and between male retailers than between type of retailer). Sub-groups are selected to represent groups of interest, and generalisability is attempted through ***thematic saturation*** rather than through quantitative outcomes.

Identification of participants. Once sub-groups have been identified, participants to represent each sub-group are identified. This can be done in a number of ways: random sampling, convenience sampling and snowball sampling are three commonly used methods.

Random sampling might be used when the researcher wants to elicit a cross-section of ideas and opinions from a particular group. A random sample aims to reduce the likelihood of bias in responses or opinions, and therefore reflects a more ***positivist*** approach to collection of data. A sampling frame can be constructed from the total number of eligible participants (e.g. names of mothers who have brought children to a health facility with fever in the past 2 weeks). A random sample can be stratified to include the sub-sample groups already identified.

Convenience sampling is used sometimes when a random sample is not possible or more commonly when the research perspective sees the generation of data as emerging through the interactions of participants with researchers rather than conceiving the data as ready-to-be 'picked' from

participants. Here, the value is placed not on attaining an objective bias-free set of opinions but on the process of eliciting and interpreting meaning from individuals who the researcher comes to know in the places and spaces they attend during their research. With convenience sampling, the researcher can still pre-specify groups of interest and seek out individuals who share these characteristics, but they do not conceive that because individuals are randomly selected that the information gained is any more valid. Often, in convenience sampling, key informants are identified who are particularly articulate, who are able to provide insights (from their perspectives) that may be richer than those provided by people who have been randomly selected to participate.

Snowball sampling is used when a large enough number of potential participants with knowledge or experience with a particular topic is not easily identified (e.g. retired civil servants with experience in a particular programme such as previous malaria control efforts) or when the topic of interest is guided by findings that emerge through the process of interviewing. Here, individuals who are included in the study are asked to identify others who may be relevant to speak with.

It is important to specify the method for sampling in reports and publications as well as research protocols.

Time and place. In addition to who to sample, responses may differ depending upon when and where participants are interviewed. E.g., perspectives of malaria risk may differ according to seasons, and may differ if the participant is interviewed at a health facility or in a malaria research setting compared to neutral surroundings. Such factors need to be considered and a consensus reached amongst researchers about when and where interviews will take place, if this is likely to influence sample characteristics and therefore findings.

2.1.2 Development of field work instruments

In-depth interviews are typically conducted with a topic guide. This may be typed on a set format with plenty of space for notes or simply be a list (with probes for each topic) for the interviewer to follow. In addition to the topic guide, the interviewer may need an introduction sheet, consent form, participant information sheet and contact summary form. It may be useful to make written plans for the following activities that typically make up an interview.

Introduction. It is useful for the interviewer to have a sheet with a list of information to cover with the participant during the introduction. The purpose is to establish credibility as the interviewer and introduce the general purpose of the study. It should cover:

The aims of the interview and expected duration

Who is involved in the process (other participants)

Why the participant's cooperation is important in collecting the information needed

What will happen with the collected information and how the participant/target group will benefit

Information and consent. The participant may be asked to provide written or oral consent. In either case, information about the research objectives and provisions for confidentiality should be explained to the participant and they should be given a copy of an information sheet if appropriate.

Warm up. Some questions to make the participant feel comfortable and establish rapport. Researchers may choose to include demographic questions here.

Topic guide with probes. This should be developed based on the objectives of the research study and may differ slightly between sub-groups, although the topics are likely to be broad enough for the different experiences of different groups to be expanded upon by respondents. A topic guide typically includes around five to ten key topics or questions (depending upon the experience and style of the interviewer, researchers may choose to specify exact questions in advance) which are designed to elicit information about specific aspects of the issue or problem. Under each topic or question, it is a good idea to specify probing questions which encourage participants to reflect more deeply on the meaning of their responses and may help respondents to think about the cause or root of the problem under investigation. This may include, for example, asking participants about real events, or 'critical incidents', which can reveal much about beliefs, attitudes and behaviour. Researchers may also choose a more open or conversational style for asking patients about real events, when the respondent is asked to describe an event, or series of events, in a narrative (story-telling) style. Using probes to elicit a more natural interviewing style results in much more data than a more structured approach to interviewing and may reveal issues or problems that had not previously been identified by researchers. It is therefore useful both at the formative stage of research and for identifying unintended consequences in evaluation. A series of interviews with different individuals can become progressively focussed on key emerging themes or explore concepts which have not yet reached theoretical saturation, and topic guides are likely to change through the ongoing process of analysis and field work.

Closing. At the end of the interview, the participant should be given an opportunity to provide any additional information or comments. This may also be a good opportunity to ask the participant for their recommendations or solutions in addressing the research problem. The interviewer can then go through a quick summary of the major information or stories collected in the interview and ask the participant if the summary covered all their major points and if they have any more to add. Finally, thank the participant for their time and give them any information and contact names for future research activities.

Examples of interview topic guides were given in CHAPTER 1. A more structured example of a data collection form for in-depth interviews, incorporating all of the above elements is available in the Supplementary Materials document: **"ACTc Qualitative Research Protocol Template and Tools"**.

Contact summary form. To aid on-going analysis, notes about the interview should be made immediately afterwards. If a number of different fieldworkers are conducting the interviews it may be useful to structure these notes using a 'contact summary form', focusing the interviewer on specific aspects useful for future analysis. The purpose is to assist researchers to understand the immediate context of the interview as well as for to identify key themes to be developed in future interviews. The forms are useful to share in near-real-time with others involved in a research team, in order to discuss issues emerging across participants and to decide on new lines of enquiry. An example of a contact summary form is shown in Box 7. It should be noted that the contact summary form (sometimes called a debriefing form) supplements, rather than replaces, ***field notes*** which should describe the context of the interview in greater detail (see also Section 2.3).

Box 7. In-depth interview contact summary form

Participant IDNO |__|__|__|__| Gender Male / Female Researcher Initials |__|__|__|

Health facility number |__|__| FGD Date |__|__/__|__/__|__| Today's date |__|__/__|__/__|__|

What were the main issues or themes that struck you during this interview?

What new information did you gain through this interview compared to previous interviews?

What new questions or inconsistencies emerged for you as a result of this interview?

Was there anything that struck you as salient, interesting, illuminating or important in this interview?

How would you describe the atmosphere of the interview?

What else was important about this interview?

Were there any problems with the topic guide (e.g. wording, order of topics, missing topics) you experienced in this interview?

Adapted from Miles & Huberman (1994)

2.1.3 Piloting

It is important to spend a period of time piloting all field work tools and procedures. For in-depth interviews, a pilot of 2-4 interviews may suffice to establish whether the framing of questions in the topic guide should be refined or further topics should be included, although further topics are always likely to arise in subsequent individual interviews due to the flexible structure of the field work method. Piloting is often part of the fieldworker training period so fieldworkers can feed into this process. This is also an opportunity for fieldworkers to observe each other to ensure interview methods are being correctly and systematically implemented and to work out interview logistics and note-taking conventions. If the topic guide is not substantively changed during this process, these interviews can be considered generally comparable with subsequent ones and included in the final analysis. In the final stage of piloting, a comprehensive standard operating procedure for the interviews should be produced, with which all fieldworkers are familiar to enable the collection and management of high quality data.

2.1.4 Preparation for field work

Preparation before field work begins involves sensitisation of local stakeholders about the research project, inviting participants, planning a time and place for interviews, setting up the interview, and setting up a data management system for recording the data. The extent to which each of these steps is needed will depend upon the objectives and scale of the research.

See also the Supporting Materials document, **"ACTc Qualitative Research Protocol Template and Tools"** for standard operating procedure (SOP) templates on Approaching and inviting participants to interviews (SOP 1) and Organising the interview (SOP 3).

Sensitisation. The sensitisation process involves giving information to local authorities and people who will be affected by the research and gaining permission to conduct the study at several levels and in a series of phases. At each phase, the process can be viewed as an opportunity for consultation with key stakeholders, whose comments can further inform the study protocol. Initially, the research team seeks permission from relevant local and national representatives and bodies, such as district medical officers and national research boards. Communities or providers where the research is targeted to take place then need to be informed about the study through meetings with leaders. These leaders may then inform and mediate with potential study participants (community members, drug vendors, health facility staff) prior to sensitisation by researchers immediately before field work activities.

In any meeting, thorough preparation may be needed by researchers to decide how best to communicate the aims and objectives of the study in ways that are locally relevant (Smith and Morrow 1996). The objectives and methods of research proposed should be described and potential participants should be told what is asked of them and what potential benefits they may receive, or risks to which they may be exposed, during the study. These discussions are especially important in intervention research in which resources may be differentially introduced, tested and denied, but they are also important during observational research to clarify expectations of all parties.

Invitation. It is important to develop rapport with research participants and invitations to participate are one way to help establish this. Invitations may be individualised and written in letter format, for example if inviting health workers at a particular facility. Alternatively, participants may be invited to participate when they attend a particular provider and in this case it is useful to have information about the possibility of being invited clearly displayed around the provider's workplace. At invitation, the participant should be informed of the general topic of the research and how long the interview is likely to take (typically 30-60 minutes).

Planning time and place. For interview research, both timing and context need to be considered in the planning stages. Time of day may affect the availability and level of engagement of participants, for example household interviews may be best held during the daytime for women or during the evening for men, and health worker interviews may be best held at the beginning or end of a shift. Time of year may also be important: if malaria is seasonal, perceptions may change depending upon the season; and patterns of behaviour may change according to the season if participants are involved in agriculture. Where interviews take place is important: participants may be more free, restricted or distracted in different settings, particularly if they may be within earshot of others when discussing sensitive topics. Information from potential participants during the sensitisation process, together with a consideration of the objectives of the research, may help to identify the best times and places for interviews. The duration of the interview should have been established during piloting, but this may vary, and the fieldworker must allow sufficient time for the interview to run on, and to review the interview and make detailed notes (e.g. via a contact summary form) immediately afterwards before subsequent interviews or commitments.

Setting up the interview. Once participants have agreed to be interviewed, the interview may need to be confirmed prior to the date, e.g., through a phone call or message. Once confirmed, or for participants recruited on the spot, the area for the interview needs to be set up. The most

appropriate place for the interview should have been identified, and on the day of the interview, the fieldworker needs to ensure the place is available, that there are comfortable seating arrangements and that any external noise will be kept to a minimum, particularly if a tape recorder is being used. Any refreshments to be provided for the participant should be prepared. The Fieldworker must ensure they have brought all necessary materials and equipment, including the topic guide, consent form, pens, notebook, tape recorder and spare batteries.

2.1.5 Collecting the data

See also the Supporting Materials document, **"ACTc Qualitative Research Protocol Template and Tools"** for standard operating procedure (SOP) templates on Giving information and getting consent (interviews) (SOP 2), Carrying out the interview (SOP 4) and Carrying out team debriefings (interviews) (SOP 5).

Giving information and gaining consent. Information sheets and consent forms should be prepared in advance, have been piloted and approved by ethics boards. The fieldworker should have been trained to explain what the participant is consenting to and ask for and respond to any questions from participants in an open manner. The researcher should not place pressure on the invited respondent to participate (see section 3.4 Ethical Issues in Qualitative Research).

Carrying out the interview. For in-depth interviews, the topic guide can be quite flexible. The fieldworker should attempt to cover all topics on the guide but the particular experiences of participants should be sought, which may lead to deviation from the expected content. The fieldworker also needs to judge whether the conversation has deviated to topics irrelevant to the interview objective and, if necessary, to guide the participant back to the topics in the guide.

In in-depth interviews, the respondent should do most of the talking since their role in the interview is as an informant or teacher to the researcher (Sobo 2009). As researchers, we essentially want to "keep them talking" on topics that are important to the study, and the specific probes or prompts written into topic guides to elicit specific types of data can help us do this, as already discussed. As a rule, open rather than closed questions should be used. Researchers should also be able to deploy prompts simply to keep the conversation going, to encourage deeper reflection by the respondent and to assist the researcher's ongoing understanding of the data being collected. A number of these types of conversational prompts are given in Box 8. Often just as important a technique for researchers, is the so-called 'silent probe', in which the researcher remains silent while maintaining an expectant, hopeful, nonjudgmental facial expression, or the 'echo probe' which entails repeating the last word or phrase that the participant offered with an upward inflection to serve as a request for clarification.

Box 8. Conversational prompts for qualitative fieldwork

Ask for a story	'What happened last time you…?'
Explore metaphors	'I'm interested you describe this as alike to X. Can you tell me more..?'
Ask for clarification	'What do you mean by..?', 'Can you say a little more about..?' 'In what way?'
Search for opinions	'What do you think of that?'

	'Do you believe that?'
Pursue the logic of an argument	'Does it follow, then, that..?'
	'Presumably,...?'
Seek comparisons	'How does that relate to..?'
	'Some others have said that..'
Check on apparent contradictions, implausibility, exaggerations or inconsistencies	'Yes, but didn't you say a moment ago..?'
	'How can that be so if..?'
	'Does it necessarily follow that..?'
	'How can that be so if..?'
Express incredulity or astonishment	'After only *six* months?'
	'Really?!'
Ask hypothetical questions	'Yes, but what if..?'
	'Supposing..?'
Aim for comprehensiveness	'Have you any other..?'
	'Do you all feel like that?'
	'Have you anything more to say on that?'
Summarise occasionally and ask for corroboration	'So..?'
	'What you're saying is..?'
	'Would it be correct to say..?'

Includes prompts adapted from Woods (2006)

Important to avoid are leading questions (for example, 'do you think malaria is a big problem here?'). An excellent guide to asking good questions and also active listening skills can be found in Haaland et al (2006), which formed the basis of the ACT Consortium training on qualitative fieldwork methods found in **"ACTc Materials - Qualitative Research Training".**

Note-taking. Researchers should take notes both during and directly after interviews. The interviewer may choose to have the topic guide (and prompts) typed with spaces between each question to manually write the participant's comments while conducting the interview, or they may choose to note responses in a separate notebook. The detail of these notes depends upon whether a tape recorder is being used to produce transcripts of the interview. If not, note-taking should attempt to capture exact ('verbatim') phrases spoken by the participant as far as possible. Detailed notes are useful even if a tape recorder is used, particularly if the recording fails. The usefulness of taking detailed notes is offset, however, by the risk of disrupting the flow of the conversation. The interviewer therefore needs to balance taking notes (as short-hand as possible) with engaging in conversation. Immediately after each interview, it is important that the interviewer reviews their notes taken during the interview, expanding their short-hand and adding important comments or points made. Delay in making these notes may mean the loss of valuable information. ***Field notes*** may also be completed detailing the setting and surroundings of the interview, interactions between the interviewer and respondent and the relative ease or unease of respondents about particular topics or these observations can be entered into a more structured 'contact summary form'.

Audio recording. It is now common to audio (or tape-) record interviews, which enables the capture of detail and nuance of what is being said. This allows the interviewer to engage more freely with the respondent, knowing that they can fill in gaps in their notes by listening to the recording later. However, it is not necessarily familiar to interviewees and the equipment and concept of recording may be associated with non-research activities, such as radio recording. It is important to have a discussion about how the recording will be used and elicit concerns from the interviewee prior to use. It may be helpful to show participants the device (if necessary giving a test run, explaining that it is recording when the light is on). It is also important to emphasise that the respondent can opt-out of being recorded, or ask for the tape to be switched off at any time, and that their recording will not be labelled with their name and will be kept in a secure location. It is important that the fieldworker makes a note of the digital file name, or location on a tape, linked to the interviewee's unique identifier, for each interview in a systematic way.

2.1.6 Managing the data

A protocol for data management should be set up at the start of the study. This needs to consider who is responsible for storing and transcribing notes and recordings, including what happens immediately after return from the field. For example, if fieldworkers stay overnight or return home late from the field, a protocol for data storage must be implemented. Once the paper and audio data arrives at the research institution, transcription into digital documents should be carried out either by the fieldworkers or by a trained data entry team who are familiar with the terminology of the study.

If working with qualitative data analysis software (such as NVivo), it may be useful to save each interview transcript and associated set of field notes and contact summary form as a single document, labelled with the ID number of the participant before importing into the software for analysis. If the data are originally typed in Microsoft Word, the use of Headings settings can be considered for each item in the topic guide for easier integration into NVivo later on (with heading settings becoming 'node' titles and interview text under the heading coded under that node, which is a useful place to start with coding a document). If there are quantitative data from demographic and work history questions, these can be entered using standard quantitative packages such as Microsoft Access, imported into NVivo and linked by participant ID number to the document containing that participant's interview transcript and notes. See Section 2.4 for further details on transcription.

2.1.7 Data analysis

Methods for analysing the qualitative data produced from in-depth interviews are similar to those from other qualitative methods and a wide range of analytic approaches to qualitative research use interviews as the main method of data collection. Section 2.5 and CHAPTER 5 outline some approaches to qualitative data analysis.

2.2 Focus Group Discussions

Focus group discussions (FGDs) are useful for collecting data about experiences, feelings, opinions and reactions that may not be revealed in one-to-one interviews but may be elicited and observable through participation in a social gathering and through interaction with others in debating issues and

exchanging views. As with in-depth interviews, FGDs produce data about perceptions and how the world is classified by participants, although the group context means a multiplicity of views and emotional processes can be elicited which is useful in determining points of contention, group norms and potential issues for intervention design. Methodologically, there are similarities with in-depth interviews, including for fieldworker skills, preparation, collecting data and for data analysis.

2.2.1 Sampling

As with in-depth interviews, there are several considerations in sampling for FGDs.

Inclusion and exclusion criteria for participants should be specified for each particular research objective. Depending upon the objective, the criteria for selecting potential participants may be quite broad. For example, if the objective is to understand perceptions of illness and malaria in a community those included may be adult women, adult men and community leaders.

Identification of sub-groups is necessary in order to form suitable focus groups that will represent the range of experiences and opinions in a wider study population. The composition of focus groups needs to be carefully considered in relation to differences in experiences or behaviours of interest to the study across social groups as well as to power relations and sensitivities that may be involved in being asked to discuss particular research topics in a semi-public manner. The unit of analysis in FGDs is the group, rather than individuals within a group, and therefore sub-groups should reflect expected differences with regards to the topic of interest. If differences in perceptions, experiences or opinions are already known or expected between certain sub-groups of the study population, for example between those who more often seek care at public or private health care providers, or those with access to greater or lesser resources, separate focus groups should be held for each sub-group to allow for those with more similar frames of reference to bring out these in a way that could be compared with other sub-groups. In addition to selection of sub-groups based on representativeness, the membership of groups should be considered in terms of the potential success of discussion between those included in each sub-group. In a successful discussion, participants are open about their opinions and able to debate. Therefore, members of the group should be others with whom they feel comfortable discussing the topic. Strong power differentials within a focus group is unlikely to allow for inclusion of all participants in the discussion. Sub-groups should therefore aim to include individuals who possess similar characteristics (for example gender or professional background) and may even be a pre-existing social group who already know each other.

Sample size for FGDs is guided by the number of groups rather than the total number of participants, because the unit of analysis is the group. For each group, the number of participants in each FGD is usually six to twelve. The number of focus groups will depend upon the scope of the research question and also the number of sub-groups identified: if FGDs are to be held with adult women, adult men and community leaders and these groups are expected to produce different data, sufficient focus groups to answer the research question for each sub-group are needed. The exact number of focus group discussions required for each sub-group will depend upon the variation in the data collected between each FGD, but typically 2-3 per sub-group is sufficient. FGDs can produce long transcripts which take time to transcribe, translate and to analyse. This needs to be borne in mind when deciding how many to complete. As ever, quality of discussions is more important than quantity.

Sampling strategy for FGDs is most commonly convenience sampling, when key 'gatekeepers' are asked to recruit the sample or an announcement is made to invite participants at a certain time and place. Depending on the situation, this may lead to smaller numbers than needed if the topic or incentive is not of interest to the potential research group. 25% over-recruitment has been recommended, inviting 15 rather than the target of 12 participants (Green and Thorogood 2004). The opposite may also occur if a general invitation is issued, and in this case potential participants can be chosen on a first-arrival basis until the group is full. The main limitation with the convenience sampling method is that the participants are unlikely to be representative of the target group. An alternative strategy is to systematically invite people from a sampling frame. This may be simpler in a formal setting such as a health facility, to recruit staff or patients and less straight forward in a community setting and is likely to result in low response rates. If the inclusion criteria for specific focus groups is strict (e.g. marital status, number of young children and duration of residence in the area), it may be necessary to use a screening questionnaire to identify suitable participants.

Time and place are important, as with interviews, and this should be considered and planned in advance for time of year; time of day; and location. In terms of location, more space is needed than for one-to-one interviews. Established local meeting places may be used, for example the meeting place for village elders or staff meetings in a clinic or hospital. For some topics, researchers attempt to find a neutral setting, such as renting out a hall, with the advantage of reducing either negative or positive associations with a particular site or building (Powell and Single 1996). However, certain groups, such as women, may feel more open in more familiar surroundings and focus groups are often held in the homes of one of the participants.

2.2.2 Development of field work instruments

As with in-depth interviews, focus group discussions are typically conducted with a topic guide. This is likely to be typed together with introductory information and probes for each topic. In addition to the topic guide, the facilitator (often termed 'facilitator', although this implies a power differential which may be unproductive) and note-taker will need consent forms, data collection forms for demographics of participants and potentially a participant information sheet. It may be useful to make written plans for the following activities that typically make up focus group discussion.

Introduction. As with in-depth interviews, the facilitator must introduce themselves and the note-taker as well as the topic and purpose of the research aiming to:

- Establish credibility as the interviewer
- Establish the general purpose of the study
- Establish the aims of the interview and expected duration
- Explain who is involved in the process (other participants)
- Explain why the participant's cooperation is important in collecting the information needed
- Explain what will happen with the collected information and how the participant/target group will benefit

In addition, some information about the focus group must be provided – often participants do not know what to expect during a FGD. The facilitator can outline the format of the discussion during the introduction: the discussion is informal, everyone is expected to participate and divergent views are welcome. It is useful to outline a set of ground rules for the discussion with the participants at the start. If participants are able to read, these may be pre-written on a flip chart which is hung in a

clearly visible location during the focus group. Participants can also be asked if they have any further rules they would like to add to the list. For an example of FGD ground rules, see Box 9.

Box 9. Ground rules for focus group discussions

- 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."

Information and consent. Once the study and research process has been discussed, oral or written consent can then be asked of participants. This can be done by the research team going around the group one by one to ask for consent. Participants may be asked for demographic information at this point too, which can be recorded in a spreadsheet format ready for importing into digital format.

Warm up. As with interviews, it is useful to start with some straight forward questions to put the group at ease. Questions that area easy to answer and interesting to participants, such as relating to recent news or events locally, can generate discussion between participants early on, giving everyone a chance to speak.

Topic guide. Topics and prompts designed to cover topics relevant to the overall research questions are listed, usually in a less structured format than for interviews in order to elicit a flexible response. The language used in the guide must be understood by all group members; it is therefore important to keep it simple and to avoid long and complex statements. The number of topics is usually less than a dozen, although the addition of new topics (by the facilitator or participant) is possible in the course of the discussion.

Closing. As with interviews, the last five to ten minutes of the discussion will consist mainly of summarising and recapping the topics and responses from the group. Prior to the summary, the facilitator should ask each participant in turn if there is anything they want to add but participants should also be given the opportunity to alter or clarify their responses as summarised by the facilitator. After the summary, all participants should be thanked for their time and at this point demographic details may be collected.

An example of a guide for a focus group discussion is given in the Supplementary Materials document: **"ACTc Qualitative Research Protocol Template and Tools"**

Note-taking. Whilst note-taking will follow the direction of the conversation, it may be useful for the note-taker to have a structured form for detailing particular elements of interest in addition to the content of the discussion. Allocating ID numbers to individual participants on a seating chart and to key verbatim statements during the discussion is particularly helpful for keeping track of individual participant contributions for transcription, later on. An example is given in Box 10.

Box 10. Example note-taker form

FGD IDNO |__|__|__|__| Facilitator Initials |__|__|__| Note-taker Initials |__|__|__|

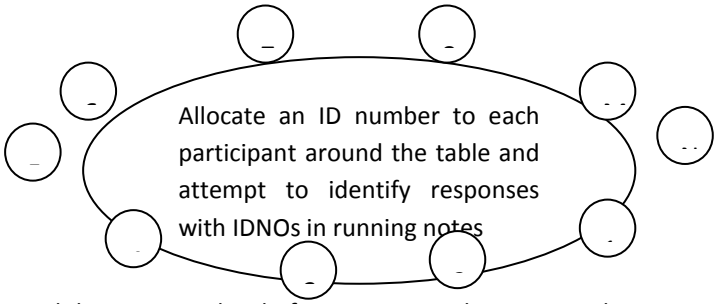
Participant sub-group type (circle): Adult men/ Adult women/ community leaders

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 (following the discussion):

Debriefing. The facilitator and note-taker should meet immediately after the session to complete their notes and go over broad themes of the discussion. A contact summary form may be used following each session, as with in-depth interviews, although here more attention is given to the

atmosphere and interaction of participants in the focus group (see **"ACTc Qualitative Research Protocol Template and Tools"** for an example). Full debriefing sessions then take place with the entire study team and can be used to discuss themes emerging from the FGDs and whether new topics or questions should be included. Overall, these debriefings should aim to assess whether the discussions are generating the information required to meet the study objectives.

2.2.3 Piloting

Piloting is important for focus group discussion methods, enabling the identification of problems in the topic guide regarding wording and interpretation of specific questions as well as areas for further training in field team techniques. The study guide can be adapted during the actual study, to reflect on-going findings, and the pilot is also useful for practicing making these revisions. The protocol should therefore include how to identify when potential changes are needed and criteria and methods (discussion with full study team and pre-testing of items) for including these in future topic guides.

2.2.4 Preparation for field work

The preparation for FGDs is similar to that described earlier for in-depth interviews (see Section 2.1.4). Additional items may be needed for setting-up in advance of a focus group discussion. A logistics checklist may be helpful, for example the list shown in Box 11.

Box 11. Checklist to bring to focus group discussions

- Focus group topic guide
- Introduction sheet
- Information sheets and consent forms (enough for all participants)
- Note-taker form
- Writing utensils for note-taker and facilitator
- Notepads for note-taker and facilitator
- A flip chart [with ground rules pre-written]
- Markers for the flip chart
- Tape for affixing flip chart pages to the wall [if needed]
- Recording equipment
    - Tape recorder
    - Spare batteries
    - [Extension cord*]
    - [Extra tapes*]
- Debriefing form

*These items are only necessary with conventional tape recorders. Digital recorders may be preferred with their higher quality and easier data management capabilities

Planning for the focus group must include agreement on the exact roles of each member of the field team, for example, how much input or direction each will give, particularly if a translator is to be used during the focus group. It is recommended that one member of the field team is the facilitator,

facilitating the discussion, and the other takes notes and checks the recording equipment during the meeting. There also needs to be consistency in methods across focus groups, so careful preparation with regard to role and responsibilities is required in the development of the protocol.

See also **"ACTc Qualitative Research Template and Tools"** for standard operating procedure (SOP) templates on Getting permission and inviting participants to focus groups (SOP 6) and Organising the focus group discussion (SOP 8).

2.2.5 Collecting the data

On the day of the focus group, the role of the facilitator is critical in terms of providing clear explanations of the purpose of the group, helping people feel at ease, and facilitating interaction between group members. The role of the note-taker is as important, with the need for good quality notes critical to the interpretation of the data collected at the discussion. Typically, focus groups will be tape recorded. If, for whatever reason, the discussion is not taped, extensive notes are required to accurately reflect the content of the discussion as well as any observations of non-verbal behaviour and group dynamics. If a tape recorder is used, this needs to be sensitive enough to capture low levels of speech at a distance of several metres. It is usually the responsibility of the note-taker to operate this, and to continue to take extensive notes, although these need not be verbatim, allowing more time for noting observations of the group. The note-taking and conversational techniques described for interviews can also be useful for conducting FGDs (see Section 2.1.5). Further tips for FGD facilitators can be found in Box 12.

Box 12. Tips for FGD facilitators

- To make participants feel comfortable, maintain a friendly and warm attitude
- During the warm-up, show interest in each participant's introduction by making eye contact and active listening (whilst discouraging digressions)
- Build rapport by showing sensitivity to the needs and feelings of participants
- Encourage participants to communicate amongst themselves
- Minimise pressure to conform to a dominant point of view: if an idea is adopted without any general discussion it is likely participants are feeling pressure to conform to a dominant viewpoint. To reduce this, the facilitator can probe for alternative views, 'We have had an interesting discussion, but let's explore other ideas or points of view. Has anyone had a different experience that they wish to share?'
- Do not show too much approval for certain participants' responses, and avoid giving personal opinions
- Do not behave like an expert
- If participants feel everyone already understands a topic it can be difficult to elicit further information – one method to reduce this is for the facilitator to convey a lack of complete understanding, 'I didn't know that, can you tell me more about it?'
- If participants are slow to respond or provide additional information, pause to give them time to reflect. Don't be afraid of silence.
- If trying to elicit further information, incomplete statements can be useful, 'I don't know, maybe in some cases…' [wait for response]

Adapted from Arhinful et al (1996) and Kreuger (1988)

See also **"ACTc Qualitative Research Protocol and Tools"** for standard operating procedure (SOP) templates on Giving information and getting consent (FGDs) (SOP 7), Carrying out the focus group discussion (SOP 9) and Carrying out team debriefings (FGDs) (SOP 10).

2.2.6 Managing the data

The data produced from a FGD should include: the audio recording; any notes made by the facilitator; the note-taker's detailed notes; the contact summary form and the demographic details of participants. Each of these must be kept confidential and a protocol developed for the handling and management of the data. ID numbers for each FGD should be used to link associated documents.

2.2.7 Data analysis

Methods for analysing the qualitative data produced from focus group discussions are similar to those from other qualitative methods. Section 2.5 and CHAPTER 5 outline standard approaches to qualitative data analysis. Two key analytical concepts, however, should be borne in mind for analysis of focus groups, specifically: (1) group dynamics and (2) quantification of responses.

The group dynamic of focus groups is an important source of understanding of how topics are discussed between members of the target population (useful for identifying culturally acceptable terminologies and approaches to topics) and in understanding shared knowledge and dominant cultural values (useful for identifying a starting point for potential interventions). The way members of the group communicate may include jokes, anecdotes, teasing, arguing and different types of narrative (Kitzinger 1995), and these can be analysed in conjunction with the specific topics being discussed to gain insight into what approaches may best be used in designing behaviour change interventions through mass media such as radio, television or cartoon strip sketches. These different methods of intra-group communication also provide insight into consensus and dissent within the group over different topics: dominant cultural values, knowledge and 'common sense' that is shared by all members may be identified as well as points of controversy which appear to be acceptable to debate within the group. These details provide important information for the design of interventions and may even form a separate 'tree' in the data analysis structure, looking at *how* topics were discussed, which can be linked to the content of discussion through matrices of codes using qualitative data analysis software (see CHAPTER 5).

In interviews, it is often possible to count the number of interviewees who give certain responses to a set question by categorising their responses either before or after reviewing the data. For focus groups, this is not possible on the level of individual participants; the unit of analysis is the focus group, because the data were generated from the interaction of this particular group (with the facilitator and note-taker) at this point in time. It is possible to quantify particular responses by the number of focus groups – for example, those that perceived certain antimalarial drugs as ineffective. This can be done manually through the use of a log book, or can be constructed using computer assisted coding.

As Sobo suggests, however "the very nature of focus group data—its social generation—makes it more suited to interpretation than statistical manipulation" (p. 179) (Sobo 2009). For example, even when a concrete list of possible responses to fever has been collected, there is no way to infer or predict from focus group data the number of people who would actually undertake one or another

response in practice. What we can conclude is what is in the response repertoire and what each response may refer to or mean.

The particular response repertoire or meaning can be qualitatively compared between groups to identify, for example, whether certain ways of viewing risk in relation so malaria are particular to, say, groups formed of women with young children when compared with notions of risk articulated in groups formed of older men, or if the consequences of adhering or not to test results in prescribing is given different weight by community health workers compared with hospital doctors. Such findings may also be 'triangulated' with findings from individual interviews or questionnaires to validate or expand on the interpretation.

2.3 Direct Observations

Direct observation of behaviour (such as what actually happens in a patient consultation) is central to holistic analysis in qualitative research (Silverman 2005). It is of interest in itself as well as in conjunction with people's accounts of their behaviour as reported in interviews or focus group discussions since, "the hidden meanings of words [spoken in formal interviews] sometimes only emerge when we observe speakers' actions, in context" (Sobo 2009). Ethnographic work alongside intervention trials has been found to be valuable in revealing insights that may be hard for project staff 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 and Lambert 2008).

Direct observation can produce qualitative and/or quantitative data about the practices of those observed, depending on the research question. The observer may be a participant in the activities of those they are observing, for example as a member of staff at a health facility or as a patient amongst a group of other patients, or the observer may be non-participatory, simply recording observations of interactions and circumstances in which others are acting.

Unstructured participant observation is the primary method used in ***ethnography*** which, through cultural immersion, enables the researcher to step into the shoes of those under study in order to develop a detailed understanding of their lives, values, beliefs, influences and constraints (see Section 1.3). This approach usually produces rich, in-depth description of the culture of a particular group and requires a relatively long period of fieldwork, usually a minimum of three months (Agar 1980) but often several years, with a relatively small sample size, typically a few villages or a single organisation. Data is in the form of fieldnotes which attempt to capture a detailed description of activities, interactions and discourses relating to the research topic of interest (Spradley 1980), noting 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 phenomenon of interest in practice. Here, the researcher principally observes activities and interactions, but also asks questions for clarification and will ask different actors about their practices (Spradley 1979), seeking to bring to light logics, concerns, classifications, processes and meanings that emerge from the intervention activities. The fieldworker records discussions and informal interviews manually in field notes, or, if an informant is likely to provide more detailed information and partake in a lengthy discussion, the field worker may ask to record the interview using a digital recorder for later transcription. The aim of the researcher is to produce a thick description of the intervention activities in the physical and social spaces that they employ (Geertz 1973).

Rapid ethnographic methods are sometimes used as an alternative, trying to meet the requirements of multi-disciplinary teams working to shorter timelines (Manderson and Aaby 1992). However, their use is controversial, with anthropologists sometimes reporting that findings have been superficial and even misleading, without in-depth understanding of the context to situate analysis (Sobo 2009). However, others have maintained that such methods have a role when the focus is on designing or evaluating public health interventions, particularly in combination with participatory approaches (Agyepong, Aryee et al. 1995). Rapid methods involve the combination of direct observation with interviews, focus groups, visualisations (mapping, seasonal calendars), document reviews and other techniques to increase the likelihood of discovering new concepts (Annett and Rifkin 1995). As opposed to the unstructured nature of observations in long-term ethnographic field work, direct observations for rapid methods are more likely to be structured, to ensure all relevant data are collected for each setting or instance, although some flexibility in categories of observations remains important.

Structured observations are typically short and conducted with a larger sample of participants than ethnographic observations. Here, the emphasis is on recording information about pre-defined categories of behaviour or talk, for example as part of an evaluation of a training intervention, to observe how participants are responding to aspects of the training or to note how trainers are adapting materials to make these more interpretable. Structured observations do not need to only include closed questions, but typically have a format that has spaces for noting pre-specified aspects of interactions or situations. The structured format may be considered to reduce the potential for bias from the researcher's own opinions of what is important about their observations, and allows data to be recorded by multiple researchers and across multiple sites systematically, allowing for direct comparability. With this approach, researchers may still be participant observers but their participation is likely to be more superficial and they will be less likely to build the relationships formed through more long-term observational research.

2.3.1 Sampling

For unstructured observations, the researcher will typically allow the sampling to emerge over time in a convenience manner, according to what and when events that may be of interest to the developing research topic are occurring and where the researcher happens to be. Therefore, beyond 'being there' for a minimum defined time, and an intention for example to observe treatment seeking for illness episodes when they occur within a particular group, a pre-defined sampling strategy is not usually employed for unstructured observations.

Sampling for structured observations often follows epidemiological standards, such as defining and selecting a cross-section of a set of scenarios of interest, such as a systematic selection of consultations or supervision sessions. Here, values placed in the sampling process include:

> Ensuring comparable numbers of consultations with patients or customers are observed for each individual provider and that numbers are sufficient to reduce observer bias and to allow clustered statistical analysis by individual provider (as a rule of thumb, a minimum of 15 patients per individual provider);
>
> Ensuring a sufficient sample of individual providers are included within each provider establishment, for the purposes of clustering in quantitative analysis.

2.3.2 Development of field work instruments

Typically, unstructured observations are noted in a fieldnotes book. Fieldnotes are accounts that describe experiences and observation the researcher has made while participating in an intense and involved manner. It is not merely a matter of accurately capturing as closely as possible observed reality, 'putting into words' overheard talk and witnessed activities as a series of 'facts', but writing involves active processes of interpretation and sense-making (Emerson, Fretz et al. 1995). Some things would be noted and written down as significant and other things may be missed or deliberately ignored, according to the researcher's sensitivities and concerns. Therefore, different descriptions of 'the same' situations and events are possible. Fieldnotes can be seen as inscriptions of social life and social discourse, in writing, the researcher 'turns it from a passing event, which exists only in its own moment of occurrence, into an account, which exists in its inscription and can be reconsulted' (Geertz 1973) (p19). In other words, the writing process transforms witnessed events, persons and places into words on paper which reflect the researcher's sense of what may be interesting to the research topic as well as what is interesting or important to the people being observed. Emerson et al (1995) outline four implications for the inscription of participatory experience:

- What is observed and ultimately treated as 'data' or 'findings' is inseparable from the observational process
- In writing fieldnotes, the field researcher should give special attention to the indigenous meaning sand concerns of the people studied
- Contemporaneously written fieldnotes are an essential grounding and resource for writing broader, more coherent accounts of others' lives and concerns
- Such fieldnotes should detail the social and interactional processes that make up people's everyday lives and activities

Structured observations require a data collection form to ensure observations are consistently recorded. The form is preferably a single sided sheet, or if necessary one two-sided sheet for ease of filling. A check-sheet format is useful, so that once the fieldworker is familiar with the format, the sheet can be filled quickly as different items are observed. Items should be unambiguous, but a key defining terms used on the check-sheet (such as 'examined for dehydration', defined as 'skin pinch/capillary refill/dry mouth') may be useful to include as an endnote on the form. The data collection form may include space for the fieldworker to draw sketches of situations, such as waiting, consulting, testing and prescribing areas. In this case, two different observation forms may be used: one for observing specific instances and another for observing general surroundings.

As described above, there are various options for how observation takes place, and these will affect the type of data collection form appropriate for use. For covert approaches such as 'mystery shoppers', the observer cannot make notes during the observation and must commit observations to memory and note these details on a data collection form as soon as possible after the observation. Overt observation is easier from the perspective of recording data: the observer may be seated at the side of a consulting room, in a village meeting or in another setting where they can record observations as they occur. This increases the number of items the observer can reasonably be expected to fill, limits recall bias and the categories on the record form may also prompt the fieldworker to look for certain observations during the study period.

The main use of direct observation in ACT Consortium projects has been to record provider diagnostic and prescribing practices, to observe intervention implementation in practice, such as training events, and to observe routine supervision activities and processes. In the design of data collection forms, the researchers are asked to define the person and activities that will be the focus of the form. For example, in provider practices, the focus may be on what the provider does, says and records, but the interaction with the patient may also be of interest if it is hypothesised that this may be affecting provider practices, and details may therefore be recorded about the interaction and patient variables. The activities of interest may include whether and how the patient is greeted, what questions are asked of the patient, what examinations are undertaken, what tests requested, what treatment and advice are given, any questions that the patient asks and the way these are responded to. Contextual factors such as the workload in the clinic may also be recorded in a systematic way.

These activities may be complemented by recording data from sources other than the consultation observation, for example patient-held records, laboratory records or health worker notes. In this case, short pilot studies can be used to inform which, if any, of these records it may be necessary to pursue. The data collection form will then need to be adapted so that these records can be added at another point in time (by the same or a separate fieldworker), or additional case report forms may need to be designed, in which case matching by identification number will be very important. If consultations are to be observed by one fieldworker and records to be pursued by another, it can sometimes be useful to have a third fieldworker co-ordinating data collection to ensure reliability of data. This is particularly useful if providers or patients are to be interviewed in addition to the observations and all findings combined in analysis.

An example of a data collection form for structured observation of drug seller interactions with customers is available in the Supporting Materials document: **"ACTc Qualitative Research Protocol Template and Tools'** but data collection forms can also include broader unstructured environmental observations in a community or facility.

2.3.3 Piloting

Experience and practice in writing fieldnotes is important, and members of a research team cannot be expected to undertake such activities without supportive supervision in the first instance. This should include reviewing fieldnotes and seeing what can be interpreted from these regularly, in order to consider what or how observations may be made and recorded differently.

For structured observations, several stages of piloting may be necessary in order to construct an effective observation form. This should take place in sites outside of the proposed study area to reduce bias for future observations with the finalised data collection form. Initially, the pilot may target observation of broad categories of activities to be refined through observation and discussion with participants. For this reason, fieldworkers should be trained to write notes about observations that were not included in the items listed on the data collection form. For example, an observation that examinations did not occur when providers and patients were of the opposite sex may be important for an intervention but not included on the data collection form. Such observations should be discussed with other members of the research team and considered for inclusion in up-dated versions of the data collection form. A more specific and relevant list of items may then be developed and the logistics of collecting this new data (including gaining consent) piloted in the next stage to elaborate a final data collection form. Field workers need to be trained in all definitions of items in the form. A useful check both during training and during the study period is to have pairs of

observers duplicate a sample of observations and compare intra-observer findings. Data entry processes and analysis strategies can also be piloted at this stage.

2.3.4 Preparation for field work

As with in-depth interviews and focus group discussions, researchers should go through the stages of *sensitisation, invitation, planning time & place* and *setting up,* as outlined in Section 2.1.4. The fieldworker should meet and explain the study to key stakeholders as well as those they are proposing to observe. In setting up, the fieldworker needs to identify the most appropriate place(s) to situate themselves in order to be able to observe proceedings. If non-participant observation is planned, the fieldworker should aim to situate themselves out of the way of participants to be least distracting. The fieldworker needs to carry the field work forms and any field guide that complements these, notebooks for extra notes, writing materials and a tape recorder (with spare batteries) if this is to be used. Fieldworkers need to be careful to dress appropriately, in a manner that does not emphasise power differentials or attract attention for being distasteful to local norms.

2.3.5 Collecting the data

During field work, the observer should strive to maintain a neutral and non-judgemental affect, and remain aware of the way their affect may shape their interactions, the responses and behaviours of those being studied, and their own interpretations and sensitivities in translating observations to fieldnotes. Skills in picking up on non-verbal communications by those under study are essential, together with the ability to note down observations as quickly as possible at the same time as remaining sentient to goings-on. The fieldworker should be sensitive to whether their note-taking is causing participants to feel uncomfortable and take steps to discuss what they are doing and/or cease to take notes at that time.

A protocol for gaining consent from participants must be established and after any questions are answered. Observations may take place back-to-back for several hours and it is advisable that the fieldworker is well nourished before beginning in order to sustain attention to detail. At the end of the day or session of observations, the observer should thank those they have been observing for their participation.

It is useful to review each set of observations and notes on the day they were noted, in order to fill in any gaps and to identify any problems or changes required to the research protocol, particularly if a data collection form is used. If working as a team, regular meetings with colleagues should also be conducted when fieldworkers should summarise their interpretations and any problems which can then be collated and discussed.

2.3.6 Managing the data

It is important to provide guidelines for data handling and management in the protocol. Fieldworkers should know how and where to store notes, forms and other materials whilst in the field, and where and who can store and access these data at the research institute. If data are to be entered quantitatively, this should be carried out as soon as possible, providing early draft datasets for researchers to identify any problems with the field work or entry processes. Quantitative data should be double entered, validated and checked. Qualitative data / fieldnotes can be typed up and identifiers used to indicate individuals, places and even each observation incident (e.g. by assigning consultations a unique ID number) so that data can be linked together involving notes, materials and quantitative findings.

2.3.7 Data analysis

Analysis of observations begins during the process of recording events – in the interpretation of what is occurring, what is important to note down and the way this is recorded. It can be helpful to continue analysis with routine debriefing sessions with others in the field team, which may broaden sensitivities of those continuing to do fieldwork and can begin to shape up a broader interpretation of the research topic. Observations can also be brought together to generate hypotheses to test with the quantitative data, and to explore with the qualitative data. Structured observations may be analysed solely quantitatively, but a combination of quantitative and qualitative data is likely to be produced and these can be analysed together with the assistance of qualitative analysis computer software. For example, quantitative data may identify that patients who asked questions were more likely to be prescribed a particular drug.

A few points to consider in the analysis of structured observations:

Descriptive statistics of the frequency of certain actions or interactions are useful, such as examinations were conducted or antimalarials prescribed. However, unless the observations are truly representative of all potential instances of interest (e.g. a random sample taken from all consultations taking place at all times of day and all days of the week) then these statistics cannot be assumed to describe frequencies (e.g. of antimalarial prescriptions) in this overall population. Rather, the findings are likely to represent the population from which the sample was drawn, such as patients seen during the morning on weekdays, which may differ systematically from the total population of patients consulting at a particular provider.

Post-coding qualitative to quantitative data can be a useful method for providing statistics about qualitative data. Whilst some interactions may be easily coded on the spot (e.g. did the provider greet the patient?), for more complex interactions it may be more appropriate to note the detail of interactions and code these afterwards (e.g. a discussion about side-effects of certain antimalarials). Some of these categories may be predicted in advance, for example patients reporting positive or negative prior experiences with specific drugs, but the researchers may prefer to capture the full discussion, enabling the lines to be coded to the predicted categories whilst the option of generating new codes remains. New codes can then be systematically applied to all of the qualitative data, and, as long as the qualitative data were systematically noted, these codes can be exported to a statistical data analysis package alongside original quantitative items on the observation form.

Quantitative data analysis can be used to search for patterns in the data. Were certain activities associated with variables observed about the patient or provider (e.g. examinations less likely for female patients, or tests less likely with male providers)? Were certain types of question from the patient associated with treatment type? These patterns can be analysed using conventional statistical techniques such as regression, adjusting for multiple predictors using multiple regression and adjusting for clustering on individual providers or facilities using cluster-adjustment methods or multi-level analysis.

Qualitative data analysis can be used to explore findings which emerge from quantitative analysis of the observations. For example, if a provider giving advice to the patient or customer was found to be associated with fewer drugs prescribed, qualitative analysis could explore the content and communication strategy of advice-giving and the interaction around this section of the consultation. Alternatively, qualitative data analysis can be conducted without the direction of quantitative findings. Here, analysis could follow the strategies outlined for in-depth interviews and focus group

discussions, looking for concepts and themes within the original notes and transcripts and building a framework of the social interaction and behaviours of those observed.

2.4 Transcription & Translation

2.4.1 Overview

Newcomers to qualitative research often mistake transcription as a technical, mundane clerical task. It is not just about 'typing (or writing) what you hear' (McLellan-Lemal 2008). Academic discipline, methodology, theoretical orientation, qualitative data analysis software, researcher experiences, timelines, and resources all ultimately influence transcription decisions and preferences (McLellan-Lemal 2008). Recent discussions of transcription and translation processes within qualitative research, however, have highlighted a lack of explicit description of methods for these activities (Temple and Edwards 2002, Duranti 2006, Davidson 2009). These authors state that transcription and translation should be given as much consideration in the planning, analysis and writing up stages as any other part of the research process, and yet this frequently fails to be the case.

From a social theory perspective, conducting transcription or translation of data is a practice of both construction and selection (Ochs 1979, Temple and Edwards 2002), influenced by the research's theoretical and methodological perspectives. As such, these practices require the same reflexive gaze as is given to all other stages of qualitative research, and researchers should actively consider their approach to transcription or translation (and that of other members of the research team) with reference to their theoretical assumptions (Duranti 2006, Roberts 2007, Davidson 2009). By failing to consider transcription or translation as an active component of the construction of knowledge within qualitative research, Duranti (2006) argues that the processes appear to become 'naturalised' and value-free. This is indicative of a positivist epistemology and, as such, at odds with the interpretive or social constructionist epistemologies of social science (Lapadat 2000).

2.4.2 Transcription

Theoretical considerations

Transcription, simply, is the act of converting audio or visual communication into a written format for analysis within research. The value of transcribing has been defined as the ability to produce highly detailed and accessible accounts of interactions or phenomena, in a format that is largely transparent and immediate for the researcher to use in analysis (Nikander 2008). However, the actual process of transcribing is far from simple, and key questions must be addressed when planning transcription as part of social science research.

Roberts states that transcription is a "*construction of knowledge rather than a transmission of knowledge*" (p19, 2007), and as such the creative role of the transcriber in the research process is identified, and must be reflected upon. In planning and conducting transcription, there are a series of decisions to be made about how and what to capture, reflecting practical and theoretical questions (Nikander 2008). Within the interpretivist epistemology, a transcription can never capture perfectly all the detail of an interaction, such as an interview or focus group discussion, and nor should it try to. Rather, it is important to create a document adequately detailed for its particular analytic purpose and appropriate to the chosen methodology for the study, whilst striving to convey

as fully as possible the experiences of the participants (Roberts 2007). In addition, it is vital to engage in explicit discussion of the dilemmas involved in the selective, interpretive transcription process and to reflect on these in light of the research's theoretical approach (McLellan-Lemal 2008, Nikander 2008, Witcher 2010).

Recommended methods

To transcribe audio or visual communication into a written format for qualitative research, the following recommendations can be considered in relation to the particular theoretical and practical boundaries of the specific study.

Preparation:

- Consider the transcription approach a reflection of the study's theoretical and methodological approaches prior to beginning research, and continue to reflect on this as transcription is conducted (Davidson 2009). Define precisely what is meant by any terms used such as 'verbatim' or 'full', and what this means for the transcription process.
- Ensure that all transcribers, whether part of the research team or external to it, are informed of the theoretical perspective(s) underlying the research project and how this links in with the transcription approach (Davidson 2009).
- Approach transcription in an open, transparent manner, acknowledging the complexity of the process and of representation (Witcher 2010).
- Familiarise yourself with the raw data by listening to/watching recordings before starting transcription, to help decide whether there are any sections that are not relevant to the study, and do not require transcription.
- If choosing not to transcribe the whole recording, think carefully about how the selected parts relate to the whole, in reflection of the study's theoretical position. Take time to define and mark out the boundaries of what is and is not to be included in a transcript (Roberts 2007).
- Consider carefully the layout of a transcription and how this will be achieved for each transcript. Standardised transcript layouts and methods will facilitate the comparison of data at the analysis stage (McLellan-Lemal 2008). Transcription processes can be piloted like other research activities. See Box 13 for standard transcribing conventions.
- Consider, in reference to the study's theoretical and methodological perspectives, the level of detail required of non-verbal communication (such as laughter, background noise), of utterances and other vocal sounds, and of interruptions, unfinished words or people talking over one another. If transcripts contain too much of this sort of detail, text can become difficult to read, making interpretation problematic.
- Erring on the side of caution and including more detail in the transcript may help avoid misinterpretation at the data analysis stage. However, be aware of including too much detail, if incongruent with the study's theoretical and methodological perspectives, as transcripts can become difficult to read, hindering analysis (Ochs 1979, McLellan-Lemal 2008).
- Decide on a notation system for capturing detail such as pauses, interruptions, intonation etc, as appropriate for the methodological approach. Existing notation systems, such as that used within Conversational Analysis may be helpful, for example for demonstrating where participants talk over one another in a focus group discussion (Roberts 2007). Ensure that the notation system is clear, consistent and well understood by all members of the research team.
- Clarify how confidential, identifying or sensitive data is to be handled within the transcript, for example whether references to places or people will be anonymised and how this will be done.

Box 13. Standard conventions for transcribing

I:	Start of each new utterance by interviewer (I or initials if more than one interviewer)
R:	Start of each new utterance by respondent
?:	Beginning of utterance by unidentified speaker
wo-	Word interrupted by next utterance
(word)	Word(s) in round brackets indicate transcriber's guess at an unclear word
WORD	Words spoken more loudly than others
(...)	Indicate unclear material omitted by transcriber

Adapted from (Curatio and LSHTM 2011)

Transcription process:

- Number each line of the transcript to facilitate referencing and quotation within the analysis phase (Roberts 2007).
- If transcribing data from multiple speakers (as in FGDs), it is ideal to be able to identify each speaker each time she or he speaks. Familiarisation with multiple voices can be done with reference to 'ice-breaker' activities led by the facilitation in which participants introduce themselves in their own voice on the recording, and to the note-taker's labelled map of participants.
- Take care with transcribing nonstandard terminology, local dialects and unusual use of words to ensure appropriate interpretation at the analysis stage. It is important for the transcriber to be conversant in local terminology and to be able to give a brief indication of the meaning of nonstandard words in brackets if it is not clear (Witcher 2010).
- Take time to revisit transcripts to check for missed or misheard words, ideally using different members of the research team (Witcher 2010).
- Be aware that approaches to transcription may alter slightly through the research process, as interests change or knowledge is produced. This should be reflected upon and discussed when evaluating findings and drawing conclusions (Davidson 2009).

Writing up:

- When writing up a study, it is very important to explain clearly the theoretical perspectives informing the transcript development and the ways in which transcription contributed to the production of knowledge in the research process. Reflect upon how the theoretical assumptions inherent in the transcription approach may have influenced the data (Davidson 2009).

Other practical transcription guidance (including equipment suggestions for audio recording) is available in the Realities Toolkit

(http://www.socialsciences.manchester.ac.uk/morgancentre/realities/toolkits/transcribing-your-data/index.html)

and from Wordsworth Transcription services (http://www.wordsworthcoop.com/generaltips.htm). A Standard Operating Procedures template for Transcribing (SOP 11) with more detailed guidance on

transcription notation is also available in the Supporting Materials document, **"ACTc Qualitative Research Protocol and Tools"**.

2.4.3 Translation

Theoretical considerations

Translation is much more than the conversion of words from one language to another; rather, it should be viewed as a process of transforming meaning and expression from the source to the target language, for a specific communicative purpose (Regmi, Naidoo et al. 2010). Translation can never be 'perfect' but will always be tempered by the linguistic structures of a language, as well as the implicit socio-cultural codes of meaning that are embedded within languages (Nida 1991, Nikander 2008). Similarly to transcription, translation should also be considered as a process of constructing knowledge, and as such, translators should be acknowledged as active agents in the research process and their influence duly evaluated (Temple and Edwards 2002, Regmi, Naidoo et al. 2010). The translation process should always be planned and performed to reflect the particular theoretical perspective adopted for the study.

Temple and Edwards (2002) and Temple and Young (2004) draw attention to the identities embedded within use of languages, such as ethnicity, gender, and class, and the subsequent hierarchies of relationships between languages. They argue that translation cannot be a neutral process, but is bound up with the politics of language, and of representation. As such, it is important to consider the identity of the translator and their perceptions of the identities of those for whom they are translating. Understanding where the borders between these identities lie, and the assumptions made by both sides is crucial for reflecting upon the influence of the translation process on data construction (Temple and Edwards 2002).

Challenges connected to translation often centre on the notions of interpreting and defining 'meaning' of words, or groups of words, particularly if they are rooted in a specific socio-cultural setting distinct from the target language (Temple and Edwards 2002). In addition, it must be acknowledged that there are multiple codes of communication beyond single or strings of words, which are inherent to the language and implicitly understood by a native speaker (Nida 1991). Nida (1991) argues that these 'extralinguistic codes' are vital to the judgement of a verbal message within a language, but are extremely difficult to convey in translation if a purely 'verbatim' or word-based translation approach is adopted.

Downing and Bogoslaw state that the translation approach should always be selected in reflection of the specific theoretical and methodological perspectives of the study, but also to achieve the particular communicative purpose of the exercise, be it translating information sheets into a local language, or interview transcripts into English for data analysis (2003). They identify several different translation approaches, each of which has its advantages and disadvantages and may be appropriate for different methodologies (Box 14).

Box 14. Approaches to translation

- *Literal translation:* a fully literal translation is impossible, and is inappropriate for most translation purposes as it does not acknowledge the contextual meaning, and the word order of the source language is forced upon target language.
- *Verbatim translation:* used to convey the real meaning of the source language, and preserving its word order when translated into the target language. However, the imposed word order may disrupt the natural grammar and structure of the target language making interpretation difficult.
- *Proper translation:* used to convey the real meaning of the source language within the natural grammar of the target language, with particular emphasis on conveying meaning.
- *Meaning translation:* used to extract meaningful elements of the source material, and the way the elements combine to form the meaning of the text as a whole. This is repackaged using words, grammar, idioms peculiar to the target language, and requires awareness of the cultural assumptions and expectations of the target language readers.

Adapted from Downing and Bogoslaw (2003).

Recommended methods

- Consider the required qualifications of the translator in reflection of the purpose and methodological approach for translation. Key qualifications may include thorough knowledge of the source and target languages, familiarity with both cultures, up-to-date knowledge of styles, dialects and linguistic changes; and accuracy and clarity in writing (Downing and Bogoslaw 2003, Regmi, Naidoo et al. 2010).
- Select a translation approach consistent with the theoretical and methodological perspectives of the study, ensuring that levels of detail are defined and all members of the research team engaged in translation are aware of the rationale behind the approach.
- Consider carefully the layout of a translation to aid comprehension and faithful interpretation of the text. For example, consider presenting the source language alongside the translation, in meaningful blocks of content to facilitate checking and interpretation.
- Consider back-translation, which is recommended by some as a method to assess fidelity of translation and to highlight any linguistic mistakes or misinterpretations (Downing and Bogoslaw 2003, Regmi, Naidoo et al. 2010). However, criticisms of back-translation include being time-consuming and expensive, and also failing to identify some erroneous literal translations (Downing and Bogoslaw 2003, McLellan-Lemal 2008).
- An appropriate compromise to back-translation may be to consider at least having different researchers checking a sample of tapes, transcripts and translations to assess fidelity and appropriate communication of meaning from the source to the translation (Regmi, Naidoo et al. 2010).
- Define criteria for evaluating the quality of translations, in reflection of theoretical and methodological perspectives. These may include: comprehensibility (especially relating to culture-specific concepts), appropriateness (in content and approach) and accuracy (faithful to the source text and key facts) (Downing and Bogoslaw 2003).
- Be aware that translation approaches may alter during the research process as knowledge is produced and assumptions are challenged or reinforced (Temple and Young 2004).

- In the data analysis and conclusion-drawing phase, evaluate and reflect upon the role of the translator in producing data and their influence on the findings and research process as a whole.

A Standard Operating Procedures template for Translation (SOP 12) is also available in the Supporting Materials document, **"ACTc Qualitative Research Protocol and Tools"**. Criteria to evaluate the quality of how researchers manage translators and the associated implications for the production of trustworthy results in cross-language studies are also available (Squires 2009).

2.5 Analytic Approach- theory that governs the methods you will choose

The particular ***analytic approach*** that a study will take needs to be mapped in advance of data collection since the theoretical framing of data collection inevitably focuses or helps refine the research question. Here, we briefly introduce the reader to the broad types of analytic approach that a qualitative research project can take.

Unlike quantitative analysis, there are no clearly agreed rules or procedures that govern the ways in which qualitative data can be collected and analysed. Nonetheless, there are traditions and debates about what constitutes effective data collection and analysis and it important to note the elements of social life that your approach is likely to obscure and those that it is likely to reveal. Approaches to analysis vary by social science discipline, by the epistemological assumptions underlying the type of enquiry (see Section 1.2), and by the focus and aims of the research. Some common analytic approaches that qualitative researchers may take are listed in Box 15; see also the University of Huddersfield's Online Qualitative Data Analysis website for discussion and further resources on a range of different approaches (http://onlineqda.hud.ac.uk/methodologies.php).

Box 15. Common qualitative analytic approaches

Traditions & approaches within qualitative analysis:

Ethnographic accounts	Discourse analysis
Life histories	Analytic induction
Narrative analysis	Grounded theory
Content analysis	Policy & evaluation analysis
Conversation analysis	

Adapted from (Spencer, Ritchie et al. 2003)

Analytic approaches can be distinguished between those that are content based and those that are thematically based. In content analysis, the frequency or saliency of key words, phrases and their synonyms in a data source (e.g., an interview transcript) is used to identify important, repeated ideas. Analysis focuses on the way ideas are presented, the frequency of their occurrence and link these to 'outside variables' such as gender or the role of the research participant (Spencer, Ritchie et al. 2003). When applied in its minimal form (word counts), the relative simplicity of this approach makes it very reliable, but, since context is usually not considered, the data it generates tends not to be very rich and potentially less valid (Namey, Guest et al. 2008). In contrast, thematic analysis focuses on the interpretation of data by the analyst, the description of explicit and implicit ideas in the data and the labelling of these ideas as themes across data sets. Since interpretations can vary across analysts, reliability can be of concern in thematic analysis, but when analysis is approached systematically and reflexively (see CHAPTER 5), the context-rich coded data that is produced may be considered to have high validity.

Among the approaches which follow a broadly 'thematic' orientation, these may be classified according to their primary focus on the use of language (e.g., conversation analysis, discourse analysis, symbolic interactionism, ethnomethodology), on developing a descriptive or interpretive

understanding of the culture under study (e.g., life histories, ethnography, the hybrid 'thematic content analysis' approach, see below) or on theory-building (e.g., grounded theory) ((Tesch 1990) in (Spencer, Ritchie et al. 2003)), although most authors would also argue that there is no such thing as purely a-theoretical analysis.

The ACT Consortium examples of qualitative data analysis discussed in CHAPTER 5 are mainly derived from data-driven thematic analyses, undertaken using Thematic Content Analysis and/or Grounded Theory approaches which are briefly introduced here.

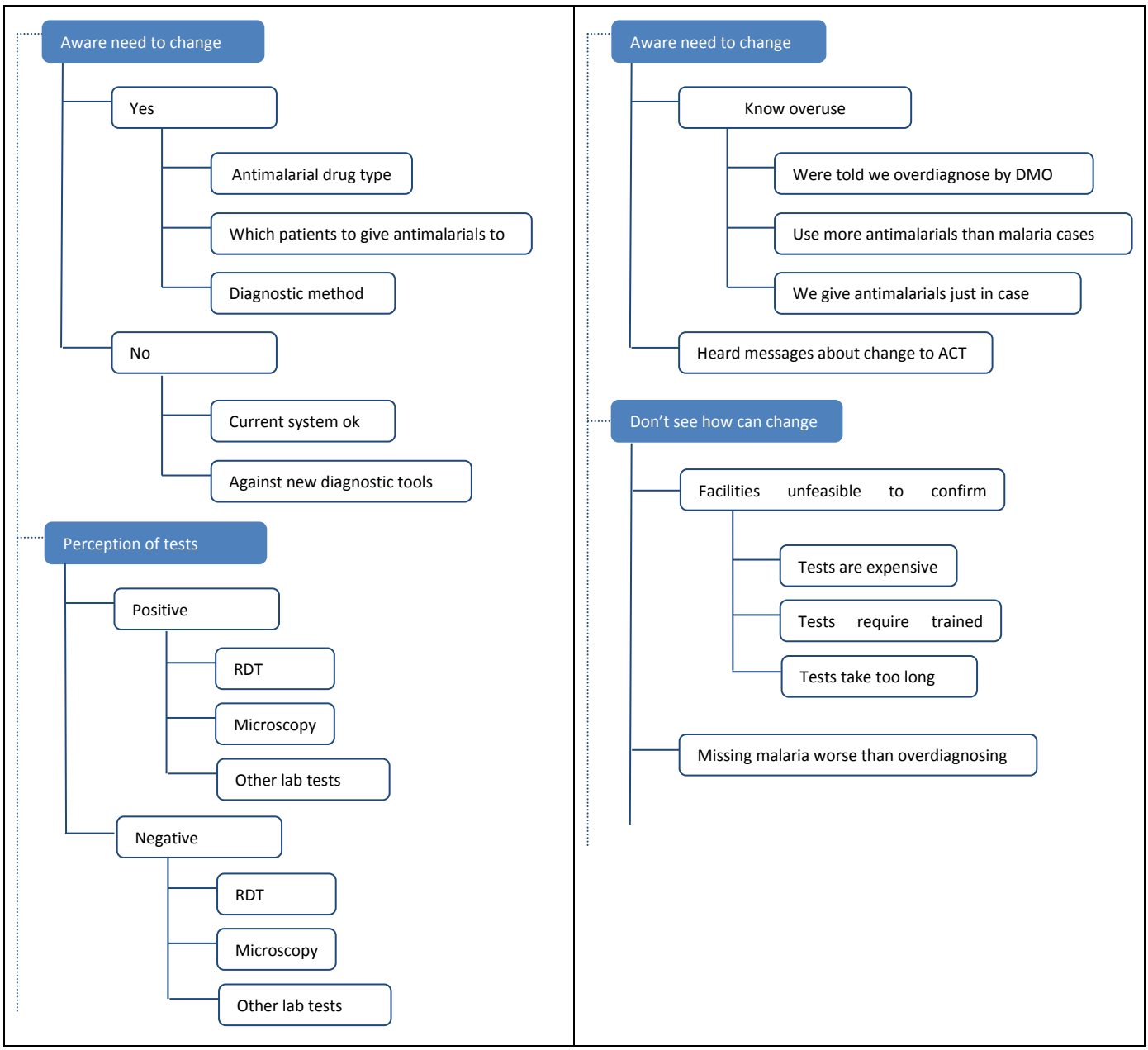
2.5.1 Thematic content analysis

Thematic content analysis is common in qualitative research in public health and aims to categorise respondents' accounts so that they can be summarised. It is usually conducted on two levels: the first is ***coding*** participant ideas into categories and the second is interpreting codes through comparative methods.

Coding and categorising. Information contained in a transcript or other research product is summarised or 'coded' following a pre-determined coding scheme (e.g., derived through discussions with fieldworkers and research coordinators) or a flexible scheme developed from the data itself (Box 16). Using flexible coding, a statement such as 'we routinely give antimalarials because with a fever we have to rule out malaria, but with so many patients the lab couldn't test them all so we just give antimalarials to cover it' might be labelled 'know overuse antimalarials', with further codes labelled 'lab constraints' and 'importance of ruling out malaria' situated hierarchically as child codes under this parent code.

For some research questions, coding at this level may be sufficient if the objective is to list participant issues around a particular topic, for example 'where do community members seek treatment for fever and what practical constraints do they have to accessing care at health facilities?' Coding and categorising the data may be sufficient to describe treatment seeking patterns and practical barriers to access.

Box 16. Comparison of pre-defined (left) vs. data-driven (right) hierarchical coding schemes explaining overuse of RDTs



Comparative interpretation. The coding of content and themes can be taken further to examine relationships between themes that have emerged and the context of particular codes. This requires the analyst to take a comparative approach to the data – how do different themes, or concepts, identified in the coding relate? For example, how does the perception of the high cost of new antimalarials and new tests relate to perceptions of patient demand, or do opinions vary between different groups of respondents such as male and female health workers? Taking this approach to analysis enables a more interpretive approach, and is useful in understanding the breadth of perceptions in the study group as well as potential points of contradiction that may provide insight into processes to target for behaviour change strategies. Comparisons may also be made between data collected from the same groups of participants over time, or between different groups of participants who have received different interventions. In this case, themes (usually attitudes, perceptions and reported behaviour) can be generated from data collected from each group

separately, followed by a comparison of the content of themes between groups. Alternatively, all data can be analysed together, followed by indexing of codes or concepts against the group the respondents belonged to.

2.5.2 Grounded Theory Approach

The emphasis of grounded theory is on generating theory from data: 'from the ground upwards' rather than imposing theory on the data by forcing data into a pre-defined structure. This approach builds upon the flexible coding and comparative analysis techniques described above. The objective is to go beyond describing and categorising the 'what' and 'how' of data in thematic content analysis, to questioning 'why', concentrating on phenomena in the data as examples of more generalisable concepts. Coding therefore moves from using descriptive to conceptual labelling, identifying what general phenomenon is represented in a section of data (or collection of descriptive codes) being analysed. Theory is built from these concepts by moving between emerging theory and the data, with emphasis on the inclusion of deviant cases in the development of theory, creating a rich, comprehensive account that is grounded in the empirical data.

The grounded theory approach is very useful for formative research to enable a comprehensive understanding of why target groups behave in a certain way which can help to identify mechanisms for change that will be acceptable and effective. This approach is inevitably more intensive and time-consuming but can give a better understanding of how participants see the world in a conceptual rather than simply practical sense.

CHAPTER 3 Setting up the Research Project

Chapter Outline

3.1 Choosing a Good Team

Building a good team for qualitative research can be undertaken in any number of ways, according to the specific circumstances, experiences of study leaders, context and project. The goal of building a good team should be two-fold:

- to ensure the right people are involved in each stage of the project, and
- to foster relationships among them to achieve a team which is resilient and responsive to changes in project circumstances, activities and staff (Mack, Bunce et al. 2008).

In ACT Consortium projects, we took a variety of approaches to building teams for qualitative research. In some countries, fieldworkers with broad public health backgrounds previously recruited to work on other parts of the clinical trial were trained in qualitative methods. In others, fieldworkers were purposely recruited to form a dedicated qualitative research team with experience in mainly social disciplines (such as social workers). Teams were managed by project-specific clinical trial managers, some received technical support from social scientists at universities in the countries where the projects were conducted, all received technical support on qualitative methods at varying levels of closeness or intensity by social scientists working across ACT Consortium projects based regionally or in the United Kingdom.

While some turn-over of field staff in research projects is inevitable, we aimed to achieve investigator continuity and familiarity with all research stages as well as the cultural context in question by recruiting sufficiently skilled local qualitative research team leaders and by ensuring that ACT Consortium social scientists who would be involved in writing up the research were involved from the beginning. Local team leaders are highly influential in the research process and team dynamics; their personal motivation and expertise can have a substantial impact on the ultimate quality of data produced (Mack, Bunce et al. 2008). In ACT Consortium projects with particularly high-functioning qualitative research teams, team leaders had excellent inter-personal and managerial skills to encourage the types of ongoing reflexive qualitative research best-practices we discuss in CHAPTER 4 (e.g., systematic, if informal, 'de-briefing' discussions in car rides after a late focus group discussion).

Social scientists working across ACT Consortium projects were normally involved in projects early on to support research design and to lead intensive training on qualitative methods. Local team leaders

then provided an essential supervisory link and were responsible for training any newly recruited staff. These leaders were also occasionally called on to provide qualitative training and analysis support in other project sites where such expertise had not yet been developed. The act of calling on qualitative research team leaders to work across projects appeared to re-affirm the qualitative research team 'identity' as an integral part of the wider trial research project, further encouraging qualitative team-building.

Having ACT Consortium social scientists involved after training was viewed as essential to provide ongoing (mainly remote) input to the data collection and analysis process through transcript-reading and critiques of coding. In some projects, these social scientists were called on to take primary responsibility for in-depth thematic analysis incorporating theory, to help local teams move writing beyond the descriptive –a key measure of quality for many of our clinical trial managers. Learn more at http://www.actconsortium.org/pages/who-we-are.html.

3.2 Training Team Members

Before fieldwork begins, field staff should be trained in:

- the research objectives
- the study protocol (including the content and purpose of topic guides)
- qualitative research data elicitation techniques
- recording data & data management
- the ethical code of conduct

It is recommended that all members of the team, however experienced individually, undergo refresher training prior to the collection of qualitative data. Training is likely to be most effective when trainees' own experiences are shared, and role-play and small group activities around each aspect of the fieldwork are conducted, including approaching potential respondents, components of giving an introduction and gaining consent, reasons and methods for confidentiality and anonymity, how to use topic guides, how to take notes and how to deal with difficult situations or respondents. Key aspects for training of field staff are similar for interviews and focus group discussions, although the content may differ.

For training workshops in ACT Consortium projects, we undertook intensive training for 5-10 days, based on a manual for field research training developed by the KEMRI-Wellcome Research Programme and WHO/TDR in Kilifi, Kenya (Haaland, Molyneux et al. 2006). This manual follows participatory methods and particularly emphasises communication skills. The slides and handouts we prepared from this manual as part of training programme are available in the Supplementary Materials folder, **"ACTc Materials - Qualitative Research Training"**.

3.3 Drafting a Protocol & Standard Operating Procedures

We developed a template for ACT Consortium project teams to draft protocols for qualitative research project (see Supplementary Materials document, **"ACTc Qualitative Research Protocol and Tools"**), including standard operating procedures (SOPs). SOPs are short guides that contain detail of procedures for each stage of preparation, data collection, data handling and analysis and are a typical element of team-based public health intervention planning. Along with detailed protocols,

SOPs are intended to support fieldworkers in their data collection and to ensure procedures are standardised. Although it's useful to have an idea of what SOPs are needed, in our experience, it was useful for the project teams to write their own SOPs in order to think through the research process and to identify misunderstandings and methodological gaps in knowledge. Like topic guides (Sections 2.1.3 and 2.2.3), data collection (Sections 1.5.3 and 2.3.3) and data management and analysis tools, SOPs should also be piloted and updated.

3.4 Ethical Issues in Qualitative Research

Before fieldwork begins, all field staff should be trained in the basic ethical principles and practices of qualitative research (Box 17), and particularly, how to administer project consent procedures.

One of the most critical principals of research ethics is maintaining confidentiality of research participants. Participants of research projects share valuable and sometimes sensitive information with the researcher, and they trust that the researcher will ensure that their identity is protected. It is imperative that no one but the researchers coordinating and conducting research activities know the names of participants. Furthermore, people other than the researchers should not have access to responses from individual participants, whether accidental or intentional. Finally, no one but the necessary researchers should have the ability to match the names of individuals to their responses.

In order to protect participant confidentiality it is helpful to develop a code sheet, listing the participants' names with a code assigned by the researcher next to each name which uniquely identifies each respondent. This code, not the respondent's name, can then be written on any data collection forms used, for example, forms for taking interview notes and writing contact summaries and codes, rather than patient names, should be used in research team discussions if these are held in public spaces. Code sheets should be kept in a secure location so that people other than the researchers do not have access to it.

In applications to research ethical review bodies, qualitative research teams should ensure that they outline how they plan to interact with research participants, how they will keep confidential data secure and what risks and benefits to participants they foresee, among other factors. Applications are required to include information sheets, consent forms and draft research tools (such as topic guides) with the caveat that all aspects of a qualitative research question (including what will be done and how) cannot be decided *a priori*, so research tools and SOPs would be expected to be refined during fieldwork. This is particularly the case for unstructured observational research during which unanticipated events such as informal conversations need to be incorporated into holistic analysis, given that "the hidden meanings of words [spoken in formal interviews] sometimes only emerge when we observe speakers' actions, in context" (Sobo 2009). Further resources on ethics in qualitative research can be found on the Association of Social Anthropologists of the UK and the Commonwealth website (http://www.theasa.org/ethics/Ethical_guidelines.pdf) and the American Anthropological Association website (http://www.aaanet.org/cmtes/ethics/Ethics-Resources.cfm). A summary of the principles outlined in the former is shown in Box 17. Example participant information sheets, consent forms and SOPs for administering consent can be found in the Supplementary Materials document, **"ACTc Qualitative Research Protocol and Tools"**.

Box 17. Common ethical principles & practices of social research

Relations with and responsibilities towards research participants

The close and often lengthy association of social researchers, especially anthropologists, with the people among whom they carry out research entails personal and moral relationships, trust and reciprocity between the researcher and research participants; it also entails a recognition of power differentials between them. Principles and practices should entail the following:

1. **Protecting research participants and honouring trust**. Social researchers should endeavour to protect the physical, social and psychological well-being of those whom the study and to respect their rights, interests, sensitivities and privacy.
2. **Anticipating harms**. Social researchers should be sensitive to the possible consequences of their work and should endeavour to guard against predictably harmful effects. Consent from participants does not absolve researchers from their obligation to protect research participants as far as possible against the potentially harmful effects of research.
3. **Avoiding undue intrusion**. Social researchers should be aware of the intrusive potential of some of their enquiries and methods. The advancement of knowledge and pursuit of information are not in themselves sufficient justifications for overriding the values and ignoring the interests of those studied.
4. **Negotiating informed consent**. Following the precedent set by the Nuremberg Trials and the constitutional laws of many countries, inquiries involving human subjects should be based on the freely given informed consent of participants. The principle of informed consent expresses the belief in the need for truthful and respectful exchanges between social researchers and the people whom they study. Negotiating consent entails communicating information such as the purpose(s) of the study, anticipated consequences of the research; the identify of funders and sponsors; the anticipated uses of the data; possible benefits of the study and possible harm or discomfort; issues relating to data storage and security; the degree of anonymity and confidentiality which may be afforded to participants. Consent is a process rather than a one-off event and should be returned to periodically by the researcher. However, for the purposes of ethics boards formal written consent is often preferred.
5. **Rights to confidentiality and anonymity**. Informants and other research participants have the right to remain anonymous and to privacy and confidentiality. Care should be taken not to infringe uninvited upon the 'private space' (as locally defined) of an individual or group; potential threats to confidentiality and anonymity should be anticipated as far as possible, and researchers should take appropriate measures to store all records securely during and after fieldwork, should remove identifiers and use pseudonyms and other technical solutions to protect privacy in field records and in oral and written forms of data dissemination; however, researchers should make clear to participants that it may not be possible to totally conceal identities and anonymity may be unintentionally compromised.
6. **Fair return for assistance.** There should be no economic exploitation of individual informants, translators and research participants; fair return should be made for their help and services.
7. **Participants' intellectual property rights.** It should be recognised that research participants have contractual and/or legal interests and rights in data, recordings and publications. Clarification must be given to participants regarding the degree to which they will be consulted prior to publication.
8. **Participants' involvement in research.** As far as possible social researchers should try and involve the people being studied in the planning and execution of research projects, and they should recognise that their obligations to the participants or the host community may not end with the completion of their fieldwork or research project.

These guidelines are adapted from the Association of Social Anthropologists 'Ethical Guidelines for Good Research Practice' which also includes sections on relations with and responsibilities towards sponsors, funders and employers as well as towards colleagues and the discipline. (www.theasa.org)

CHAPTER 4 Running a Good Quality Project

Chapter Outline

In a number of areas, the principles for running a qualitative research project well are similar to those for running clinical or other types of research, and as such, do not require much expansion here. From a project management perspective, the techniques for recruiting and managing research staff, overseeing budgets, monitoring timescales and managing processes around materials, resources and logistics, are all applicable for qualitative research as for other types of research projects. Similarly, the institutional and governance requirements around adhering to ethical standards, appropriate reporting of project progress and maintaining data management standards are common across qualitative and other projects. However, from a scientific perspective, values about what constitutes good 'quality' research and how to assure it throughout a study differ for qualitative research. It is this process of assuring quality that will be described in the sections below, including a suggested approach to assessing and strengthening quality while research activities are underway.

4.1 Ongoing Quality Assurance

4.1.1 Defining quality assurance for qualitative research

The concept of quality assurance of clinical trials is well established, as are the mechanisms and processes for enacting it, informed largely by the Good Clinical Practice (GCP) guidelines (European Medicines Agency 2002). In contrast, there is an absence of established, universally-recognised guidance for assuring quality of qualitative research, even when this is alongside clinical trials work (Reynolds, Kizito et al. 2011). This in part reflects ongoing debate among qualitative researchers from different epistemological positions and paradigms over what constitutes 'quality' in qualitative research, and how to enact or demonstrate it (Devers 1999). This is further compounded by the vast range of different methods and methodological approaches that can be employed in qualitative research, plus the challenges of responding to expectations for quality from other research paradigms, for example when qualitative research is part of a mixed methods approach. The positivist epistemology underpinning the GCP guidelines and clinical research, including the rigidity of guidance based on checklists of criteria for quality, are inappropriate for use with qualitative research with its largely interpretive epistemology and often more flexible, subjective methods.

As such, it is important to develop a definition of, and strategy for, 'quality assurance' that is both appropriate and feasible for supporting and improving the quality of qualitative research.

4.1.2 Quality assurance approach

The recommended approach described here reflects a specific conceptualisation of quality assurance in relation to the principles and methods of qualitative research. First, it seeks to address two key aims:

1. To help ensure that research is of the highest possible scientific credibility; and
2. To enable investigators to respond to external demands – from funders, peer reviewers, policy makers – for evidence of quality and quality assurance.

Second, the approach comprises two perspectives toward quality within qualitative research:

1. *A process-oriented perspective*: a series of mechanisms adopted throughout the research process to assure quality, guided by a set of key principles of 'good practice' for research;
2. *An output-oriented perspective*: adopting techniques that can demonstrate to an external audience that the quality of the research has been assured.

These two perspectives reflect the conclusions of a review which explored the discourse around quality and quality assurance in qualitative research literature (Reynolds, Kizito et al. 2011). This review recommended that quality assurance strategies be developed to facilitate the qualitative researcher to enact principles of quality at each stage of the research process, but which also offers opportunities for researchers to demonstrate to external audiences the credibility of their research.

4.1.3 Defining principles of good practice

It is important at the outset of designing a quality assurance strategy to make explicit the values or principles of quality that pertain to the particular epistemological, theoretical and methodological perspectives of the qualitative research project to be undertaken. An example set of principles of quality, or 'good practice', coupled with working definitions for each, are presented in Box 18. This agreed set of principles can then orient research and act as a framework against which the ongoing quality of the research can be assessed and assured.

Box 18. Principles and definitions of good qualitative practice

- **Reflexivity** - the researcher reflects upon their position, assumptions and biases and considers the influence of these on the research process, outcomes and findings.
- **Transparency** - honesty in relation to the representation of the data with open presentation of decision-making and interpretation throughout the research process.
- **Comprehensiveness** - pursuing ideas to the fullest extent possible, to capture the richest data available within the confines of the study and to explore a wide range of interpretations of the data.
- **Responsibility** - understanding the role of each research team member in producing good quality data, and recognizing each person's responsibility to ensure this happens.
- **Ethical practice** - conducting research in a manner that does not bring harm, discomfort or distress to participants and which follows the ethical codes of the institution(s) that have approved the study.
- **Systematic approach** - a methodical and logical process for outlining and achieving each stage of the research process, in order to answer the research question in the most appropriate way.

4.1.4 Plan of activities to assure quality

In order to assure quality throughout the research process, mechanisms and activities which reflect the chosen principles of quality can be planned to facilitate quality assurance at each stage. This plan can be flexible in its approach, and should be revisited periodically to identify whether additional activities to improve quality are needed, or if revisions are required. For example, it may not be appropriate to evaluate every principle of good practice at each research stage, but each should at least be considered as the plan is being developed. Additionally, more than one activity can be used to assess one particular principle. Examples of activities that can be implemented to assure quality in relation to different principles of good practice are available in Table 4.

Table 4. Example quality assurance activities for each research stage

Research Stage	Principle of Quality	Activity / mechanism
Research design	*Comprehensiveness*	Explore wide range of theoretical and methodological perspectives relevant to research question, to situate the framing of this study.
	Reflexivity	Explicitly acknowledge epistemological position and theoretical framework and consider inherent assumptions from these.
	Etc . . .	Etc . . .
Training	*Responsibility*	Train each member of the field team on aims and theoretical orientation of study, as well as their own position in relation to production of results and quality of the research.
	Etc . . .	Etc . . .
Preparation & piloting	*Transparency*	Clear documentation detailing how study tools were piloted, how they were evaluated and how decisions were made about revisions to the tools and processes.
	Etc . . .	Etc . . .
Recruitment	*Ethical practice*	Recruit participants in accordance with ethically-approved protocol, and ethical guidelines to ensure appropriate informed consent process.
	Etc . . .	Etc . . .
Data collection	*Systematic approach*	Develop standard operating procedures before qualitative data collection begins, and pilot them, to ensure they are conducted systematically by field team.
	Transparency	Documentation of discussions around topic guide (including individual questions) and of any changes suggested and made to questions, with explanations.
	Reflexivity	Field team meet after each data collection event to discuss it and their positions in relation to the data collected.
		Regular meetings with field team and senior investigators during data collection to reflect on interpretations of emerging data and how this is shaping the data collection process.
	Etc . . .	Etc . . .
Data Management	*Ethical practice*	Ensure confidentiality of data is maintained through appropriate coding and storage of data.
	Etc . . .	Etc . . .
Transcription and translation	*Systematic approach*	Develop a clear set of guidelines for transcription and translation, to ensure that accuracy of transcription is checked against the original recording, and back-translations are conducted to ensure appropriate interpretation of meaning across the sample.
	Etc . . .	Etc . . .
Data analysis	*Responsibility*	Create opportunities for each member of the field team to contribute interpretations of the data as collection is ongoing, to ensure their continuing motivation towards and understanding of the study aims.
	Etc . . .	Etc . . .

Writing up and dissemination	*Comprehensiveness*	Devise a strategy for writing up findings that ensures the range of key themes and constructs are presented faithfully, and contradictions or variations across the sample are reported and appropriately considered in the writing up.
	Etc . . .	Etc . . .

4.1.5 Responsibility for quality assurance

Reflecting the process-oriented perspective partly underpinning this proposed quality assurance strategy, it is recommended that each member of the research team is trained to understand the role they play in the production of data, and thus the responsibility they have towards enacting the principles of good research practice in their work. Ensuring research team members understand the aims of the study and feel motivated and committed towards them will help to reinforce their sense of responsibility towards assuring quality.

In addition, it could be beneficial to identify particular members of the research team to take official responsibility for ensuring the activities identified to help assure quality (for example, as presented in Table 4), are undertaken and communicated accordingly, to inform any resulting decision-making. It could also be beneficial to assign target dates for each of these activities to be undertaken by, as well as dates for periodic reviews by field team members and senior investigators of the quality assurance strategy to make revisions to timings and activities where necessary. Responsibility for ensuring that the quality assurance strategy as a whole is implemented and periodically reviewed can be allocated to a senior member of the research team.

4.2 Monitoring Qualitative Research

As part of the quality assurance strategy, it may be advisable to plan an external assessment of the quality of research activities as they are being undertaken to inform whether, and how, the research can be strengthened. This fits with the broader aims of quality assurance, as it can facilitate the improvement of quality at several stages of the research process and can also be cited as a systematic measure undertaken by the researchers to assure quality.

Our suggested approach for quality assessment and strengthening (QAS) is informed by the practice of monitoring in clinical trials research which is commonly defined as the act of overseeing the process and progress of a trial through a series of checks to ensure it is being conducted, recorded and reported in line with the protocol, SOPs and relevant regulatory requirements (Williams 2006). Audits are also commonly conducted as part of monitoring processes in clinical research, and the QAS approach we undertook draws on this, recommending that research teams engage with social scientists external to the study to conduct the assessment of quality.

A sample protocol for conducting QAS for qualitative research, with explanations of each step and sample tools for collecting and reporting data on quality assessment is available in the Supplementary Materials document, **"ACTc Protocol - Quality Assurance Monitoring for Qualitative Research"**. This protocol gives an overview of our QAS approach reflecting the interpretive epistemological perspective underpinning the qualitative research undertaken in ACT Consortium projects as well as the principles of quality discussed above. It is intended that this QAS design offers an opportunity for research teams to reflect on their own practice to reinforce a broader strategy of

quality assurance for a project apart from formal audits. The protocol includes further discussion on how it can be adapted and tailored to suit to individual qualitative research projects.

CHAPTER 5 Interpreting Qualitative Data

Chapter Outline

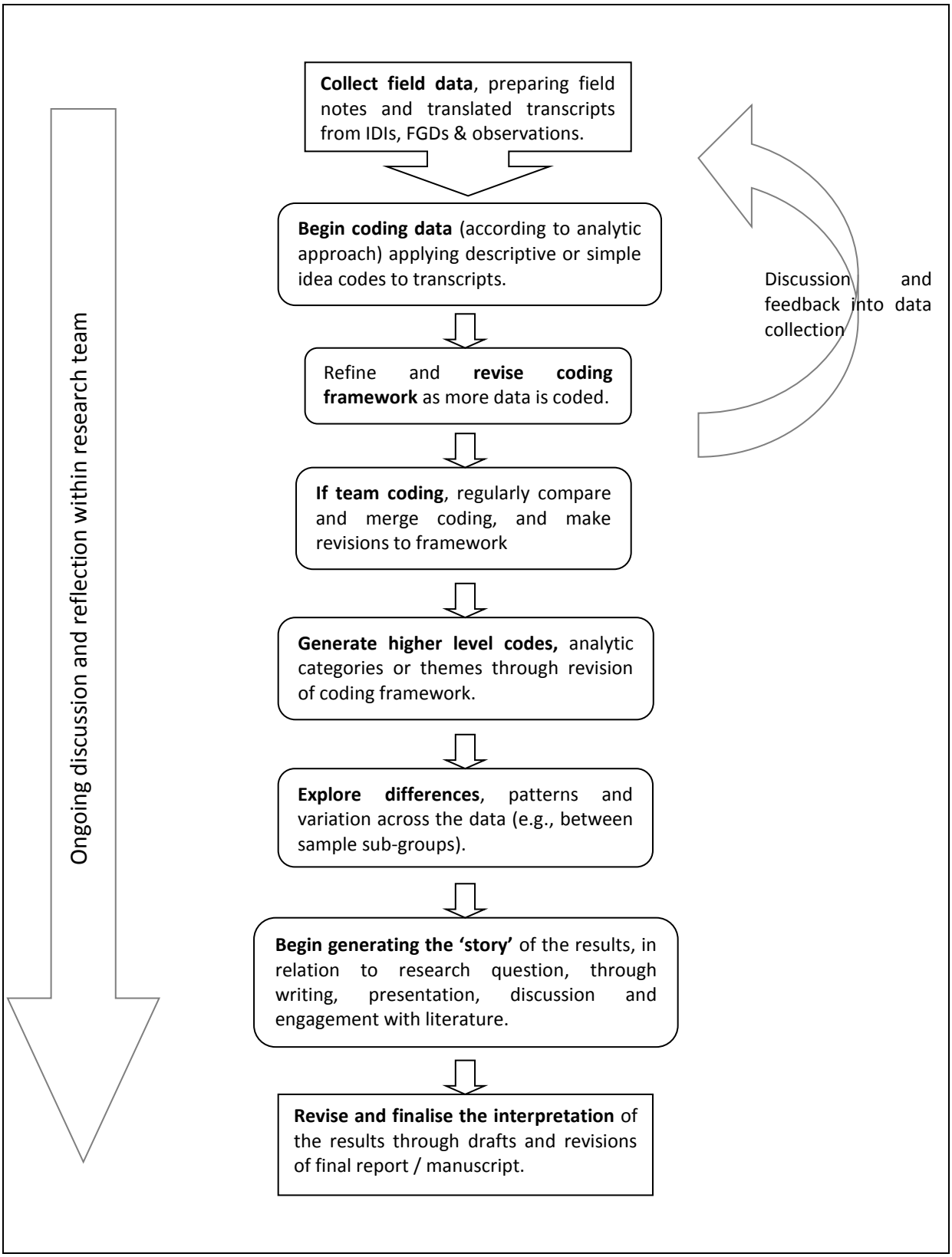
5.1 Coding & Analysis of Qualitative Data

5.1.1 An overview of the analytic process

After field work has commenced and the management of raw data has been completed (for example, transcription and translation where necessary), qualitative data analysis will begin. Depending on the ***analytic approach*** chosen for the project (see section 2.5), data analysis may take place after fieldwork has been completed, or alongside it, iteratively feeding into the ongoing field work activities to explore new ideas or themes identified in the analysis. For a useful, detailed guide to the analytic process, see (Auerbach and Silverstein 2003).

Overall, the process of analysing qualitative data is not one with compulsory, fixed stages or a definite endpoint. Rather, it should involve a range of activities with ongoing reflection to explore patterns, themes and/or theoretical constructs in the data, identified through a systematic, transparent and comprehensive process. A diagram outlining the key phases that qualitative data analysis often involves is presented below (Figure 3).

Figure 3. Phases of qualitative data analysis



5.1.2 Using computer software

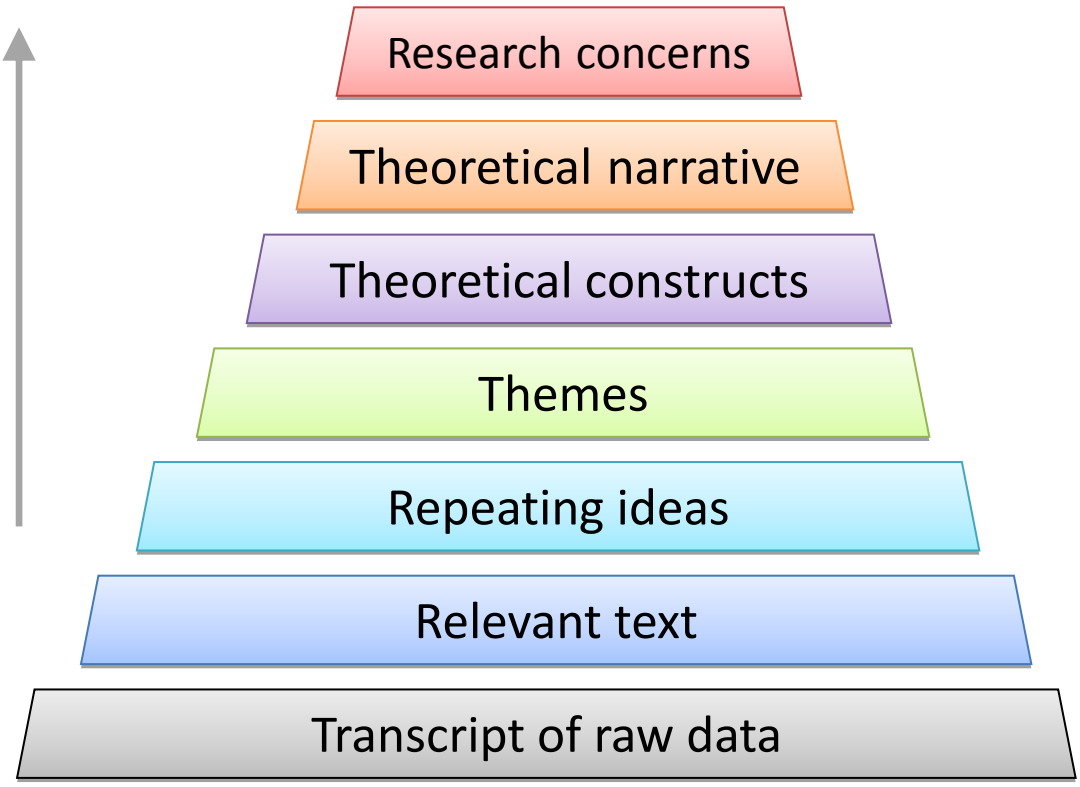
Unlike the use of statistical software packages for quantitative data, qualitative data analysis programs do not do the analysis for you –no qualitative data analysis software provides researchers with a methodological or analytic framework. This type of software simply offers ways to manage, explore and assign codes to your data. The interpretation of these codes and the thinking involved in generating a theoretical 'narrative' from the coded data is still the responsibility of the researcher(s) (Auerbach and Silverstein 2003). There is an assumption that the use of software makes the analysis process more robust and of better quality, but this is not necessarily true. Software packages for qualitative data analysis are based on the same principles you would use to analyse data 'by hand' – building up a narrative of interpretation across the dataset based on identifying units of meaning in the individual sources of data. The advantages of using software for this process include the ability to store and manage large datasets with multiple sources of data, and the ability to easily share coding frameworks with others, meaning revisions can be identified, coding patterns can be compared and different files of coding can be merged. However, getting to grips with using a program may not be worth the time it would take if the qualitative dataset is very small (for example only a handful of interviews), and for some analytic approaches it may not be appropriate, for example, where interpretation of the field work event as a *whole* is of primary importance.

Various different programs are available, including some free, downloadable applications; the CAQDAS Networking Project website (caqdas.soc.surrey.ac.uk) provides independent guidance to help researchers choose between qualitative data analysis software and offers up-to-date reviews of the capabilities and limitations of several of the most commonly used. Perhaps one of the most commonly used and recognised is NVivo by QSR International (subscription-based). Some of the specific recommendations in this guidance reflect the experiences of ACT Consortium researchers in using NVivo for analysis and may not be applicable for other programs. For a more detailed guide on using NVivo for qualitative analysis see (Bazeley 2007).

5.1.3 The coding procedure

Coding is the practice of categorising data (e.g., sections of text from transcripts) by meanings or ideas, as they are interpreted by the research team. The data are read line by line and labels (codes) are allocated to sections of text to illustrate the underlying meaning or concepts (Strauss and Corbin 1998). Groups of codes are then built up in an iterative process. The process of assigning codes to data, arranging and revising codes to generate groups or categories and investigating patterns across the data will vary by the different ***analytic approaches*** selected, as will the terminology for describing each stage. However, the principles of moving from looking at small units of data, interpreting their meaning, and then building up to identify meaningful categories across the whole dataset is fairly similar across most analytic approaches. This is depicted in Figure 4 and expanded on in the sub-sections below.

Figure 4 Depiction of the coding procedure used in qualitative data analysis. Adapted from (Auerbach and Silverstein 2003).



1. Familiarisation with raw data

The starting point for coding and analysis is initial familiarisation with the data. This should be done by reading through all the raw transcripts at least once (and/or any other sources of data, e.g., contact summary forms, field notes), to begin understanding each in its entirety. Immediate ideas or thoughts arising from this familiarisation can be noted down in a memo or similar document (ideally dated and with reference to the transcript(s) that prompted the thoughts), and can feed into the analysis at a later stage, for example when exploring themes or theoretical constructs.

2. Considering what is relevant

Interviews, focus group discussions, observations and other qualitative methods can produce huge amounts of data, particularly when accompanied by contact summaries or reflective field notes. Again, depending on the analytic approach chosen, it will likely be important to keep an open perspective when starting coding of the data. In most cases, this will involve seeking to identify ideas, themes and constructs from the data themselves (according to a *data-driven* approach, see Section 2.5), rather than applying pre-defined codes or categories to them. However, this does not mean that all of the data and the ideas they reflect will be relevant for the research question in hand, and the time-consuming nature of qualitative analysis will mean that a more strategic approach to coding may be advisable.

One way to help researchers determine relevancy is to refer back to the original purpose of the research. At the outset of analysis, it is recommended that each researcher involved in coding the data remind themselves of the objectives of the research, and outline the theoretical standpoints and analytic approaches adopted for the study.

3. Applying codes to data – first level coding

A code (called a 'node' in NVivo) is a label representing an idea conveyed within a unit of data, usually a segment of text from a transcript. To begin coding from a 'bottom-up' approach (i.e., without a pre-defined coding framework) a few transcripts can be selected to develop an initial coding framework, to be applied to other transcripts. As each transcript is read line by line, look for ideas, or units of meaning, in each small segment of data. Highlight the segment of text, and assign it a code with a label that reflects or summarises the idea. An example of coded text from a focus group discussion from a study on people's experiences of participating in a clinical study in Tanzania (www.actconsortium.org/InterACTperceptions) is presented below (Box 19, displaying both the original Kiswahili and the translated English text). There are likely to be multiple ideas within a section of data, for example, in a participant's response to a question. These should all be assigned a separate code; the same section may thus be assigned several, overlapping codes.

Box 19. Example of coded text

Code: 'I used to squabble with the researchers about taking my blood'

(FGD-A1-Females)

. . .

Facilitator: na unafikiri pale mwanzo ulikuwa na wasiwasi kama vile damu ilivyokuwa inatolewa kadri unavyoshiriki?

Facilitator: Do you think in the beginning you were so anxious like the way you were being drawn the blood when you were participating?

Respondent 03: Wasiwasi lazima ulikuwepo, kama mimi nilikuwa nagombana nao sana kwa sababu walikuwa wakichukua damu nkiona nawaambia bado? 'mbona mnachukua damu nyingi' damu yangu itaisha hadi nikashawishika nisirudi tena lakini wakanihudumia vizuri mpaka nikazoea.

Respondent 03: Worries had to be there, like me I used to squabble with them the way they were taking the blood, when I met them I asked not again? 'Why are you taking a lot of blood, my blood will get finished', but they persuaded me to come back again and gave me a good service until I got used to it.

. . .

Tips on first-level coding:

- When selecting text to code, select (and code) the text surrounding the idea of interest, including (where appropriate) the question or dialogue prompting the response, and both the original and English language versions of the relevant text. This means that when looking at the code later, separate from the full transcript, the context of the idea – how it emerged in the interview / discussion – will be apparent to the researcher. Including the original language helps the researcher to understand the relationship (and distance) between the labelled code and its origins as data, if the validity of translations needs to be re-examined at a later point.
- Always be as descriptive as possible when naming ideas as codes, so they describe and convey the idea clearly. This is particularly useful for when coding in a group, where other researchers need to be able to interpret your coding. If the code is slightly ambiguous, or may be misunderstood, add a 'description' in the code's properties (if using software) or in a master codebook (if using one). Some authors recommend writing full definitions, inclusion and

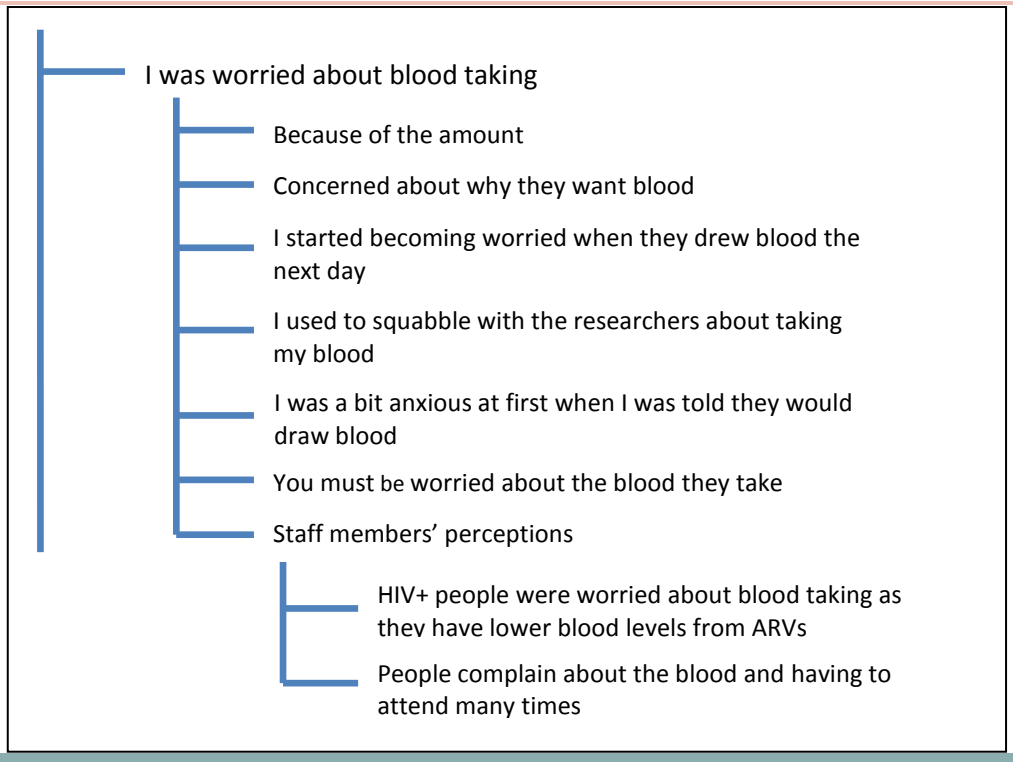
exclusion criteria for codes, along with examples of a typical participant statement coded to the idea, to make coding as systematic as possible (MacQueen, McLellan-Lemal et al. 2008).

- For first level coding, the more basic the unit of meaning and the fuller the description of the idea behind each segment of text, the better. This enables the fullest base of ideas from which to begin building up themes and more complex constructs. It also helps make transparent the process of interpreting the data, which is valuable for other coders in the team and for demonstrating the quality of the research process.
- *In vivo* codes take words or phrases verbatim from transcripts to capture a concept described by the participant. They can be particularly helpful for ensuring a close link between the interpretation of meaning and the raw data, and also for exploring the natural terminology and discourse across a dataset. An example of an *in vivo* code from the Tanzanian study described above, which became a central component of the analysis, is 'in the project they really care for us', originating from several different sections of data where participants stated those words directly in focus group discussions.
- Coding using gerunds (the noun form of verbs such as '*being admitted* to hospital') rather than for topics (such as 'hospital admission') is most likely to focus analysis immediately on the processes, actions, and meanings that are relevant to the social phenomena under study, which could otherwise remain invisible in the text. Coding text this way invokes analytic questions from the start, allowing a faster transition from the process of describing data to explaining it (Charmaz 2012).

4. Grouping codes – second level coding

As more and more codes are generated from the first transcript(s), there will be some repeating ideas emerging. If an idea interpreted from a section of text is the same as a code previously created, the relevant text can be allocated to the existing code, rather than creating a new one. This will build up a collection of repeating ideas. However, if the idea is similar but slightly different to existing codes, a new code can be created. Similar codes can eventually be grouped together, labelling the group by the commonality between the codes. An example of a grouped set of codes is given below (Box 20), relating to the coding example presented above.

Box 20. Example of grouped coding



As codes are progressively grouped for the initial transcript(s), an initial coding framework will begin to develop, which can then be used on subsequent transcripts. The framework at this stage should be seen as very flexible and open to additions and revisions, as more transcripts are coded. As other transcripts are coded using this framework, existing groups of codes may be combined into higher level themes or ideas, or they may be broken back down and reconfigured as a deeper interpretation of the data develops.

Grouping codes represents the beginning of the process of moving from detailed description and summary of units of text, to a more analytic interpretation of the dataset as a whole. Groups of codes themselves should be combined as the analysis progresses, into themes and finally into constructs, with the hierarchy of groups of codes reflecting an increasingly abstracted, theoretical interpretation of the data. Box 21 presents an example of a hierarchy of grouped codes, taken from the study of participation in a clinical study in Tanzania, and displays the lower level groups of descriptive codes towards the bottom right, moving upwards and left to the highest level theoretical construct at the top.

Box 21. Example hierarchy of grouped codes from low level description to higher level theoretical construct

- 01 PARTICIPATION CONSTRUCTS AN ONGOING RELATIONSHIP
    - + Between future providers and receivers of care
    - + Between participants and their health
    - + Between study and community
    - - Relationship between participants and the study
        - + Engagement between participants
        - + Maintaining the relationship
        - - Engagement with the trial
            - + Can differ according to HIV status
            - + Distance between participants and trial
            - - Enacted through trial activities
                - + Concerns are resolved
                - + Creates new experiences
                - - Trial activities can raise issues
                    - + I asked questions during the trial
                    - + I had concerns during the trial

Tips on second-level coding:

- When grouping idea codes, try to resist grouping them simply according to the question that was asked. In their responses people often tell us more than the answer to that one question, and it is important to make the most of what they say. So, it is better to group the codes by the themes that come out rather than the questions they follow.
- Try to avoid using ambiguous labels as categories, for example 'Supervision' or 'Attitudes', as it is likely you will end up grouping many different ideas and concepts under these broad codes. Groups of codes should represent a specific concept, clearly detailed in the label, for example 'Supervision is unsupportive'.

5.1.4 Coding in a team

Given the multiple possible interpretations of qualitative data when coding, and the implicit or explicit assumptions underlying the analysis which they embody (MacQueen, McLellan-Lemal et al. 2008), a systematic and transparent procedure for managing this process is required when coding is done by more than one person. The advantages of team coding include the ability to work through large datasets in less time and the multiple perspectives that different team members lend to comprehensively interpreting the meaning of data. This is not to say, however, that team coding is necessarily better than working alone, and there are some key considerations for ensuring the process is robust and of good quality. For more discussion of the dynamics of team coding, see (MacQueen, McLellan-Lemal et al. 2008).

A recommended approach to managing team coding is to engage all coders in the initial development of the coding framework, by asking each to code the same one or several transcripts (following appropriate training on the analytic approach to be used). After this first round of coding has been conducted, each person's coding can be merged into one (if using a software program) and compared. At this point, a meeting to explore and discuss differences and similarities between the different coding should be held, with each researcher reflecting on how they interpreted the transcripts and how codes were created and allocated. Disparities between interpretations of the data and/or of codes should be discussed, with agreement on how to interpret them in the future. Following this meeting, the merged coding should be revised to develop a coding framework that each researcher should use to code the next set of transcripts.

It is recommended that this process of comparing coding, discussing interpretations and agreeing revisions to the framework should occur regularly throughout the course of coding all the data, ideally after every two or three transcripts. Coders should be reminded that the framework is flexible, and they should be encouraged to create new codes and revise existing codes as they progress. Each of these revisions or additions should be discussed at the regular meetings, and incorporated into the revised framework as appropriate. Depending on the experience of the coders and the size of the dataset, it may be preferable for each coder to work on the same sub-set of transcripts (for example the first six), as the initial coding framework develops, and any considerable differences of interpretation are identified and negotiated. Following that, researchers may be able to code different transcripts, provided one person is responsible for merging the coding at regular stages, and manages the process of discussing and agreeing revisions to the coding framework. As more of the dataset is coded, the identification of new ideas and codes will likely become less frequent, as the analysis moves towards a 'saturation' of themes.

To ensure team coding is conducted well, a clear protocol (or manual) for the process of managing data, coding and revising the framework is recommended.

5.1.5 Moving from descriptive to analytic coding

Regardless of the specific research question, methodology and analytic approach undertaken, it is likely to be beneficial to move from a more descriptive interpretation of the data to a more analytic and theoretical one. This is based on the idea that descriptive analysis of qualitative data may only be able to generate findings specific to the population and context of the individual study. In contrast, a more analytic – or 'higher level' – interpretation will help link the data to existing theoretical categories, models or theories which can help situate the findings in relation to a wider context of social knowledge and thus make them more applicable outside the immediate study setting.

There is no specific method to move coding and interpretation from the descriptive to the analytic, but there are a number of techniques that facilitate this:

Continual re-grouping, revising and refining of the coding framework

As more data is coded and more descriptive codes are generated, the coding team and/or lead analyst should take time regularly to group the descriptive codes into common themes or categories. This can be done iteratively, so higher and higher level groupings are generated from collections of codes, thus developing a more analytic interpretation of the coded data. As Charmaz suggests, "By

analysing both your data and your emerging ideas about them throughout inquiry, you integrate and streamline data collection and analysis. Through studying your emerging analysis, you focus data collection on analytic questions. Gathering focused data helps you to test and sharpen your ideas. [...] Something kinesthetic occurs when we are coding; we are mentally and physically active in the process" (Charmaz 2012).

Use of memos, notes or other reflexive devices

As coding is ongoing, analysts should frequently reflect on how they are interpreting the data and generating individual codes. A memo (or note by the researcher) can be used to capture any reflections on how codes are generated and/or grouped, as part of ongoing consideration of the emerging categories or themes of interest and how they relate to the overall research question. They can also be used to capture any questions or broader ideas arising in the mind(s) of the analysts as they proceed through the data, to be returned to at a later date to 'test' or validate. Memos therefore "give you a handle on your material and a place to consider, question, and clarify what you see as happening in your data" (Charmaz 2012). Dating memos and linking them to the relevant transcript or part of the coding can help to chart the progression of the 'higher level' thinking alongside the progression of the more detailed coding. These devices are thus valuable for encouraging continual reflection on the coding process in relation to the dataset as a whole, the research question and the theoretical orientation of the study, and engaging with broader theoretical constructs. In this way, memo-writing is the intermediate step between coding and writing the first draft of a manuscript.

Creating models, maps or charts

Exploring emerging ideas or themes pictorially can help refine the thinking process from concentrating on the detail of components of individual transcripts, to considering the relationships between data, themes, and groups of codes. Matrices can also be used to summarise and sort (e.g., case study) data to spot connections and interrelationships which are difficult to see in ordinary text based format (Miles and Huberman 1994). Both can be created using functions in qualitative data analysis software, or by hand. They can be particularly useful when used as part of team discussions of coding revisions and interpretation of the data.

Conducting searches or queries on the coding

The relationships between different sources of data, sample sub-groups and any other variables of interest in connection to the coding can be explored through search or query mechanisms, either by hand or through functions in software programs such as NVivo. These searches can aid comparative interpretation of the data, not only considering ideas identified within transcripts or other individual sources of data, but also between transcripts and across the dataset as a whole. Searches may include the comparison of coding under particular domains of interest between different sub-groups, between different time points or exploring overlaps between coded groups or categories. This can generate patterns of relationships between lower level coding that can move interpretation to a broader, analytic perspective over the dataset as a whole, as well as helping to highlight and explore 'negative/deviant cases', and/or contradictory ideas and themes.

Engaging with literature

Interpreting data analysis through engagement with theoretical literature, including reflection on the original theoretical orientation of the research, is vital for situating the findings within a broader

existing knowledge base. Critical consideration of the findings in relation to established theoretical models or ideas is commonly presented in the 'Discussion' section of the write-up of qualitative research, but explicit engagement with this earlier, during the analysis stage, is important for developing a robust and comprehensive set of themes and constructs from the data.

5.2 Writing up Qualitative Data

Analysis of qualitative data does not end with coding, or even with the application of techniques described above. The construction of a results 'narrative', through which the key interpretations of the data in a study are communicated, is a process that is likely to involve multiple revisions, reconsiderations and reflections on the data and what interpretations the research team seeks to convey. At this point, it is important to remember that the coded data is simply one interpretation, or a set of interpretations of your data that may shift as you write-up your findings into different formats. As different analytic avenues are explored and you develop particular narratives for presentations at conferences for example, you may find yourself going back to the coded data and revising your interpretations. This re-working of the data is an important way of is an essential step of the analytical process.

Although writing up research into a manuscript for publication is often the endpoint, there may be a number of activities that occur beforehand which shape the final results narrative, and which thus could be considered part of the analytic process. After coding, a 'results report' can be produced to share with the wider research team, which seeks to construct a narrative that presents the themes, constructs and theories relevant to answering the research question. This results report may be reviewed and revisions made, further shaping the narrative and the presentation of findings. Alongside, or soon after, there may be dissemination events through which the results narrative is presented and feedback is invited from relevant stakeholders. This may be done in a formal, structured way, for example if taking a more participatory approach to the research and using stakeholders' perceptions of the initial findings to further modify and shape the results narrative. Alternatively, this may be done in a less structured way, for example, by reflecting on comments or questions made following a presentation of findings at a conference or meeting.

The process of writing up the research into a final report or manuscript for publication will vary according to the required format of the document and the number of authors contributing to its production. In a typical situation, one social scientist will take the lead in writing a first draft of the paper (or lead on the majority of sections of it) and it will then be circulated among the co-authors for contributions, comments, edits and reflections. This collaborative process is likely to involve multiple drafts of the paper, with frequent revisions made as the narrative is refined, and the message deemed most relevant to the audience (including funders, journal editors, peer reviewers, policy makers and the academic community). Negotiating the balance of data description, analytic and theoretical interpretation, and illustration of findings using examples from the data, can be challenging, particularly within the confines of a word limit, but is important for conveying the key messages in a compelling and effective way. It is also important to represent fairly the instances where the data did not fit or correspond closely with the dominant themes or constructs, offering consideration of the possible reasons behind this. Checklists for reporting qualitative research may also be useful at this stage Tong, Sainsbury et al. (2007). For more detailed discussion of these issues

and (re)presenting qualitative analysis in a written paper see (Sandelowski 1998) and (Sandelowski and Leeman 2012).

5.3 Synthesizing Findings in a Consortia Approach

One of the advantages of working in a multi-project consortium is that qualitative data has the potential to be analysed across contexts to draw powerful, policy-relevant conclusions. The challenge for the ACT Consortium was to make sense of data from multiple sites that were collected on the same general topic but often in slightly different ways and for different purposes. Our objective was to try to draw conclusions across these sets of data, without treating them as the same; to keep them fragmented in initial analyses and represent them as such. In this section we review two approaches to analysing qualitative data across projects, Secondary Analysis and Synthesis, and discuss how we decided to use each in our consortium approach. At the time of writing this guidance document, analysis from most projects was still underway. Readers can check the ACT Consortium website for anticipated publications arising from this style of analysis.

5.3.1 Secondary analysis

Secondary analysis is the use of pre-existing data collected for a specific research question to answer a different (though possibly linked) research question. The value of secondary analysis lies predominantly in its efficiency, being able to address additional research aims without the need for additional data collection. It is also arguably ethical, in that unnecessary use of resources, time and participants' involvement are avoided as no new data is collected. However, the process of secondary analysis poses a number of other ethical and methodological issues including to what extent the original participants' consent covers additional use of their data and challenges associated with using data collected according to a specific theoretical approach for a new research question potentially informed by a different framing.

Qualitative researchers conceptualise their research as iterative, embodied and intuitive. Building on the idea of the uniqueness of the researcher-subject relationship in qualitative research can be a notion that data is only decipherable to the "expert eye": that is only the researcher who has carried out data collection is in a position to be able to effectively understand and analyse their data (Broom, Cheshire et al. 2009). Supporting this perspective, Mauthner et al imply that primary researchers have such a specific and privileged relationship to the data they generate, that the perspectives, knowledge, insight and reflexivity is unavailable to anyone not involved in data collection and that this knowledge is crucial to the production of analyses and claims arising from the data: (Mauthner, Parry et al. 1998). There can be a sense that "to just pick up information and re-use it", as in the case of analysts acquiring data from a repository and conducting a secondary analysis, would have much detrimental consequences for reliable interpretation and analysis (Broom, Cheshire et al. 2009). Existing relationships (and presumably knowledge of the research), might be seen as reducing the disconnect between fieldwork and meaning making, although "distance" may aid the process of secondary analysis, open up new avenues of enquiry and engender new kinds of insights into the data (Irwin and Winterton 2011). Moore raises the interesting perspective that if qualitative data is "co-produced" between researcher and participants, then "secondary analysis" is less the analysis of pre-existing data than the recontextualisation or reconstruction of it: the co-production of it from another perspective. Once it has been recontextualised, she suggests that what is currently termed secondary analysis might

better be described as primary analysis of a different order of data (Moore 2007), and thus new insights, knowledge and claims are valid.

Working with multi-site data

If you are considering making qualitative data available for secondary analysis later on (for example, by a consortium researcher unfamiliar with the original data), particular types of information about the production of qualitative data in context to assist this can be purposely collected (see Box 22), potentially along with *metadata* (structured bibliographic documentation about data which explain the origin, purpose, time, geographic location, creator, access conditions and terms of use) (Van den Eynden, Corti et al. 2011). The context of data collection becomes particularly important, for example, when considering the data from common questions asked across different projects.

Box 22. Types of contextual information that assist secondary analysis of qualitative data

Conversational contexts relate to the preservation of the record of the conversation, a recording or a model transcript providing an accurate recording of audible utterances and in some cases non-word sounds and gestures, as well as interaction between the interviewer and interviewee (Van den Berg 2005, Bishop 2006).

***Situational* contexts** include those of both the setting (including geographical location and building and room descriptions) and time of events, and the project including participants and the researcher. It is also useful to know how participants were selected and recruited and what they know about the process of selection and the project, as well as whether they know each other or the researcher (from outside the research or from previous data collection as part of the research). In addition, knowable or visible characteristics of the participants might also be documented i.e. gender, skin colour or other aspects of appearance that might be relevant to the data and from which it is possible inferences might be made which might otherwise elude the secondary researcher (Van den Berg 2005).

Institutional/cultural contexts include those relating specifically to the projects and to the wider cultural contexts. Documents charting the development, processes, instruments, design, sampling and anonymisation strategies and outputs should also be available for secondary analysis (Bishop 2006), as well as pilot research, geographical and temporal coverage of the dataset and a complete list of all data files making up the dataset. Grey literature such as book reviews, newspaper clippings and commentaries may be useful to provide an idea of historical and cultural context. When considering how much detail to provide, more is better than less (Bishop 2006).

Irwin and Winterton suggest that diverse qualitative research strategies across a dataset will render data less amenable to secondary analysis, as does the type of research method used: for example ethnographic methods, relying on cultural immersion, identification and theory building, create data that is more tightly bound to the researcher (Irwin and Winterton 2011). They suggest that interview type data might be more readily conducive to secondary analysis.

5.3.2 Synthesis

Synthesis differs from secondary analysis of data in that it seeks to bring together the findings of multiple research studies to interpret aggregated results, rather than re-analysing existing (raw)

data. The value of synthesis is that it seeks to assess the applicability of individual research findings beyond their study contexts (the 'inferential generalisability' of findings (Lewis and Ritchie 2003)), and to move towards generation of more theoretical interpretations of the topic in question. As such, it can bring disparate pieces of research together to help develop and consolidate the evidence base around a particular topic. For qualitative research, the traditional systematic review and meta-analysis techniques used for quantitative and clinical research are often considered inappropriate and a range of synthesis methods which reflect the epistemological bases of qualitative research have been developed (Table 5). Again, however, there are substantial challenges with bringing together qualitative research findings produced through differing theoretical and methodological approaches (Pope and Mays 2006, Ring, Jepson et al. 2011).

Table 5. Approaches to synthesis of qualitative research

Type of synthesis	Summary of method	Advantages	Disadvantages
Narrative synthesis (Fisher, McKevitt et al. 2011)	Evidence on key themes is extracted from multiple studies and summarised through the development of a narrative	-Aggregates papers -Useful for synthesising studies with a wide range of different research designs	-Doesn't necessarily integrate evidence or develop new cumulative knowledge -No consensus on constituent elements of narrative synthesis and conditions for establishing trustworthiness -Can be more prone to bias as approach does not rest on an authoritative body of knowledge or reliable and rigorous techniques tried and tested and further developed
Realist synthesis (Rycroft-Malone, McCormack et al. 2012)	Draws out the central theories or causal mechanisms identified within multiple studies and builds an explanation of the body of research by telling the story of the evolution of the field of enquiry or mapping the domains covered by the literature	-Can accommodate a great diversity of evidence including quantitative and qualitative research -Can produce compelling stories for policy makers and practitioners -Looks at what works and what doesn't work -Suitable for synthesising complex behavioural interventions: could provide useful insights about the mechanisms of programme success or failure and conflicting results of similar studies -Stakeholder driven	-Few worked examples of this in the literature: untested approach -Not one prescribed approach to undertaking a realist synthesis; rather, there is a set of principles that should be applied to the issue being explored whilst taking into account "realism" -Time consuming and resource intensive. -Findings won't be generalisable: they will be theoretically transferable theories to be tested in different contexts and with different groups
Grounded theory approaches [including constant comparative method; comparative case study method] (Finfgeld 1999) (Carlsen, Glenton et	Applies the same or similar methods to synthesis used to generate the original research (constant comparison and theoretical sampling)	-Can be usefully used to synthesise qualitative studies and possibly quantitative and qualitative evidence -Reliant on researcher having a thorough knowledge of principles and application of grounded	-Unsuitable for novices? -Might be difficult to incorporate quantitative data -Might be unsuitable for synthesising studies that didn't analyse data using a grounded theory approach

al. 2007)		theory in primary research	
Meta-ethnography (Pound, Britten et al. 2005) (Walter, Emery et al. 2004)	Brings together findings from individual interpretive accounts to produce a new interpretation	-Interpretive rather than aggregative: can reconcile seemingly unique and diverse data to produce a more general theory	-Qualitative literature not well recorded or indexed in bibliographic databases -Qualitative studies require quality appraisal -Requires high level of expertise in qualitative methods ("translation" requires interpretation and judgement)
Thematic synthesis (Thomas and Harden 2008) (Morton, Tong et al. 2010)	Seeks to identify and bring together the main, recurrent or most important issues or themes arising from a body of literature. The themes identified will be shaped by the specific review questions.	-Provides a means of organising and summarising findings from a large body of research -As a narrative approach it is often used for combining qualitative and quantitative findings	-Its flexibility is associated with a lack of transparency: can be difficult for readers to understand how an analysis was undertaken -Like content analysis, it is unclear whether thematic analysis should reflect the frequency of themes or its explanatory significance
Meta-study (Tamminen and Holt 2010) (Edwards, Pang et al. 2010)	Seeks to critique existing research by analysing the theory, methods and findings of each study prior to a synthesis which generates new knowledge and understanding.	-Has an explicit systematic methodology that can be followed in relation to sampling, appraisal and synthesis -Flexibility of method to synthesise data collected under different conditions, different theoretical perspectives and yielding dissimilar kinds of knowledge	-May be less suitable for synthesising a range of qualitative and quantitative or mixed method studies as the approach seems to suit the synthesis of studies that provide a sufficient depth of qualitative data

Sources: (Mays, Pope et al. 2005, Pope, Mays et al. 2007, Barnett-Page and Thomas 2009, Edwards, Pang et al. 2010, Ring, Jepson et al. 2011, Rycroft-Malone, McCormack et al. 2012)

5.3.3 Synthesis vs. secondary analysis in a consortium project

From the variety of methods discussed above, it is clear that even within specific types of qualitative synthesis there is considerable flexibility in the methods that can be used and no "right" or "wrong" way to approach the synthesis, indeed this flexibility may present more challenges than the rigid approach that is the format of a systematic review, for example.

The ACT Consortium was in a unique position in terms of having access to a significant amount of raw, coded and analysed data (in the form of manuscripts), and a team of core qualitative researchers who were familiar with much of this qualitative data, in some cases having had a central role in its design, collection and analysis. A number of methods to produce cross-cutting analyses could therefore be used, depending on the objective of a particular analysis and the datasets available.

The following are some approaches to multi-site analysis that we considered in our project and which may be relevant to other research consortia:

1. There is likely to be a considerable amount of data to analyse, especially if secondary analysis of raw data is undertaken. Consider tools and approaches to facilitate this, including

mind mapping software and matrices. For comprehensive examples of the use of matrices in qualitative data analysis and synthesis see Miles and Huberman's sourcebook (Miles and Huberman 1994).

2. Consider some of the approaches suggested by Irwin and Winterton to handling high volumes of qualitative data (Irwin and Winterton 2011). This could include sampling a range of focus group discussions or interviews from different projects for what the data reveals about a particular topic, i.e. experiences of having an RDT.

3. In terms of suitable types of qualitative synthesis to consider, realist synthesis, which is particularly appropriate for reviewing complex interventions as its central tenet, is that it considers the causal mechanisms behind what works for whom and in what contexts in each study. It could be considered for projects which have similar underlying theories of change and have gathered appropriate qualitative data, perhaps as part of the evaluation stage.

4. A meta-ethnographic approach, that can reconcile diverse data and transform and interpret it to go beyond the primary studies and produce a new overall interpretation, could also be considered.

5. A metastudy approach would also be useful, particularly for combining studies that have been led by different qualitative researchers and/or that have different theoretical orientations and different research questions. The advantage here is that this approach specifically requires the critical consideration of the different disciplinary perspective and theoretical orientation of the researcher, plus the methodological orientations, procedures, assumptions and structures of the research, prior to analysis and a synthesis which creates an new interpretation, taking into account the findings of the three phases preceding it.

SUMMARY

In this document, we have outlined approaches that researchers can take when using qualitative methods in complex health interventions research. These are derived from the specific needs of the ACT Consortium projects, which were trans-national by nature, but we anticipate they will be relevant to a wider group of researchers who are undertaking similar work. We have attempted to cover the range of activities required to carry out good quality, informative qualitative research in this topic area. We began with an introduction to the ways qualitative research may be useful in interventions research – to help to define interventions, as well as to understand 'what happened' when interventions have been rolled out. We then described some of the most commonly used methods in qualitative fieldwork, and some principles to bear in mind when planning for such fieldwork and in managing data. We alerted readers to the importance of considering the analytic approach at the early stages of qualitative research, and went into further detail on the nuts and bolts of coding and interpretation later in the guidance. A key area of learning for us was in assuring quality of research, especially carried out trans-nationally, and being able to demonstrate this quality. In response to this, we developed some guidance, included as a chapter here, for projects to undertake constructive activities to assure quality. An outstanding challenge for us has been in writing up qualitative research findings in a meaningful way that goes beyond description of the responses of different participants involved in research activities. Researchers with experience in social theory as well as in the local political and economic contexts that frame the qualitative research carried out appear to be essential for generating research findings that provide a meaningful contribution to questions being asked by both academics and public health practitioners. We recommend, therefore, that in undertaking qualitative research as described in this document, investment is made not only in ensuring a good quality process of field research and data management, but also to employ qualified and experienced social scientists to lead the research and interpretation processes.

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Additional resources for qualitative methods are listed on the Online QDA and Intute websites: http://onlineqda.hud.ac.uk/resources.php

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ACT Consortium projects with qualitative research

- The PRIME trial: Improving health centres to reduce childhood malaria in Uganda
  www.actconsortium.org/PRIME
- PROCESS: Evaluating how the PRIME intervention worked in practice
  www.actconsortium.org/PROCESS
- Use of rapid diagnostic tests to improve malaria treatment in the community in Uganda
  www.actconsortium.org/RDThomemanagement
- Introducing rapid diagnostic tests in drug shops to improve the targeting of malaria treatment
  www.actconsortium.org/RDTdrugshops
- Perceptions and impact of introducing rapid diagnostic tests in drug shops
  www.actconsortium.org/RDTperceptions
- IMPACT 2: Evaluating policies in Tanzania to improve malaria diagnosis and treatment
  www.actconsortium.org/IMPACT2
- Cost-effectiveness of interventions to support the introduction of malaria rapid diagnostic tests in Cameroon
  www.actconsortium.org/REACTCameroon
- Costs and effects of strategies to improve malaria diagnosis and treatment in Nigeria
  www.actconsortium.org/REACTNigeria
- Strategies for expanding access to quality malaria diagnosis in south-central Asia where malaria incidence is low
  www.actconsortium.org/ACTAfghanistan
- Giving ACT drugs to patients with positive result in malaria rapid diagnostic test
  www.actconsortium.org/RDTGhana
- Targeting ACT drugs: the TACT trial
  www.actconsortium.org/TACT
- Understanding perceptions of HIV-positive people taking malaria treatment
  www.actconsortium.org/InterACTperceptions
- How perceptions of malaria medication affect adherence
  www.actconsortium.org/ACTiaPerceptions
- Collating drug safety data from ACT Consortium studies
  www.actconsortium.org/drugsafetydatabase
- Collecting safety data in antimalarial drug trials
  www.actconsortium.org/safetydatacollection

- How the use of rapid diagnostic tests influences clinicians' decision to prescribe ACTs www.actconsortium.org/RDTclinicianbehaviour
- Access and quality of malaria diagnosis and treatment in South-East Asia www.actconsortium.org/ACTCambodia