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Chapter 15 Social and behavioural research

1. Purposes of social and behavioural research in intervention trials

Social and behavioural research is often conducted during the design and evaluation of health interventions. In the design phase, 'formative research' is conducted in the community in which the proposed trial is to be conducted to explore the context in which the intervention will be delivered and to examine ways in which the intervention might be optimized. Examples are given later in this chapter. The outcome of such research should help define the content and delivery of the intervention package and ensure that the study protocol takes proper account of local conditions. In the evaluation phase, either during or after a trial, social and behavioural research is often used as part of a 'process evaluation' to understand aspects of the implementation of the intervention, such as in the context of intervention coverage, comparing how the intervention was supposed to be delivered, compared to how it was actually delivered, and to understand 'pathways of change' in the case of behavioural intervention trials (i.e. what the components of the intervention that led to, or did not lead to, behaviour change were).

The methods applied derive from a variety of disciplines, including anthropology, sociology, and psychology. They include both qualitative and quantitative approaches. In Section 3, we outline qualitative methods that are commonly incorporated in the design and conduct of intervention trials. Rather than detailing all possible methods, examples are given of how different methods can be used in the context of such trials.

1.1. Formative research to define the intervention package

All of the component parts of an intervention (the 'intervention package') to be tested in the field trial and the method of delivering the intervention should be clearly defined. To maximize the potential for the intervention package to be effective, it should draw on local priorities and contexts, as well as best practice from elsewhere. With the potential exception of some 'proof of concept' trials, the intervention must have the realistic prospect of being affordable, given the resources available at the household level and to the local health system, either immediately after the trial or in the foreseeable future. It must be acceptable to the community, and it must be feasible for it to be implemented by those charged with delivering the intervention in the trial (e.g. local health workers). If the intervention tested in the trial is poorly designed or does not have the potential to meet these criteria, this greatly reduces the chance that the intervention will be adopted into routine practice at the conclusion of the trial, even if it is found to be effective. To optimize evaluation methods, particularly in the context of 'complex' interventions, the intended mechanisms of effect should be clearly articulated in advance, for example, through a logic model (see Section 1.1.2).

In the context of this chapter, we use the term 'intervention package', rather than simply intervention, to emphasize that, even if the core intervention under evaluation is a single item, such as a vaccine or a drug, it will always be necessary to deliver it as part of an intervention package, which will have a number of different components that have to fit together for there to be a significant effect on the health outcomes of interest. An intervention package can be regarded as composed of the core intervention and complementary activities to promote uptake and use of the core intervention. Varying amounts and types of formative research are required, depending upon the nature of the core intervention and how fully it has already been defined. As discussed in Chapter 2, the core intervention under trial varies widely from products or technologies such as vaccines, drugs, food supplements; behaviours such as hand-washing and exclusive breastfeeding, or care seeking from a health facility in response to danger signs; different methods of delivering or managing health services, such as delivery of services through visits by community health workers to the home, rather than through visits by users of the services to a clinic or dispensary, or different methods of supervision of health workers. Whichever intervention type, it is likely that the intervention and package will require one or more components beyond the core idea or technology.

Formative research to define intervention packages typically involves fieldwork and review of the literature before an intensive period of design and pilot testing of the intervention package. An example of the role of formative research in intervention design is shown in Figure 15.1, which was developed in the context of trials of the delivery of drug treatment interventions against malaria (see <http://www.actconsortium.org>).

1.1.1. Fieldwork

Formative research fieldwork aims to understand the 'problem' that will be targeted by the trial, to gain an understanding of the 'audience' for the intervention and to understand the context in which the intervention will take place. For example, the over-diagnosis of malaria by health workers has been identified as a major problem across malaria endemic countries. Prior to a trial to improve the diagnosis of fevers in north-east Tanzania, anthropological research at hospitals had described how clinicians operated through shared 'mindlines', rather than following clinical guidelines, shaped by perceived patient expectations and norms established with peers and historically in the wider medical community (Chandler et al., 2008). An intervention package designed to improve the diagnosis of malaria would require changing these norms in a manner that would not undermine clinical autonomy. The audience for the trial intervention was defined to be both clinicians and patients at dispensary level facilities. Further qualitative work was carried out with these groups to learn what existing ideas and situations supported the use of diagnostic tests and to discuss how these could be built upon to develop intervention activities and messages that would encourage a change in practice.

Table 15.1 outlines four areas for exploration in formative research: understanding the current policy and operational context of behaviour; understanding current practice in the local context; understanding current perceptions; and understanding whether the population of interest perceives a need for change, and their ideas for how this might be achieved. Each area may be explored, using different methods and with different participants.

The identification of existing practices, ideas, and scenarios upon which to build intervention design is important in formative research. Identifying only barriers to a particular health practice can be limiting in designing an effective intervention. An approach to identify existing beneficial practices is 'positive deviance inquiry', which uses multiple methods. For example, a research group may want to improve child malnutrition by promoting beneficial child feeding behaviours that exist in the community but are only practised by a minority of households. Here, the study team might identify two sets of households with similar levels of material wealth and other characteristics, but with different levels of child nutrition. A small descriptive study, including structured observation of child feeding practices and interviews of various household members, can be carried out to try to identify potentially beneficial behaviours, which might subsequently be confirmed in a larger study with a representative sample. A detailed manual of how to apply this methodology is available (<http://www.positivedeviance.org>) (Sternin et al., 1998).

An important characteristic of the core intervention to be explored at this stage may be its cost. In efficacy trials, the product or intervention is typically provided to research participants, free of change. In trials designed to mimic what might happen when an intervention is introduced into public health practice, a product may be sold to participants, at the cost users will pay when the product eventually is available through routine distribution channels. One major focus of formative research at this stage may therefore be on evaluating not only the acceptability and feasibility of use, but also the willingness to pay for the intervention (see also Chapter 19).

1.1.2. Literature review

In addition to fieldwork, the formative stage of intervention design requires review of previous work. Systematic reviews of evidence of other interventions that have been more and less successful in achieving similar objectives are recommended as a first step (see Chapter 3 and Medical Research Council, 2008). In addition, identification and specification of the theory or theories used to guide the design of the intervention and its delivery are recommended, in order to strengthen the effectiveness of the intervention, as well as to enable evaluations to contribute to wider bodies of theory about 'what works'. This is especially relevant for behavioural interventions. Care must be taken in identifying an appropriate behaviour change theory to ensure that the theory reflects well the situation found locally in formative fieldwork research. Certain cognitive-based models, such as the health belief model, that centre on replacing 'beliefs' with biomedical 'knowledge' and replacing 'myths' with 'truth' have been criticized for taking too little account of the local issues around health, care seeking, and care giving, and not relating these to their social, economic, and political contexts. Even in the absence of the explicit use of theory to guide intervention design, social science approaches are useful in enabling depiction of the implicit pathway of change (how change will be brought about) and the hypotheses embedded within this. Such a depiction is often termed a 'logic model' or 'theory of change' or 'impact model' and can help to tighten up an intervention design as well as to identify where evaluation activities are required, in order to test hypothesized pathways of change. For a discussion of these aspects, see National Institute for Health and Clinical Excellence (2007).

Figure 15.2 shows a framework for a logic model.

Analysis of the intervention details and the context in which it is implemented is important for the proper interpretation of trial outcomes, so that the applicability of the trial results in other situations can be assessed.

1.1.3. Developing and pilot testing intervention delivery

Once the core intervention is defined, the details of the intervention's delivery require development to promote understanding, acceptance, and utilization of the core intervention, or to improve physical, financial, and cultural access to the core intervention. Details to develop and pilot-test for the effective delivery of the intervention include activities, materials, and 'purveyors' (explained in the following paragraphs).

Activities to accompany a core intervention might include the design of workshops, media spots, or engagements with opinion leaders. When the intervention to be introduced is new to the potential recipients, a small-scale pilot introduction may be carried out. This can help to refine the activities and identify needs for materials and the optimal characteristics of the purveyor(s) who will deliver different components of the intervention package. An example is a pilot feasibility study carried out in rural Zimbabwe to design an intervention to target adolescent sexual health (Power et al., 2004). Teachers were trained in four schools to deliver weekly lessons on reproductive health. Feedback and responses to the materials and delivery were gained through questionnaires, in-depth interviews, focus group discussions, and participant observation with pupils, parents, teachers, and education officers. The research found that the intervention as originally conceived was unlikely to be deliverable because the classroom was not the appropriate context for delivering the intervention, the school infrastructure was not suitable to deliver the intervention materials, and existing materials were inadequate for the intervention. As a result, substantial changes were made to the design of the intervention prior to formal testing in a large community randomized trial.

Materials for the intervention delivery might include printed instructions and/or a film of how to use the product or how to perform the behaviour; vouchers to be provided to the poor who otherwise could not afford the product; materials for the channels through which the product will be sold or distributed such as pharmacies, shops, and health facilities; and print or audiovisual materials for communication activities such as radio broadcasts, protocols for community meetings, and posters. The development of these materials should draw on best practice in communication science, together with either information already gained from local formative research or participatory research at the design stage. Participatory, or 'action' research, can lead to the development of intervention materials that are more effective and acceptable to end-users. An example is the development of a treatment guideline for the effective case management of malaria in children at home by caregivers (Ajayi et al., 2009). Several forms of modified focus group discussion sessions were undertaken, with ideas depicted in illustrations by a graphic artist. The emerging guideline, in a cartoon format with a local language script, was subject to multiple rounds of pre-testing by end-users, during which edits were made to the pictures and text to increase comprehension and interpretation of the stories. Pre-testing of materials with community members is essential before finalizing them. Images, statements, and even colours can often portray different meanings to different people. To avoid misinterpretation, community members should be shown drafts of materials and systematically asked for their comprehension and interpretation of each element of a poster, video, or audio broadcast. An excellent manual for pre-testing that includes principles for clear communication has been produced for the WHO (Haaland, 2001).

Purveyors are the people who will deliver the intervention. Attention must be given to their selection, training, and supervision. These may include facility-based health workers, community health workers, traditional healers, private and informal sector providers, traditional birth attendants, women's groups, and community or religious leaders. Small-scale studies can be conducted to investigate which type of person might be the most appropriate as the purveyors of the intervention. These might be based on either discussions of hypothetical options with the potential recipients of the intervention or pilot projects to implement one or more alternative options. Examples of projects with a comprehensive package of complementary activities and people to implement these activities in the field were a programme for the social marketing of bed-nets in Tanzania (Schellenberg et al., 2001) and an education and counselling programme on exclusive breastfeeding for HIV-infected mothers in a trial in Zimbabwe (Iliff et al., 2005).

1.2. Formative research to adapt the study protocol

1.2.1. Study design and procedures

Chapter 4 describes decisions to be made regarding study design such as selection of interventions, allocation of interventions and unit of randomization, and method of implementation. Often, such decisions are made far from the

study site, and they will always benefit from detailed information about the study site. Formative research conducted to inform the study design may examine different topics, including:

Selection of study site: Typically, there are a number of possible locations at which a trial may be conducted. Requirements of the trial may include enrolment of people with specific characteristics, and long-term follow-up of those enrolled in the trial. The decision on the choice of site may be informed by analysis of existing census data or other datasets, or interviews on community characteristics such as patterns of migration, economic activities, and observation of health programmes already being implemented by local organizations (see Chapter 9).

Randomization: Qualitative data can inform decisions about the unit of randomization (individual, village, cluster of villages, sub-district, etc.) and the boundaries of the units for group randomization. An understanding of the social structure and the social context of the target behaviour is useful for identifying the importance of administrative or social groups. For example, if a target behaviour is known to be habitual to a group and the intervention relies on individuals making changes as part of a group, the unit of randomization should be that group, rather than individuals within the group. Another consideration may be defining boundaries to minimize the potential for contamination, due to interactions between those assigned to different trial arms. Formative research can reveal common interactions and social and logistic boundaries.

Promotion of trial participation: Prior to the start of a trial, its usefulness and the priority given to the research question should be established from the perspective of the hosting communities. If the question or methods are not aligned with local interests, changes to the intervention or evaluation may need to be made (see Chapter 9). Once a trial is launched, it is desirable that a high proportion of those eligible to participate in the trial agree to do so when invited. A high refusal rate may jeopardize the generalizability of the trial findings or may even threaten its viability. Thus, it is important to implement activities to promote understanding and acceptance of the research activities and create the conditions under which truly informed consent is possible. These might include community meetings to discuss why certain communities or persons will receive the intervention, while others will not, and print or counselling materials to explain the risks and benefits of participation. This component may also elicit community input to improve the trial protocol itself, as occurred in the design phase of a clinical trial on the safety and efficacy of antiretroviral and nutrition interventions to reduce post-natal transmission of HIV conducted in Malawi (van der Horst et al., 2009). Qualitative studies were conducted to assess the acceptability of three alternative efficacy study designs and the feasibility of participant recruitment for such study designs.

Participatory methods can be used to engage communities in the design and implementation of the trial interventions. For example, a feasibility study for a microbicide trial in Mwanza Tanzania formed a city-level CAB, with representatives from among the potential trial participants elected from each ward. Through workshops and meetings, both with the CAB and wider groups of potential trial participants, many modifications were made to both the trial design and the study procedures. CAB members expressed concerns about the sale of blood specimens for witchcraft purposes, whether speculae for pelvic examinations would be reused and therefore be unclean, insufficient transport allowances for attending the trial assessments, and delayed reporting of laboratory test results. In response, the study team invited CAB members to observe the preparation and storage of blood specimens and the use of the autoclave in the laboratory, raised the amount for reimbursements, introduced HIV rapid testing, and accelerated the feedback of laboratory results (Shagi et al., 2008; Vallely et al., 2007).

1.2.2. Consent procedures and measurement tools

Obtaining truly informed consent for participation in an intervention trial is very challenging. The researcher's perception of an intervention and its possible beneficial and adverse effects may be very different from those of potential trial participants. Social science investigations conducted in the trial community, prior to designing the informed consent procedures, may give the investigator a much better understanding of how the community is likely to view the proposed trial and will inform the ways in which the trial should be presented to potential participants to facilitate their understanding of both the potential risks and potential benefits and of why the trial is being conducted. Issues around informed consent are discussed further in Chapter 6, Section 2.4.

Social and behavioural research methods can also help inform the design of quantitative outcome measures for the trial. Tasks include formulation of questions and definition of appropriate forms of measurement. Some trials make the mistake of measuring outcomes through open questions, thinking that closed questions introduce bias. In addition

to the fact that post-coding of open questions is very time-consuming (see Chapter 20), problems caused by incomplete responses to open questions may outweigh the limitations of closed questions. Also, open questions have lower test–retest reliability, leading to difficulties when pre–post comparisons are made. Nichter et al. (2002) outline a systematic process for informing the design of survey instruments through formative research.

2. Social and behavioural research in evaluation

Social and behavioural research conducted during and after the trial may facilitate understanding and interpretation of the trial results. Two methodological approaches for this purpose are process evaluation (process documentation, process learning) and evaluation of pathways of change.

2.1. Process evaluation to understand implementation

Process evaluation is a term applied to a range of data collection activities conducted during the implementation of a trial to assess, at a minimum, whether the intervention is being implemented according to the study protocol. This is important to document and report, in order to determine whether an intervention's apparent success or failure is attributable to the intervention's concept or theory or to the way it was implemented. Table 15.2 shows six aspects of process evaluation that have been described by Saunders et al. (2005) to guide data collection activities.

Each of the intervention components and its delivery methods should be subject to a process evaluation, resulting in the documentation of the six aspects in Table 15.2. Data collection may be quantitative, such as the number of subjects who receive an information leaflet, or qualitative such as perceptions of the political agenda behind an information leaflet that affects the 'dose received' of a particular message. Data may be collected through self-completion questionnaires, for example, by trainers who can record the amount of content actually delivered, the relative participation of different members of the group, and their impressions of the level of understanding for the various objectives of the training. Direct observations of activities can also provide an assessment of how well a particular intervention activity was delivered and can provide interpretations of the delivery in context, for example, to note other activities or events occurring at the same time that could support, or conflict with, the trial intervention. Interviews may also be used with both purveyors and intended recipients to understand what was delivered and what was received, and to give an understanding of why some aspects of an intervention may have been more effective than others. The data collected can be used in the interpretation of the final trial outcomes. The data can be incorporated into final analyses quantitatively, for example, in dose–response or per protocol analyses. The qualitative data can also be used to interpret what any change may be attributable to, in terms of the intervention delivered and received.

Process evaluation can also identify difficulties with implementation that occurred and how these difficulties were addressed.

2.2. Evaluation of pathways of change

In the evaluation of pathways of change, which is particularly relevant for behavioural interventions or multi-component interventions, the researcher aims to establish the relationship between any changes detected in trial outcome data and the intervention package, taking into account contextual factors that may have shaped the intervention and outcome variables. The objectives of an evaluation of pathways of change are to establish plausibility that outcomes are attributable to the intervention and to depict the mechanisms by which an intervention had effect, including identification of contextual factors considered significant in supporting these mechanisms. Two approaches can be taken to understanding pathways of change: hypothesis testing and hypothesis generating. These approaches are complementary and should be considered together to maximize understanding of the trial and generalizability of the results.

2.2.1. Hypothesis testing research

The hypothesis testing approach relies on prior specification of the intended pathway of change, for example, through a logic model. Steps along the pathway can be identified, and the relationships between these steps tested. For example, a multi-component trial in Uganda to enhance the quality of care at rural health facilities included a workshop series on patient-centred services. The hypothesized pathway of change was that health workers would attend the workshops and participate in individual reflection, conceptualization, experimentation, group reflection, and planning in the workshops; would feel motivated and able to change their practice; health worker interactions with care seekers would be more patient-centred; care seekers would detect, and be more satisfied with, this style of

communication; and community members would subsequently be more attracted to attending the enhanced health facilities. The study included a process evaluation to document the attendance, participation, and learning, followed by a pathway evaluation to assess communication between health workers and care seekers using audio recordings, care seeker satisfaction with their interactions with health workers, and logs of attendance at health facilities (Chandler et al., 2013a).

2.2.2. Hypothesis-generating research

A hypothesis-generating approach intends to understand 'what happened' from the perspective of the target population, from the time of intervention delivery to outcome evaluation activities. Here, unintended pathways of change can be captured, together with information on factors that affect the delivery, uptake, and use of an intervention in practice, as well as factors that may influence the outcomes of interest in the trial. Unstructured methods are best suited to this task to enable the research team to discover findings that may not have been hypothesized or depicted in the logic model. Project ethnography is one methodological approach to capture what actually happened. Here, an anthropologist, or someone similarly trained, carries out detailed participant observation, for example, working alongside the intervention implementation team for the trial, or even as a member of that team. Analysis of the in-depth data from these observations can provide insights into why and how members of the target community took up, adapted, or ignored different intervention components. Project ethnography can capture interpersonal relationships and power dynamics among the multiple actors involved and provide insights that would have ordinarily been missed. Evans and Lambert (2008) provide an excellent example of the value of project ethnography in illuminating key factors in the successful implementation of an intervention related to HIV. Other methods include in-depth interviews and focus group discussions with implementers, stakeholders, and the target population.

Further information and examples about using social research to carry out formative studies and evaluations of pathways of change in LMICs can be found at <http://www.actconsortium.org/qualitativemethodsguidance>.

3. Commonly used methods in social research

Qualitative research methods commonly used in field trials of health interventions include direct observation, interviews with key informants, focus group discussions, and participatory methods. These relatively open-ended techniques are suitable for exploring how an intervention might be perceived, the priorities of different members of the community, and ways that people view a trial from the perspective of potential participants. These methods are used to provide information relevant to devising intervention components, such as communication strategies, as well as devising trial methods, for example, to ensure recruitment and designing effective and appropriate data collection instruments.

The aim of qualitative research is to understand the perspectives of specific groups of individuals. In doing this, researchers are attempting to learn about the social worlds in which others live: their experiences with specific issues, their points of reference around particular topics, and broader factors that shape these, from local to global, historical, and political economic factors. When studying the world from a social perspective, it is recognized that what people say and do is contingent on the scenario in which words are being spoken and the action taken. Qualitative research attempts to make sense of, or interpret, phenomena in terms of the meanings people bring to them, and qualitative research practice recognizes the role of the researcher in bringing out these meanings. Key concerns in qualitative research are therefore how best to interpret perspectives of others and how to integrate into analyses the subjective nature of this interpretation. Both of these issues are relevant in research to guide intervention development, as well as to evaluate trial outcomes.

When considering methods to interpret others' perspectives, most qualitative research embraces the following four concepts: *explorative flexibility, iteration, triangulation*, and *contextualization.* Although the researcher has specific topics to be explored, it is assumed that new questions will emerge frequently, as the research progresses. Specific techniques and associated data collection methods are refined and modified throughout the research process. A *flexible* approach is adopted whereby unanticipated findings are explored, as new lines of inquiry develop, unproductive forms of data collection are dropped, and new methods developed, without losing sight of the original research objectives. There is an emphasis on in-depth investigation. The same or different key informants and other respondents may be interviewed repeatedly, with each new interview building upon the previous one with increasing refinement and focus. This *iterative* process applies not only to specific methods, but also to the qualitative research process as a whole. Multiple fieldwork strategies may be employed, including one-to-one conversation, as in key

informant interviewing, group discussions, and direct observations of actual behaviour. The use of multiple methods in conjunction, or *triangulation*, adds depth to an inquiry of the phenomenon in question. Rather than being a strategy for validation, triangulation adds richness and breadth, enabling a more rigorous exploration of the complexity of a phenomenon, through its multiple representations. Qualitative research may be used to help researchers understand the social, cultural, historic, political, and economic context within which an intervention trial will be conducted. Such c*ontextualization* is particularly valuable during the initial planning phases and also to help understand unexpected trial findings.

When considering how to integrate the subjective nature of interpretation into analyses, the concept of *reflexivity* is crucial to qualitative research. This requires that the researcher explicitly acknowledges his or her motivations and theoretical positions in relation to a piece of research and makes an effort to reflect and articulate these in decisions made in fieldwork and interpretations. For example, if a researcher feels alignment with ideals of market-led provision of health care, this may affect the way in which they ask questions and interpret responses, which can impact the shape of an intervention developed and the way a trial outcome is interpreted. Being reflexive about political, economic, and theoretical agendas underlying one's own motives for, or implementation of, the research can allow greater transparency, as well as the opportunity to challenge and reconsider these perspectives. Methods for attaining a reflexive stance include keeping reflexive diaries and field-notes and discussing decisions reflexively as a team. This approach has been proposed to be extended beyond qualitative activities to trial conduct in general to promote transparency and encourage more realistic accounts of trial contexts that are often in flux, allowing anticipation of barriers to recruitment and potential sources of bias which can be addressed in trial activities or analyses (Wells et al., 2012).

We have outlined some of the principal qualitative social science research methods. More detailed descriptions of the main qualitative research methods are given by Kielmann et al. (2011) and Bryman (2012). Chandler et al. (2013b) have also produced a compilation of guidance for carrying out qualitative research in the context of health interventions and provide a parallel protocol template document which includes example topic guides and standard operating procedures (SOPs) and a set of training materials for field teams (<http://www.actconsortium.org/resources.php/72/qualitative-methods-for-international-health-intervention-research>).

3.1. Direct observation

Direct observation includes both unstructured and structured observations. These methods are useful for learning about the everyday context relevant to an intervention. Spending an extended time observing these enables the researcher to appreciate the factors that may be relevant to an intervention, in relation to other priorities in the community and activities and concerns of the group of interest. This may be important for both the development of appropriate interventions and in the interpretation of trial outcomes.

3.1.1. Unstructured observation

Unstructured observation is the cornerstone of ethnography, the classical methodology of anthropology. Ethnographers often undertake *participant observation* when they endeavour to become a functioning member of a community and engage in local activities, watching carefully what others do and how they react to the ethnographer's own behaviour. The purpose is to attempt to view the community from the perspective of a participating member, rather than as an outsider. In many situations, *non-participant observation* is more feasible and can allow for a more systematic description of activities, in which the observer is not directly part of the activity under study. Non-participant observations may concentrate on an individual (for example, a pregnant woman), location (such as the kitchen or a water collection site), or event (for example, a wedding party or a market). The observer attempts to record as much behaviour as possible, including actions, conversations, description of the physical locale, and other relevant features. Focused observations often require some preliminary examination of the activity or location to prepare the observer. For example, the investigator may have a general impression of the interior of a rural house but may not know the kind and quantity of cooking utensils, nor how they are washed or stored. Some research questions require detailed observations on how a procedure is actually carried out. For example, how a mother mixes water with rehydration salts at home for the treatment of diarrhoea or how a health worker interacts with a client and/or carries out a medical procedure. Such observations may be used in the design of questionnaires and to confirm or refine data collected through interviews.

Unstructured observational activities are often carried out together with informal and formal interviews and group discussions. Observations and reviews of discussions are typically recorded in detailed field-notes, following the activity. Analysis is ongoing, often involving a daily review and reflection on occurrences and the way they have been interpreted by the ethnographer. Unstructured observation can be useful at all stages of the research relating to a trial, for example, in understanding how guidelines are used in practice by health workers, in preparation for, or the evaluation of, an intervention to improve clinical practice relating to a particular guideline such as treatment with antimalarial drugs or antibiotics. The rate-limiting step is often the availability of trained researchers to carry out such activities and ongoing analyses.

3.1.2. Structured observation

Structured observations involve the recording of behaviours or the outcomes of behaviours by trained observers, through the use of a pre-coded or partly coded data collection instrument. Structured observation methods can be used for continuous monitoring or for spot checks on a behaviour. These approaches are used when the behaviours that are to be studied in detail have been identified (possibly through unstructured observation), and it is clear what information is needed (for example, time of day, frequency, duration, and types of behaviour).

The researcher observes, as unobtrusively as possible, occurrences of events or behaviours. A dilemma faced by every observer is where to focus attention and what details to record. The data collection instruments are designed to help focus the researcher's attention on matters of greatest relevance to the research question. Predetermined structure limits discovery but assures relevance and consistency. The complexity of structured observation instruments varies. Some studies focus on detailed description of one or two events of interest, breaking them into fine units of activities, noting who performs them where, with what tools, and for how long, as was done in a study of hand-washing practices in Bangladesh reported by Stanton and Clemens (1987). Structured observations can form part of larger ethnographic studies, which has the advantage that the findings can be interpreted in the wider social context, enabling a more careful interpretation to feed into behaviour change interventions. For example, Chandler et al. (2008) conducted an ethnographic study of health workers' treatment of malaria, incorporating structured observations of clinical consultations within a wider study of the over-diagnosis of malaria in Tanzania, informing the design of interventions tested in a 3-arm cluster randomized trial. Unlike most methods described in this chapter, structured observation may yield data amenable to statistical analysis. This holds potential for repeated observations to monitor behaviour change over time.

3.2. In-depth interviews

In-depth interviews usually aim to get a comprehensive understanding of a participant's perspective, in their own words, of the issues under study. Such interviews may take a narrative approach whereby the interviewer aims to hear the 'story' of the participant in a historical perspective, probing for more detail on areas of interest to the research, for example, access to maternal health care services. In-depth interviews may also be used to explore individuals' ideas and concepts about particular issues, with the interviewer asking questions relating to specific topics identified as being of interest to the research objective. In both cases, a topic guide or list of questions may be used, as an aide-memoire, and may include specific questions that have been pilot-tested. The objective is to use this guide to explore the experiences and perspectives of each respondent, as they feel able and willing to explain themselves. Thinking of relevant and useful probing questions is an important skill for the interviewer who must bear in mind the research objective, while engaging with, and pursuing, trains of thought of respondents. They must be able to use new pieces of information to take the interview in previously unplanned, but relevant, directions. A further key skill in interviewing is the ability to create rapport and ensure confidentiality, such that the respondent feels comfortable and confident in expressing their views and experiences.

In-depth interviews take significant time to set up, carry out, transcribe (and translate), and interpret. This means they can usually only be conducted with a few carefully selected individuals. Depending on the objectives of the study, respondents for in-depth interviews may be 'key informants' or individuals selected as representing particular characteristics of interest (for example, mothers who have lost a child, migrants). Key informants, in the context of intervention trials, tend to be of three types: administrators/community leaders or other persons in positions of power, community-based health workers, and individuals in the community with specialized areas of expertise or experience (for example, traditional birth attendants, traditional healers). Key informants are identified through casual inquiry of formal and informal leaders and other pivotal community members, or through more systematic methods such as consensus analysis or social network analysis (Bernard and Ryan, 2010). Informants become 'key', because they are

more knowledgeable, co-operative, and accessible than other respondents and often are interviewed on multiple occasions. They serve to inform the investigator about selected aspects of the culture and customs of a community and may be used to provide information throughout the course of the study.

3.3. Focus group discussions

Focus group discussions are a useful method for getting to know shared values and points of reference. Focus groups can also be a good opportunity to generate and test out initial ideas for an intervention, with the ability for group members to offer, modify, or reject ideas for introducing changes relevant to a particular health problem.

In a focus group discussion, a small group of participants (usually six to 12), under the guidance of a facilitator, are encouraged to talk about topics which are thought to be of special importance to the respondents and to the investigation. Topic guides are utilized by the facilitator to stimulate discussions around areas of interest. Participants are selected from specific target groups whose ideas and experiences are germane to the study. Participants in a focus group are best chosen to avoid power differentials that could lead to some individuals dominating the discussion. Generally, participants are of the same sex and age group, but similarity in other characteristics may be important, depending upon the research question. For example, in the case of an evaluation of a trial to improve maternal health services, participants may include those who took up the intervention and those who did not, but they should not also include the health workers (whether from the formal or informal sector) who provide such services. It is important, but difficult, to ensure that participants are comfortable with one another, which may mean a natural grouping, such as a village microfinance group of women which may or may not be desirable as a sampling unit, depending upon the research question and the potential for divulgence of confidential information during the discussion.

For discussions to be productive, the facilitator must have skills in understanding and encouraging positive group dynamics and must be able to keep in mind the research objectives, in order to steer the discussion to maximize time spent on matters that may be relevant to the research question. In addition to the facilitator, it is useful to have an observer who makes notes and is alert for non-verbal cues. This observer may also collect demographic data from participants and ensure they receive refreshments. If possible, a focus group discussion should be tape-recorded and later transcribed in full. However, if it is thought that this would unduly inhibit open discussion, detailed notes should be taken by the observer as close to verbatim as possible.

The number of focus groups held will depend on the number of different relevant groups in the community of interest. Focus group sessions usually last for at least an hour and continue until the facilitator considers that all the participants have expressed their opinions adequately on the topics under investigation. Transcribing and translating focus group discussions can take a considerable amount of time, with transcripts typically running to 50–100 pages. Coding and analysis of such transcripts takes a correspondingly long time. To make the most of this method, it is therefore important to think carefully about sampling, the topics for discussion, and the facilitator's level of experience and familiarity with the research questions.

3.4. Participatory research

Participatory research methods aim to enable change at a local level through a process of sequential reflection and action carried out with and by local people. This is distinct from the other methods outlined in this chapter, which, in a general sense, can be considered to be carried out 'on people.' In participatory research, the focus is on basing research and planning on local knowledge and perspectives, situating power more evenly between researchers and the researched. In their purest form, participatory, or 'action', research approaches do not start out with a specific intervention in mind but aim to respond to local priorities and needs, and aim to empower local bodies to define and develop their own interventions. This is done through a series of facilitated discussions, workshops, planning sessions, and activities. In health research, a number of trials have adopted a form of this approach, by providing a structure within which local actors can define their priorities and intervention methods. An example is the Health Workers for Change programme, a series of six workshops which aimed to address the interpersonal component of quality of care by enabling participants to explore provider–client relations within a gender-sensitive context. This programme was implemented and evaluated in four country contexts, in each of which the intervention played out differently guided by the local participants, and was found to allow difficult issues to be discussed openly, fostered problem solving, and helped health workers to develop practical plans to address problems that could strengthen district health systems (Fonn et al., 2001).

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Figures

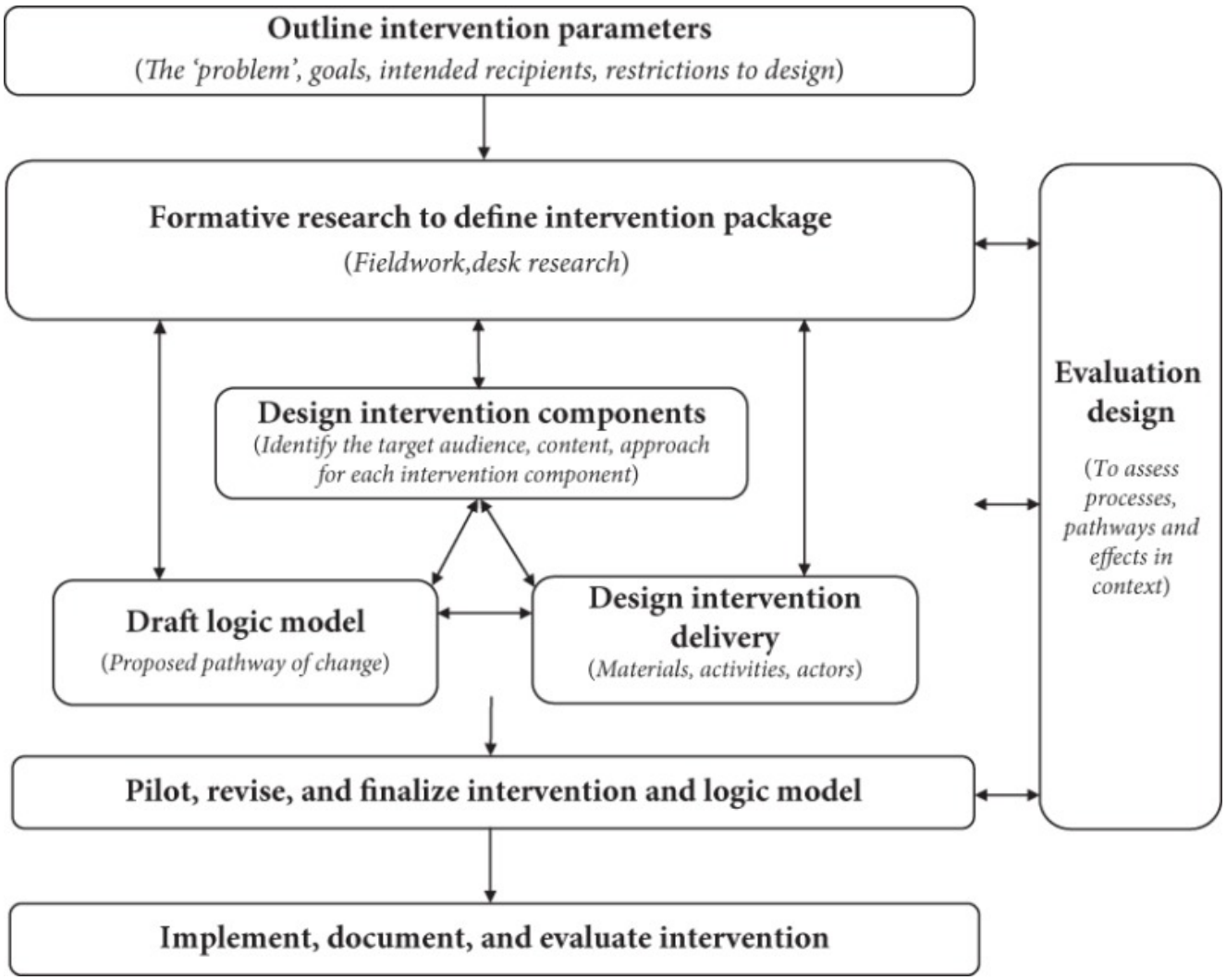

Figure 15.1

Example of the role of formative research in intervention design.

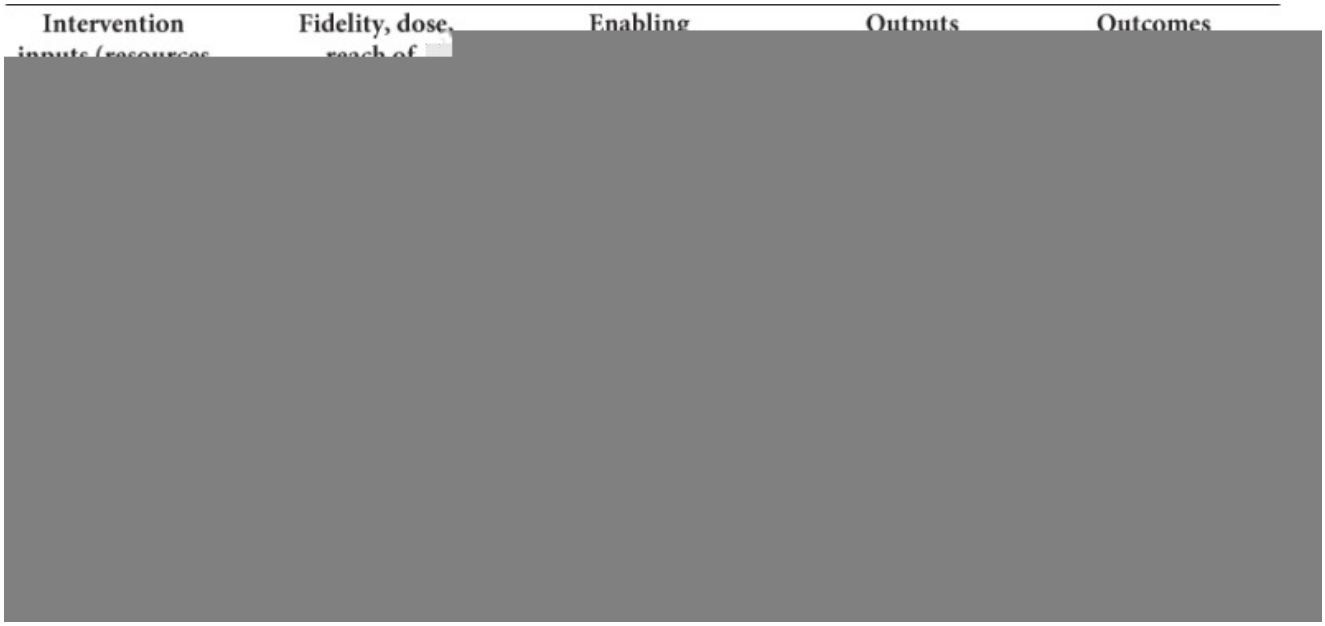

Figure 15.2

Framework for a logic model of an intervention's pathway of change.

Tables

Table 15.1 Areas for exploration in formative research for the design of an intervention package to improve the diagnosis and treatment of fevers

Area of exploration	Method	Potential participants and sources	Information gathered
Understanding the context of behaviour and potential for change	In-depth interviews, desktop research	◆ Key stakeholders related to the current behaviour ◆ Policy documents ◆ Historical and anthropological reports	◆ Policy and operational influences on current practice (guidelines, supervision, in-service training) ◆ Feasibility and willingness to implement behaviour change ◆ Existing or previous interventions with similar topics or behaviours
Understanding current practices	Direct observation	◆ Families ◆ Mothers ◆ Drug sellers ◆ Policy makers	◆ How practices are enacted in context, looking at the role of spaces, time, economics, and other priorities in shaping practices
Understanding perceptions of practices	In-depth interviews	◆ Key informants ◆ Patients ◆ Health workers	◆ Prevailing perceptions of practices in the groups of interest ◆ Narratives of experiences of the group of interest, showing meaning interpreted in actions and words of selves and others, social context of behaviour of interest
Understanding priorities and logistics for change	Focus group discussions	◆ Community groups ◆ Patients ◆ Drug sellers ◆ Health workers ◆ District officials	◆ Exploration of perceived need and priorities for change ◆ Generation of ideas for intervention messages and materials ◆ Exploration of readiness for different interventions in context ◆ Identification of social and structural issues to address in a given intervention activity

Table 15.2 Six dimensions of process evaluation

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 of the intervention that were delivered
Dose received (exposure or adherence)	Extent to which participants actively engage with, interact with, are receptive to, and/or use materials or recommended resources. Can include initial and continued use
Reach (participation rate or coverage)	Proportion of subjects who receive or participate in the intervention; includes documentation of barriers to participation
Recruitment and retention	Procedures used to approach and attract participants at individual or organizational levels; includes maintenance of participant involvement in the intervention
Context	Aspects of the environment that may influence intervention implementation or study outcomes

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