Chapter 9   Community engagement

1. Introduction to community engagement

The impetus to conduct trials of major public health interventions will often be from research centres or universities, in collaboration with the Ministry of Health (MOH). The intervention trial team will usually select the communities which they consider are most suitable for the conduct of a trial. The active and continued engagement with people within these communities is essential for the successful execution of the field trial. This chapter aims to provide practical guidance to researchers on ways of approaching community engagement in trials in LMICs, including identifying some common pitfalls.

The terms 'community' and 'engagement' attract debate and controversy around their meanings and the social, ethical, and political implications of their application in development and biomedical research practice. These aspects will not be explored in detail in this chapter but are discussed elsewhere (Participants in the Community Engagement Consent Workshop, 2013). The present chapter should also be read in conjunction with Chapters 6 and 15, as understanding of the ethical responsibilities of researchers working in LMICs underpins the overall importance of community engagement and the planning of its components (see Chapter 6), and community engagement is essentially a social endeavour, with many overlaps with social and behavioural research approaches and methods (see Chapter 15).

For the purposes of this chapter, community engagement will be defined as the process of the trial team working collaboratively with the community on all aspects of the study which affect the community and its well-being. Overall, engagement should typically involve continuous mutual learning and communication between researchers and a range of community members before and during a trial and after a trial ends.

2. Planning and initiating community engagement

2.1. Defining communities and aims of engaging communities

The overarching goal of community engagement is to create and maintain mutual understanding and trust between researchers and the communities in which the trial takes place. Community engagement is supportive of many different aspects of good science and ethics in research. Examples are fostering broad support for research activities, facilitating good informed consent processes, encouraging sustained participation, reducing risks of rumours and loss of trust, and making falsification of information less likely. From a community perspective, engaging with the trial team can help to ensure that the benefits of participation by community members outweigh the costs to them and supports their autonomy (i.e. informed, uncoerced decision making) within the trial. But community engagement is also seen as a good in itself, in demonstrating the trial team's respect for the community and what has been described as 'cultural humility' (Participants in the Community Engagement Consent Workshop, 2013).

As a first step, it is important to establish clearly who 'the community' is, or communities are, in relation to the trial and who the leaders or representatives of those communities are. In many instances, the community will be defined, at least initially, by the trial team and may thereby be relatively artificial. Often, trial communities are defined as all those living within a particular geographical area, but, for some trials, the community may be a social or an activity-based group such as intravenous drug users or sex workers. Defining communities is not necessarily straightforward. For example, what are the relevant communities for trials whose participants are regular migrants (for example, people who move seasonally between two geographical locations in pursuit of employment) or for trial participants who are selected at their place of work, such as factory workers, who live within wider social and geographical communities? In many trials, researchers have to engage with several communities and several different types of communities. If problems arise in relation to the trial in any one community, this may slow, or in extreme cases, jeopardize the conduct of the whole trial.

When the participants in a trial are selected from a specific subgroup of the population, such as a particular occupational group, or people who share a particular behaviour, such as men who have sex with other men, careful thought needs to be given to which aspects of the community engagement will apply only to the social community

that the trial participants come from, and which will apply to the wider community from which they are drawn. For example, in a trial in Tanzania, women who worked in specific locations, such as bars, restaurants, and guesthouses, were invited to participate in an HIV prevention trial, because they were at relatively high risk of HIV infection. It was decided that the reason why this 'high-risk' occupational group had been selected for the trial would not be discussed explicitly in community engagement activities with the wider geographical community and their representatives. It was also decided that community engagement structures (such as the representatives of the trial's CAB and its subgroups) would be drawn from trial participants and that communication with the wider geographical community would be kept to a minimum to avoid further stigmatization of women from these occupations (Shagi et al., 2008). In Kenya, a similar approach was adopted for a study working with men who have sex with men, but, over time, members of the wider geographical community became concerned that researchers were promoting homosexuality; following protests and media attention, far greater attention was placed on communication with the wider community.

While the overarching goals for community engagement have been described earlier in this section, this must be followed by defining the specific objectives of community engagement with each of the specific trial communities. These objectives will help to define the overall strategy, in relation to who should be involved, how, throughout and after the trial, and what methods and resources will be needed for the community engagement process.

Both the trial and community engagement activities will inevitably have implications and impacts which are not expected or intended. Community engagement can never be a prefabricated and entirely predictable set of activities that could apply to different settings; rather it needs to be seen as a dynamic and an ever-changing set of negotiated relationships (Lavery et al., 2010). The objectives and activities identified at the outset may need to be modified over time, in response to emerging issues and shifting priorities over the course of the trial. For this reason, community engagement must not be seen as an entirely linear process, nor its effectiveness evaluated as though it were.

2.2. Preliminary investigations in study communities

As early as possible, even during the process of identifying the communities, the trial team should work together with community leaders and local experts to begin to develop a strategy for achieving and sustaining community engagement throughout the trial. Many of the specific issues to be considered will depend upon the nature of the intervention and the kind of participation anticipated from the community, so it is important to contextualize planning to the specifics of the trial. The aim is to develop as close a partnership as possible between the trial team and all relevant communities in all aspects of the trial's design, implementation, interpretation, and dissemination. To achieve this, sustained two-way channels of communication must be created that facilitate regular exchange of information between community stakeholders and the trial team. The formation of a specific CAB, in some cases with representation from several Community Advisory Groups (CAGs), is one means of supporting this ongoing communication and is discussed in more detail in Section 2.3. Given some of the recognized problems with CABs, many trials engage with several CAGs, without one overall CAB. For simplicity, we shall use CAB/G to represent both concepts in the rest of this chapter.

Figure 9.1 outlines the main steps involved in engaging communities with the many activities involved in a field trial.

Preliminary studies and participatory planning processes can reduce the risk of potential pitfalls by accommodating the perspectives and preferences of different community members, as far as possible, and can provide some accountability. Various ethnographic and participatory methods can be used to explore community characteristics to ascertain the local relevance of the diseases under study and to facilitate the participation of community members in the proposed trial. Some of these methods are described in more detail in Chapter 15. Participatory rural appraisal (PRA) and participatory learning and action (PLA) methods may be particularly helpful (Chambers, 2008). Of particular note, exploration of views around aspects of trials that are unfamiliar to community members are likely to need methodological approaches, based on participatory forms of information sharing and discussion to generate meaningful engagement.

Deciding who should speak for the community, based on accurate knowledge of local interest groups and their likely representativeness, can be an essential, but difficult, step, given the likely range of different interests. Errors at this stage can damage the relationship of the trial team with the community. It may be useful for the trial team to listen to multiple community voices. It should also be recognized that some communities may simply not be interested in a trial as it is planned, or at all. A common failing in planning is for researchers not to recognize the complexity of, and dynamics between, various interest groups in a community and to assume that the official community authorities, such

as government administrators or traditional leaders, accurately represent the views of all groups within the community. If the trial requires active involvement of, for example, the poorest and least educated, a careful investigation of who could best represent their views will be important. These complexities and dynamics are also reflected within and between extended families and households, such that the views of the least empowered (often young mothers) may be particularly difficult to ascertain and take into account.

In relation to understanding community perceptions and practices relevant to the trial, researchers can draw on preliminary participatory planning processes, including local experts and community representatives and leaders. It may be easy for researchers to overlook important differences between their own health beliefs and practices and those of community members, in ways that can have major practical and ethical implications for the conduct of the trial (including the engagement of the community in, or its rejection of, the trial and any future research). For example, in some areas where infection with *Schistosoma haematobium* is endemic, some people regard blood in the urine as a normal part of a child's development, so an intervention that prevents this may be unpopular, unless this belief is taken account of in planning the intervention. Differences in health beliefs and practices are also likely to exist across the community, making them less easy for researchers to recognize and generating the need for flexibility in the way research is implemented. The preliminary investigations undertaken to explore community perceptions and practices can also begin to sensitize communities in a positive way to the future research. In some situations, these early investigations will reveal that more focused and detailed social science or multidisciplinary studies are needed to explore particular issues (see Chapter 15).

There is a growing body of work documenting experiences with community engagement from many different settings (for example, Cheah et al., 2010; Gikonyo et al., 2008; Marsh et al., 2010, 2011; Reddy et al., 2010; Shubis et al., 2009). These studies illustrate how community engagement and input, particularly where well planned, can improve consent procedures and promote better understanding of the purposes of research among study participants. However, they also illustrate the complexity of doing community engagement well (it can never be an easily ticked off checklist!). It is also important to recognize that community engagement can sometimes lead to unexpected, and sometimes unwanted, outcomes such as raised expectations among community members, confusions about the roles of community members, and conflicts within communities (Angwenyi et al., 2013). These studies illustrate the importance of thinking about community engagement goals, activities (for example, roles of different boards or committees), and monitoring and responding to issues and ideas, as they arise.

2.3. Setting up Community Advisory Groups or Boards

An important initial step to facilitate community engagement in a trial is often the establishment of a CAG or CAB. The exact form of a CAG/B is likely to vary, depending on the context of the trial, but each one is generally made up of representatives of the trial community and serves as a liaison body between the trial team and local communities. Investigators can liaise with the CAG/Bs to ensure there is a clearly articulated engagement strategy which has defined objectives and appropriate approaches to assess effectiveness. Issues of governance, such as the degree of responsibility and formality of the CAG/Bs and their relation to other district and community organizations, must be worked out, according to the specific needs of the trial and circumstances of the community. One engagement approach, adopted by a long-term international research programme in Kenya, has been to have regular interactions with a relatively large network of local residents put forward as representatives by their own communities. This network is consulted on a range of studies for a fixed period of time (Kamuya et al., 2013).

The primary role of a CAG/B is to provide input to study planning, including early stage advice on the acceptability of planned research and how to maximize this, and continuous advice throughout the study, including:

◆ practical study arrangements for transport, follow-up, informed consent, and assent processes at individual and community levels, reimbursements, and study compensations and benefits

◆ consideration of the potential issues and sensitivities associated with the trial in the context in which it will be conducted. For example, past or current exposure to research programmes or interventions may have an adverse or a positive effect on the planning for a future trial. Knowledge and understanding of this history is an important topic to discuss in the early stages of engagement. Since some of these sensitivities and issues are likely to emerge during the course of the trial, rather than being anticipated at the start, the advice of a CAG/B throughout the trial is likely to be important

◆ identification of important people and groups to involve in the trial, for what purpose, and at what stage in the conduct of the trial. Examples include those to consult on study design, the 'gatekeepers' whose support must be

sought, those to assist in creating awareness of the study within the community, and those best placed to provide feedback from the various interest groups about the research activities.

While working through CAG/Bs has been shown to strengthen research relationships and ethical practice, challenges include defining which communities should be represented, selecting representatives as CAG/B members, ensuring clarity in roles and adequate training to fulfil those roles, facilitating appropriate motivation of members, moving beyond tokenism or window dressing, and avoiding politicization. These challenges are most likely for small groups or boards with long-standing, highly formalized structures. A specific set of tensions have been identified around the potentially conflicting dual functions that some CABs have of both advancing the research and protecting the community.

Given these issues and the overall importance of seeking community inputs to trial planning and conduct throughout the trial, it will generally be important for researchers to seek actively to understand the views of a wider range of community members. This will involve the use of a range of different community engagement mechanisms and require the skills of experienced community liaison staff. In complex or controversial situations, social science research methods can help to understand, and sometimes to build on, wider community views to support decision making on appropriate research practice.

Taken together, creative engagement of community stakeholders and champions who have local knowledge and expertise, through CAG/Bs and other formal and informal mechanisms, is important for establishing community rapport and trust, implementing the research, and ensuring community involvement and counsel throughout the execution of the research.

3. Engaging community stakeholders

3.1. Engaging national and regional administrations

Appropriate regard must be paid to the local and national social, political, and administrative structures and procedures. It is important to determine in which order the various preliminary contacts should be made (Figure 9.1).

At the national level, research investigators must comply with appropriate administrative, political, and research consent procedures. These may include obtaining consent from national research councils, ethics committees, and civil society interest groups. With increasing community-based efforts in many LMICs in recent years, many different groups may be active at the research site. Their activities may compete with, or enhance, the proposed research operations. Where other groups are operating in the study area, it is important to create strategic alliances with the programme implementers to ensure their support and cooperation for the various elements of the study. However, investigators must exercise caution, especially if tensions exist between different groups in the communities, as allying the trial to such a group may adversely impact the trial's community partnerships. Religious organizations are often powerful advocates, favoured by the communities, but may be strongly opposed to some intervention strategies or to each other, so it is important to think carefully and act strategically, in terms of how the trial team approaches and relates to them.

3.2. Engaging district health teams and health providers

Generally, research trials are conducted at the sub-national level and therefore require close coordination with local authorities and ongoing programmes and activities at that level. Investigators should seek opportunities for leveraging the interest, advice, and support of the local health authorities, including building synergy between research and routine health care programmes and services, as far as possible. An early meeting with the local health management team(s) for the area covered by the trial (in this book, referred to as the district health management team(s) (DHMTs)) should be arranged to discuss the planned trial, review the specifics of the interventions to be tested, and explore opportunities for partnership in planning and execution. Depending on the relevance of the trial for international and national policy, it may be important to have early discussions with the DHMT on ways in which the new intervention could best be integrated with ongoing programmes if the trial were to show a beneficial effect of the intervention under study. The involvement of MOH health care providers in the research will help align operations, prevent conflict in services and scheduling, and facilitate their perceptions of transparency, so they do not feel threatened or intimidated by the trial. Their endorsement is critical, as study participants are likely to consult them for advice or to alleviate their fears about possible adverse outcomes of the intervention. Physical integration of research activities

within routine health service facilities can also provide opportunities to develop local health system infrastructure, with further positive effects on these key relationships, as well a provide long-term benefits to the community.

The DHMT can also foster community partnerships between the researchers and informal networks of opinion leaders, potential champions, and service providers such as traditional birth attendants, community health workers, and community health councils. Inclusion of influential traditional healers in the community engagement process may also help, since they will be consulted by some community members and are often highly influential within the community. Endorsements from the DHMT and other health care providers trusted by the communities can facilitate subsequent engagement within the communities.

3.3. Engaging community leaders

A multi-pronged, multi-stage strategy may be essential to explore and identify appropriate community leaders from the communities and to ascertain their willingness to support the planned trial activities. Community advocates from the private or public sector, including health providers from the local health facility or district hospital, or researchers who have previously worked in those sites can facilitate the identification of these formal and informal community leaders. They may include village leaders, traditional healers, religious leaders, traditional birth attendants, leaders of women's clubs, farmers' clubs, midwives, or others. The first consultation may involve discreet enquiries to determine these power structures and the level of influence and trust that they have among the community members. Usually, there are multiple leaders, and a CAG/B could include members from among these, with representatives from each community segment that is relevant to the trial—political, geographic, religious, and socio-economic.

Appropriate formative research methods, such as key informant interviews, focus group discussions, and observation (see Chapter 15), can be applied to appreciate local norms and to guide effective and appropriate protocols for community engagement. The best ways of providing the information on the purpose of the trial, potential benefits and risks, roles and expectations within the trial, how best to detect and address potential AEs, etc. can be established through dialogue with key informants within the community. This may be particularly important if the health problem being addressed is a community priority and a placebo arm is part of the study design. If community volunteers are to be engaged for enrolment of trial participants, follow-up, distribution of interventions, or data collection, their recruitment, oversight, and norms for remuneration should be discussed with community representatives, where possible (for example, CAG/Bs or other established mechanisms), as these can be complex (Molyneux et al., 2013). Community representatives can also help with the design of appropriate household and participant consent procedures. Concepts, such as trial 'blinding' and randomization, are not likely to be readily understood by community members, so the investigators should work with community representatives to establish how best to communicate these ideas to potential participants, using local illustrations and rationale.

The duration of this process will depend on the past exposure of the community to research trials, the complexity of the trial or trial-related issues, and the trial team's pre-existing knowledge of the community. In isolated communities, with poor linkages to health personnel or other public entities, the process may need to be longer and require more rigorous dialogues with the community leaders to ensure that locally appropriate ways of interacting are not violated. Some traditional practices may require tokens of appreciation. For example, in some societies, it is appropriate to give a community leader a small gift at the commencement of a formal visit. In others, the norm is for 'visitors' to be given a small gift. These local practices must be within research norms and should not unduly influence participation or compliance. Cultural and language barriers should be considered in approaching the leaders and decision makers in communities. Locally employed community liaison staff, other front-line research staff, and local representatives might assist in selecting a respected advocate who speaks the local dialect or language, where needed.

3.4. Working with the wider community

It is often important and useful for community liaison staff or researchers to introduce the study to the wider community, from which participants may be drawn, at public meetings organized in conjunction with community leaders or representatives. In some situations, CAG/B members or other community representatives may play an important role in this introduction, including explaining the expectations from the community of the trial team and describing the characteristics of the potential participants who will be recruited. Community representatives or leaders must have a reasonable level of understanding of the technical and ethical aspects of the study to take on this initial introduction, since there are risks of important (often inadvertent) misrepresentation.

Early on, it may be sufficient to provide a general introduction to the trial, along with some details of the benefits and potential risks associated with participation. A transparent process should be adopted to solicit questions and to address concerns truthfully. It is critically important to establish mechanisms to ensure that there is a continuing dialogue and interchange between the community and the researchers throughout the trial, and regular meetings with representative groups (such as a CAG/B or community leaders) and periodic open meetings with the community should usually be a part of this process.

Initial public meetings can be used to begin the process of recruitment in some situations by inviting interested individuals or families to attend follow-up meetings that will feed into later informed consent processes.

3.5. Roles of front-line research staff in community engagement

With respect to the engagement of the trial team with the community, it is very important to consider the range of formal and informal interactions that front-line staff (fieldworkers, research assistants, community facilitators, counsellors, health workers) have with trial participants, their families, and the wider community from which participants are drawn. Front-line staff often come from the communities involved in the research and have the greatest amount of formal and informal interaction about the trial (i.e. engage the most) with community members. In mediating between the often very different priorities and concerns of well-resourced research institutions and relatively poor communities without good access to affordable quality health care, front-line staff are not simply neutrally observing and adhering to formal, externally derived ethical rules. Instead, they play a crucial, and often under-recognized and under-supported, role in 'doing ethics' in the field, for example, negotiating tensions between benefits approved in protocols with participants' and communities' needs and demands (Kamuya et al., 2013). In establishing and maintaining interactions and relationships between study participants, non-participants in a community, and research staff, front-line workers also have a central role in the success and quality of the science itself.

Front-line research staff vary enormously in how embedded they are in the communities of a trial, and how embedded they are has differing implications for their social relationships and associated practical and ethical strengths and dilemmas. At one end of the spectrum, staff may continue to live in their own homes and neighbourhoods over the course of the trial, and, at the other end, they may not live in any of the specific study communities but be employed to work across a large geographical area and travel out to work in trial communities every day. There should be careful consideration at the outset of a trial of how different strengths and challenges, related to how closely each member of the trial team is related to the trial community, might be balanced across a team. Where a trial is employing new staff in areas of few opportunities for paid employment, this can be a highly contentious issue. It can be helpful, where possible, to introduce systems that are open and transparent (as opposed to being solely based on, for example, community leader recommendations).

Also important is ensuring careful participatory training and interactions with front-line staff from the outset and throughout the trial. These interactive sessions should be two-way—staff should feel free to make supervisors and PIs aware of gaps in their own understanding, challenges that they face, and ideas on how to strengthen research, and researchers should share their perceptions, understanding, and knowledge of the requirements for trial success. This open, respectful two-way exchange will help the senior researchers to learn about local priorities and concerns and how to respond to these in a way that balances local needs and priorities with trial and (inter)national requirements, while, at the same time, maximizing the understanding and ownership of key trial issues among front-line staff, and hence their ability to communicate these effectively with the trial community. Training and supportive supervision sessions are likely to need to include information on what a trial is and how the rights of participants are protected in trials, benefits to local communities from this trial, and what happens when the trial ends. Role plays and demonstrations, based on local knowledge and experience, can help to develop a range of strategies for field staff to cope with both expected and unexpected scenarios. In some scenarios, such as discussion of highly sensitive topics or where there are interactions with very vulnerable communities, it may be important to ensure that fieldworkers have access to counsellors. Where trials or research programmes are large or long-term, it may be important to professionalize this cadre of staff, including establishing systems by which such workers can, if performing well, advance their careers and increase their remuneration. This may include giving such staff training opportunities.

4. Strategy and content of information for communication

Appropriate communication strategies and content should be designed and developed for different community audiences, depending on the nature of the information to be conveyed in the trial (also see Chapter 23). Depending on

the specific requirements of the trial, these strategies may need to operate at several levels of the trial community, including communication with individuals, specific target groups, or the wider public. For example, community engagement can feed into, and overlap with, consent processes, which are discussed in Chapter 6 and are a clearly key activity in any trial (Participants in the Community Engagement Consent Workshop, 2013). All communication activities must use culturally appropriate methods and take into consideration the target audience's beliefs and norms, numeracy and literacy skills, power structures, gender issues, and other community dynamics that may differ from those of the trial team. Special issues may arise related to the collection of blood, urine, or stool specimens (see Chapter 17, Section 2).

Participatory methods, using visual aids, can be used to illustrate and simplify scientific concepts related to the trial. Community health workers, traditional birth attendants, and other community health care providers with established credibility may sometimes be appropriate people to communicate with community members at various levels throughout the trial. But their motivation, training, other activities, and sustained engagement will need to be managed in collaboration with other community representatives (Angwenyi et al., 2013). Forms of participatory theatre, song, and dance can be effective in introducing new studies in contexts where these are established and valued means of communication. In some settings, radio, roadshows, and mobile phone messaging have been used to communicate with communities about research (Ndebele et al., 2012).

While much of the content of the information to be conveyed will depend on the details of the trial, it will be important in all cases to emphasize general information on the nature of research, including the voluntary nature of participation and the confidentiality of any information provided by the participants. Given common public concerns about safety in intervention trials, it may also be helpful to give a basic explanation of international and national research review processes for all studies and, for trials of drugs and vaccines, the trial phases, so that the current study is widely seen in this context. CABs and front-line staff can provide good support in assessing the appropriateness and comprehensibility of information included in messages and materials to support communication about the trial.

5. Sustaining community engagement

The initial discussions with the community leaders will provide insights for developing good strategies for sustained community engagement. Intervention studies evaluating medical products or vaccines will require close monitoring, and therefore continuous surveillance and frequent engagement with a CAB and other community members. AEs, often unpredictable, may worry local communities, harm the reputation of the trial and its parent research institutions, and damage the credibility of the researchers. Such events need to be appropriately managed. Effective management and reporting mechanisms, with clearly defined protocols, should be established as part of wider community engagement strategies. Informal meetings and fora can be held periodically to engage community members about their perspectives of the trial and to address any concerns in a timely manner. Frequent two-way information flow between the investigators, front-line staff, CAGs, other representative groups, and individual community members can foster trust, ensure sustainability, and enhance management oversight.

In long-term field trials, even if excellent procedures have been established to incorporate the ideas of community members and to respond to concerns at the outset, new expectations may evolve over time, and perceptions may change. Good sustained community engagement mechanisms should ensure that the trial team is aware of these issues, and it will be necessary to work with the front-line staff and representative groups to decide how best to address them.

Some trials may involve community members in substantial inconvenience. If procedures are time-consuming, participants may become fatigued and their initial enthusiasm may wane. Generally, it is important to discuss what time of day, or what time of year, is most convenient for the community members. Sometimes, compensating individuals, in the form of money or food, for time lost from work or other activities may be warranted, and, in some cultures, it may be considered appropriate to compensate the participant if a blood sample is taken. However, this could be a disastrous practice in some settings, as it may fuel commonly held rumours that blood is being bought and sold by researchers. Various strategies have been adopted by researchers to ensure culturally appropriate compensation for trial participation such as through the provision of health care services. These strategies need careful thinking through for each trial, ideally with community input. Mechanisms for referral to appropriate health care and compensation if harm does occur are key elements of trial protocols and could be informed by community representatives. All benefits must be viewed carefully from an ethical standpoint, with the aim of ensuring that people are compensated appropriately, but intra-family and community conflicts are minimized, and individuals are not

'coerced' to participate in the study against their will (Molyneux et al., 2012). See Chapter 6 for further discussion of these issues.

Consideration of the frequency and nature of feedback of results is important in all trials and must be considered from the outset. It is important to distinguish between feedback of individual and of overall (aggregate) trial results.

For individual test results, a common reason for a participant to refuse to provide a second blood sample is that no information was provided regarding the result of tests on the first sample. Sometimes, this problem may be avoided by conducting some laboratory tests on site. For example, haemoglobin, rapid tests for malaria, and tests for a large number of other conditions can be performed in the field. Rapid diagnostic tests for malaria, for example, can be done on the spot, and immediate treatment can then be provided, if indicated. Where this is not possible, individual results can be fed back to participants, and the practical and health implications of doing so for individuals and the research team may need careful deliberation and clear communication with both trial participants and the wider trial community.
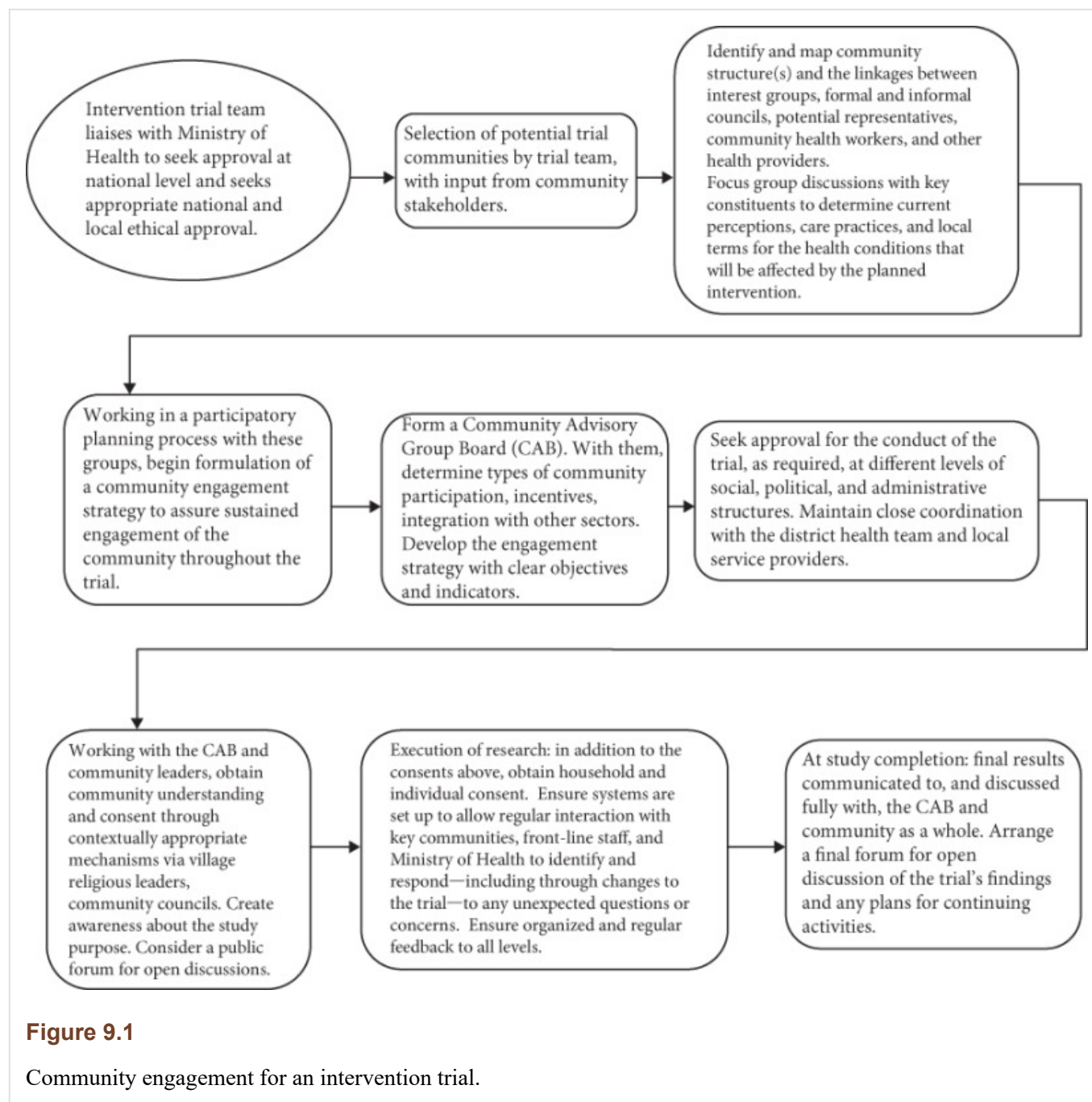
For overall trial results, it is important to keep local health workers and the DHMT informed of the progress of the trial and of the results, as they accumulate and at the end of the trial. Newsletters or district and provincial meetings can be used to communicate the results to them. At the completion of the trial, the final results of the study should be communicated to, and discussed with, the participants and the trial community as a whole. The implications for the community should be discussed with them, as well as with all the authorities involved. Such feedback is essential, not only from an ethical point of view, but it may also pave the way for co-operation in future research activities and for sustained health-seeking behaviour on the part of the community members. For example, research on the feedback of findings from a malaria vaccine trial in Kenya showed that sharing of aggregate findings was very much appreciated and that the inclusion of individual results in feedback sessions reassured participants of trial safety and helped ensure that positive results of the trial were not over-interpreted. Feedback sessions also offered an opportunity to explain key information and respond to emerging community questions and ultimately re-evaluate and re-negotiate trial relationships and benefits (Gikonyo et al., 2013).

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Figures

Intervention trial team liaises with Ministry of Health to seek approval at national level and seeks appropriate national and local ethical approval.

Selection of potential trial communities by trial team, with input from community stakeholders.

Identify and map community structure(s) and the linkages between interest groups, formal and informal councils, potential representatives, community health workers, and other health providers.
Focus group discussions with key constituents to determine current perceptions, care practices, and local terms for the health conditions that will be affected by the planned intervention.

Working in a participatory planning process with these groups, begin formulation of a community engagement strategy to assure sustained engagement of the community throughout the trial.

Form a Community Advisory Group Board (CAB). With them, determine types of community participation, incentives, integration with other sectors. Develop the engagement strategy with clear objectives and indicators.

Seek approval for the conduct of the trial, as required, at different levels of social, political, and administrative structures. Maintain close coordination with the district health team and local service providers.

Working with the CAB and community leaders, obtain community understanding and consent through contextually appropriate mechanisms via village religious leaders, community councils. Create awareness about the study purpose. Consider a public forum for open discussions.

Execution of research: in addition to the consents above, obtain household and individual consent. Ensure systems are set up to allow regular interaction with key communities, front-line staff, and Ministry of Health to identify and respond—including through changes to the trial—to any unexpected questions or concerns. Ensure organized and regular feedback to all levels.

At study completion: final results communicated to, and discussed fully with, the CAB and community as a whole. Arrange a final forum for open discussion of the trial's findings and any plans for continuing activities.

Figure 9.1

Community engagement for an intervention trial.

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