9.2: 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 behavior, 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.

Figure 9.1 Community engagement for an intervention trial.

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 as- sent 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.