9.3: 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 inter- vention 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 appropri- ate 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 intro- duce 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 im-
portant 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 re- search 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.