9.5: 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 ‘co-erced’ 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 behavior 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).