16.1: Introduction to field organization and ensuring data of high quality

The complexity of the organization of a field trial will vary, according to the planned size of the trial population, the frequency of follow-up, the expected duration of the trial, and its location. For example, a trial of the long-term effects of a hepatitis B vaccine in The Gambia involved enrolling a population of 120,000 infants, many of whom lived in remote rural areas, and linking their vaccination status to outcome events measured several decades later (The Gambia Hepatitis Study Group, 1987; van der Sande et al., 2007). Such a trial is a much more complex undertaking than, say, a trial to assess the immunogenicity of a new measles vaccine, involving a few hundred subjects, conducted in or near a major population centre and completed within a year or two.

Whether a trial is small or large, it is important to plan the organization of the trial in detail before starting any substantial field activities. The design of the trial should be reviewed to identify all the procedures and tasks that it is necessary to undertake to meet the study objectives, and the logistics developed to carry out these procedures and tasks in a timely fashion. During this planning, it may become clear that compromises have to be made between what is theoretically desirable and what is logistically possible. For example, in a vaccine trial, it may be of great interest to relate the immune response to vaccination to subsequent protection against disease on an individual-by-individual basis. This would involve collecting a blood sample from all participants before vaccination, shortly after vaccination, and possibly at repeated intervals thereafter. In practice, it may not be feasible to do this in the full trial population, for reasons of cost or because those in the trial population would not accept repeated blood samples being taken. Thus, relating protection against disease to individual responses to vaccination might have to be excluded from the objectives or restricted to a substudy in selected trial participants.

A checklist of some of the most important items that it may be necessary to consider when planning a field trial is given in Box 16.1. Trial investigators should draw up a detailed and specific list tailored to the requirements of their particular trial.
It is important that the field team understands, and is sensitive to, local customs and cultures. This will be facilitated if many of the field team members are recruited from the community in which the trial is to be conducted. The planning for the trial must take into account cultural practices that may affect both the acceptability of the trial and the organizational arrangements for conducting it.

In planning the organization of the trial, it is critical to always keep in mind the overall objectives of the trial, as specified in the study protocol. Detailed planning should start at an early stage, as, once activities get under way, it is easy to ‘lose sight of the wood for the trees’, unless there is a clear plan of activities to refer to. A checklist that covers some of the most important organizational aspects of field trials is given in Box 16.2.

Box 16.1 A checklist for planning a field trial

1. Proposed trial
   ◦ Title
   ◦ Purpose
   ◦ Type
   ◦ Population included: location and numbers involved
   ◦ Expected duration of trial
   ◦ Persons in charge: both central and field
   ◦ Address, phone/fax numbers, website, and e-mail addresses of trial headquarters
   ◦ Initiate a field manual and study diary to record all decisions and changes made during planning and conduct of trial (see Section 2)

2. Clearances: legal and ethical
   ◦ Local authority (district health officers, local government)
   ◦ Police
   ◦ Government—MOH—others, as appropriate
   ◦ Local population—informed consent procedures

3. Location
   1. Climate
   2. Geographical features
   3. Maps
   4. Roads, including routes, distance, and time taken to travel between survey sites in different road conditions
   5. River conditions
   6. Airstrips (where relevant)
   7. Electricity supply
   8. Mobile phone network coverage
   9. Internet access

4. Data collection and storage
   ◦ Type
   ◦ Regularity
5. Staff requirements
   ◦ Functional categories
   ◦ Number
   ◦ Existing/new staff
   ◦ Training and support/supervision requirements

6. Accommodation
   ◦ Location (survey team, support group, females/males)
   ◦ Tents/housing arrangements
   ◦ Electricity
   ◦ Water

7. Supplies
   ◦ Immediate
   ◦ Replenishments
   ◦ Stockpile
   ◦ Ordering and recording systems
   ◦ Food/cooking
   ◦ Water/purification
   ◦ Fuel (vehicles, electricity generators, cooking, etc.)
   ◦ Refrigeration

8. Transportation
   ◦ Vehicles (for example, cars, motorbikes, bicycles, boats)
   ◦ Maintenance
   ◦ Tools (for repairs, but also for digging them out of mud holes, and for emergencies—such as reflective vests and emergency triangles)
   ◦ Spares

9. Equipment
   ◦ Field
   ◦ Laboratory
   ◦ Survey equipment
   ◦ Record forms
   ◦ Questionnaires
   ◦ Computer hardware
   ◦ Computer software
   ◦ Stationery
   ◦ Chemicals
Generator
Waterproofing
Photographic equipment
GPS equipment
Electronic data collection equipment (PDAs, tablet computers, mobile phones, etc.)
Tape recorders
Mobile phones
Backup generators (and backups for other vital equipment)
Medical care for staff (for example, drugs and instructions for needle-stick injuries)
Medicines and drugs for participants
Records
Other equipment

10. Specimens
Receipt and handling (for example, gloves, sharps disposal boxes)
Pick-up schedules
Refrigeration containers
Instruction slips for participants
Labelling and other recording supplies

11. Other
Develop field manual
Data entry equipment, staff, and systems
Other communication equipment (for example, email, Internet, radio)
Written SOPs for every aspect of the trial
Job descriptions, staff contracts, and a human resource manual
Bank and accounting systems

Box 16.2 A checklist of organizational activities for a field trial
The activities are listed in the order in which they might be done.

**Planning**

- Define the trial question(s), and work out the implications of these for the planning of the trial.
- Develop the preliminary study design that includes the purpose and estimates of population size and duration of the trial.
- Consult with MOH officials at headquarters and district levels.
- Consult those with relevant experience in local district government, community leaders, and health workers.
- Visit local communities to discuss the trial, and learn about the local population, their needs and perceptions, and how the proposed trial would fit into their priorities.
- Choose an appropriate population sample for the trial.
• Decide which observations and measurements are needed, and standardize the techniques.
• Conduct preliminary studies (for example, qualitative, feasibility, or validation studies).
• Design and pilot-test record forms and questionnaires (electronic and/or paper).
• Make arrangements for staff recruitment, training, and supervision; secure equipment, transport, and finance; arrange accommodation.

**Organization**

• Obtain co-operation from local leaders.
• Develop a manual of field operations and all specific SOPs.
• Train survey staff.
• Arrange for laboratory procedures and specimen storage, both short- and long-term.
• Draw up a daily work plan for all staff.
• Pilot-test all organizational details.

**During the fieldwork**

• Supervise and provide feedback to all staff to ensure their work is at a high standard throughout.
• Monitor participant compliance and follow-up with representatives of the trial participants and local leaders if there are problems.
• Make both scheduled and unscheduled checks on all study procedures.
• Conduct regular staff meetings for reporting progress, discussion of problems and potential solutions, and for maintenance of morale.

**Analysis and communications**

• At an early stage, develop an analytical plan for each phase or round of data collection, and for the trial as a whole.
• Enter data into a computer, and then check and analyse it as soon as possible.
• Make regular checks on the data, preferably daily, to assess quality and completeness.
• Discuss results and their interpretation with health workers, community leaders, or others (as appropriate) to obtain their feedback and comments.
• Write a report, incorporating comments on the trial's strengths and limitations, its results, and recommendations for new or improved health programmes.
• Distribute the report, and discuss the trial's findings and recommendations with relevant local authorities, other organizations, and with local and international media, as appropriate.
• Disseminate the trial results and policy implications, using multiple dissemination channels—not just the main technical report. The audiences should include study participants and/or their representatives locally, nationally, and internationally, as appropriate, for example, through meetings, newsletters, press releases and/or radio programmes, peer-reviewed journal articles, policy briefs, on the organization’s website, presentations at conferences, etc.
• Take steps to try to ensure that appropriate action is taken, based on the trial’s outcomes, at international, national, and local levels.

• Consider evaluating any changes introduced as a result of the trial to estimate their effectiveness.