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Chapter 16 Field organization and ensuring data of high quality

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.

2. Manual of field operations and study diary

The tasks and procedures necessary to achieve each objective of a trial should be listed. A manual of field operations should be prepared, in which each procedure to be carried out is detailed and each task described fully (for example, step-by-step instructions for the administration and completion of questionnaires, the method to be used for weighing infants, including maintenance procedures for the weighing scales, checklists for equipment, and the materials required for each procedure). Each fieldworker should be given a copy of the manual, or of those parts of the manual that are relevant to their work, and these must be updated if changes are made to procedures, as the trial progresses. The field manual for the trial should not only provide a clear set of rules for actions under different circumstances, but it can also serve as a long-term record of the detailed design aspects of the trial. This latter feature may be of special value in trials of long duration where investigators may change or they may forget previous decisions or the reasons for them.

In addition to the field manual, it is very valuable to maintain a trial diary, in which the progress of the trial is recorded, problems noted, and solutions recorded. This will be useful in maintaining consistency of decisions throughout the trial. These notes may be of value for final reports on the trial, in which documentation of particular

events during the course of the trial may be needed (for example, recording exactly when a particular disease epidemic took place or when fieldwork had to stop because of adverse weather conditions or civil disturbance).

To guard against loss and to facilitate the subsequent search for events of interest, it is recommended that the diary is maintained as a computer file with backups, rather than just in a paper notebook. The latest version of the field manual should also be stored electronically, so that it can be updated and modified easily.

3. Personnel issues

Field trials may involve a large number of personnel, often for considerable periods, working under difficult conditions, and the staffing arrangements must be well organized. Each person should know what they have to do and when they have to do it, to whom they should report, and when, where, and how they should do this. A job description should be prepared for each position, incorporating the tasks specified in the field manual. Preparing such job descriptions forces the investigator to work out in advance what each individual will do, and then inform each worker formally what is expected of him or her. The job descriptions specify not only the tasks to be undertaken, but also the workload (for example, the approximate number of thick and thin blood films to be collected per day) and the quality of work expected. The minimum educational levels and training required for each position should also be specified. Personnel for the posts should be recruited and trained for their specific tasks, based on their job descriptions. Training should include an overview of the objectives and flow of the study, research ethics, especially related to confidentiality and relationships with study participants, reporting and supervision systems, personal safety and security, and training on the specific tasks for that position. It may also need to include training related to teamwork and communication skills, and information technology skills (such as the use of laptops, PDAs, mobile phones, or tablet computers for data collection, or the use of GPS devices). Increasingly, it is expected or required that at least relatively senior personnel have received basic training and ideally have been certified in ‘GCP’ (see Section 7).

It may be beneficial to provide staff with initial training in more than one set of tasks, as this will allow easier transfer of staff between positions, if necessary. Managerial and supervisory activities, with appropriate hierarchical relationships and lines of authority, need to be established. An organizational chart illustrating the lines of authority may be useful. Each staff member should be broadly familiar with the responsibilities of other staff. Staff should be made aware of health and safety procedures, for example, what to do if there is a road traffic accident or an armed robbery or someone has a needle-stick injury (see Chapter 17, Section 8).

The composition of the field team should directly reflect the specific activities they must undertake. It might include, for example, a driver, a registration clerk, one or more interviewers, an assistant to take temperatures and to measure heights and weights or to test eyes, a clinician for physical examinations and the application of any clinical intervention procedures, a laboratory technician to collect blood, urine, or stool specimens for laboratory tests, and a medical or pharmacy assistant or nurse for dispensing medications. A constraint on the size of a field team may be the number of persons who can be accommodated in the trial vehicle, along with the equipment they must use in the field. It will be useful to draw up an organizational plan outlining the activities and functions of the members of such a team, with a diagram showing how the team will operate in the field. This should include a careful, and if possible, pilot-tested, estimate of the average and range of times that each participant is expected to take at each step in the field survey. Ideally, these times should be approximately equal for each step to avoid bottlenecks developing. To achieve this, it may be necessary to have different numbers of workers at individual steps in the participant flow. For example, in a follow-up survey in an adolescent HIV prevention trial in Tanzania, the main survey team of 14 people included two drivers with their vehicles, a team leader, one registration clerk, two male and two female interviewers, a laboratory technician and laboratory assistant, a nurse who supervised young women taking self-administered vaginal swabs, two HIV testing counsellors, and a clinician (who also did dispensing).

Detailed descriptions of the procedures to be followed for each of the activities should be included in the field manual (for example, how the census form should be completed, how the items on the form should be checked, what should be done with the form at the end of the day).

Frequent and effective supervision of field activities is essential for ensuring the collection of high-quality data (see Section 7.2), but also for keeping the fieldwork moving, according to the timetable, for maintaining field team morale, and for preventing the escalation of any disputes or disagreements. Field team leaders have primary responsibility for the activities of their team, and they should regularly report progress and any problems or issues arising to the field supervisors. The field supervisors should, in turn, report to the project coordinator who monitors overall progress of the study and reports to the PIs, government officials, and funders.

Mobile phones are commonly used during supervision of field activities. For example, they might be used by field team leaders to provide supervisors with daily updates which include basic data on the number of participants seen, refusals, and any problems encountered via text messages or phone calls. Supervisors, in turn, can use mobile phones to advise and guide team leaders and to provide field teams with lists of participants or households to interview or re-interview. Prompt transfer and data entry of completed paper questionnaires can aid supervision through providing early and frequent feedback to field teams on data inconsistencies or errors. Wireless transfer of data collected in the field to the central data section, either via the Internet or mobile phones, is increasingly being used and offers increased opportunity for the early identification of problems with data collection or the interpretation of questions by participants. Such data transfer should be encrypted and password-protected to ensure it remains secure and confidential. Timely transfer of field data to the central or field trial office allows databases of the data collected to be kept up to date and delays or other problems can be acted on promptly.

It is essential that checks on data quality are incorporated into routine field procedures. Examples of these are given in Section 7. It is also important to keep a close check on the arrangements for laboratory specimen collection, storage, and shipment back from the field to the base laboratory (see Chapter 17).

As a general principle, the designer of fieldwork procedures should think carefully of everything that could realistically go wrong and put systems in place for what should be done in the event that these problems occur, for example, what should be done if one or more team member falls ill, a vehicle or other piece of equipment, such as a centrifuge or freezer, breaks down, or if a national holiday is declared at short notice. Overcoming such problems may require staff being trained to be able to fill in for each other, there being two of each vital piece of equipment, or the potential for emergency repair or replacement of equipment. The details of what should be done will partly depend on the remoteness of the field work from the trial coordination centre.

Field teams that spend extended periods of time in the field can be prone to internal disputes and disagreements, and the importance of good team dynamics and team leadership should not be underestimated. In some circumstances, movement of staff between teams during the course of the trial can be beneficial, for example, to strengthen a weaker team or to improve team dynamics.

Good financial management is essential for staff morale. Salaries and allowances should be paid on time, and staff provided with medical insurance cover and legal protection against being sued in relation to their trial work. Petty cash should be available when required. A detailed record of expenditures should be kept together with receipts, as a senior staff member will have to account for all funds issued and spent. For large studies, it will be essential to employ an administrator to take care of these aspects, as they may be very time-consuming. Systems must be put in place to prevent fraud, and staff should be made aware of the policies regarding accountability when equipment or supplies go missing or are stolen (see Chapter 18).

4. Physical location and facilities

An issue to be resolved early in the planning of a field trial is whether the study participants should be seen at a central location, at a series of local assembly points, or be visited on a house-to-house basis. The decision will depend upon the procedures to be carried out, the nature of equipment required, the time the study procedures take, the population size, density, and distribution, and the environmental and physical conditions.

A central assembly point may be most efficient for the study team, since more people can be seen in a day than in a house-to-house survey. If heavy or delicate non-portable equipment must be used, then a central assembly point cannot be avoided. Even if some of the data collection or physical or laboratory examinations have to be done at a central location, it is often advisable to conduct the census, and sometimes questionnaire interviews, at the houses of participants.

One advantage of a house-to-house survey is that it is possible to be reasonably sure of being able to compile a list of most of those who are eligible for the trial. Any persons who do not report to a central assembly point can then be identified, and, if necessary, attempts made to find them. Individuals who are not present during the home visit might be able to attend the central assembly point at another time. Tracing those missing can be costly and time-consuming, and decisions about the benefits of doing this, as compared to the time and effort required to visit individual households, need to be considered in the planning phase. Also, the likely magnitude of ‘non-response’ may need to be estimated during the pilot phase (see Chapter 13). Sometimes, a combination of both approaches may be suitable, whereby someone visits each household to conduct a household census and identifies all potentially eligible individuals who are given an appointment to go to a central location for the actual data collection.

Careful planning of the physical layout for the flow of people from one part of the field station to the next is important. Special attention may have to be given for carrying out the physical examination, in order to ensure both privacy and adequate light. Usually, there is little difficulty about making such arrangements when the examinations are conducted at a central assembly point, but, for more mobile surveys, special arrangements may be necessary, ranging from simple screening under a shady tree to the use of a tent with special lighting.

In addition to whatever arrangements are made for the interviewing, examinations, and specimen collection from study subjects, there are supporting functions that will require physical facilities. These include a headquarters for administration; a room for team training courses, meetings, and review of activities and problems on a daily basis; space for computer processing of data; file storage space; laboratory accommodation; stores for equipment and supplies; and transport garaging. The various components may be needed at one place or at several places or may need to be mobile.

If the field team must live away from home for long periods, they may be able to obtain local accommodation, but other accommodation might have to be provided (for example, tents). Accommodation and cooking facilities should be arranged in advance, and employment of a cook will save on staff time and improve staff morale (if the cook is good!). Food may need careful storage and cooking, in order to avoid food poisoning. Water for drinking may need to be purified, filtered, or boiled. Refuse disposal and toilets may also be needed.

Where the field teams will use electrical equipment for their activities, a reliable source of electricity will be required. Even if there is a normally reliable local electricity supply, some form of backup supply should be considered. In some cases, using solar power or project vehicles to charge equipment may be sufficient, though it is usually wise to have an additional backup source such as a portable generator. In some places, there will be no local mains electricity, and then it is essential for the team to have their own electricity supply and strongly advisable to have a backup for that too in case of malfunction. Similarly, ease of access to the Internet and the quality and extent of mobile phone network coverage should be taken into account if field teams will be expected to communicate with headquarters in these ways.

5. Equipment and supplies

The major items of equipment and reagents required must be specified in the study protocol. The choice of what technical equipment to buy should be influenced by what the investigators or others in the field have used and whether it has been found to produce valid results and is reliable in the specific field contexts required (and this will include servicing arrangements). The power requirements of electronic equipment should be considered prior to purchase. Some equipment and supplies may need to be pre-ordered from abroad, as they may not be available locally, so considerable pre-planning may be required. This is likely to be particularly relevant for the clinical and laboratory equipment and supplies (see Chapter 17). It may be important to order a basic supply of spare parts at the same time as ordering equipment, if local availability is in doubt. Purchasing of equipment and supplies locally can be open to many kinds of fraud (see Chapter 18), and steps should be taken to ensure not only that a fair price is obtained, but also that the goods are genuine and of high quality.

The field manual should include lists of all the equipment required for each of the trial procedures (for example, record cards, questionnaires, needles and syringes, laboratory supplies) and for the support of those procedures (for example, vehicles, filing cabinets and files, benches, screens, tents). Providing ‘packing lists’ to individual team members and checking that they have all the items on their list prior to departure from headquarters each day can reduce the number of requests from the field for additional supplies. Systems need to be put in place to ensure that maintenance and quality control of equipment is carried out, according to a standard schedule. Some laboratory equipment will need standardization, validation, servicing, and revalidation (see Chapter 17).

Provision for transport is essential in most LMICs. One of the most expensive items of equipment are trial vehicles, so the decision as to whether to purchase or hire them, and, if purchasing, whether to buy new or second-hand, requires careful consideration and price comparisons. Key issues are not only the capacity, purchase price, or daily hire price, but also fuel consumption, type of fuel and its local availability and price, and vehicle maintenance and reliability. It is a false economy to purchase a cheaper vehicle if it is more liable to break down, losing days of work, while it is repaired or dug out of the mud. It is also important to check whether the funding agency imposes restrictions on which vehicles can be purchased or how vehicles should be disposed of at the end of the trial.

Transporting people and equipment will require careful planning. Extra time should be allowed for possible mishaps. If possible, backup transport should be available in case of emergencies. Maintenance of vehicles and close

supervision of their use are essential. Control and discipline of vehicle use are key factors in the conduct of almost all field trials. Particular problems may arise if field staff are issued with vehicles (for example, motorcycles) that they keep at home, rather than return to a central parking place on a daily basis. When staying overnight in the field, all vehicles should be parked overnight in a secure site, such as the guesthouse or hotel where the team are staying where there is a security guard. If necessary, a guard should be hired for this purpose.

Great care should also be taken in hiring drivers, and a practical driving test that includes a section that mimics difficult field conditions should be included. It is important to remember that having a good, safe driver could not only save considerable time wasted through breakdowns or getting stuck in mud, but may also save the lives of field team members. Linked to this, strict rules as to who may and who may not drive the trial vehicles and for what purposes should be specified and enforced.

Maintenance, fuel supply, and the use of vehicles for purposes other than those for which they were intended can pose substantial problems. Careful monitoring of vehicle fuel consumption is essential, as it is not uncommon for drivers to supplement their income through fuel fraud. Common tricks include having an agreement with the fuel supplier that the receipt will show a larger volume of fuel than is actually given, siphoning off fuel, or unauthorized use of the vehicle (for example, as a taxi). Although each such theft only costs the project a relatively small amount, fuel often accounts for a substantial proportion of the non-staff recurrent costs of a field trial, and the losses can quickly add up to a sizeable amount. As well as each vehicle having a logbook with each journey requiring signed authorization by a senior member of staff, other useful techniques for minimizing fuel fraud is to allocate each vehicle to a single driver, with checks on prior fuel consumption carried out whenever the vehicle passes from one driver to another, and regular checks of fuel consumption, with the record being from full tank to full tank.

Illicit exchange of vehicle parts by vehicle mechanics is also not uncommon, either with or without the driver's knowledge. Again, this can be minimized by selecting a reputable garage and, if necessary, marking key vehicle parts. Vehicle theft can jeopardize a field trial, so, where possible, it is very important to fit vehicles with a satellite tracking device, an immobilizer, and a gear-locking device.

Of all vehicles, motor bicycles are the most dangerous. They are often driven by fieldworkers who are young men who enjoy the status that the motorbicycle gives them and may be prone to showing off. Very strict monitoring of their use is essential. All the rules given above should apply to motorbicycle, as well as other trial vehicles, plus all motorbicycle users (drivers and their passengers) should always wear a full-face helmet. Motorbicycles are less stable, particularly in muddy or sandy conditions, when carrying two (or more!) people, rather than one, so this should be avoided, whenever possible.

Loss of other stores and supplies can also be a major problem, particularly due to theft. A staff member at the trial base should be appointed to be solely responsible for all the stores, maintaining inventories and issuing items. Each item issued should be signed for by an individual team member who should also be expected to sign the store inventory book upon return of the item. Transferring equipment between team members in the field should be discouraged and, if necessary, should be accompanied by documentation signed by both team members. Staff should be provided with an SOP for equipment, which includes instructions on the correct use, storage, maintenance, and charging of the equipment. Staff need to know what to do when equipment is lost or stolen or stops working properly. It is advisable to provide field teams with extra backup equipment. If this is not possible, such as for large or expensive laboratory equipment, plans should be in place to deal swiftly with breakdowns.

6. Timetable for field activities

An organizational timetable should be constructed which shows all of the field activities and indicates when each will be undertaken. An example of such a timetable, for a trial of the effect of regular vitamin A supplementation on episodes of diarrhoea and respiratory infections, is shown in Figure 16.1 (Betty Kirkwood, personal communication). The dates for fieldwork may have to be fixed some time in advance. The time required for preparations and pilot testing may overlap with training, but all three must be completed before the start of the main fieldwork. Similarly, analysis and consultations should be completed, before the final report is produced.

The planning of trial activities must take account of climatic and seasonal factors. These may affect access to the trial area (for example, flooding) and the activities of those in the area such as to make them difficult to survey (for example, seasonal migrations for work, working on farms during the planting or harvesting seasons). It may be important to plan activities to take into account market days, local holidays and festivals, and activities of the local medical services (for example, antenatal clinics). Also, adequate plans must be made to allow for staff leave (both

annual leave, sickness absences, and compassionate leave such as to attend funerals or to look after a close relative). The timetable should fit into local practices, if possible (for example, in Muslim countries, if most people do not work on a Friday, the trial should be planned to fit in with this).

7. Ensuring data of high quality

To be able to derive reliable and accurate conclusions from a health intervention trial, it is important to ensure that all processes and procedures, at all stages in the conduct of the trial, are performed at high quality. The many steps involved in planning and carrying out trials are described in the other chapters of this book. Here, we focus on the actions needed to ensure that all data collected are of high quality and that this high quality can be demonstrated both to those directly involved in the trial and to all those external to the trial but who have responsibilities or interests in relation to the trial. The general principles and some of the terminology that is commonly used related to what is called 'Good Clinical Practice' or 'GCP' will be described, but this chapter is not a GCP manual. Investigators who require formal training in GCP should contact a local internationally accredited institution that offers such training or one of the many internationally accredited online courses that are available from groups such as the Clinical Research Network of the United Kingdom (UK)'s National Institute for Health Research (<http://www.crncc.nihr.ac.uk>) or the OnlineGCP Group (<http://www.onlinegcp.com>).

If high-quality data are to be achieved, the investigator and all of the trial team must accept the need for rigour in the collection of all data and in the checks built into every step of the trial.

7.1. Regulatory requirements and good clinical practice

The ICH (1996) (<http://www.ich.org>) is an internationally accepted set of standards that are intended to apply to all research on human subjects. It is mainly applied in the context of trials of medicinal products, but increasingly there is an expectation that observational epidemiological studies will be conducted to a similar standard. The aim of the guidelines is to ensure the safety and rights of all participants in the research study, while, at the same time, ensuring that the study is likely to achieve valid and reproducible results.

Based on the ICH–GCP guidelines, regulatory bodies, such as the US Food and Drug Administration (<http://www.fda.gov>) and the European Medicines Agency (<http://www.ema.europa.eu/ema>) have set out a rigorous series of procedures and checks that must be followed in clinical trials of new drugs and vaccines to provide the standard of evidence necessary for the licensing of a new product. There is a widespread misconception that all trials (including field trials of social or public health interventions or of alternative delivery mechanisms for licensed drugs or other medical products) must meet all requirements of such regulatory bodies—often called being 'fully GCP-compliant'. This is not the case, and some flexibility is appropriate as to exactly how closely the GCP guidelines are implemented for non-licensing trials (i.e. of an intervention for which a licence is not being sought from a regulatory agency). However, all trials should comply with the basic principles contained within the ICH–GCP guidelines. The basic principles are that all studies involving human subjects should be conducted ethically (including that the interests of participants should be central to the trial design and implementation) and that all data collected should be of high quality and be likely to be valid. Furthermore, the investigators must be able to demonstrate that both these fundamental principles have been met. A trial can comply with the principles of GCP without meeting all the regulatory requirements for the licensing of a new product. This is important, since the full regulatory requirements are very demanding and will greatly increase the cost and human resources required. At an early stage in the planning of any trial, and certainly before any proposal is submitted to a funding agency or ethics committee, the PI and sponsor must make a clear decision as to whether their proposed trial needs to be 'fully GCP-compliant'. As discussed in Chapter 2,many field trials in LMICs do not test investigational products but test the effectiveness of alternative delivery strategies for licensed products, or test interventions that do not include any medicinal products at all, such as trials of health promotion or other public health interventions.

The key individuals and institutions that have responsibility for ensuring that a trial is complying with the principles of GCP have been defined in Chapter 7. The trial sponsor has overall responsibility for all aspects of the trial; the PI has primary responsibility for ensuring that the trial is carried out according to protocol; and the ethics committee (sometimes called the Institutional Review Board (IRB)) has primary responsibility for monitoring the ethical aspects of the trial. To ensure trial data are of high quality, the sponsor 'should determine the appropriate extent and nature of monitoring which should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial' (International Conference on Harmonisation, 1996).

7.2. Supervision and data checks

Although, in some large trials, someone is designated to be the overall quality manager, the entire trial team should have data quality at the forefront of their minds. From the start, the investigator should assign quality assurance tasks to the team and build quality assurance (QA) processes into the trial procedures.

The two key principles for obtaining high-quality data are to plan ahead and to check everything. Nothing should be taken on trust, and, while remaining optimistic, it should be assumed that anything that could go wrong might go wrong!

Key issues in data quality are covered in other chapters: clear case definitions and valid measures of all trial outcomes in Chapter 12; preliminary studies and pilot tests in Chapter 13; questionnaire design, selection, and training of fieldworkers in Chapter 14; and some of the checks that can be done on the quality of the data collected are given in Chapter 20. In this chapter, we focus on steps that can be taken once fieldworkers have been deployed at the end of their initial training to ensure both that the data that they collected is of high quality and that this high quality can be demonstrated to external trial auditors. Most of these activities fall under field supervision.

In successful field supervision, prevention is better than cure. A supervision system should be designed not only to detect problems and provoke responses to solve them, but also to prevent problems from occurring in the first place. For example, if fieldworkers know that every piece of data they collect might be checked but have no way to know which pieces will actually be checked, they are more likely to always be careful. Conversely, if the fieldworker knows that only data collected on a Tuesday will be checked, then he or she may be less conscientious on other days.

Also, it is important to institute a system for checking all data collected, and especially data critical for identifying and linking data on the same individual throughout the trial. Examples of checks that should be built into field supervision include checks of completed forms, observation of work, replicated collection of a sample of data, checks without repeated data collection, review of errors detected after data collection, and checks with participants and community representatives.

The record forms that each fieldworker completes should be checked for accuracy and completeness. Because of delays between data collection and entering the data into a computer, if paper forms are used, some preliminary checks should be done before the forms are submitted, while the fieldworker is still in the vicinity of the participant, and before the participant's situation may have changed. When the data are directly entered electronically, checks for data completeness, range, and consistency can be incorporated into the data capture program.

Each fieldworker should receive regular scheduled visits from their supervisor, during which the supervisor observes them carrying out their routine data collection tasks and gives them constructive feedback and a chance to discuss any issues that they have faced. These scheduled visits should be particularly frequent during the early phases of the trial. Observation tests whether the fieldworker knows how to carry out their tasks (competence) and can do so when being observed, and provides an opportunity for the supervisor to identify and correct any problems with their understanding of how the data should be collected. For example, they may have misunderstood how to measure a child's height or may not be asking questions exactly as they are written in the questionnaire. However, it does not show whether they actually do so when they are not being observed (performance) (see later in this section).

Throughout a survey, it is important to monitor the performance of each interviewer and to institute corrective training, if required. One means of quality control (QC) is to organize for a proportion of respondents (selected at random) to be re-interviewed by another interviewer. Discrepancies in the two interviews may identify deficiencies in the interview methods of one or other interviewer. It is not an uncommon experience in large surveys that some interviewers complete some questionnaires without ever having seen the 'respondents'. A good system of checking, supervision, and QC is necessary to prevent this, or at least to detect it soon after it occurs, so that remedial action can be taken.

To check whether the fieldworker actually collects the data correctly when not being observed, unscheduled checks need to be implemented. For example, in a field trial of vitamin A supplementation in northern Ghana, each fieldworker received unscheduled, as well as the scheduled, visits from the supervisor, who would ask permission to sit in on any interview that was happening or about to happen when they arrived and then collect the forms that the interviewer had completed earlier that day. These would be sealed in an envelope in front of the fieldworker. The supervisor would then go back to the previous five households that had been visited that day. In two households, they would merely ask the household whether the fieldworker had actually visited them, conducted an interview with an

appropriate person, and taken the appropriate biological specimens from them. This checked that the fieldworker was not fabricating the data. In the other three households, they would request an independent partial re-interview of the trial participant. When they returned to the trial office, the supervisor would then submit their own forms and the original forms collected by the fieldworker, and the data centre would generate a comparison of the two.

Various checks can, and should, be carried out after data collection. For example, all data incompleteness (for example, missing items on the questionnaire) or variables that are out of range (for example, an infant's weight being recorded as 100 grams) or inconsistent (for example, a woman recorded with penile warts or a person recorded with fever in one part of the questionnaire but afebrile in another) should be identified. It is useful for all such errors to be tabulated on a regular basis by the fieldworker and the field team. Such tabulations will show which fieldworkers or field teams have more errors detected. The reasons for these can then be investigated, and steps put in place to rectify them. One method that has been used for this has been to send data queries back to the fieldworker. For example, if a check shows that a participant's height is lower than it was in a previous study round, the fieldworker can be asked to go back to collect that participant's height again. Ideally, the fieldworker should not be told why they are being asked to re-collect the height, let alone what they had entered the height as during their recent visit or during the previous round. In the field trial of vitamin A, this method was extended, so that each fieldworker received some such requests, even when there was no reason to suspect an error in the data. These checks occasionally identified errors that were not detectable by routine range or consistency checks.

Finally, it is important that the trial team has periodic meetings with participants or their representatives and with other members of the trial communities to check that they are happy with the activities of the fieldworkers and their supervisors.

An important principle is that every error or problem that is detected should provoke a response. This is for two reasons. First, if errors are not investigated and acted on, the effort of detecting them is wasted, and also the field staff may interpret this to imply that the importance of data quality is being neglected. Second, since it is never possible to check every piece of data collected, any errors that are detected are likely to be the 'tip of the iceberg'.

The actions taken when errors are detected should not generally be punitive but should include support and further training to help the fieldworker improve. However, if this fails to correct the problem, or if the errors have come about through data fabrication, disciplinary mechanisms should be in place, and ultimately these may need to include termination of employment.

It is important that field staff are aware of all the types of checks that will be conducted on the data they collect. This is partly to avoid their feeling that they have been spied on behind their backs, but also so that they will be encouraged to ensure that all data are collected as well as possible.

It is a good plan to have weekly fieldwork meetings which include reports from individuals, on progress, work accomplished, identified problems and how they were solved, queries, etc. This also provides an opportunity for systematic feedback from the central administration on fieldworker performance, including results of repeat interviews for quality checks. Meetings of this kind may greatly assist in maintaining staff morale and improving the quality of the data collected.

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Figures

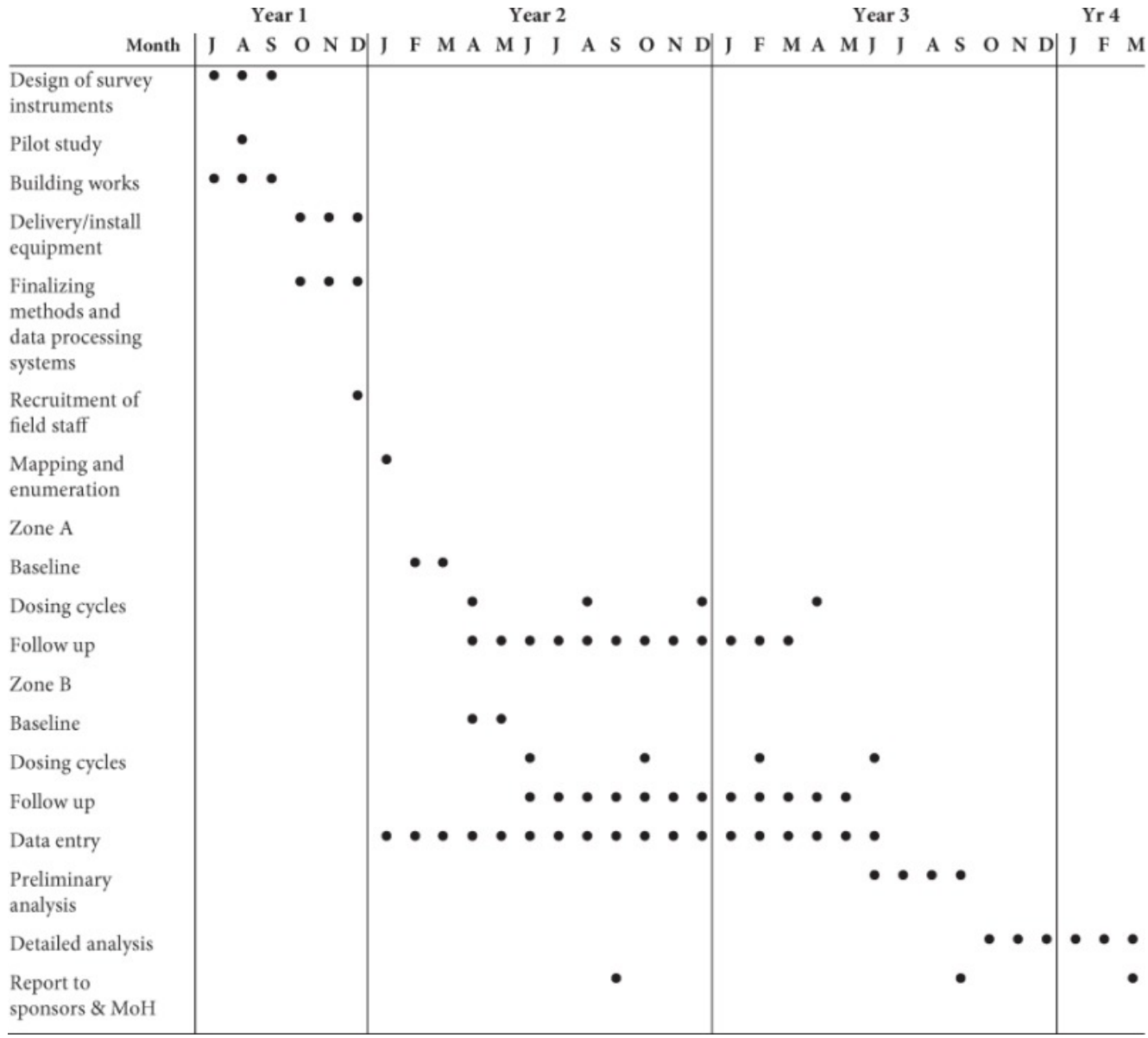

Figure 16.1

Example of an organizational timetable for a field trial.

Boxes

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)
    - Police2Clearances: legal and ethical (cont.)
    - Government—MOH—others, as appropriate
    - Local population—informed consent procedures
3. Location
    - Climate
    - Geographical features
    - Maps
    - Roads, including routes, distance, and time taken to travel between survey sites in different road conditions
    - River conditions
    - Airstrips (where relevant)
    - Electricity supply
    - Mobile phone network coverage
    - Internet access
4. Data collection and storage
    - Type
    - Regularity
    - Timing
    - Method of data collection (for example, pen and paper, electronic)
    - Logistics

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)11 Other (cont.)
    - 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.

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