23.3: Reporting the final results

In the absence of major problems during a trial, the most intensive phases of communication are before the initiation of the trial and when the final results are available. Dissemination of the reports of the trial findings is a substantial undertaking and must be considered an integral part of the conduct of the study and a major responsibility of the investigators. Research that is not appropriately disseminated is likely to fail to achieve its proper impact.

3.1 Planning the sequence of communications

The order of reporting of the results of a trial needs careful planning. In general, it is a good idea to follow a sequence whereby the results are first reported and discussed in confidence with all senior trial investigators, then, in confidence, with national and local health or other relevant government officials, representatives of the funding agency, and, when appropriate, with institutions who may be contacted by governments or the press to give their opinion on the results (such as UN agencies). All people involved in these steps should agree not to divulge the results to anyone else. These steps should occur, before the results are made public internationally. For example, it is bad practice for the results of a trial to be reported at an international conference or through a press release before the national and local government officials, trial participants, and representatives of the funding agency have been made aware of them. Also, some medical and scientific journals do not allow the results of a trial they are to publish to be presented at public conferences or released to the media before the journal article is published, so, where appropriate, it is worth trying to synchronize the publication of the trial results in a journal with the first international presentation of the results. Where this is not feasible (for example, the first suitable conference is not going to happen for several months after the results are ready, or the journal’s review process will be too lengthy), it is important to discuss this with the journal in advance.
3.2 Report to the sponsor

Whatever the outcome of a trial, a number of different communications must be prepared. For all trials, it is recommended that a comprehensive report be prepared, detailing all the trial procedures and the full results. The preparation of this report should be a work in progress throughout the trial, with the final complete report serving as a permanent record for the study team and a reference for anyone who wants to know exactly what was done in the trial. It will also be invaluable for the conduct of any re-survey of the trial population and may provide legal documentation with respect to registration of a new product or if questions about the study arise, for any reason, in the future. If the results of a trial are to be used as part of the registration procedures for a new product, it is important to liaise with the regulatory authorities at an early stage in the planning of the trial, so that the appropriate records are kept and the proper recording procedures are used (see Chapter 20). Specific guidance has been prepared by the ICH on what should be included in a clinical study report that is going to be used to support registration of a new drug or vaccine (International Conference on Harmonisation, 1995).

3.3 Trial participants and the study communities

It is the responsibility of the investigators to report back the results to those whose participation made the trial possible, i.e. those in the study communities. As emphasized in Chapters 6, 7, and 9, the investigating team should be in regular communication with the participants and their communities throughout the trial, but there is a special responsibility to make the community aware of the findings at the end of the trial. This might be done through public meetings with community members, to answer any questions they may have regarding the study, and through meetings with community leaders and local officials. It might also be appropriate to prepare a short report on the findings, written in such a way as to be readily comprehensible to a lay audience and which can be distributed to community members.

3.4 Local and government officials

For most trials, it will have been necessary to have sought the permission for the conduct of the trial from the local administration, and often from the Ministry of Health (MOH). It is important that the results of a trial are carefully discussed with such officials, before they are made publicly available. When trial results are publicly released, it may be useful to have national meetings opened by the MOH or the Director of Medical Services, or their representatives, and to have regional, district, or local meetings opened by equivalent local officials. Sometimes, it is appropriate to also disseminate the findings of a trial through local, national, and international mass media (print, radio, TV, and/or webcast (a live broadcast via the Internet) or podcast (a digital audio or video file that can be downloaded from a website to a media player or computer)), or in the form of a film.

The findings should also be reported formally to the local and national research and health policy decision makers. As well as reporting the results in full, the implications that the findings have for the health system should be reviewed with all appropriate health authorities, both governmental and non-governmental. It is important that a clearly written summary of the main results and their implications is included, usually at the front of the report, as many of those for whom the results are relevant will not have the time or inclination to study all the fine details.
3.5 Reporting in the scientific literature

It is expected that the results of all intervention trials will be published in peer-reviewed journals. Investigators will generally wish their findings to reach a wide audience and may target international journals as an outlet for the results of a trial. If the findings in a trial are mainly of local interest, a national journal may be more appropriate. Journal papers will generally be much shorter than the comprehensive study report discussed in Section 3.2. A general guide on how to write a paper reporting the results of a trial is given in Appendix 23.1. Specific guidance on the form a paper should take is detailed by the particular journal selected. The choice of the journal to which to submit a manuscript will be influenced by a number of factors, including the target audience for the scientific results, their local or international significance, how quickly the paper will be published (journals vary substantially in the time they take to have a paper peer-reviewed and processed for publication), how exciting the results are (it is unfortunately true that journals are biased towards publishing papers that have new or unexpected findings), and whether the journal has a history of publishing intervention trials of the kind conducted. It is a good idea to select the journal before starting to draft the article, as each journal has different requirements regarding, for example, the permissible length of articles and the referencing style for papers cited in the text. It is also strongly recommended that the most recent CONSORT guidelines are read for the particular trial design that has been used (<http://www.consort-statement.org>). These provide guidance on what information should be included in any report of results of a trial, and they have been adopted by many journals. For example, it is now widely considered to be essential that a flow diagram is prepared that starts with the number of all individuals (and, where appropriate, clusters of individuals) who were invited to participate in the trial and ends with all those who provided data on the primary trial outcome(s), showing when and why any participants or potential participants ‘dropped out’. An example of a CONSORT diagram is shown in Figure 23.1. A checklist of items that the CONSORT guidelines specify should be included in the report of a randomized trial is given in Appendix 23.2.

Since different journals have different target audiences, it may be important to publish different aspects of the study in different journals, in order to ensure dissemination of specific findings to the most relevant groups. As mentioned in Chapter 7, to report trials in most journals, it is now essential that the trial has been registered on an internationally recognized trial registration site, so this must be done before the first participant is enrolled into the trial.

Traditionally, publication of an article in a scientific journal was free to the author, but the reader (or their library) needed to pay for the journal issue or individual article. However, in the era of electronic publishing, there is a rapidly increasing number of ‘open access’ journals, in which the author pays for publication, but the article is then free to the reader. Also, it is increasingly possible for authors to pay so that an electronic version of their article is freely available to readers of traditional ‘closed access’ journals. Some funding agencies now insist on all research that they have paid for being open access. Such costs should be included in the trial budget, though some journals give discounts or waive the publication fees for articles submitted by research teams from LMICs. One major advantage of publishing in an open access journal is that readers who do not have access to well-resourced libraries, many of whom are in LMICs, but do have access to the Internet, can access the articles without payment.

3.6 Media coverage

A common practice is to prepare and disseminate a press release to selected media outlets a day or two in advance of the formal release of the trial results. This is to allow journalists to prepare their stories in advance. All such press...
releases should clearly state that the information they contain is ‘embargoed’ until a particular time and date. This means that the journalist is not permitted to publish the results until after that deadline.

Figure 23.1 CONSORT diagram for a cluster randomized trial of an adolescent sexual and reproductive health intervention in Tanzania.

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### 3.7 The funding agency

The funding agency will also require a final report on the outcome of the study, as well as a financial report. Sometimes, it is sufficient to send drafts of papers that are to be published, but often the agencies will require a special report in a specific format.

Successful investigators need funding for their research, and many field trials cost very large amounts, so it is sensible to put considerable effort into ensuring that there is excellent communication and feedback provided to the funding agency—both to facilitate the current trial and future approaches for funding! Whenever possible, the investigators should seek an opportunity to report and discuss the findings of the trial with a person in the funding agency. As well as ensuring they know the outcomes that their funds have helped to generate, it also gives the investigators the opportunity to discuss how the funding agency might be able to help with implementation of the recommendations arising from the...
trial and to discuss further research ideas.

Most funding agencies are also keen to participate in the dissemination of research results and will, for example, put out a press release to coincide with the publication of a paper on a trial they have supported.