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Chapter 23 Reporting and using trial results

1. Planning communications

It is important to communicate the progress of a trial, from its initiation to its end, to all the people and institutions (the stakeholders) likely to have an interest in the trial and its results. Planning this communication should start before the proposal for the trial is submitted for clearance and funding, and the communication plan should be reviewed and updated periodically throughout the trial.

Many researchers do not give communication and dissemination sufficient attention. This can lead to resistance to its initiation, because community members or local or national officials feel annoyed that they have not been consulted or kept informed, and lack of communication may cause misunderstandings during the trial which may impede its progress. From an early stage in a trial, it is often useful to involve or to consult a person with past experience in communicating with policy makers and the general public about the conduct of a trial, ideally someone familiar with research in the context of the trial. At a minimum, in a large field trial, it is advisable to involve such an expert during the planning of the overall trial communication action plan and during the planning of the final dissemination of the findings of the trial.

A useful starting point is for the trial team to construct a list of all the potential stakeholders and to think through what information should be provided to each of them, in what format, and when. An example of extracts from the communication action plan for a trial of an adolescent sexual and reproductive health intervention in Tanzania is given in Appendix 23.3.

At a minimum, stakeholders must be told what the purpose of the trial is and what is going to happen from the start, be kept informed about the progress of the trial, and be given the results of the trial and a chance to comment on these.

There are many different communication formats and media, some, or all, of which can be used effectively at different stages in a trial. Depending on the circumstances, these may include public meetings, pamphlets, brochures, newsletters, films, press releases and briefings, web pages, academic journal articles, technical briefing documents, and policy briefing documents. While interested academics and researchers are likely to read journal articles reporting the design and results of a trial in detail, few other stakeholders will. Conversely, policy makers will want a brief and concise report that focuses on the main findings and their implications for policy. Managers of public health programmes will want suggestions as to how the results of the trial might cause them to consider making specific modifications to their programmes, and they are also likely to want an indication of what any changes are likely to cost. So it is essential to consider what communication formats are most useful for different audiences. Communication and dissemination of trial progress and results should not all be left to the end of the trial.

Comprehensive guidance on formulating a communication plan for a clinical trial is given in Robinson et al. (2010).

2. Communication before and during the trial

We have emphasized, in other chapters, the importance of adequate preparation before starting a trial. A very important aspect of these preparations includes meetings with community leaders, community advisory boards (CABs), and public meetings involving potential trial participants to explain fully the purposes of the trial and what it will involve. There should be ample time allocated at these meetings for questions, and indeed suggestions from those in the local community may lead to changes in the trial plan. It is also crucial to obtain permission from local and national officials for the conduct of the trial and to allocate sufficient time for discussions with those officials, who may also suggest modifications to the trial. Ideally, there will be representation from local and/or national officials on the trial steering committee, which is a good way of keeping them in touch and being able to call upon their advice at all stages of the trial.

Once the trial has started, to ensure the continuing collaboration from the trial participants, those in the community in which the trial is being conducted will need both information on the progress of the trial and the opportunity to comment throughout the trial. There will also be a need to keep the local health and government administration

informed of activities. At a minimum, local and national officials should receive communication at least once a year; some may need this much more frequently (also see Chapters 7 and 9).

It is very important that any problems which are encountered during the conduct of the trial are rapidly identified by the trial investigators, and immediate steps are taken to make any necessary modifications to trial procedures and to explain to trial participants and community officials the reasons for any changes. Problems which are dealt with quickly are less likely to endanger the continued conduct of the trial than problems which are ignored for too long, with effective action either being delayed or not initiated. Regular meetings with the CAB should be a good conduit for early recognition of problems or issues being raised by trial participants or other members of the community.

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.

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.

4. From research findings to public health action

4.1. Sharing and synthesizing findings

Major changes in public health policy are rarely based on the results of a single trial. It is important therefore for investigators to make themselves aware of any other trials that are being, or have been, conducted to answer similar questions to their own and to be open to the possibility of sharing their results, so they can be synthesized. If contact is made with those who are conducting other trials at an early stage, it may be possible to ensure that the data collected are comparable, which will greatly facilitate such synthesis and the formal meta-analysis of the results (see Chapter 3).

4.2. Researchers and policy

Final analyses and the dissemination of results are essential tasks that must be completed at the end of a trial, but an important further responsibility of researchers is to review the findings with the relevant government and non-governmental authorities and to explore implications for the overall health policy of the country and for the design of specific disease control strategies and programmes. From the beginning of the planning of a trial directed towards an important public health problem, the appropriate policy and planning (as well as implementation) arms of the MOH should be involved. Where the intervention involves other ministries, such as education, social services, agriculture, youth, women's affairs, this applies equally to them. Even when the Ministry does not have direct responsibility for the actual conduct of the trial, formulation of conclusions from the analysis of trial results requires their input and participation, as they are usually responsible for changes to health programmes that may be necessary because of the results of the trial.

Sometimes, trials are conducted to establish a principle (for example, a particular way of constructing a vaccine results in some protection against the target disease), and they may be an intermediate step in developing an intervention that might be of public health value. However, most field trials are of interventions that could be potentially used for specific public health actions. While the rigorous conduct of a trial is the primary responsibility of the researchers, the responsibility for ensuring that research findings are put to their proper use in public health programmes generally lies with policy makers, especially in the MOH. Unfortunately, in most countries, policy makers have a poor understanding, and sometimes appreciation, of health research, and frequently health researchers have a similarly poor understanding of the role and function of policy makers and of what they require from researchers to be able to do their job well. All too often in the past, researchers have considered that once they have conducted the trial and communicated the findings to the policy makers their job is done. As discussed in the next section of this chapter, it is not!

Furthermore, it is not sufficient for the research team to merely forward the main trial report or scientific article to the policy makers. Few will have the time to read such reports, and even fewer will have the inclination to do so. It is

essential that the research team provides policy makers and programme managers with the results and their interpretation in a language and format that they will both understand and find easy to act upon. An example of how the abstract of a scientific article describing trial results was converted into a suitable summary for policy makers is given in Box 23.1.

A variety of useful mechanisms that would assist in communication between decision makers and researchers are implemented in some countries. Health planning units may have responsibility for regularly reviewing, and even funding, health systems research. Other mechanisms include ad hoc, or regular, seminars at the Ministry level. A more comprehensive approach can be achieved through national health policy or epidemiology boards. These boards are composed of scientists, government policy makers, leaders in non-governmental organizations, and often lay people, and they have responsibility for reviewing and funding important public health research activities. Whether this mechanism or some other is used, it is of critical importance to have a way of effectively and speedily translating research results into public health action.

Many health systems in developing countries have partially devolved responsibility for health care to sub-national levels such as the district level. Thus, health intervention research should be mentioned in the district health plan, even if the research itself is not undertaken by the district health team but by a specialized research group. This will ensure regular review of the progress and implications of the research. Decentralization offers an excellent opportunity to link research with local public health practice.

4.3. Introducing an intervention into public health programmes

The main results from a trial will state what the effects of the intervention were on the primary and secondary trial outcomes. However, for a policy maker to be able to decide whether a successful intervention should be introduced, they need additional information. This includes knowing what the intervention will cost, how the intervention can best be integrated into existing health and social systems and what the likely positive or negative secondary effects of introducing such interventions will be on other interventions or outcomes, and whether the intervention is likely to be equally effective in all contexts or will only be effective in some, such as among specific age, sex, and socio-economic groups, or in certain geographical areas. While collecting such information may well require additional research, sometimes through Phase IV studies (see Chapter 22), trial investigators should carefully think through whether it would be possible to collect some useful information on these areas during the original trial. For example, it is usually possible to collect data on the costs of the trial intervention (see Chapter 19), to document any implications for other health and social interventions, and to conduct appropriate analyses to provide some indications as to whether the effects of the intervention differed by subgroup. Further useful information on the likely reproducibility of the findings of the trial in other populations can also come from the synthesis of findings from different trials (see Chapter 3).

The costs of introducing a new intervention must also be analysed, and some of the key issues involved in collecting information of intervention costs have been covered in Chapter 19. Ideally, these costs should be assessed in relation to other uses of the resources, and the benefits (years of healthy life gained or loss of DALYs averted) per unit expenditure required for adding the intervention to the health system would be compared with benefits that could be gained by the same expenditure on another health programme. Issues related to such cost-effectiveness analyses have been discussed in Chapter 19. Even if cost-effectiveness analyses are not carried out, it is essential that the trial investigators are able to report what it costs to deliver the intervention within the trial. Such costs should exclude the costs of the evaluation of that intervention (see Chapter 19).

Before a newly proven intervention can be put into operation, the Ministry must consider how the new intervention should best be integrated with other existing interventions. For example, malaria vaccines, when developed, will have to be integrated into the existing vaccination programme for other diseases and will have to be added to whatever the existing malaria control strategy is, which may include vector control (for example, through insecticide spraying), vector–human biting reduction (for example, through the provision of insecticide-treated nets), and case detection and treatment measures. An overall integrated strategy for control will have to be developed, and this might require trials of various combinations of interventions to determine the optimal mix. Such studies are discussed in Chapter 22.

Another important issue that the Ministry must consider is that the efficacy of an intervention measured in the circumstances of a trial can rarely be attained when the intervention is implemented under routine circumstances. System-level or community effectiveness (coverage and efficacy as actually achieved by the routine health service), rather than trial eficacy, is the measure of relevance for the Ministry (Tanner et al., 1993). Demonstration of high

levels of efficacy under field trial conditions is important but, by itself, is not necessarily sufficient to justify the widespread introduction of the intervention, without further studies directly relevant to its implementation. Practical examples of this approach are given in Chapter 22.

The importance of understanding the setting and circumstances in which the intervention will be used in a public health programme must be understood both by policy makers and researchers. When the public health importance of an intervention is being assessed, managerial constraints must be considered that may make it impossible to achieve useful levels of efficacy. The principles and methods of continuous quality improvement management, with its emphasis on making sure that the right things get done, in the right way, and at the right time, are proving to be a useful approach to the management of health systems in developing countries. Such approaches may help ensure that the efficacy, as demonstrated under trial conditions, can be approached under routine conditions. An example of the use of these methods applied to improving the primary health care system in rural Nigeria is given in Zeitz et al. (1993).

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Appendix 23.1. Guidance on how to write a scientific paper reporting the results of a trial

Planning the publication strategy

It is important that the results of an intervention trial are published as soon as possible after the trial data have been analysed and the results are available. Generally, the sponsor will require a comprehensive report covering all aspects of the trial. Once such a report has been prepared, papers for publication in scientific journals can be prepared, based on the full report. It is good practice to try to include all of the important findings from the trial in one main paper and to avoid so-called ‘confetti’ publishing where the results are distributed among multiple different papers. While the trial is ongoing, it may be worth publishing a paper on the design and methods used in the trial (some journals specialize in publishing summaries of trial protocols, for example, *Trials* <http://www.trialsjournal.com>), as then reference can be made to this paper when the main results are published, without having to repeat details of the methodology.

The choice of which journal to submit a paper to will depend on the topic under study, and unfortunately on the results. Some journals are more likely to publish papers with ‘positive’ findings than those showing no effect of an intervention. Most authors will seek to publish their results in a journal with high ‘impact’ (i.e. likely to be read by

many people), but it is important to think about who the target audience for the paper is and which journals that audience is most likely to read. It is a good idea to scan past issues of the journal to see the sorts of paper they publish to judge whether there is likely to be interest in publication of the results of a specific trial.

Once the decision has been made of which journal to submit a paper to, it is important to read the instructions to authors, as these vary from journal to journal. Links to websites, which provide instructions to authors for over 6000 journals in the health and life sciences, are given at <http://mulford.utoledo.edu/instr/>.

Drafting a paper

Shown in Box A23.1 is the general structure that most scientific papers have if they are presenting original study results. Approaches to writing papers vary from author to author, but one that we have found useful is outlined here. Also shown in the box is the order in which we suggest different sections of the paper might be drafted.

What parts of a paper are read and by whom?

The vast majority of readers of a journal will scan the title of a paper, and they may look at the list of authors. It is important therefore to highlight, in so far as is possible, the subject of the research and the 'headline' finding in the title, in order to provoke interest in reading further. A much smaller proportion of readers will read the abstract/summary than the title, but it is important to try to get all of the messages you want to convey into the summary, as a very small proportion of readers will go beyond that point and read the main body of a paper. A small number of readers will scan the tables and figures, so these should be made as comprehensible as possible, without having to read the paper. Unfortunately, in most instances, a miniscule proportion of those who access the journal will read the whole paper, but these may be the people who really matter!

A good place to start the writing of a paper is to decide on the title! It is suggested that this is revisited, once the drafting of the paper is finished, to consider whether any revision is appropriate. Thus, it is listed as both 1 and 13 in Box Box A23.1.

Authorship

An issue which is frequently contentious is who should be included as an author in a paper and in which order the authors should appear. Journals give guidelines as to what contributions are sufficient to merit authorship. Also many journals require that an account is given of the contribution that each author made to the research reported. There is no simple answer as to who should, and who should not, be included as an author, but it is good practice to plan the publications that are likely to come out of a specific trial well in advance of the final analysis of the results and to agree who will be included as an author in different publications. It should also be decided who will be the 'lead' authors with the primary responsibility of producing the first draft of specific papers. However, all authors share responsibility for the contents of the paper. It is important to remember this, even if you are only one of many authors in the middle of the publication list. Errors in a publication are usually permanent, and, even if corrections are made in a subsequent communication, these are often missed by readers.

Tables

The most critical component in constructing a paper is deciding on, and designing, the tables (or figures) that are needed to describe the study and to summarize the results. Once the tables and figures have been constructed, writing the paper around them should be relatively straightforward. There are four aspects of a trial to which the tables will generally relate:

1. description of the characteristics of the study population
2. main results
3. secondary findings
4. your findings in the context of other studies (though a table on these is not always needed).

Ensure that the title of each table is adequate to inform the reader of its content. Try to work out a complete description of the trial results through tables (and figures), even if later the content of smaller tables might be incorporated into the text. Avoid duplication of data in tables *and* figures. Plan the tables and figures, such that the

paper can be largely 'read', based on these alone. Keep tables as simple as possible, and avoid unnecessary data, especially data that are not referred to in the text. Two simple tables are better than one complicated table. Label the rows and columns of each table very clearly, and, to the extent possible, avoid abbreviations. Avoid too many significant figures after the decimal point in numbers. For example, an OR of 4.7 is probably sufficient, rather than 4.735. In general, relate the number of decimal places included to the width of the CIs. For example, OR = 1.2 (95% CI: 0.1, 9.7) is more appropriate than OR = 1.23 (95% CI: 0.13, 9.68), whereas OR = 1.48 (95% CI: 1.41, 1.55) is more appropriate than OR = 1.5 (95% CI: 1.4, 1.6). When the tables (and figures) have been drafted, it is a good idea to give them to a colleague who is unfamiliar with the trial for them to tell you how they interpret them.

Figures

Figures may be a very powerful way of illustrating findings in a trial. They should be kept as simple as possible, but, if they are too simple, question whether they are really necessary. Consider whether a specific point is better made with a figure or table, and use one or the other, but not both. Label all axes of a graph very clearly, and give the units of measurement either in the figure or in the legend to the figure. For maps and similar diagrams, give a key to all of the symbols used, and show the scale diagrammatically (not 1 cm = 1 km, as the journal may shrink the figure). Have an arrow pointing north on all maps. Avoid using multiple colours, unless really necessary, as many journals are either only printed in black and white or charge extra for colour figures; and, anyway, many readers will print or photocopy a colour figure in black and white.

Results

The section of a paper describing the results of the trial should follow directly from the tables. Summarize what is shown in the tables, with appropriate reference to them. Start with the simplest analysis, for example, simple description of differences, without adjustment for confounding factors, etc. Then develop and describe more sophisticated analyses, as appropriate. Comment on all data shown in each table. If data are not commented upon, question the need to include them in tables. When estimates of effect are given (for example, vaccine efficacy), also include the CIs (usually 95%) and the 'p-value', but only if this contributes information beyond the CI.

Discussion

In the initial part of the discussion, focus on the key result(s) of the trial being presented, and summarize the overall findings. Discuss the strengths and limitations of the trial, for example, possible biases that could have influenced the results, and discuss the additional analyses that have been performed to control for potential biases, as appropriate. Then, put the findings of the trial in the context of other such studies, summarizing those studies as necessary, possibly in tabular or figure form. Then, draw overall conclusions derivable from the present study and other similar studies. Finally, make any recommendations for public health action or further research.

Materials and methods

Much of the materials and methods section may have been included in a previous paper, and it may be sufficient merely to summarize them and make reference back to that paper. However, this section of the paper must provide sufficient information for the reader to understand what was done, without having to go back to any previously published paper. The kinds of information that a reader will hope to glean from this section (or the earlier paper) are summarized in Box A23.2.

Introduction/background

The introductory section of the paper should be kept as brief as possible, giving the minimum necessary background information to explain any current controversies and why the trial was conducted. Make reference to any recent review papers, as appropriate. Specify the hypotheses that the study was designed to evaluate in quantitative terms.

Summary/abstract

Most journals will give specific instructions of how the summary should be formatted and the maximum number of words allowed. The reasons for doing the trial and why it is important should be summarized in one or two sentences. There should then be a concise summary of results, using the maximum number of words allowed by the journal. Include as many of the key findings as possible, including summary estimates of the effect, with CIs and p-values. Finally, in a sentence or two, summarize the implications of the results and their public health relevance.

Acknowledgements

Funding agencies for a trial will often require their contribution to be referred to in a specific way (for example, including the grant reference). There should also be acknowledgement of the contributions of all those who facilitated the conduct of the trial who are not included as authors. These will usually include local health authorities, study participants, fieldworkers, laboratory workers, other study staff, including key administrative staff, local medical staff, and any advisors or consultants. If in doubt as to whether someone should be acknowledged or not, it is generally diplomatic to include them!

References

Authors should avoid trying to impress with how widely read they are and should only include references to papers which are key to the content of the current paper. Use recent review articles, and select from more accessible journals (for example, open access), wherever possible. Make sure that all of the references are complete (for example, check using PubMed at <http://www.ncbi.nlm.nih.gov/pubmed>), and it is bad practice to include references to articles you have not read! Pay strict attention to the instructions that the journal gives for the formatting of references. For this purpose, it is useful to have invested in a good reference manager system (for example, Reference Manager, Endnote, or Mendeley (<http://www.mendeley.com>)—which is free).

Appendix 23.2. Checklist of information to include when reporting a randomized trial

The Consolidated Standards of Reporting Trials (CONSORT) Group have produced several very useful documents (see <http://www.consort-statement.org/>) about how to report trials. These include a very useful checklist (Schulz et al., 2010) which is reproduced with permission in Table A23.1 (abstracted from <http://www.consort-statement.org>).

Appendix 23.3. A communication action plan for a trial (Annabelle South, Aoife Doyle, David Ross, personal communication)

These extracts are from the aims and objectives and then two key tables (Tables A23.2 and A23.3) and a box (Box A23.3) within the initial communication action plan for the MEMA kwa Vijana (MkV) Trial's Long-term Evaluation (Doyle et al., 2010). This was a cluster randomized trial of an adolescent sexual and reproductive health (ASRH) intervention in rural Tanzania. The intervention had four main components (Obasi et al., 2006):

1. *in-school sexual and reproductive health education* through teacher-led, peer-assisted participatory lessons that included the use of drama, stories, and games
2. *youth-friendly reproductive health services*, education of health workers about the needs, and methods of providing sexual and reproductive health (SRH) services to youth
3. *community-based condom promotion and distribution*, for and by youth
4. *community activities* to create a supportive environment for the adolescent sexual health interventions.

MEMA kwa Vijana (MkV) Communication Strategy (excerpts)

Aims

1. Inform ASRH policy and programme design in Tanzania and internationally.
2. Increase national and international awareness and uptake of relevant MkV findings, materials, and activities.

Objectives

1. Increase stakeholder awareness of, and commitment to, the importance of evidence-based ASRH policy making.
2. Improve awareness of availability and policy relevance, and increase uptake of MkV findings, materials, and activities.
3. Strengthen ASRH programming and implementation within non-governmental organizations and other civil society organizations through their involvement and partnership in networks and capacity-building activities.

Figures

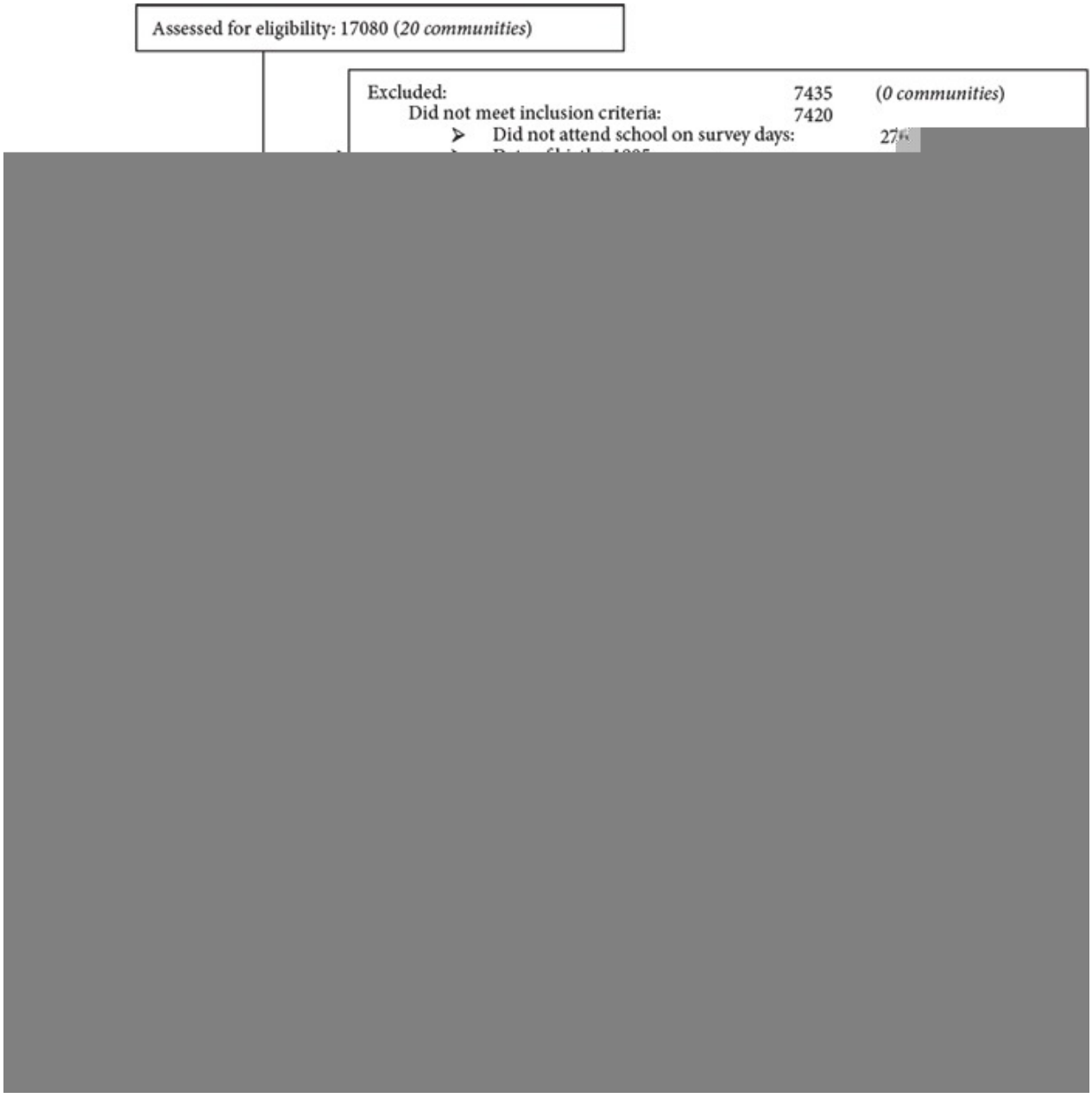

Figure 23.1

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

Reproduced from Ross, D. A., et al., Biological and behavioural impact of an adolescent sexual health intervention in Tanzania: a community-randomized trial, *AIDS,* Volume 21, Issue 7, pp.1943–55, Copyright © 2007, with permission from Lippincott Williams & Wilkins, Inc. This image is not covered by the Creative Commons licence terms of this publication. For permission to reuse please contact the rights holder.

Tables

Table A23.1 Consort 2010—checklist of information to include when reporting a randomized trial

Section/topic	Item no.	Checklist item
Title and abstract		
	1a	Identification as a randomized trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts)
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial), including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomization		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomization; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses such as subgroup analyses and adjusted analyses
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomization, together with reasons

Section/topic	Item no.	Checklist item
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalizability	21	Generalizability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits, and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

Table A23.2 Example of extracts from a communication action plan for a trial: target audiences

Level	Audience	Importance	Influence	Objectives addressed
1. International	1.1 All-party UK parliamentary group on SRH and HIV	Moderate. Potential facilitator	Well placed to help to increase awareness of MkV and stimulate debate about ASRH policy and programming	(1) (2)
	1.2 USAID	Moderate. Potential facilitator		(1) (2)
	1.3 CIDA	Moderate. Potential facilitator		(1) (2)
	1.4 DFID, UK	High. Potential facilitator	DFID African Policy Department and Irish Aid are co-funding the trial and are well placed to help to increase awareness of MkV and stimulate debate about ASRH policy and programming	(1) (2)
	1.5 Irish Aid	High. Potential facilitator		(1) (2)
	1.6 Scientific community	High. Potential facilitators and blockers	Can help to disseminate our results and materials at scientific conferences and in publications. Could try to block our findings if do not accept them	(2)
2. African regional	2.1 African Union Commission	Moderate. Potential facilitator or blocker	Could disseminate findings and materials to high-level policy makers in Africa	(1) (2)
	2.2 Southern African Development Community	Moderate. Potential facilitator or blocker	Their recent expert Think Tank meeting recommended further studies to strengthen the evidence base in this area as an urgent priority	(1) (2)
	2.3 New Partnership for Africa's Development	Low. Potential facilitator	Not clear yet how influential this group will be. Keep under review	(1) (2)
	2.4 Pan-African Parliament's Committee on Health, Labour, and Social Affairs	Low. Potential facilitator or blocker	Not clear yet how influential this group will be. Keep under review	(1) (2)
	2.5 Health Ministers' and Education Ministers' Forum	High. Potential facilitator or blocker	Well placed to help to increase awareness of MkV and stimulate debate about ASRH policy and programming	(1) (2)
3. National	3.1 Ministry of Labour, Employment, and Youth Development, Department of Youth Development (DYD)	Medium. Implementer. Potential facilitator or blocker	DYD oversees National Youth Policy and deals with out-of-school youth. Potential implementer of Youth Condom Promoter and Distributor Component of MkV Intervention	(1) (2)

Level	Audience	Importance	Influence	Objectives addressed
	3.2 Ministry of Education and Vocational Training (MOEVT), AIDS Coordinating Unit (ACU)	High. Potential facilitator or blocker	ACU coordinates all HIV and AIDS activities within MOEVT and handles NGO involvement	(1) (2)
	3.3 MOEVT, Department of Primary Education (DPE)	Very high. Implementer of in-school component of MkV intervention. Potential facilitator or blocker	DPE oversees activities in primary school	(1) (2)
	3.4 Ministry of Health and Social Welfare, Reproductive and Child Health Services Section (RCHS) and Adolescent Reproductive Health Working Group (ARHWG)	Very high. Implementer of youth-friendly health services component of MkV intervention. Potential facilitator or blocker	The RCHS has taken the lead in developing and promoting multi-sectoral ASRH materials. ARHWG has direct policy influencing capacity	(1) (2)
	3.5 Tanzania Commission on AIDS (TACAIDS)	High. Potential facilitator or blocker	Is within the Prime Minister's office and has the mandate for the coordination of all activities concerning the national response to HIV/AIDS	(1) (2)
	3.6 Family Health International (FHI), Usadi, Juhudi, Ari, Nguzo za Afya (UJANA) Project and Coordinating Committee of Youth Programming (CCYP)	High. Potential facilitators or blockers	UJANA is likely to be the largest youth HIV programme in Tanzania for the next 4 years. CCYP is supported by FHI and is a useful forum for national coalition building	(1) (2) (3)
4. Regional	4.1 Regional Commissioner's Office	High. Potential facilitator or blocker	Overall responsibility for all activities within the Mwanza region. The Regional Administrative Secretary has been fully informed and involved in MkV from the outset and appears supportive but may be transferred	(1) (2)
	4.2 Regional Education Office and Forums	High. Potential facilitator or blocker	The Regional Education Office provides the policy link between MOEVT national and district levels. The forums provide an important venue for influencing regional, and hence district, policy, and for information being conveyed to national level	(1) (2)

Level	Audience	Importance	Influence	Objectives addressed
	4.3 Regional Health Management Team (RHMT)	High. Potential facilitator or blocker	RHMT is the policy link between Ministry of Health and Social Welfare (MOHSW) headquarters, the regional administration, and the districts	(1) (2)
	4.4 Mwanza Policy Initiative (MPI)	Low. Potential facilitator or blocker	The initiative builds capacity to strengthen civil society engagement in policy processes. Potential venue for publicizing MkV and its findings	(1) (2) (3)
5. District, ward, and village	5.1 Full Council	High. Enabler	Main decision-making body in the district. ASRH is already within district plans	(1) (2)
	5.2 Council's Multi-sectoral AIDS Committee	High. Potential facilitator or blocker	Brings together all sectors to address HIV and AIDS	(1) (2) (3)
	5.3 Young people	High. Enablers and primary target group	Aim should be to actively engage young people in all aspects of the intervention	(1) (2)
	5.4 Farming associations	Low. Potential facilitators or blockers	MkV unlikely to be seen as important to their mandate	(1) (2) (3)
	5.5 Religious leaders	Moderate. Potential facilitators or (especially) blockers	Could order young people not to participate in MkV activities but could also support our messages and contribute choirs, etc. to events	(1) (2) (3)

Source: data courtesy of Annabelle South, Aoife Doyle, and David Ross, (personal communication).

Table A23.3 Example of extracts from a communication action plan for a trial: list of activities

Activities	Target	Time	Lead person	Expected results	Indicator
1. MkV Advisory Committee	Gatekeepers in key government ministries from national and regional levels; trial funders; researchers; Key NGOs working in ASRH	Annual meetings: Jun 2007, 2008, 2009	PI	Forum to update key stakeholders on MkV-related research and to receive feedback	Attendance lists and minutes from advisory committee meetings
2. Set up mailing, e-mail, and phone lists	National policy makers Regional/district officials NGOs/CSOs Media Scientific community	May 2007 and then kept up to date	Communications officer	Mechanism for communicating with key stakeholders	Complete up-to-date lists
3. Develop and disseminate MkV introductory information packs	National policy makers Regional/district officials NGOs/CSOs Media Scientific community Young people	Development April 2007–July 2007. (a) Must be ready for national stakeholders' meeting	Communications officer	MkV advocacy materials in a consistent, innovative, and professional format (MkV brand) that are suitable for different stakeholders. Greater local and national interest in MkV interventions and trial results when they become available	(a)–(f) Availability of information packs Also: (d) Number of newspaper articles, radio/television pieces mentioning MkV (e) Articles, reports, presentations that mention MkV
4. Development of MkV website (online publications, intervention materials, photos of activities, and provides links to other ASRH projects and organizations)	National policy makers Regional/district officials NGOs/CSOs Media Scientific community Young people	July 2007, then updated frequently with new material	Communications officer	Greater local, national, and global interest in MkV interventions, and trial results when they become available	Website metrics (hits, time, etc.)
5. Video shows with MkV video	Ward and village level authorities and community members	September 2007	Communications officer	Greater local understanding and acceptance of MkV interventions	Number attending, informal feedback from organizers and attendees

Source: data courtesy of Annabelle South, Aoife Doyle, and David Ross, (personal communication).

Boxes

Box 23.1 Example of how results in a technical journal article were rewritten for policy makers

Document A is the abstract from a paper that presented the main results from two parallel trials that compared vitamin A supplementation of young children vs placebo in northern Ghana. Document B is an excerpt from the Policy Brief prepared for dissemination of the results of the trials within Ghana and internationally.

A. The abstract from the scientific publication

Although most studies on the effect of vitamin A supplementation have reported reductions in child mortality, the effects on child morbidity are less clear. We have carried out two double-blind, randomized, placebo-controlled trials of vitamin A supplementation in adjacent populations in northern Ghana to assess the impact on childhood morbidity and mortality.

The Survival Study included 21 906 children aged 6–90 months in 185 geographical clusters, who were followed for up to 26 months. The Health Study included 1 455 children aged 6–59 months, who were monitored weekly for a year. Children were randomly assigned either 200 000 IU retinol equivalent (100 000 IU under 12 months) or placebo every 4 months; randomisation was by individual in the Health Study and by cluster in the Survival Study.

There were no significant differences in the Health Study between the vitamin A and placebo groups in the prevalence of diarrhoea or acute respiratory infections; of the symptoms and conditions specifically asked about, only vomiting and anorexia were significantly less frequent in the supplemented children. Vitamin A supplemented children had significantly fewer attendances at clinics (rate ratio 0.88 (95% CI 0.81–0.95), p = 0.001), hospital admissions (0.62 (0.42–0.93), p = 0.02), and deaths (0.81 (0.68–0.98), p = 0.03) than children who received placebo. The extent of the effect on morbidity and mortality did not vary significantly with age or sex. However, the mortality rate due to acute gastroenteritis was lower in vitamin A supplemented than in placebo clusters (0.66 (0.47–0.92), p = 0.02); mortality rates for all other causes except acute lower respiratory infections and malaria were also lower in vitamin A clusters, but not significantly so.

Improving the vitamin A intake of young children in populations where xerophthalmia exists, even at relatively low prevalence, should be a high priority for health and agricultural services in Africa and elsewhere.

B. The policy brief (excerpt)

Two randomised controlled trials were carried out in northern Ghana to evaluate the effect of 4-monthly vitamin supplements on child mortality and morbidity. They were conducted in neighbouring populations, where xerophthalmia, the eye disease caused by severe vitamin A deficiency, occurred but was not very common.

The mortality trial showed that vitamin A supplementation reduced child mortality by 19%, and this result was very unlikely to have occurred by chance. This result confirms the results of earlier trials in Asia, but is the first in Africa to show such an effect.

The morbidity trial results were intriguing in that they showed that vitamin A supplementation reduced indicators of severe illness—hospital admissions and clinic attendances—but did not reduce the overall frequency of illnesses. In other words, it appears that vitamin A supplementation may not reduce the number of illnesses that children will suffer from, but will reduce the number of those infections that go on to cause severe and life-threatening illness or death.

Taken together, these two trials' results may help to explain puzzling findings reported by previous morbidity trials which did not find any impact of vitamin A supplementation on the frequency of child morbidity, but only measured the overall frequency of illnesses rather than their severity.

The two trials show that improving the vitamin A status of young children should be given high priority by health and agricultural services in Africa and elsewhere in populations where xerophthalmia occurs, even when it is not very common.

Adapted from the *Lancet*, Volume 342, Issue 8862, Ghana VAST Study Team, Vitamin A supplementation in northern Ghana: effects on clinic attendances, hospital admissions, and child mortality, pp.7–12, Copyright © 1993, with permission from Elsevier, http://www.sciencedirect.com/science/journal/01406736; and from Ghana VAST Study Team, Results and policy implications of the Ghana Vitamin A Supplementation Trials, Copyright © 1993.

Box A23.1 Structure of paper and suggested order in which to write the sections

1, 13	Title
2	Authors
10	Abstract/summary
9	Introduction/background
8	Materials and methods
6	Results
7	Discussion
12	Acknowledgements
11	References
3	Tables
5	Legends to figures
4	Figures

Box A23.2 Information that should be included in the Materials and Methods section of a paper

Descriptions of:

- study area (relevant features)
- study design adopted (for example, cluster randomized trial)
- study population
- sample size determination
- methods of selection/exclusion of participants
- randomization methods and blinding
- informed consent procedures
- measurement methods
- laboratory assays
- follow-up methods
- computing and statistical packages used
- statistical methods employed
- ethical approval (and data and safety monitoring arrangements).

Box A23.3 Example messages for different audiences (drafted after the trial results were known)

Messages about the MkV interventions

- MkV aims to help young people to protect themselves from STIs and unwanted pregnancies.
- MkV is an innovative adolescent health programme, including teacher-led, peer-assisted sessions in school classrooms. It uses carefully designed and tested education materials and provides youth-friendly health services.

General information on SRH education in schools

- Half of all students in primary schools in rural Mwanza Region have had sex by the time they are 15 years old.
- ASRH education in schools has previously been shown not to increase students' sexual activity in many studies around the world.
- ASRH interventions in schools and health units need to be supported by sustained interventions in the wider community.

Messages for international technical agencies (WHO, UNAIDS, UNESCO, UNFPA, etc.)

- The MkV trial in Tanzania rigorously evaluated the impact of an innovative, multi-component package of interventions delivered by government departments.
- It demonstrated that the package of MkV interventions substantially improved participants' sexual health-related knowledge, reported attitudes, and some reported sexual risk behaviours, but there was no evidence that it reduced HIV, other STIs, or pregnancies.

Message for government department of primary education

- After a pilot project in 60 schools, the MkV sexual health education programme has been successfully scaled up to over 600 schools through existing government systems and has been shown to improve students' knowledge.

Source: data courtesy of Annabelle South, Aoife Doyle, and David Ross, (personal communication).

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