Guidelines

UNICEF/UNDP/World Bank/WHO Special Programme for Research & Training in Tropical Diseases (TDR)

FAME editorial guidelines

Published on behalf of FAME (Forum for African Medical Editors)

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FAME

EDITORIAL GUIDELINES

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Special Programme for Research and
Training in Tropical Diseases (TDR)

TDR/RCS/FAME/04.2

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Acknowledgements

FAME has compiled its guidelines from existing ones and would like to acknowledge with thanks the following sources:

Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice, COPE Report 1999.

Available from URL:
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Last updated: 1999.

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Last updated: 2003.

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Last updated: 6-10-2002.

Acronyms

CONSORT	Consolidated Standards of Reporting Trials
COPE	Committee on Publication Ethics
CSE	Council of Scientific Editors
FAME	Forum for African Medical Editors
HINARI	Health InterNetwork Access to Research Initiative
ICMJE	International Committee of Medical Journal Editors
QUOROM	Quality of Reporting of Meta-analyses
TDR	UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)
WAME	World Association of Medical Editors
WMA	World Medical Association
WHO	World Health Organization

Publishing health journals in the African context

Overburdened and isolated health professionals

Health professionals in Africa cope with larger patient loads, handle a wider range of diseases, and deal with a greater disease burden than those in industrialized countries. They have small budgets and little support with basic resources for diagnosis and care. Their access to up-to-date information and communication technology, including internet services, is limited. In addition they lack interaction and synergy with other professionals and have few subscriptions to medical journals.

Publishing health research results from Africa

African health research is often published in developed country scientific journals. Surveys conducted on publications derived from WHO/TDR research grants have shown repeatedly that most articles are published in mainstream biomedical journals which are beyond the reach of health workers in Africa. This practice is often compounded by local and international research institutions that seek additional research funding and recognition in the wider scientific community. While local medical journals in Africa should be playing a central role in disseminating local research results and furthering continuing medical education, they suffer from prejudice and lack of interest on the part of potential contributors and readers.

Economic and other constraints

A postal survey carried out on 63 African medical journals in July 2002 found that the majority of medical and health journals were under-funded, did not publish regularly, lacked high quality articles and standard peer review practice and were mostly invisible to the rest of the international medical community.

Most medical journals in Africa are published by academic institutions or professional associations with limited financial resources against a background of economic recession and high production costs. Journal production depends on voluntary, honorary and part-time contributions from professionals with often inadequate technical training. Technical skills of editors need to be upgraded in most settings. In general, manuscript reviewers are limited in number and the required technical capacity is largely lacking. Many are non-compliant with journal guidelines, some have conflict of interest, and others lack confidentiality and objectivity. Moreover, there is rarely professional and academic recognition for the reviewers' input.

As regards the quality and variety of articles published in Africa, there is, overall, a lack of balance between original research and review of available evidence. Authors lack proper orientation and advice. The current emphasis put on the international citation-based rating of scientific articles published in high profile journals introduces a further bias against local medical journals. The dissemination of local medical journals is problematic due to high mailing costs and the lack of efficient distribution channels. Thus, health workers in peripheral settings have little opportunity to read articles about health research carried out in their own country or articles about continuing medical education.

Networking among different journals in the continent is non existent, leaving most journal editors to work in isolation. More and more, medical editors have to grapple with ethical considerations related to research settings and research result publishing. At the same time, many researchers and authors lack the knowledge required to address comparable ethical issues while conducting and reporting their research and are rarely oriented or supported by their respective institutions.

FAME (Forum for African Medical Editors)

The creation of FAME (Forum for African Medical Editors) has been the first step taken by 15 African medical journal editors to set up a professional association and network that will review the problems faced by their journals and try to find common solutions. The FAME secretariat is at present located in KEMRI, Nairobi, Kenya. A list-serv for FAME members and interested partners is already operational at fame@who.int

The Steering Committee of FAME met for the first time in Mombasa, Kenya, from 22 to 24 April, 2003. One of the main recommendations of the FAME Steering Committee was to produce FAME editorial guidelines that would be approved and applied by African medical journals in order to standardize their practices and improve the quality and visibility of their publications.

Why the guidelines were developed

While other regions of the world have developed guidelines for publications of scientific research, none are available yet for the African setting. Moreover, existing guidelines are accessible mostly on a number of internet web sites which make their consultation and use difficult in the African environment.

FAME has proposed to review existing guidelines, adapt them to Africa and compile them into a brief printed handbook. The guidelines cover essential areas of editorial and publishing standards, ethics and scientific integrity as well as data reporting and analysis, referencing and bibliographic citations.

How the guidelines were developed

During the first FAME Steering Committee Meeting in Mombasa, three FAME editors were selected to prepare the FAME editorial guidelines. It was understood that since editorial best practices had already been discussed and adopted by other editors' associations such as WAME, CSE and COPE, the FAME guidelines should be based on those and adapted to fit the African health publishing context. In July 2003, TDR facilitated the meeting in Geneva, of three FAME editors (African Health Sciences (Uganda), Ethiopian Medical Journal (Ethiopia) and Revista Médica de Moçambique (Mozambique))and the Editor of the Bulletin of the World Health Organization to review existing editorial guidelines and compile FAME ones.

FAME guidelines address the needs of the three main actors in medical journal publishing: the editors, the reviewers and the authors. While editors should have an overview of the whole editorial process, reviewers and authors will find useful information about the way they should conduct their work. Essential documents such as the Uniform Requirements for Manuscripts to Biomedical Journals (http://www.icmje.org/index.html) and the Helsinki Declaration have been reproduced in the appendices of this booklet for ready reference. Users are also invited to visit, whenever possible, the web sites of other international editors' associations on which the FAME guidelines are based.

What the guidelines aim to do

The compilation of editorial guidelines into a small booklet distributed to African medical journal editors should serve to promote high standards of health research publishing in Africa, encourage the development of an African community of health researchers who communicate with one another, and facilitate effective communication of African health research results at the national, regional and international level.

To further encourage journal editors to follow these guidelines, FAME plans to give accreditation to journals that meet the FAME editorial guidelines. The accreditation will be done once a year by the FAME Secretariat and endorsed by FAME Board of Trustees.

A FAME accredited journal will receive a certificate and will have the FAME logo printed on the cover of each issue of the journal. In addition it will receive free FAME membership for one year. This is expected to promote recognition of African public health and medical journals and improve the quality of health research and delivery of health care to the peoples of Africa.

Editors and their responsibilities

Editors provide direction for the journal and build strong management. They must consider and balance the interests of many stakeholders, including readers, authors, staff, owners, editorial board members, advertisers and the media.

Responsibility for Quality of Content [1]

Editors are responsible for selecting papers which are new, original, important contributions to knowledge; which present valid and repeatable results in sufficient detail for readers to assess the validity of the inferences drawn; and which are logically consistent and refer appropriately to previous work. Whether or not journal editors are experts in a journal's specific field, they should be able to rely on the expertise of editorial staff, advisors, and peer reviewers.

Editors are responsible for clearly defining and implementing the journal's ethical standards. They are also responsible for establishing procedures to help maintain journal quality.

Editors' Responsibilities to Authors

Editors are responsible for:

- Establishing the policies for authorship and submission of manuscripts to the journal. [2]
- Treating authors with fairness, courtesy, objectivity, and honesty. [3]
- Rendering timely decisions and responses to authors' queries.
- Protecting the integrity of the editorial decision making process and the privileged nature of every author's work.
- Providing guides for preparing and submitting manuscripts (see ICMJE Uniform requirements for Manuscripts submitted to Biomedical Journals in the appendix).

Editors' Responsibilities to Readers and the Public

Editors are responsible for:

- Learning about the readers' needs and interests. [4]
- Maintaining the quality of the journal's content by ensuring that each article provides the evidence readers need to evaluate the authors' conclusions. [5]
- Maintaining the journal's internal integrity (for example by separating scientific content, editorials and advertising).
- Disclosing ownership of the journal, authorship of articles, and funding of the research published.
- Ensuring access to, and long term preservation of, the published information.

Editors' Responsibilities to Peer Reviewers [6]

Editors are responsible for:

- Assigning papers for review appropriate to the reviewers' area of interest and expertise.
- Allowing reviewers appropriate time to complete their reviews.
- Providing reviewers written explicit instructions regarding the journal's expectations for the content, quality, and timeliness of their reviews.

- Providing guides and standards for reviewers (preferably in written form) that promote thoughtful, fair, constructive, and informative reviews and facilitate the efficient, timely, handling of the papers.
- Finding ways to recognize the contribution of reviewers.

Editors and conflict of interest [7]

Editors should not have personal financial involvement in manuscripts they consider for publication. An editor should disqualify him- or herself from any decision-making role on a manuscript addressing a subject on which he or she has a potential conflict of interest.

Editors may also disqualify themselves from evaluating submissions by local colleagues or friends or submissions that clash with their personal convictions. Where there may be a conflict of interest, a guest editor or associate editor can be invited to oversee the review process.

Editorial decision making [8]

Editors must make decisions and stand by them, but reconsider them when appropriate.

When an editor seeks revision of a manuscript, he/she should make clear which revisions are essential, and which are optional.

If the comments of the reviewers are contradictory, the editor must decide and tell the authors which comments the authors should follow.

Editors may add their own comments and suggestions for revision, and they are responsible for ensuring that manuscripts meet the journal's guidelines.

Decisions to reject a manuscript may be based on scientific weakness (poor research design, inappropriate methods of study), lack of originality, lack of importance and relevance to the objectives of the journal.

The editor should explain to authors the reasons for decisions to reject manuscripts.

Revised manuscripts should be evaluated by editors, to determine if the revisions are satisfactory.

Editors should establish a mechanism to deal with appeals of decisions, particularly decisions to reject manuscripts, but are not obliged to reconsider every manuscript that was rejected.

Editors should immediately reject a resubmitted manuscript that was previously rejected and has not been revised.

Determination of the niche, comparative advantage and content of the journal

The editor should have a vision of the content of the journal based on the needs and interests of readers, the most promising areas of research in the field, and the extent to which the journal should try to attract and publish this research. [9]

The focus of the journal could be narrowed to a specific discipline, geographic region, or to studies of particular topics. On the other hand, the contents of the journal could be broadened by publishing different types of articles such as editorials, review articles, news articles or issues devoted to a particular theme.

Possible types of contribution to the journal [10]

There are many different types of articles that can be published. Only a few examples are given hereafter. For each one the editor must decide on the length (number of words) and structure.

- Editorials: usually provide commentary and analysis concerning an article in the issue of the journal in which they appear. They may include an illustration or table. They are nearly always solicited although, occasionally, unsolicited editorials may be considered.
- Research articles: consist of reports of original research that are likely to change clinical practice or thinking about a disease. Other types of articles which can be considered for the research section are: reports of randomized trials, brief communications or research letters, systematic reviews and meta-analyses. Systematic reviews establish where the effects of health care are consistent and research results can be applied across populations, settings, and differences in treatment (e.g. dose); and where effects may vary significantly. Meta-analyses use statistical methods to summarize the results of independent studies and provide more precise estimates of the effects of health care than those derived from the individual studies included in a review.
- Review articles: They are disease-oriented clinically focused overviews for the generalist, covering epidemiology, pathophysiology, diagnosis, and management. All review articles undergo the same peer-review and editorial process as original research reports. They should be written for general physicians, not specialists.
- Debates or round table discussions: A round table is composed of an article on a controversial subject of current public health importance and a debate to which some discussants are invited to contribute.
- Case reports: describe conditions or events that have not been previously reported.
- Personal perspectives: are nearly always solicited. Perspectives provide background and context for an article in the issue in which they appear. There are no reference citations.
- News: a medical journal can have a section to cover news about science, medicine, policy issues, and people.
- Letters to the Editor: They can be comment letters on what has been published in the journal. Correspondence letters are not usually peer-reviewed. All journals should have space in which published work can be questioned, and errors pointed out. Authors should always be given the opportunity to reply to any letter about their work that is accepted for publication. Later work that amplifies previously published work may also warrant publication as a letter to the editor rather than publication as new original article.
- Reviews of books or electronic media: Analysis of a recent book, new web site, film, play, CD-ROM, etc, of public health interest.

Manuscript evaluation [11]

The editor must establish a process for the review of manuscripts. Manuscripts may be reviewed by the editor(s), editorial board members, external reviewers, or a combination of these people. The editor may establish a system for rapid review of especially important manuscripts.

A manuscript can be rejected without outside review, for example if the subject matter is outside the scope of the journal, a manuscript on the same topic is just about to be published, the quality of the manuscript is poor, or criteria for the submission of manuscripts are not met.

Many journals have manuscripts reviewed by two people, because some manuscripts need to be evaluated by people with different types of expertise or to minimize biased decisions.

Identification and evaluation of reviewers

Reviewers are advisors to authors and editors but the editor must be the one who makes the final decisions on acceptance of manuscripts.[12] Peer-reviewers are external experts chosen by editors to provide written opinions with the aim of improving the quality of the manuscript.[13] The purpose of the peer-review process is to assure the accuracy and rigor of any work prior to its being widely disseminated. [14]

The editor should establish a reviewer database that includes information about the expertise of each reviewer as well as addresses and other contact information.

The editor may identify potential reviewers from:

- personal knowledge of the topic
- authors referenced in the manuscript
- membership of the society that publishes the journal
- computer searches of databases such as PubMed

The editor is responsible for keeping track of reviewers, and taking steps to make sure reviews are completed in a timely manner. The editor may also wish to include in the reviewer database judgements regarding the promptness and quality of reviewers.

Reviewers and their responsibilities [15]

The first responsibility of reviewers is to evaluate manuscripts critically but constructively and to prepare detailed comments about the research and the manuscript to help authors improve their work.

The evaluation should include assessment of the originality and importance of the research; the design of the study; the methods of study, including analytic and statistical methods; ethical issues; the presentation of the results; possible confounding ; the strength of the conclusions; and the overall quality of the manuscript. The reviewers can also be asked to grade some characteristics of the manuscript, such as originality, quality, accuracy, readability and interest to readers, or to complete detailed questionnaires about these qualities and even assign a priority score.

The second responsibility is to make a recommendation to the editor regarding the suitability of the manuscript for publication in that journal. Reviewers should give written comments about the manuscript to support their recommendation to the editor regarding acceptance or rejection.

Reviewers should declare to the editor any potential conflicts of interest with respect to the authors or the content of a manuscript they are asked to review, and if such conflicts exist, should decline to review the manuscript. Conflicts of interest regarding reviewers concern not only financial issues, but also rivalry, academic scientific and technologic competition, and philosophical values and beliefs.

Other responsibilities of reviewers include treating the manuscript as a confidential document and completing the review promptly. When reviewers receive invitations to review manuscripts and it is unlikely that the reviews can be finished within the time frame specified by the journal, they should decline the opportunity and explain the reason. Reviewers should not show the manuscript to anyone else without the express consent of the editor.

If reviewers suspect misconduct, they should write in confidence to the editor.

Reviewers should not make derogatory comments about the manuscript in their comments for the authors. If reviewers do make such comments, the editor may choose to edit the comments or even withhold all the reviewer's comments from the authors.

Reviewers should not make any use of the data, arguments, or interpretations, nor retain or copy the manuscript.

Reviewers should not communicate directly with authors or even identify themselves to authors.

Reviewers should be provided with guidelines on how to review the manuscript and how to meet their dual responsibility of providing constructive comments for the author and advice to the editor.

Rewarding reviewers

Peer-reviewers are "responsible scientists anxious only to further science." They volunteer to assess the strengths and weaknesses of manuscripts.[16] Few journals pay reviewers.

Reviewers are rewarded through recognition of their expertise and by being publicly thanked or given free copies or subscriptions to the journal. Reviewers have the right to expect to be informed of the outcome of the review process for the manuscripts they refereed for journals. It is useful to send each reviewer the comments of the other reviewer(s). [17]

Authors and their responsibilities [18]

The award of authorship should balance intellectual contributions to the conception, design, analysis and writing of the study against the collection of data and other routine work. If there is no task that can reasonably be attributed to a particular individual, then that individual should not be credited with authorship.

To avoid disputes over attribution of academic credit, it is helpful to decide early on in the planning of a research project who will be credited as authors, as contributors, and who will be acknowledged.

All authors must take public responsibility for the content of their paper, but only one of them should be the corresponding (contact) author.

Policies for authors

Authors are required to identify the organizations that provided support for the research and describe the role played by these organizations in the study and the analysis of the results. [19]

Authors should declare actual and potential conflict of interests when they submit their manuscripts. This is important because journals don't research possible conflicts of interest and are not expected to "police" authors. An author's failure to declare conflict of interest interferes with the reader's entitlement to know this potential source of bias. Authors should disclose to the editors all personal financial and other relationships they may have with the manufacturer of any product mentioned in the manuscript or the manufacturers of competing products. [20]

The contributions of persons who are acknowledged for their assistance in the research should be described, and their assent to be acknowledged should be documented. [21]

Policies for submission of manuscripts [22]

The topics of research and types of articles considered for publication in the journal should be clearly defined and publicised.

Authors should be required to verify the originality of manuscripts submitted for publication, and to identify other related manuscripts that they have published or submitted to other journals.

The authors should clearly state, in the manuscript, the name of the institutional review /ethics committee that approved the research; and that all human subjects or their representatives gave informed consent.

Authors are often required to transfer copyright of the manuscript, if accepted, to the journal.

The authors should follow journal policies and guidelines, which are freely available, regarding format, length of manuscripts, number of figures and tables and method of submission (hard copy or electronic or both).

General issues

Role of the editorial board [23]

The role of the board and qualifications for membership will vary from journal to journal. Ideally it should comprise accomplished scholars that guarantee the scientific quality of the journal.

The board will share in making policy decisions and is responsible for ensuring that the content of the journal is of high quality: accurate, valid, reliable, credible, authoritative, relevant to the journal's scope and mission, readable, and comprehensible.

The board is responsible for complying with the guidelines and procedures of their sponsoring Organization, including fiscal responsibility and adhering to the agreed-upon publication schedule.

An editorial board is efficient when its functions are clearly defined, its members have varied interests and expertise, and its size is limited. The term of service on the editorial board should be limited, so that the editor is continually exposed to new people and new ideas.

Conflicts of interest [24]

Conflicts of interest in publishing can be defined as sets of conditions in which an author, editor, or reviewer holds conflicting or competing interests that could result in bias or improper decisions.

These interests may be personal, commercial, political, academic or financial. Financial interests may include employment, research funding, stock or share ownership, payment for lectures or travel, consultancies and company support for staff.

Such interests, where relevant, must be declared to editors by researchers, authors, and reviewers. Editors should also disclose relevant conflicts of interest to their readers. If in doubt, disclose.

Ethics and good publication practice [25]

Editors, reviewers and authors should follow the Helsinki Declaration article 27, which states:

"Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication."

Authors should document that their research was approved by the appropriate institutional review committee for the protection of human subjects, and that all human subjects or their representatives gave informed consent.

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the latest version of the Helsinki Declaration.

Plagiarism [26]

Plagiarism ranges from the un-referenced use of others' published and unpublished ideas, including research grant applications, to submission under "new" authorship of a complete paper, sometimes in a different language.

It may occur at any stage of planning, research, writing, or publication: it applies to print and electronic versions. All sources should be disclosed, and if large amounts of other people's written or illustrative material are to be used, permission must be sought.

Redundant publication [27]

Redundant publication occurs when two or more papers, without full cross-reference, share the same hypothesis, data, discussion points, or conclusions. This should be avoided.

Previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, but full disclosure should be made at the time of submission.

Re-publication of a paper in another language is acceptable, provided that there is full and prominent disclosure of its original source at the time of submission.

At the time of submission, authors should disclose details of related papers, even if in a different language, and similar papers in press.

Dealing with misconduct [28]

If doubts arise about the honesty of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued (including possible consultation with the authors).

However, it is not the task of editors to conduct a full investigation or to make a determination; that responsibility lies with the institution where the work was done or with the funding agency. The editor should be promptly informed of the final decision, and if a fraudulent paper has been published, the journal must print a retraction. If this method of investigation does not result in a satisfactory conclusion, the editor may choose to publish an expression of concern with an explanation.

The retraction or expression of concern should appear on a numbered page in a prominent section of the journal. It should be listed in the contents page, and include in its heading the title of the original article. The text of the retraction should explain why the article is being retracted.

In case of misconduct, sanctions may be applied. For details see the latest version of the COPE guidelines at the following URL: http://www.publicationethics.org.uk

Correction of errors

Errors that are noted in published articles require the publication of a correction or erratum.

Advertising and the media [29]

Media relations

Authors approached by the media should give a balanced account of their work and point out where evidence ends and speculation begins. Authors could help journalists to produce accurate reports, but refrain from supplying additional data.

Editors should establish policies regarding how they and authors, should communicate with the public.

In general, authors should not publicize their work until it has been reviewed and published, except in the rare circumstances in which the research is of vital public health importance. The editor may grant permission for the information to be disseminated to the public before actual publication.

All efforts should be made to ensure that patients who have helped with the research should be informed of the results by the authors before the mass media, especially if there are clinical implications.

Advertising

Editorial decisions must not be influenced by advertising revenue or reprint potential: editorial and advertising administration must be clearly separated.

Advertisements that mislead must be refused, and editors must be willing to publish criticisms, according to the same criteria used for material in the rest of the journal.

The editorial content of the journal should be separated from the advertising content to the greatest extent possible in the published journal, whether printed or electronic.

Monitoring and evaluation

Editors are responsible for monitoring and evaluation of the editorial and production process (from manuscript receipt to publication).

It might be useful to publish annual editorial audits, which include the total number of manuscripts submitted, acceptance rate, and the average turn-around time for all manuscripts.

In order to assess relevance and use, editors should carry out readers' surveys periodically.

Journal distribution and marketing

The success of a journal will depend on how effectively it is promoted and marketed. This involves costs, which must be taken care of in the budget.

The commonest methods of distributing journals are:

- Hand delivery
- Direct mail
- Distribution agents
- Distribution at meetings and conferences
- Electronic publication

Avenues for promotion marketing of journals include:

- Flyers, leaflets and brochures
- Review and listing in other journals and publications
- Subscription agents
- Exhibitions and book fairs
- Abstracting and indexing services such as *Medline*
- Local booksellers

Abstracting and indexing services

Inclusion of a journal in internationally published abstracting and indexing services increases both the credibility of the journal and the potential for its dissemination to a wider audience. Editors are advised to strive to get their journals indexed in international and regional databases.

Some of the best known bibliographic databases are *Medline* (free internet access through *PubMed*), *CAB Abstracts*, *EMBASE*, *Web of Science (Science Citation Index and Social Science Citation Index*), *Popline*, *Pascal* and the WHO regional *Index medici.* Indexing services provide citations (author, title of article, title of journal, volume, issue and page numbers) of original articles. They

also provide keywords and abstracts to enable users, anywhere in the world, to retrieve articles of interest.

The major subscribers to electronic bibliographic databases are libraries which also hold journal subscriptions for universities and research institutes. More and more libraries subscribe to packages of electronic journals which can be linked to PubMed.

Electronic publishing [30]

The main advantages of publishing a journal electronically are the speed at which articles can be made available, their wide distribution through internet and their linking to bibliographic citations in some international databases (see above). Electronic publication also allows data to be included in various forms with the article (colour photographs, video, data sets, sound, animations, hyperlinks to further or related information).

Preparing material electronically for printed publications is just a step away from distributing it electronically on the web. Most desktop publishing material can be easily converted to a web-ready format. The next stage consists in finding a web site to host the journal. For developing countries a number of opportunities exist such as the INASP project called AJOL (African Journal OnLine) http://www.inasp.org.uk/ajol, Bioline International http://www.bioline.org.br or SciELO (Scientific Electronic Library Online) http://www.scielo.br

Editors should keep in mind, however, that access to electronic journals is often severely limited in Africa by chronic power cuts, lack of computers and reliable internet services, and high connectivity fees. Hence, users of the electronic version of an African medical journal are more likely to live in industrialized rather than in developing countries, and traditional hard-copies are still necessary to reach most physicians, nurses and researchers across Africa.

Although web publishing ensures greater visibility to journals, financial gains from publishing on internet may be minimal for African journals as users do not readily pay for single articles. One possibility is to join schemes whereby smaller publishers work together, through larger publishers, to sell a combined package of their journals to consortia and other large customers (see http://www.alpsp.org)

Notes and acknowledgements

[1] The next two paragraphs were taken and adapted from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors. (pt 1) http://www.councilscienceeditors.org/services/ .

[2] Taken from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors: Responsibilities of Editors pt 4. http://www.wame.org/syllabus.htm

[3] The next four points have been adapted from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors.

[4] Adapted from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors.

[5] Next three paragraphs were taken from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors.

[6] Adapted and shortened from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors.

[7] Abridged from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors.

[8] This section has been borrowed and adapted from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (point 6).

[9] Taken from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (point 2C)

[10] Freely adapted from BMJ Advice to contributors: BMJ sections http://bmj.bmjjournals.com/advice/sections.shtml

[11] Adapted and abridged from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (point 4)

[12] From World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (point 4 F)

[13] Taken from Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice (pt 5)

[14] From World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (pt 5B)

[15] Taken and adapted from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (point 5A)

[16] Quoted from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors (point 6)

[17] Adapted from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (point 5C II &III)

[18] Taken from Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice, Authorship pt 1,2 & 3. http://www.publicationethics.org.uk/cope1999/gpp/gpp.phtml

[19] Taken from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (pt 3A II & III)

[20] Adapted from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors (point 3A)

[20] From World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (pt 3A IV)

[22] From World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (pt 3B)

[23] Adapted from World Association of Medical Editors, WAME. A Syllabus for Prospective and Newly Appointed Editors (pt 1 The Editorial Process 1D)

[24] Freely adapted from Council of Science Editors, (CSE). Editorial Policy Statements approved by the CSE Board of Directors (point 4) and Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice (pt 4)

[25] Adapted from Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice (pt 1)

[26] Taken from Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice (pt 7)

[27] Taken from Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice (pt 6)

[28] Adapted from Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice: Dealing with misconduct

[29] Adapted from Committee on Publication Ethics, (COPE). Guidelines on Good Publication Practice (pt 9 & 10)

[30] Freely adapted from Youdeowei A. A guidebook on journal publishing in agriculture and rural development. Oxford, INASP, 2001

Main editors' associations web sites:

- Committee on Publication Ethics, (COPE). http://www.publicationethics.org.uk/. Last updated: 2002. Last visited: 13-8-2003.
- Council of Science Editors, (CSE). http://www.councilscienceeditors.org/. Last updated: 2003. Last visited:13-8-2003.
- European Association of Science Editors, (EASE). http://www.ease.org.uk / Last updated: 2003. Last visited:13-8-2003.
- International Committee of Medical Journal Editors, (ICMJE). http://www.icmje.org/index.html Last updated: 2001. Last visited:13-8-2003.
- World Association of Medical Editors, WAME. http://www.wame.org/. Last updated: 26-10-2001. Last visited:13-8-2003.

Selected readings

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International Committee of Medical Journal Editors

Appendix 1

Uniform Requirements for Manuscripts Submitted to Biomedical Journals

Updated October 2001

Publication Ethics: Sponsorship, Authorship, and Accountability
International Committee of Medical Journal Editors (see end of text)

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. The group became known as the Vancouver Group. Its requirements for manuscripts, including formats for bibliographic references developed by the National Library of Medicine, were first published in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Journal Editors (ICMJE), which meets annually; gradually it has broadened its concerns.

The committee has produced multiple editions of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Over the years, issues have arisen that go beyond manuscript preparation. Some of these issues are now covered in the Uniform Requirements; others are addressed in separate statements.

The entire Uniform Requirements document was revised in 1997. Sections were updated in May 1999 and May 2000. A major revision is scheduled for 2001. The total content of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals may be reproduced for educational, not-for-profit purposes without regard for copyright; the committee encourages distribution of the material.

Journals that agree to use the Uniform Requirements (over 500 do so) are asked to cite a version published in 1997 or later in their instructions to authors.

It is important to emphases what these requirements do and do not imply.

First, the Uniform Requirements are instructions to authors on how to prepare manuscripts, not to editors on publication style. (But many journals have drawn on them for elements of their publication styles.)

Second, if authors prepare their manuscripts in the style specified in these requirements, editors of the participating journals will not return the manuscripts for changes in style before considering them for publication. In the publishing process, however, the journals may alter accepted manuscripts to conform with details of their publication style.

Third, authors sending manuscripts to a participating journal should not try to prepare them in accordance with the publication style of that journal but should follow the Uniform Requirements.

Authors must also follow the instructions to authors in the journal as to what topics are suitable for that journal and the types of papers that may be submitted-for example, original articles, reviews, or case reports. In addition, the journal's instructions are likely to contain other requirements unique to that journal, such as the number of copies of a manuscript that are required, acceptable languages, length of articles, and approved abbreviations.

Participating journals are expected to state in their instructions to authors that their requirements are in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals and to cite a published version.

Issues To Consider Before Submitting a Manuscript

Redundant or Duplicate Publication

Redundant or duplicate publication is publication of a paper that overlaps substantially with one already published.

Readers of primary source periodicals deserve to be able to trust that what they are reading is original unless there is a clear statement that the article is being republished by the choice of the author and editor. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources.

Most journals do not wish to receive papers on work that has already been reported in large part in a published article or is contained in another paper that has been submitted or accepted for publication elsewhere, in print or in electronic media. This policy does not preclude the journal considering a paper that has been rejected by another journal, or a complete report that follows publication of a preliminary report, such as an abstract or poster displayed for colleagues at a professional meeting. Nor does it prevent journals considering a paper that has been presented at a scientific meeting but not published in full or that is being considered for publication in a proceedings or similar format. Press reports of scheduled meetings will not usually be regarded as breaches of this rule, but such reports should not be amplified by additional data or copies of tables and illustrations.

When submitting a paper, the author should always make a full statement to the editor about all submissions and previous reports that might be regarded as redundant or duplicate publication of the same or very similar work. The author should alert the editor if the work includes subjects about which a previous report has been published. Any such work should be referred to and referenced in the new paper. Copies of such material should be included with the submitted paper to help the editor decide how to handle the matter.

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect editorial action to be taken. At the least, prompt rejection of the submitted manuscript should be expected. If the editor was not aware of the violations and the article has already been published, then a notice of redundant or duplicate publication will probably be published with or without the author's explanation or approval.

Preliminary reporting to public media, governmental agencies, or manufacturers, of scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances or public health hazards such as serious adverse effects of drugs, vaccines, other biological products, or medicinal devices, or reportable diseases. This reporting should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance.

Acceptable Secondary Publication

Secondary publication in the same or another language, especially in other countries, is justifiable, and can be beneficial, provided all of the following conditions are met.

1. The authors have received approval from the editors of both journals; the editor concerned with secondary publication must have a photocopy, reprint, or manuscript of the primary version.
2. The priority of the primary publication is respected by a publication interval of at least one week (unless specifically negotiated otherwise by both editors).
3. The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.

4. The secondary version faithfully reflects the data and interpretations of the primary version.
5. The footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part and states the primary reference. A suitable footnote might read: "This article is based on a study first reported in the [title of journal, with full reference]."

Permission for such secondary publication should be free of charge.

Protection of Patients' Rights to Privacy

Patients have a right to privacy that should not be infringed without informed consent. Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that the patient be shown the manuscript to be published.

Identifying details should be omitted if they are not essential, but patient data should never be altered or falsified in an attempt to attain anonymity. Complete anonymity is difficult to achieve, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity.

The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained it should be indicated in the published article.

Reporting guidelines for specific study designs

Research reports frequently omit important information. The general requirements listed in the next section relate to reporting essential elements for all study designs. Authors are encouraged in addition to consult reporting guidelines relevant to their specific research design. For reports of randomized controlled trials authors should refer to the CONSORT statement (www.consort-statement.org). This guideline provides a set of recommendations comprising a list of items to report and a patient flow diagram.

Requirements for Submission of Manuscripts

Summary of Technical Requirements

- Double space all parts of manuscripts.
- Begin each section or component on a new page.
- Review the sequence: title page, abstract and key words, text, acknowledgments, references, tables (each on separate page), legends.
- Illustrations, unmounted prints, should be no larger than 203 x 254 mm (8 x 10 inches).
- Include permission to reproduce previously published material or to use illustrations that may identify human subjects.
- Enclose transfer of copyright and other forms.
- Submit required number of paper copies.
- Keep copies of everything submitted.

Preparation of Manuscript

The text of observational and experimental articles is usually (but not necessarily) divided into sections with the headings Introduction, Methods, Results, and Discussion. Long articles may need

subheadings within some sections (especially the Results and Discussion sections) to clarify their content. Other types of articles, such as case reports, reviews, and editorials, are likely to need other formats. Authors should consult individual journals for further guidance.

Type or print out the manuscript on white bond paper, 216 x 279 mm (8.5 x 11 inches), or ISO A4 (212 x 297 mm), with margins of at least 25 mm (1 inch). Type or print on only one side of the paper. Use double spacing throughout, including for the title page, abstract, text, acknowledgments, references, individual tables, and legends. Number pages consecutively, beginning with the title page. Put the page number in the upper or lower right-hand corner of each page.

Manuscripts on Disks

For papers that are close to final acceptance, some journals require authors to provide a copy in electronic form (on a disk); they may accept a variety of word-processing formats or text (ASCII) files.

When submitting disks, authors should:

1. be certain to include a print-out of the version of the article that is on the disk;
2. put only the latest version of the manuscript on the disk;
3. name the file clearly;
4. label the disk with the format of the file and the file name;
5. provide information on the hardware and software used.

Authors should consult the journal's instructions to authors for acceptable formats, conventions for naming files, number of copies to be submitted, and other details.

Title Page

The title page should carry 1) the title of the article, which should be concise but informative; 2) the name by which each author is known, with his or her highest academic degree(s) and institutional affiliation; 3) the name of the department(s) and institution(s) to which the work should be attributed; 4) disclaimers, if any; 5) the name and address of the author responsible for correspondence about the manuscript; 6) the name and address of the author to whom requests for reprints should be addressed or a statement that reprints will not be available from the authors; 7) source(s) of support in the form of grants, equipment, drugs, or all of these; and 8) a short running head or footline of no more than 40 characters (count letters and spaces) at the foot of the title page.

Authorship

All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.

Authorship credit should be based only on: 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.

Authors should provide a description of what each contributed, and editors should publish that information. All others who contributed to the work who are not authors should be named in the Acknowledgments, and what they did should be described (see Acknowledgments).

Increasingly, authorship of multicenter trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the Acknowledgments or in an appendix (see Acknowledgments).

The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed.

Abstract and Key Words

The second page should carry an abstract (of no more than 150 words for unstructured abstracts or 250 words for structured abstracts). The abstract should state the purposes of the study or investigation, basic procedures (selection of study subjects or laboratory animals; observational and analytical methods), main findings (giving specific data and their statistical significance, if possible), and the principal conclusions. It should emphasize new and important aspects of the study or observations.

Below the abstract authors should provide, and identify as such, 3 to 10 key words or short phrases that will assist indexers in cross-indexing the article and may be published with the abstract. Terms from the Medical Subject Headings (MeSH) list of Index Medicus should be used; if suitable MeSH terms are not yet available for recently introduced terms, present terms may be used.

Introduction

State the purpose of the article and summarize the rationale for the study or observation. Give only strictly pertinent references and do not include data or conclusions from the work being reported.

Methods

Describe your selection of the observational or experimental subjects (patients or laboratory animals, including controls) clearly. Identify the age, sex, and other important characteristics of the subjects. Because the relevance of such variables as age, sex, and ethnicity to the object of research is not always clear, authors should explicitly justify them when they are included in a study report. The guiding principle should be clarity about how and why a study was done in a particular way. For example, authors should explain why only subjects of certain ages were included or why women were excluded. Authors should avoid terms such as "race," which lacks precise biological meaning, and use alternative descriptors such as "ethnicity" or "ethnic group" instead. Authors should specify carefully what the descriptors mean, and tell exactly how the data were collected (for example, what terms were used in survey forms, whether the data were self-reported or assigned by others, etc.)..

Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Reports of randomized clinical trials should present information on all major study elements, including the protocol (study population, interventions or exposures, outcomes, and the rationale for statistical analysis), assignment of interventions (methods of randomization, concealment of allocation to treatment groups), and the method of masking (blinding).

Authors submitting review manuscripts should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

Ethics

When reporting experiments on human subjects, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 1983. Do not use patients' names, initials, or hospital numbers, especially in illustrative material. When reporting experiments on animals, indicate whether the institution's or a national research council's guide for, or any national law on, the care and use of laboratory animals was followed.

Statistics

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as the use of P values, which fails to convey important quantitative information. Discuss the eligibility of experimental subjects. Give details about randomization. Describe the methods for and success of any blinding of observations. Report complications of treatment. Give numbers of observations. Report losses to observation (such as dropouts from a clinical trial). References for the design of the study and statistical methods should be to standard works when possible (with pages stated) rather than to papers in which the designs or methods were originally reported. Specify any general-use computer programs used.

Put a general description of methods in the Methods section. When data are summarized in the Results section, specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample." Define statistical terms, abbreviations, and most symbols.

Results

Present your results in logical sequence in the text, tables, and illustrations. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations.

Discussion

Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the Introduction or the Results section. Include in the Discussion section the implications of the findings and their limitations, including implications for future research. Relate the observations to other relevant studies.

Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not completely supported by the data. In particular, authors should avoid making statements on economic benefits and costs unless their manuscript includes economic data and analyses. Avoid claiming priority and alluding to work that has not been completed. State new hypotheses when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

Acknowledgments

List all contributors who do not meet the criteria for authorship, such as a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as "clinical investigators" or "participating investigators," and their function or contribution should be described, for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients."

Because readers may infer their endorsement of the data and conclusions, all persons must have given written permission to be acknowledged.

References

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure.

Use the style of the examples below, which are based on the formats used by the NLM in Index Medicus. The titles of journals should be abbreviated according to the style used in *Index Medicus*. Consult the *List of Journals Indexed in Index Medicus*, published annually as a separate publication by the library and as a list in the January issue of *Index Medicus*. The list can also be obtained through the library's web site (http://www.nlm.nih.gov).

Avoid using abstracts as references. References to papers accepted but not yet published should be designated as "in press" or "forthcoming"; authors should obtain written permission to cite such papers as well as verification that they have been accepted for publication. Information from manuscripts submitted but not accepted should be cited in the text as "unpublished observations" with written permission from the source.

Avoid citing a "personal communication" unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text. For scientific articles, authors should obtain written permission and confirmation of accuracy from the source of a personal communication.

The references must be verified by the author(s) against the original documents.

The Uniform Requirements style (the Vancouver style) is based largely on an ANSI standard style adapted by the NLM for its databases. Notes have been added where Vancouver style differs from the style now used by NLM.

Articles in Journals

1. Standard journal article

List the first six authors followed by et al.
(Note: NLM now lists up through 25 authors; if there are more than 25 authors, NLM lists the first 24, then the last author, then et al.)

- Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996 Jun 1;124 (11):980-3.

As an option, if a journal carries continuous pagination throughout a volume (as man y medical journals do) the month and issue number may be omitted.

(Note: For consistency, the option is used throughout the examples in Uniform Requirements. NLM does not use the option.)
Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996;124:980-3.

More than six authors:
Parkin DM, Clayton D, Black RJ, Masuyer E, Friedl HP, Ivanov E, et al. Childhood leukaemia in Europe after Chernobyl: 5 year follow-up. Br J Cancer 1996;73:1006-12.

2. *Organization as author*

The Cardiac Society of Australia and New Zealand. Clinical exercise stress testing. Safety and performance guidelines. Med J Aust 1996; 164: 282-4.

3. *No author given*

Cancer in South Africa [editorial]. S Afr Med J 1994;84:15.

4. *Article not in English*

(Note: NLM translates the title to English, encloses the translation in square brackets, and adds an abbreviated language designator.)
Ryder TE, Haukeland EA, Solhaug JH. Bilateral infrapatellar seneruptur hostidligere frisk kvinne. Tidsskr Nor Laegeforen 1996;116:41-2.

5. Volume with supplement

Shen HM, Zhang QF. Risk assessment of nickel carcinogenicity and occupational lung cancer. Environ Health Perspect 1994;102 Suppl 1:275-82.

6. Issue with supplement

Payne DK, Sullivan MD, Massie MJ. Women's psychological reactions to breast cancer. Semin Oncol 1996;23(1 Suppl 2):89-97.

7. *Volume with part*

Ozben T, Nacitarhan S, Tuncer N. Plasma and urine sialic acid in non-insulin dependent diabetes mellitus. Ann Clin Biochem 1995;32(Pt 3):303-6.

8. *Issue with part*

Poole GH, Mills SM. One hundred consecutive cases of flap lacerations of the leg in ageing patients. N Z Med J 1994;107(986 Pt 1):377-8.

9. *Issue with no volume*

Turan I, Wredmark T, Fellander-Tsai L. Arthroscopic ankle arthrodesis in rheumatoid arthritis. Clin Orthop 1995;(320):110-4.

10. *No issue or volume*

Browell DA, Lennard TW. Immunologic status of the cancer patient and the effects of blood transfusion on antitumor responses. Curr Opin Gen Surg 1993:325-33

11. *Pagination in Roman numerals*

Fisher GA, Sikic BI. Drug resistance in clinical oncology and hematology. Introduction. Hematol Oncol Clin North Am 1995 Apr;9(2):xi-xii.

12. *Type of article indicated as needed*

Enzensberger W, Fischer PA. Metronome in Parkinson's disease [letter]. Lancet 1996;347:1337.
Clement J, De Bock R. Hematological complications of hantavirus nephropathy (HVN) [abstract]. Kidney Int 1992;42:1285.

13. *Article containing retraction*

Garey CE, Schwarzman AL, Rise ML, Seyfried TN. Ceruloplasmin gene defect associated with epilepsy in EL mice [retraction of Garey CE, Schwarzman AL, Rise ML, Seyfried TN. In: Nat Genet 1994;6:426-31]. Nat Genet 1995;11:104.

14. *Article retracted*

Liou GI, Wang M, Matragoon S. Precocious IRBP gene expression during mouse development [retracted in Invest Ophthalmol Vis Sci 1994;35:3127]. Invest Ophthalmol Vis Sci 1994;35:1083-8.

15. *Article with published erratum*

Hamlin JA, Kahn AM. Herniography in symptomatic patients following inguinal hernia repair [published erratum appears in West J Med 1995;162:278]. West J Med 1995;162:28-31.

Books and Other Monographs

(Note: Previous Vancouver style incorrectly had a comma rather than a semicolon between the publisher and the date.)

16. *Personal author(s)*

Ringsven MK, Bond D. Gerontology and leadership skills for nurses. 2nd ed. Albany (NY): Delmar Publishers; 1996.

17. *Editor(s), compiler(s) as author*

Norman IJ, Redfern SJ, editors. Mental health care for elderly people. New York: Churchill Livingstone; 1996.

18. *Organization as author and publisher*

Institute of Medicine (US). Looking at the future of the Medicaid program. Washington: The Institute; 1992.

19. *Chapter in a book*

(Note: Previous Vancouver style had a colon rather than a p before pagination.) Phillips SJ, Whisnant JP. Hypertension and stroke. In: Laragh JH, Brenner BM, editors. Hypertension: pathophysiology, diagnosis, and management. 2nd ed. New York: Raven Press; 1995. p. 465-78.

20. *Conference proceedings*

Kimura J, Shibasaki H, editors. Recent advances in clinical neurophysiology. Proceedings of the 10th International Congress of EMG and Clinical Neurophysiology; 1995 Oct 15-19; Kyoto, Japan. Amsterdam: Elsevier; 1996.

21. *Conference paper*

Bengtsson S, Solheim BG. Enforcement of data protection, privacy and security in medical informatics. In: Lun KC, Degoulet P, Piemme TE, Rienhoff O, editors. MEDINFO 92. Proceedings of the 7th World Congress on Medical Informatics; 1992 Sep 6-10; Geneva, Switzerland. Amsterdam: North-Holland; 1992. p. 1561-5.

22. *Scientific or technical report*

Issued by funding/sponsoring agency: Smith P, Golladay K. Payment for durable medical equipment billed during skilled nursing facility stays. Final report. Dallas (TX): Dept. of Health and Human Services (US), Office of Evaluation and Inspections; 1994 Oct. Report No.: HHSIGOEI69200860. Issued by performing agency: Field MJ, Tranquada RE, Feasley JC, editors. Health services research: work force and educational issues. Washington: National Academy Press; 1995. Contract No.: AHCPR282942008. Sponsored by the Agency for Health Care Policy and Research.

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Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis (MO): Washington Univ.; 1995.

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Larsen CE, Trip R, Johnson CR, inventors; Novoste Corporation, assignee. Methods for procedures related to the electrophysiology of the heart. US patent 5,529,067. 1995 Jun 25.

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25. *Newspaper article*

Lee G. Hospitalizations tied to ozone pollution: study estimates 50,000 admissions annually. The Washington Post 1996 Jun 21;Sect. A:3 (col. 5).

26. *Audiovisual material*

HIV+/AIDS: the facts and the future [videocassette]. St. Louis (MO): Mosby-Year Book; 1995.

27. *Legal material*

Public law:
Preventive Health Amendments of 1993, Pub. L. No. 103-183, 107 Stat. 2226 (Dec. 14, 1993).

Unenacted bill:
Medical Records Confidentiality Act of 1995, S. 1360, 104th Cong., 1st Sess. (1995).

Code of Federal Regulations:
Informed Consent, 42 C.F.R. Sect. 441.257 (1995).

Hearing:
Increased Drug Abuse: the Impact on the Nation's Emergency Rooms: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Government Operations, 103rd Cong., 1st Sess. (May 26, 1993).

28. *Map*

North Carolina. Tuberculosis rates per 100,000 population, 1990 [demographic map]. Raleigh: North Carolina Dept. of Environment, Health, and Natural Resources, Div. of Epidemiology; 1991.

29. *Book of the Bible*

The Holy Bible. King James version. Grand Rapids (MI): Zondervan Publishing House; 1995. Ruth 3:1-18.

30. *Dictionary and similar references*

Stedman's medical dictionary. 26th ed. Baltimore: Williams & Wilkins; 1995. Apraxia; p. 119-20.

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The Winter's Tale: act 5, scene 1, lines 13-16. The complete works of William Shakespeare. London: Rex; 1973.

Unpublished Material

32. *In press*

(Note: NLM prefers "forthcoming" because not all items will be printed.) Leshner AI. Molecular mechanisms of cocaine addiction. N Engl J Med. In press 1996.

Electronic Material

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Morse SS. Factors in the emergence of infectious diseases. Emerg Infect Dis [serial online] 1995 Jan-Mar [cited 1996 Jun 5];1(1):[24 screens]. Available from: URL: http://www.cdc.gov/ncidod/EID/eid.htm

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CDI, clinical dermatology illustrated [monograph on CD-ROM]. Reeves JRT, Maibach H. CMEA Multimedia Group, producers. 2nd ed. Version 2.0. San Diego: CMEA; 1995.

35. *Computer file*

Hemodynamics III: the ups and downs of hemodynamics [computer program]. Version 2.2. Orlando (FL): Computerized Educational Systems; 1993.

Tables

Type or print out each table with double spacing on a separate sheet of paper. Do not submit tables as photographs. Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Give each column a short or abbreviated heading. Place explanatory matter in footnotes, not in the heading. Explain in footnotes all nonstandard abbreviations that are used in each table. For footnotes use the following symbols, in this sequence:

- Identify statistical measures of variations, such as standard deviation and standard error of the mean.
- Do not use internal horizontal and vertical rules.
- Be sure that each table is cited in the text.
- If you use data from another published or unpublished source, obtain permission and acknowledge them fully.

The use of too many tables in relation to the length of the text may produce difficulties in the layout of pages. Examine issues of the journal to which you plan to submit your paper to estimate how many tables can be used per 1000 words of text.

The editor, on accepting a paper, may recommend that additional tables containing important back-up data too extensive to publish be deposited with an archival service, such as the National Auxiliary Publication Service in the United States, or made available by the authors. In that event an appropriate statement will be added to the text. Submit such tables for consideration with the paper.

Illustrations (Figures)

Submit the required number of complete sets of figures. Figures should be professionally drawn and photographed; freehand or typewritten lettering is unacceptable. Instead of original drawings, x-ray films, and other material, send sharp, glossy, black-and-white photographic prints, usually 127 x 173 mm (5 x 7 inches) but no larger than 203 x 254 mm (8 x 10 inches). Letters, numbers, and symbols should be clear and even throughout and of sufficient size that when reduced for publication each item will still be legible. Titles and detailed explanations belong in the legends for illustrations not on the illustrations themselves.

Each figure should have a label pasted on its back indicating the number of the figure, author's name, and top of the figure. Do not write on the back of figures or scratch or mar them by using paper clips. Do not bend figures or mount them on cardboard.

Photomicrographs should have internal scale markers. Symbols, arrows, or letters used in photomicrographs should contrast with the background.

If photographs of people are used, either the subjects must not be identifiable or their pictures must be accompanied by written permission to use the photograph (*see* Protection of Patients' Rights to Privacy).

Figures should be numbered consecutively according to the order in which they have been first cited in the text. If a figure has been published, acknowledge the original source and submit written permission from the copyright holder to reproduce the material. Permission is required irrespective of authorship or publisher except for documents in the public domain.

For illustrations in color, ascertain whether the journal requires color negatives, positive transparencies, or color prints. Accompanying drawings marked to indicate the region to be reproduced may be useful to the editor. Some journals publish illustrations in color only if the author pays for the extra cost.

Legends for Illustrations

Type or print out legends for illustrations using double spacing, starting on a separate page, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend. Explain the internal scale and identify the method of staining in photomicrographs.

Units of Measurement

Measurements of length, height, weight, and volume should be reported in metric units (meter, kilogram, or liter) or their decimal multiples.

Temperatures should be given in degrees Celsius. Blood pressures should be given in millimeters of mercury.

All hematologic and clinical chemistry measurements should be reported in the metric system in terms of the International System of Units (SI). Editors may request that alternative or non-SI units be added by the authors before publication.

Abbreviations and Symbols

Use only standard abbreviations. Avoid abbreviations in the title and abstract. The full term for which an abbreviation stands should precede its first use in the text unless it is a standard unit of measurement.

Sending the Manuscript to the Journal

Send the required number of copies of the manuscript in a heavy-paper envelope, enclosing the copies and figures in cardboard, if necessary, to prevent the photographs from being bent. Place photographs and transparencies in a separate heavy-paper envelope.

Manuscripts must be accompanied by a covering letter signed by all coauthors. This must include 1) information on prior or duplicate publication or submission elsewhere of any part of the work as defined earlier in this document; 2) a statement of financial or other relationships that might lead to a conflict of interest (see below); 3) a statement that the manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work; and 4) the name, address, and telephone number of the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs. The letter should give any additional information that may be helpful to the editor, such as the type of article in the particular journal that the manuscript represents and whether the author(s) would be willing to meet the cost of reproducing color illustrations.

The manuscript must be accompanied by copies of any permissions to reproduce published material, to use illustrations or report information about identifiable people, or to name people for their contributions.

Separate Statements

Definition of a Peer-Reviewed Journal

A peer-reviewed journal is one that has submitted most of its published articles for review by experts who are not part of the editorial staff. The number and kind of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of the reviewers' opinions may vary, and therefore each journal should publicly disclose its policies in its instructions to authors for the benefit of readers and potential authors.

Editorial Freedom and Integrity

Owners and editors of medical journals have a common endeavor-the publication of a reliable and readable journal, produced with due respect for the stated aims of the journal and for costs. The functions of owners and editors, however, are different. Owners have the right to appoint and dismiss editors and to make important business decisions in which editors should be involved to the fullest extent possible. Editors must have full authority for determining the editorial content of the journal. This concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake. To secure this freedom in practice, the editor should have direct access to the highest level of ownership, not only to a delegated manager.

Editors of medical journals should have a contract that clearly states the editor's rights and duties in addition to the general terms of the appointment and that defines mechanisms for resolving conflict.

An independent editorial advisory board may be useful in helping the editor establish and maintain editorial policy.

All editors and editors' organizations have the obligation to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical community.

Conflict of Interest

Conflict of interest for a given manuscript exists when a participant in the peer review and publication process-author, reviewer, and editor-has ties to activities that could inappropriately influence his or her judgment, whether or not judgment is in fact affected. Financial relationships with industry (for example, through employment, consultancies, stock ownership, honoraria, expert testimony), either directly or through immediate family, are usually considered to be the most important conflicts of interest. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

Public t rust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Bias can often be identified and eliminated by careful attention to the scientific methods and conclusions of the work. Financial relationships and their effects are less easily detected than other conflicts of interest. Participants in peer review and publication should disclose their conflicting interests, and the information should be made available so that others can judge their effects for themselves. Because readers may be less able to detect bias in review articles and editorials than in reports of original research, some journals do not accept reviews and editorials from authors with a conflict of interest.

Authors

When they submit a manuscript, whether an article or a letter, authors are responsible for recognizing and disclosing financial and other conflicts of interest that might bias the ir work. They should acknowledge in the manuscript all financial support for the work and other financial or personal connections to the work.

Reviewers

External peer reviewers should disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe it to be appropriate. The editors must be made aware of reviewers' conflicts of interest to interpret the reviews and judge for themselves whether the reviewer should be disqualified. Reviewers should not use knowledge of the work, before its publication, to further their own interests.

Editors and Staff

Editors who make final decisions about manuscripts should have no personal financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, should provide editors with a current description of their financial interests (as they might relate to editorial judgments) and disqualify themselves from any decisions where they have a conflict of interest. Published articles and letters should include a description of all financial support and any conflict of interest that, in the editors' judgment, readers should know about. Editorial staff should not use the information gained through working with manuscripts for private gain.

Project-Specific Industry Support for Research

Authors

Scientists have an ethical obligation to submit creditable research results for publication. Moreover, as the persons directly responsible for their work, scientists should not enter into agreements that interfere with their control over the decision to publish the papers they write.

Editors and Staff

Editors who make final decisions about manuscripts should have no personal financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, should provide editors with a current description of their financial interests (as they might relate to editorial judgements) and disqualify themselves from any decisions where they have a conflict of interest. Published articles and letters should include a description of all financial support and any conflict of interest that, in the editors' judgement, readers should know about. Editorial staff should not use the information gained through working with manuscripts for private gain.

Editors should require authors to describe the role of outside sources of project support, if any, in study design; in the collection, analysis and interpretation of data; and in the writing of the report. If the supporting source had no such involvement, the authors should so state. Because the biases potentially introduced by the direct involvement of supporting agencies in research are analogous to methodological biases of other sorts (e.g., study design, statistical and psychological factors), the type and degree of involvement of the supporting agency should be described in the Methods section. Editors should also require disclosure of whether or not the supporting agency controlled or influenced the decision to submit the final manuscript for publication.

Corrections, Retractions, and "Expressions of Concern" about Research Findings

Editors must assume initially that authors are reporting work based on honest observations. Nevertheless, two types of difficulty may arise.

First, errors may be noted in published articles that require the publication of a correction or erratum of part of the work. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is unlikely and should be handled by editors and authors on an individual basis. Such an error should not be confused with inadequacies exposed by the emergence of new scientific information in the normal course of research. The latter require no corrections or withdrawals.

The second type of difficulty is scientific fraud. If substantial doubts arise about the honesty of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued (including possible consultation with the authors). However, it is not the task of editors to conduct a full investigation or to make a determination; that responsibility lies with the institution where the work was done or with the funding agency. The editor should be promptly informed of the final decision, and if a fraudulent paper has been published, the journal must print a retraction. If this method of investigation does not result in a satisfactory conclusion, the editor may choose to publish an expression of concern with an explanation.

The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section of the journal, be listed in the contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible people. The text of the retraction should explain why the article is being retracted and include a bibliographic reference to it.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author's institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done they may choose to publish an announcement to the effect that the validity of previously published work is not assured.

Confidentiality

Manuscripts should be reviewed with due respect for authors' confidentiality. In submitting their manuscripts for review, authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend. Authors' rights may be violated by disclosure of the confidential details of the review of their manuscript. Reviewers also have rights to confidentiality, which must be respected by the editor. Confidentiality may have to be breached if dishonesty or fraud is alleged but otherwise must be honored.

Editors should not disclose information about manuscripts (including their receipt, their content, their status in the reviewing process, their criticism by reviewers, or their ultimate fate) to anyone other than the authors themselves and reviewers.

Editors should make clear to their reviewers that manuscripts sent for review are privileged communications and are the private property of the authors. Therefore, reviewers and members of the editorial staff should respect the authors' rights by not publicly discussing the authors' work or appropriating their ideas before the manuscript is published. Reviewer s should not be allowed to make copies of the manuscript for their files and should be prohibited from sharing it with others, except with the permission of the editor. Editors should not keep copies of rejected manuscripts.

Opinions differ on whether reviewers should remain anonymous. Some editors require their reviewers to sign the comments returned to authors, but most either request that reviewers' comments not be signed or leave the choice to the reviewer. When comments are not signed the reviewers' identity must not be revealed to the author or anyone else.

Some journals publish reviewers' comments with the manuscript. No such procedure should be adopted without the consent of the authors and reviewers. However, reviewers' comments may be sent to other reviewers of the same manuscript, and reviewers may be notified of the editor's decision.

Medical Journals and the Popular Media

The public's interest in news of medical research has led the popular media to compete vigorously to get information about research as soon as possible. Researchers and institutions sometimes encourage the reporting of research in the popular media before full publication in a scientific journal by holding a press conference or giving interviews.

The public is entitled to important medical information without unreasonable delay, and editors have a responsibility to play their part in this process. Doctors, however, need to have reports available in full detail before they can advise their patients about the reports' conclusions. In addition, media reports of scientific research before the work has been peer reviewed and fully published may lead to the dissemination of inaccurate or premature conclusions.

Editors may find the following recommendations useful as they seek to establish policies on these issues.

1. Editors can foster the orderly transmission of medical information from researchers, through peer-reviewed journals, to the public. This can be accomplished by an agreement with authors that they will not publicize their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication in the journal, in return for which the journal will cooperate with them in preparing accurate stories (see below).
2. Very little medical research has such clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal. In such exceptional circumstances, however, appropriate authorities responsible for public health should make the decision and should be responsible for the advance dissemination of information to physicians and the media. If the author and the appropriate authorities wish to have a manuscript considered by a particular journal, the editor should be consulted before any public release. If editors accept the need for immediate release, they should waive their policies limiting prepublication publicity.
3. Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific meetings or to the abstracts from these meetings (see Redundant or Duplicate Publication). Researchers who present their work at a scientific meeting should feel free to discuss their presentations with reporters, but they should be discouraged from offering more detail about their study than was presented in their talk.
4. When an article is soon to be published, editors may wish to help the media prepare accurate reports by providing news releases, answering questions, supplying advance copies of the journal, or referring reporters to the appropriate experts. This assistance should be contingent on the media's cooperation in timing their release of stories to coincide with the publication of the article.

Policies for Posting Biomedical Journal Information on the Internet

Electronic publishing (which includes the Internet) is publishing. Authors, editors, and publishers of biomedical journals who post medical and health information connected to these publications on the Internet should follow the policies established by the International Committee of Medical Journal Editors as the "Uniform Requirements for Authors Submitting Articles to Biomedical Journals" and related statements.

The nature of the Internet requires some special considerations within these well established and accepted policies. As a minimum, sites should indicate the names of editors, authors, and contributors and their affiliations, relevant credentials, and relevant conflicts of interest; documentation and attribution of references and sources for all content; information about copyright; disclosure of site ownership; and disclosure of sponsorship, advertising, and commercial funding.

Linking from one health or medical Internet site to another may be perceived as a recommendation of the quality of the second site. Journals thus should exercise caution in linking to other sites. If links to other sites are posted as a result of financial considerations, such should be clearly indicated. All dates of content posting and updating should be indicated. In electronic, as in print layout, advertising and promotional messages should not be juxtaposed with editorial content. Any commercial content should be clearly identified as such.

Advertising

Most medical journals carry advertising, which generates income for their publishers, but advertising must not be allowed to influence editorial decisions. Editors must have full responsibility for advertising policy. Readers should be able to distinguish readily between advertising and editorial material. The juxtaposition of editorial and advertising material on the same products or subjects should be avoided, and advertising should not be sold on the condition that it will appear in the same issue as a particular article.

Journals should not be dominated by advertising, but editors should be careful about publishing advertisements from only one or two advertisers as readers may perceive that the editor has been influenced by these advertisers.

Journals should not carry advertisements for products that have proved to be seriously harmful to health-for example, tobacco. Editors should ensure that existing standards for advertisements are enforced or develop their own standards. Finally, editors should consider all criticisms of advertisements for publication.

Supplements

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as a second part of a regular issue, and are usually funded by sources other than the journal's publisher. Supplements can serve useful purposes: education, exchange of research information, ease of access to focused content, and improved cooperation between academic and corporate entities. Because of the funding sources, the content of supplements can reflect biases in choice of topics and viewpoints. Editors should therefore consider the following principles.

1. The journal editor must take full responsibility for the policies, practices, and content of supplements. The journal editor must approve the appointment of any editor of the supplement and retain the authority to reject papers.
2. The sources of funding for the research, meeting, and publication should be clearly stated and prominently located in the supplement, preferably on each page. Whenever possible, funding should come from more than one sponsor.
3. Advertising in supplements should follow the same policies as those of the rest of the journal.
4. Editors should enable readers to distinguish readily between ordinary editorial pages and supplement pages.
5. Editing by the funding organization should not be permitted.
6. Journal editors and supplement editors should not accept personal favors or excessive compensation from sponsors of supplements.
7. Secondary publication in supplements should be clearly identified by the citation of the original paper. Redundant publication should be avoided.

The Role of the Correspondence Column

All biomedical journals should have a section carrying comments, questions, or criticisms about articles they have published and where the original authors can respond. Usually, but not necessarily, this may take the form of a correspondence column. The lack of such a section denies readers the possibility of responding to articles in the same journal that published the original work.

Competing Manuscripts Based on the Same Study

Editors may receive manuscripts from different authors offering competing interpretations of the same study. They have to decide whether to review competing manuscripts submitted to them more or less simultaneously by different groups or authors, or they may be asked to consider one such manuscript while a competing manuscript has been or will be submitted to another journal. Setting aside the unresolved question of ownership of data, we discuss here what editors ought to do when confronted with the submission of competing manuscripts based on the same study.

Two kinds of multiple submissions are considered: submissions by coworkers who disagree on the analysis and interpretation of their study, and submissions by coworkers who disagree on what the facts are and which data should be reported.

The following general observations may help editors and others dealing with this problem.

Differences in Analysis or Interpretation

Journals would not normally wish to publish separate articles by contending members of a research team who have differing analyses and interpretations of the data, and submission of such manuscripts should be discouraged. If coworkers cannot resolve their differences in interpretation before submitting a manuscript, they should consider submitting one manuscript containing multiple interpretations and calling their dispute to the attention of the editor so that reviewers can focus on the problem. One of the important functions of peer review is to evaluate the authors' analysis and interpretation and to suggest appropriate changes to the conclusions before publication. Alternatively, after the disputed version is published, editors may wish to consider a letter to the editor or a second manuscript from the dissenting authors. Multiple submissions present editors with a dilemma. Publication of contending manuscripts to air authors' disputes may waste journal space and confuse readers. On the other hand, if editors knowingly publish a manuscript written by only some of the collaborating team, they could be denying the rest of the team their legitimate coauthorship rights.

Differences in Reported Methods or Results

Workers sometimes differ in their opinions about what was actually done or observed and which data ought to be reported. Peer review cannot be expected to resolve this problem. Editors should decline further consideration of such multiple submissions until the problem is settled. Furthermore, if there are allegations of dishonesty or fraud, editors should inform the appropriate authorities.

The cases described above should be distinguished from instances in which independent, non-collaborating authors submit separate manuscripts based on different analyses of data that are publicly available. In this circumstance, editorial consideration of multiple submissions may be justified, and there may even be a good reason f or publishing more than one manuscript because different analytical approaches may be complementary and equally valid.

About the ICMJE

The International Committee of Medical Journal Editors (ICMJE) is an informal group whose participants fund their work on the URM. The ICMJE is not a membership organization. Editors are encouraged to join organizations that offer educational programs, meetings, publications, and other opportunities to interact with colleagues. Examples of such groups are given below.

Council of Science Editors (CSE): www.CouncilScienceEditors.org
The European Association of Science Editors (EASE): www.ease.org.uk
Society for Scholarly Publishing (SSP): www.sspnet.org
The World Association of Medical Editors (WAME): www.WAME.org

Authors of the Current Uniform Requirements and Separate Statements

The ICMJE participating journals and organizations and their representatives who approved the revised Uniform Requirements in May 2000 should be cited as authors of the documents on this website.

Frank Davidoff, *Annals of Internal Medicine*; Fiona Godlee, BMJ; John Hoey, *Canadian Medical Association Journal*; Richard Glass, *JAMA*; John Overbeke, *Nederlands Tijdschrift voor Geneeskunde*; Robert Utiger, *New England Journal of Medicine*; M.Gary Nicholls, *New Zealand Medical Journal*; Richard Horton, *The Lancet*; Magne Nylenna, *Tidsskrift for Den Norske legeforening*; Liselotte Hojgaard, *Ugeskrift for Laeger*. Sheldon Kotzin, U.S. National Library of Medicine.

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Inquiries about the Uniform Requirements only should be sent to Christine Laine, MD, MPH at the ICMJE secretariat office, American College of Physicians-American Society of Internal Medicine, 190 N. Independence Mall West, Philadelphia, PA 19106-1572, USA. Phone, 215-351-2660; fax, 215-351-2644; e-mail: www.claine@mail.acponline.org. Please do not send inquiries about individual journal styles and policies to this address.

The Uniform Requirements has been published in several journals. Please cite a version that appeared in the primary journal literature on or after 1 January 1997; for example:

International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. Ann Intern Med. 1997;126:36-47.

International Committee of Medical Journal Editors: www.icmje.org

Initiated: 1964

17.C
Original: English

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly
Helsinki, Finland, June 1964
and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
and the
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002

A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects**.** Medical research involving human subjects includes research on identifiable human material or identifiable data.

2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.

15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

20. The subjects must be volunteers and informed participants in the research project.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient’s information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.

24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.

25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists. *(See footnote*)*

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

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32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

FOOTNOTE:

Note of Clarification on Paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

♣ ♣ ♣

6.10.2002

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa) and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.

CONSORT statement

The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials

*David Moher, Kenneth F Schulz, Douglas G Altman, for the CONSORT Group**

To comprehend the results of a randomised controlled trial (RCT), readers must understand its design, conduct, analysis, and interpretation. That goal can be achieved only through total transparency from authors. Despite several decades of educational efforts, the reporting of RCTs needs improvement. Investigators and editors developed the original CONSORT (Consolidated Standards of Reporting Trials) statement to help authors improve reporting by use of a checklist and flow diagram. The revised CONSORT statement presented here incorporates new evidence and addresses some criticisms of the original statement. The checklist items pertain to the content of the Title, Abstract, Introduction, Methods, Results, and Discussion. The revised checklist includes 22 items selected because empirical evidence indicates that not reporting this information is associated with biased estimates of treatment effect, or because the information is essential to judge the reliability or relevance of the findings. We intended the flow diagram to depict the passage of participants through an RCT. The revised flow diagram depicts information from four stages of a trial (enrolment, intervention allocation, follow-up, and analysis). The diagram explicitly shows the number of participants, for each intervention group, included in the primary data analysis. Inclusion of these numbers allows the reader to judge whether the authors have done an intention-to-treat analysis. In sum, the CONSORT statement is intended to improve the reporting of an RCT, enabling readers to understand a trial's conduct and to assess the validity of its results.

A report of a randomised controlled trial (RCT) should convey to the reader, in a transparent manner, why the study was undertaken, and how it was conducted and analysed. Inadequately reported randomisation, for example, has been associated with bias in estimating the effectiveness of interventions.[1,2] To assess the strengths and limitations of an RCT, readers need and deserve to know the quality of its methods.

Despite several decades of educational efforts, RCTs are still not being reported adequately.[3–6] For example, a review[5] of 122 recently published RCTs that assessed the effectiveness of selective serotonin reuptake inhibitors as a first-line management strategy for depression found that only one paper described randomisation adequately. Inadequate reporting makes the interpretation of RCTs difficult, if not impossible. Moreover, inadequate reporting borders on unethical practice when biased results receive false credibility.

History of CONSORT

In the mid-1990s, two independent initiatives to improve the quality of reports of RCTs led to the publication of the CONSORT statement,[7] which was developed by an international group of clinical trialists, statisticians, epidemiologists, and biomedical editors. CONSORT has been supported by a growing number of medical and health-care journals[8–11] and editorial groups, including the International Committee of Medical Journal Editors (ICMJE, The Vancouver Group),[12] the Council of Science Editors (CSE), and the World Association of Medical Editors (WAME). CONSORT is published in Dutch, English, French, German, Japanese, and Spanish. It can be accessed together with other information about the CONSORT group on the internet.[13]

The CONSORT statement consists of a checklist and flow diagram for reporting an RCT. For convenience, the checklist and diagram together are called simply CONSORT. They are primarily intended for use in writing, reviewing, or assessing reports of simple two-group parallel RCTs.

Preliminary data indicate that the use of CONSORT does indeed help to improve the quality of reports of RCTs.[14,15] In an assessment[14] of 71 RCTs, published in three journals in 1994, allocation concealment was not clearly reported in 43 (61%) of the trials. 4 years later, after these three journals required that authors reporting an RCT use CONSORT, the proportion of papers in which allocation concealment was not clearly reported had dropped to 30 of 77 (39%, mean difference −22% [95% CI −38 to −6]).

The usefulness of CONSORT is increased by continuous monitoring of biomedical publications, which allows it to be modified dependent on the merits of maintaining or dropping current items, and including new items. For example, when Meinert[16] observed that the flow diagram did not provide important information about the number of participants who entered each phase of an RCT (ie, enrolment, treatment allocation, follow-up, and data analysis), the diagram could be modified to accommodate the information. The checklist is similarly flexible.

This iterative process makes the CONSORT statement a continually evolving instrument. Although participants in the CONSORT group and their degree of involvement vary over time, members meet regularly to review the need to

Lancet 2001; **357:** 1191–94

*Members listed at end of paper

The revised CONSORT statement is also published in *JAMA* 2001; **285:** 1987–91 and *Ann Intern Med* 2001; **134:** 657–62.

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refine CONSORT. At the 1999 meeting, the participants decided to revise the original statement. This report reflects changes determined by consensus of the CONSORT group, partly in response to emerging evidence on the importance of various elements of RCTs.

Revision of the CONSORT statement

13 members of the CONSORT group met in May, 1999, with the main objective of revising the original CONSORT checklist and flow diagram, as needed. The group discussed the merits of including each item in the light of current evidence. As in developing the original CONSORT statement, our intention was to keep only those items deemed fundamental to reporting standards for an RCT. Some items not regarded as essential could well be highly desirable and should still be included in an RCT report even though they are not included in CONSORT. Such items include approval of an institutional ethics review board, sources of funding for the trial, and a trial registry number—eg, the International Standard Randomized Controlled Trial Number (ISRCTN) used to register the RCT at its inception.[17]

Shortly after the meeting, a revised version of the checklist was circulated to the group for additional comments and feedback. Revisions to the flow diagram were similarly made. All these changes were discussed when CONSORT participants met in May, 2000, and the revised statement was finalised shortly afterwards.

The revised CONSORT statement includes a 22-item checklist (table) and a flow diagram (figure). Its main aim is to help authors improve the quality of reports of simple two-group parallel RCTs. However, the basic philosophy underlying the development of the statement can be applied to any design. In this respect, additional statements for other designs will be forthcoming from the group. CONSORT can also be used by peer reviewers and editors to identify reports with inadequate description of trials and those with potentially biased results.[1,2]

During the 1999 meeting, the group also discussed the benefits of developing an explanatory document to improve the use and dissemination of CONSORT. The document is patterned on reporting of statistical aspects of clinical research,[18] and was developed to help facilitate the recommendations of the ICMJE's Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Three members of the CONSORT group, with assistance from members on some checklist items, drafted an explanation and elaboration document. That document[19] was circulated to the group for additions and revisions and was last revised after review at the latest CONSORT group meeting.

Changes to CONSORT

(1) In the revised checklist, a new column for "Paper section and topic" integrates information from the "Subheading" column that was contained in the original statement.
(2) The "Was it reported?" column has been integrated into a "reported on page number" column, as requested by some journals.
(3) Each item of the checklist is now numbered and the syntax and order have been revised to improve the flow of information.
(4) "Title" and "Abstract" are now combined in the first item.
(5) Although the content of the revised checklist is similar to the original, some items that were previously combined

	Item number	Descriptor	Reported on page number
Title and abstract	1	How participants were allocated to interventions (eg, "random allocation", "randomised", or "randomly assigned").	
Introduction			
Background	2	Scientific background and explanation of rationale.	
Methods			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors, &c).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomisation			
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).	
Allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were aware of group assignment. If not, how the success of masking was assessed.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	
Results			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention to treat". State the results in absolute numbers when feasible (eg, 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% CI).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	
Adverse events	19	All important adverse events or side-effects in each intervention group.	
Discussion			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalisability	21	Generalisability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

Checklist of items to include when reporting a randomised trial

are now separate. For example, previously authors were asked to describe "primary and secondary outcome(s) measure(s) and the minimum important difference(s), and indicate how the target sample size was projected". In the new version, issues pertaining to outcomes (item 6) and sample size (item 7) are separate, enabling authors to be more explicit about each. Moreover, some items request additional information. For example, for outcomes, authors are asked to report any methods used to improve the quality of measurements, such as multiple observations.

(6) The item asking for the unit of randomisation (eg, cluster) has been dropped because specific checklists have been developed for reporting cluster RCTs[20] and other design types[13] since publication of the original checklist.

(7) Whenever possible, new evidence is incorporated into the revised checklist. For example, authors are asked to be explicit about whether the analysis reported is by intention to treat (item 16). This request is based partly on the observations[21] that authors do not adequately describe and apply intention-to-treat analysis, and that reports not providing this information are less likely to provide other relevant information such as losses to follow-up.[22]

(8)The revised flow diagram depicts information from four stages of a trial (enrolment, intervention allocation, follow-up, and analysis). The revised diagram explicitly shows the number of participants, for each intervention group, included in the primary data analysis. Inclusion of these numbers lets the reader know whether the authors have done an intention-to-treat analysis.[21–23] Because some of the information might not always be known, and to accommodate other information, the structure of the flow diagram might need to be modified for a particular trial. Inclusion of the participant flow diagram in the report is strongly recommended but might be unnecessary for simple trials such as those without any participant withdrawals or dropouts.

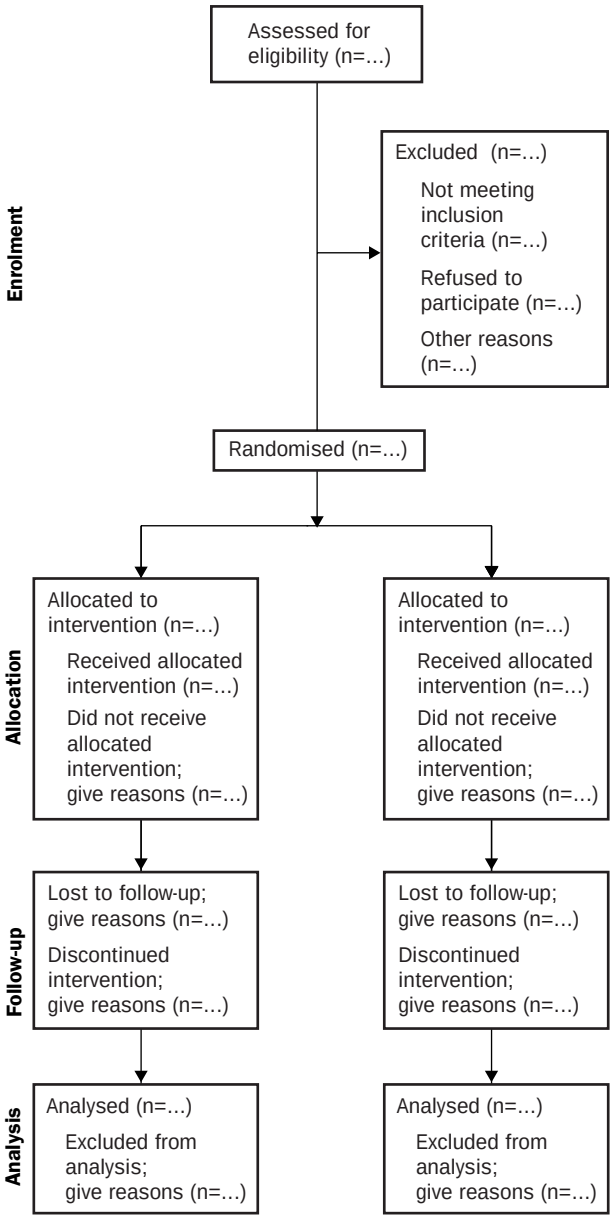
Discussion

Specifically developed to guide authors about how to improve the quality of reporting of simple two-group parallel RCTs, CONSORT encourages transparency with reporting of the methods and results so that reports of RCTs can be interpreted readily and accurately. However, CONSORT does not address other facets of reporting that also require attention, such as scientific content and readability of RCT reports. Some authors in their enthusiasm to use CONSORT have modified the checklist.[24] We recommend against such modifications because they could be based on a different process from the one used by the CONSORT group.

The use of CONSORT seems to reduce, if not eliminate, inadequate reporting of RCTs.[14,15] Potentially, the use of CONSORT should positively influence the manner in which RCTs are conducted. Granting agencies have noted this potential relation, and in at least one case[25] have encouraged researchers to consider in their application how they have dealt with the CONSORT items.

The evidence-based approach used to develop CONSORT has also been used to develop standards for reporting meta-analyses of randomised trials,[26] meta-analyses of observational studies,[27] and diagnostic studies (Jeroen Lijmer, personal communication). Health economists have also started to develop reporting standards[28] to help to improve the quality of their reports.[29] The intent of all these initiatives is to improve the quality of reporting of biomedical research,[30] and by doing so, to bring about more effective health care.

The revised CONSORT statement will replace the original one in the journals and groups that already support



Flow diagram of the progress through the phases of a randomised trial

it. Journals that do not yet support CONSORT may do so by registering on the CONSORT website.[13] To convey to authors the importance of improved quality in the reporting of RCTs, we encourage supporting journals to reference the revised CONSORT statement and the CONSORT internet address in their Instructions to Contributors. Since the journals publishing the revised CONSORT statement have waived copyright protection, CONSORT is now widely accessible to the biomedical community. The CONSORT checklist and flow diagram can also be accessed at the CONSORT website.

A lack of clarification of the meaning and rationale for each checklist item in the original CONSORT statement has been remedied with the development of the CONSORT explanation and elaboration document,[19] which can also be found on the CONSORT website. This document reports the evidence on which the checklist items are based, including the references, which had annotated the checklist items in the previous version. We also

encourage journals to include reference to this document in their Instructions to Contributors.

Emphasising the evolving nature of CONSORT, the CONSORT group invites readers to comment on the updated checklist and flow diagram through the CONSORT website.[13] Comments and suggestions will be collated and considered at the next meeting of the group in 2001.

Contributors

David Moher, Ken Schulz, and Doug Altman participated in regular conference calls, identified participants, participated in the CONSORT meetings, and drafted the paper. David Moher and Leah Lepage planned the CONSORT meetings, identified and secured funding, invited the participants, and planned the meeting agenda. The members of the CONSORT group listed below attended the CONSORT meetings and provided input towards the revised checklist, flow diagram, and text.

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Review

Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement

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Summary

Background The Quality of Reporting of Meta-analyses (QUOROM) conference was convened to address standards for improving the quality of reporting of meta-analyses of clinical randomised controlled trials (RCTs).

Methods The QUOROM group consisted of 30 clinical epidemiologists, clinicians, statisticians, editors, and researchers. In conference, the group was asked to identify items they thought should be included in a checklist of standards. Whenever possible, checklist items were guided by research evidence suggesting that failure to adhere to the item proposed could lead to biased results. A modified Delphi technique was used in assessing candidate items.

Findings The conference resulted in the QUOROM statement, a checklist, and a flow diagram. The checklist describes our preferred way to present the abstract, introduction, methods, results, and discussion sections of a report of a meta-analysis. It is organised into 21 headings and subheadings regarding searches, selection, validity assessment, data abstraction, study characteristics, and quantitative data synthesis, and in the results with "trial flow", study characteristics, and quantitative data synthesis; research documentation was identified for eight of the 18 items. The flow diagram provides information about both the numbers of RCTs identified, included, and excluded and the reasons for exclusion of trials.

Interpretation We hope this report will generate further thought about ways to improve the quality of reports of meta-analyses of RCTs and that interested readers, reviewers, researchers, and editors will use the QUOROM statement and generate ideas for its improvement.

Lancet 1999; **354:** 1896–900
See Commentary page ????????

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Introduction

Health-care providers and other decision-makers now have, among their information resources, a form of clinical report called the meta-analysis,[1-4] a review in which bias has been reduced by the systematic identification, appraisal, synthesis, and, if relevant, statistical aggregation of all relevant studies on a specific topic according to a predetermined and explicit method.[3] The number of published meta-analyses has increased substantially in the past decade.[5] These integrative articles can be helpful for clinical decisions, and they may also serve as the policy foundation for evidence-based practice guidelines, economic evaluations, and future research agendas. The value of meta-analysis is evident in the work of the international Cochrane Collaboration,[6,7] the primary purpose of which is to generate and disseminate high-quality systematic reviews of health-care interventions.

Like any research enterprise, particularly one that is observational, the meta-analysis of evidence can be flawed. Accordingly, the process by which meta-analyses are carried out has undergone scrutiny. A 1987 survey of 86 English-language meta-analyses[8] assessed each publication on 23 items from six content areas judged important in the conduct and reporting of a meta-analysis of randomised trials: study design, combinability, control of bias, statistical analysis, sensitivity analysis, and problems of applicability. The survey results showed that only 24 (28%) of the 86 meta-analyses reported that all six content areas had been addressed. The updated survey, which included more recently published meta-analyses, showed little improvement in the rigour with which they were reported.[9]

Several publications have described the science of reviewing research,[1] differences among narrative reviews, systematic reviews, and meta-analyses,[2] and how to carry out,[3,4,10] critically appraise,[11–15] and apply[16] meta-analyses in practice. The increase in the number of meta-analyses published has highlighted such issues as discordant meta-analyses on the same topic[17] and discordant meta-analyses and randomised-trial results on the same question.[18]

An important consideration in interpretation and use of meta-analyses is to ascertain that the investigators who did the meta-analysis not only report explicitly the methods they used to analyse the articles they reviewed, but also report the methods used in the research articles they analysed. The meta-analytical review methods used may not be provided when a paper is initially submitted: even when they are, other factors such as page limitations, peer review, and editorial decisions may change the content and format of the report before publication.

Several investigators have suggested guidelines for reporting of meta-analyses.[3,19] However, a consensus across disciplines has not developed. After the initiative to

improve the quality of reporting of randomised controlled trials (RCTs),[20–22] we organised the Quality of Reporting of Meta-analyses (QUOROM) conference to address these issues as they relate to meta-analyses of RCTs. This report summarises the proceedings of that conference. The issues discussed might also be useful for reporting of systematic reviews (ie, meta-analysis, as defined above, without statistical aggregation), particularly of RCTs.

Methods

The QUOROM steering committee began with a comprehensive review of publications on the conduct and reporting of meta-analyses. The databases searched included MEDLINE and the Cochrane Library,[23] which consists of the Cochrane Database of Systematic Reviews, the Cochrane Controlled Trials Register, the York Database of Abstracts of Reviews of Effectiveness, and the Cochrane Review Methodology Database. We examined reference lists of the retrieved articles and individual personal files. Articles of potential relevance were retrieved and critically appraised by the QUOROM steering committee. The committee generated a draft agenda for the conference, which included six domains requiring discussion and debate. The content areas were slightly modified during preliminary discussions at the conference and are reported as: the search for the evidence; decision-making on which evidence to include; description of the characteristics of primary studies; quantitative data synthesis; reliability and issues related to internal validity (or quality); and clinical implications related to external validity (or generalisability).

In planning the QUOROM conference, the steering committee identified clinical epidemiologists, clinicians, statisticians, and researchers who conduct meta-analysis as well as editors from the UK and North America who are interested in meta-analysis. These 30 individuals were invited to a conference in Chicago on Oct 2–3, 1996. Participants were surveyed before the meeting to elicit their views on current reporting standards of meta-analyses and whether these needed improvement. In addition, they were sent relevant citations for review and were asked to indicate in which of the six groups they wished to participate.

The conference included small-group and plenary sessions. Each small group had a facilitator who was a member of the steering committee and was responsible for ensuring the discussions of as many as possible of the issues relevant to their specific remit. Each small group also had a recorder, who was responsible for documenting the main points and the consensus on each issue discussed during that session; the recorder presented the group's consensus during the plenary sessions. During the plenary sessions, an elected scribe from each small group was responsible for recording the principal points relevant to that group's charge that arose during the plenary discussion.

The participants in each small group were asked to identify items that they thought should be included in a checklist of standards that would be useful for investigators, editors, and peer reviewers. We asked that, whenever possible, items included in the checklist be guided by research evidence that suggested that a failure to adhere to the particular checklist item proposed could lead to biased results. For example, a substantial lack of sensitivity and specificity of MEDLINE searches is evident.[24] Therefore, the checklist suggests that investigators explicitly describe all search strategies used to locate articles for inclusion in a meta-analysis. In considering whether candidate items were essential, each subgroup used a modified Delphi technique[25] that was replicated in the plenary sessions.

Heading	Subheading	Descriptor	Reported? (Y/N)	Page number
Title		Identify the report as a meta-analysis [or systematic review] of RCTs[26]		
Abstract		Use a structured format[27]		
		Describe		
	Objectives	The clinical question explicitly		
	Data sources	The databases (ie, list) and other information sources		
	Review methods	The selection criteria (ie, population, intervention, outcome, and study design); methods for validity assessment, data abstraction, and study characteristics, and quantitative data synthesis in sufficient detail to permit replication		
	Results	Characteristics of the RCTs included and excluded; qualitative and quantitative findings (ie, point estimates and confidence intervals); and subgroup analyses		
	Conclusion	The main results		
		Describe		
Introduction		The explicit clinical problem, biological rationale for the intervention, and rationale for review		
Methods	Searching	The information sources, in detail[28] (eg, databases, registers, personal files, expert informants, agencies, hand-searching), and any restrictions (years considered, publication status,[29] language of publication[30,31])		
	Selection	The inclusion and exclusion criteria (defining population, intervention, principal outcomes, and study design[32]		
	Validity assessment	The criteria and process used (eg, masked conditions, quality assessment, and their findings[33–36])		
	Data abstraction	The process or processes used (eg, completed independently, in duplicate)[35,36]		
	Study characteristics	The type of study design, participants' characteristics, details of intervention, outcome definitions, &c,[37] and how clinical heterogeneity was assessed		
	Quantitative data synthesis	The principal measures of effect (eg, relative risk), method of combining results (statistical testing and confidence intervals), handling of missing data; how statistical heterogeneity was assessed;[38] a rationale for any a-priori sensitivity and subgroup analyses; and any assessment of publication bias[39]		
Results	Trial flow	Provide a meta-analysis profile summarising trial flow (see figure)		
	Study characteristics	Present descriptive data for each trial (eg, age, sample size, intervention, dose, duration, follow-up period)		
	Quantitative data synthesis	Report agreement on the selection and validity assessment; present simple summary results (for each treatment group in each trial, for each primary outcome); present data needed to calculate effect sizes and confidence intervals in intention-to-treat analyses (eg 2×2 tables of counts, means and SDs, proportions)		
Discussion		Summarise key findings; discuss clinical inferences based on internal and external validity; interpret the results in light of the totality of available evidence; describe potential biases in the review process (eg, publication bias); and suggest a future research agenda		

Quality of reporting of meta-analyses

Results

The conference resulted in the QUOROM statement: a checklist (table) and a flow diagram (figure). The checklist of standards for reporting of meta-analyses describes our preferred way to present the abstract, introduction, methods, results, and discussion sections of a report of a meta-analysis. The checklist is organised into 21 headings and subheadings to encourage authors to provide readers with information on searches, selection, validity assessment, data abstraction, study characteristics, quantitative data synthesis, and trial flow. Authors are asked to provide a flow diagram (figure) providing information about the number of RCTs identified, included, and excluded and the reasons for excluding them.[10]

Pretesting

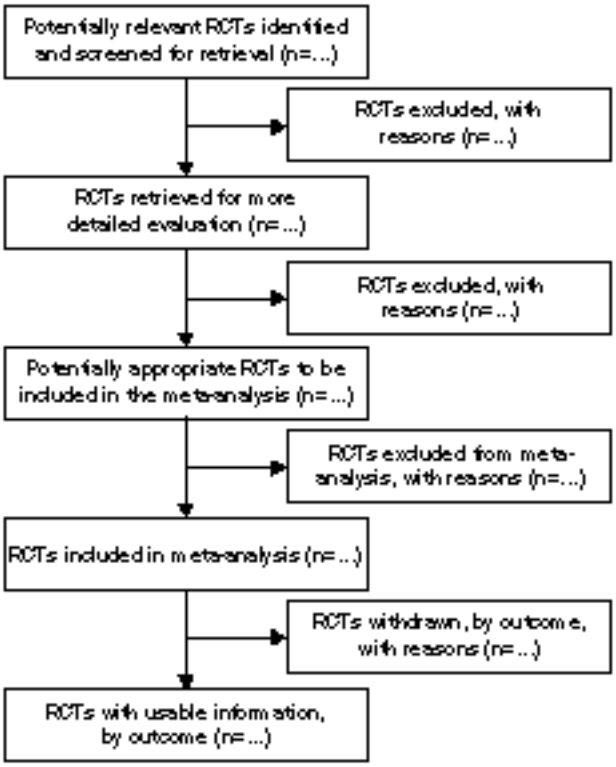
After development of the checklist and flow diagram, two members of the steering committee (DM, DJC) undertook pretesting with epidemiology graduate students studying meta-analysis, residents in general internal medicine, participants at a Canadian Cochrane Center workshop, and faculty members of departments of medicine and of epidemiology and biostatistics. One group of candidates for a master's degree in epidemiology used the checklist and flow diagram to report their meta-analyses as if their work were being submitted for publication. Feedback from these four groups was positive, most users stating that the checklist and flow diagram would be likely to improve reporting standards. Modifications of the checklist (eg, inclusion of a statement about major findings) and changes to the flow diagram (eg, more detail) were incorporated.

Discussion

In developing the checklist, we identified supporting scientific evidence for only eight of 18 items to guide the reporting of meta-analyses of RCTs.[26-39] Some of this evidence is indirect. For example, we ask authors to use a structured abstract format. The supporting evidence for this item was collected by examining abstracts of original reports of individual studies[27] and may not pertain specifically to the reporting of meta-analyses. However, the QUOROM group judged this a reasonable approach by analogy with other types of research reports and pending further evidence about the merits of structured abstracts for meta-analyses.

We have asked authors to be explicit in reporting the criteria used when assessing the "quality" of trials included in meta-analyses and the outcome of the quality assessment. There is direct and compelling evidence to support recommendations about reporting on the quality of RCTs included in a meta-analysis. A meta-analytic database of 255 obstetric RCTs provided evidence that trials with inadequate reporting of allocation concealment (ie, keeping the intervention assignments hidden from all participants in the trial until the point of allocation) overestimated the intervention effect by 30% compared with trials in which this information was adequately reported.[33] Similar results for several disease categories and methods of quality assessment have been reported.[34] These findings suggest that inclusion of reports of low-quality RCTs in meta-analyses is likely to alter the summary measures of the intervention effect.

We also ask authors to be explicit in reporting assessment of publication bias, and we recommend that the discussion should include comments about whether the results obtained may have been influenced by such bias. Publication bias derives from the selective publishing of studies with statistically significant or directionally positive results,[40–42] and it can lead to inflated estimates of efficacy in meta-analyses. For example, trials of single alkylating agents versus multiple-agent cytotoxic chemotherapy in the treatment of ovarian cancer have been analysed.[39] Published trials yielded significant results in favour of the multiple-agent therapy, but that finding was not supported when the results of all trials—both those published and those registered but not published—were analysed.



Progress through the stages of a meta-analysis for RCTs

The statement asks authors to be explicit about the publication status of reports included in a meta-analysis. Only about a third of published meta-analyses report the inclusion of unpublished data.[29,43] Although one study found that there were no substantial differences in the dimensions of study quality between published and unpublished clinical research,[42] another suggested that intervention effects reported in journals were 33% greater than those reported in doctoral dissertations.[44] The role of the "grey literature" (difficult to locate or retrieve) was examined in 39 meta-analyses that included 467 RCTs, 102 of which were grey literature.[29] Meta-analyses limited to published trials, compared with those that included both published and grey literature, overestimated the treatment effect by an average of 12%. There is still debate between editors and investigators about the importance of including unpublished data in a meta-analysis.[43]

We have asked authors to be explicit in reporting whether they have used any restrictions on language of publication. Roughly a third of published meta-analyses have some language restrictions as part of the eligibility criteria for including individual trials.[30] The reason for such restrictions is not clear, since there is no evidence to support differences in study quality, and there is evidence that language restrictions may result in a biased summary.

The reports of 127 RCTs written in English, compared with those reported in four other languages, showed little or no difference in several important methodological features.[45] Similar results have been reported elsewhere.[31] The role of language restrictions has been studied in 211 RCTs included in 18 meta-analyses in which trials published in languages other than English were included in the quantitative summary.[30] Language-restricted meta-analyses overestimated the treatment effect by only 2% on average compared with language-inclusive meta-analyses. However, the language-inclusive meta-analyses were more precise.[30]

Reports of RCTs with statistically positive results are more likely than those with negative results to be published in English.[31] Likewise, there is emerging evidence to suggest that reports of RCTs from certain countries mostly have statistically positive results.[46]

We used several methods to generate the checklist and flow diagram: a systematic review of the reporting of meta-analyses; focus groups of the steering committee; and a modified Delphi approach during the conference. Although we did not involve certain users of meta-analyses (policy-makers or patients), we formally pretested this document with representatives of several constituencies who would use the recommendations and made modifications accordingly.

The QUOROM group also discussed the format of a meta-analysis report, how best to assess the impact of the QUOROM statement, and how best to disseminate it. The format we recommend includes 15 subheadings that reflect the sequential stages in the conduct of the meta-analysis within the text of the report of a meta-analysis. The checklist included in the statement can also be used during the planning, performing, and reporting of a meta-analysis and during peer review of the report after its submission to a journal.

We delayed publication of the QUOROM statement until its impact on the editorial process had been assessed. We organised an RCT involving eight medical journals to assess the impact of use of QUOROM criteria on journal peer review. Accrual is now complete and we will report the trial results elsewhere.

After about 5 weeks of electronic posting we had received five comments from investigators, whom we thank for their thoughtful consideration of the statement. Several issues, in particular in relation to terminology, cannot be addressed in the statement at present. The QUOROM group is agreed on the importance of making changes to the checklist in the light of documented evidence and must resist changes based on opinion or anecdotal evidence unless there is a compelling rationale for doing otherwise. Nonetheless, the issues raised have been noted for consideration and discussion in future.

Several queries addressed the distinction between the meta-analysis and systematic review. As we indicate in the introduction, and throughout the statement, the QUOROM group agreed to observe the distinction as defined by the Potsdam consultation on meta-analysis.[3]

We were also asked to clarify the checklist item asking investigators to interpret their results in light of the totality of evidence. Increasingly, several meta-analyses on the same topic are reported.[47-49] If other similar reports are available, authors should discuss their results as they relate to such evidence.

For the QUOROM statement to continue to be useful, it must remain evidence based and up to date. Members of the QUOROM group need to survey the literature continually to help inform themselves about emerging evidence on reporting of meta-analyses. This information needs to be collated and presented annually for two purposes. The first is decisions on which checklist items to keep, delete, or add; these decisions can be made similarly to the selection of the original items. The second purpose is so that an up to date summary on the reporting of meta-analyses can be prepared. These efforts are being coordinated through a website. This approach is similar to the CONSORT initiative.

In summary, our choice of items to include in a meta-analysis report was based on evidence whenever possible, which implies the need to include items that can systematically influence estimates of treatment effects. Currently, we lack a detailed understanding of all the factors leading to bias in the result of a meta-analysis. Clearly, research is required to help improve the quality of reporting of meta-analyses. Such evidence may also act as a catalyst for improving the methods by which meta-analyses are conducted.

The QUOROM checklist and flow diagram are available on *The Lancet*'s website [www.thelancet.com]. We hope that this document will generate further interest in the field of meta-analysis and that, like the CONSORT initiative, the QUOROM statement will become available in different languages and locations as it is disseminated. We invite interested readers, reviewers, researchers, and editors to use the QUOROM statement and generate ideas for improvement.

Contributors

David Moher, Deborah Cook, Susan Eastwood, Ingram Olkin, Drummond Rennie, and Donna Stroup developed the QUOROM statement. They all planned the meeting, participated in regular conference calls, identified and secured funding, identified and invited participants, and planned the meeting agenda. All of them helped write the report, including revisions.

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Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement checklist

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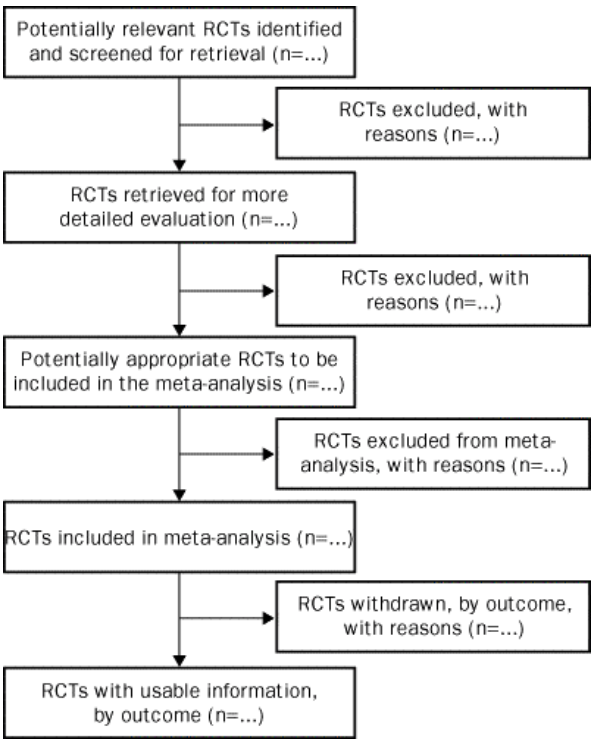
Discussion		Summarise key findings; discuss clinical inferences based on internal and external validity; interpret the results in light of the totality of available evidence; describe potential biases in the review process (eg, publication bias); and suggest a future research agenda		

Quality of reporting of meta-analyses

Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement flow diagram



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