

# Uniform Requirements for Manuscripts Submitted to Biomedical Journals

International Committee of Medical Journal Editors<sup>1</sup>

## Background

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 emphasize 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

The requirements were updated on May 2000

<sup>1</sup>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 Lægeforening*; Liselotte Hojgaard, *Ugeskrift for Læger*. Sheldon Kotzin, U.S. National Library of Medicine.

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](http://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

### 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 × 279 mm (8.5 × 11 inches), or ISO A4 (212 × 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 coauthors. 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 (URL: <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 many 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.: HHSIGOE169200860. 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.: AHCPR28 2942008. Sponsored by the Agency for Health Care Policy and Research.
  23. *Dissertation*  
Kaplan SJ. Post-hospital home health care: the elderly's access and utilization [dissertation]. St. Louis (MO): Washington Univ.; 1995.
  24. *Patent*  
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.
- Other published material**
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.

31. *Classical material*

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**

33. *Journal article in electronic format*

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>

34. *Monograph in electronic format*

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 backup 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 × 173 mm (5 × 7 inches) but no larger than 203 × 254 mm (8 × 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.

#### 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 × 254 mm (8 × 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.

#### 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 trust 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.

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 their work. They should acknowledge in the manuscript all financial support for their work and other financial or personal connections to the work.

##### **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.

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. Reviewers 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 for 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) URL: <http://www.CouncilScienceEditors.org>.

The European Association of Science Editors (EASE) URL: <http://www.ease.org.uk>

Society for Scholarly Publishing (SSP) URL: <http://www.sspnet.org> The World Association of Medical Editors (WAME) URL: <http://www.WAME.org>

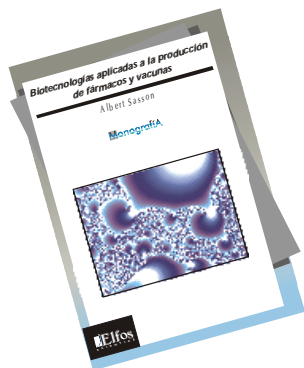
### Acknowledgments

The following members of the ICMJE helped author the 1997 version and should be acknowledged in citations of the May 2000 version.

Linda Hawes Clever, *Western Journal of Medicine*; Lois Ann Colaianni, U.S. National Library of Medicine; George Lundberg, *JAMA*; Richard G. Robinson, *New Zealand Medical Journal*; Richard Smith, *BMJ*; Bruce P. Squires, *Canadian Medical Association Journal*; Martin VanDer Weyden, *The Medical Journal of Australia*; and Patricia Woolf, Princeton University.

Inquiries about the Uniform Requirements only should be sent to Kathleen Case 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: [kathyc@mail.acponline.org](mailto:kathyc@mail.acponline.org). Please do not send inquiries about individual journal styles and policies to this address.

This document may be copied and distributed without charge for not-for-profit, educational purposes. A digital version is available on various web sites, including the ICMJE web site (URL: <http://www.icmje.org>).



## Biotecnologías aplicadas a la producción de fármacos y vacunas

Albert Sasson

ISBN 959-235-013-2

**MonografíaS**

*Las biotecnologías constituyen una de las tecnologías que más influyen de manera global en los avances científicos y tecnológicos del mundo moderno. Su influencia comprende prácticamente todas las áreas del conocimiento y de la producción de bienes, desde el esclarecimiento de mecanismos moleculares de funciones muy específicas, hasta la creación de nuevas variedades de plantas y el desarrollo de nuevos procesos industriales. Sin embargo, es en la industria farmacéutica donde se están produciendo los aportes más importantes, debido a la contribución de la biotecnología a la producción de fármacos y vacunas, ya sea mediante microorganismos manipulados genéticamente mediante técnicas de ADN recombinante o por otras tecnologías no menos novedosas.*

*En este libro, Albert Sasson ofrece una valiosa y bien documentada información que abarca desde los antecedentes científicos hasta las tendencias actuales y futuras de la comercialización de los fármacos y vacunas obtenidos por métodos biotecnológicos.*

### Entre otros temas...

- ❖ Productos y procedimientos comerciales basados en organismos modificados genéticamente
- ❖ El proyecto sobre el genoma humano
- ❖ Bioindustria médica
- ❖ Las biotecnologías en la industria farmacéutica de América Latina: panorama, realizaciones y perspectivas
- ❖ Perspectivas en el desarrollo y la comercialización de los productos biotecnológicos



**Envíe su solicitud a:**  
 Elfos Scientiae  
 Apartado 6072,  
 La Habana 6, Cuba.  
 Tel.: (53-7) 33 1917  
 Fax: (53-7) 33 1917  
 E-mail: [elfos@cigb.edu.cu](mailto:elfos@cigb.edu.cu)  
<http://www.elfoscientiae.com.cu>

Precio: \$12.00 USD