MANUSCRIPT CRITERIA AND INFORMATION

These instructions apply to all categories of manuscripts including, for example, Letters to the Editor and submissions to special journal departments.

Send manuscripts to the Editor, Marjorie A. Bowman, MD, MPA, *Archives of Family Medicine*, University of Pennsylvania Health System, 1126 Penn Tower, 399 S 34th St, Philadelphia, PA 19104-4385. Manuscripts are considered with the understanding that they have not been published previously in print or electronic format and are not under consideration by another publication or electronic medium. A complete report following presentation or publication of preliminary findings elsewhere (eg, in an abstract) can be considered. Include copies of possibly duplicative materials that have been previously published or are currently being considered elsewhere.

Cover Letter

Designate 1 author as correspondent and provide a complete address, telephone number, and fax number. Manuscripts should have no more than 6 authors; a greater number requires justification. Authors may add a publishable footnote explaining order of authorship.[1]

In the cover letter include (1) statement on authorship responsibility, (2) statement on financial disclosure, and (3) 1 of the 2 following statements on copyright or federal employment. Each of these 3 statements must be signed by *all* authors (see form on page 395).

1. **Authorship Responsibility.** "I have participated sufficiently in the conception and design of this work or the analysis and interpretation of the data (when applicable), as well as the writing of the manuscript, to take public responsibility for it. I believe the manuscript represents valid work. I have reviewed the final version of the submitted manuscript and approve it for publication. Neither this manuscript nor one with substantially similar content under my authorship has been published or is being considered for publication elsewhere, except as described in an attachment. If requested, I shall produce the data on which the manuscript is based for examination by the editors or their assignees."

2. **Financial Disclosure.** "I certify that any affiliations with or involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the manuscript (eg, employment, consultancies, stock ownership, honoraria, expert testimony) are disclosed below."

Research or project support should be listed in an acknowledgment.

3. **Copyright Transfer.** "In consideration of the action of the American Medical Association (AMA) in reviewing and editing this submission, the author(s) undersigned hereby transfers, assigns, or otherwise conveys all copyright ownership to the AMA in the event that such work is published by the AMA."

4. **Federal Employment.** "I was an employee of the US federal government when this work was conducted and prepared for publication; therefore, it is not protected by the Copyright Act and there is no copyright of which the ownership can be transferred."

Editorial Review and Processing

Peer Review. All submitted manuscripts are reviewed initially by an ARCHIVES editor. Those manuscripts with insufficient priority for publication are returned promptly. Other manuscripts are sent to expert consultants for peer review. Peer reviewer identities are kept confidential. Attempts are made to keep author identities confidential.

Rejected Manuscripts. Rejected manuscripts will not be returned to authors unless specifically requested in the cover letter. Original illustrations, photographs, and slides will be returned.

Editing. Accepted manuscripts are copy edited according to AMA style and returned to the author for approval. Authors are responsible for all statements made in their work, including changes made by the copy editor and authorized by the corresponding author.

Reprints. Reprint order forms are included with the edited typescript sent for approval to authors. Reprints are shipped 6 to 8 weeks after publication.

All accepted manuscripts become the permanent property of the AMA and may not be published elsewhere without written permission from both the author(s) and the AMA.

Manuscript Preparation[2-6]

- Manuscripts should be prepared in accordance with the *American Medical Association Manual of Style*[2] and/or the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals."[3]

- Submit the original manuscript and 3 copies, typed on 1 side of standard-sized white bond paper. Use ample margins.

- Double-space throughout, including title page, abstract, text, acknowledgments, references, legends for illustrations, and tables. Start each of these sections on a new page, numbered consecutively in the upper right-hand corner, beginning with the title page. Authors' names should appear only on the title page.

- Provide copy that can be scanned by an optical character reader: no smudges or pencil or pen marks. Use only standard 10- or 12-pitch type and spacing. Do not use 10-pitch type with

12-pitch spacing. If prepared on a word processor, do not use proportional spacing; use unjustified (ragged) right margins and letter-quality printing.

• On the title page type the full names, highest academic degrees, and affiliations of all authors. If an author's affiliation has changed since the work was done, list the new affiliation as well.

• Use Système International (SI) measurements.[5]

• Use generic names of drugs, unless the specific trade name of a drug used is directly relevant to the discussion.

• Do not use abbreviations in the title or abstract and limit their use in the text.

Abstract. Include a *structured abstract* of no more than 250 words for reports of original data from clinical investigations with human subjects. (See Instructions for Preparing Structured Abstracts on page 396.) For other major manuscripts, include an abstract of no more than 150 words. Abstracts are not required for Editorials, Commentaries, and Special Features of the ARCHIVES.

Informed Consent. For experimental investigations of human or animal subjects, state in the "Methods" section of the manuscript that an appropriate institutional review board approved the project. For those investigators who do not have formal ethics review committees (institutional or regional), the principles outlined in the Declaration of Helsinki should be followed.[6] For investigations of human subjects, state in the "Methods" section the manner in which informed consent was obtained from the subjects.

Case Descriptions and Photographs. Include a signed statement of consent to publish all case descriptions and photographs from all patients (parents or legal guardians for minors) who can be identified in such written descriptions and photographs.

References. Number references in the order they are mentioned in the text; do not alphabetize. In text, tables, and legends, identify references with superscript arabic numerals. In listing references, follow AMA style, abbreviating names of journals according to *Index Medicus*. Note: List all authors and/or editors up to 6; if more than 6, list the first 3 and "et al."

Examples of Reference Style:

1. Lomas J, Enkin M, Anderson GM, Hannah WJ, Vayda E, Singer J. Opinion leaders vs audit and feedback to implement practice guidelines: delivery after previous cesarean section. *JAMA*. 1991;265:2202-2207.
2. Marcus R, Couston AM. Water-soluble vitamins: the vitamin B complex and ascorbic acid. In: Gilman AG, Rall TW, Nies AS, Taylor P. *Goodman and Gilman's The Pharmacological Basis of Therapeutics*. 8th ed. New York, NY: Pergamon Press; 1990:1530-1552.

Authors are responsible for the accuracy and completeness of their references and for correct text citation.

Tables. Double-space on separate sheets of standard-sized white bond paper. Title all tables and number them in order of their citation in the text. If a table must be continued, repeat the title on a second sheet, followed by "(cont)."

Illustrations. Submit, in triplicate, (1) 5 × 7-in glossy photographs for all graphs and black-and-white photographs; (2) high-contrast prints for roentgenograms; (3) color transparencies (carefully mounted and packaged) for color illustrations. Computer-generated graphics produced by high-quality laser printers (300 dots per inch) also are acceptable. Number illustrations according to their order in the text. Affix a label with figure number, name of first author, short form of the manuscript title, and an arrow indicating "top" to the back of the print. Never mark on the print or the transparency itself.

• Double-space legends (maximum length, 40 words) on separate pages. Indicate magnification and stain used for photomicrographs.

• Acknowledge all illustrations and tables taken from other publications and submit written permission to reprint from the original publishers.

Manuscript Checklist

1. Include original manuscript and 3 copies.
2. Include in the cover letter statements—signed by each author—on (*a*) authorship responsibility, (*b*) financial disclosure, and (*c*) copyright transfer or federal employment.
3. Leave right margins unjustified (ragged).
4. Check all references for accuracy and completeness. Put references in proper format in numerical order, making sure each is cited in the text.
5. Send 3 sets of all illustrations.
6. Provide and label an abstract.
7. Include complete consent forms for identifiable patient descriptions and photographs.
8. Include research or project support and funding in an acknowledgment.
9. Include written permission from publishers and authors to reproduce or adapt previously published illustrations and tables.
10. Designate a corresponding author and provide a complete address, telephone number, and fax number.

REFERENCES

1. The International Committee of Medical Journal Editors. Statements from the International Committee of Medical Journal Editors. *JAMA*. 1993;269:2282-2286.
2. Iverson CL, Dan BB, Glitman P, et al. *American Medical Association Manual of Style*. 8th ed. Baltimore, Md: Williams & Wilkins; 1988.
3. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. *JAMA*. 1993;269:2282-2286.
4. Lundberg GD, Flanagin A. New requirements for authors: signed statements of authorship responsibility and financial disclosure. *JAMA*. 1989;262:2003-2004.
5. Lundberg GD. SI unit implementation—the next step. *JAMA*. 1988;260:73-76.
6. 41st World Medical Assembly. Declaration of Helsinki: recommendations guiding physicians in biomedical research involving human subjects. *Bull Pan Am Health Organ*. 1990;24:606-609.

INSTRUCTIONS FOR PREPARING STRUCTURED ABSTRACTS

All manuscripts that are reports of original data from clinical investigations with human subjects should be submitted with structured abstracts as described below.

Reports of Original Data From Clinical Investigations With Human Subjects

Authors submitting manuscripts reporting the results of clinical investigations should prepare an abstract of no more than 250 words under the following headings: Objective, Design, Setting, Patients (or Other Participants), Interventions (if any), Main Outcome Measure(s), Results, and Conclusions. The content following each heading should be as follows:

1. *Objective.* The abstract should begin with a clear statement of the precise objective or question addressed in the report. If more than one objective is addressed, the main objective should be indicated and only key secondary objectives stated. If an a priori hypothesis was tested, it should be stated.

2. *Design.* The basic design of the study should be described. The duration of follow-up, if any, should be stated. As many of the following terms as apply should be used.

A. Intervention studies: randomized control trial (see Glossary for the definition of this and other technical terms); nonrandomized control trial; double-blind; placebo control; crossover trial; before-after trial.

B. For studies of screening and diagnostic tests: criterion standard (that is, a widely accepted standard with which a new or alternative test is being compared; this term is preferred to "gold standard"); blinded or masked comparison.

C. For studies of prognosis: inception cohort (subjects assembled at a similar and early time in the course of the disorder and followed thereafter); cohort (subjects followed forward in time, but not necessarily from a common starting point); validation cohort or validation sample if the study involves the modeling of clinical predictions.

D. For studies of causation: randomized control trial; cohort; case-control; survey (preferred to "cross-sectional study").

E. For descriptions of the clinical features of medical disorders: survey; case series.

F. For studies that include a formal economic evaluation: cost-effectiveness analysis; cost-utility analysis; cost-benefit analysis. For new analyses of existing data sets, the data set should be named and the basic study design disclosed.

3. *Setting.* To assist readers to determine the applicability of the report to their own clinical circumstances, the study setting(s) should be described. Of particular importance is whether the setting is the general community, a primary care or referral center, private or institutional practice, ambulatory or hospitalized care.

4. *Patients or Other Participants.* The clinical disorders, important eligibility criteria, and key sociodemographic features of patients should be stated. The numbers of participants and how they were selected should be provided (see below), including the number of otherwise eligible subjects who were approached but refused. If matching is used for comparison groups, characteristics that are matched should be specified. In follow-up studies, the proportion of participants who completed the study must be indicated. In intervention studies, the number of patients withdrawn for adverse effects should be given.

For selection procedures, these terms should be used, if appropriate: random sample (where "random" refers to a formal, randomized selection in which all eligible subjects have a fixed and usually equal chance of selection); population-based sample; referred sample; consecutive sample; volunteer sample; convenience sample. These terms assist the reader to determine an important element of the generalizability of the study. They also supplement (rather than duplicate) the terms used by professional indexers when articles are entered into computerized databases.

5. *Intervention(s).* The essential features of any interventions should be described, including their method and duration of administration. The intervention should be named by its most common clinical name (for example, the generic term "chlorthalidone"). Common synonyms should be given as well to facilitate electronic textword searching. This would include the brand name of a drug if a specific product was studied.

6. *Main Outcome Measure(s).* The primary study outcome measurement(s) should be indicated as planned before data collection began. If the paper does not emphasize the main planned outcomes of a study, this fact should be stated and the reason indicated. If the hypothesis being reported was formulated during or after data collection, this information should be clearly stated.

7. *Results.* The main results of the study should be given. Measurements that require explanation for the expected audience of the manuscript should be defined. Important measurements not included in the presentation of results should be declared. As relevant, it should be indicated whether observers were blinded to patient groupings, particularly for subjective measurements. Due to the current limitations of retrieval from electronic databases, results must be given in narrative or point form rather than tabular form if the abstract is to appear in computerized literature services such as MEDLINE. If possible, the results should be accompanied by confidence intervals (for example, 95%) and the exact level of statistical significance. For comparative studies, confidence intervals should relate to the differences between groups. For nonsignificant differences for the major study outcome measure(s), the clinically important difference sought should be stated and the confidence interval for the difference between the groups should be given. When risk changes or effect sizes are given, absolute values should be indicated so that the reader can determine the absolute as well as relative impact of the finding. Approaches such as "number needed to treat" to achieve a unit of benefit are encouraged when appropriate; reporting of relative differences alone is usually inappropriate. If appropriate, studies of screening and diagnostic tests should use the terms "sensitivity," "specificity," and "likelihood ratio." If predictive values or accuracy is given, prevalence or pretest likelihood should be given as well. No data should be reported in the abstract that do not appear in the rest of the manuscript.

8. *Conclusions.* Only those conclusions of the study that are directly supported by the evidence reported should be given, along with their clinical application (avoiding speculation and overgeneralization), and indicating whether additional study is required before the information should be used in usual clinical settings. Equal emphasis must be given to positive and negative findings of equal scientific merit.

To permit quick and selective scanning, the headings outlined above should be included in the abstract. For brevity, parts of the abstract can be written in phrases rather than complete sentences. (For example: "2. *Design.* Double-blind randomized trial," rather than "2. *Design.* The study was conducted as a double-blind, randomized trial.") This technique may make reading less smooth but facilitates selection scanning and allows more information to be conveyed per unit of space.

Adapted from Haynes RB, Mulrow CD, Huth EJ, Altman DG, Gardner MJ. More informative abstracts revisited. Ann Intern Med. *1990;113:69-76.*

Glossary of Methodologic Terms

BEFORE-AFTER TRIAL. Investigation of therapeutic alternatives in which individuals of one period and under one treatment are compared with individuals at a subsequent time, treated in a different fashion. If the disorder is not fatal and the "before" treatment is not curative, the same individuals may be studied in the before and after periods, strengthening the design through increased group comparability for the two periods. See also CROSSOVER TRIAL.

BLIND or BLINDED. Masked. Unaware. The term may be modified according to the purpose of the blinding. For example, clinicians or patients can be blind to the treatments that patients are receiving and observers can be blind to each other's assessments, making their observations uninfluenced by one another (see also DOUBLE-BLIND). To avoid confusion, the term MASKED is preferred in studies in which vision loss of patients is an outcome of interest.

CASE-CONTROL STUDY (CASE-REFERENT OR CASE-COMPARISON STUDY). Study generally used to test possible causes of a disease or disorder, in which individuals who have a designated disorder are compared with individuals who do not have the disorder with respect to previous current exposure to a putative causal factor. For example, persons with hepatic cancer (cases) are compared with persons without hepatic cancer (controls) and history of hepatitis B is determined for the two groups. A CASE-CONTROL STUDY is often referred to as a RETROSPECTIVE STUDY (even if patients are recruited prospectively) because the logic of the design leads from effect to cause.

CASE SERIES. A series of patients with a defined disorder. The term is usually used to describe a study reporting on a consecutive collection of patients treated in a similar manner, without a concurrent control group. For example, a surgeon might describe the characteristics of and outcomes for 100 consecutive patients with cerebral ischemia who received a revascularization procedure. See also CONSECUTIVE SAMPLE.

COHORT. A group of persons with a common characteristic or set of characteristics. Typically, the group is followed for a specified period to determine the incidence of a disorder or complications of an established disorder (that is, prognosis), as in COHORT ANALYTIC STUDY (prospective study) (see also INCEPTION COHORT).

COHORT ANALYTIC STUDY. Prospective investigation of the factors that might cause a disorder in which a cohort of individuals who do not have evidence of an outcome of interest but who are exposed to the putative cause are compared with a concurrent cohort who are also free of the outcome but not exposed to the putative cause. Both cohorts are then followed to compare the incidence of the outcome of interest.

CONFOUNDER, CONFOUNDING VARIABLE. A factor that distorts the true relationship of the study variables of central interest by virtue of being related to the outcome of interest but extraneous to the study question and unequally distributed among the groups being compared. For example, age might confound a study of the effect of a toxin on longevity if individuals exposed to the toxin were older than those not exposed.

CONSECUTIVE SAMPLE. Sample in which the units are chosen on a strict "first come, first chosen" basis. All individuals who are eligible should be included as they are seen.

CONVENIENCE SAMPLE. Individuals or groups selected at the convenience of the investigator or primarily because they were available at a convenient time or place.

COST-BENEFIT ANALYSIS. A form of economic assessment, usually from society's perspective, in which the costs of medical care are compared with the economic benefits of the care, with both costs and benefits expressed in units of currency. The benefits typically include reductions in future health care costs and increased earnings due to the improved health of those receiving the care.

COST-EFFECTIVENESS ANALYSIS. An economic evaluation in which alternative programs, services, or interventions are compared in terms of the cost per unit of clinical effect (for example, cost per life saved, cost per millimeter of mercury of blood pressure lowered, or cost per quality-adjusted life-year gained). The last form of measuring outcomes (and equivalents such as "healthy days of life gained") gives rise to what is also referred to as COST-UTILITY ANALYSIS.

COST-UTILITY ANALYSIS. See COST-EFFECTIVENESS ANALYSIS.

CRITERION STANDARD. Preferred term to "gold standard." A method having established or widely accepted accuracy for determining a diagnosis, providing a standard to which a new screening or diagnostic test can be compared. The method need not be a single or simple procedure but could include follow-up of patients to observe the evolution of their conditions or the consensus of an expert panel of clinicians, as is frequently used in the study of psychiatric conditions. CRITERION STANDARD can also be used in studies of the quality of care to indicate a level of performance, agreed to by experts or peers, to which the performance of individual practitioners or institutions can be compared.

CROSSOVER TRIAL. A method of comparing two or more treatments or interventions in which subjects or patients, on completion of the course of one treatment, are switched to another. Typically, allocation to the first treatment is by random process. Participants' performance in one period is used to judge their performance in others, usually reducing variability. See also BEFORE-AFTER TRIAL.

DATA SET. Raw data gathered by investigators.

DOUBLE-BLIND or DOUBLE-MASK. (1) Neither the subject nor the study staff (those responsible for patient treatment and data collection) are aware of the group or intervention to which the subject has been assigned. (2) Any condition in which two different groups of persons are purposely denied access to information in order to keep that information from influencing some measurement, observation, or process.

ECONOMIC EVALUATION. Comparative analysis of alternative courses of action in terms of both their costs and consequences.

END POINT. See OUTCOMES.

GOLD STANDARD. See CRITERION STANDARD.

INCEPTION COHORT. A designated group of persons, assembled at a common time early in the development of a specific clinical disorder (for example, at the time of first exposure to the putative cause or at the time of initial diagnosis), who are followed thereafter (see also COHORT).

LIKELIHOOD RATIO. For a screening or diagnostic test (including clinical signs or symptoms), expresses the relative odds that a given test result would be expected in a patient with (as opposed to one without) a disorder of interest.

MASKED. See BLIND.

MATCHING. The deliberate process of making a study group and a comparison group comparable with respect to factors that are extraneous to the purpose of the investigation but that might interfere with the interpretation of the study's findings (for example, in case-control studies, individual cases might be matched or paired with a specific control on the basis of comparable age, sex, clinical features, or a combination).

NONRANDOMIZED CONTROL TRIAL. Experiment in which assignment of patients to the intervention groups is at the convenience of the investigator or according to a preset plan that does not conform to the definition of RANDOM. See also RANDOMIZED CONTROL TRIAL.

OUTCOMES. All possible changes in health status that may occur in following subjects or that may stem from exposure to a causal factor or from preventive or therapeutic interventions. The narrower term END POINTS refers to health events that lead to completion or termination of follow-up of an individual in a trial or cohort study, for example, death or major morbidity, particularly related to the study question.

PRIMARY CARE. Medical care provided by the clinician of first contact for the patient. Typically, the primary care physician is a general practitioner, family practitioner, primary care internist, or primary care pediatrician. Primary care may also be administered by health professionals other than physicans, notably, specially trained nurses (nurse practitioners) and physician assistants. Usually, a general practitioner, family practitoner, nurse practitioner, or physician assistant provides only primary care services but a person with specialty qualifications may provide primary care, alone or in combination with referral services (see also REFERRED CARE). Thus, it is the nature of the contact (first compared with referred) that determines the care designation rather than the qualifications of the practitioner.

PRIMARY CARE CENTER, PRIMARY CARE SETTING. Medical care facility that offers first-contact health care only. Patients requiring specialized medical care are referred elsewhere. Some primary care centers provide a mixture of primary and referred care. Thus it is the nature of the service provided (first contact) rather than the setting per se that distinguishes primary from more advanced levels of care. See also PRIMARY CARE, REFERRED CARE, TERTIARY CARE CENTER.

PROSPECTIVE STUDY. See COHORT and COHORT ANALYTIC STUDY.

RANDOM. Governed by a formal chance process in which the occurrence of previous events is of no value in predicting future events. The probability of assignment of, for example, a given subject to a specified treatment group is fixed and constant (typically 0.50) but the subject's actual assignment cannot be known until it occurs.

RANDOM SAMPLE. A sample derived by selecting sampling units (for example, individual patients) such that each unit has an independent and fixed (generally equal) chance of selection. Whether a given unit is selected is determined by chance (for example, by a table of randomly ordered numbers).

RANDOMIZATION, RANDOM ALLOCATION. Allocation of individuals to groups by chance, usually done with the aid of a table of random numbers. Not to be confused with systematic allocation (for example, on even and odd days of the month) or allocation at the convenience or discretion of the investigator.

RANDOMIZED TRIAL (RANDOMIZED CONTROL[LED] TRIAL, RANDOMIZED CLINICAL TRIAL, RCT). Experiment in which individuals are randomly allocated to receive or not receive an experimental preventive, therapeutic, or diagnostic procedure and then followed to determine the effect of the intervention.

REFERRED CARE. Medical care provided to a patient when referred by one health professional to another with more specialized qualifications or interests. There are two levels of referred care: secondary and tertiary. Secondary care is usually provided by a broadly skilled specialist such as a general surgeon, general internist, or obstetrician. Tertiary care is provided on referral of a patient to a subspecialist, such as an orthopedic surgeon, neurologist, or neonatologist. See also TERTIARY CARE CENTER.

RETROSPECTIVE STUDY. See CASE-CONTROL STUDY.

SECONDARY CARE. See REFERRED CARE.

SENSITIVITY. The sensitivity of a diagnostic or screening test is the proportion of people who truly have a designated disorder who are so identified by the test. The test may consist of or include clinical observations.

SEQUENTIAL SAMPLE. See CONSECUTIVE SAMPLE.

SPECIFICITY. The specificity of a diagnostic or screening test is the proportion of people who are truly free of a designated disorder who are so identified by the test. The test may consist of or include clinical observations.

SURVEY. Observational or descriptive, nonexperimental study in which individuals are systematically examined for the absence or presence (or degree of presence) of characteristics of interest.

TERTIARY CARE. See REFERRED CARE.

TERTIARY CARE CENTER. A tertiary care center is a medical facility that receives referrals from both primary and secondary care levels and usually offers tests, treatments, and procedures that are not available elsewhere. Most tertiary care centers offer a mixture of primary, secondary, and tertiary care services so that it is the specific level of service rendered rather than the facility that determines the designation of care in a given study. See also REFERRED CARE.