

MANUSCRIPT CRITERIA AND INFORMATION

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The original typescript plus 3 high-quality copies must be submitted, including legends, tables, and references. All copy, including references, legends, and tables, must be typed double-spaced on 8½ × 11-inch, heavy-duty white bond paper. Margins must be at least 1 inch. **Do not use justified right margins.** All illustrations must be originals, not copies.

Abstract. Include a *structured abstract* of no more than 250 words for reports of original articles and reviews. For detailed instructions, see "Instructions for Preparing Structured Abstracts."

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Checklist for Authors

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- One original and 3 copies of manuscript, including abstract, legends, and tables, each **stapled** as a complete unit.
- Four sets of all illustrations, clearly labeled as described in the instructions, all submitted in original format and not copied.
- Number all pages.
- Double-space manuscript (text and references), and leave right margins **unjustified** (ragged).
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References. *References* should be listed in *consecutive numerical order* as they are cited in the text, *not alphabetically*. Once a reference is cited, all subsequent citations should be to the original number. All references must be cited in the text or tables. Unpublished data and personal communication are not encouraged and may not be listed as references. References to journal articles should include, in this order, (1) authors (list all authors and/or editors up to 6; if more than 6, list the first 3 and "et al"), (2) title, (3) journal name as abbreviated in *Index Medicus*, (4) year, (5) volume number, and (6) inclusive page numbers. References to books should include (1) authors (list all authors and/or editors up to 6; if more than 6, list the first 3 and "et al"), (2) chapter title, if any, (3) editor, if any, (4) title of book, (5) year, (6) city, and (7) publisher. Volume and edition numbers, specific pages, and name of translator should be included when appropriate. The author is responsible for the accuracy and completeness of the references and for their correct text citation.

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Data Access and Responsibility. For reports containing original data, at least 1 author (eg, the principal investigator) should indicate that he or she "had full access to all the data in the

study and takes responsibility for the integrity of the data and the accuracy of the data analysis" (DeAngelis CD, Fontanarosa PB, Flanagin A. Reporting financial conflicts of interest and relationships between investigators and research sponsors. *JAMA*. 2001;286:89-91).

Group Authorship. If authorship is attributed to a group (either solely or in addition to 1 or more individual authors), all members of the group must meet the full criteria and requirements for authorship (copyright, authorship responsibility, and disclosure). A group must designate at least 1 or more individuals as authors or members of a writing group who meet full authorship criteria and requirements and who will take responsibility for the group, in which case the other group members are not authors, but may be listed in an acknowledgment (Flanagin A, Fontanarosa PB, DeAngelis CD. Authorship for research groups. *JAMA*. 2002;288:3166-3168).

Titles. *The title* must be *short*, specific, clear, and not exceed 42 characters per line, including punctuation and spaces (2-line limitation). The title page should include the **complete** names, academic affiliations, and highest academic degrees of all authors. Please limit the number of authors to a maximum of 8. If the manuscript was presented at a meeting, indicate the name of the organization, the location, and the date of presentation.

Units of Measure. Conventional units of measure are preferred, with *Système International (SI)* units expressed secondarily (in parentheses). In tables and figures, a conversion factor to SI may be presented in the footnote or legend to economize space. Exceptions to this policy include calories, hematocrit, glycosylated hemoglobin, blood cell counts, and ejection fraction, for which conventional units alone should be expressed. The metric system is preferred for length, area, mass, and volume.

Illustrations. Submit 4 **original** illustrations, unmounted and untrimmed. They should clarify and augment the text. Do not send original artwork. Send high-contrast glossy prints (not photocopies). Computer-generated graphics produced by high-quality laser printers are acceptable for black-and-white line art only. Type the figure number, name of senior author, and arrow indicating "top" on a gummed label and affix to the back of each illustration. All lettering in illustrations must be legible after reduction to column size. Illustrations should preferably be in a proportion of 5 × 7 inches. *Color illustrations* are accepted for publication at no charge to the author if the editors believe that color will add significantly to the published manuscript. Positive color transparencies (35 mm preferred) must be submitted for an evaluation. Color prints must be accompanied by original transparencies. Computer-generated graphics produced by high-quality laser printers are not acceptable. Original illustrations, photographs, and slides from rejected manuscripts will be returned to authors.

Digital Art Submissions. RGB color submissions are preferred. Calibrated color proofs should be submitted with color digital files, if possible. The canvas size of continuous-tone images should be at least 5 inches wide (depth not important) with an image resolution of at least 350 ppi. Line art images should have a minimum resolution of 1270 ppi. Formats accepted are EPS, TIFF, and JPG.

Legends. Type all legends consecutively and double-spaced. Please limit each legend to a maximum of 40 words.

Tables. Each table must be typed double-spaced, including all headings, on a separate sheet of 8½ × 11-inch paper. Do not use larger paper. If a table must be continued, use a second sheet and repeat all heads and stubs. Each table must have a title.

The final version of the tables should be placed in a separate file (preferably MS Word or Excel). Do not embed the tables

in the text of the article. Make certain that each item in the table is inside its own table cell. Do not use paragraph returns (to start new rows) and tabs (to start new columns) to format the table.

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Instructions for Preparing Reports of Randomized Controlled Trials

The checklist (see **Table**) should be used as a guideline and submitted with the manuscript. In addition, include a flow diagram illustrating the progress of patients throughout the trial (see **Figure** for example).

The checklist and flow diagram will be reviewed along with the manuscript. If the manuscript is accepted, the flow diagram will be published.

OTHER INFORMATION

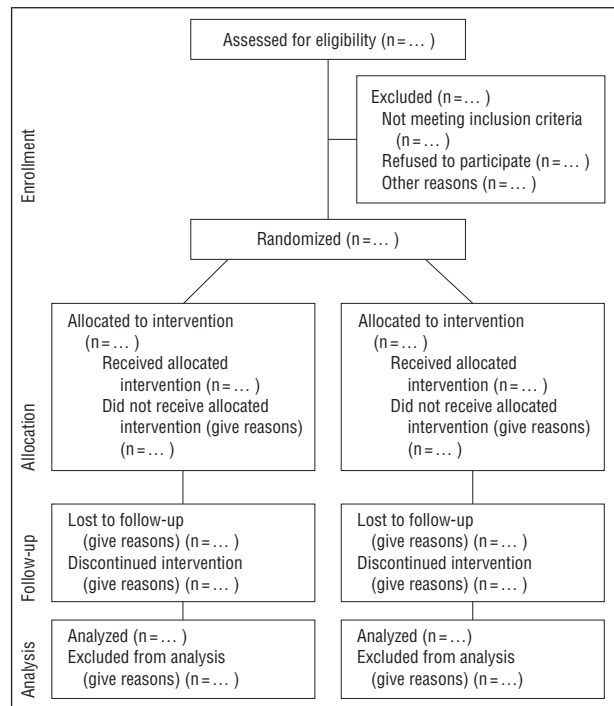
Clinical Notes. The ARCHIVES will consider Clinical Notes for review. These reports should provide a new or unique contribution and consist of 800 words or less, 4 references, and 1 illustration. The synopsis-abstract may not exceed 80 words.

Correspondence or Brief Communications. The Editor is pleased to receive letters that pertain to material published in the ARCHIVES. Such contributions should be 250 words or less, typewritten, double-spaced without an abstract, and clearly marked "for publication," with no more than 2 references.

Image of the Month. Due to the overwhelmingly positive response to the Image of the Month feature, the *Archives of Surgery* will temporarily discontinue accepting submissions for this feature. It is anticipated that requests for submissions will resume in mid-2004.

Operative Techniques. A variety of simple and complex procedures will be presented in Operative Techniques. Drawings of operative photographs should clearly illustrate sequential steps in the procedure. Each drawing should be accompanied by a legend and sufficient descriptive text so that the reader is taken through the procedure in an orderly fashion. Color drawings or photographs may be utilized if they would clearly enhance the reader's understanding of the procedure.

Acknowledgments. Illustrations from other publications must be acknowledged to include author(s), title of article, title of journal or book, volume number, pages, and month and year and submitted with the publisher's (or copyright holder's) permission to the ARCHIVES when the manuscript has been formally accepted. Permission to reproduce or adapt material must include republishing in print and online editions of *Archives of Surgery* and its licensed versions. (See permission



Flow diagram of subject progress through the phases of a randomized trial. Adapted from Moher D, Schulz KF, Altman D, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA*. 2001;285:1987-1991.

form online at <http://archsurg.ama-assn.org/cgi/content/full/139/3/343-b/DC3>.)

Statistical Review. Manuscripts containing statistical evaluation should include the name and affiliation of the statistical reviewer. The Editor may request that the author provide a statistical review prior to final acceptance.

Informed Consent. Manuscripts reporting the results of experimental investigations on human subjects must include a statement in the "Methods" section that the institutional review board has approved the project and/or that informed consent was obtained from all adult participating subjects and from parents or legal guardians for minors.

Reference to Patients. Patients may be referred to by number or, in anecdotal reports, by fictitious names. Real names or initials must not be used in the text, tables, or illustrations.

Animal Experiments. When reporting experiments on animals, please indicate that the institution's or the National Research Council's guide for or any national law on the care and use of laboratory animals was followed.

Photographic Consents. A letter of consent must accompany all photographs of patients in which a possibility of identification exists. It is *not* sufficient to simply cover the eyes to mask identity. (See patient consent form online at <http://archsurg.ama-assn.org/cgi/content/full/139/3/343-b/DC2>.)

Checklist of Items to Include When Submitting Reports of Randomized Controlled Trials to the Archives of Surgery*

Section and Topic	Item	Descriptor	Was It Reported? Yes or No?	If Yes, What Page No.?
Title and abstract	1	How participants were allocated to interventions (eg, "random allocation," "randomized," or "randomly assigned").	___	___
Introduction				
Background	2	Scientific background and explanation of rationale.	___	___
Methods				
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	___	___
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	___	___
Objectives	5	Specific objectives and hypotheses.	___	___
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors).	___	___
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	___	___
Randomization				
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).	___	___
Allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	___	___
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	___	___
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	___	___
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	___	___
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	___	___
Recruitment	14	Dates defining the periods of recruitment and follow-up.	___	___
Baseline data	15	Baseline demographic and clinical characteristics of each group.	___	___
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (eg, 10/20, not 50%).	___	___
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% confidence interval).	___	___
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	___	___
Adverse events	19	All important adverse events or side effects in each intervention group.	___	___
Comment				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.	___	___
Generalizability	21	Generalizability (external validity) of the trial findings.	___	___
Overall evidence	22	General interpretation of the results in the context of current evidence.	___	___

*This checklist of 22 items is intended to assist authors, editors, and reviewers by ensuring that information pertinent to the trial is included in the study report. Adapted from Moher D, Schulz KF, Altman D, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA*. 2001;285:1987-1991.

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 - if requested, I will provide the data or will cooperate fully in obtaining and providing the data on which the manuscript is based for examination by the editors or their assignees; and
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All manuscripts that are (1) reports of original data or (2) reviews, including meta-analyses, should be submitted with structured abstracts as described below. For other types of articles, submit a narrative abstract of no more than 135 words.

Reports of Original Data

Authors submitting manuscripts reporting original data should prepare an abstract of no more than 250 words under the following headings: Hypothesis, 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. **Hypothesis.** The abstract should begin with a clear statement of the precise hypothesis addressed in the report. If more than one hypothesis is addressed, the main proposition should be indicated. 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 text-word 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

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

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.

Review Manuscripts (Including Meta-analyses)

Authors submitting review manuscripts and reports of the results of meta-analyses should prepare an abstract of no more than 250 words under the following headings: Objective, Data Sources, Study Selection, Data Extraction, Data Synthesis, and Conclusions. The content following each heading should be as follows:

1. **Objective.** The abstract should begin with a precise statement of the primary objective of the review. The focus of this statement should be guided by whether the review emphasizes factors such as cause, diagnosis, prognosis, therapy, or prevention. It should include information about the specific population, intervention, exposure, and test or outcome that is being reviewed.

2. **Data Sources.** A succinct summary of data sources should be given, including any time restrictions. Potential sources include experts or research institutions active in the field, computerized databases and published indexes, registries, abstract booklets, conference proceedings, references identified from bibliographies of pertinent articles and books, and companies or manufac-

turers of tests or agents being reviewed. If a bibliographic database is used, the exact indexing terms used for article retrieval should be stated, including any constraints (for example, English language or human subjects).

3. **Study Selection.** The abstract should describe the criteria used to select studies for detailed review from among studies identified as relevant to the topic. Details of selection should include particular populations, interventions, outcomes, or methodologic designs. The method used to apply these criteria should be specified (for example, blind review, consensus, multiple reviewers). The proportion of initially identified studies that met selection criteria should be stated.

4. **Data Extraction.** Guidelines used for abstracting data and assessing data quality and validity (such as criteria for causal inference) should be described. The method by which the guidelines were applied should be stated (for example, independent extraction by multiple observers).

5. **Data Synthesis.** The main results of the review, whether qualitative or quantitative, should be stated. Methods used to obtain these results should be outlined. Meta-analyses should state the major outcomes that were pooled and include odds ratios or effect sizes and, if possible, sensitivity analyses. Numerical results should be accompanied by confidence intervals, if applicable, and exact levels of statistical significance. Evaluations of screening and diagnostic tests should address issues of sensitivity, specificity, likelihood ratios, receiver operating characteristic curves, and predictive values. Assessments of prognosis could include summarizations of survival characteristics and related variables. Major identified sources of variation between studies should be stated, including differences in treatment protocols, co-interventions, confounders, outcome measures, length of follow-up, and dropout rates.

6. **Conclusions.** The conclusions and their applications should be clearly stated, limiting generalization to the domain of the review. The need for new studies may be suggested.

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, gender, 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 physicians, notably, specially trained nurses (nurse practitioners) and paramedics. Usually, a general practitioner, family practitioner, nurse practitioner, or paramedic 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 se-

lected 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.