Instructions for Structured Abstracts

Reports of Original Data

Manuscripts reporting original data require an abstract of no more than 275 words under the following specific headings: **Objective, Design, Setting, Participants, Interventions**, **Main Outcome Measure(s), Results, Conclusions**, and **Key Words.** The content following each heading should be as follows.

Objective: Begin with a clear, concise (e.g., To investigate the ….) statement of the precise objective or question addressed in the report. If more than 1 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.

Design: Describe the basic study design. State the duration of follow-up, if any. As many of the following terms as apply should be used:
1. Intervention studies: randomized controlled trial (see Glossary for the definition of this and other technical terms); nonrandomized controlled trial; double-blind; placebo control; crossover trial; and/or before-after trial.
2. For studies of screening and diagnostic tests: criterion standard (ie, a widely accepted standard with which a new or alternative test is being compared; this term is preferred to *gold standard*); and/or blinded or masked comparison.
3. 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); and/or validation cohort or validation sample of the study involves the modeling of clinical predictions.
4. For studies of causation: randomized controlled trial; cohort; case control; and/or survey (preferred to "cross-sectional study").
5. For descriptions of the clinical features of medical disorders: survey; and/or case series.
6. For studies that include a formal economic evaluation: cost-effectiveness analysis; cost-utility analysis; and/or cost-benefit analysis. For new analyses of existing data sets, the data set should be named and the basic study design disclosed.

Setting: Describe the study setting(s). Of particular import is whether the setting is the general community, a primary care or referral center, private or institutional practice, or ambulatory or hospitalized care.

Participants (or Animals, Specimens, Cadavers): Subjects include, but are not limited to, controls, laboratory animals, etc. State clinical disorders, important eligibility criteria, and key sociodemographic features. Provide the numbers of participants and how they were selected (see below), including the number of otherwise eligible subjects who were approached but refused. If matching is used for comparison groups, specify characteristics that are matched. In follow-up studies, indicate the proportion of participants who completed the study. In intervention studies, give the number of patients who withdrew due to adverse effects.

For selection procedures, use the following terms, 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; or convenience sample. These terms help readers determine an important element of study generalizability. They also supplement (rather than duplicate) the terms used by indexing services.

Interventions: Describe the essential features of all interventions, including their method and duration of administration. The intervention should be identified by its most common clinical name (eg, the generic term *chlorthalidone*). Common synonyms should be given as well to facilitate electronic textword searching. This includes the brand name of a drug if a specific product was studied. NOTE: If the study does not contain any interventions, then the following form should be used: **Interventions:** Not applicable.

Main Outcome Measure(s): Indicate the primary study outcome measurement(s) as planned before data collection began. If the study does not emphasize the main planned outcomes of a study, state this fact and indicate the reason. If the hypothesis being reported was formulated during or after data collection, state this information clearly.

Results: Provide the main study results. Define measurements requiring explanation for the expected audience of the article. Indicate whether observers were blinded to patient groupings, particularly for subjective measurements. Results must be given in narrative rather than tabular form. If possible, the results should be accompanied by CIs (eg, 95%) and the exact level of statistical significance. For comparative studies, CIs should relate to the differences between groups. For nonsignificant differences for the major study outcome measure(s), state the clinically important difference sought and give the CI for the difference between the groups. When risk changes or effect sizes are given, indicate absolute values so that readers 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 are given, give prevalence or pretest likelihood as well. Report no data in the abstract that do not appear in the article.

Conclusion(s): Conclusions must be directly supported by the evidence reported. Avoid speculation and overgeneralization, and indicate whether additional study is required before the information should be used in usual clinical settings.

Key words: Authors must include on the title page of their manuscripts 3 to 5 key words from NLM's Medical Subject Headings (MeSH) (http://www.nlm.nih.gov/mesh/MBrowser.html).

To permit quick and selective scanning, the headings outlined above must be included in the abstract. For brevity, parts of the abstract may be written in phrases rather than

complete sentences. (For example: "**Design:** Double-blind randomized trial." rather than "**Design:** The study was conducted as a double-blind, randomized trial.")

Systematic/Meta-analytic Reviews

Review articles and meta-analyses require an abstract of no more than 250 to 300 words under the following headings: **Objective, Data Sources, Study Selection, Data Extraction, Data Synthesis, Conclusions,** and **Key Words.** The content following each heading should be as follows.

Objective: Begin with a precise statement (e.g., To investigate the ….) of the primary objective of the review. The focus should be guided by whether the review emphasizes factors such as cause and diagnosis, prognosis, therapy, or prevention. It should include information about the specific population, intervention or exposure, and test or outcome being reviewed.

Data Sources: Succinctly summarize data sources, 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 manufacturers of tests or agents being reviewed. If a bibliographic database is used, state the exact indexing terms used for article retrieval, including any constraints (eg, English language or human).

Study Selection: 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. Specify the method used to apply these criteria (eg, blind review, consensus, or multiple reviewers). State the proportion of initially identified studies that met selection criteria.

Data Extraction: Describe the guidelines used for abstracting data and assessing data quality and validity (eg, criteria for causal inference). State the method by which the guidelines were applied (eg, independent extraction by multiple observers).

Data Synthesis: State the main results of the review, whether qualitative or quantitative. Outline the methods used to obtain these results. 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 CIs, 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 summaries of survival characteristics and related variables. State the major identified sources of variation between studies, for example, differences in treatment protocols, cointerventions, confounders, outcome measures, length of follow-up, and drop-out rates.

Conclusions: State the conclusions and their applications clearly, limiting generalization to the domain of the review. Suggest directions for new studies.

Key Words: See above under Reports of Original Data. A glossary of methodologic terms is available here.