

*a guide to writing*  
*for* OBSTETRICS &  
GYNECOLOGY

Fourth Edition

The American College  
of Obstetricians and  
Gynecologists



*A Guide to Writing for Obstetrics & Gynecology*  
Fourth Edition

Additional copies are available free of charge.

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# CONTENTS

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|                                                                                            |            |
|--------------------------------------------------------------------------------------------|------------|
| <b>Preface</b>                                                                             | <b>v</b>   |
| <b>Foreword: The Evolution of the Journal</b>                                              | <b>vii</b> |
| <b>Getting Started</b>                                                                     | <b>1</b>   |
| Planning Your Manuscript                                                                   | 1          |
| Drafting Your Manuscript                                                                   | 2          |
| <b>The Trimmings: Title, Précis, and Abstract</b>                                          | <b>4</b>   |
| Title                                                                                      | 4          |
| Running Foot                                                                               | 5          |
| Title Page                                                                                 | 5          |
| Précis                                                                                     | 6          |
| Abstract                                                                                   | 6          |
| <b>The Heart of the Matter: Introduction, Methods, Results, Discussion, and References</b> | <b>8</b>   |
| Introduction                                                                               | 8          |
| Materials and Methods                                                                      | 9          |
| Results                                                                                    | 11         |
| Discussion                                                                                 | 13         |
| References                                                                                 | 15         |
| <b>Statistics</b>                                                                          | <b>17</b>  |
| Statistical Methods                                                                        | 17         |
| Statistical Screening                                                                      | 19         |
| <b>Style</b>                                                                               | <b>23</b>  |
| Syntax                                                                                     | 23         |
| Person and Voice                                                                           | 24         |
| Tense                                                                                      | 24         |
| Grammar                                                                                    | 25         |
| American Versus British Spellings                                                          | 26         |

|                                                                                                            |           |
|------------------------------------------------------------------------------------------------------------|-----------|
| Generic Versus Commercial Names                                                                            | 26        |
| Numbers                                                                                                    | 26        |
| Units of Measurement                                                                                       | 27        |
| Troublesome Terms                                                                                          | 28        |
| Jargon, Acronyms, and Abbreviations                                                                        | 29        |
| Resources                                                                                                  | 30        |
| <b>Toward a Final Product</b>                                                                              | <b>32</b> |
| Table and Figure Preparation                                                                               | 32        |
| Evidence-Based Medicine                                                                                    | 33        |
| Clinical Trial Registration                                                                                | 36        |
| Manuscript Submission                                                                                      | 36        |
| <b>Pitfalls, Minefields, and Other Things to Avoid</b>                                                     | <b>40</b> |
| Redundant Publication                                                                                      | 40        |
| Lumping Versus Splitting                                                                                   | 41        |
| Conflicts of Interest                                                                                      | 42        |
| <b>What Happens Next?</b>                                                                                  | <b>43</b> |
| The Review Process and Initial Disposition                                                                 | 43        |
| Rejection                                                                                                  | 44        |
| Revision                                                                                                   | 45        |
| Acceptance                                                                                                 | 47        |
| Final Thoughts                                                                                             | 48        |
| <b>Appendixes</b>                                                                                          |           |
| A. Authorship                                                                                              | 50        |
| B. Methodologic Terms                                                                                      | 53        |
| C. Abbreviations List                                                                                      | 59        |
| D. Consolidated Standards of Reporting Trials<br>(CONSORT)                                                 | 64        |
| E. QUOROM Guidelines for Meta-Analyses and Systematic<br>Reviews of Randomized Controlled Trials           | 68        |
| F. MOOSE Guidelines for Meta-Analyses and Systematic<br>Reviews of Observational Studies                   | 70        |
| G. Standards for Reporting of Diagnostic Accuracy<br>(STARD)                                               | 73        |
| H. Clinical Trial Registration: A Statement From the<br>International Committee of Medical Journal Editors | 77        |

## PREFACE

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*Obstetrics & Gynecology* has the largest circulation of all peer-reviewed obstetrics and gynecology journals. In the category of general obstetrics and gynecology, the journal currently has the highest ranking impact factor (a measure of the frequency with which the average article in a journal has been cited in a particular year). More than anything else, a journal's reputation and prestige reflect the quality of the articles it publishes. *Obstetrics & Gynecology* enjoys an excellent standing because it receives submissions of high quality. However, improvement is always possible. *A Guide to Writing for Obstetrics & Gynecology* was written for just that purpose—to help prospective authors write better articles. It may be especially helpful to those who are just beginning their medical writing careers.

The first three editions of *A Guide to Writing for Obstetrics & Gynecology*, published in 1991, 1995, and 2000, respectively, proved to be remarkably popular. Requests for copies continue to arrive virtually every day. A number of other medical journals have asked for permission to reprint portions of the guide, and we have gladly granted them authority.

A new century is upon us, and the time seems appropriate for a fourth edition. Whereas the second and third editions represented a rather modest revision of the first, the fourth edition reflects a thorough revamping and some expansion consistent with changes that have occurred with the editorial office, the publisher, and the field of scientific publishing. We have expanded the areas we think will be most useful for authors: how to prepare artwork, how to conform with evidence-based guidelines, and how to use the electronic manuscript submission system.

We also have designed this booklet to complement the Instructions for Authors, which can be found on our Web site ([www.green](http://www.green)

journal.org). The Instructions for Authors is detailed and instructional in nature and provides information on specifics such as formatting and references. The goal of *A Guide to Writing for Obstetrics & Gynecology* is to provide an educational framework of support and resources for authors. We will take you through each step of writing a manuscript for *Obstetrics & Gynecology*, from planning through submission. We will explain the peer-review process and what is expected when a manuscript is returned for revision. We also will outline the process when a manuscript is accepted for publication.

This fourth edition represents the efforts of those who developed the previous editions as well as those newly associated with the journal, all of whom share and contribute to its goal of publishing quality scientific information in obstetrics and gynecology. In particular, we would like to acknowledge the work of Roy M. Pitkin, MD (Editor Emeritus), who initiated the guide. We also would like to express our gratitude to the family of James H. Harger, MD. He provided a helpful critique of a draft of this guide just before his death on February 5, 2004.

Science and medicine depend on communication, especially written communication from one scholar to another, to transmit observations, conclusions, interpretations, and speculations. The peer-review system has developed over the past 350 years as the principal form of that communication. Although this guide is intended for authors submitting manuscripts to *Obstetrics & Gynecology*, much of this information is helpful for those writing manuscripts for any medical journal. Nevertheless, writers should always study the specific instructions of each journal intended for submission.

The purpose of *A Guide to Writing for Obstetrics & Gynecology* is to help authors with medical writing. The road might not be clear, and can be arduous, but it is nearly always interesting, usually satisfying, and most of the time enjoyable. Many of us have something to say, but most of us can improve our way of saying it.

The Editors

## FOREWORD: THE EVOLUTION OF THE JOURNAL

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The appearance of the first issue of *Obstetrics & Gynecology*—Volume 1, Number 1—in January 1953 not only launched a journal but it also began a tradition of excellence in medical communication that has now spanned half a century. The “Green Journal,” as it was known familiarly and affectionately from the beginning, would come to occupy a preeminent role in continuing education in obstetrics and gynecology throughout the nation and eventually the world.

The Green Journal’s success has reflected, more than anything else, a pervasive sense of commitment—on the part of the founders and subsequent leaders of the American College of Obstetricians and Gynecologists (ACOG) who give it unqualified support and freedom, constituents who read it, reviewers and Editorial Board members who ensure the quality of its content, and the editors who have guided its course. Remarkably, over the first 49 years of its existence, the journal had only four Editors: Ralph A. Reis (1952–1965), S. Leon Israel (1966–1971), Richard F. Mattingly (1972–1985), and Roy M. Pitkin (1986–2001). The sense of continuity provided by these terms has in turn imparted strength that comes from stability.

*Obstetrics & Gynecology* enters its second half-century under a new editor, James R. Scott, reinforced by a history and a tradition that equips it to meet the challenges of the 21st century.

Modified from Pitkin RM. The Green Journal: 50 years on. Washington, DC: ACOG; 2003.



## GETTING STARTED

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No matter how fascinating your experimental results, or how intriguing your clinical observations, your work must be published before it can be evaluated and repeated by your colleagues. When your research leads to interesting or even startling conclusions you want to share with the world, you sit down to write your manuscript. Even if your discovery is brilliant, bad writing might render your manuscript unpublishable, or at least delay publication while it is extensively revised.

If your scientific education included one or more writing courses, you are among the fortunate. More likely it centered on technical details and proper procedure.

You might have been drilled on anatomy but never on sentence structure. You are probably keenly able to distinguish between physiologic and pathologic changes, but you might not be able to distinguish between restrictive and nonrestrictive clauses.

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*Nothing in science has any value to society if it is not communicated...*

—Anne Roe

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There is so much emphasis on publishing in the sciences that researchers feel driven to create articles that others will read and even quote. Are you writing this manuscript because you feel a need to publish or because you have done something that is worth publishing? The latter is the better reason. Analyzing the goals of your research, and the manuscript presenting it, is an important first step.

### Planning Your Manuscript

When you have determined why you are writing your manuscript, define what you want to say. What is your purpose or objective? Is your study designed appropriately to accomplish it?

Planning your manuscript begins with planning your study. Planning what you will say in your manuscript will assist your thinking

process about the proper study design, inclusion and exclusion criteria, cohort sizes, definitions, statistical methods, and outcome measures. The kind of manuscript you hope to write, and to some extent where you hope to publish it, can influence the way the research is conducted. An author usually chooses a target journal based on its readership and circulation (Whom do you wish to reach?), its prestige (Is it an important journal in your field?), and what is known of its reviewing practices (Are its reviews considered objective, fair, and thorough; how long does the process take?).

When you decide that what you have to report is important, choose the best format for presenting your work. *Obstetrics & Gynecology* accepts submission of the following types of articles:

- **Original Research:** A full-length report of original basic or clinical investigation.
- **Case Report:** A brief description of up to three cases that are unusual and instructive and not previously reported.
- **Systematic Review:** A comprehensive review of publications relating to a specific clinical subject accompanied by critical analysis and conclusions.
- **Current Commentary:** A short essay on issues, opinions, experiences, or perspectives of clinical relevance to obstetrics and gynecology.
- **Personal Perspectives:** An essay offering insights into the practice of medicine, with an emphasis on the unique physician–patient relationship. A short essay for light reading addressing a topic pertinent to the discipline, including humor or satire, also is appropriate for this section.
- **Letter to the Editor:** A question or challenge to an article published recently in the journal.

## **Drafting Your Manuscript**

You have decided where your work fits in the scheme of the journal you have selected for submission. Your research is done, or you have treated a patient whose course was unusual and instructive. You are

ready to write about your findings, and you feel confident that you have something important to say. How and where do you get started? Before you begin your first draft, ask yourself the four “Whats”:

1. What is the question or purpose? (Introduction)
2. What did you do? (Methods)
3. What did you find? (Results)
4. What does it mean? (Discussion or Comment).

This is a simple approach to help you get started. Before you begin writing your manuscript, you may want to construct an outline of your article. Start with a working title and a Roman numeral one, followed by the word “Introduction.” You have begun. Keep in mind that each item of your outline probably will be a topic sentence, and each topic sentence will be expanded into a paragraph. Paragraphs will then become sections, and eventually a manuscript will result.

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*They say writing the first line  
of a book is the hardest part.  
Thank God that's over.*

—Willie Nelson

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As you draft your manuscript, constantly keep in mind the need for accuracy, clarity, and brevity. Check and double-check your data for accuracy, and be sure that the manuscript precisely follows the Instructions for Authors. When you are confident that you have reported your work in precise detail, give your manuscript to colleagues and have them check it again for absolute accuracy. For instance, the abstract must be checked carefully to make sure that all data in it are consistent with the text. As for clarity, if your writing is unclear and your meaning is unintelligible, your readers will not understand what you are reporting. In fact, if your manuscript lacks clarity, it probably will not get published. Brevity must be your watchword. Editorial space is precious and there is a limit to the number of pages in an issue; remember also that the competition is as determined to publish as you are.

## THE TRIMMINGS: TITLE, PRÉCIS, AND ABSTRACT

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Taking the time to carefully consider the title, précis, and abstract can benefit you and the manuscript's chance of acceptance. Similarly, attention to authorship policies, financial disclosure, acknowledgments, and other journal policies will help ensure timely publication.

### Title

How would you find your article in MEDLINE? The answer will help you decide on a title. The title should describe your study and identify your article's subject, although usually it cannot tell the entire story. If the title said it all, why would anyone bother to read the article? Clinicians and clinical investigators comprise the primary readership of *Obstetrics & Gynecology*. Considering the audience may be helpful when determining the title of your manuscript. Long titles are impossible for the reader to comprehend at a glance and might lead to inappropriate indexing. As a general rule, titles in *Obstetrics & Gynecology* are limited to 100 characters (including spaces).

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*A good title should be like a good metaphor: it should intrigue without being too baffling or too obvious.*

—Walker Percy

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In recent years, some authors have favored titles with subject–verb construction, as in “Glucose does cross the placenta.” However, *Obstetrics & Gynecology* does not permit this type of title. The reason is that in the table of contents, we use a précis, a declarative sentence that states the conclusion(s); if the title were also of subject–verb construction, the table of contents listing would contain two sentences

with the same, and often identical, information. Introductory phrases such as “A study of...” or “Comprehensive investigations into...” or “A discussion of...” should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include “A Randomized Controlled Trial,” “A Meta-Analysis,” or “A Systematic Review,” as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

### **Running Foot**

For *Obstetrics & Gynecology*, a running foot must be provided with the manuscript. This is simply a shortened form of the article’s title that appears on the bottom of each page. You may write the running foot first. Forcing yourself to state the scope of your article tersely may help you focus on how you want your article listed in MEDLINE. You then can compose your title accordingly.

### **Title Page**

The first page of the manuscript should list the article title, names and major degree(s) of the authors, and the source of the work or study. A corresponding author should be designated and full contact information should be listed for that person. For information on authorship eligibility, see Appendix A.

The first page should also list any acknowledgments, as well as financial support. Acknowledgments of individuals who contributed to the study, but not sufficiently to be authors, is permitted as long as the contribution was specific and professional in nature. Acknowledgment of general assistance, such as “advice and encouragement” or patient referral, is not usually permitted, nor is manuscript review unless this contribution was substantial, such as translating foreign-language publications. *Obstetrics & Gynecology* does not allow the acknowledgment of services rendered in the normal course of employment, such as secretarial, clinical, or technical services. Written permission must be obtained from all individuals named in the acknowledgments.

## Précis

The précis for the table of contents should state in present tense the conclusion(s) of your report in a single declarative sentence of no more than 25 words. The précis should be very specific. It should tell what was found, not what was done. In other words, it should be the “take-home” message for the reader.

Avoid “promissory” statements, such as claims that something “is discussed” or that certain facts “are presented.” Also, avoid trying to condense the Abstract:

### *Example of What Not to Do:*

“We reviewed 347 cases of cord prolapse during the first stage of labor and found the outcome was better in the 189 delivered by cesarean than in the 158 delivered vaginally.”

### *Example of What to Do:*

“Cesarean delivery gives better results than vaginal delivery when cord prolapse occurs during the first stage of labor.”

## Abstract

The abstract is the most important section of the article because it is the part that will be read by the most people. An increasing number of readers will never actually see the entire article; their only contact with it will be the abstract they obtain from an electronic literature search. The Editor and reviewers will read the abstract first. If it is confusing, they might not understand its message, and the manuscript will likely be rejected. If your manuscript is accepted and published, readers will scan the abstract first to decide whether to read the whole article.

*Obstetrics & Gynecology* uses a “structured abstract” format. It is written in the past tense, does not contain references or commercial names, and has few abbreviations. Using a uniform abstract format facilitates peer review, helps clinical researchers locate applicable articles, and allows more accurate cataloging of articles. Each heading of a structured abstract should start a new paragraph. One or two sentences per section are usually adequate.

- For **Original Research**, the structured abstract uses four subheadings—Objective, Methods, Results, and Conclusion. The word limit is 250.
- For **Reviews**, the structured abstract uses five subheadings—Objective; Data Sources; Methods of Study Selection; Tabulation, Integration, and Results; and Conclusion. The word limit is 300.
- For **Case Reports**, the structured abstract uses three subheadings—Background, Case, and Conclusion. The word limit is 125.

Different rules for abstracts govern the following article types:

- For **Current Commentary** submissions, the abstract should be a single paragraph of no more than 250 words that states what was done, what was found, and what the findings mean.
- For **Personal Perspectives** essays, an abstract is not needed.

Important data (eg, sample size, mean values of critical measurements, important statistical characteristics) should be included in your abstract, and all data in the abstract must come directly from the manuscript in consistent form. Abstract data should be cross-checked against your Results section for consistency. A study of 6 major medical journals found that in a random sample of articles, 18–68% of abstracts were deficient.<sup>1</sup>

Be careful when selecting facts for your abstract. A sea of numbers accompanied by *P* values will deter all but the most dedicated readers. An abstract made of nonquantitative conclusions and devoid of data will not do justice as a summary of your manuscript. *Obstetrics & Gynecology* has a specific policy that, if any of the important comparisons lack statistical significance, the abstract must address the study's statistical power to identify differences.

## THE HEART OF THE MATTER: INTRODUCTION, METHODS, RESULTS, DISCUSSION, AND REFERENCES

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Each section of the manuscript plays a specific role in presenting the data and your conclusions. The way you structure them can mean the difference between acceptance and rejection. The approach that follows applies specifically to a report of original research. Other types of articles published by *Obstetrics & Gynecology* (case reports, reviews, personal perspectives, current commentaries) will use somewhat different formats. However, the basic principle of following a logical order will be common to all.

### Introduction

The Introduction section of your manuscript sets the stage. Objective, purpose, aim, goal, and hypothesis have slightly different meanings but are all ways of answering the critically important question, “What was the purpose?” The reason(s) you did the study must be stated as specifically as possible for the reader to understand what you did and why. An example of a specific statement is “we tested the hypothesis that pregnancy is accompanied by decreased plasma glucose concentrations.” By contrast, the statement, “Our goal was to learn more about glucose concentrations in pregnancy” is not specific enough to be able to judge whether or not you accomplished it.

Most Introductions are too long and cover material with which the readers of *Obstetrics & Gynecology* are already familiar. The Introduction is not the place for a review of the literature. However, a *brief* overview of publications might be useful, particularly to establish relevance of the question, supported by reference citations. The Introduction should be one to two paragraphs that include only

important background information, explain the rationale or why the study is important, and conclude with a direct statement about the purpose of the study (why it was done and what is to be learned).

The Introduction also can give some indication of why the question is important, interesting, or controversial. It should provide an overview of the method you used to address the problem and a brief statement regarding the general type of study: retrospective or prospective, observational or experimental, open or masked, case series, cohort, or randomized trial.

The importance of a clear statement of the objective(s) cannot be overemphasized. The Introduction should always conclude with a clear-cut purpose of the study. The objective or purpose is the “anchor” to which all else will be related. Reviewers and editors will ask “Is the methodology appropriate to the objective? Do the results relate to the objective? Are the conclusions accomplished in the objective?”

## **Materials and Methods**

In the Materials and Methods section of your manuscript, describe how the research was done, materials that were used, the study population, demographics (if needed), and methods or procedures used. Give enough detail for critique and replication of your procedures and confirmation of your results. Reproducibility of the methodology is one test of a well-written manuscript.

When you use methods that have been published before, the publication(s) should be cited without repeating the description. Be wary of citing obscure journals: “...the management of diabetic control during pregnancy was as described in our publication (Smith AA, Jones BB, Brown CC. Diabetic control during pregnancy. *Milanes J Psychol Existential* 1937;24:1023–34).” If earlier methods have been modified, only the modifications(s) need be given. Report as objectively as possible, in simple terms, what you did, when you did it, to whom, and how, citing references only when necessary.

When listing selection criteria, your participants should not be identified beyond their qualifications for the study. Inclusion and

exclusion criteria should be stated explicitly. Always disguise the identity of participants. If you include photographs, X-rays, or ultrasonograms of individuals, be sure their identities are obscured. If participants are described individually, they should not be identified by names, initials, or hospital numbers.

The Methods section should be written in the past tense, avoiding jargon and acronyms. Do not make the reader guess if your study was retrospective or prospective, in vivo or in vitro, or performed on human or animal subjects (randomized controlled trials are always prospective, and review articles are always retrospective, so there is no need to repeat the fact in those cases). Do not include unnecessary information; it is sufficient to state what was done and what is required to reproduce the results.

Avoid subheadings except in the most complex of manuscripts. Subheadings should only enhance understanding; otherwise, use a topic sentence at the beginning of each paragraph to indicate a change of subject.

Your writing should be precise. “Methods are similar to cookbook recipes. If a reaction mixture was heated, give the temperature. Questions such as ‘how’ and ‘how much’ should be precisely answered by the author...”<sup>2</sup> Details must be balanced between enough and too much. The Methods section must identify the statistical methods used. If references must be cited for statistical methods, standard reference books usually are preferable to articles that report the designs or methods. Be specific when identifying any computer programs used, and include the version if that is important. It is not necessary to name the brand and model of your computer hardware, but you should provide the name and location of the software’s manufacturer. For example:

The statistical software package SPSS 12.0 (SPSS Inc., Chicago, IL) was used for all data analyses.

Similarly, the manufacturer name and location should be provided when citing a brand-name product (eg, drugs or equipment). Note, however, that generic names are preferred.

### ***Institutional review board***

All human studies must address the issue of institutional review. If your study protocol was approved by an institutional review board (IRB), the name of the IRB should be provided. If not, a letter from the IRB chair stating that approval for the study was not required at your institution must be submitted. Failure to provide this information can significantly delay the publication of a potentially acceptable manuscript.

### ***Informed consent***

If your study involves humans, you should obtain informed consent from each participant. The forms and approvals do not need to be included with the manuscript, but the Editor might request them during manuscript evaluation. Experimental procedures on humans should follow the ethical standards for human experimentation established by the Declaration of Helsinki of 1975, revised in 1983. We urge authors to review the Declaration whenever they are designing, conducting, and reporting research.<sup>3</sup>

## **Results**

In the Results section, describe findings in logical sequence. The emphasis here is on the observations of your research; the implications of your findings and their pertinence to other relevant research will come in the Discussion section. The importance of accuracy in scientific communication cannot be overstated. Errors can occur in a thousand ways, but whatever the cause, mistakes will damage the credibility of your research. Therefore, check and recheck your data for accuracy and consistency. Make sure the numbers “add up” in the tables and are consistent between tables, text, and abstract.

Although your Results section should parallel your Methods section, be careful not to repeat what you have discussed already. Give a factual accounting of what you found. Report your findings in

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*I pass with relief from the tossing  
sea of Cause and Theory to the  
firm ground of Result and Fact*

— Sir Winston Spencer Churchill

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actual numeric data; if you want to give percentages or other proportions, they should be in parentheses. You might want to emphasize what you did not find, particularly if that information deviates from what was expected.

The Results section will often be one of the shorter sections of the manuscript, especially if you have described your methods well and you save interpretation and comparison for the Discussion. Keep in mind the “Joe Friday rule” (“Just the facts, ma’am”) and present your findings as clearly and simply as possible. Don’t be overzealous in your attempts to write briefly and concisely, particularly if you find yourself resorting to pronouns without paying close attention to antecedents. Example: “In 35% of the patient population, the test was negative after treatment, even though it included only those who had tested positive in the past.” The immediate antecedent to the word “it” is “treatment”; the next possible antecedent is “test.” However, the writer intended “it” to refer to “patient population.” The only cure for that sentence is to put it out of its misery. The benevolent writer will resurrect it as two separate statements.

In the Methods and Results sections, the first-person active voice generally lends brevity and strength. Consider: “The study population was taken from those who presented with premature rupture of membranes.” Rewrite the sentence: “The participants presented with premature rupture of membranes.” Repetitive use of the passive voice makes dull reading and tends to lull the reader to sleep. However, a succession of staccato active-voice sentences might sound like a machine gun. Strike some balance between the two extremes, but keep your writing authoritative and unequivocal. Why should someone believe in your research if you do not sound like you do?

After drafting your Results section and rechecking it for completeness and accuracy, go through it and test it for wordy phrases, consistent use of the past tense, misplaced antecedents, active voice whenever possible, and any repetition of data from the Methods section. An example of wordiness and a misplaced antecedent: “When our first test was concluded, it found that....” Did the test do the finding? Would you give results before the test was concluded? Switch to the active voice and be concise: “The results of our first test indicated....”

## Discussion

Many of the manuscripts submitted to *Obstetrics & Gynecology* contain Discussions that are too long. The Discussion does not require a complete review of the literature or a long restatement of the results. Instead, the Discussion should place the study in context for the reader: Why are your findings new and different from what is already in the literature, and how are they clinically relevant? The Discussion section should include the following elements:

1. The interpretation and implications of your results, taking into account the study hypothesis, source of potential bias, or imprecision
2. The external validity of the findings
3. General interpretation of the results in the context of current evidence and in relation to the purpose(s) in your Introduction

You may extrapolate and interpret data in the Discussion, but be aware that your interpretation might be biased by what you hoped to find rather than what you actually found. You may elaborate and even speculate, but keep in mind that the line between implication and unfounded speculation can be indistinct.

The Discussion can begin with a general summary statement of the results in a sentence or two, but you should avoid recapitulating your findings. Briefly summarize any similarities to prior publications and explain any differences, if possible. Report the clinical implications of your results, except when such applications are obvious or impractical. Use caution, however, when drawing conclusions from your study about recommendations for clinical practice. Such statements, particularly when couched in terms such as “the standard of care,” can be misinterpreted and misused. Explain any weaknesses in your methods and emphasize the importance of your results. Strive for balance between overemphasis (“this is the best study ever done”) and underemphasis (“this only indicates the need for more study”).

Claims of priority (eg, first reports) are discouraged because they are often difficult to prove. If your claim of first report is based on a

systematic search of the literature, that search should be described (search engine, search terms, time, and languages encompassed by the search). For example:

This is the first case (MEDLINE; 1966–May 2004; English language; search terms: “hirsutism,” “adrenal,” and “menopause”)...

A search of MEDLINE (English language; 1966–2003; search terms: “hypertension” and “pregnancy”) revealed no other cases.

If a claim of priority is not based on a systematic search but only on your level of awareness, the claim is not permitted.

The Discussion often is difficult to write. You have validated your facts, your study supports your hypothesis, and you might have discovered something of great importance that you did not expect to find. However, you are wary of making unfounded claims or of overinterpreting your data. Writing a list of the few (two to five) points you want to make about the study and then building a paragraph around each point might be helpful.

The following outline, adapted from Docherty and Smith,<sup>4</sup> is one way of organizing the Discussion section. Each of the five points would usually rate a paragraph.

1. A brief (no more than one or two sentences) restatement of the principal findings.
2. A balanced analysis of the strengths and weaknesses of the present study.
3. Relation of the study's strengths and weaknesses to other reports, stressing especially any differences in results.
4. Suggestion of potential mechanisms of the observations and the study's meanings for researchers, clinicians, or policymakers.
5. Questions raised by the findings and their implications for additional research.

The Discussion should build to the important conclusion—the SW2C (“so what and who cares?”)—of your report. The closing will

often correspond to the “bottom line” statement of your précis. However, any summary of the study or its findings should be reserved for the abstract.

## References

More errors are made in references than in any other part of a manuscript. Such errors may not seem especially serious, but they do reflect an author’s scholarship. Therefore, you must check the references against the original source and not trust the accuracy of another writer’s reference list. Double-check the reference list for careless typographic errors before submitting the manuscript and after any revisions, and peruse the reference list when reviewing the proofs. More importantly, make certain you interpret cited studies correctly in relation to your arguments; errors in this regard are likely to be picked up by the expert reviewers who evaluate the manuscript. Citation errors occur in two ways. Mechanical errors occur in the misspelling of an author’s name or in citing the wrong title, year, volume, or page. The second and more subtle mistake is to draw a conclusion that is not based on the original data. This type of error often results from the practice of relying on another author’s interpretations rather than verifying the original reference itself. This error is not only more subtle, but also far more serious than simply listing an incorrect page range.

Cite only those references that are vital to your study. The general tendency is to cite too many sources rather than too few. If you identify the important or key publications related to your research, it is usually not necessary to list all others unless there is something substantially new, different, and relevant. An exception to this rule is the systematic review, when a careful analysis usually requires a comprehensive listing; thus, review articles typically have longer reference lists than other types of articles.

At all times, strive to cite the primary rather than a secondary source. Citation of a secondary source might be appropriate when you wish to emphasize an interpretation by the author of the secondary source or if the primary source is not available to you.

*Obstetrics & Gynecology* requires that all reference list entries represent full-length articles in peer-reviewed publications that are generally available. The basis of this policy is to assure the reader that references cited by number carry the strength that comes from peer review. Other types of references, including non-peer-reviewed articles, unpublished data, in press items, personal communications, letters, theses, package inserts, submissions, meeting presentations, or abstracts, should be avoided unless absolutely necessary, in which case they should be given in parentheses in the text and their nature clearly indicated:

“Jones, in a letter (Jones AB. Diabetes mellitus and fetal outcome [letter]. *BMJ* 1989;290:764), reported....”

Each reference must be numbered and listed in the order it was cited in the text. All references should be cited in the text, even those included in table and figure legends. References should be cited on the line with parentheses. You might consider assembling your references in a computerized reference list.

## STATISTICS

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Scientific research usually is quantitative in nature and, therefore, relies heavily on statistical analysis for its proper understanding, interpretation, and application. Thus, statistics are integral to most scientific and medical writing. Consideration of statistical aspects should begin when research is planned, not when it is under way or has been completed because several critical aspects of experimental design depend directly on such considerations. Statistical planning and analysis usually are best done in consultation with someone who has special knowledge and experience in this area, such as a biostatistician or an epidemiologist. In addition, guidance on how to report statistics in medical research is readily available (Appendix B).<sup>5</sup>

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*To consult a statistician after an experiment is finished is like asking him to conduct a post-mortem examination. He can perhaps say what the experiment died of.*

—R. A. Fisher

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### Statistical Methods

The statistical methods you use to describe and analyze your observations depend to a very important degree on the manner in which the data are distributed and the sample size. When the distribution follows the familiar bell-shaped curve, also called normal or Gaussian distribution, a useful way of summarizing it is calculation of the arithmetic mean and some indication of distribution, such as standard deviation. Data not distributed normally (eg, skewed) are better summarized by calculating the median and some indication of range (such as the interquartile range). Similarly, parametric tests are used to test statistical significance when distributions are normal, whereas data not normally distributed require nonparametric

means of analysis, unless the sample is large. All statistical tests to be used in analytic studies should be decided during the study design and described in the Materials and Methods section of any resulting manuscripts. If any of the statistical procedures are unusual and not likely familiar to the average reader, they should be identified by references.

Clinical investigation typically involves many independent variables, all of them potentially influencing the dependent variable(s) or outcome(s). In such cases, multiple comparisons using univariate means of analysis for each independent variable can be misleading. A multivariable technique, such as multiple regression analysis, can tease out the effect of one variable while controlling simultaneously for the effect of all the other variables in the model.

Dichotomous data (eg, sick versus well) should be presented as relative risks or odds ratios with 95% confidence intervals and not just with *P* values. In addition, reports of diagnostic or screening techniques should include indices of validity—sensitivity, specificity, positive predictive value, and negative predictive value—based on an established standard. Likelihood ratios offer even more clinical usefulness.

The only definitive way of evaluating an intervention is by a randomized controlled trial. Specific rules govern such trials and the terms “random” or “randomized” must not be used unless the rules of randomization have been followed precisely.<sup>6–7</sup> The method of random assignment must always be identified and, unless it is obvious, assurance that it is truly random must be provided. Allocation concealment is essential in randomized controlled trials. Masking is another powerful investigative tool, particularly important when the outcome is subjective or has subjective aspects. If masking is used, strategies to maintain the level of masking should be delineated.

Authors of randomized controlled trials should report outcome data as both absolute and relative effects. In addition to the relative risk (RR), we encourage presentation of the number needed to treat for benefit (NNTb) or harm (NNTh).<sup>8–9</sup> The number needed to treat (NNT) is the reciprocal of the absolute risk reduction (ARR). For example, assume that administration of a prophylactic antibiotic

reduced the risk of febrile morbidity after an operation from 30% to 10%. That would be an absolute risk reduction of 20%, or 0.20. The reciprocal of that would be  $1/0.20$ , which equals 5. The NNT here is 5. Stated alternatively, five patients would have to be treated with the antibiotic to prevent one from having febrile morbidity.

However, assume that the antibiotic reduced the risk from 30% to only 25%, an absolute risk reduction of 5%, or 0.05. Now the number needed to treat is  $1/0.05$ , which equals 20. In this example, 20 patients would have to receive the antibiotic to benefit one. The “number needed to treat” helps clinicians understand the impact of interventions. The number needed to treat for harm is calculated similarly.

## Statistical Screening

As part of the review process, the statistical editor examines each manuscript that either contains or should contain statistical analysis based on specific screening criteria (see Box 1). If you use this checklist before submitting your manuscript, you will have a good chance of “passing” this aspect of manuscript evaluation.

Because of our substantial experience with routine screening for statistical-design matters, we are able to identify the types of defects found most commonly. Depending on their seriousness (ie, how they affect the study’s conclusions), these problems can cause the manuscript to be rejected or require additional information or analysis before it can be accepted.

The most common deficiency we encounter is failure to provide a clear basis for sample size. Sample size should always be addressed, but it is particularly critical when statistical analysis indicates a lack of significant difference in any comparisons. In other words, is there really no difference, or is there possibly one and the sample is too small to permit its detection (ie, type II statistical error)?

Sample size in analytical studies is determined by the effect to be detected, the probability of type I error, the statistical power, and the variability of the outcome measure. The source of the variance estimate should be specified. If estimation of a mean or proportion is the primary objective of the study, then the margin of error

### Box 1. STATISTICAL SCREENING CRITERIA

These criteria will help you with manuscript preparation.

1. The participant population is completely defined. Rules for inclusion or exclusion of participants are stated.
2. An appropriate study design was used to achieve the objectives.
3. A clear and complete statement of how the sample size was determined is included.
4. A statement is included that adequately describes or references all statistical procedures used.
5. The statistical analyses used are appropriate.
6. Procedures to maintain masking, if appropriate, are clearly stated.
7. If a participant will receive multiple treatments (as in a crossover design), order has been randomized.
8. The rules for assigning participants to treatments are included in the protocol.
9. The conclusions drawn from the statistical analysis are justified.

should be specified; the effect to be detected and the power would not apply in studies limited to estimation.

The risk of a type II error will be minimized by estimating sample size during the planning process. For studies with insufficient power, reporting results as relative risks or odds ratios with 95% confidence intervals will convey to readers the imprecision in results due to the inadequate sample size. *Post hoc* power calculations should not be done.

Probably the second most common deficiency we encounter is use of specific statistical tests under conditions that violate their underlying assumptions. Parametric tests assume normal distribution, and if the distribution is non-normal, nonparametric tests usually are required. Independence of observations is an assumption of most tests and would be violated if the study population included,

for example, women who contributed more than one pregnancy, multifetal pregnancies with each fetus considered a unit, or multiple measures on the same participants. There are ways of handling those types of cases, but special statistical treatment is needed.

Another common error involves the description of ordinal data such as numeric scoring systems (eg, Apgar score, Bishop score, biophysical profile). It is usually inappropriate to describe such data by calculation of mean and standard deviation and the test for significance by Student *t* test. Two ways of handling such data are to compute the medians and compare them by a nonparametric test or tabulate the proportion above and below a certain clinically important cutoff value.

Failure to describe fully the study population also is a frequent deficiency. Demographic characteristics should be given to a degree of detail appropriate to the study, preferably in tabular form, and inclusion and exclusion criteria should be stated clearly and explicitly. Careful explanation of the means by which interventions or treatments were assigned is essential. Why were some participants exposed to one intervention and others to another?

Use common sense when deciding how far to carry your calculations. For example, calculating mean estimated blood loss or estimated fetal weight to the nearest tenth of a milliliter or gram, respectively, connotes a degree of accuracy unwarranted by the nature of the estimates. Also, pay attention to the places to the right of decimals used to report *P* values and confidence intervals; as a general rule, no more than three (eg,  $P < .001$ ) should be necessary.

The level of alpha generally (although arbitrarily) considered statistically significant is  $P \leq .05$ , meaning that there is a 5% or less likelihood of difference by chance. Alpha clearly represents a continuum, and  $P = .06$  is not much different from  $P = .04$ , although they lie on different sides of the “significance level.” It is informative to report the *P* value for nonsignificant comparisons. There is always a possibility of a difference by chance. Thus, the *P* value is never identically equal to .000.

An alternative to *P* values is calculating (usually 95%) confidence intervals, which generally is more informative because it indicates

the direction and strength of the association.<sup>10</sup> Although the 95% confidence interval also tells the reader if the difference is statistically significant at the .05 level, confidence intervals should not be used as a “back-door” method of hypothesis testing.<sup>11</sup>

Finally, keep in mind the difference between statistical significance and clinical importance. All tests of statistical significance depend heavily on the sample size and, theoretically, any difference will be statistically significant if the sample is large enough. However, such a difference might not be important in a practical or clinical sense. In large studies, trivial differences become highly statistically significant. For example, in a study of several thousand women, a difference in systolic blood pressure of 1 mm Hg would be highly statistically significant but clinically unimportant. Similarly, the lack of a significant difference statistically does not mean that the difference is clinically meaningless. If two different operations for the same disease were randomly tested in a sample of 20 subjects and all 10 recovered after one operation but two of the 10 died from the second operation, that difference would certainly merit attention, although it was not statistically significant.

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*It has been said that a fellow  
with one leg frozen in ice and  
the other leg in boiling water is  
comfortable—on average.*

—J. M. Yancey

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## STYLE

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Straightforward writing boils down to three words: “Keep it simple.” Let your watchwords be “When in doubt, leave it out.” Give your reader credit, write with clarity and emphasis, and avoid the urge to be repetitious.

### Syntax

Careless writing breeds syntax errors. In some cases, such mistakes cause great confusion: “[the referenced researcher] reported one patient (0.6%) treated by primary radical surgery who had an ovarian metastasis of 159 with adenocarcinoma of the cervix.” What is an “ovarian metastasis of 159”? After editing the sentence reads, “...reported that only one of 159 women with adenocarcinoma of the cervix treated by primary radical surgery had an ovarian metastasis.” Another example shows how syntax can convey unintended messages: “The patient delivered a viable female infant weighing 2,350 g by cesarean for a double footling breech presentation.” What would the infant have weighed by vaginal delivery? Drastic changes in meaning come from alterations in word order.

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*The difference between the right word and the nearly right word is the same as that between lightning and the lightning bug.*

—Mark Twain

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Consider the following: “Medical records from 100 patients were reviewed during 1950–1990.” That statement implies that records were reviewed for 40 years; actually, the patients were seen during the 40 years and the record review (it is hoped) required much less time.

Objective reading is the most reliable way to spot syntax errors. Before you submit your manuscript, ask a knowledgeable colleague who has not been involved in your research and has nothing to gain from its publication to read it. Then listen to that reader’s critique.

## Person and Voice

In the past, using the first person was discouraged in scientific writing because it was considered vain and egotistic to claim your work by stating, “We chose our subjects from...” or “Our observations supported the research of others....” However, avoiding the first person causes proliferation of the passive voice: “Subjects were chosen from...” or “The research of others was supported by our observations....” Scientific editing has softened formerly stringent requirements regarding the first person and now encourages judicious use of the first person (eg, “I, we”). The active voice is preferable, although not always possible. It is difficult to write in the active voice without using the first person repetitively, and this kind of repetition can be boring. The second person, “you,” is reserved for giving direction, for example, “Use the first person when you want to avoid repetition of the passive voice.” That is a direct and expressed use of the second person. There also is an unexpressed use: “To avoid repetition of the passive voice, [you] use the first person.”

One of the most common errors in scientific writing is the “remote verb”: “Women taking oral contraceptives, or who were postmenopausal, or who were not sexually active were excluded.” As far as the subject (“women”) of that sentence is concerned, the verb (“were excluded”) has left town. Again, the recommendation is first person, active voice: “We excluded women who were....”

Third person, “he, she, it, they” or a noun such as “researcher,” is used to relate who did something or what they did. The third person should not be used instead of the first person because, besides being stilted and falsely modest, it causes confusion. Example: “The authors believe....” Which authors? Those who wrote this article or some who wrote another article?

## Tense

You are reporting work you have completed. Therefore, with a few exceptions, your writing should be in the past tense. One exception occurs when work was done in the past but has clear relevance to the present. In such a case, present perfect tense is better (eg, “Jones and Smith have shown that certain HPV infections can lead

to cancer of the cervix.”). When expressing a concept with continuing present implications, present tense can be used to emphasize current (and presumably future) importance (eg, “Most experts recognize that certain HPV infections can lead to cervical cancer.”).

Write the abstract in the past tense. Write the Introduction in the past tense when referring to your own work: “We therefore studied the pulsatility index...” and in either present perfect or present tense when citing the established work of others that is particularly important today: “The pulsatility index is believed to indicate....” Use the past tense in the Methods section to describe how you did your study, chose your subjects, or analyzed your data. Use the same structure for the Discussion as for the Introduction: past tense for your work and present perfect or present tense for the established and accepted work of others. There are many exceptions to all of these “rules,” and the best way to learn correct use of tense is to read the journal critically, watching for change of tense in the various sections.

## **Grammar**

Another common error that can make the meaning of a sentence ambiguous and embarrassingly humorous is the dangling participle. For example: “Suffering from the ravages of time and weather, I was able to buy the house for a low price.” Sentences should be recast to avoid such construction: “I was able to buy the house for a low price because of its weathered and ravaged condition.” Participles must be positioned properly to make sure that a sentence says what you intend it to.

Adverbs and other qualifiers intended to strengthen a statement can have the opposite effect. Often the temptation to use qualifiers stems from an unconscious urge to prop up a weak argument. If you are tempted to use an adverb (nearly, very, totally), give it the “pregnant and dead” test: Those two conditions cannot be qualified, so it is poor style to say “very pregnant” or “totally dead.” For the most part, adverbs are useless and annoying in scientific writing.

Test your manuscript for less-than-obvious redundancies such as “intrauterine fetal” and “prospective randomized.” Likewise, be on the look-out for tautologies, the second cousins to redundancies. The fol-

lowing contains an unnecessary adverb, a redundancy, and a tautology. “At 2 PM Tuesday afternoon (redundant to PM), following Grand rounds, Dr. Smith will subsequently (an unnecessary adverb that is also redundant to ‘following’) speak. The speech is entitled: ‘Your Female Patient: She Is Pregnant or She Is Not’ (a tautology, excluding no possibility).” Comparative terms should make clear what is being compared. If they do not, the result is a “naked comparative.” For example, “Labor induction with hourly oxytocin incremental increases is associated with fewer episodes of uterine hyperstimulation.” Fewer than what? Likewise, “This treatment gives better results.” Better than what? Ask such questions when you write sentences that contain comparatives.

### **American Versus British Spellings**

*Obstetrics & Gynecology*, as an American publication, uses the American form of English spellings, avoiding British digraphs, which retain, from their Latin and Greek origins, combinations of vowels that have only one sound, for example: labor instead of labour, gynecology instead of gynaecology, hematology instead of haematology.

### **Generic Versus Commercial Names**

Use generic names for drugs or instruments, and do not capitalize them. Generic names avoid any appearance of unpaid advertising. If a commercial name is necessary, it must be capitalized and the name and location (city and state or nation) of the manufacturer stated in parentheses, for example: “Sharplan laser (Laser Industries, Tel Aviv, Israel).” Commercial names cannot be used in the title, précis, or abstract.

### **Numbers**

In general, spell out numbers one through nine and use Arabic numerals for all numbers greater than nine. Exceptions include:

- Numbers in tables and in figures
- Numbers used to describe time, age, or pregnancy history
- Numbers used to indicate standard or scientific measurements or units of time (eg, 1 day, 1 kg, one subject)

Commas should be used in numerals of 1,000 or more. Avoid using a numeral at the beginning of a sentence by rewording the sentence or adding a phrase such as “a total of” in front of the numeral. If a quantity is used at the beginning of a sentence, it must be spelled out; if the quantity has a unit, that too must be spelled out:

Twenty milligrams was the daily regimen.

The daily regimen was 20 mg.

## Units of Measurement

Give units of measure in the SI (International System of Units) system. When values may be more readily understood if another system of units is used (eg, pounds instead of kilograms), convert the value to the alternative system and give it parenthetically after the SI value. Use the following abbreviations with numerals only; spell out when used alone.

|          |                                                                                         |
|----------|-----------------------------------------------------------------------------------------|
| Eq       | equivalent                                                                              |
| g        | gram                                                                                    |
| <i>g</i> | gravity (acceleration due to [eg, 200 <i>g</i> ])                                       |
| Gy       | gray (unit of radiation; convert rads to grays<br>[1 Gray = 100 rads], not centigrays ) |
| L        | liter                                                                                   |
| M        | molar (concentration)                                                                   |
| mcg      | microgram                                                                               |
| mEq      | milliequivalent                                                                         |
| mg       | milligram                                                                               |
| mG       | milligauss, measurement of magnetic field exposure                                      |
| mL       | milliliter (convert cubic centimeters to milliliters<br>[1 cc = 1 mL])                  |
| mm       | millimeter                                                                              |
| osm      | osmole                                                                                  |

## Troublesome Terms

Another aspect of accurate writing is choosing the correct term. The following terms often are used incorrectly:

**And/or:** Considered by many semanticists to be inappropriate in most cases; either “and” or “or” (depending on the context) alone will nearly always suffice.

**Cesarean, cesarean delivery, or cesarean birth** instead of cesarean section: Most etymologists believe that “cesarean” and “section” originated from Latin verbs that both mean “to cut,” therefore, cesarean section is a redundancy. Do not capitalize cesarean.

**Demise:** An archaic form; “death” is usually a better choice, and less euphemistic.

**Diabetic:** The use of this word as a noun to describe someone with the disease is considered by some to be condescending. Therefore, “diabetic” should be used only as an adjective.

**Dilation, dilatation:** *Dilation* is the act of dilating (eg, a cervix, a pupil), whereas *dilatation* is the state of being dilated. The first describes a type of movement, the second describes the result of that type of movement. Examples: “Dilation began when contractions were 10 minutes apart.” “After 3 hours of labor, dilatation was 5 cm.”

**Down syndrome:** This eponym should not be written in the possessive form, because Down neither owned nor had the condition. See *Dorland’s Illustrated Medical Dictionary* for rules on eponym usage.

**Expire:** A euphemism; the preferred word is “die.”

**Fewer, less:** Use “fewer” when referring to “a smaller number of”; use “less” when referring to “a smaller amount.”

**Intrauterine:** Refers to all intrauterine members collectively, not one of them. For example, “intrauterine growth restriction” might be appropriate if there is evidence that a fetus, placenta, and amniotic fluid are all growth restricted; however, when (as is usually the case) the diagnosis is based on birth weight, “fetal growth restriction” is better. Note: “restriction” is preferred to “retardation.”

**May, might:** *May* states the possibility of an action. For example, “The physician may remove the tumors through hysteroscopy.” However, the use of “may” in an interrogative sentence indicates a request for permission. For example, “May I observe the procedure?” *Might* places doubt on the possibility. For example, “The procedure might not be necessary.”

**Parameter:** Avoid this overused and misused word; “index” and “characteristic” are good substitutes.

**Patient:** Physicians, presumably because they spend so much time with patients, overuse the term when describing research. “Patient” should be used only when referring to an actual patient, not a participant in investigations. Repetition of the same word makes dull reading, with “patient” the most common example. Introduce a little variety by using other terms such as “woman, participant.”

**Precipitate labor:** Labor that occurs with undue rapidity is precipitate, not precipitous (very steep).

**Principle, principal:** *Principle* is always a noun and means fundamental, such as rules, beliefs, truths. *Principal* can be either a noun or an adjective, and means chief, major, or of first importance.

**Significant, significance:** In scientific writing, “significance” usually refers to statistical significance, and, to avoid confusion, is best used only in that sense. For example, in the sentence, “Following the procedure, there was no significant pain,” the reader is unsure as to whether the difference in pain before and after the procedure was statistically significant or whether the author simply wants to indicate that pain was not appreciable or severe or substantial.

## **Jargon, Acronyms, and Abbreviations**

Every discipline has its own specialized and technical language that over time becomes its jargon. The situation in medicine is compounded by the tradition of using Latin and Greek terms and their abbreviations in prescription writing. Such terms might be acceptable in conversations among physicians, and perhaps in a medical record, but they should be avoided in scholarly writing. For exam-

ple: Write, “The patient took (or was given) digoxin 0.5 mg twice daily,” rather than, “The patient was placed on digoxin 0.5 mg BID” (patients might be on a bedpan, but not on a drug). Use, “The patients were observed monthly for 1 year,” rather than, “For 1 year, on a monthly basis, the patients were followed” (by Sherlock Holmes?). Note that for this journal the abbreviation of liter is “L” (eg, milliliter is “mL”) to avoid confusion with the Arabic numeral 1 in print (eg, 1 L versus 1 l).

Acronyms are a specialized form of jargon. A few are so widely used that they have become fully accepted (eg, AIDS, HELLP syndrome) and can be used if you follow journal policies about acronyms and abbreviations. *Obstetrics & Gynecology* permits only standard acronyms and abbreviations, such as those listed in *Dorland’s Illustrated Medical Dictionary* and those listed in Appendix C. However, in case of doubt, spell it out. Take special care to avoid acronyms created solely for your article. The colloquial acronym OB/GYN (or Ob/Gyn) is not allowed in *Obstetrics & Gynecology*.

## Resources

Maintaining an editorial style helps ensure consistency. The style used by *Obstetrics & Gynecology* is based on several authorities, which should be consulted for further reference (see Box 2).

Authors who have difficulty with language usage may benefit from independent editorial assistance in manuscript preparation. These services may be especially useful for those who are not native English speakers (see Box 3).

## Box 2. RESOURCES

Questions you have about journal style may be answered by consulting the following resources:

American Medical Association. American Medical Association manual of style: a guide for authors and editors. 10th ed. Chicago (IL): AMA; 2007. (*Medical and technical abbreviations, nomenclature, units of measurement*)

Chicago manual of style: the essential guide for writers, editors, and publishers. 15th ed. Chicago (IL): The University of Chicago Press; 2003. (*Punctuation, names, and terms*)

Dorland's illustrated medical dictionary. 31st ed. Philadelphia (PA): Saunders; 2007. (*Spelling, medical terminology*)

Merriam-Webster's collegiate dictionary. 11th ed. Springfield (MA): Merriam-Webster; 2003. (*Spelling, word division*)

Strunk W Jr, White EB. The elements of style. 4th ed. Boston (MA): Allyn and Bacon; 2000. (*Writing style*)

International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Philadelphia (PA): ICMJE; 2003. Available at: <http://www.icmje.org>. Retrieved September 3, 2004. (*Reference style*)

United States Pharmacopeial Convention. USP dictionary of USAN and international drug names. Rockville (MD): USP; 2003. (*U.S. drug names*)

Last JM. A dictionary of epidemiology. 4th ed. New York (NY): Oxford University Press; 2001. (*Statistical terminology*)

## Box 3. EDITORIAL SERVICES

Freelance editorial services may be useful in writing or revising a manuscript to promote clarity and comprehension. Some sources of such editorial help may be agencies, local schools and universities, or national organizations such as the American Medical Writer's Association (<http://www.amwa.org>) or the Council of Science Editors (<http://www.councilofscienceeditors.org>).

## TOWARD A FINAL PRODUCT

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Although the correlation might not always apply, a carefully prepared manuscript usually suggests well-conducted research. At the other extreme, a sloppy, disorganized, error-filled manuscript raises concerns about the care with which the investigation was done. Regardless of how meritorious the science, if your manuscript is not well written and carefully prepared, it may be rejected or will have to be revised extensively to meet the journal's requirements. Attention to manuscript preparation shortens the revision process. Before submitting the manuscript, consult our Instructions for Authors and complete the checklist. Do not just look at it; check the manuscript against the list for every point. Many manuscripts are returned to authors because they have not followed the Instructions for Authors. Spelling checkers are available in almost all word-processing packages; use them.

### Table and Figure Preparation

Tables and figures can be helpful for comparisons and swift comprehension, and a general rule is no more than one figure or table for each two or three printed pages of text. Usually, a table or figure is extraneous if its message can be given fully in a sentence or two in the text. For example, a graph showing a simple regression can be expressed in the text in a sentence giving the formula and correlation coefficient. Tables are multicolumnar by definition; single column listed items should be treated as text. Be sure to avoid duplication between text and tables or figures. If you wish to present your data in tables or figures, describe them only in summary fashion in the text. If you wish to give the actual data in the text, the table or figure becomes superfluous.

Examine your tables and figures for essential data. Complex tables and figures, particularly those with numerous abbreviations and footnotes, are difficult to read and, thus, add little to your manuscript.

Formatting of tables and figures is a common problem with submitted manuscripts. Adhering to some basic guidelines can improve the value of tables and figures and aid in the editorial process (see Box 4 for figure guidelines).

Figures should illustrate your data and facilitate the reader's understanding. There is no need for pictures of abnormal findings that are well known to most readers or of ultrasound images that cannot be verified independently. The use of color is at the Editor's discretion, and a cost to the author may be incurred. Each figure needs a concise legend telling what the figure represents and explaining any marks, such as arrows. Legends should be grouped on one page numbered as part of the manuscript at the end. Do not include legends on the figures themselves.

Tables should have column headings. Create tables using the table function in word processing software. Do not use tabs or spaces to create columns.

If your manuscript includes any tables or illustrations published previously, you will need to obtain a statement in writing from the holder of the copyright, giving permission for republication, and show credit to the original source. Many publishers now have online systems for submitting permissions request; please consult the publisher directly for more information. Note that *Obstetrics & Gynecology* requires that permission be obtained to reproduce material in both print and electronic format.

## **Evidence-Based Medicine**

Evidence-based approaches are becoming more important to the scientific literature. *Obstetrics & Gynecology* has incorporated specific guidelines for reporting randomized controlled trials (ie, CONSORT),<sup>12</sup> meta-analyses and systematic reviews of randomized controlled trials (ie, QUOROM),<sup>13</sup> meta-analyses and systematic reviews of observational studies (ie, MOOSE),<sup>14</sup> and studies of diagnostic accuracy (ie, STARD).<sup>15</sup>

#### **Box 4. GENERAL FIGURE GUIDELINES**

Use the following checklist as a guide when preparing figures for submission to the journal. See also <http://cjs.cadmus.com/da/index.jsp>.

##### **Flow charts**

- Arrows, not lines, are used
- Boxes are not shaded (if shading is removed, make subordinate boxes smaller for clarity)
- Boxes look the same (eg, boxes with straight edges and boxes with rounded edges are not used in the same flow chart)
- Text and numbers are ordered per journal style (eg, "Total patients [N = 30]" not "30 total patients")

##### **Bar and line graphs**

- Three-dimensional bar graphs are reformatted as two-dimensional bar graphs
- Hairline rules are avoided
- Bars in a chart are clearly differentiated (eg, white, black, diagonal lines; avoid shades of gray)
- Only the first letter of the first word is capitalized on axis labels and text in keys
- Symbols in line graphs are easily distinguishable by shape (circle, square, triangle), color (white or black), and size
- Lines are easily distinguishable when printed in black and white
- "N" or "n" have been checked for proper usage ("N" is the entire population under study; "n" is a sample of the population under study)<sup>16</sup>

##### **Ultrasound or magnetic resonance imaging photographs**

- Any marks or text that may identify a patient are removed
- Critical areas are identified with arrows on the figure
- Arrows are clear, sharp, and large enough to accommodate reduction in size when published

##### **X-rays or photomicrographs (ie, a photo of a microscope image)**

- Critical areas are identified with arrows on the figure
- Arrows are clear, sharp, and large enough to accommodate reduction in size when published

(continued)

#### **Box 4. GENERAL FIGURE GUIDELINES (continued)**

##### **X-rays or photomicrographs (ie, a photo of a microscope image) (continued)**

- Magnification and stain data and a scale bar are provided for photomicrographs

##### **Photographs of people**

- A release has been obtained if the patient is recognizable

##### **Figures in general**

- Labels and symbols are large enough to withstand reduction (the suggested minimum is 9 point type)
- Letters are the same size and style within each figure
- The first letter of the first word in each box or each label is capitalized; all other words are lowercase
- Any text that looks “digitized” or is low resolution is corrected
- Related figures are the same size for uniformity
- Boxes around figures have been removed
- Figure titles/legends are listed on a separate page
- All footnotes are moved to the figure legend
- Inconsistencies between the figure legend and figure are noted (eg, if a figure is black and white and the word “red” is used in the legend)
- Personal patient information (eg, initials) has been removed
- *P* values are in proper format (eg,  $P < .01$ ,  $P = .001$ )
- Units are checked for proper format (eg, liters should be expressed with a capital “L”; mL not ml)
- Symbols do not appear as the first “word” (eg, use “Patients (%)” rather than “% of patients”)
- The word “Number” is written out (ie, avoid the # symbol or the abbreviation “No.”)
- Unapproved abbreviations are written out and approved abbreviations are defined in the legend
- Misspellings are corrected
- Permission has been obtained and a credit line appears for art reprinted from other sources

In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, QUOROM, or STARD guidelines, as appropriate. A completed CONSORT checklist should accompany randomized controlled trials, and a completed STARD checklist should accompany studies of diagnostic accuracy. The checklists and guidelines are reprinted here (Appendixes D–G) and also are available on our web site ([www.greenjournal.org](http://www.greenjournal.org)).

### **Clinical Trial Registration**

*Obstetrics & Gynecology* has endorsed the statement from the International Committee of Medical Journal Editors that all clinical trials must be enrolled in a central registry in order to be considered for publication (Appendix H).<sup>17, 18</sup> This requirement will lessen the chance of publication bias by making all trials (published or unpublished) available to clinicians, investigators, and the public, even those that are negative or reflect unfavorably on a research sponsor's product.

### **Manuscript Submission**

When submitting a manuscript via the online system, Editorial Manager (<http://ong.editorialmanager.com>), authors create accounts and upload their manuscripts and relevant table and figure files. Complete instructions are available on the site for first-time users. Editorial Manager provides authors with the ability to do away with mailing and paper copies, and it allows authors to check on the status of their manuscripts. If you submit your manuscript using Editorial Manager, you should not submit hard copies to the editorial office; the electronic copy is sufficient. If you submit your manuscript electronically, art saved in a digital format should accompany it (see <http://www.greenjournal.org> for specifications). A hard copy of figures may be requested if the manuscript is accepted.

First-time users of the Editorial Manager system should go to <http://ong.editorialmanager.com> to register. If you have submitted a manuscript previously or if you are a reviewer for the journal, do not register, simply log in. The registration screen will ask for your contact information. It is important that you include a valid e-mail

address because the system corresponds with authors electronically. Once you have registered, click on “Submit a new manuscript” and follow the links and instructions on each page.

For technical questions such as acceptable file types, installing programs, or system compatibility, please contact [editorialsolutions@lww.com](mailto:editorialsolutions@lww.com). For general questions regarding manuscript submission, please contact the editorial office at [em@greenjournal.org](mailto:em@greenjournal.org). See Box 5 for answers to frequently asked questions about the Editorial Manager system.

Although *Obstetrics & Gynecology* encourages authors to submit their manuscripts via Editorial Manager, hard copy submissions are still accepted. These submissions should be sent to the attention of “The Editor,” *Obstetrics & Gynecology*, 409 12th Street, SW, Washington, DC 20024. If you submit a hard copy of your manuscript, it should be accompanied by copies of the art and a disk containing the electronic manuscript file. The editorial office will scan your figures for peer-review purposes.

## **Box 5. FREQUENTLY ASKED QUESTIONS ABOUT EDITORIAL MANAGER**

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### **1. How do I get started?**

Have you reviewed for the journal or submitted a manuscript before? If Yes, click on the author “Login” to begin your submission. If No, click on the “Register” link to create a new account.

Either review or enter your complete contact information. Be sure that your information is correct and current.

Have all files ready for uploading on your desktop before entering the system. This will keep you organized and allow you to complete your submission in a timely manner.

### **2. Do I need a cover letter?**

Yes, you should include a cover letter. Your cover letter indicates your intention of submitting your manuscript to *Obstetrics & Gynecology*. It is also your opportunity to bring any outstanding issues to the attention of the Editor. It is attached as a separate file as part of your submission.

### **3. How do I submit the author agreement form and checklist?**

You may submit scanned copies of the submission checklist and author agreement form. If scanning is not an option, these items may be sent via facsimile to the editorial office. Be sure to include complete title and author information on these documents.

### **4. How do I submit artwork (figures)?**

After saving your figures in a digital format (see <http://www.greenjournal.org> for specifications), you can upload these files into Editorial Manager.

If you cannot scan your illustrations for uploading into the Editorial Manager system, you may submit hard copy figures to the editorial office where they will be scanned and uploaded for you.

*(continued)*

### **Box 5. FREQUENTLY ASKED QUESTIONS ABOUT EDITORIAL MANAGER *(continued)***

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**5. Should I follow up my Editorial Manager submission with a paper copy?**

No, please submit your manuscript in only one way: hard copy or electronically.

**6. How do I know my manuscript was uploaded properly?**

Once you submit your manuscript or the editorial office submits it for you, you will be required to approve the resulting file, which is in portable document format (PDF). Your manuscript cannot proceed through peer review without your approval.

**7. I am checking the PDF file and I see text that looks like gibberish or tables and figures are missing.**

If you have not already done so, be sure that the most current version of Acrobat Reader (Adobe Systems Inc., San Jose, CA) has been installed on your computer. You will need this software for viewing PDF files. You can download this program for free once you have logged in to the Editorial Manager system. Using an outdated version will often cause viewing problems.

**8. I am an author of a manuscript, and I have logged in, but I can't see this particular manuscript in my account.**

The Editorial Manager system corresponds only with the corresponding author. If you did not submit the manuscript, you will not have access to its progress.

**9. How will I know when a decision is made on my manuscript?**

The Editorial Manager system will send you a decision letter via e-mail as soon as the Editor has submitted a decision.

**10. How do I submit revisions to my manuscript?**

Follow the same steps for submitting a new manuscript. When you are ready to attach files, be sure to remove all old files before uploading the revised manuscript.

## PITFALLS, MINEFIELDS, AND OTHER THINGS TO AVOID

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New and experienced authors alike may encounter ethical issues when preparing their manuscripts. This chapter is designed to define these dilemmas and help authors avoid them.

### Redundant Publication

We require that your manuscript be submitted solely to *Obstetrics & Gynecology*. If any of the material in the manuscript (other than an abstract of not more than 300 words) is submitted or planned for publication elsewhere in any form (including electronic media), the author should identify the other submission in the cover letter and include a copy of that publication. This does not apply to documented materials from other sources such as quotations, figures, and tables. Failure to comply with this stipulation may lead to a judgment of redundant publication. Authors found responsible for redundant publication may be barred from submitting manuscripts for up to 3 years; furthermore, a statement identifying the nature and source of the redundant publication may be printed in the journal.

The issue of duplication is further clarified by the International Committee of Medical Journal Editors: "Readers of primary source periodicals, whether print or electronic, 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. Duplicate publication of original research is particularly problematic because it can result in inadvertent double counting or

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*The world is a quagmire  
and we must try to keep to  
the heights.*

—Honoré Balzac

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inappropriate weighting of the results of a single study, which distorts the available evidence.”<sup>18</sup> Further, if you have submitted your manuscript to another journal and it has been rejected, you should mention this in your cover letter and include the previous reviewers’ comments and the changes you made in response to those comments. You may note the presentation of all or part of your manuscript at a scientific meeting such as the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists.

### **Lumping Versus Splitting**

Should a large and complex data set be lumped together into a single comprehensive manuscript or should it be split into smaller sections and published independently? There is no categorical answer to that question, and the ultimate decision must rely on common sense about how readers will best understand the data. In general, the better guide is to preserve the integrity of the entire work by presenting it in toto, rather than breaking it into small pieces. However, sometimes a comprehensive report of a complicated investigation can be too formidable to be assimilated as a whole, leading to important aspects being overlooked. In such cases, division into logical segments can help convey your message. Such “publication ad seriatim” must be defensible against the charge that you are simply trying to wring the maximum number of articles from your research.

Sometimes, an author breaks his study into small sections and writes a manuscript on each. Such “salami publication” gets its name from the analogy of slicing salami into increasingly thinner slices. If a manuscript has this appearance, the author should identify the situation clearly in the cover letter and manuscript and provide copies of all relevant publications or submissions.

Not explaining fully any splitting or lumping in submissions raises the possibility of attempted deception and can lead to a question of redundant publication. The best protection against such a charge is full and complete disclosure at submission.

## **Conflicts of Interest**

When you submit your manuscript, you must identify potential conflicts of interest of a financial or other nature. If uncertain as to what might be considered a potential conflict of interest, the authors should err on the side of full disclosure and provide as much information as possible regardless of dollar amount.

Organizations or individuals that provide financial and other substantive support of your work must be identified on the title page. All financial relationships with any organization that might have an interest in the work must be identified in an attachment to the author agreement form (eg, ownership or stock holdings, or the source of funding for honoraria or consultantships).

Every article published in *Obstetrics & Gynecology* includes a financial disclosure statement on the first page. If authors have nothing to disclose, a statement is included to that effect.

## WHAT HAPPENS NEXT?

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When your manuscript is entered in the manuscript submission system (Editorial Manager), either by you or the editorial office, you will be sent an e-mail acknowledging its receipt. All further correspondence regarding your manuscript will be sent electronically. From the date of submission, you can expect to receive notification regarding the status of your manuscript in approximately 6 weeks.

### **The Review Process and Initial Disposition**

The literature of science stands squarely on the peer-review system, having evolved from its beginnings in the 17th century to today, when virtually all original scientific research is reported by this means. All submissions to *Obstetrics & Gynecology* are reviewed by experts in the relevant subject areas. The experts prepare written critiques that the editors consider in arriving at a decision about acceptability.

Manuscripts are reviewed initially by the Editor-in-Chief, Deputy Editor, or Associate Editor. All manuscripts are additionally reviewed by a member of the Editorial Board and by one to three special expert reviewers. The Editorial Board member is probably not an expert in your field and represents the general readership, thus complementing the expert peer reviewers.

After the reviews are returned, the Editor responsible for your manuscript reads it thoroughly and studies the reports of the individual referees in arriving at an initial disposition. Very rarely is a manuscript judged to be acceptable as submitted. More often, a manuscript may be accepted contingent upon certain revisions, in which case it is returned with a list of what is needed. If there appears to be little likelihood that the manuscript can be made acceptable, it will be declined with a letter relaying the basis of the decision to the author.

## Rejection

Rejection of a manuscript is always disappointing. You believed you had something important to communicate to your colleagues, but upon peer review, your manuscript was deemed unacceptable. The reasons for rejection vary. The methodology may be judged flawed or inappropriate, or the conclusions may be felt to be unjustified. Many times, there is nothing basically wrong with the work, but it seems more confirmatory than original, and for this reason has insufficient priority to meet present stringent requirements for acceptance. The most common reasons that manuscripts submitted to *Obstetrics & Gynecology* are rejected are listed in Box 6.

In dealing with the discouragement and frustration from rejection of a manuscript, bear in mind that it has become harder and harder to have a manuscript accepted. The number of pages available has not kept pace with the number of manuscripts written or the number of prospective authors. Thus, many manuscripts that would have been accepted a few years ago are rejected today.

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*Your paper is both interesting and original. Unfortunately, the part that is interesting is not original, and the part that is original is not interesting.*

—Samuel Johnson

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### **BOX 6. COMMON REASONS FOR REJECTION OF MANUSCRIPTS IN *OBSTETRICS & GYNECOLOGY***

- Format not consistent with the Instructions for Authors
- Flawed methods (study design)
- Inappropriate statistical analysis
- Stylistic, grammatical, and English language errors
- Unsubstantiated conclusion(s)
- Insufficient priority

## Revision

If you are told that your manuscript is not acceptable in its present form, but that further consideration can be given to a revised manuscript, you need to study the critiques carefully and decide whether you can address them (see Box 7 for examples of common requests

### **Box 7. COMMON REVISION REQUESTS FROM *OBSTETRICS & GYNECOLOGY***

- Submit author agreement forms signed by all authors
- Examine figures to ensure that they are of the highest quality
- Determine whether to print figures in color or black and white (authors are responsible for the cost of printing in color)
- Check word count and manuscript formatting against the Instructions for Authors
- Use only approved abbreviations and acronyms
- Avoid inconsistencies between the abstract and the manuscript
- Correct any misspelled words, incorrect use of the English language, and copyedited suggestions
- Ensure readability by having the language usage reviewed by a native English speaker who has published in the sciences
- Provide justification for having more authors than usually allowed
- Disclose any information about the financial aspects of the study
- Provide evidence of institutional review board approval or exemption
- Eliminate claims of priority (eg, “first” report) or justify with details of a MEDLINE search
- Obtain written consent from subjects
- Follow the CONSORT, QUOROM, MOOSE, or STARD guidelines as appropriate
- If applicable, verify that the clinical trial is enrolled in a central registry

for revision). If you think you can, begin working on a revision. If, however, you find that one or more flaws identified cannot be remedied, revision might not be worth the effort. If you are told that your manuscript is acceptable for publication providing you make minor revisions, you will, of course, want to make those changes.

Carefully read the critiques by the Editor and the referees. Remember that reviewers are selected for their technical expertise in your field. Heed their comments. The Editors will notice, usually not favorably, if you ignore any of the comments of the reviewers. Your cover letter must address each reviewer's comments, point by point. You also must respond to the comments from the Editor. In those instances when you disagree with a criticism, from either the Editor or a reviewer, and feel no change is necessary, address the issue in your rebuttal. In this case, you need to present a clear and convincing argument of your position.

Your revised manuscript will be easy to follow if you respond to all criticisms in an organized manner. To facilitate review, the Editors prefer that the cover letter include the comments made by the reviewer followed by your response. If the comments of the reviewers are not numbered, then number them and respond to them in numeric order (ie, "Referee I, point 1; Referee II, point 2"). By numbering the comments you will be less likely to overlook a problem, and the review of your revised manuscript will be greatly facilitated.

If you are advised to reduce the length of your manuscript or any of its sections, make every effort to reduce it. If you do not, the manuscript will probably be returned to you once again, or it may even be rejected.

In January 2004, *Obstetrics & Gynecology* began publishing the "level of evidence" for all original research articles (see Box 8). The Editor's decision letter will contain the level of evidence. This rating is established by the reviewers and Editor. In your cover letter, indicate whether you agree with this rating. If you feel the score is incorrect, indicate the proper classification and your rationale for listing it as such.

Permitting an author to submit a revision is no guarantee the manuscript will be accepted. It only indicates a judgment that it may

### Box 8. LEVEL OF EVIDENCE

The levels of evidence are:

I: A randomized, controlled trial

II: A cohort or case-control study that includes a comparison group

III: An uncontrolled descriptive study including case series

become acceptable with revision. Sometimes the author thinks he or she has responded satisfactorily, but the Editors and reviewers disagree, and the manuscript is rejected after it has been revised.

#### Acceptance

Your revised manuscript will be reviewed carefully by the Editor and might be sent to the reviewers for re-analysis. If all the concerns from the original

*...There are days when the result is so bad that no fewer than five revisions are required. In contrast, when I'm greatly inspired, only four revisions are needed.*

—John Kenneth Galbraith

review are judged to have been addressed satisfactorily, the manuscript is ready to be accepted. If concerns remain, it will be returned for further revision until the Editor believes it is in acceptable condition.

Acceptance for publication or rejection in *Obstetrics & Gynecology* requires unanimous agreement of the Editorial Committee, composed of the Editor-in-Chief, Deputy Editor, and Associate Editor. This committee meets by teleconference weekly and considers manuscripts recommended for acceptance or rejection by the responsible Editor.

Once your manuscript is accepted for publication, you will be notified in writing and the manuscript will be copyedited and typeset. In due course you will receive an electronic copy of your page proofs via e-mail. These proofs represent your article as it will be printed. Carefully read the accompanying instructions and communicate any necessary changes to the contact person indicated. This will be your last opportunity to check your article for accuracy. If corrections are

not received from you within 48 hours, it is the journal's policy to proceed with publication.

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## Final Thoughts

The goal of *Obstetrics & Gynecology* is to produce a clinically relevant journal with impeccable science that is useful to our readers in practice. Articles published during the past half century reflect the broad changes that have taken place in obstetrics and gynecology in the United States, and *Obstetrics & Gynecology* defines for many readers what it means to be an obstetrician–gynecologist. The goal of the Editors is to ensure that this journal remains the preferred source for authors and clinicians of original research articles and high-quality systematic reviews and is the forum for new ideas and interest in the specialty. *A Guide to Writing for Obstetrics & Gynecology* is just one instructional tool designed to benefit our authors and assist the journal in reaching that goal. We hope that you agree, and we thank you for your contributions to *Obstetrics & Gynecology*.

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## APPENDIX A.

# AUTHORSHIP

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### Definition

To qualify as an author of an article published in *Obstetrics & Gynecology*, an individual must have participated sufficiently in the work described to take public responsibility for it. Such participation ordinarily includes:

- Involvement in conception or design of the project
- Important contribution(s) to critical aspects of the conduct of the research
- Drafting the article submitted and revising it for important intellectual content
- Approval of the final form submitted

Participation that does not qualify for authorship includes:

- Data gathering
- Provision of financial or other support

The Editor may request a description of the specific contribution of each of the authors listed. This information may be published with the article.

### Certification

*Obstetrics & Gynecology* requires that the submitted manuscript be accompanied by a statement signed by each of the authors affirming that he or she meets the requirements of authorship, certifying the originality of the work and sole submission to this journal, and providing information regarding any financial conflict of interest, as well as transferring copyright if the manuscript is accepted. This is a legal document, and each author's signature is the journal's only

proof that he or she approves the manuscript in the form submitted, concurs with its submission to *Obstetrics & Gynecology*, and transfers copyright if the manuscript is accepted.

Submissions missing signed author agreement forms will be accepted for evaluation, but the corresponding author will be notified immediately of the omission and directed to provide the missing signatures. No manuscript can be accepted for publication until a fully and properly executed form has been received. Individuals cannot be listed as authors if they do not submit a signed agreement form.

The author agreement form can be found in the back of every issue of *Obstetrics & Gynecology* or online at [www.greenjournal.org](http://www.greenjournal.org). All signatures need not be on the same form. Original documents, electronic (scanned) documents, and fax copies are all acceptable. You must also complete the section headed "Corresponding author" at the top of the form.

### **Consortium Authorship**

Authorship by consortium, group, or collective is permissible, but there must be at least one person from said bodies named in the author byline. Listing a person as "for" the group rather than "and" the group is preferable because with "and" each member is considered an author and must complete the required authorship agreement form. Consortia count as one author. The membership roster (names and city, with no duplication of authors) may be published as an appendix, provided it is not too long. If the Editor judges the list to be excessive, a statement might be printed indicating how the names and institutions of the members can be obtained.

### **Numbers**

The maximum number of authors ordinarily permitted for original research reports and reviews is six, and for all other types of articles (case reports, personal perspectives, current commentaries) four is the maximum number. Exceptions to the six-author rule can be made in the case of research reports involving multiple institutions, where one author per institution may be listed, as long as in the letter

of submission or revision the corresponding author describes the contribution of each author.

When an original research report that does not emanate from multiple institutions has more than six authors, it will be reviewed according to customary procedures. If this evaluation indicates that the report has sufficient potential that it should be returned to the authors for revision, at this point the corresponding author will be told the journal's policy and advised that as a condition of further consideration, either the number of authors needs to be reduced to six or fewer or a waiver of the policy requested. A request for waiver should be based on justification of the need for a large number of authors, a statement of the specific contribution of each of the proposed authors, and a description of how each met the definition of authorship.

## **Order**

Resolve in what order authors will be listed. The first author should be the person who contributed most to the work and wrote most of the manuscript. Other names usually follow in order of their relative contributions, although some prefer to list the senior laboratory or departmental leader last. This is permissible only if that individual fulfilled the criteria of authorship applicable to all. The awarding of honorary or guest authorship is unacceptable. The authors rather than the Editor should resolve any disagreements about authors and their contributions, although the Editor may request a description of the role of one or more of the authors and may decide to publish that information with the article. Noting that more than one author contributed equally to the work is not permitted.

## APPENDIX B.

# METHODOLOGIC TERMS

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**Accuracy:** The degree to which a measurement or an estimate based on measurements represents the true value of the attribute that is being measured.

**Ascertainment bias:** Systematic failure to represent equally all classes of cases or persons that are supposed to be represented in a sample. This may arise because of the nature of the sources from which persons come; from a diagnostic process influenced by culture, custom, or idiosyncrasy; or, for example, in genetic studies, from the statistical chance of selecting from large or small families.

**Bias:** Deviation of results or inferences from the truth, or processes leading to such deviation; it is any trend in the collection, analysis, interpretation, publication, or review of data that can lead to conclusions that are systematically different from the truth. Three frequently occurring types of bias include selection bias, information bias, and confounding. *Selection bias* is error due to systematic differences in characteristics between those who are selected for study and those who are not. *Information bias*, also called observational bias, is a flaw in measuring exposure or outcome data that results in different quality (accuracy) of information between comparative groups. Recall bias is an example of information bias. *Confounding* describes a situation in which the effects of two processes are not separated; it is the distortion of the apparent effect of an exposure on risk brought about by the association with other factors that can influence the outcome.

**Case-control study:** An observational study of persons with a disease of interest and a suitable control group of persons without the disease, retrospective in design, starting after the onset of disease, and looking back at postulated causal factors.

**Cohort study (longitudinal or follow-up study):** An observational study over a long period with comparison of incidence rates in groups that differ in exposure levels, prospective in design (see historical cohort study), starting with exposed groups, and following them over time.

**Confidence interval:** An indication of the variability of a point estimate, such as an odds ratio or relative risk. In general, the wider the confidence interval, the less precise the point estimate. The 95% confidence interval is often used. As an example, if the 95% confidence interval for an odds ratio or for a relative risk does not overlap 1.0, then one would reject the null hypothesis.

**Confounding variable (confounder):** A variable that can cause or prevent the outcome of interest, is not an intermediate variable, and is associated with the factor under investigation. Unless it is possible to adjust for confounding variables, their effects cannot be distinguished from those factor(s) being studied.

**Cost-benefit analysis:** An economic analysis in which the costs of medical care and the benefits of reduced loss of net earnings due to preventing premature death or disability are considered.

**Cost-effectiveness analysis:** An economic analysis that seeks to estimate the costs and effectiveness of an activity or to compare similar alternative activities to estimate the relative degree to which they will obtain the desired objectives or outcomes. The preferred action or alternative is one that requires the least cost to produce a given level of effectiveness, or provides the greatest effectiveness for a given level of cost. In the health care field, outcomes are measured in terms of health status.

**Cross-sectional study:** An observational study of prevalent cases that examines relationships between diseases and other variables of interest at a given time.

**Decision analysis:** A quantitative approach to evaluating the relative values of different management options. The range of choices can be plotted on a decision tree, and at each branch, or decision node, the probabilities of each outcome that can be predicted are displayed.

**Detection bias:** Bias due to systematic error(s) in methods of ascertainment, diagnosis, or verification of cases in an epidemiologic study. An example is verification of diagnosis by laboratory tests in hospital cases but failure to apply the same tests to cases outside the hospital.

**Historical cohort study (historical prospective study, nonconcurrent prospective study, prospective study in retrospect):** A cohort study conducted by reconstructing data about persons at a time or times in the past. The method uses existing records about the health or other relevant aspects of a population as it was at some time in the past and determines the current (or subsequent) status of members of this population with respect to the condition of interest. Different levels of past exposure to risk factor(s) of interest must be identifiable for subsets of the population. See also cohort study.

**Incidence:** The number of instances of illness commencing, or persons falling ill, during a given period in a specified population. More generally, the number of new events (eg, new cases of a disease in a defined population) within a specified period.

**Meta-analysis:** The process of using statistical methods to combine the results of different studies; a pooling of results from a set of randomized controlled trials.

**Multivariable analysis:** A set of techniques used when the variation in several independent variables is studied simultaneously.

**Negative predictive value:** The percentage of people with a negative test result who do not have the disease of interest.

**Null hypothesis (test hypothesis):** The statistical hypothesis that one variable has no association with another variable or set of variables, or that two or more population distributions do not differ from one another. In simplest terms, the null hypothesis states that the results observed in a study, experiment, or test are no different from what might have occurred as a result of the operation of chance alone.

**Number needed to treat (NNT):** The number of patients who must be treated with an intervention for a specific period of time to prevent one bad outcome or result in one good outcome. The NNT is the

reciprocal of the absolute risk reduction, the difference between event rates in the intervention and placebo groups in a clinical trial.

**Observational study:** An epidemiologic study that does not involve any intervention, experimental or otherwise. Case-control, cohort, and cross-sectional studies are observational studies in which the investigator observes without intervention other than to record, classify, count, and statistically analyze results.

**Odds ratio (cross product ratio, relative odds):** The ratio of two odds. The exposure odds ratio for a set of case-control data is the ratio of the odds in favor of exposure among the cases ( $a/b$ ) to the odds in favor of exposure among noncases ( $c/d$ ).

**Positive predictive value:** The percentage of people with a positive test who actually have the disease of interest.

**P-value:** The probability that a test statistic would be as extreme or more extreme than observed if the null hypothesis were true. The letter  $P$ , followed by the symbol  $<$  (less than) and a decimal notation such as .01 or .05, is a statement of the probability that the difference observed could have occurred by chance if the groups were really alike (ie, under the null hypothesis). Investigators may arbitrarily set their own significance levels, but in most biomedical and epidemiologic work, a study result whose probability value is less than 5% ( $P < .05$ ) or 1% ( $P < .01$ ) is considered sufficiently unlikely to have occurred by chance and would justify the designation “statistically significant.” By convention, most investigators choose  $P \leq .05$  as statistically significant.

**Power (statistical power):** The ability of a study to demonstrate an association if one exists. The power of the study is determined by several factors, including the frequency of the condition under study and its variance, the magnitude of the effect, the study design, and sample size.

**Precision:** A measure of random error or chance; precision does not imply accuracy.

**Prevalence:** The number of events (eg, instances of a given disease or other condition) in a given population at a designated time; some-

times used to mean prevalence rate. When used without qualification, the term usually refers to the situation at a specified time (point prevalence).

**Randomized clinical trial (randomized controlled trial):** A prospective, experimental study in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not receive an experimental preventive or therapeutic procedure, maneuver, or intervention, and followed to assess results; this study design is the criterion standard of hypothesis testing.

**Relative risk:** The ratio of risk of disease or death among the exposed to that of the risk among the unexposed; this usage is synonymous with risk ratio. If the relative risk is above/greater than 1.0, there is a positive association between the exposure and the disease; if it is less than 1.0, there is a negative association.

**Sensitivity and specificity:** Sensitivity is the proportion of truly diseased persons in the screened population who are identified as diseased by the screening test. Specificity is the proportion of truly nondiseased persons who are so identified by the screening test.

**Stratification:** The process of or result of separating a sample into several subsamples according to specified criteria such as age groups and socioeconomic status. The effect of confounding variables may be controlled by stratifying the analysis of results. For example, lung cancer is known to be associated with smoking. To examine the possible association between urban atmospheric pollution and lung cancer, controlling for smoking, the population may be divided into strata according to smoking status. The association between air pollution and cancer can then be appraised separately within each stratum and combined across strata by proper statistical techniques. Stratification is used not only to control for confounding effects but also as a way of detecting modifying effects.

**Systematic error:** Consistent (one-sided) variation of measurements from the true values.

**Type I error:** The error of rejecting a true null hypothesis when it is true; that is, declaring that a difference exists when it does not.

**Type II error:** The error of failing to reject a false null hypothesis when it is false; that is, declaring that a difference does not exist when in fact it does.

**Validity:** The degree to which the inferences drawn from a study are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn.

Adapted from A Dictionary of Epidemiology, fourth edition, by John M. Last, edited for the Intl. Epidemiological Assn. by copyright © 2001 by Oxford University Press, Inc. Used by permission of Oxford University Press, Inc.

## APPENDIX C.

# ABBREVIATIONS LIST

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Use only standard abbreviations, such as those listed in *Dorland's Illustrated Medical Dictionary* and the *American Medical Association Manual of Style*, in addition to the following list of acceptable abbreviations.

\* = Use abbreviation after first mention regardless of number of times used

† = Do not spell out anywhere

|                    |                                                                                     |
|--------------------|-------------------------------------------------------------------------------------|
| AF                 | amniotic fluid                                                                      |
| AFI                | amniotic fluid index                                                                |
| AFP                | alpha fetoprotein                                                                   |
| AGA                | appropriate for gestational age                                                     |
| AGC                | atypical glandular cells                                                            |
| AIDS*              | acquired immunodeficiency syndrome                                                  |
| ASC                | atypical squamous cells                                                             |
| ASC-H              | atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesions |
| ASC-US             | atypical squamous cells of undetermined significance                                |
| AVM                | arteriovenous malformation                                                          |
| β-hCG†             | beta subunit of human chorionic gonadotropin                                        |
| BPD                | biparietal diameter                                                                 |
| bpm                | beats per minute                                                                    |
| BPP                | biophysical profile                                                                 |
| BSO                | bilateral salpingo-oophorectomy                                                     |
| C-1, C-2, C-3, etc | abbreviations for cervical vertebra, spinal nerves, or dermatomes                   |
| CA 125†            | cancer antigen 125                                                                  |
| CD-ROM†            | compact disk-random access memory                                                   |
| CI                 | confidence interval                                                                 |
| CIS                | carcinoma in situ                                                                   |

|                                 |                                                  |
|---------------------------------|--------------------------------------------------|
| CO <sub>2</sub>                 | carbon dioxide                                   |
| COX                             | cyclooxygenase                                   |
| CPD                             | cephalopelvic disproportion                      |
| CPT-4                           | Current Procedural Terminology, 4th edition      |
| CST                             | contraction stress test                          |
| ΔOD <sub>450</sub> <sup>†</sup> | delta optical density 450 nm                     |
| D&C                             | dilation and curettage                           |
| D&E                             | dilation and evacuation                          |
| DHEAS                           | dehydroepiandrosterone sulfate                   |
| DNA <sup>†</sup>                | deoxyribonucleic acid                            |
| DVT                             | deep vein thrombosis                             |
| DXA                             | dual energy X-ray absorptiometry                 |
| ECC                             | endocervical curettage                           |
| EDD                             | estimated date of delivery                       |
| EFM                             | electronic fetal monitoring                      |
| EGA                             | estimated gestational age                        |
| ELISA*                          | enzyme-linked immunosorbent assay                |
| ET                              | estrogen therapy                                 |
| EXIT                            | ex utero intrapartum treatment                   |
| FAS                             | fetal alcohol syndrome                           |
| FHR                             | fetal heart rate                                 |
| FIO <sub>2</sub> <sup>†</sup>   | fraction of inspired oxygen                      |
| GBS                             | group B streptococci                             |
| GDM                             | gestational diabetes mellitus                    |
| GIFT                            | gamete intrafallopian transfer                   |
| H&E                             | hematoxylin-eosin                                |
| HBIG                            | hepatitis B immune globulin                      |
| Hb A <sub>1c</sub>              | hemoglobin A <sub>1c</sub>                       |
| hCG                             | human chorionic gonadotropin                     |
| HELLP                           | hemolysis, elevated liver enzymes, low platelets |
| HIV*                            | human immunodeficiency virus                     |
| HLA                             | human leukocyte (or lymphocyte) antigen          |
| hMG                             | human menopausal gonadotropin                    |
| HNPCC                           | hereditary nonpolyposis colorectal carcinoma     |
| HSG                             | hysterosalpingography                            |
| HSIL                            | high-grade squamous intraepithelial lesions      |

|                                |                                                                               |
|--------------------------------|-------------------------------------------------------------------------------|
| HT                             | hormone therapy                                                               |
| ICD-9-CM                       | International Classification of Diseases, 9th Revision, Clinical Modification |
| IgA, IgG, etc                  | immunoglobulin A, G, etc                                                      |
| INR                            | international normalized ratio                                                |
| ITP                            | immune thrombocytopenic purpura                                               |
| IUD                            | intrauterine device                                                           |
| IUGR                           | intrauterine growth restriction                                               |
| IVF-ET                         | in vitro fertilization-embryo transfer                                        |
| IVIG                           | intravenous immunoglobulin                                                    |
| IVM                            | in vitro maturation                                                           |
| L-Name                         | N <sup>G</sup> -nitro-L-arginine methyl ester                                 |
| L-1, L-2, L-3, etc             | abbreviations for lumbar vertebra, spinal nerves, or dermatomes               |
| L/S ratio                      | lecithin/sphingomyelin ratio                                                  |
| LAVH                           | laparoscopically assisted vaginal hysterectomy                                |
| LBW                            | low birth weight                                                              |
| LEEP                           | loop electrosurgical excision procedure                                       |
| LGA                            | large for gestational age                                                     |
| LPD                            | luteal phase deficiency                                                       |
| LSIL                           | low-grade squamous intraepithelial lesions                                    |
| LVEDD                          | left ventricular end-diastolic dimension                                      |
| MAUDE                          | Manufacturer and User Facility Device Experience                              |
| MeSH <sup>†</sup>              | medical subject headings                                                      |
| MIC                            | minimum inhibitory concentration                                              |
| MoM                            | multiples of the median                                                       |
| MSAFP                          | maternal serum alpha-fetoprotein                                              |
| NICU                           | neonatal intensive care unit                                                  |
| NTD                            | neural tube defect                                                            |
| OA                             | occiput anterior                                                              |
| OAB                            | overactive bladder                                                            |
| OCP                            | oral contraceptive pill                                                       |
| OP                             | occiput posterior                                                             |
| OR                             | odds ratio                                                                    |
| OT                             | occiput transverse                                                            |
| Paco <sub>2</sub> <sup>†</sup> | partial carbon dioxide pressure in arterial blood                             |

|                                      |                                                                 |
|--------------------------------------|-----------------------------------------------------------------|
| $\text{PaO}_2^\dagger$               | partial oxygen pressure in arterial blood                       |
| $\text{PAO}_2^\dagger$               | partial oxygen pressure in alveolar gas                         |
| PAPP-A                               | pregnancy-associated plasma protein A                           |
| Pap test <sup>†</sup>                | Papanicolaou test                                               |
| $\text{PCO}_2^\dagger$               | partial carbon dioxide pressure                                 |
| $\text{PGE}_2, \text{PGF}_{2\alpha}$ | prostaglandin $\text{E}_2, \text{F}_{2\alpha}$                  |
| PGY-1, -2, -3, -4, -5 <sup>†</sup>   | postgraduate year-1, -2, -3, -4, -5                             |
| $\text{pH}^\dagger$                  | hydrogen ion concentration                                      |
| PIGF                                 | placental growth factor                                         |
| PIH                                  | pregnancy-induced hypertension                                  |
| PMS                                  | premenstrual syndrome                                           |
| $\text{Po}_2^\dagger$                | partial oxygen pressure                                         |
| POP                                  | pelvic organ prolapse                                           |
| POP-Q                                | pelvic organ prolapse quantification                            |
| PROM                                 | premature rupture of membranes                                  |
| PUBS                                 | percutaneous umbilical cord blood sampling                      |
| PVR                                  | postvoid residual volume                                        |
| RCT                                  | randomized controlled trial                                     |
| RDA                                  | recommended dietary allowance                                   |
| RDS                                  | respiratory distress syndrome                                   |
| RIA                                  | radioimmunoassay                                                |
| RNA <sup>†</sup>                     | ribonucleic acid                                                |
| RR                                   | relative risk                                                   |
| S-1, S-2, S-3, etc                   | abbreviations for sacral vertebra, spinal nerves, or dermatomes |
| S/D                                  | systolic/diastolic ratio                                        |
| $\text{Sao}_2^\dagger$               | oxygen saturation, arterial                                     |
| SARS                                 | severe acute respiratory syndrome                               |
| SCH                                  | supracervical hysterectomy                                      |
| SEM                                  | standard error of the mean                                      |
| SERMS                                | selective estrogen receptor modulators                          |
| SFlt-1                               | soluble fms-like tyrosine kinase-1                              |
| SGA                                  | small for gestational age                                       |
| SIL                                  | squamous intraepithelial lesion                                 |
| $\text{Spo}_2^\dagger$               | oxygen saturation as measured by pulse oximetry                 |

|                    |                                                                                |
|--------------------|--------------------------------------------------------------------------------|
| SUI                | stress urinary incontinence                                                    |
| T-1, T-2, T-3, etc | abbreviations for thoracic vertebra, spinal nerves, or dermatomes              |
| TAH                | total abdominal hysterectomy                                                   |
| TORCH              | toxoplasmosis, other viruses, rubella, cytomegalovirus, herpes simplex viruses |
| Tris <sup>†</sup>  | tris(hydroxymethyl)aminomethane ( $C_4H_{11}NO_3$ )                            |
| TSS                | toxic shock syndrome                                                           |
| TVT                | tension-free vaginal tape                                                      |
| TVT-O              | transobturator tension-free vaginal tape                                       |
| UI                 | urinary incontinence                                                           |
| UUI                | urge urinary incontinence                                                      |
| VAS                | visual analog scale                                                            |
| VBAC               | vaginal birth after cesarean                                                   |
| VIN                | vulvar intraepithelial neoplasia                                               |
| VZV                | varicella zoster virus                                                         |

## APPENDIX D.

# CONSOLIDATED STANDARDS OF REPORTING TRIALS (CONSORT)

**Table 1.** Checklist of Items to Include When Reporting a Randomized Trial

| Section and Topic         | Item No. | Descriptor                                                                                                                                                                               | Reported on Page No. |
|---------------------------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <i>Title and Abstract</i> | 1        | How participants were allocated to interventions (eg, “random allocation,” “randomized,” or “randomly assigned”).                                                                        |                      |
| <i>Introduction</i>       |          |                                                                                                                                                                                          |                      |
| Background                | 2        | Scientific background and explanation of rationale.                                                                                                                                      |                      |
| <i>Methods</i>            |          |                                                                                                                                                                                          |                      |
| 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). |                      |

(continued)

**Table 1.** Checklist of Items to Include When Reporting a Randomized Trial  
(continued)

| Section and Topic          | Item No. | Descriptor                                                                                                                                                                                 | Reported on Page No. |
|----------------------------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <i>Methods (continued)</i> |          |                                                                                                                                                                                            |                      |
| Sample size                | 7        | How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.                                                                               |                      |
| <i>Randomization</i>       |          |                                                                                                                                                                                            |                      |
| 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.                                       |                      |

(continued)

**Table 1.** Checklist of Items to Include When Reporting a Randomized Trial  
(continued)

| Section and Topic       | Item No. | Descriptor                                                                                                                                                                                                                                                                                                                                    | Reported on Page No. |
|-------------------------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <i>Results</i>          |          |                                                                                                                                                                                                                                                                                                                                               |                      |
| 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.                                                                                                                                                                       |                      |

(continued)

**Table 1.** Checklist of Items to Include When Reporting a Randomized Trial  
(continued)

| Section and Topic          | Item No. | Descriptor                                                                                                                                                                            | Reported on Page No. |
|----------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <i>Results (continued)</i> |          |                                                                                                                                                                                       |                      |
| Adverse events             | 19       | All important adverse events or side effects in each intervention group.                                                                                                              |                      |
| <i>Comment</i>             |          |                                                                                                                                                                                       |                      |
| 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.                                                                                                             |                      |

Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. CONSORT Group (Consolidated Standards of Reporting Trials). JAMA 2001;285:1987–91. Copyrighted © 2001, American Medical Association. All rights reserved.

## APPENDIX E.

# QUOROM GUIDELINES FOR META-ANALYSES AND SYSTEMATIC REVIEWS OF RANDOMIZED CONTROLLED TRIALS

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|                        |                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Title</i>           | Identify the study as a meta-analysis (or systematic review) of randomized controlled trials                                                                                                                                                                                                                                                                                         |
| <i>Abstract</i>        | Use the journal's structured format                                                                                                                                                                                                                                                                                                                                                  |
| <i>Introduction</i>    | <b>Present</b> <ul style="list-style-type: none"><li>• The clinical problem</li><li>• The biological rationale for the intervention</li><li>• The rationale for the review</li><li>• An explicit statement of objectives which includes the study population, the condition of interest, the exposure or intervention, and the outcome(s) considered</li></ul>                       |
| <i>Sources</i>         | <b>Describe</b> <ul style="list-style-type: none"><li>• The information sources in detail (eg, databases, registers, personal files, experts, agencies, hand-searching)</li><li>• Any restriction (years considered, publication status, language of publication)</li></ul>                                                                                                          |
| <i>Study Selection</i> | <b>Describe</b> <ul style="list-style-type: none"><li>• Inclusion and exclusion criteria (defining population, intervention, main outcomes, and study design)</li><li>• How clinical heterogeneity was assessed</li><li>• Methods used for validity assessment</li><li>• The criteria and process used for validity assessment (eg, masked conditions, quality assessment)</li></ul> |

- The data abstraction process (eg, completed independently, in duplicate)
- Study characteristics and how clinical heterogeneity was assessed
- The principal measures of effect (eg, relative risk)
- Method of combining results (statistical testing and confidence intervals)
- Handling of missing data
- How statistical heterogeneity was assessed
- Rationale for any a-priori sensitivity and subgroup analyses

### ***Result***

### **Present**

- A meta-analysis profile summarizing trial flow
- Descriptive data for each trial (study design, participant characteristics, sample size, details of intervention, outcome definitions, length of follow-up)
- Agreement on the selection and validity assessment
- Simple summary results (for each treatment group in each trial, for each primary outcome)
- Data needed to calculate effect sizes and confidence intervals in intention-to-treat analyses

### ***Discussion***

### **Discuss**

- Key findings
- Clinical inferences based on internal and external validity
- The results in light of the totality of available evidence
- Strengths and weaknesses
- Potential biases in the review process (eg, publication bias)
- Future research agenda

Modified from Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. *Quality of Reporting of Meta-analyses*. Lancet 1999;354: 1896–900. Reprinted with permission from Elsevier.

## APPENDIX F.

# MOOSE GUIDELINES FOR META-ANALYSES AND SYSTEMATIC REVIEWS OF OBSERVATIONAL STUDIES

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|                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Title</i>        | Identify the study as a meta-analysis (or systematic review)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <i>Abstract</i>     | Use the journal's structured format                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <i>Introduction</i> | <b>Present</b> <ul style="list-style-type: none"><li>• The clinical problem</li><li>• The hypothesis</li><li>• A statement of objectives that includes the study population, the condition of interest, the exposure or intervention, and the outcome(s) considered</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <i>Sources</i>      | <b>Describe</b> <ul style="list-style-type: none"><li>• Qualifications of searchers (eg, librarians and investigators)</li><li>• Search strategy, including time period included in the synthesis and keywords</li><li>• Effort to include all available studies, including contact with authors</li><li>• Databases and registries searched</li><li>• Search software used, name and version, including special features used (eg, explosion)</li><li>• Use of hand searching (eg, reference lists of obtained articles)</li><li>• List of citations located and those excluded, including justification</li><li>• Method of addressing articles published in languages other than English</li></ul> |

- Method of handling abstracts and unpublished studies
- Description of any contact with authors

***Study Selection*** **Describe**

- Types of study designs considered
- Relevance or appropriateness of studies gathered for assessing the hypothesis to be tested
- Rationale for the selection and coding of data (eg, sound clinical principles or convenience)
- Documentation of how data were classified and coded (eg, multiple raters, blinding, and inter-rater reliability)
- Assessment of confounding (eg, comparability of cases and controls in studies where appropriate)
- Assessment of study quality, including blinding of quality assessors, stratification or regression on possible predictors of study results
- Assessment of heterogeneity
- Statistical methods (eg, complete description of fixed or random effects models, justification of whether the chosen models account for predictors of study results, dose–response models, or cumulative meta-analysis) in sufficient detail to be replicated

***Result*** **Present**

- A graph summarizing individual study estimates and the overall estimate
- A table giving descriptive information for each included study
- Results of sensitivity testing (eg, subgroup analysis)
- Indication of statistical uncertainty of findings

***Discussion*** **Discuss**

- Strengths and weaknesses
- Potential biases in the review process (eg, publication bias)

- Justification for exclusion (eg, exclusion of non–English-language citations)
- Assessment of quality of included studies
- Consideration of alternative explanations for observed results
- Generalization of the conclusions (ie, appropriate for the data presented and within the domain of the literature review)
- Guidelines for future research
- Disclosure of funding source

Modified from Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000;283:2008–12. Copyrighted © 2000, American Medical Association. All rights reserved.

## APPENDIX G.

# STANDARDS FOR REPORTING OF DIAGNOSTIC ACCURACY (STARD)

**Table 1.** Checklist for the Reporting of Studies of Diagnostic Accuracy

| Section and Topic                   | Item No. | On Page No.                                                                                                                                                                                    |
|-------------------------------------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Title/Abstract/<br/>Keywords</i> | 1        | Identify the article as a study of diagnostic accuracy (recommend MeSH heading “sensitivity and specificity”).                                                                                 |
| <i>Introduction</i>                 | 2        | State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups.                                           |
| <i>Methods</i>                      |          | <i>Describe</i>                                                                                                                                                                                |
| Participants                        | 3        | The study population:<br>The inclusion and exclusion criteria, setting and locations where the data were collected.                                                                            |
|                                     | 4        | Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?  |
|                                     | 5        | Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected. |

(continued)

**Table 1.** Checklist for the Reporting of Studies of Diagnostic Accuracy  
(continued)

| Section and Topic           | Item No. | On Page No.                                                                                                                                                                                     |
|-----------------------------|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Methods (continued)</i>  |          | <i>Describe</i>                                                                                                                                                                                 |
| Participants<br>(continued) | 6        | Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?                                    |
| Test methods                | 7        | The reference standard and its rationale.                                                                                                                                                       |
|                             | 8        | Technical specifications of material and methods involved, including how and when measurements were taken, and cite references for index tests and reference standard.                          |
|                             | 9        | Definition of and rationale for the units, cutoffs, and categories of the results of the index tests and the reference standard.                                                                |
|                             | 10       | The number, training, and expertise of the persons executing and reading the index tests and the reference standard.                                                                            |
|                             | 11       | Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers. |
| Statistical methods         | 12       | Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (eg, 95% confidence intervals).                                  |
|                             | 13       | Methods for calculating test reproducibility, if done.                                                                                                                                          |

(continued)

**Table 1.** Checklist for the Reporting of Studies of Diagnostic Accuracy  
(continued)

| Section and Topic | Item No. | On Page No.                                                                                                                                                                                                                                         |
|-------------------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Results</i>    |          | <i>Report</i>                                                                                                                                                                                                                                       |
| Participants      | 14       | When study was done, including beginning and ending dates of recruitment.                                                                                                                                                                           |
|                   | 15       | Clinical and demographic characteristics of the study population (eg, age, sex, spectrum of presenting symptoms, comorbidity, current treatments, recruitment centers).                                                                             |
|                   | 16       | The number of participants satisfying the criteria for inclusion that did or did not undergo the index tests and the reference standard; describe why participants failed to receive either test (a flow diagram is strongly recommended).          |
| Test results      | 17       | Time interval from the index tests to the reference standard, and any treatment administered between.                                                                                                                                               |
|                   | 18       | Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.                                                                                             |
|                   | 19       | A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard. |
|                   | 20       | Any adverse events from performing the index tests or the reference standard.                                                                                                                                                                       |

(continued)

**Table 1.** Checklist for the Reporting of Studies of Diagnostic Accuracy  
(continued)

| Section and Topic          | Item No. | On Page No.                                                                                                     |
|----------------------------|----------|-----------------------------------------------------------------------------------------------------------------|
| <i>Results (continued)</i> |          | <i>Report</i>                                                                                                   |
| Estimates                  | 21       | Estimates of diagnostic accuracy and measures of statistical uncertainty (eg, 95% confidence intervals).        |
|                            | 22       | How indeterminate results, missing responses, and outliers of the index tests were handled.                     |
|                            | 23       | Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done. |
|                            | 24       | Estimates of test reproducibility, if done.                                                                     |
| <i>Discussion</i>          | 25       | Discuss the clinical applicability of the study findings.                                                       |

Abbreviation: MeSH, Medical Subject Heading.

Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: The STARD Initiative. Standards for Reporting of Diagnostic Accuracy. *Ann Intern Med* 2003;138:40–4.

## APPENDIX H.

# CLINICAL TRIAL REGISTRATION: A STATEMENT FROM THE INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS

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Altruism and trust lie at the heart of research on human subjects. Altruistic individuals volunteer for research because they trust that their participation will contribute to improved health for others and that researchers will minimize risks to participants. In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to conduct research ethically and to report it honestly. Honest reporting begins with revealing the existence of all clinical studies, even those that reflect unfavorably on a research sponsor's product.

Unfortunately, selective reporting of trials does occur, and it distorts the body of evidence available for clinical decision making. Researchers (and journal editors) are generally most enthusiastic about the publication of trials that show either a large effect of a new treatment (positive trials) or equivalence of two approaches to treatment (noninferiority trials). Researchers (and journals) typically are less excited about trials that show that a new treatment is inferior to standard treatment (negative trials) and even less interested in trials that are neither clearly positive nor clearly negative because inconclusive trials will not in themselves change practice. Regardless of their scientific interest, trial results that place financial interests at risk are

particularly likely to remain unpublished and hidden from public view. The interests of the sponsor or authors notwithstanding, anyone should be able to learn of any trial's existence and its important characteristics.

The case against selective reporting is particularly compelling for research that tests interventions that could enter mainstream clinical practice. Rather than a single trial, it is usually a body of evidence, consisting of many studies, that changes medical practice. When research sponsors or investigators conceal the presence of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers, and experts who write practice guidelines or decide on insurance coverage policy. If all trials are registered in a public repository at their inception, every trial's existence is part of the public record, and the many stakeholders in clinical research can explore the full range of clinical evidence. We are far from this ideal at present because trial registration is largely voluntary, registry data sets and public access to them varies, and registries contain only a small proportion of trials. In this Editorial, published simultaneously in all member journals, the International Committee of Medical Journal Editors (ICMJE) proposes comprehensive trials registration as a solution to the problem of selective awareness and announces that all 11 ICMJE member journals will adopt a trials registration policy to promote this goal.

The ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. Trials must register at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after July 1, 2005. For trials that began enrollment prior to this date, the ICMJE member journals will require registration by September 13, 2005, before considering the trial for publication. We speak only for ourselves, but we encourage editors of other biomedical journals to adopt similar policies. For this purpose, the ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

Studies designed for other purposes, such as to study pharmacokinetics or major toxicity (eg, phase 1 trials), would be exempt.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. An acceptable registry must include at minimum the following information: a unique identifying number, a statement of the intervention (or interventions) and comparison (or comparisons) studied, a statement of the study hypothesis, definitions of the primary and secondary outcome measures, eligibility criteria, key trial dates (registration date, anticipated or actual start date, anticipated or actual date of last follow-up, planned or actual date of closure to data entry, and date trial data are considered complete), target number of subjects, funding source, and contact information for the principal investigator. To our knowledge, at present, only [www.clinicaltrials.gov](http://www.clinicaltrials.gov),<sup>1</sup> sponsored by the United States National Library of Medicine, meets these requirements; there may be other registries, now or in the future, that meet all these requirements.

Registration is only part of the means to an end; that end is full transparency with respect to performance and reporting of clinical trials. Research sponsors may argue that public registration of clinical trials will result in unnecessary bureaucratic delays and destroy their competitive edge by allowing competitors full access to their research plans. We argue that enhanced public confidence in the research enterprise will compensate for the costs of full disclosure. Patients who volunteer to participate in clinical trials deserve to know that their contribution to improving human health will be available to inform health care decisions. The knowledge made possible by their collective altruism must be accessible to everyone. Required trial registration will advance this goal.

## Reference

1. ClinicalTrials.gov Web site. Available at: <http://www.clinicaltrials.gov>. Accessed August 18, 2004.

DeAngelis CD, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the international committee of medical journal editors. *JAMA* 2004;292:1363–4. Copyrighted © 2004, American Medical Association. All rights reserved.