The Journal of
Thoracic and Cardiovascular Surgery

Information for Authors

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General Information

The Editors of *The Journal of Thoracic and Cardiovascular Surgery* aim to promote excellence in the discipline and educate those practicing and interested in our specialty. To this end, the Journal accepts submissions in the form of original articles, brief communications, review articles, clinical-pathological conferences, and letters to the Editor on topics pertaining to the most recent developments in cardiothoracic transplantation, general thoracic surgery, surgery for acquired and congenital cardiovascular disease and technical and physiologic issues as they relate to the specialty. The *Journal* commits to rigorous peer review, freedom from commercial influence, and promotion of the highest ethical and scientific standards in our specialty.

Editorial Policies

Review: Three or more referees review each article. Acceptance is based on significance, originality, and validity of the material presented. If the article is accepted for publication, editorial revisions may be made to aid clarity and understanding without altering the meaning. Authors are given the opportunity to name a reviewer whom they believe is expert and impartial in their area of interest.

Guidelines for Reviewers: Because more papers are submitted to *The Journal of Thoracic and Cardiovascular Surgery* than can be published, only the very best papers should be recommended for publication. Accordingly, a manuscript should be evaluated not only with respect to its scientific competence and accuracy, but also its relative importance in the field of thoracic and cardiovascular surgery and for its probable interest to our readership. Among the issues to consider are:

- What is the importance of the research question or subject field study?
- Are the methods and experimental techniques adequate?
- Do the results seem to be reliable and presented clearly?
- Is the discussion relevant?
- Are the conclusions reasonable?
- Are the illustrations and references appropriate and necessary?
- Is the abstract informative and written in a style that will make it intelligible to readers who do not work in the specific area addressed by the abstract?
- Is the writing clear and the organization of the paper sound?
- What is the originality of the work?

If you recommended that a paper be shortened, you should indicate on the form "Comments to Authors" in which places it could be abbreviated and which figures or tables could be omitted. Please remember that it is the job of the copy editor to identify typographical and syntactic errors. Please focus your "Comments to Authors" on queries and constructive criticism. Do not put statements in the "Comments to Authors" form regarding the acceptability of the paper. If the editorial office or the other reviewers decide to reject the paper, such statements could be problematic.

Scientific Responsibility: Only those individuals who made direct contributions to the intellectual content of the paper may be listed as authors. Persons designated as authors should meet *all* of the following criteria:

1. Conceived and planned the work that led to the paper or interpreted the evidence presented, or both.
2. Wrote the paper, or reviewed successive versions and took part in the revision process.
3. Approved the final version.

The authors should describe the role of the study's sponsors in the following areas:

1. The design of the study
2. The collection, analysis, and interpretation of the data
3. Writing the report
4. Making the decision to submit for publication

The JTCVS editorial staff will not consider for publication a report in which the researcher did not have full access to the data, the ability to analyze them independently from the sponsor, and sole authority to make the final decision regarding publication. The Editor may, if he deems it necessary, require a copy for verification of its content.

After a manuscript is accepted for publication, no author can be removed from the author list without the written permission of that author.

Conflict of Interest: When the proposed publication concerns any commercial product, either directly or indirectly, the author must include in the cover letter a statement (1) indicating that he or she has no financial or other interest in the product or distributor of the product or (2) explaining the nature of any relation between himself or herself and the manufacturer or distributor of the product. Other kinds of associations, such as consultancies, stock ownership, or other equity interests or patent-licensing arrangements, also must be disclosed. If, in the Editor's judgment, the information disclosed represents a potential conflict of interest, it may be made available to reviewers and may be published at the Editor's discretion; authors will be informed of the decision before publication.

Sources of outside support for research, including funding, equipment, and drugs, must be named in the cover letter. The role(s) of the funding organization, if any, in the collection of data, its analysis and interpretation, and in the right to approve or disapprove publication of the finished manuscript must be described in the Methods section of the text.

Informed Consent: The *Journal* adheres to the principles set forth in the Helsinki Declaration (www.wma.net/e/policy/17-c_e.html) and holds that all reported research conducted with human participants should be conducted in accordance with such principles. Reports describing data obtained from research conducted in human participants must contain a statement in the Methods section indicating approval by the institutional review board and affirmation that informed consent was obtained from each participant. If patients are identifiable from illustrations, photographs, case reports, or other study data, release forms (or copies of the figures with the appropriate release statement) giving permission for publication must be submitted with the manuscript.

Humane Animal Care: All papers reporting experiments using animals must include a statement in the Methods section giving assurance that all animals have received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" (www.nap.edu/catalog/5140.html). Papers submitted from outside the United States must be in compliance with the guidelines established by their country's government or those of the National Institutes of Health and must include a statement to that effect in the Methods section.

Consultant Statistician and Statistical Methods: All manuscripts with statistical analysis are required to undergo biostatistical review to ensure adequate and appropriate study design, analysis, interpretation, and reporting. The *Journal* requires that a biostatistician review these manuscripts prior to submission. The most appropriate way to involve a biostatistician is as a consultant or coauthor from the investigators' home institution or collaborative group. The individual must complete and sign the Statistical Collaboration/Review Release Statement, available online (www.ctsnet.org/journals/jtcsstatisticalmethods.pdf) and published twice yearly (January and July issues) in the *Journal.* Manuscripts may undergo further biostatistical review by the *Journal* after submission. Additional information on statistical methods can be found in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (www.icmje.org).

Checklist

- ☐ Cover letter
  - __Manuscript category designation
  - __Single-journal submission affirmation
  - __Conflict of interest statement (if appropriate)
  - __Sources of outside funding, equipment, drugs
- ☐ Copyright Transfer/Author Declaration Statement
- ☐ Permission to reproduce published material in all forms and media or to cite unpublished data
- ☐ Informed consent statement (in Methods)
- ☐ Humane animal care statement (in Methods)
- ☐ Funding agency's role in data interpretation (in Methods)
- ☐ Signed Statistical Collaboration/Review Release Statement
- ☐ Original manuscript submitted via jtcvs.editorialmanager.com
  - ☐ Title page
    - __Title of article
    - __Full name(s), academic degrees, and affiliation(s) of authors
    - __Corresponding author
    - __Telephone (business and home), fax, and E-mail address for corresponding author
    - __Word count
  - ☐ Abstract (250 words; double-spaced)
  - ☐ Ultramini-abstract (50 words; double-spaced)
  - ☐ Text (double-spaced)
  - ☐ References (double-spaced; separate pages)
  - ☐ Tables (double-spaced; separate pages)
  - ☐ Figure legends (double-spaced; separate pages)
  - ☐ Figures (separate files; no paperclips on hardcopy; properly identified)
- ☐ Letter to the Editor

Copyright Statement: According to the Copyright Act of 1976, all manuscripts must be accompanied by the Copyright Transfer and Author Declaration Statement form that is available online at www.ctsnet.org/journals/jtcscopyrightform.pdf and in each issue of the *Journal* following the Information for Authors section. All authors must sign this statement.

Article Preparation

Manuscripts must be written so that a reasonably well-informed member of the thoracic surgical community can understand them. The primary goal of the *Journal* is the dissemination of information and education. Arcane content must be explained and considered understandable by the editorial staff. Articles are chosen based on their probability of achieving this goal. Authors are encouraged to follow the principles of clear scientific writing, such as those described by Gopen and Swan.[1]

Original Research Articles: The *Journal* publishes original research in surgery and translational physiology as it relates to acquired and congenital cardiovascular disease, cardiothoracic transplantation, and general thoracic surgery. Meritorious work from closely related specialties, such as anesthesiology, molecular biology, pathology, pulmonary medicine, cardiology, and perfusion, will receive appropriate consideration if the linkage to our specialty is clear.

Article length must be no longer than 6 printed pages, not including title and abstract. The following approximations between printed pages and typed pages are offered to help you calculate the number of printed pages your typed manuscript will translate to:

- 1 printed page = 3.7 typed 8.5 × 11 pages, double-spaced (approximately 250 typed words per page)
- 0.67 printed page = 30 typed references (maximum allowed; double-spaced)
- 1 printed page = 4 tables or figures with legends

Clinical-Pathological Conference: This can be an important educational tool and has recently been added to the content of the *Journal.* Acceptance will be based upon the learning opportunities presented by careful exposition of the case material, scholarly use of the literature to present treatment options, and discussion of patient outcome in the context of evidence-based medicine as the determinant for management and diagnosis-based issues. Unusual or rare entities are better treated as brief communications. Content should include appropriate illustrative material and may be supplemented by additional illustrative content that will appear in electronic form and may include digitized videos and illustrations.

Brief Communications: The Editors are interested in brief clinical contributions containing substantive information concerning clinical studies or a pertinent observation. The article should contain no more than 750 words and 2 tables or figures and no more than 5 references. These submissions will be chosen on their discussion and educational value and on their scholarly use of the literature.

Evolving Technology: Submissions to this section provide an opportunity to make the surgical community aware of novel technical additions to our specialty prior to the time that such innovations have undergone traditional trials and early application. Submissions to this section will be accepted on the basis of novel and important approaches to issues in our specialty. At times, work at a theoretical level will be considered. Communications should be brief (no more than 750 words) and are not required to contain references, although their use is not discouraged.

Letters to the Editor: Readers are encouraged to submit commentary on articles published in the *Journal.* Letters should be of broad interest to readers and not designed to "split hairs." Conflicting opinions on broad issues are particularly welcome when documentation is possible. Letters may be published together with a reply from the original author. If the original author does not respond, a notation indicating "Response declined" will be published. Letters to the Editor should not exceed 500 words, 1 figure or table, 3 authors, and 5 references. Substantive Letters to the Editor are indexed in Index Medicus.

Manuscript Preparation

Title Page: Provide a concise, informative title, with no unnecessary words (eg, Studies in . . .). List all authors' academic degrees and affiliations. Include all sources of funding for the work and complete name, address, business and home telephone and fax numbers, and E-mail address of the corresponding author. Also include article word count.

Abstract: The structured abstract should be limited to 250 words, should not include acronyms or abbreviations, and should contain the following sections:

1. Objective(s): describe the hypothesis or the purpose of the study
2. Methods: identify the study design and statistical methods used
3. Results: describe the outcome of the study and the statistical significance, if appropriate
4. Conclusions: state the significance of the results

Please provide a word count and do not use acronyms or abbreviations.

Ultramini-abstract: Provide 1 to 3 sentences of no more than 50 words total, containing the essence of the manuscript, to include immediately beneath the title of the paper in the table of contents.

Units of Measurement: Report measurements of length, height, weight, and volume in metric units (meter, kilogram, or liter) or their decimal multiples. Give temperatures in degrees Celsius and blood pressures in millimeters of mercury. All hematologic and clinical chemistry measurements should be reported in the metric system in terms of the International System of Units (SI). The authors should also add alternate or non-SI units before publication. See www.acponline.org/journals/resource/unifreqr.htm for more details.

Abbreviations: Except for units of measurements, abbreviations are discouraged. Abbreviations that are used should be defined at first mention. Internationally accepted abbreviations such as AIDS, DNA, SD, and TNM need not be defined. For commonly accepted abbreviations, word usage, symbols, and so forth, please consult *Scientific Style and Format*[2] and the *American Medical Association Manual of Style.*[3]

References: Limit references to directly pertinent published works or papers that have been accepted for publication. Number references serially in the text and list them, on a separate sheet of paper, double-spaced, at the end of the paper in numerical order. Reference format should conform to that set forth in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (www.acponline.org/journals/resource/unifreqr.htm) and journal abbreviations should conform to the style used in the *Cumulated Index Medicus.* The style of citation should be as follows:

Journals: authors' last names and initials; title of article; journal name; date; volume number, and inclusive pages (list all authors when six or fewer; when seven or more, list six and add *et al*):

> Graeber GM, Gupta NC, Murray GF. Positron emission tomographic imaging with fluorodeoxyglucose is efficacious in evaluating malignant pulmonary disease. *J Thorac Cardiovasc Surg.* 1999;117:719-27.
>
> Lytle BW, Blackstone EH, Loop FD, Houghtaling PL, Arnold JH, Akhrass R, et al. Two internal thoracic artery grafts are better than one. *J Thorac Cardiovasc Surg.* 1999;117:855-72.

Books: authors' last names and initials; chapter title, editor's name, book title, edition, city, publisher, date, and pages:

> Mollnes TE. Analysis of in vivo complement activation: In: Herzenberg LA, Weir DM, Herzenberg LA, Blackwell C, editors. Weir's handbook of experimental immunology. Volume 78, 5th ed. Boston: Blackwell Science; 1997, p. 78.1-78.8.

Unpublished data and personal communications should be cited only in the text, not as a numbered reference. Authors wishing to cite unpublished material must have a letter of permission from the originator of the communication to do so. This letter should be submitted with the manuscript.

Figures: For help with preparing electronic artwork for both on-screen review and eventual publication, see the information page created by Elsevier Science (www.elsevier.nl/homepage/sab/artwork).

Figures must be of professional quality. When possible, please use or supply first-generation artwork. Number figures in the order of their appearance in the text.

NOTE: JTCVS will need print quality copies of artwork for each figure at a later stage (with the final version) only if the paper is accepted for publication.

The *Journal* will reproduce free of cost to the author a reasonable number of black and white illustrations. Authors are asked to assume the cost of printing their color illustrations. When color illustrations accompany a manuscript, the publisher will contact the author with the exact cost of including color illustrations. The decision whether or not to include color is the author's.

Efficient Use of Space in Figures:

- Eliminate blank spaces that contain no information (eg, delete points on the x and y axes that do not contain data)
- Do not border a figure or a key with a box
- If they fit, place keys that apply to the figure within the figure itself (without a box); if the key does not fit in the figure, place it at the end of the legend
- Create figures in scale with each other to the extent possible

Effective Formatting in Figures:

- Do not use background horizontal lines
- Avoid 3-dimensional art
- Make sure both axes are labeled
- Most art will be one column wide. Ensure that all data and type within a figure are sized according to this guideline to the extent possible
- Use uppercase and lowercase type: It is much easier to read than all capital letters
- Vary the size and weight of the type of the various components of the figure, eg, set titles in bold and at least 2 point sizes larger than axes numbers and labels
- Use a consistent type face throughout (Times Roman is the most readable font; avoid sans serif types such as Courier)
- Use a bold typeface for emphasis; it is much more readable that italics or underlining
- Avoid gray shading; it does not reproduce well
- Make lines thick enough to ensure adequate reproduction (extremely thin lines do not reproduce well.

General Instructions:

- Identify print proofs of figures on the back with figure number and name of the first author; when necessary, indicate the top with an up arrow
- Please include hardware and software information, in addition to the file names, with figures submitted electronically or on disk
- For figures submitted in electronic format, all images should be at least 5 inches wide. Images should be provided in EPS or TIF format (for those mailed to the Editorial Office, on Zip Disk, CD, floppy, Jaz, or 3.5 Magneto Optical)
- Graphics software such as Photoshop and Illustrator, not presentation software such as PowerPoint, CorelDraw, or Harvard Graphics, should be used to create art
- Color images need to be CMYK, at least 300 dpi, with a digital color proof, not a color laser print or color photocopy. *Note:* This proof will be used at press for color reproduction
- Gray scale images should be at least 300 dpi accompanied by a proof
- Line art (black and white or color) and combinations of gray scale and line art should be at least 1200 DPI and accompanied by a proof
- For best reproduction, screening, shading, and lettering on a dark background should be avoided.

Tables: Tables should be self-explanatory and should supplement, not duplicate, the text. Type on pages separate from the text. Provide a brief title for each. Abbreviations used in table should be defined at the bottom of the table.

Cover Letter: Include with the manuscript a cover letter that provides (1) the category of manuscript (eg, original research, Brief Communication, Letter to the Editor); (2) statement that the material has not been previously published or submitted elsewhere for publication; (3) information about any personal conflicts of interest of any of the authors; and (4) names of sources of outside support for research, including funding, equipment, and drugs (see Conflict of interest above). You may also submit the name of one reviewer of your choice. You should include that individual's mailing address, telephone number, fax number, and E-mail address. You should know that the reviewer will be asked to review the manuscript at your request but will also be informed that his or her identity will be kept confidential.

Manuscript Submission

Electronic Submission: **All manuscripts must be submitted via Editorial Manager** (http://jtcvs.editorialmanager.com) **and should include the following items (as appropriate):**

- Cover letter
- Abstract and mini-abstract
- Title page and manuscript using word processing file (pdf files are not acceptable)
- Tables (tables may either be included in the file with the manuscript or attached as separate files)
- Figures (attach as separate files); hard copy requested if manuscript is accepted for publication

The following items that accompany the manuscript may be scanned and submitted electronically or submitted by mail if scanning is not an option:

- Copyright Transfer/Author Declaration Statement
- Permission to reproduce published material (if applicable)
- Statistical Collaboration/Review Statement (if applicable)

Note: To view your manuscript in PDF format on Editorial Manager, you must have Adobe Acrobat Reader 5.0 installed on your computer.

General Guidelines:

- Format all text elements as double spaced for easier reading
- Insert page breaks between the title page, abstract, ultramini-abstract, and first page of text.
- Begin text, acknowledgements, references, and figure legends, respectively, on separate pages.
- Begin each table on a separate page.
- Write text in clear concise language, using accepted standards of English style and usage. Define unfamiliar or new terms when first used and avoid use of jargon, clichés, and laboratory slang.
- *NOTE:* It is the author's responsibility to ensure that each submitted version of the manuscript is the correct version and that each version is clearly marked.
- Include on the title page the title of the article and the author(s) name(s), degree(s), and institutional affiliation(s) as well as the name, business and telephone number, fax number, and E-mail address of the corresponding author. Where necessary, identify each author's affiliation by superscript numbers matched to the appropriate institutions.

Revised Manuscripts:

- Revised manuscripts must be submitted in three parts as word-processing files (pdf files are not acceptable): (1) cover letter with responses to reviewers' comments; (2) revised, marked manuscript showing additions and deletions; (3) revised, unmarked manuscript
- The organization of a revised manuscript is very important in the review process. Most manuscripts submitted to the *Journal* are revised at least once. Please structure your response as follows:
  - The reviewer's comment to which you are responding
  - Your response
  - How that response is manifest in the revised manuscript
  - A response to each and every reviewer comment

Manuscript Processing

Acknowledgment of Receipt: Each submission is assigned a unique number and acknowledged by E-mail. The editorial office considers the manuscript number a confidential communication, which should be given only to other authors of the paper. The editorial office staff releases information about manuscripts only to authors who provide the manuscript number. Information about a specific manuscript can be obtained via Editorial Manager only by the corresponding author or his designated representative who has access to his personal username and password.

Return of Manuscripts: Neither unaccepted papers nor their original figures, photographs, and slides are returned to the authors unless this is specifically requested in the cover letter. Illustrations for papers that have been accepted for publication will not be returned unless specifically requested by the author.

Print References

1. Gopen GD, Swan JA. The science of scientific writing. *Am Sci.* 1990;78:550-8.
2. Scientific Style and Format: The CBE Manual for Authors, Editors, and Publishers, 6th ed. New York: Cambridge University Press; 1994.
3. Iverson, Cheryl, et al, editors. American Medical Association Manual of Style, 9th ed. Baltimore: Williams and Wilkins, 1998.

The Journal of
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Statistical Methods

Because data and their analyses often constitute the supporting evidence for inferences drawn from studies submitted to the *Journal*, the Editors remind authors that all manuscripts with statistical analyses undergo statistical review by the *Journal*. The review includes study design, analysis, interpretation, and reporting. The manuscripts are not published without an acceptable rating by the statistical editorial staff. Therefore, to minimize revision and delays, authors should request review of such manuscripts by a statistician prior to submission. This is best done by involving a statistician as a collaborator from the inception to completion of the study.

The Editors subscribe to the statistical guidelines contained in the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (Ann Intern Med 1997;126;36-47). These are as follows:

> Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verity the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as the use of *P* values, which fails to convey important quantitative information. Discuss the eligibility of experimental subjects. Give details about randomization. Describe the methods for and success of any blinding observations. Report complications of treatment. Give numbers of observations. Report losses to observation (such as dropouts from a clinical trial). References for the design of the study and statistical methods should be to standard works when possible (with pages stated) rather than to papers in which the designs or methods were originally reported. Specify any general-use computer programs used.
>
> Put a general description of methods in the Methods section. When data are summarized in the Results section, specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid non-technical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample." Define statistical terms, abbreviations, and most symbols.

We recognize that there are a number of schools of differing statistical philosophy, and we take these differences into account. Nevertheless, over the years, a number of specific items have been raised repeatedly by statisticians when reviewing manuscripts. The Editors have compiled a list of these and present them in the form of guidelines, with the intent of being helpful to authors, not prescriptive. The guidelines have been formulated as a checklist and appear twice yearly, in the January and July issues.

Statistical Guidelines for Manuscript Submission

Authors should prepare manuscripts in light of the guidance provided in "Notes from the Editors" (*J Thorac Cardiovasc Surg.* 1996;112:209-20). Authors should also consult published checklists such as Gardner MJ, Machin D, Campbell MJ, "Use of Check Lists in Assessing the Statistical Content of Medical Studies" (*BMJ.* 1986;292:810-2) and Bailar JC, Mosteller F, "Guidelines for Statistical Reporting in Articles for Medical Journals" (*Ann Intern Med.* 1988;108:226-73). For papers reporting events after heart valve procedures, consult Edmunds LH Jr, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD, "Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations. Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity of The American Association for Thoracic Surgery and The Society of Thoracic Surgeons" (*J Thorac Cardiovasc Surg.* 1996;112:708-11). For reports of randomized clinical studies, consult Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz K, Simel D, Stroup DF, "Improving the Quality of Reporting of Randomized Controlled Trials" (*JAMA.* 1996;276:637-9). See also Piantadosi S, Gail M, "Statistical Issues Arising in Thoracic Surgery Clinical Trials." In: Pearson FG, Deslauriers J, Ginsberg RJ, Hiebert CA, McKneally MF, Urschel HC Jr, editors. Thoracic Surgery. New York: Churchill Livingstone; 1995. p. 1652-70, and Kirklin JW, Barratt-Boyes BG, "The Generation of Knowledge From Information, Data and Analyses." In: Cardiac Surgery, New York: Churchill Livingstone; 1993. p. 249-82.

Checklist

Notation and terminology. Explain meaning of notations such as SE, SD, CL, or CI in abstract, methods, and tables when they first appear. **Distinguish between a variable**, an item that can take on different values for each subject or observation, such as temperature and blood pressure, **and a parameter**, a constant, such as the mean. **Distinguish between prevalence,** a proportion of subjects or observations, and **incidence or rate**, a quantity expressed per unit of time. **Distinguish between multivariable**, referring to several predictor or explanatory variables or risk factors, **and multivariate**, referring to simultaneous analysis of several out-

come variables. The latter is a relatively recent change in statistical definitions. An accessible source of statistical terms can be found in Piantadosi S, Kirklin J, Blackstone E. Statistical Terminology and Definitions. In: Pearson FG, Deslauriers J, Ginsberg RJ, Hiebert CA, McKneally MF, Urschel HC Jr, editors. Thoracic Surgery. New York: Churchill Livingstone; 1995. p. 1649-52.

Distinguish between descriptive statistics and expression of uncertainty of parameter estimates. When describing the values for a variable (eg, baseline information), descriptive statistics such as median and quartiles or the mean and standard deviation are appropriate. In particular, when the distribution of values is skewed, nonparametric descriptors such as quartiles are appropriate, not mean and standard deviation. In contrast, the uncertainty of parameter estimates is expressed commonly in terms of confidence limits (intervals) or, when these are symmetric, the standard error.

P *values.* Although it is not possible with all statistical tests, and although it is contrary to some statistical philosophies, we recommend use of exact *P* values unless $P < .001$ or $P > .2$ as measures of evidence. Thus, we recommend against use of "$P < .05$ was considered significant" or the abbreviation NS, or symbols representing various levels of statistical significance.

Authors sometimes interpret large *P* values to mean, "There is no difference between groups." This is generally contrary to the facts because differences are evident. We prefer the use of the phrase, "The differences could be due to chance ($P > .2$)."

The term "significant" is ambiguous, because it fails to distinguish so-called statistical from clinical significance. We recommend against the use of the term "significant," suggesting that a synonym such as "important" be used to signify "clinical significance." Statistical significance often can go unstated when accompanied by a *P* value.

P values alone do not convey the magnitude of the effect or difference, nor its precision. Therefore, we will recommend the use of estimates of strength (eg, coefficients, odds ratios, hazard ratios) and confidence limits (intervals), tolerance intervals, or credibility intervals to convey this information. Use of these intervals is particularly important when the conclusion is that no effect or association was observed (equivalence).

Other specific expressions of uncertainty. In many settings, particularly when the number of patients or subjects is small, proportions should be accompanied by confidence limits (intervals). We do not prescribe a specific confidence interval, such as 95%, or intervals equivalent to ± 1 standard deviation, since the appropriate confidence limits may vary with the situation. A consistent schema for expressive variability would include ± 1 standard deviation for normally distributed continuous variables, 15 and 85 percentiles for skewed distributions, and 70% confidence limits for proportions. Increasingly, approximations to parameter estimation and measures of uncertainty are being supplemented by computer-intensive resampling (bootstrap) methods.

Presentation of time-related events. In most circumstances, we recommend that the following information accompany presentations of time-related events: point estimates, preferably at the time of each event using a product limit method; asymmetric confidence limits at periodic intervals; and the number of patients at risk at periodic intervals.

Nonrandomized comparisons. Unlike experimental comparison studies that nearly always should be randomized, randomization in the clinical setting is often neither feasible nor ethical. Incresingly, multivariable matching methods for adjusting for ascertainable selection bias are becoming prevalent, well understood, and accessible (eg, use of propensity scores).

Mutliple group comparisons and repeated measurements. In comparing three or more groups, statistical methods appropriate for multiple group comparisons and contrasts should be employed. If these groups have a natural ordinal relationship one with another, then methods that account for trend should be employed. When multiple measurements are obtained across time in the same patient or subject, methods of longitudinal data analyses (a relatively new field of statistics that has supplanted traditional repeated measures methodology) are recommended.

Multivariable analyses. Many studies lend themselves to methods that take into account simultaneously multiple variables (risk factors, predictor variables, independent variables, co-variables). Reports of multivariable analyses must state the model used, all variables that were examined, how the variables were coded in the final models, the extent of testing for interactions, the degree to which conformity to a linear gradient (for continuous or ordinal variables) was examined and accounted for, the degree to which the assumption of proportional hazards was tested when using such models, colinearity of variables, possibility of overfitting, and methods used for model validation.

Statistical Collaboration/Review Release Statement

I am a person with a masters or doctoral degree (or equivalent) in biostatistics or related field. I have experience in the design, analysis and interpretation of biomedical data of the type used in this paper. I take scientific responsibility for the analysis and interpretation of the data presented in the final version of this manuscript.

Statistician's signature: _____ Date: _____

There are no statistical methods presented in this paper.

Corresponding author's signature: _____ Date: _____