

Annals of Internal Medicine®

Information for Authors

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Information for Authors

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I. General Information About *Annals of Internal Medicine*

A. Mission and Scope

Annals of Internal Medicine's mission is to promote excellence in medicine, enable physicians and other health care professionals to be well-informed members of the medical community and society, advance standards in the conduct and reporting of medical research, and contribute to improving the health of people worldwide. To achieve this mission, the journal publishes a wide variety of original research, review articles, practice guidelines, and commentary relevant to clinical practice, health care delivery, public health, health care policy, medical education, ethics, and research methodology. In addition, the journal publishes personal narratives that convey the art of medicine.

B. Readership and Reach

Annals of Internal Medicine has a large readership that includes the members of the American College of Physicians (160,000 in 2022) and many more physicians, health care professionals, and researchers worldwide. *Annals* print issues are distributed to more than 100,000 readers worldwide, and free online access is available to many articles at [Annals.org](https://www.annals.org) as part of its commitment to readers, authors, and society. Because *Annals* is a selective journal provided to members and subscribers, an article-level open-access option supported by article processing charges is not provided. However, our free, publicly accessible content includes: Clinical Guidelines, ACP Position Papers, AHRQ Comparative Effectiveness Reviews, NIH Conferences, Summaries for Patients, In the Clinic Patient Information Pages, and selected other content. Abstracts, Tables of Contents, E-mail Alerts, and Podcasts are also free. In addition to the access described above, *Annals* provides many countries in the developing world with immediate free access through the HINARI program.

Annals of Internal Medicine is among the most highly cited and influential journals in the world. The most recent (2022) Impact Factor for *Annals of Internal Medicine* is 39.2 (Clarivate Analytics). *Annals* is the most cited and highest ranked internal medicine journal. *Annals of Internal Medicine* is indexed in BIOSIS Previews, CAB Direct, Chemical Abstracts Service (CASSI), CINAHL, Current Contents - Clinical Medicine, Current Contents - Live Science, EMBASE, Index Medicus, MEDLINE, PubMed, Science Citation Index, Science Citation Index Expanded, and Scopus.

The full text of all articles from *Annals* is digitally preserved through [Portico](#), [Scholars Portal](#), and [LOCKSS](#) (Lots of Copies Keeps Stuff Safe).

C. Publisher

The American College of Physicians ([ACPOne.org](https://www.acponline.org)), publisher of *Annals of Internal Medicine*, is the largest medical specialty organization and the second largest physician member group in the United States. ACP members include internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians specialize in the care of adults. Statements expressed in *Annals of Internal Medicine* reflect the views of the authors and not necessarily the policies of the

journal or its Editors, the American College of Physicians, or the institutions that the authors are affiliated with, unless so identified.

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Authors reusing content in a submitted manuscript to *Annals* should refer to Section III.E, below.

II. Preparing Manuscripts for Submission

A. Article Types

For submission, your manuscript does not need to conform to all of the formatting specifications used for publication that are noted here. These instructions, however, may serve as a guide to content that will be useful in the evaluation of your submitted manuscript.

Annals publishes a variety of article types, as listed below. The links accompanying each article type provide details about the article type and specific formatting requirements. General formatting guidelines are presented in the sections following the article types, and Section II.C contains guidance on reporting statistical findings.

Note that *Annals* publishes some content that is produced internally and does not represent material that is submitted for peer review by external authors. This material includes special features, such as In the Clinic, ACP Journal Club, Annals Consult Guys, and Annals On Call.

Article Types

Article Type	Article Type Description
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Original Research	Reports of original analyses of data on prevalence, causes, mechanisms, diagnosis, course, treatment, and prevention of disease. [Peer reviewed] More details
Reviews: Systematic and Meta-analyses	Reviews that systematically find, select, critique, and synthesize evidence relevant to well-defined questions about diagnosis, prognosis, or therapy. [Peer reviewed] More details

<i>Annals of Internal Medicine</i> Guidance for Rapid Reviews, Living Reviews, and Living Guidelines	<p>A Rapid Review is a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner (1).</p> <p>A Living Review is a systematic review that is routinely up-dated at defined intervals, incorporating relevant new evidence as it becomes available. Both rapid reviews and traditional systematic reviews may become living reviews.</p> <p>Living guidelines or other formal recommendation documents that are based on a living systematic review should follow an analogous approach for updates as described for “living” reviews.</p> <p>More details</p>
Clinical Guidelines, including synopses	Official recommendations from professional organizations on issues related to clinical practice and health care delivery. [Peer reviewed] More details
Position Papers	Official statements from professional organizations on issues related to clinical practice, health care delivery, and public health. [Peer reviewed] More details
Research and Reporting Methods	Articles related to research methods or reporting standards. [Peer reviewed] More details
Reviews: Narrative	Review articles that use informal methods to collect and interpret information, which is often summarized subjectively in narrative form. Narrative reviews are especially suitable for describing cutting-edge and evolving developments and underlying theory. [Peer reviewed] More details
Academia and the Profession	Descriptions and evaluations of innovations in medical education, training, professionalism, and career development. [Peer reviewed] More details

Ad Libitum	Poetry. More details
Editorials	Commentary on current topics or on papers published elsewhere in the issue. [Typically solicited and reviewed by editors] More details
Graphic Narratives/Comics	Original graphic narratives, comics, animation/video, and other creative forms addressing medically relevant topics. [Peer reviewed] More details
History of Medicine	Essays, reports, or biographical sketches related to the history or evolution of medicine. [Peer reviewed] More details
Ideas and Opinions	Essays representing opinions, presenting hypotheses, or considering controversial issues. [Usually peer reviewed; sometimes solicited by editors] More details
In the Balance	Pairs of essays that take contrary views on unsettled questions related to the practice of medicine. [Peer reviewed; typically solicited by editors] More details
Letters: Observations Brief Research Reports	Brief research reports. [Peer reviewed] More details
Case Reports/Series	Case reports/series. [Peer reviewed] More details
Letters: Correspondence	Correspondence about an <i>Annals</i> publication. [Not peer reviewed] More details
Medicine and Public Issues	Articles related to the economic, ethical, sociological, or political environment in medicine [Peer reviewed] More details
On Being a Doctor	Short personal essays about the experience of being a physician. [Peer reviewed] More details
On Being a Patient	Short personal essays about the experience of being a patient. [Peer reviewed] More details
Personae (cover photograph)	Photographs that capture the personality of people in the context of their daily lives. [reviewed by editors] More details

B. Article Formatting

For submission, your manuscript does not need to conform to all of the formatting specifications used for publication that are noted here. These instructions, however, may serve as a guide to content that will be useful in the evaluation of your submitted manuscript.

Authors should write for a sophisticated general medical readership; follow principles of clear scientific writing (Council of Science Editors. *Scientific Style and Format*. 8th ed. Chicago: Univ Chicago Pr; 2014.) and statistical reporting (see Section II.C. General Statistical Guidance); and prepare manuscripts according to recommended reporting guidelines and checklists whenever possible. Manuscripts that follow these recommendations generally fare better than those that do not.

Annals maintains an in-house style manual that is heavily based on principles outlined in the *AMA Manual of Style*, 11th edition. Authors should adopt bias-free and person-first language, as outlined by the American Psychological Association.

1. Title Page

Title: Give the title and subtitle (if any). Title should be concise (15 words or fewer), reflect the study design/article type (e.g., randomized controlled trial, systematic review), and contain terms that will assist in identifying the article in electronic searching. Also provide a short or “running” title of 7 or fewer words.

Authors: List authors in the order in which they are to appear in the byline of the published article. In the case of group authorship, identify one or more authors who will have responsibility for the publication. Give the institutional affiliation for each author, financial support information, and contact information for the corresponding author. *Annals* follows the International Committee of Medical Journal Editors (ICMJE) recommendations for defining authors and nonauthor collaborators.

In the case of group authorship, all members of the group should be listed on the title page, separated from the byline authors. Authors and nonauthor collaborators should be clearly labeled and identified.

Section V.A of Information for Authors provides guidance regarding group authorship.

Word Count: List the word count for the text of the manuscript. Don't include the abstract, figure legends, titles of tables, footnotes (for figures or tables), or the references in the manuscript word counts.

2. Abstracts

Authors should follow the Abstract format guidelines provided for the particular article type that they are submitting.

3. Text

Annals strongly encourages authors to follow EQUATOR reporting recommendations when presenting original data or the findings of a systematic review (www.equator-network.org). All submitted manuscripts should include page numbers.

4. Acknowledgments

Acknowledge only persons who have contributed to the scientific content or provided technical support. When used, professional writing assistance must be acknowledged. If those assisting with the writing do not meet criteria for authorship their contributions should be noted in the acknowledgments. Authors must obtain written permission from anyone they list in the Acknowledgments section, including confirmation of the nature of the contribution.

At submission, the corresponding author must attest that they listed everyone who contributed significantly to the work in the Acknowledgments section and have collected letters of permission stating they have approved the language describing their work related to the article. The corresponding author should be able to provide these letters if requested by the editor.

5. References

References should follow the standards summarized in the National Library of Medicine's *Citing Medicine*, 2nd edition. These resources are regularly updated as new media develop. See www.nlm.nih.gov/bsd/uniform_requirements.html for sample references that conform to the style specified by the National Library of Medicine.

- Number references, using Arabic numerals in parentheses, in the order in which they first appear in the text. References cited in a table/figure should appear in numerical order relative to the first citation of the table/figure in the text. For example, if the last reference cited before the table/figure in question is mentioned as reference 14, and that table/figure contains 5 references that have not been cited, the references in the table/figure would be numbered 15 through 19. Reference citations in the text would then recommence with number 20.
- Use the reference style of the National Library of Medicine, including the abbreviations of journal titles.
- List all authors when there are 3 or fewer; when there are more than 3 authors, list only the first 3 and add "et al."
- Do not use *ibid.* or *op cit.*
- Include an "available from" note for documents that may not be readily accessible.
- Cite symposium papers only from published proceedings.
- When citing an article or book accepted for publication but not yet published, include the title of the journal (or name of the publisher) and the year of expected publication.
- Include references to unpublished material in the text, not in the references (for example, papers presented orally at a meeting; unpublished work [personal communications, papers in preparation]), and submit a letter of permission from the cited persons to cite such communications (in general, avoid citations to unpublished scientific results).
- Ensure that URLs used as references are active and available (the references should include the date on which the author accessed the URL). Citations to Wikipedia are permitted only if they are used to support statements about popular sentiment about an issue.

6. Footnotes

Use footnotes only on the title page and in tables. Do not use footnotes in the text. Footnote symbols, in the order in which they should be used, are *, †, ‡, §, ||, ¶, **, ††, ‡‡, and so on. Do not use numbers or letters.

7. Tables

Number tables with Arabic numerals in the order in which they appear in the text. Label tables with titles that concisely describe the content of the table so that a reader can understand the table without referring to the text. Tables may contain abbreviations that we do not permit in the text but should contain a footnote that explains the abbreviation. Give the units of measure for all numerical data in a column or row. Place units of measure under a column heading or at the end of a side heading only if those units apply to all numerical data in the column or row.

8. Figures

Number figures with Arabic numerals in the order in which they appear in the text. Each figure should have a figure legend that begins with a short title. Reduce the length of legends by using phrases rather than sentences. Explain all abbreviations and symbols on the figure, even if an explanation appears in the text. For pictures of histologic slides, give stain and magnification data at the end of the legend for each part of the figure. If no scale marker appears on the figure, give the original magnification used during the observation, not that of the photographic print.

9. Supplementary Material

Author should follow limitations on word count and tables/figures as outlined in Section [A. Article Types](#). Additional materials can be organized into a data supplement and be submitted with the article. The supplement can comprise several components, including a list of nonauthor collaborator names/information, details on methodology, additional tables and figures, etc., and it may have its own references section, if applicable.

Supplementary material should include its own Table of Contents page detailing the contents of the file. Ensure all components of the supplementary material are appropriately labeled in numerical order (e.g., Supplement Table 1, Supplement Table 2) if they are cited individually in the main article.

During revision, editors may ask that some material be moved out of the supplementary material and into the article as appendix material. Appendix materials are copyedited, typeset, and published online. Similarly, the editors may request that some content from the main article be moved into the supplementary material.

Note: If material is moved into an appendix and it contains references, those references should be numbered as they appear in the main article's references section. If any references appear only in the appendix, they can be added consecutively at the end of the text's reference section.

If the article is accepted for publication, supplementary material will not undergo copyediting or production but will be published as ancillary material for download with the online version of the article.

Study protocols, statistical analysis plans, and/or other related study materials or documents are considered supplementary material and will be posted with the article online at [Annals.org](#), but these should be submitted separately from the content outlined above because these materials would not have transmittable copyright.

C. General Statistical Guidance

This section provides details on presentation, multivariable analyses, measurement error, measures of effect and risk, missing data, longitudinal analyses, and figures and tables.

1. Presentation

Percentages

Report percentages to one decimal place (i.e., xx.x%) when sample size is ≥ 200 .

To avoid the appearance of a level of precision that is not present with small samples, do not use decimal places (i.e., xx%, not xx.xx%) when sample size is < 200 .

Standard deviations

Use “mean (SD)” rather than “mean \pm SD” notation. The \pm symbol is ambiguous and can represent standard deviation or standard error.

Standard errors

Report confidence intervals, rather than standard errors, when possible.

P values

For *P* values between 0.001 and 0.20, please report the value to the nearest thousandth. For *P* values greater than 0.20, please report the value to the nearest hundredth. For *P* values less than 0.001, report as “ $P < 0.001$.”

“Trend”

Only use the word *trend* when describing a test for trend or dose-response.

Avoid the term *trend* when referring to *P* values near but not below 0.05. In such instances, simply report a difference and the confidence interval of the difference (if appropriate) with or without the *P* value.

Descriptive tables

In tables that simply describe the characteristics of 2 or more groups (e.g., Table 1 of a clinical trial):

- Report averages with standard deviations, not standard errors, when data are normally distributed.
- Report median (minimum, maximum) or median (25th, 75th percentile [interquartile range, or IQR]) when data are not normally distributed.
- Avoid reporting *P* values as there can be imbalance when *P* values are not significant (because of small sample size) and balance when *P* values are significant (because of large sample size).

Figures

When developing informative graphics, follow these simple rules of thumb:

- Avoid pie charts and 3-dimensional graphics.
- Avoid simple bar plots that do not present measures of variability.
- For meta-analysis forest plots, provide the raw data (numerators and denominators) in the margins.

- For survival plots, provide the numbers of people at risk by group and time below the horizontal axis.

Reproducibility

Describe the statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results (www.icmje.org/recommendations/).

Statistical software and code

Specify in the statistical analysis section the statistical software—version, manufacturer, and the specific functions, procedures, or programs—used for analyses.

For Bayesian methods, provide full code, including starting values and priors, within an appendix.

When statistical code is provided within an appendix, it should be well-annotated for comprehension by interested readers. (Localio AR, Goodman SN, Meibohm A, et al. [Statistical code to support the scientific story](#). *Ann Intern Med*. 2018;168:828-829. doi:10.7326/M17-3431)

Provide more detailed methods and results (e.g., sensitivity analyses) that cannot be described within the main body of the paper within an appendix.

2. Multivariable Analysis

Screening covariates

Approaches that select factors for inclusion in a multivariable model only if the factors are “statistically significant” in “bivariate screening” are not optimal. A factor can be a confounder even if it is not statistically significant by itself because it changes the effect of the exposure of interest when it is included in the model, or because it is a confounder only when included with other covariates.

Useful resource:

- Sun GW, Shook TL, Kay GL. Inappropriate use of bivariable analysis to screen risk factors for use in multivariable analysis. *J Clin Epidemiol*. 1996;49:907-916. [PMID: 8699212]

Model building

Authors should avoid stepwise methods of model building, except for the narrow application of hypothesis generation for subsequent studies. Stepwise methods include forward, backward, or combined procedures for the inclusion and exclusion of variables in a statistical model based on predetermined *P* value criteria. Better strategies than *P* value–driven approaches for selecting variables are those that use external clinical judgment. Authors might use a bootstrap procedure to determine which variables, under repeated sampling, would end up in the model using stepwise variable selection procedures. Regardless, authors should tell readers how model fit was assessed, which interactions were explored and how and why they were explored, and the results of those assessments.

Useful resources:

- Collett D, Stepniowska K. Some practical issues in binary data analysis. *Statist Med.* 1999;18:2209-2221. [PMID: 10474134]
- Mickey RM, Greenland S. The impact of confounder selection criteria on effect estimation. *Am J Epidemiol.* 1989;129:125-137. [PMID: 2910056]
- Steyerberg EW, Eijkemans MJC, Harrell FE Jr, et al. Prognostic modeling with logistic regression analysis: a comparison of selection and estimation methods in small data sets. *Statist Med.* 2000;19:1059-1079. [PMID: 10790680]
- Steyerberg EW, Eijkemans MJC, Habbema DF. Stepwise selection in small data sets: a simulation study of bias in logistic regression analysis. *J Clin Epidemiol.* 1999;52:935-942. [PMID: 10513756]
- Altman D, Andersen PK. Bootstrap investigation of the stability of a Cox regression model. *Statist Med.* 1989;8:771-783. [PMID: 2672226]
- Mick R, Ratain MJ. Bootstrap validation of pharmacodynamic models defined via stepwise linear regression. *Clin Pharmacol Ther.* 1994;56:217-222. [PMID: 8062499]
- Harrell FE Jr, Lee KL, Mark DB. Multivariable prognostic models: issues in developing models, evaluating assumptions and adequacy, and measuring and reducing errors. *Statist Med.* 1996;15:361-387. [PMID: 8668867]

Tables reporting multivariable analyses

Authors sometimes present tables that compare one by one an outcome with multiple individual factors followed by a multivariable analysis that adjusts for confounding. If confounding is present, as is often the case, the one-way comparisons are simply intermediate steps that offer little useful information for the reader. In general, omit presenting these intermediate steps in the manuscript and do not focus on them in the Results or Discussion.

3. Measurement Error

If several risk factors for disease are considered in a logistic regression model and some of these risk factors are measured with error, the point and interval estimates of relative risk corresponding to any of these factors may be biased either toward or away from the null value; the direction of bias is never certain. In addition to potentially biased estimates, confidence intervals of correctly adjusted estimates will be wider, sometime substantially, than naive confidence intervals. Authors are encouraged to consult the references below for strategies to address this problem.

Useful resources:

- Rosner B, Spiegelman D, Willett WC. Correction of logistic regression relative risk estimates and confidence intervals for measurement error: the case of multiple covariates measured with error. *Am J Epidemiol.* 1990;132:734-745. [PMID: 2403114]
- Carroll R. Measurement error in epidemiologic studies. In: *Encyclopedia of Biostatistics.* J Wiley; 1998. ISBN: 0471975761

4. Measures of Effect and Risk

Clinically meaningful estimates

Authors should report results for meaningful metrics rather than reporting raw results. For example, rather than reporting the log odds ratio from a logistic regression, authors should transform coefficients into the appropriate measure of effect size, odds ratio, relative risk, or risk difference. Estimates, such as an odds ratio or relative risk, should not be reported for a 1-unit change in the factor of interest if a 1-unit change lacks clinical meaning (age, mm Hg of blood pressure, or any

other continuous or interval measurement with small units). All estimates should reflect a clinically meaningful change, along with 95% confidence bounds.

Between-group differences

For comparisons of interventions (e.g., trials), focus on between-group differences, with 95% confidence intervals of the differences, and not on within-group differences. State the results using absolute numbers (numerator/denominator) when feasible. When discussing effects, refer to the confidence intervals rather than *P* values and point out for readers if the confidence intervals exclude the possibility of significant clinical benefit or harm.

Odds ratios and predicted probabilities

Authors often report odds ratios for multivariable results when the odds ratio is difficult to interpret or not meaningful. First, the odds ratio might overstate the effect size when the reference risk is high. For example, if the reference risk is 25% (odds = 0.33) and the odds ratio is 3.0, the relative risk is only 2.0. Statements such as “3-fold increased risk” or “3 times the risk” are incorrect. Second, readers want an easily understood measure of the level of risk (and the confidence intervals) for different groups of patients as defined by treatment, exposure, and covariates. Consider providing a table of predicted probabilities for each of the factors of interest, and confidence intervals of those predicted probabilities. Moreover, a multiway table that cross-classifies predicted probabilities by the most important factor and then adjusts for the remaining factors will often be more meaningful than a table of adjusted odds ratios. Standard commercial software can produce predicted probabilities and confidence bounds.

Useful resource:

- Altman DG, Deeks JJ, Sackett DL. Odds ratios should be avoided when events are common. *BMJ*. 1998;317:1318. PMID: 9804732

Hazard ratios and standardized cumulative incidence

Authors often report results from analysis of survival or time-to-event data using hazard ratios estimated from proportional hazards Cox models. Hazard ratios are notoriously difficult to interpret clinically, may be sensitive to the length of follow-up, and rely on model assumptions, such as proportional hazards. In addition, presenting estimates of effect in both absolute and relative terms increases the likelihood that results will be correctly interpreted. For all of these reasons, we recommend that authors present cumulative incidence curves (inverted Kaplan-Meier plots) along with tabular summaries of absolute differences in cumulative incidence, with 95% confidence bounds, at meaningful times, when reporting results from survival analyses. When such an analysis requires covariate adjustment, authors can estimate and present covariate-standardized (weighted) cumulative incidence curves with differences in adjusted cumulative incidence at meaningful times.

Useful resources:

- Hernan MA. The hazards of hazard ratios. *Epidemiology*. 2010;21:13-15. [PMID: 20010207]
- Uno H, Wittes J, Fu H, et al. [Alternatives to hazard ratios for comparing the efficacy or safety of therapies in noninferiority studies](#). *Ann Intern Med*. 2015;163:127-134. doi:10.7326/M14-1741
- Therneau T, Crowson CS, Atkinson EJ. Adjusted Survival Curves. <https://cran.r-project.org/web/packages/survival/vignettes/adjcurve.pdf>

- Cole SR, Hernan MA. Adjusted survival curves with inverse probability weights. *Comput Methods Programs Biomed.* 2004;75:45-49. [PMID: 15158046]
- Zhang X, Zhang MJ. SAS macros for estimation of direct adjusted cumulative incidence curves under proportional subdistribution hazards models. *Comput Methods Programs Biomed.* 2011;101:87-93. doi:10.1016/j.cmpb.2010.07.005
- Storer BE, Gooley TA, Jones MP. Adjusted estimates for time-to-event endpoints. *Lifetime Data Anal.* 2008;14:484-495. doi:10.1007/s10985-008-9098-9.

5. Missing Data

Missing variables

Always report the frequency of missing variables and how the analysis handled missing data. Consider adding a column to tables or a row under figures that makes clear the amount of missing data. Avoid using a simple indicator or dummy variable to represent a missing value. Replacing missing predictors with dummy variables or missing indicators generally leads to biased estimates.

Useful resources:

- Sterne JA, White IR, Carlin JB, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ.* 2009;338:b2393. [PMID: 19564179]
- Vach W, Blettner M. Biased estimation of the odds ratio in case-control studies due to the use of ad hoc methods or correcting for missing values of confounding variables. *Am J Epidemiol.* 1991;134:895-907. [PMID: 1670320]
- Vach W, Blettner M. Missing data in epidemiologic studies. In *Encyclopedia of Biostatistics.* J Wiley; 1998:2641-2654. ISBN: 0471975761
- Greenland S, Finkle WD. A critical look at methods for handling missing covariates in epidemiologic regression analyses. *Am J Epidemiol.* 1995;142:1255-1264. [PMID: 7503045]
- Allison PD. *Missing Data.* Sage Publications; 2002. ISBN: 0761916725

Missing outcomes

Always report the frequency of missing outcomes and follow-up data, reasons and any patterns for the missing data, and how you handled missing data in the analyses. Do not use a last observation carried forward approach (LOCF) to address incomplete follow-up even if the original protocol prespecified that approach for handling missing data. LOCF approaches understate variability and result in bias. The direction of the bias is not predictable. Although the method of addressing missing data may have little import on findings when the proportion of missing data is small (e.g., <5%), authors should avoid using outdated or biased methods to address incomplete follow-up. Appropriate methods for handling missing data include imputation, pattern-mixture (mixed) models, and selection models. Application of these methods requires consideration of the patterns and potential mechanisms behind the missing data.

Useful resources:

- Fitzmaurice GM, Laird NM, Ware JH. *Applied Longitudinal Analysis.* J Wiley; 2011: chapters 17, 18. ISBN: 0470380277
- Molenberghs G, Kenward MG. *Missing Data in Clinical Studies.* J Wiley; 2007. ISBN: 0470849811
- Molenberghs G, Verbeke G. *Models for Discrete Longitudinal Data.* Springer; 2005: chapters 26-32. ISBN: 0387251448

- National Research Council. The Prevention and Treatment of Missing Data in Clinical Trials. Panel on Handling Missing Data in Clinical Trials. Committee on National Statistics, Division of Behavioral and Social Sciences and Education. National Academies Pr; 2010. ISBN: 0309158145
- Liao J, Stack CB. [Annals Understanding Clinical Research: implications of missing data due to dropout](#). *Ann Intern Med*. 2017;166:596-598. doi:10.7326/M17-0195

6. Longitudinal Analyses

Consider using longitudinal analyses if outcome data were collected at more than 1 time point. Some methodological and reporting options follow. With an appropriate model for longitudinal analysis, you can report differences within groups over time, differences between groups, and differences across groups of their within-group changes over time (usually the key contrast of interest). You can control for any confounding that might emerge, such as a difference in a variable (e.g., body weight) among those who remained in the study until completion. Longitudinal analysis options include a population averaged analysis (generalized estimating equations [GEEs], for example) that estimates the time by treatment interaction and adjusts variance for the repeated measures within individuals over time. Another option is a mixed effects model, with random effects for patient, and the estimate of interest being the time by treatment interaction. In choosing a model, consider whether any missing data are missing at random (i.e., “ignorable” missing data) or missing dependent on the observed data (i.e., informative missing data). In GEE analyses, missing data are assumed to be missing completely at random independent of both observed and unobserved data. In random coefficient analysis, missing data are assumed missing at random dependent on observed data but not on unobserved data.

Useful resources:

- Fitzmaurice GM, Laird NM, Ware JH. *Applied Longitudinal Analysis*. J Wiley; 2011. ISBN: 0470380277
- Singer JD, Willett JB. *Applied Longitudinal Data Analysis*. Oxford Univ Pr; 2003. ISBN: 0195152964
- Twisk JWR. *Applied Longitudinal Data Analysis for Epidemiology: A Practical Guide*. Cambridge Univ Pr; 2003. ISBN: 0521819768

7. Sensitivity Analysis and Unmeasured Confounding

Analyses of observational data that attempt to assess causality between an exposure and an outcome are generally subject to confounding due to unmeasured or omitted covariates. In these settings, authors should carry out formal sensitivity analysis to assess how strong an unmeasured confounder would need to be to explain away an observed association. One relatively easy to use method that does not require strong assumptions is the E-value, proposed by VanderWeele and Ding (2017), an article that contains many references, includes a technical appendix, and points to available software. After conducting formal sensitivity, or bias analysis, authors can discuss the likelihood that the reported results are due to residual confounding.

Useful resources:

- VanderWeele TJ, Ding P. [Sensitivity analysis in observational research: introducing the E-value](#). *Ann Intern Med*. 2017;167:268-274. doi:10.7326/M16-2607
- Ding P, VanderWeele TJ. Sensitivity analysis without assumptions. *Epidemiology*. 2016;27:368-377. [PMID: 26841057]

- Lin DY, Psaty BM, Kronmal RA. Assessing the sensitivity of regression results to unmeasured confounders in observational studies. *Biometrics*. 1998;54:948-963. [PMID: 9750244]

8. Meta-analysis

Issues to consider before pooling

Consider all sources of clinical variation across studies (e.g., study populations, interventions or comparators, outcome definition, and timing) when making decisions about how and when to pool quantitatively.

Note that potential sources of methodological or clinical heterogeneity (e.g., risk of bias, intensity of an intervention, particular study population) identified a priori provide the strongest and most meaningful basis for explaining study heterogeneity. State whether you identified potential sources of heterogeneity prior to initiating your review and analyses, and describe whether and how you carried out subgroup or sensitivity analyses or meta-regression to explore that heterogeneity. Make clear which such analyses were prespecified and which were not.

Consider the number of studies and their relative size when deciding whether or not to pool. It is true that you can compute a pooled treatment effect when you have at least 2 studies; but you need to ask yourself, "Does it make clinical or methodological sense to do so?"

When the included studies naturally fall into subgroups based on patient populations or clinical features, it is often more informative to stratify the primary analysis based on the subgroups.

Statistical tests of heterogeneity or visual inspection of the variation via a forest plot are insufficient guides to pooling when there are fewer than 10 studies.

When the studies provide inconsistent estimates that vary widely, an overall treatment effect may not represent the actual treatment effect. In this case, a narrative presentation and critique can be clinically more informative. Such discussion should consider characteristics of these studies and patient populations that might account for the observed differences in effect sizes.

When there are a small number of studies that vary greatly in size, it may be more clinically informative to consider the larger study or studies separately from the smaller ones. For example, suppose you have 3 relatively small homogeneous studies and 1 fairly large trial based on the same population of patients. If the study estimates from the smaller trials are consistent with that observed in the larger trial, pooling is appropriate. If the study estimates from the smaller trials are quite different from the larger trial, a pooled estimate may not provide a good summary of the evidence. In this case, a more detailed description and analysis of the information from the larger trial alone can be more clinically informative.

Useful resource:

- Cornell JE, Liao JM, Stack CB, et al. [Annals Understanding Clinical Research: evaluating the meaning of a summary estimate in a meta-analysis](#). *Ann Intern Med*. 2017;167:275-277. doi:10.7326/M17-1454

Choosing an appropriate pooling method

Use pooling methods that are appropriate for the data. For example, when it is appropriate to pool studies whose estimates vary widely, please be aware of the literature on the inadequate performance of the DerSimonian-Laird method for estimating confidence bounds and *P* values when the number of studies is small or when there are substantive differences among study estimates. In such situations, use one of the more robust alternative random-effects estimators such as the profile likelihood method, the Sidik-Jonkman estimator with the Hartung-Knapp small sample adjustment, or hierarchical Bayesian models, any of which provide a better accounting of uncertainty.

Useful resources:

- Cornell JE, Mulrow CM, Localio AR, et al. [Random-effects meta-analysis of inconsistent effects: a time for change](#). *Ann Intern Med*. 2014;160:267-270. doi:10.7326/M13-2886
- IntHout J, Ioannidis JPA, Borm GF. The Hartung-Knapp-Sidik-Jonkman method for random effects meta-analysis is straightforward and considerably outperforms the standard DerSimonian-Laird method. *BMD Medical Research Methodology*. 2014;14:25.

Pooling studies with low event rates

When summarizing studies with 0 or very low event rates, avoid using methods, such as the Peto or the Mantel-Haenszel method with the standard 0.5 continuity correction. These methods underestimate variance and result in confidence intervals that are too narrow. Either the exact Mantel-Haenszel without continuity correction or the treatment group continuity correction provides the reasonably robust and accurate estimates when there are zero events in one of the treatment groups.

Useful resources:

- Bradburn MJ, Deeks JJ, Berlin JA, et al. Much ado about nothing: a comparison of the performance of meta-analytical methods with rare events. *Stat Med*. 2007;26:53-77. [PMID: 16596572]
- Sweeting MJ, Sutton AJ, Lambert PC. What to add to nothing? Use and avoidance of continuity corrections in meta-analysis of sparse data. *Stat Med*. 2004;23:1351-1375. [PMID: 15116347]
- Mulrow CD, Cornell JE, Localio AR. [Rosiglitazone: a thunderstorm from scarce and fragile data](#). *Ann Intern Med*. 2007;147:585-587. doi:10.7326/0003-4819-147-8-200710160-00013
- Cai T, Parast L, Ryan L. Meta-analysis for rare events. *Stat Med*. 2010;29:2078-2089. [PMID: 20623822]
- Rucker G, Schwarzer G, Carpenter J, Olkin I. Why add anything to nothing? The arcsine difference as a measure of treatment effect in meta-analysis with zero cells. *Stat Med*. 2009;28:721-738. [PMID: 19072749]

Documenting your methods

Identify the specific statistical model used to pool the data, evaluate statistical heterogeneity, and construct subgroup analyses. Specify the software platform (SAS, Stata, R, etc.) as well as the actual program and options specified for each of the analyses. For example, specify the exact random effects method used to pool treatment effects or compute your meta-regression. If you use meta-regression, specify how the independent variables are coded for the model. Simple binary variables and mean values are easily understood and modeled. Note that proportions are naturally nonlinear and are best represented and modeled on either the logit or arcsine scale.

For more complex analyses, such as network meta-analyses and hierarchical Bayesian, provide a detailed technical appendix that includes software code annotated for reader comprehension.

Useful resource:

- Localio AR, Goodman SN, Meibohm A, et al. [Statistical code to support the scientific story](#). Ann Intern Med. 2018;168:828-829. doi:10.7326/M17-3431

Additional guidance

Avoid using funnel plots and regression tests for small study effects when there are too few studies to adequately assess small study effects (fewer than 10).

Avoid using outdated or overly simplistic methods for risk of bias assessments and summary quality scores (e.g., Jadad scale). Consider using the Cochrane Risk of Bias tool for clinical trials. The ROBIN-I or the Newcastle-Ottawa are good tools for assessing risk of bias for observational studies, and the QUADAS II for diagnostic test studies.

Provide numerator and denominator data for the individual trials in forest plots.

9. Statistical Significance and P Values

Avoid interpreting results based upon statistical significance alone, and follow the principles of proper use and interpretation of the *P* value from the American Statistical Association. (ASA's Statement on Statistical Significance and P-values) Consider the clinical importance of observed differences and the width of 95% confidence intervals when interpreting results. In situations where results are consistent with "no difference" be sure to differentiate results that are indeterminate (consistent with clinically meaningful benefits) from those that are negative (rule-out clinically meaningful benefits).

Useful resources:

- Greenland S, Senn SJ, Rothman KJ, et al. Statistical tests, *P* values, confidence intervals and power: a guide to misinterpretations. Eur J Epidemiol. 2016;31:337-350. [PMID: 27209009]
- Goodman SN, Berlin JA. [The use of predicted confidence intervals when planning experiments and the misuse of power when interpreting results](#). Ann Intern Med. 1994;121:200-206. doi:10.7326/0003-4819-121-3-199408010-00008
- Goodman SN. A dirty dozen: twelve *p*-value misconceptions. Semin Hematol. 2008;45:135-140. [PMID: 18582619]
- Wasserstein RL, Lazar NA. The ASA's statement on *p*-values: context, process, and purpose. The American Statistician. 2016;70:129-133. doi:10.1080/00031305.2016.1154108

10. Figures and Tables

The following references give useful information about the design and format of informative tables and figures:

- Tufte ER. The Visual Display of Quantitative Information. Graphic Pr; 1983:178. ISBN: 0961392142
- Wainer H. How to display data badly. The American Statistician. 1982;38:137-147. doi:10.1080/00031305.1984.10483186

- Wainer H. *Visual Revelations: Graphical Tales of Fate and Deception From Napoleon Bonaparte to Ross Perot*. Lawrence Erlbaum Associates; 1997. ISBN: 038794902X
- Pocock SJ, Clayton TC, Altman DG. Survival plots of time-to-event outcomes in clinical trials: good practice and pitfalls. *Lancet*. 2002;359:1686-1689. [PMID: 12020548]

D. Special Considerations for Particular Types of Work

1. Clinical Trial Registration

Annals follows the trials registration policy of the International Committee of Medical Journal Editors (ICMJE). *Annals* only considers trials that have been appropriately registered and will reject those that are not appropriately registered. Authors should consult ICMJE.org for details of the policy, which requires registration of required details in an ICMJE accepted registry before the start of patient enrollment for clinical trials that began enrollment on or after July 1, 2005.

As defined by the ICMJE, a clinical trial is any research project that prospectively assigns people (or a group of people within clustered trials) to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a medical intervention and a health outcome. A medical intervention is any intervention used to modify a health outcome, and includes but is not limited to drugs, surgical procedures, devices, behavioral treatments, and process-of-care changes. Nonrandomized trials are not exempt from the registration requirement if they meet the above criteria.

Exemptions to this policy are infrequent. However, if you believe that circumstances warrant an exception, we would be willing to consider your request. The issues that contribute to our consideration of such situations are listed below and should be addressed in your request.

- A detailed explanation for why the trial was registered late.
- The reason that prompted trial registration.
- The precise date of trial registration and the date the first participant was enrolled.
- The number and percentage of patients, compared to the final sample size, enrolled prior to registration.
- Information from the protocol or IRB application indicating the primary outcome/secondary outcome. The primary outcome/secondary outcome as stated in the trial registration. An explanation for any discrepancies between the primary/secondary outcome in any of the supporting documentation (trial registration, SAP, etc) and as stated in the manuscript.
- Your assurances that no interval analysis was conducted prior to the registration of the trial.
- Any other information you think relevant to the request.

2. Systematic Review and Meta-analysis Registration

Annals supports but does not require prospective registration of systematic reviews and meta-analyses in an international registry, such as PROSPERO.

3. Data Sharing and Reproducible Research

Authors should be prepared to provide original study data and statistical code if requested by the editors to assist in the editors' understanding of method used and to evaluate those methods. The editors may also request access to study data during the peer-review process, and if no other explanations or justification are provided, may cease consideration of a manuscript if the authors cannot or will not provide the data. These data will be treated confidentially and not shared beyond the editorial staff without specific permission from the authors. When statistical code is provided, it

should be well-annotated for comprehension (Localio AR, Goodman SN, Meibohm A, et al. Statistical code to support the scientific story. *Ann Intern Med.* 2018;168:828-829. doi:10.7326/M17-3431).

Annals requires authors submitting manuscripts reporting the results of a clinical trial to submit a copy of the study protocol with all dated amendments. If the manuscript is accepted for publication, the protocol will be published as a supplement to the article on *Annals.org*. If necessary, *Annals* will consider publication of protocols that redact proprietary information from introduction and background sections.

To encourage transparency and reproducible research (Laine C, Goodman SN, Griswold ME, et al. Reproducible research: moving toward research the public can really trust. *Ann Intern Med.* 2007;146:450-453. doi:10.7326/0003-4819-146-6-200703200-00154), *Annals* publishes a statement with every original research article, systematic review/meta-analysis, and brief research report indicating the authors' willingness to share the following items with the public:

- Study protocol (original and amendments)
- Statistical code used to generate results
- Data set from which the results were derived

Annals strongly encourages but does not typically require the sharing of these items unless the article is reporting the results of a clinical trial in which case sharing of the protocol is required (see above). However, we do require that authors state their willingness to share, and any conditions for sharing. Access to these items may range from completely unrestricted (e.g., free availability of all the items via posting on an open-access website) to restricted (e.g., availability of certain portions of the items to approved individuals through written agreements with the author or research sponsor).

Manuscripts submitted to *Annals* that report the results of clinical trials must contain a data sharing statement that meets the ICMJE recommendations as described below.

Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. If the data sharing plan changes after registration, this should be reflected in the statement submitted and published with the manuscript and updated in the registry record. Data sharing statements must indicate the following: whether individual deidentified participant data (including data dictionaries) will be shared ("undecided" is not an acceptable answer); what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analysis plan); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

Authors of secondary analyses using shared data must attest that their use was in accordance with the terms (if any) agreed to upon their receipt. They must also reference the source of the data using its unique, persistent identifier to provide appropriate credit to those who generated it and allow searching for the studies it has supported. Authors of secondary analyses must explain completely how theirs differ from previous analyses. In addition, those who generate and then share clinical trial data sets deserve substantial credit for their efforts. Those using data collected by others should seek collaboration with those who collected the data. As collaboration will not always be possible, practical, or desired, the efforts of those who generated the data must be recognized.

III. Manuscript Submission and Review

A. How to Submit a Manuscript

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B. Correspondence Between Authors and *Annals*

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If the list of authors changes between submission and final acceptance of an article, it is the corresponding author’s responsibility to explain the changes to the editors in writing and to obtain written documentation that all of the authors (including any deleted and added authors) approve of the author changes.

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As part of the initial submission process, we also ask the corresponding author to attest that the authors had access to all the study data, take responsibility for the accuracy of the analysis, and had authority over manuscript preparation and the decision to submit the manuscript for publication. We

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In the Methods section of the text, authors must state the funding source for the work and describe the role(s) of the funding organization in the design of the study; the collection, analysis, and interpretation of the data; and the decision to approve publication of the finished manuscript. If the funding source had no such involvement, the authors should state that.

D. Protocols and Other Materials

Authors of manuscripts that report clinical trial results must submit the original preenrollment protocol (ideally prepared according to the 2013 SPIRIT standards) with any amendments that were made. All such material must be appropriately dated. For accepted articles reporting clinical trials, *Annals* will publish the protocol as a supplement to the article.

We also encourage submission of a protocol or an active link to a curated site where the protocol may be found if your manuscript reports a cohort, case-control, cross-sectional, or systematic review and meta-analysis study for which there is a protocol. *Annals* strongly encourages authors of accepted articles reporting cohort, case-control, cross-sectional, or systematic review and meta-analysis studies to post the protocol or provide an active link to it.

If your submission describes the results from a survey or questionnaire, please submit a copy of these materials, as it will improve the speed and quality of the review process. Other associated files that you may consider submitting include but are not limited to the following:

- Cover letter with specific points that you want to make to the editors
- Studies related to the submission that have been accepted for publication or published
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E. Preprint Servers, Related Work, Duplicate Publication, and Use of Previously Published Material in Submitted Manuscripts

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Editors and associate editors discuss many of the papers that are peer reviewed at a weekly manuscript conference. Editors recuse themselves from discussing manuscripts and avoid participation in decisions about manuscripts if they have a close personal or professional relationship with any of the authors. Quantitative or methods-focused papers that pass initial review are usually also reviewed by our statistical editors at a weekly statistical conference.

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Annals can publish only a fraction of all papers submitted each year. In recent years, 8% of all unsolicited submissions and <5% of original research articles were accepted. Editors judge the potential importance and newness of material and consider scientific rigor using established methodological criteria. They select manuscripts based on the strength of the paper compared with other papers under review, the need for *Annals* to represent a balanced picture of important advances in internal medicine, and the number of accepted papers in the paper's category and topic area. Almost all papers that we accept require editorial or statistical revision before publication.

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We send the reviewers' comments to authors whether or not we accept the article. On occasion, we reject an article but invite a resubmission that addresses specific concerns of the editors. We aim to accept a high percentage of reinvited articles and specify conditions that the authors must meet before we will accept the manuscript. We determine whether to send the reinvited manuscript for further external peer review or internal editorial and statistical review on a case-by-case basis.

J. Fast-Track Review and Publication

Authors may request expedited review for manuscripts of very high quality that report findings that are likely to immediately affect practice or policy. We give priority for fast-tracking to large clinical trials and manuscripts reporting results likely to have an immediate impact on patient safety. If authors think that their manuscript warrants expedited review and publication, they should contact the Editor in Chief (claine@acponline.org) with their request and rationale. They should also include an electronic version of the manuscript and, for trials, the protocol and registry identification number.

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Not all manuscripts reviewed via the fast-track mechanism will be found suitable for rapid publication. Some manuscripts reviewed through this process may require substantial revision and cannot be published until a satisfactory revision is available.

K. Submitting an Appeal

The editors expect appeals infrequently and seldom reverse their original decisions. Many rejections involve editors' judgments of priority that authors usually cannot address through an appeal. However, authors who think that their manuscripts were erroneously rejected may e-mail an appeal letter to the editor who handled the manuscript. The letter should detail the author's concern and state how the manuscript could be revised or clarified to address key problems mentioned by editors and reviewers. Editors only consider appeals that are submitted within 2 months of the manuscript's rejection and consider appeals only once. Upon receiving the appeal, editors may confirm their decision to reject the manuscript, invite a revised manuscript, or seek additional peer review or statistical review of the original manuscript.

IV. What to Expect After Acceptance

A. Postacceptance Copyediting

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We will also ask each author to confirm that they meet authorship criteria as defined by the ICMJE (see Section V.A), document their contributions, and transfer copyright to the American College of Physicians (ACP) (see Section I.D).

C. Scheduling of Accepted Papers and Proofs

We notify authors when they can expect to receive proofs. Authors who think they may not be able to examine proofs within 48 hours of receiving them should call the Production Manager (215-351-2645) to designate a colleague who will review proofs.

D. Prepublication Embargo Policy

Annals publishes new material every Tuesday with an embargo that lifts at 5:00 p.m. (U.S. Eastern time) on the Monday before. Issues are published on the third Tuesday of each month. *Annals* sends advance copies of journal articles to members of the news media the week before publication. Reporters may not publish stories based on this information until 5:00 p.m. (U.S. Eastern time) the day before the date of publication of an issue. Authors are free to discuss their research with representatives of the media but should not distribute copies of papers accepted for publication in *Annals*. They should consent to be interviewed only if the reporter agrees to abide by the embargo and will not publish until after the embargo period.

Providing copies of manuscripts or detailed information to media, manufacturers, or government agencies of scientific information described in a manuscript that has been accepted but not yet published violates the policies of *Annals* and many other journals. *Annals* may grant an exception to this rule when the paper or letter describes major therapeutic advances, public health hazards (such as serious adverse effects of drugs, vaccines, other biological products, or medical devices), or reportable diseases. Prepublication disclosure as part of sworn testimony before legislative or judiciary bodies may also be acceptable. Authors should discuss any possible prepublication disclosure with the editors in advance and obtain their agreement.

E. Research Articles Based on Funding by U.S. Federal Agencies

The American College of Physicians (ACP), publisher of *Annals of Internal Medicine*, supports authors' adherence to the NIH Public Access Policy and the 2013 Office of Science and Technology Policy memo "Increasing Access to the Results of Federally Funded Scientific Research" (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf). Authors of articles reporting research funded by federal agencies with more than \$100 million in research and development expenditures, including the National Institutes of Health, are granted permission to provide a copy of the accepted manuscript version to the agency's publicly accessible repository. "Accepted manuscript" refers to the prepublication version for which *Annals*

has issued a notice of final acceptance. Authors should not submit copies of the final published version (e.g., PDF or HTML versions copied from *Annals.org*) or redrawn and formatted figures and tables to the funding agency's publicly accessible repository.

Neither the ACP nor *Annals of Internal Medicine* can assume responsibility for prepublication versions of articles. To limit confusion about multiple versions of article content, the "accepted manuscript version" submitted to the agency's publicly accessible repository should prominently display the following disclaimer immediately following the title:

This is the prepublication, author-produced version of a manuscript accepted for publication in *Annals of Internal Medicine*. This version does not include postacceptance editing and formatting. The American College of Physicians, the publisher of *Annals of Internal Medicine*, is not responsible for the content or presentation of the author-produced, accepted version of the manuscript or any version that a third party derives from it. Readers who wish to access the definitive published version of this manuscript and any ancillary material related to this manuscript (e.g., correspondence, corrections, editorials, linked articles) should go to *Annals.org* or to the issue in which the article appears. Those who cite this manuscript should cite the published version, as it is the official version of record.

Authors are responsible for informing the funding agency's publicly accessible repository that it should not make the accepted manuscript publicly available in the repository until 6 months after the date of publication in *Annals of Internal Medicine*.

V. Research and Publication Ethics

Annals follows the recommendations, policies, guidance, and processes related to research and publication ethics developed by the International Committee of Medical Journal Editors, the Council on Publication Ethics, and the Council of Science Editors. These sources provide information about issues such as authorship criteria, duplicate publication, scientific misconduct, defining and managing potential conflicts of interest, editorial independence, retraction of publications, and the treatment of research participants.

A. Authorship

Annals follows the International Committee of Medical Journal Editors (ICMJE) recommendations for defining authors and contributors (see: www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html). The ICMJE recommends basing authorship on the following 4 criteria: Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND drafting the work or reviewing it critically for important intellectual content; AND final approval of the version to be published; AND agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work they have done, authors should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

B. Group Authorship

When a multiauthor group has conducted the work, it is prudent for the group to decide who will be an author before the work is started and confirm who is an author before submitting the manuscript

for publication. All members of the group named as authors should meet the four criteria for authorship as defined by the ICMJE, including approval of the final manuscript, and each author should be prepared to take public responsibility for the work. They will also be expected as individuals to complete disclosure of interest and author forms. In order to properly acknowledge and index the names of group members, there should be a note accompanying the group name on the byline. This note should list all group members and note whether they are authors or nonauthor collaborators.

The attribution and indexing paradigms differ depending on the roles of the group author and its members. The following are the 3 most common scenarios that authors should consider when they are submitting their group authored work.

1. When individual authors are writing with a group (i.e., “and” connecting the individuals to the group in the byline), all members of that group should qualify for authorship. Their names should be listed on the title page separate from the byline, and they should be identified as authors. These members will complete disclosure of interest and authorship forms, as well as receive communications from the journal about the article submission. After publication, all authors (both the byline authors and the group members) will be indexed as authors.
2. When individual authors are writing on behalf of a group (i.e., “for the” or “on behalf of” connecting the individuals to the group in the byline), all members of that group would not qualify for authorship. Their names should be listed on the title page separate from the byline, and they should be identified as nonauthor collaborators. (In cases where the list of nonauthor collaborator names is excessively long, this list can be supplied in a separate document.) Although these members do not need to complete disclosure of interest and authorship forms nor will they receive communications from the journal about the article submission, the corresponding author should attest to having permission to publish each person’s name as a nonauthor collaborator. After publication, the byline authors will be indexed as authors and the nonauthor collaborators will be indexed as collaborators.
3. When an article is written by a group (i.e., solely the group name in the byline), all members of that group should qualify for authorship. Their names should be listed on the title page separate from the byline, and they should be identified as authors. These members will complete disclosure of interest and authorship forms, as well as receive communications from the journal about the article submission. After publication, the group members will be indexed as authors.

This information must be given at the time of submission. If the article is accepted for publication, during production, the list of nonauthor collaborator names will be published in an online appendix or an online supplement, depending on the number of names.

Information on how the National Library of Medicine handles group authorship is available at www.nlm.nih.gov/bsd/policy/authorship.html.

C. Artificial Intelligence

At submission, *Annals* requires authors to attest whether they used artificial intelligence (AI)–assisted technologies (such as Large Language Models [LLMs], chatbots, or image creators) in the production of submitted work. Authors who use such technology should describe, in both the cover letter and the submitted work, how they used it. Chatbots (such as ChatGPT) should not be listed as authors because they cannot be responsible for the accuracy, integrity, and originality of the work, and these responsibilities are required for authorship (<https://www.icmje.org/recommendations/>). Therefore,

human authors are responsible for any submitted material that included the use of AI-assisted technologies.

D. Human Subjects Research

Research that involves human participants also includes investigations that use only human blood, tissue, or medical records. The authors must confirm review of the study by the appropriate institutional review board or affirm that the protocol is consistent with the principles of the Declaration of Helsinki (www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/). If the authors did not obtain institutional review board approval before the start of the study, they should so state and explain the circumstances. If the study was exempt from review, the authors must state that such exemption complied with the policy of their local institutional review board. They should affirm that study participants gave their informed consent or state that an institutional review board approved conduct of the research without explicit consent from the participants.

If patients are identifiable from illustrations, photographs, pedigrees, case reports, or other study data, the authors must attest in writing that they have obtained signed release from each such individual (or copies of the figures with the appropriate release statement) giving permission for publication with the manuscript. To maintain confidentiality about the identity of subjects, authors should not submit these permission forms to the journal but must keep them on record.

E. Scientific Misconduct and Breaches of Journal Policy or Ethical Standards

In addition to breaches in procedures related to human subjects, research misconduct includes issues related to the fabrication or falsification of data, and plagiarism. Violations of publication ethics include duplicate publication, misrepresentation of author contributions, and failure to disclose potential financial conflicts of interest. Should the editors suspect research misconduct or violations of publication ethics related to manuscripts submitted for review, the journal reserves the right to notify and forward the submitted manuscript to the chief executive officer and/or dean of the sponsoring institution, the funding institution, or other appropriate authority for investigation. *Annals* recognizes the responsibility to notify the appropriate authorities but does not undertake the actual investigation or make determinations of misconduct. The editors will notify the authors of the journal's intention to report a suspicion of research misconduct or violation of publication ethics.

F. Reader Comments and Responsibility to Respond to Them

Readers can post comments at our website to published articles any time after publication. To do so, use the "Comment" tab that appears to the left of the online version of the relevant article at Annals.org. Readers wishing to comment must have access to the article. Access may be obtained if the article is free, the reader is a subscriber/member, the reader is accessing the article via an institutional subscription, or the person purchased pay per view access. For details regarding formatting requirements for Comments, see the table in Section II.A. Article Types.

Only those comments posted within 8 weeks of the article's publication will be eligible to be considered for publication in the *Annals* Letters section. Exceptions will be made if a late comment notes a factual error that requires correction. *Annals* will ask authors of the article to draft a response to comments selected for the Letters section. Authors have a responsibility to review comments about their articles. They should consider responding to any that they believe warrant response and must promptly respond to comments that raise questions about possible errors in the

manuscript. Authors' responses to comments that raise questions about possible errors should either acknowledge and correct the error or confirm that no error was present.

Appendix

Article Types – More Information

ARTICLE TYPE: ORIGINAL RESEARCH

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Original Research	Reports of original analyses of data on prevalence, causes, mechanisms, diagnosis, course, treatment, and prevention of disease. [Peer reviewed]
Title	Indicate the study design in the title (e.g., add “randomized trial” or “cost-effectiveness analysis” to the full title of the manuscript).
Abstract	≤ 275 words, structured Structure (all study designs except cost-effectiveness studies): Background, Objective, Design, Setting, Patients (or Participants), Interventions (if any), Measurements, Results, Limitations, Conclusion, Primary Funding Source Structure for cost-effectiveness studies: Background, Objective, Design, Data Sources, Target Population, Time Horizon, Perspective, Intervention, Outcome Measures, Results of Base-Case Analysis, Results of Sensitivity Analysis, Limitations, Conclusion, Primary Funding Source Also state: <ul style="list-style-type: none">▪ Registration: If the study is registered, specify the registry and the study’s unique registration number at the end of the abstract.
Text	≤ 3500 words (excludes abstract and references); note that if accepted for publication, the editors may request shortening even if manuscript falls below this limit. Structure: Introduction, Methods, Results, Discussion Funding Source: Identify the funding source for the study and its role in the study’s design, conduct, and reporting. Put this information under the last subheading of the Methods section and title the subhead “Role of the Funding source.” IRB Approval: Confirm that an Institutional Review Board approved the study prior to data collection. If an Institutional Review Board did not review the study, provide documentation that not seeking Institutional Review Board review was in accordance with the policy of your institution.
References	75 or fewer bibliographic references
Tables/figures	No more than 4-6 tables or figures (combined)
Reporting guidelines	Follow relevant reporting recommendations. The EQUATOR site includes the following guidelines, which <i>Annals</i> endorses: Controlled Trials: CONSORT Cost-effectiveness Analyses: CHEERS

Diagnostic Test Studies: STARD 2015
Observational Studies: STROBE
Molecular Epidemiology: STROBE-ME
Qualitative Research: COREQ
Genetic Risk Prediction Studies: GRIPS
Quality Improvement Studies: SQUIRE
Multivariable Prediction Model for Individual Prognosis Or Diagnosis:
TRIPOD

Protocol

We encourage authors to submit the study protocol that was approved by the Institutional Review Board. In the case of trials, authors should submit the original trial protocol approved by the Institutional Review Board and subsequent amendments. Make sure that these documents are dated appropriately.

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ARTICLE TYPE: SYSTEMATIC REVIEWS AND META-ANALYSES

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Reviews: Systematic Reviews and Meta-analyses	Reviews that systematically find, select, critique, and synthesize evidence relevant to well-defined questions about diagnosis, prognosis, or therapy. For information on the types of reviews <i>Annals</i> publishes, see: The Editors. Reviews: Making sense of an often tangled skein of evidence . <i>Ann Intern Med.</i> 2005;142:1019-1020. [Peer reviewed]
Abstract	≤ 275 words Structure: Background, Purpose, Data Sources (must include start and end search dates), Study Selection, Data Extraction, Data Synthesis, Limitations, Conclusions, Primary Funding Source Also state: <ul style="list-style-type: none">▪ Registration: If the study is registered, specify the registry and the study's unique registration number at the end of the abstract.
Title	Add "A systematic review" or "A systematic review and meta-analysis" as a subtitle.
Text	≤ 4000 words (excludes abstract and references), note that if accepted for publication the editors may request shortening even if manuscript falls below this limit. Structure: Introduction, Methods, Results, Discussion Methods: Subheadings should be: Data Sources and Searches; Study Selection; Data Extraction and Quality Assessment; and Data Synthesis and Analysis. For studies that present numerical data and use statistical inference, include a section under Methods that describes the methods and specific statistical software used for the statistical analysis. Funding Source: Identify the funding source for the study and its role in the study's design, conduct, and reporting. Put this information under the last subheading of the Methods section and title the subhead "Role of the Funding source."
References	No limit, although if includes more than 100 references, the references may need to be in an online-only appendix.
Tables/figures	Aim to include no more than 4 tables or figures (combined) within the body of the manuscript. Additional tables and figures can be included as supplementary material. Among the tables and figures should be a flow diagram that depicts the search and selection processes and evidence tables.
Reporting guidelines	Follow relevant reporting recommendations. The EQUATOR includes the following guidelines: PRISMA reporting guideline for systematic reviews and meta-analysis MOOSE reporting guidelines for meta-analysis of observational studies ENTREQ reporting guideline for synthesis of qualitative research

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ANNALS OF INTERNAL MEDICINE GUIDANCE FOR RAPID REVIEWS, LIVING REVIEWS, AND LIVING GUIDELINES

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A **Rapid Review** is a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner (1).

A **Living Review** is a systematic review that is routinely up-dated at defined intervals, incorporating relevant new evidence as it becomes available. Both rapid reviews and traditional systematic reviews may become living reviews. Living reviews are underpinned by continual surveillance and screening of evidence; immediately include any newly identified important evidence (data, studies or information); and are supported by up-to-date communication about the status of the review and any new evidence being incorporated (2). Core methods of living systematic reviews are similar to those of systematic reviews, though living reviews should additionally include explicit, transparent, and predefined decisions on how frequently new evidence is sought and screened, and when and how new evidence is incorporated into the review (3).

Protocol Registration

Authors should post or register their protocol on an institutional, government, WHO, Open Science Framework, or PROSPERO registry website prior to manuscript submission. They should include the registry name and dated protocol when submitting the manuscript. If the review is not registered with PROSPERO and *Annals* accepts the review for publication, authors will be asked to apply for retrospective PROSPERO registration. If there is a valid reason that a protocol cannot be posted on such sites, the authors should submit the protocol with the manuscript and, if accepted for publication, *Annals* will publish the protocol as a supplement.

Format

Authors should follow the general *Annals* format requirements for Systematic Reviews and Meta-analyses (see “Information for Authors” at [Annals.org](#)). Rapid reviews, including rapid reviews intended to be “living” reviews, should have the following: clearly formulated questions; methods sections that describe sources and searches, selection criteria, data extraction and assessment, and synthesis methods; results that synthesize rather than catalog evidence, with flow charts and other graphics as necessary; and discussions that mention limitations of the review. In the instance of a living review, the methods section should define the review as a living review, and search sections should describe ongoing surveillance methods and periodicity. Methods sections should specify modified methods of the rapid review or the living rapid review, such as: not posting the protocol to PROSPERO; limiting searches to English language literature; searching only a few databases; searching preprint servers; crowd-distributed screening or extraction; limiting searches or inclusion by date; use of automation (e.g., text mining) for screening; or single reviewer extraction or assessment. “Living” reviews that include searches of preprint servers and protocols should describe planned methods for tracking, screening, and appraising records found in such searches, as well as planned methods for reappraisal of records that are subsequently published.

Updates for Living Systematic Reviews: Surveillance Comments, Update Alert of New Evidence, Major Update

Annals asks authors of living reviews to commit to the following: periodic posting of surveillance searches and alerts of new evidence and submission of new articles for consideration when

substantive new evidence (see below) is identified. Editors will review these commitments on an annual basis and communicate with authors regarding their continuation. Surveillance Comments and Alerts of New Evidence should include no more than 5 authors who take responsibility for providing the updated information on behalf of the authors of the initial article.

Surveillance Comment

Annals will require authors of living reviews to post a comment to the initial review on a periodic basis (i.e., the interval specified in the reviews' methods) that describes the results of updates of searches. If no new evidence was identified, this comment will serve to alert readers that an updated search was performed that identified no new eligible evidence.

Alert of New Evidence

If new evidence was identified that does not substantively change conclusions of the published parent rapid review, authors should cite and briefly describe and critique the new evidence. Review of new evidence should always include assessment of its risk of bias using methods cited in the published systematic review. If not, new methods of critique must be clearly stated. Minor updates should be brief but should try to contextualize for readers what the new evidence adds to existing evidence. Minor updates should not include major re-analyses of data; new methods of synthesis of multiple pieces of evidence; or sequential or simple cumulative meta-analyses. Alerts will be published in the letters section of the journal and will be indexed by NLM and linked to the NLM citation of the initial review. These alerts can include updated evidence tables and flow charts as supplements to the published letter .

Major Updates

When new evidence is substantive (large well-designed study or studies when previous literature was inconsistent or lesser quality or multiple new studies of varying size and quality body) that changes the nature or strength of the conclusions or when synthesis of evidence requires major changes in methods, authors should submit a new article for review and publication. Authors should first consult editors regarding whether the accumulated evidence is substantive enough to warrant a major update. The majority of methods and search strategies do not need to be repeated with updates, though new flow diagrams are needed. Review of new evidence should always include assessment of its quality or risk of bias and use methods cited in the published parent systematic review. If not, new methods of critique must be clearly stated. Updates with substantive new evidence should focus on synthesis of evidence, and should not just be a cataloging of individual pieces of evidence. Updates might involve reclassifications or new groupings of data as well as additional classifications of data (new tests or interventions). Any changes in methods with updates (e.g., a meta-analysis when previous versions of the review have only included narrative synthesis) will need to be described in the updated review; such changes likely indicate the need for a major update. The updated "living" review should follow the format requirements specified above for the initial version of the review.

If the authors do not provide updates at pre-specified intervals, the editors may alert readers that no updates were provided and may discontinue agreement to consider future updates.

"Living" Clinical Guidelines

"Living" guidelines or other formal recommendation documents that are based on a living systematic review should follow an analogous approach for updates as described for "living" reviews. Briefly, the methods section of the initial guideline should describe the planned updating methodology, and the

different levels of updates will similarly be handled as surveillance comments, alerts letters, or new guideline articles based on whether new evidence is identified and, if so, whether it substantively changes the nature or strength of the recommendations.

1. Khangura S, Konnyu K, Cushman R, et al. Evidence summaries: the evolution of a rapid review approach. *Syst Rev*. 2012;1:10. doi:10.1186/2046-4053-1-10

2. Elliott JH, Turner T, Clavisi O, et al. Living systematic reviews: an emerging opportunity to narrow the evidence-practice gap. *PLoS Med*. 2014;11:e1001603. doi: 10.1371/journal.pmed.1001603

3. Elliot JH, Synott A, Turner T, et al. The Living Systematic Review Network. Living systematic review: 1. Introduction- the why, what, how, and when. *J Clin Epidemiology*. 2017;91:23-30. doi:10.1016/j.jclinepi.2017.08.010.

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ARTICLE TYPE: CLINICAL GUIDELINES

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Clinical Guidelines	Official recommendations from professional organizations on issues related to clinical practice and health care delivery. <i>Annals</i> is most interested in publishing the primary guideline documents but will also consider synopses of guidelines when the primary document is published elsewhere. Synopses should focus on those issues of most relevance to generalist clinicians. [Peer reviewed]
Abstract	≤ 275 words, structured
	Structure: Use the following subheadings: Description, Methods, and Recommendations
Title	Include the name of the responsible organization in the title and identify the article as a clinical guideline.
Text, References, Tables/Figures	<u>Primary Guideline Reports</u> : <i>Annals</i> is flexible with length, references, and other format requirements given the variability in the format of guidelines developed by different organizations. However, if guidelines are lengthy (>4000 words), we may require the production of an executive summary document, with the full document published as an online-only appendix. A concise table or concise graphic summarizing the recommendations and other key points is desirable. <u>Guideline Synopses</u> : Guideline Group members followed by key references should be listed at the end. For additional information on guideline synopses, please see: Laine C, Taichman D, Mulrow C. Trustworthy clinical guidelines . <i>Ann Intern Med</i> . 2011;154:774-775.
Authors	All individuals named as authors should meet authorship criteria (see Section V.A. Authorship) and must complete author forms and disclosure of interest forms. Nonauthor collaborators should be listed and identified.
Reporting guidelines	We expect authors to include standard reporting elements suggested by the guideline groups (Institute of Medicine: Clinical Practice Guidelines We Can Trust ; Guidelines International Network: Toward International Standards for Clinical Practice Guidelines). Guidelines that meet standards will fare more favorably than those that do not.

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ARTICLE TYPE: POSITION PAPERS

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Position Papers	Official statements from professional organizations on issues related to clinical practice, health care delivery, and public health. [Peer reviewed]
Abstract	≤ 275 words, unstructured
Title	Include the name of the responsible organization in the title and identify the article as a position paper.
Text	≤ 4000 words (excludes abstract and references). Papers >4000 words may be considered at the discretion of the editors, but will generally require an Executive Summary document of ≤1500 words with the full document published as a online-only appendix. In such cases, the total word count (executive summary plus online-only appendix) may not exceed 6000, and material in the Executive Summary should not be repeated in the appendix. Position papers should include the following sections: Introduction, Methods, Recommendations/Position Statements, Conclusion
Authors	All individuals named as authors should meet authorship criteria (see Section V.A. Authorship) and must complete author forms and disclosure of interest forms. Nonauthor collaborators should be listed and identified.

ARTICLE TYPE: RESEARCH AND REPORTING METHODS

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Research and Reporting Methods	Articles related to research methods or reporting standards. [Peer reviewed]
Abstract	≤ 275 words Abstract format and word limits depend on the content of the article. If article is a narrative overview, the abstract should be unstructured. If article presents original research or a systematic review , follow those guidelines for structured abstract.
Text	≤ 3500 words (excludes references); note that if accepted for publication, the editors may request shortening even if manuscript falls below this limit. Note: Research and Reporting Methods articles that present original data (e.g., original research or systematic reviews/meta-analyses) should follow our guidance for the pertinent article type.
References	75 or fewer bibliographic references
Tables/Figures	Aim to include no more than 4 tables or figures (combined) within the body of the manuscript. Additional tables and figures can be included as supplementary material.

ARTICLE TYPE: NARRATIVE REVIEWS

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Reviews: Narrative	Review articles without detailed structured methods to identify, collect, appraise, and interpret information that are often summarized descriptively in a narrative form. Narrative reviews are especially suitable for describing cutting-edge and evolving developments and underlying theory. For information on the types of reviews <i>Annals</i> publishes, see: The Editors. Reviews: Making sense of an often tangled skein of evidence . <i>Ann Intern Med.</i> 2005;142:1019-1020. [Peer reviewed]
Abstract	≤ 275 words, unstructured
Title	Add “A narrative review” as a subtitle
Text	≤ 3500 words (excludes abstract and references) note that if accepted for publication the editors may request shortening even if manuscript falls below this limit
References	75 or fewer bibliographic references
Tables/figures	No more than 4 tables or figures (combined) Include a box listing 3 to 7 take-home points that link back to the original questions that the review set out to answer.

ARTICLE TYPE: ACADEMIA AND THE PROFESSION

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Academia and the Profession	Descriptions and evaluations of innovations in medical education, training, professionalism, and career development. [Peer reviewed]
Abstract	≤ 275 words Abstract format and word limits depend on the content of the article. If article is a narrative overview, the abstract should be unstructured. If article presents original research or a systematic review , follow those guidelines for structured abstract.
Text	≤ 3500 words (excludes references), note that if accepted for publication, the editors may request shortening even if manuscript falls below this limit. Note: Academia and the Profession articles that present original data (e.g., original research or systematic reviews /meta-analyses) should follow our guidance for pertinent article type.
References	75 or fewer bibliographic references
Tables/figures	Aim to include no more than 4 tables or figures (combined) within the body of the manuscript. Additional tables and figures can be included as supplementary material.

ARTICLE TYPE: AD LIBITUM

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Ad Libitum Poetry; original work not previously published elsewhere [Peer reviewed]
Text ≤ 80 lines

ARTICLE TYPE: EDITORIALS

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Editorials	Commentary on current topics or on papers published elsewhere in the issue. [Typically solicited and reviewed by editors]
Abstract	None
Text	1000 words maximum (excludes references)
References	10 or fewer bibliographic references
Tables/Figures	Typically no tables or figures but occasional exception at the editors' discretion

ARTICLE TYPE: GRAPHIC NARRATIVE

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Graphic Narrative/ Comic	Original graphic narratives, comics, animation/video, and other creative forms addressing medically relevant topics. We encourage work capturing the experiences of those who provide and receive care, be they poignant, thought-provoking, or just plain entertaining. [Peer reviewed]
Abstract	None
Notes	<p>Both color and black-and-white submissions are acceptable and should be provided as a complete, single PDF file no larger than 30 Mb. (A larger file for higher resolution of accepted work may be submitted later if necessary.) We cannot accept submissions of hard copy work, but we can accept videos. <i>Annals</i> cannot accept scripts without artwork or art samples without a story.</p> <p><i>Annals</i> will not consider work that has been previously published or posted online, but may consider work that has been previously posted in part in certain venues at the editors' discretion.</p> <p>Submissions accepted for publication will be published in online-only at Annals.org.</p>

ARTICLE TYPE: HISTORY OF MEDICINE

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History of Medicine	Essays, reports, or biographic sketches related to the history or evolution of medicine. [Peer reviewed]
Abstract	≤ 275 words, unstructured
Text	≤ 4000 words (excludes references); note that if accepted for publication, the editors may request shortening even if manuscript falls below this limit.
References	75 or fewer bibliographic references
Tables/Figures	1 table or figure

ARTICLE TYPE: IDEAS AND OPINIONS

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Ideas and Opinions	Essays representing opinions, presenting hypotheses, or considering controversial issues. [Sometimes solicited by editors, typically peer reviewed]
Abstract	None
Text	1000 words maximum (excludes references)
References	10 or fewer bibliographic references
Tables/Figures	Typically no tables or figures but occasional exception at the editors' discretion

ARTICLE TYPE: IN THE BALANCE

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In the Balance	Pairs of essays that each take contrary views on unsettled questions related to the practice of medicine. [Typically solicited by editors, typically peer reviewed]
Abstract	None
Text	1000 words maximum (excludes references)
References	10 or fewer bibliographic references
Tables/figures	Typically no tables or figures but occasional exception at the editors' discretion

ARTICLE TYPE: BRIEF RESEARCH REPORTS

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Brief Research Reports	Concise reports of original data that are limited in scope and/or preliminary in nature. [Peer reviewed]
Authors	Typically 5 or fewer, although exceptions made at editors' discretion
Abstract	None
Text	700 words maximum (excludes references) Structure: Background, Objective, Methods and Findings, Discussion, and References
References	5 or fewer bibliographic references
Tables/Figures	Maximum of 2 tables or figures (combined)
Reporting guidelines	For adverse drug events, follow ADR reporting guideline: Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. <i>Lancet</i> . 2000;356:1255-1259. [PMID: 11072960]

ARTICLE TYPE: CASE REPORTS

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Case Reports/Series	Reports presenting a single patient or a series of patients using a structured format (Background, Objective Case Report, Discussion, References). These reports should be descriptive in nature and refrain from including inferential analyses. [Peer reviewed]
Authors	Typically 5 or fewer, although exceptions made at editors' discretion
Abstract	None
Text	700 words maximum (excludes references) Structure: Background, Objective, Case Report, Discussion, and References
References	5 or fewer bibliographic references
Tables/Figures	Maximum of 2 tables or figures (combined)
Reporting guidelines	For adverse drug events, follow ADR reporting guideline: Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. <i>Lancet</i> . 2000;356:1255-9. [PMID: 11072960]

ARTICLE TYPE: LETTERS: CORRESPONDENCE

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Text	1500 words maximum (excludes references)
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