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Publication Process

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The *New England Journal of Medicine* (NEJM) employs a rigorous peer review and editing process to evaluate all manuscripts for scientific accuracy, novelty, and importance. This painstaking publication process has been tested over many decades and is a major reason for the *Journal's* reputation as the world's leading medical journal.

NEJM receives over 4,500 original research submissions each year — more than a dozen each business day — with over half coming from outside the U.S.

At least five experts review and edit each Original Article or Special Article manuscript published by NEJM. Of thousands of research reports submitted each year, about 5% are eventually published by NEJM.

The peer review process works to improve research reports while preventing overstated results from reaching physicians and the public. Each published NEJM manuscript benefits from hundreds of hours of work by editors, statistical experts, manuscript editors, illustrators, proofreaders, and production personnel, who work



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to ensure that every paper meets exacting standards.

About the Editors

The NEJM core editorial team comprises nine physician editors and one Ph.D. geneticist.

Drs. Eric J. Rubin (Editor-in-Chief), Edward W. Campion (Executive and Online Editor), and Mary Beth Hamel (Executive Deputy Editor) lead and direct the work of seven deputy editors, nine associate editors, and the Perspective editor.

Deputy Editors

NEJM deputy editors — most of whom also spend some portion of their time in patient care, medical research, or teaching — manage non-research content appearing in NEJM. They also serve key roles in the research review process, ensuring that no manuscript under review by NEJM can be declined without the agreement of at least two NEJM editors.

Associate Editors

Nine NEJM associate editors are chosen for their expertise in major areas of medicine. Associate editors play central roles in managing the peer review process and in decisions to accept or decline manuscripts for publication in NEJM. In addition to their work for NEJM, they also hold full-time positions at academic medical centers.

The Path of a Research Manuscript

NEJM Executive Deputy Editor Mary Beth Hamel, M.D., M.P.H., reviews each research manuscript submission and determines whether it meets essential NEJM criteria to warrant further consideration and peer review. About 10% of submitted papers are declined at this stage without further editorial consideration.

A paper passing Dr. Hamel's initial review moves to an appropriate associate editor, who

determines whether it meets fundamental criteria for:

- Quality
- Novelty
- Potential clinical impact

If so, the associate editor sends the manuscript to at least two peer reviewers.

Should an associate editor wish to decline a paper without peer review, it goes first to a deputy editor for a second opinion; if the deputy editor disagrees with the associate editor, the paper will be sent on for peer review.

Peer Review

NEJM maintains a database of more than 30,000 peer reviewers worldwide in all areas of medicine. In almost all cases, two peer reviewers evaluate each submission within one to two weeks and submit written reports to the NEJM editors.

During peer review, all manuscripts are considered privileged communications. Without prior approval from the NEJM editorial office, peer reviewers are expressly prohibited from:

- Copying manuscripts
- Sharing with others
- Discussing their personal evaluations or recommendations

NEJM also instructs peer reviewers to:

- Report immediately any possible personal, professional, or financial conflicts of interest with authors or related to a paper's topic; where conflicts arise, NEJM editors find substitute reviewers.
- Destroy manuscript copies once reviews are complete.

Full Editorial Team Review and Statistical Review

Using peer reviews and their own judgments, NEJM associate editors then decide whether to decline a manuscript (a decision which must be seconded by a deputy editor) or to bring it to a weekly editorial meeting attended by all NEJM deputy editors, associate editors, and statistical consultants for discussion and

debate.

Following discussion at a weekly editorial meeting, a paper will be assigned one of three statuses:

- **Rejection:** Publication is declined; reviewers' comments are provided to authors.
- **Provisional Rejection:** The manuscript is not suitable for publication unless the authors conduct further research or collect additional data.
- **Revision:** NEJM has interest in the paper, but the manuscript is not acceptable in its current form and must be revised before further consideration for publication. If a manuscript is moved to Revision status, the paper will be sent on for statistical review — an additional, rigorous review step. Most research manuscripts published by NEJM undergo at least one statistical review by one of five statistical consultants prior to acceptance.

More on the Revision Process

The associate editor communicates a paper's status to its authors in a letter detailing questions raised in the review process and, where applicable, recommending revisions needed to meet NEJM standards for publication. Authors respond to the associate editor with a revised manuscript and letter detailing their changes.

When authors resubmit a revised manuscript, the associate editor again reviews it and decides whether further peer or statistical review is needed and often brings the paper back to a weekly editorial meeting for further discussion.

If additional outside review is not needed, the manuscript will be sent to a deputy editor for additional editing and revisions in collaboration with the associate editor and its authors.

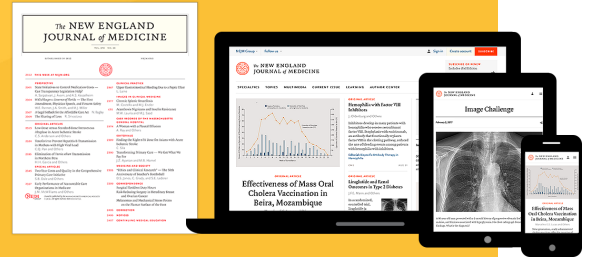
Final Review & Acceptance for Publication

The NEJM Editor-in-Chief reviews all final (revised) submissions and may raise further questions. The Editor-in-Chief is the only person who can officially accept a paper for publication. Following Dr. Rubin's formal acceptance for publication, a paper will then move through rigorous processes for manuscript editing, production, illustration, design, and publication.

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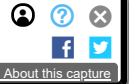
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Our mission since 1812 has been to bring physicians the best research at the intersection of biomedical science and clinical practice. We are interested in original research that will change clinical practice or teach us something new about the biology of disease. We also publish reviews, cases, commentary, and other content of interest to the medical community.

The dedication of generations of researchers, authors, reviewers, and physician editors has made NEJM the most widely read and respected medical journal and website in the world, and the oldest continuously published medical periodical. Here are a few reasons why we hope you'll decide to send us your best work:

- More than 600,000 readers in nearly every country in the world read NEJM each week.
- Our impact factor (Science Citation Index rating) was 54.420 in 2013, the highest among general medical journals.
- We publish only the top 5% of the 5,000 research submissions we receive each year, more than half of those coming from outside of the U.S.
- All research articles are freely available six months after publication, and we provide unrestricted online access at the time of publication to more than 115 low-income countries.
- We offer an expedited publication process for select papers and will respond to any pre-submission inquiry within one week.

We have a highly-rigorous peer-review and editing process in which we evaluate manuscripts for scientific accuracy, novelty, and importance. Each article we publish benefits from hundreds of hours of work by physician editors, statistical experts, illustrators, manuscript editors, proofreaders, and production personnel, who work to ensure that it meets our exacting standards. This thorough work prior to publication is a major reason for our reputation as the "gold standard" for the latest research and best practices in medicine.

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- Our editor-in-chief will review your manuscript, and assign it to an associate or deputy editor with expertise in the field.
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




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Appendix 03

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As the oldest continuously-published medical journal, our mission since 1812 has been to bring to physicians the best research at the intersection of biomedical science and clinical practice. We are interested in publishing original research that is **destined to change clinical practice and teaches something new about the biology of disease**. In addition to original research, NEJM publishes reviews, cases, commentary, and other content that is of interest to medical professionals.

The dedication of generations of researchers, authors, reviewers, and physician editors has made NEJM the most widely read and respected medical journal and website in the world.

Submitting to NEJM



NEJM uses highly rigorous editorial, peer, and statistical review processes to evaluate manuscripts for scientific accuracy, novelty, and importance.

Step 1: Acquaint yourself with NEJM [Editorial Policies](#), [Article Types](#), options for [Presubmission Inquiry](#) and [Rapid Review](#), Statistical Reporting Guidelines (if applicable), and key NEJM Style Elements.

Step 2: Prepare materials for submission including cover letter (optional), main text, tables, figures, supplementary appendix, clinical trial protocol and statistical analysis plan (if applicable).

Step 3: Submit your manuscript to the [NEJM online submission](#) system by clicking on the red button at the top left hand side of this page.

IMPORTANT TO NOTE

Authors are expected to refrain from discussing the submission of their manuscript(s) (or the intention to submit) to NEJM with anyone, including colleagues and journalists. The editors will also keep this information confidential.

NEJM accepts the submission of manuscripts that have previously been posted on a nonprofit preprint server. Authors should notify NEJM of any preprint related to a manuscript submission.

Presubmission Options

Most NEJM article types are both solicited (invited by NEJM editors) and unsolicited (submitted at author discretion via the NEJM online manuscript submission system).

PRESUBMISSION INQUIRY

Authors unsure of the suitability of their manuscript for publication may save considerable time and effort by sending a [Presubmission Inquiry](#). An NEJM editor will generally respond by email within one week.

INVITED/COMMISSIONED ARTICLES

Certain article types, including reviews and editorials, are usually solicited by NEJM editors in advance of submission. However, authors interested in proposing ideas for these article types may also send [Presubmission Inquiries](#).

RAPID REVIEW

Authors may request a [Rapid Review](#) of their manuscripts. NEJM generally replies to Rapid Review requests within three business days and an initial decision on publication will typically be reached within two weeks.

Those studies that are most often approved for a rapid peer review generally:

- Deal with urgent public health concerns
- Have potential to dramatically change clinical practice or to affect mortality
- Are timed to imminent meeting presentations

Approval for [Rapid Review](#) does not guarantee acceptance of the manuscript, nor does it guarantee expedited publication if the manuscript is accepted as each of these decisions is made separately.

Statistical Reporting Guidelines

Our Statistical Consultants recommend the following best statistical practices in manuscripts submitted to the *Journal*. We recommend that you follow them in the design and reporting of research studies.

For all studies:

- The Methods section of all manuscripts should contain a brief description of sample size and power considerations for the study, as well as a brief description of the methods for primary and secondary analyses.
- The Methods section of all manuscripts should include a description of how missing data have been handled. Unless missingness is rare, a complete case analysis is generally not acceptable as the primary analysis and should be replaced by methods that are appropriate, given the missingness mechanism. Multiple imputation or inverse probability case weights can be used when data are missing at random; model-based methods may be more appropriate when missingness may be informative. For the

Journal's general approach to the handling of missing data in clinical trials please see [Ware et al](#) (N Engl J Med 2012;367:1353–1354).

- Significance tests should be accompanied by confidence intervals for estimated effect sizes, measures of association, or other parameters of interest. The confidence intervals should be adjusted to match any adjustment made to significance levels in the corresponding test.
- Unless one-sided tests are required by study design, such as in noninferiority clinical trials, all reported P values should be two-sided. In general, P values larger than 0.01 should be reported to two decimal places, and those between 0.01 and 0.001 to three decimal places; P values smaller than 0.001 should be reported as $P < 0.001$. Notable exceptions to this policy include P values arising from tests associated with stopping rules in clinical trials or from genome-wide association studies.
- Results should be presented with no more precision than is of scientific value and is meaningful given the available sample size. For example, measures of association, such as odds ratios, should ordinarily be reported to two significant digits. Results derived from models should be limited to the appropriate number of significant digits.

For clinical trials:

- Original and final protocols and statistical analysis plans (SAPs) should be submitted along with the manuscript, as well as a table of amendments made to the protocol and SAP indicating the date of the change and its content.
- The analyses of the primary outcome in manuscripts reporting results of clinical trials should match the analyses prespecified in the original protocol, except in unusual circumstances. Analyses that do not conform to the protocol should be justified in the Methods section of the manuscript. The editors may ask for additional analyses that are not specified in the protocol.
- When comparing outcomes in two or more groups in confirmatory analyses, investigators should use the testing procedures specified in the protocol and SAP to control overall type I error — for example, Bonferroni adjustments or prespecified hierarchical procedures. P values adjusted for multiplicity should be reported when appropriate and labeled as such in the manuscript. In hierarchical testing procedures, P values should be reported only until the last comparison for which the P value was statistically significant. P values for the first nonsignificant comparison and for all comparisons thereafter should not be reported. For prespecified exploratory analyses, investigators should use methods for controlling false discovery rate described in the SAP — for example, Benjamini–Hochberg procedures.
- When no method to adjust for multiplicity of inferences or controlling false discovery rate was specified

in the protocol or SAP of a clinical trial, the report of all secondary and exploratory endpoints should be limited to point estimates of treatment effects with 95% confidence intervals. In such cases, the Methods section should note that the widths of the intervals have not been adjusted for multiplicity and that the inferences drawn may not be reproducible. No P values should be reported for these analyses.

- Please see [Wang et al](#) (N Engl J Med 2007;357:2189–2194) on recommended methods for analyzing subgroups. When the SAP prespecifies an analysis of certain subgroups, that analysis should conform to the method described in the SAP. If the study team believes a post hoc analysis of subgroups is important, the rationale for conducting that analysis should be stated. Post hoc analyses should be clearly labeled as post hoc in the manuscript.
- Forest plots are often used to present results from an analysis of the consistency of a treatment effect across subgroups of factors of interest. Such plots can be a useful display of estimated treatment effects across subgroups, and the editors recommend that they be included for important subgroups. If subgroups are small, however, formal inferences about the homogeneity of treatment effects may not be feasible. A list of P values for treatment by subgroup interactions is subject to the problems of multiplicity and has limited value for inference. Therefore, in most cases, no P values for interaction should be provided in the forest plots.
- If significance tests of safety outcomes (when not primary outcomes) are reported along with the treatment-specific estimates, no adjustment for multiplicity is necessary. Because information contained in the safety endpoints may signal problems within specific organ classes, the editors believe that the type I error rates larger than 0.05 are acceptable. Editors may request that P values be reported for comparisons of the frequency of adverse events among treatment groups, regardless of whether such comparisons were prespecified in the SAP.
- When possible, the editors prefer that absolute event counts or rates be reported before relative risks or hazard ratios. The goal is to provide the reader with both the actual event frequency and the relative frequency. Odds ratios should be avoided, as they may overestimate the relative risks in many settings and be misinterpreted.
- Authors should provide a flow diagram in CONSORT format. The editors also encourage authors to submit all the relevant information included in the CONSORT checklist. Although all of this information may not be published with the manuscript, it should be provided in either the manuscript or a supplementary appendix at the time of submission. The CONSORT statement, checklist, and flow diagram are available on the [CONSORT](#) website.

For observational studies:

The validity of findings from observational studies depends on several important assumptions, including those relating to sample selection, measured and unmeasured confounding, and the adequacy of methods used to control for confounding. The Methods section of observational studies should describe how these and other relevant issues were managed in the design and analysis.

- If an observational study included a prespecified SAP with a description of hypotheses to be tested, a signed and dated version of that plan should be included with the manuscript submission. The *Journal* encourages authors to deposit SAPs for observational studies in one of the online repositories designed for this purpose.
- When appropriate, observational studies should use prespecified accepted methods for controlling family-wise error rate or false discovery rate when multiple tests are conducted. In manuscripts reporting observational studies without a prespecified method for error control, summary statistics should be limited to point estimates and 95% confidence intervals. In such cases, the Methods section should note that the widths of the intervals have not been adjusted for multiplicity and that the inferences drawn from the inferences may not be reproducible. No P values should be reported for these analyses.
- If no prespecified analysis plan exists, the Methods section should provide an outline for the planned method of analysis, including
 - Eligibility criteria for the selection of cases and method of sampling from the data, with a diagram as appropriate.
 - A description of the association or causal effect to be estimated and the rationale for this choice.
 - The prespecified method of analysis to draw inference about treatment or exposure effect or association.
- Studies reporting the effect of a treatment or exposure should show the distribution of potential confounders and other variables, stratified by exposure or intervention group. When the analysis depends on the confounders being balanced by exposure group, differences between groups should be summarized with point estimates and 95% confidence intervals when appropriate.
- Complex models and their diagnostics can often be best described in a supplementary appendix. Authors are encouraged to conduct an analysis that quantifies potential sensitivity to bias from unmeasured confounding; absent that, authors must provide a discussion of potential biases induced by unmeasured confounders.
- Authors are encouraged to retest findings in a similar but independent study or studies to assess the robustness of their findings.

Key Journal Style Elements

UNITS OF MEASUREMENT

Authors should express all measurements in conventional units, with Système International (SI) units given in parentheses throughout the text. Figures and tables should use conventional units, with conversion factors given in legends or footnotes. In accordance with the Uniform Requirements, however, manuscripts containing only SI units will not be returned for that reason.

ABBREVIATIONS

Except for units of measurement, abbreviations are strongly discouraged; the first time an abbreviation appears, it should be preceded by the words for which it stands.

DRUG NAMES

Generic names should be used. When proprietary brands are used in research, include the brand name and the name of the manufacturer in parentheses after the first mention of the generic name in the Methods section.

Prepare Materials for Submission

COVER LETTER

Though cover letters are not required, the [NEJM Online Submission system](#) contains a text field through which important information that is not in the metadata, such as a meeting presentation date or a major conflict of interest not in the manuscript, should be communicated with initial manuscript submissions.

MANUSCRIPT TEXT FILE

Compile all text, references, figure legends, and tables into a single double-spaced digital file (preferably an MS Word document). NEJM will also accept text (.txt), or Rich Text Format (.rtf) files.

TITLE PAGE

Create a title page that includes:

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- Contact information for one corresponding author

ABSTRACT

Provide an abstract of not more than 250 words with four labeled paragraphs containing the following:

- Background: Problem being addressed in the study
- Methods: How the study was performed
- Results: Salient results
- Conclusions: What the authors conclude from study results
- Trial registration number

IDENTIFYING DATA

At appropriate places in the manuscript, please provide the following items:

- If applicable, a statement that the research protocol was approved by relevant institutional review boards or ethics committees and that all human participants gave written informed consent
- Identities of those who analyzed the data
- For clinical trials, registration number and registry name (see: N Engl J Med 2004;351:1250-1)
- For studies containing microarrays, accession numbers and repository name

REFERENCES

References must be double-spaced and numbered consecutively as they are cited. References first cited in a table or figure legend should be numbered so they will be in sequence with references cited in the text at the point where the table or figure is first mentioned. List all citation authors when there are six or fewer; when there are seven or more, list the first three, followed by et al.

The following are sample references:

1. Shapiro AMJ, Lakey JRT, Ryan EA, et al. Islet transplantation in seven patients with type 1 diabetes mellitus using a glucocorticoid-free immunosuppressive regimen. N Engl J Med 2000;343:230-8.
2. Goadsby PJ. Pathophysiology of headache. In: Silberstein SD, Lipton RB, Dalessio DJ, eds. Wolff's headache and other head pain. 7th ed. Oxford, England: Oxford University Press, 2001:57-72.
3. Kuczmarski RJ, Ogden CL, Grammer-Strawn LM, et al. CDC growth charts: United States. Advance data from vital and health statistics. No. 314. Hyattsville, Md.: National Center for Health Statistics, 2000. (DHHS publication no. (PHS) 2000-1250 0-0431.)
4. Medicare: trends in fees, utilization, and expenditures for imaging services before and after implementation of the Deficit Reduction Act of 2005. Washington, DC: Government Accountability Office, September 2008. (<http://www.gao.gov/new.items/d081102r.pdf>.)

Numbered references to personal communications, unpublished data, or manuscripts either “in preparation” or “submitted for publication” are unacceptable. If essential, such materials can be incorporated at appropriate places in the text.

TABLES

All tables should be included at the end of the manuscript text file. Double-space tables (including footnotes) and provide a title for each table. For Original Articles, there is normally a limit of five figures and tables (total) per manuscript. Extensive tables or supplementary materials will be published as supplemental materials with the digital version of the article.

Figures and Illustrations

Authors can either insert figures into text files (preferred) or upload figure files separately. Low-resolution images may be submitted for peer review, but be aware that NEJM may, at a later stage, request high-resolution versions that comply fully with detailed [Technical Guidelines for Figures](#).

Supplementary Appendix

A manuscript’s Supplementary Appendix should be paginated, with a table of contents, followed by a list of investigators (if there is one), text (such as methods), figures, tables, and then references. Reference citations in the Appendix and the corresponding list of references should be self-contained with respect to the Appendix. The Appendix must be submitted in two formats: PDF and MS Word (or another editable text format). The Appendix will not be edited for style and will be presented online as additional information provided by the authors.

Supplementary Figures and Tables

For outcome scales, provide in the figure legend or table footnotes the range, sign, and minimally important difference (if known). There must be an informative reference citation for the scale. Each figure should include a title and a legend, which should appear on the same page as the figure itself. Tables in the Supplementary Appendix should be labeled Table S1, Table S2, etc. Each table should be

accompanied by a title and, if necessary, footnotes.

Trial Protocol and Statistical Analysis Plan (SAP)

Please include a clinical trial’s protocol and statistical analysis plan with the submission. The protocol may be redacted of proprietary information, but must include information on the patient flow and outcomes. *Journal* editors may ask for more information on redacted protocols.

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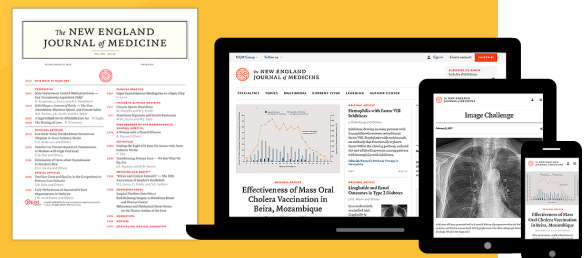
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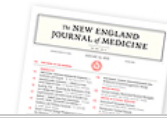
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The reference citations in the Appendix and corresponding list of references should be self-contained with respect to the Appendix.

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