Patient Safety – Guidelines for Authors

Welcome to *Patient Safety*, a peer-reviewed publication that highlights the latest in original research, advanced analytics, and contemporary healthcare issues!

Our mission is to bring clinicians, administrators, and patients the information they need to prevent harm and improve safety by disseminating evidence-based, peer-reviewed research; editorials addressing current and sometimes controversial topics; and analysis of data from one of the largest adverse event reporting databases in the world.

We invite you to submit articles that are aligned with our mission, including original research, reviews, commentaries, case studies, data analyses, quality improvement studies, or other manuscripts that will advance patient safety.

Together we can save lives.

Patients Included™

Patient Safety believes the patient is central to everything we do. *Patient Safety* complies with the guidelines set forth in the Patients Included™ charter for journals, which include having at least two patient members on the editorial board; regularly publishing editorials, reviews, or research articles authored by patients; peer review by patients; and being full open access.

Authorship

Patient Safety adopts the following authorship criteria from the International Committee of Medical Journal Editors (ICMJE):

- 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 revising 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.

Any designated authors must meet all four criteria, and any person meeting all four criteria will be considered an author.

The corresponding author will be the primary point of contact and be available to respond to inquiries in a timely manner during and after the publication process.

Individuals who contribute to the publication but do not meet all four criteria will not be designated as authors, although their contribution will be acknowledged.

Conflicts of Interest

Definition

A conflict of interest occurs when a participant in the publication process has a financial, personal, academic, political, religious, or other interest or affiliation that could influence the opinion, honesty, integrity, or decisions of the participant in their work related to the publication. The publication process includes planning, research, manuscript preparation, review, and editorial decisions. Participants include authors, reviewers, editors, journal staff, and editorial board members.

Authors

Authors are required to complete the journal's conflict of interest form at the time of manuscript submission. Failure to complete the required conflict of interest form will result in rejection of the manuscript. If there is no conflict of interest, this must also be explicitly stated as "none declared." All sources of funding must be acknowledged in the manuscript. All relevant conflicts of interest and sources of funding must be included on the title page of the manuscript with the heading "Conflicts of Interest and Source of Funding."

For example:
Conflicts of Interest and Source of Funding: Author A is a paid consultant for Organization X, or Author B has received honoraria from Company Z. No conflicts were declared for the remaining authors.

Failure to Disclose a Potential Conflict of Interest

If a conflict of interest is discovered from other sources after manuscript submission or publication, the journal will investigate the alleged conflict. If the conflict is substantiated and the manuscript has been published, the journal will take necessary action to inform its readers of the conflict. This may include publishing the findings of the investigation.

Reporting Conflicts of Interest to Readership

The journal will publish any conflicts of interests to its readers, including authors' conflicts of interest, sources of support for the published work, and authors' access to the study data.

Plagiarism

Plagiarism in the simplest context is taking someone else's work and representing it as your own. *Patient Safety* is committed to the integrity of its content and uses guidelines and resources established by the Committee on Publication Ethics (COPE) to address plagiarism in submitted and published manuscripts, including publicationethics.org/files/plagiarism%20A.pdf and publicationethics.org/files/plagiarism%20B.pdf. Authors should familiarize themselves with the various aspects of plagiarism, including self-plagiarism, and must ensure that submitted work is free from plagiarism, both intentional and accidental.

All manuscripts are reviewed with plagiarism-detecting software. Manuscripts may be rejected based on the results of this review, even if they were previously accepted.

Open Access

Patient Safety believes its content should be available to all readers, and authors should have no financial barriers to having their work published; therefore, *Patient Safety* is published as an open access journal. There are no subscription fees for readers and no processing fees for authors.

Copyright

Patient Safety will only publish manuscripts that have not been published previously in their entirety. (Abstracts or older, previously published versions of manuscripts may be considered.) Authors retain copyright of their published articles and grant the Patient Safety Authority a license to publish the article and identify itself as the original publisher.

Creative Commons License

All articles will be free, downloadable, and available to share at the time of publication. All articles are published under the Creative Commons Attribution-Noncommercial license. For more information, go to creativecommons.org/licenses/.

Compliance with funding requirements for accessibility

Patient Safety recognizes that certain funders require manuscripts to be published in PubMed Central® prior to or at the time of publication. Please inform the managing editor at the time of publication acceptance if such requirements apply to your manuscript.

Confidentiality

Patient Safety recognizes that submitted manuscripts are confidential property of the author and will take measures to protect that confidential property to the extent allowable by law.

Peer-Review Process

Most manuscripts submitted to *Patient Safety* go through a double-blind, peer-review process, meaning both the author and the reviewer's identity are unknown to each other. The editor is under no obligation to send a submitted manuscript for review and they are under no obligation to accept or reject a manuscript based on the recommendations of a reviewer. The peer-review process is designed to provide both the author and the editor unbiased, critical feedback on the suitability of the manuscript for publication. Suitability includes originality, relevance to the field of patient safety, integrity of any research studies, and overall quality of writing.

Original research submissions must include any relevant research protocols, statistical analysis methodology, and contracts associated with the research study. Authors are required to state whether data is available for third parties to view and/or reanalyze. The journal may require the author to provide *Patient Safety* the original data prior to publication for independent data analysis.

Exclusion will not be based on insignificant or inconclusive findings. *Patient Safety* encourages submissions with such findings, as it believes they are equally relevant to advance learning in the field.

Protection of Research Participants

The rights of individual human research subjects are the most important priority in any research study, and no potential knowledge gained by the study supersedes those rights. *Patient Safety* is committed to upholding those rights. Authors must ensure that research studies were conducted in accordance with the Declaration of Helsinki as revised in 2013 (www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/). All submitted research must have been approved by an institutional review board (IRB), and the editor reserves the right to ask for verification of this approval at any time. If the author has reason to believe that any aspect of the research study was not in accordance with the

Declaration of Helsinki as revised in 2013, they must provide a written, detailed explanation to the editor.

Individual human research subjects have a right to privacy. All personal, identifiable information should be removed from the manuscript. In the event personal, identifiable information is included in the manuscript for valid, scientific purposes, the author must provide the subject's informed consent. Additionally, the subject will have the opportunity to review the manuscript and to withdraw their consent prior to publication.

Clinical Trials

Patient Safety adopts the following definition of a clinical trial from ICMJE: "any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention *and* a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events."

For publication consideration, all clinical trials must be registered in a public trial registry at or before the time of the first patient enrollment. Manuscripts that contain clinical trials not registered in a public trial registry at or before the time of first patient enrollment will be rejected.

Animal Rights

Patient Safety does not anticipate that any studies on animals will be included in any manuscript. However, any manuscript that does include studies regarding animals must include a statement from the author that includes the following affirmation that the study complied with international, national, or institutional standards for the humane treatment of animals and that the study was approved by an ethics review committee. The author must also provide a description of the ethics review committee approval process and reference to what internationally, nationally, or institutional guidelines are followed in the process. The editor retains the right to reject the manuscript on the basis of any animal welfare concerns.

Scientific Misconduct, Expression of Concern, and Retraction

Patient Safety uses guidelines and resources established by COPE to respond to allegations of scientific misconduct: publicationethics.org/resources/guidelines-new/cooperation-between-research-institutions-and-journals-research-integrity. The author's institutions and funders may be notified, and *Patient Safety* may elect to publish an expression of concern or a retraction.

Expressions of concern and any retractions will be labeled as such, appear in the table of contents, and include the title of the original article. Retracted articles will remain in the public domain and will remain labeled as such.

Duplicate Submissions and Prior Publication

Authors may not submit manuscripts to more than one journal at a time. The author must inform the editorial staff if the manuscript was previously published on a preprint server. The editor in

their sole discretion may agree to duplicate publication if the second journal agrees and it is deemed to be in the best interest of the public.

If an author chooses to include their work on a preprint server, that work must be clearly labeled as not peer-reviewed and include a conflict of interest statement. The author is responsible for notifying the editor if the work was posted on a preprint server, and it is the author's responsibility to ensure that preprints are amended at the time of final publication.

Patient Safety follows the guidelines set forth by ICMJE regarding the posting of trial results in registries prior to publication (www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).

Patient Safety follows the guidelines set forth by COPE if it suspects duplicate publication (publicationethics.org/case/duplicate-publication-6).

Images and Figures, and "Digital Artwork"

All figures must be uploaded through the submission portal along with the manuscript.

- *Patient Safety* accepts color figures for publication.
- Artwork should be saved as TIFF, PNG, EPS, or MS Office (DOC, PPT, XLS) files. High-resolution PDF files are also acceptable.
- Diagrams, drawings, graphs, and other line art must be vector-based or saved at a resolution of at least 1200 dpi. If created in an MS Office program, send the native (DOC, PPT, XLS) file.
- Photographs, radiographs. and other halftone images must be saved at a resolution of at least 300 dpi.
- Photographs and radiographs with text must be saved in PostScript format or at a resolution of at least 600 dpi.
- Each figure must be saved and submitted as a separate file. Figures should not be embedded in the manuscript text file.
- Cite figures consecutively in your manuscript.
- Number figures in the figure legend in the order in which they are discussed.
- Upload figures consecutively into the submission portal.

Figure Legends

Include legends for all figures. They should be brief and specific, and they should appear on a separate manuscript page after the references. Use scale markers in the image for electron micrographs and indicate the type of stain used.

Tables

Group all tables in a separate file. Cite tables consecutively in the text and number them in that order. Each table must appear on a separate page or tab and include the table title, appropriate column heads, and explanatory legends (including definitions of any abbreviations used). Do not embed tables within the body of the manuscript. They should be self-explanatory and supplement, rather than duplicate, the material in the text.

Prepublication and Media

Authors agree not to publicize their work while the accompanying manuscript is under review for publication. Nothing shall preclude an author from discussing presentations of their work conducted at scientific meetings with the media; however, those discussions should be limited to the information presented in the meeting.

Release of information by the author prior to publication for public health matters of an emergent or critical nature takes priority over any publication considerations. Release of information by authors for this purpose, will not, in and of itself, cause a manuscript to be rejected. Decisions to release information due to emergent or critical public health concerns must be made by the appropriate authorities, not at the sole discretion of the author, and should be discussed with the editor whenever possible.

Patient Safety will work collaboratively with authors and the media to help ensure accurate information for media coverage. The editor and staff may prepare press releases, provide embargoed advance copies of the article to the press, and answer questions to help coordinate media releases and the publication of the article.

Manuscript Submission

All manuscripts must be submitted through the online submission portal. *Patient Safety* uses a double-blind, peer-review process. Therefore, all author information must be entered directly into the portal. The manuscript must not contain the names of any authors or institutions.

Each submission must contain a cover letter that includes all disclosures related to prior publication and permission to reprint any visuals that accompany the manuscript.
Authors should follow the submission guidelines for each submission type.

General guidelines

For review purposes, manuscripts need not follow every detail of our journal style; however, our style guide is included below for reference. Accepted manuscripts that already follow our house style can be prepared more easily for publication.

After acceptance, editors will advise the author on formatting and style during the revision and editing process, as well as make recommendations for clarity and readability. Prior to publication, copyeditors will ensure the manuscript meets *Patient Safety*'s house style. Authors will have the opportunity to review proofs and discuss proposed changes with our editors, but we reserve the right to make final decisions on matters of style.

Patient Safety articles use *Citing Medicine: The NLM Style Guide for Authors, Editors, and Publishers* format for references. (Current edition: www.ncbi.nlm.nih.gov/books/NBK7256/)

Patient Safety generally follows the *American Medical Association (AMA) Manual of Style* (10th edition), with some exceptions, most notably regarding citations. (See below for guidelines on citing references.) *Merriam-Webster's Collegiate Dictionary* (11th edition) and *Stedman's Medical Dictionary* (28th edition) also should be used as standard references.

Highlights of the AMA style include:

- Degrees below the master's level (e.g., BA, BS) are not listed in bylines or elsewhere; however, if a bachelor's degree in a medical or health-related field is the highest degree held, it may be listed. U.S. fellowship designations (e.g., FACP, FAAN, FACS) and honorary designations (e.g., PhD[Hon]) are not used in bylines. In contrast, non-U.S. designations such as the British FRCP and the Canadian FRCPC (attained through a series of qualifying examinations) should be listed in bylines.
- The nonproprietary name of a drug should always be used, and the proprietary name should almost never be used. The exceptions to this rule are reports of adverse events that might be unique to a specific product formulation, or comparison of a generic

formulation of a drug with the drug that was first approved. When both the nonproprietary and proprietary names are used, the nonproprietary name should appear first, with the proprietary name capitalized and in parentheses.

e.g., The lot of penicillin G potassium (Pentids) was inspected and found to meet the industry production standards.

- Nonproprietary names are preferred over chemical names and registry numbers.
- A code designation is a temporary designation assigned to a product by the institution or manufacturer and may be used to refer to a drug under development before a nonproprietary name has been assigned. Codes may be numeric, alphabetic, or alphanumeric; letters in alphanumeric codes designate the institution or manufacturer assigning the code designation of the drug and are followed by numbers to designate the chemical compound.
    - If a nonproprietary name has been assigned to a drug, the nonproprietary name is preferred over the drug's temporary code designation. If both the code and the nonproprietary name are provided, such as in discussion of the history of a drug, the nonproprietary name should be used preferentially and the code name may be added in parentheses.

      e.g., Mifepristone (formerly known as RU 486) was approved by FDA on September 28, 2000.
- Abbreviations should not be used except in rare instances (e.g., trimethoprim-sulfamethoxazole may not fit in a table heading and may need to be abbreviated, e.g., TMP-SMX; in that case the expansion should be provided in a table footnote).
- Nonproprietary names are preferred over unofficial trivial names for drugs, except to reproduce the exact language used as part of a study (e.g., in a questionnaire), for historical reasons, or rarely when readers may be unfamiliar with the nonproprietary name. When reproducing the exact language used in a study, the nonproprietary name should be provided in brackets after the term used in the study.

  e.g., The participants were asked, "Have you ever taken AZT [zidovudine] or ddI [didanosine]?" Participants who said they had taken zidovudine or didanosine were classified as having had prior exposure to antiretroviral agents.
- Drugs often contain a pharmacologically inactive component, e.g., a base, salt, or ester, that is not responsible for the drug's mechanism of action but lends stability or other properties to the drug. Drugs with both an active and inactive component generally require a two-part name that provides the active and inactive portion of the drug. Inorganic salts and simple organic acids are named in the order cation-anion (e.g., sodium chloride, magnesium citrate). For more complex organic compounds, the active component is named first (e.g., oxacillin sodium).
- Chemical names are often too complex for general use. In such cases, shorter nonproprietary names may be created. For example, for the drug erythromycin acistrate, acistrate refers to the 2′-acetate (ester) and octadecanoate (salt). For the drug erythromycin estolate, estolate refers to the double salt propanoate and dodecyl sulfate.
- When a drug is referred to as a general category, the international nonproprietary name (INN) for the drug can be used without providing the inactive moiety. However, if a specific drug is discussed for a specific use, particularly when more than one formulation is available, the inactive moiety should be included with the drug name.

  e.g., The patient was given erythromycin ethylsuccinate, 400 mg by mouth every six hours.
    - The inactive component should not be used when referring to an organism's sensitivity to an antibiotic or to allergic reactions to drugs.

      e.g., The woman developed urticaria after taking erythromycin.

- If both the nonproprietary name and the proprietary name are provided together, the inactive component is given only once.

  e.g., The patient had been taking hydralazine (Apresoline) hydrochloride in the 1980s but developed an urticarial papular rash.

- Some drug names, such as those used in topical preparations, include the percentage of active drug contained in the preparation. In these cases the percentage should be listed after the drug name.

  e.g., The patient was treated with adalapalene gel, 1%.

- If drug names appear in the title or subtitle, (1) use the approved generic or nonproprietary name, (2) omit the nonbase moiety unless it is required, and (3) avoid the use of proprietary names unless (a) several products are being compared, (b) the article is specific to a particular formulation of a drug (e.g., the vehicle, not the active substance, caused adverse reactions), or (c) the number of ingredients is so large that the resulting title would be clumsy and a generic term, such as "multivitamin tablet," would not do.
- Regimens that include multiple drugs may be referred to by an abbreviation after the nonproprietary names of the drugs have been provided at first mention.

  e.g., The MOPP (methotrexate, vincristine sulfate [Oncovin], prednisone, and procarbazine hydrochloride) regimen for advanced Hodgkin disease was compared with MOPP alternating with ABVD (doxorubicin hydrochloride [Adriamycin], bleomycin sulfate, vinblastine sulfate, and dacarbazine).

- Drug doses are expressed in conventional metric mass units (e.g., milligrams or milligrams per kilogram), rather than in molar SI units. Moreover, certain drugs (such as insulin or heparin) may be prepared as mixtures and have no specific molecular weight, thereby precluding their expression in mass units. Although other drug dose units such as drops (for ophthalmologic preparations), grains (for aspirin), and various apothecary system measurements (e.g., teaspoonfuls, ounces, and drams) may be encountered clinically, these units generally are not used. Also, the units for drug doses are often different from the units used to measure drug concentrations, such as in therapeutic drug levels.
- The Celsius scale (°C) is used for temperature measurement.
- Use the Oxford (serial) comma to separate elements in a series of three or more terms.

Exceptions to AMA style include:

- Always use commas in numbers over 1,000, rather than a thin space.
- In general, spell out numbers one through nine. Use numerals for 10 or above and whenever preceding a unit of measure or referring to ages of people, animals, events, or things, as well as in all tabular matter and in statistical and sequential forms.

In-text citations must be formatted according to the Citation-Sequence System, in which superscripted numbers refer to items in the end reference list, sequentially numbered in the text and the list in the order in which they appear. Use the same number for all subsequent in-text references to the same source.

When multiple references occur, separate numbers not in a continuous numeric sequence with commas. Continue more than two numbers in a continuous sequence with a dash; if there are only two consecutive numbers, separate them with a comma.

Example

In-text reference:

According to the National Academy of Medicine (NAM), everyone is likely to experience at least one diagnostic error during his or her lifetime[1], and studies estimate that 12 million adults in the United States could be subject to diagnostic error each year[2,3]. Diagnostic error has been identified as the leading cause of medical malpractice claims[4-6], with the majority of occurrences being classified as high severity and more than one-third resulting in death[6].

Reference list:

1. National Academies of Sciences, Engineering, and Medicine. Improving diagnosis in health care. Washington (DC): The National Academies Press; 2015. Also available: https://www.nap.edu/catalog/21794/improving-diagnosis-in-health-care.
2. Singh H, Meyer AN, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf. 2014 Sep;23(9):727-31. Also available: http://dx.doi.org/10.1136/bmjqs-2013-002627. PMID: 24742777
3. Misdiagnosed: docs' mistakes affect 12 million a year. [internet]. New York (NY): NBC News; 2014 Apr 16 [accessed 2018 Jun 28]. [5 p]. Available: https://www.nbcnews.com/health/health-news/misdiagnosed-docs-mistakes-affect-12-million-year-n82256.
4. Saber Tehrani AS, Lee H, Mathews SC, Shore A, Makary MA, Pronovost PJ, Newman-Toker DE. 25-Year summary of US malpractice claims for diagnostic errors 1986-2010: an analysis from the National Practitioner Data Bank. BMJ Qual Saf. 2013 Aug;22(8):672-80. Also available: http://dx.doi.org/10.1136/bmjqs-2012-001550. PMID: 23610443
5. Troxel DB. The Doctor's Advocate. Diagnostic error in medical practice by specialty. [internet]. Napa (CA): The Doctors Company; 2014 [accessed 2018 Jun 05]. [7 p]. Available: https://www.thedoctors.com/the-doctors-advocate/third-quarter-2014/diagnostic-error-in-medical-practice-by-specialty/.
6. Hanscom R, Small M, Lambrecht A. Diagnostic accuracy: room for improvement. Boston (MA): Coverys; 23 p. Also available: https://www.coverys.com/PDFs/Coverys_Diagnostic_Accuracy_Report.aspx.

One resource available to assist with creating citations and checking manuscripts for errors is the National Library of Medicine (NLM) online citation generator.

Most research manuscripts, reviews, and case studies should be no more than 4,000 words, excluding the abstract, figures, tables, and references. *Patient Safety* encourages its authors to write succinctly and for a wide audience. *Patient Safety* has a diverse readership which includes patients, physicians, nurses, pharmacists, allied health professionals, diagnostic professionals, and others. Do not assume the reader understands highly technical medical jargon. Health literacy affects people of all backgrounds, including those in the medical profession, as well as people of all education levels. If the average reader needs to look up a word in your manuscript, they may not finish reading it. Use words that are easily understandable.

Original research

Original research manuscripts must be prepared and submitted using the guidelines set forth by ICMJE: www.icmje.org/recommendations/browse/manuscript-preparation/preparing-for-submission.html.

Systematic reviews and meta-analyses

Systematic reviews and meta-analyses must be prepared and submitting using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines: prisma-statement.org/.

Case reports

Patient Safety publishes original case reports that contribute to patient safety knowledge. Manuscripts must contain at least one of the following criteria: unusual patient safety event, unusual contributing factor to a common patient safety event, or findings that highlight new causes of a patient safety event. New preventative techniques generally require further evidence beyond a single case report and will not be considered for case reports. The manuscript must include a title page, abstract, keywords, introduction, discussion, and conclusion. Authors are strongly encouraged to include the patient perspective in the manuscript whenever possible.

Authors must include affirmation that written consent was obtained from any patients or their legal representatives to publish the case report. The consent must be made available to the editor at their request. Manuscripts without affirmation of consent will be rejected. Cases should be deidentified to provide anonymity for the patient, though authors should not change important details about the case.

Data Analyses

Patient Safety publishes data analyses that contribute to patient safety knowledge. Manuscripts must contain at least one of the following criteria: new macro-level trends; new event types; new information related to known event types; or it must highlight areas associated with a high combination of frequency, severity, and possibility of solution. The manuscript must include a title page, abstract, introduction, results, and conclusion. The manuscript may include a discussion.

Quality Improvement Studies

Patient Safety publishes quality improvement studies that contribute to the advancement of patient safety. It is not necessary to have achieved the desired outcome to be considered for publication; lessons are also learned in projects that do not achieve the desired outcome. Manuscripts must follow the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines: www.squire-statement.org/index.cfm?fuseaction=Page.ViewPage&pageId=504.

Commentaries

Patient Safety publishes commentaries on recently published articles, generally within the last six months. Commentaries on original research articles may be submitted at any time. Commentaries should not exceed 2,000 words. Commentaries may provide a challenge to an article, expand on the original author's position, or provide a personal perspective or experience related to the article. Commentaries are subject to the peer-review process.

Patient Safety also publishes commentaries submitted by patients and family members. The purpose of these commentaries is to enhance patient safety knowledge for healthcare providers or other patients. These commentaries should describe the author's experience as it relates to patient safety. Commentaries may include either positive or negative experiences and should include suggestions for improvement. Commentaries must respect the privacy of any healthcare provider or institution involved. Commentaries should not exceed 2,000 words.

Other narratives

Patient Safety may consider manuscripts that do not fit in any of the above categories. Authors should contact the editor for submissions outside of the above categories.