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Official publication of the American College of Chest Physicians

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Chest 2010;137;1479-1482
DOI 10.1378/chest.09-3024

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ISSN:0012-3692

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CHEST Postgraduate Education Corner

MEDICAL WRITING TIP OF THE MONTH

Changes in the Ethos of Medical Publications as Reflected in Progressive Alterations in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (1979-2008)

Takako Kojima, MA; and J. Patrick Barron, BA

CHEST 2010; 137(6):1479–1482

Abbreviations: CONSORT = Consolidated Standards of Reporting Trials; ICMJE = International Committee of Medical Journal Editors; URM = Uniform Requirements for Manuscripts Submitted to Biomedical Journals

Since its publication in 1979,[1] the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URM), a document created by what is known today as the International Committee of Medical Journal Editors (ICMJE), has become a standard format for submission to > 600 international journals.[2] What set out to be *the* standardized format has now evolved into *a* "worldwide accepted guideline" that places great emphasis on the concern for ethical issues in medical writing and publishing, including conflict of interest and authorship. Changes in the intervening editions of the URM over the past 30 years highlight significant changes in mainline approaches to medical publishing, such as a movement toward greater transparency, an increased concern for ethical issues, and a stronger emphasis on each journal's editorial preferences (Instructions for Authors) regarding manuscript submission.

Manuscript received December 18, 2009; revision accepted January 25, 2010.

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DOI: 10.1378/chest.09-3024

URM Format

The first URM in 1979[1] provided information on the basic components of a manuscript, that is, what should be included in each, how it should be presented, and how an actual manuscript should be submitted. By 1997,[3] the URM had been divided into sections according to the technical and ethical aspects of the paper. In 2003,[4] the URM was composed of nine separate sections, each with subdivisions, and it began to emphasize the importance of the Instructions to Authors of each journal to "meet each journal's particular editorial needs."[4] The 2007 URM [5] gives similar information on the physical properties of the manuscript, for both manual and electronic submissions, to ensure that manuscripts are well presented and easy to read and edit for reviewers.

Reporting Clinical Trials/Statistics

Thirty years ago, authors only needed to describe the selection of experimental subjects and the methods and procedures used in the investigation. By 1997,[3] the URM required more detailed information on the study subjects. Further changes in the 2003 URM[4] included providing information on the eligibility or exclusion of study subjects, an explanation as to how the subjects were chosen, and the criteria for those eligible, in addition to the reasons for restrictions to a certain group. This was an attempt to clearly inform the reader how and why the investigation was conducted in a certain way. If race or ethnicity were used as variables for a study, the author needed to define how each was measured and to justify its relevance.

The issue of reporting clinical trials has become a vital concern over the past 20 years. Since its first

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publication in 1996, the Consolidated Standards of Reporting Trials (CONSORT statement) has been supported by the ICMJE.[6] In later years, the CONSORT statement began to appear, not in the Methods section, but in a new subsection, titled "Reporting Guidelines for Specific Study Designs," in which authors were encouraged additionally to consult reporting guidelines relevant to their specific research design.[4,7] As stated in the article by Huth and Case,[8] "in 2000, revisions [of the 1997 URM[3]] included stronger statements on preliminary release of information to the press and reporting guidelines for specific study designs, with a reference to the CONSORT guidelines."

The CONSORT statement set guidelines for reporting specific study designs, including randomized controlled studies, making it possible for authors to present accurate information concerning the negative elements, or limitations, of a study, because there is a tendency to place too much focus on only the positive aspects of an investigation. Authors were also instructed to consult the instructions to authors of their target journal, reflecting an increased emphasis on the requirements of individual journals and how requirements for presenting different study types were becoming more specific. Although not mentioned in the CONSORT statement, obtaining approval from ethical institutional review boards is becoming increasingly obligatory. Reporting losses to observation (such as dropouts from a clinical trial)[9] and "reporting complications of treatment"[2] reflected a move toward more blanket and transparent reporting of all clinical trials. The 2003 URM[4] emphasizes that the *P* value is not the only statistical instrument to show significant values when testing statistical hypotheses.

References

Until 1997, the URM cited only samples of mainstream reference formats. The 1997 URM,[3] however, asked authors to provide detailed information when referring to a personal communication, as well as to obtain written permission from the source of communication, and demanded a written statement from the person being quoted confirming the accuracy of the communication. Authors were advised to avoid citing a personal communication unless it was essential information unobtainable elsewhere.

The 2003 URM[4] specified what materials were suitable for references and specifically advised against including retracted articles unless there was a definite need to refer to the question of the retraction *per se*. Authors became responsible for checking the accuracy of reference materials. This was a reflection of how the URM then saw the accuracy of reference materials as an important responsibility resting on the shoulders of the author. An article by Foote[10] on the accuracy of references mentioned that accuracy not only includes basic information on the author, title of the article, and year of publication, and so forth, but also requires that the citation itself accurately supports the statement. In addition, she advised not to depend on the accuracy of references cited in other published articles because some authors do not check their references carefully.

Ethical Issues

The increased concern regarding ethical issues can be seen clearly in the changes found in the 1991[11] and 1997[3] URMs, as ethical issues became important enough to warrant their own separate section. The only statement that seemed to concern the ethical aspects of medical publishing in the 1979 URM[1] was that on human and animal experimentation. It stated that these experiments should follow the standards set by the individual institutions where the experiments were taking place, or should follow the Helsinki Declaration of 1975. Changes can be seen in 1988[9] when the new headings "Ethics" and "Statistics" were added. Although what was described under "Ethics" was similar to a statement in the 1982 URM,[12] the 1988 version noted the revision of the Helsinki Declaration in 1983. A new section on patients' rights, appearing for the first time in 1997, stated that authors must obtain written informed consent from the patient, or the patient's parents or guardian, if any photographs or identifying information was to be published in the work. The URM stated that such information should be presented only if essential to the investigation, and that the patient, or provider of consent, should be allowed to see the manuscript before submission.

Conflict of Interest

The issue of conflict of interest was not introduced at the time of the first edition. In 1991,[11] the URM asked authors to include a statement on "financial relationships that may pose a conflict of interest." In the 1997 URM,[3] authors were required to mention any "relationships that may pose a conflict of interest." The removal of the word "financial" indicated that any possible relationship whatsoever that might cause a conflict of interest was now the target of attention. In addition, a separate statement appeared under the issue of conflict of interest concerning authors, reviewers, editors, and editorial staff. By 2007,[5] all information concerning potential conflicts of interest had to be provided on a page following the title page, and authors were enjoined to consult the instructions to authors of the target journal before submission.

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Authorship

Authorship criteria were introduced for the first time in 1988.[9] Only a person satisfying all three conditions (contributing substantially to the analysis and interpretation of data; writing a draft of the article and revising it for intellectual content; and giving final approval of the paper to be published) could be credited as an author.

In 1991,[11] the order of authorship became a joint decision of all coauthors. The 1997 URM[3] stated that editors could ask how each coauthor contributed to the work, and that this information might be published. By 2003,[4] the URM stated that individual authors must be identified if the work were conducted by a large group, that each author must meet the authorship criteria, and that it was essential to complete the authorship and conflict of interest disclosure forms of the target journal. Concerning the order of authorship, Vollmer,[13] in his article, stated that this should ideally reflect the amount of intellectual contribution of the coauthors. Because this may become difficult for large, collaborative studies, he suggested listing the authors on early drafts as "your name and others to be determined" to prevent any future disagreements.

Duplicate Publication

The 1979 URM[1] briefly mentioned the issue of duplicate publication, albeit in a prominent position, explaining that submitted manuscripts must be original, not published in another journal or under consideration for publication elsewhere. By 1988,[9] the URM permitted secondary publication in another language if the following conditions were met: (1) the editors of both journals were fully informed, and a copy, reprints, or manuscript of the primary publication was given to the editor concerned with secondary publication; (2) there was a publication interval of $\geq$ 2 weeks after the primary publication; (3) the secondary publication was aimed at a different target audience and was preferably not a simple translation of the primary publication; (4) the secondary version accurately reflected the data and interpretations of the primary one; and (5) readers, including documenting agencies, were notified of the editing and publishing for a national audience of the secondary version, which resembled the primary version and was based on the same data and interpretations, in a footnote on the title page of the secondary version.[9,11]

In addition to the above-mentioned conditions, the 2008 URM[14] currently requires (6) that the title of the secondary publication indicate clearly that it is a secondary publication, and (7) that editors should understand that the NLM indexes the primary version. It should also be noted that in the latest version, the interval required between the primary and secondary publication is now only 1 week (unless otherwise specified).[14]

The issue of duplicate publication and its consequences became stricter in 1997[3] after redundant publication, or publication of material similar or identical in content to the submitted manuscript, was mentioned for the first time.

What These Changes Reflect

The changes highlighted here reflect a steady and vigorous move toward greater transparency in medical publications, in addition to a marked increase in concern for ethical issues. Although the 1979 URM[1] focused mainly on the structure of the manuscript, and its aim was to standardize the format of submitted manuscripts, the 2008 URM[14] has now incorporated the significance of ethical issues involved in reporting study trials, authorship, conflicts of interest, and also, to some extent, the accuracy in citing reference materials, into the standardized format of the URM. Not only does this reflect a perceived need for greater transparency in medical publications, but also the increased emphasis on the responsibility of the author. There is, thus, a need for authors to provide accurate and clear information on the eligibility and exclusion of subjects for the study, to cite accurate sources of reference material, to obtain written permission for all data and information used in the submitted manuscript, and to ensure that all requirements and criteria are met for authorship, acknowledgments, and the final submission process.

Present-day medical publishing greatly emphasizes the importance of ethics and, as Irwin[15] states, "there are signs everywhere" of increased awareness of scientific misconduct and the need for more intense adherence to codes of ethics in performing and reporting research. This movement is also reflected in changes made to the Declaration of Helsinki, the *American Medical Association Manual of Style*, and the instructions to authors of different journals, in addition to the URM, and the establishment of the Committee on Publication Ethics in 1997.[15]

The changes also reflect a slight reduction in total dependency on the URM and a stronger emphasis on each journal's editorial policies regarding manuscript submission. Authors are encouraged throughout the URM to consult the instructions for authors regarding issues such as electronic submission, acceptable abbreviations, units of measurement, format for abstracts, submission requirements, and policies on duplicate publication. Furthermore, a considerable

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number of journals are requesting corresponding authors to indicate the exact nature of the contributions of each person listed as an author. This is in line with the instructions of the URM for transparency and integrity in authorship.

Take-Home Message

In 1979, only 18 participating journals recognized the URM. Today, the document has been translated into many different languages, including Japanese (http://ronbun.jp). It is recognized for helping authors and editors across the world promote a consistent stylistic level of submitted manuscripts, and it provides important support for editors should they find themselves in problematic situations.

In its early years, controversies surrounding the URM involved issues regarding formats and other aspects of style, such as references, units of measurement, and abbreviations. By the middle 1980s, the ICMJE clearly started to shift its focus to consideration of important ethical issues facing authors and editors.[8] Now, after 30 years, the URM has grown to encompass changes in the ethics of medical publishing, acknowledging the fact that each journal possesses a unique history and has policies that need to be recognized. The URM has also moved toward a tailor-made representation of the actual academic contributions of those who publish in medicine, so that the nature of their exact contributions can be evaluated and verified accurately.

Acknowledgments

Financial/nonfinancial disclosures: The authors have reported to *CHEST* that no potential conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

Other contributions: The authors express their gratitude for the constructive comments of Professor Toshimasa Yoshioka of the Department of Medical Education of Tokyo Women's Medical University.

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