Ethical Issues in Studying Submissions to a Medical Journal

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A protocol to prospectively study characteristics of meta-analyses submitted to a weekly medical journal raised several ethical issues. In submitting a manuscript for publication, authors do not implicitly consent to have their work used for research. Authors must be free to refuse to consent, without it affecting their chances for publication. Systematically analyzing data on manuscript characteristics might influence the decision to publish. Having investigators who are not on the editorial staff or peer reviewers extract the manuscripts’ characteristics breaks the confidentiality of the author-editor-reviewer relationship. In response to these issues, we added a statement to our journal’s instructions for authors that submitted manuscripts may be systematically analyzed to improve the quality of the editorial or peer review process. Authors had to actively consent to participate, but editors and external reviewers were unaware of which authors were participating. The manuscript characteristics were not shared with authors, editors, or external reviewers. The investigators were blinded to each manuscript’s author and institution. After we addressed ethical issues encountered in studying manuscripts submitted to a medical journal, 99 of 105 authors submitting a meta-analysis during the study’s first 24 months agreed to participate.


JAMA is a weekly general medical journal receiving more than 4000 submissions a year with a 10.8% acceptance rate for unsolicited manuscripts. Two meta-analysts (D.F.S. and S.B.T.) approached the journal’s staff proposing a study: editors and external peer reviewers would systematically assess the methodological characteristics of meta-analyses submitted to the journal; then, the meta-analysts would cor-

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relate those characteristics with acceptance for publication. In response, the JAMA editors raised several ethical concerns.

First, in submitting manuscripts for publication, authors do not implicitly consent to have their work used for research. Yet, obtaining consent could be logistically difficult and slow down the review process. In a written survey of JAMA editors, with the inclusion of their names optional, 8 editors indicated that authors should actively consent, 3 indicated that authors might be assumed to consent unless they actively refused, and 1 supported either approach. (We surveyed editors of JAMA only, since that was the study’s site.)

Second, authors must feel free to refuse consent for their manuscript’s use in research, without fear that such refusal would affect their manuscript’s chances for publication. Third, systematically retrieving and analyzing data on manuscript characteristics might delay review or influence the judgment of external peer reviewers and editors. Also, manuscripts included in the study should be assessed the same as those not included. Fourth, sending manuscripts to external experts who are not editors or reviewers would break the confidential author–editor–reviewer relationship.2–4

To address these concerns, we took the following steps. First, we added a statement to our journal’s instructions for authors: “Information from submitted manuscripts may be systematically collected and analyzed as part of research to improve the quality of the editorial or peer review process.” Only those meta-analyses whose authors actively consented to participate were included in the study. A senior editor (R.M.G.) identified all meta-analyses as they were submitted. Corresponding authors were sent a letter inviting their participation, which stated that we were studying editorial decisions about publishing manuscripts, that the author’s consent or refusal to participate would not affect the reviewers’ or editors’ evaluation or decision, and that all information would remain confidential with results reported only in the aggregate.

Second, editors handling manuscripts and external peer reviewers were blinded to whether an individual author was participating. Authors faxed their response to an editor (C.M.O.) who works outside the main JAMA offices and who did not edit or review any JAMA meta-analyses during this study. External peer reviewers were not told that a study was being conducted, as reviewers were not the subject of the study. The meta-analysts (D.F.S. and S.B.T.) did not serve as external peer reviewers for meta-analyses submitted to JAMA during this study.

Third, we changed the protocol to avoid affecting the review process. Instead of editors and external peer reviewers, the meta-analysts (D.F.S. and S.B.T.) extracted the manuscripts’ characteristics. Their findings were not shared with the authors, editors, or external peer reviewers.

Fourth, the meta-analysts were blinded to the manuscript’s source by removing the title page and any other information that might identify authors or affiliations. After the meta-analysts assessed each manuscript independently and resolved any differences by consensus, they returned the manuscript to the JAMA office.

Finally, the Human Subjects Review Office of the Centers for Disease Control and Prevention, Atlanta, Ga, initially reviewed the protocol and consent form. After noting that no human interaction took place, data were not identifiable, no sensitive questions were asked, and the risk to subjects was minimal, they determined that the informed consent was adequate and the protocol was exempt from full review. There is no equivalent to an institutional review board at JAMA or the American Medical Association.

During the first 24 months, 105 meta-analyses were submitted. The authors of 99 agreed to participate. Four actively refused and 2 did not respond to initial or follow-up invitations.

Through obtaining authors’ active consent to participate, keeping editors handling meta-analyses unaware of authors’ participation, maintaining the usual review process, blinding investigators to authors and their institutions, and submitting the protocol to an institutional review board, we responded to ethical issues in conducting a study of unpublished manuscripts submitted to a medical journal. Most authors were willing to participate in this prospective observational research using their submitted manuscripts.

References
2. JAMA Instructions for Authors. JAMA. 1998; 279:67-68.