Emerging ethical issues in instructions to authors of high-impact biomedical journals

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Public interest in issues concerning the maintenance of high ethical standards in the conduct of scientific research and its publication has been increasing. Some of the developments in these issues as reflected in the publication of the medical literature are traced here. This paper attempts to determine whether public interest is reflected in the specific requirements for authors for manuscript preparation as stated in the ‘Instructions to Authors’ for articles being prepared for submission to 124 ‘high-impact’ journals. The instructions to authors of these journals were read on the Web for references to ethical standards or requirements. The ethical issues that the instructions most often covered were specifically related to the individual journal’s publication requirements. The results suggest that while the editors and publishers of the biomedical literature are concerned with promoting and protecting the rights of the subjects of the experiments in the articles they publish, and while these concerns are not yet paramount, they are evolving and growing.

INTRODUCTION

Emphasis on and interest in upholding standards of ethical conduct in the pursuit of high powered scientific investigation is more prevalent and of more concern now than ever before [1]. Scientific misconduct was defined by the U.S. Department of Health and Human Services in 1990 as plagiarism (presenting another’s ideas without attribution); fabrication (presenting unsubstantiated facts or data); falsification (changing or selecting certain data to achieve a desired result, misrepresenting evidence, facts, or authorship); or other serious deviations from accepted practice in proposing, conducting, or reporting research [2]. Today the definition has expanded to include such issues as conflict of interest and protection of patient’s rights.

Standards and requirements for adherence to high ethical principles, in both the conduct and reporting of scientific research, are being instituted by sponsoring agencies, publishers, professional associations, and interested groups. The growth of “big science,” competition for research funding, the commercialization of science, well-publicized reports of scientific misconduct, and legal and governmental interference with the scientific community have combined to create the perception of a need for self-regulation and guidance in the conduct of science and the dissemination of scientific information.

In 1978, a self-appointed group of journal editors formed the International Committee of Medical Journal Editors and issued the technical guidelines for the submission of manuscripts that has come to be known as the “Vancouver style,” or the Uniform Requirements for the Submission of Manuscripts to Biomedical Journals. Their initial guidelines have evolved to include statements on the ethical conduct of authors, editors, and peer reviewers [3]. Supplementary statements on issues surrounding publication ethics include statements on retraction of research findings, confidentiality, competing manuscripts based on the same study, order of authorship, guidelines for the protection of patients’ rights to anonymity, and conflict of interest.

Responding to widely reported and unrelated cases of scientific misconduct, including fabricating data and conducting clinical trials without permission of the university ethics committee, at locations around the world, the editors of the British publications Gut, BMJ, Lancet, British Journal of Anaesthesia, Journal of Bone and Joint Surgery, Annals of Rheumatic Diseases, Pre-Hospital Immediate Care, Journal of Clinical Pathology, and Journal of Medical Screening formed a committee in 1997 to help editors with issues of publication ethics [4]. The prevention, detection, investigation, and punishment of research misconduct are necessary in order for the scientific community to retain its right to self-regulation [5]. The editors formed the UK Committee on Publication Ethics (COPE); this committee has defined the best practice in the ethics of scientific publishing [6]. The guidelines address study design and ethical
approval, data analysis, authorship, conflict of interest, peer review process, redundant publication, plagiarism, duties of editors, media relations, advertising, and how to deal with misconduct.

This paper attempts to determine whether ’high-impact’ journals reflect this interest in the propagation of high ethical standards in the conduct of scientific research and its publication in the specific requirements for preparing manuscripts for submission as stated in the ’Instructions to Authors.’

Development of ethical considerations

Editors and publishers are devoting additional attention to scrutinizing manuscripts to ensure compliance with legal and ethical issues. The American Medical Association Manual of Style: A Guide for Authors and Editors (9th edition, 1998) has an 85-page section titled ’Ethical and Legal Considerations’ [7]. Topics covered include authorship responsibilities; acknowledgements; duplicate publication; scientific misconduct; conflict of interest; intellectual property; confidentiality; protecting individual rights; and defamation and libel. In 1989 (8th edition), these issues were not considered important, and only eight pages were devoted to the same section. The seventh edition (1981) contains the first mention of the ’Uniform Requirements,’ and covers copyright, publication consents, and informed consent. The Stylebook and Editorial Manual (5th edition, 1971) had less than one page in a chapter titled ’General Information and Policy Notes’ on copyright law, patient identification, and photo consent. This was expanded to two pages in the sixth edition (1976).

In 1987, Weller considered the relationship of the contents of a journal’s instructions to authors to its prestige as measured by its ISI Journal Citation Report ranking, appearance on core lists, or minimum circulation. She found that the more prestigious the journal, the more elaborate the instructions, that as the prestige of the journal went up, so did the amount of instructional information provided on peer review, ethical research standards, grant information, and financial disclosure. Weller suggested using consideration of a journal’s editorial policies as reflected in its instructions to authors as a factor for librarians to consider in serial collection management [8].

A 1966 survey conducted by the Boston University Law–Medicine Institute found that most medical journal editors did not see monitoring submissions to their journal for protection of subjects’ rights as one of their responsibilities [9]. In 1970, the Council of Biology Editors issued a recommendation on ’ethical experimentation and the editor’ [10]. The council said that when editors evaluate the acceptability of a report of research on human subjects, they should apply ethical as well as other criteria. They recommended ethical review at the editorial level and proof of institutional review board (IRB) approval.

Brackbill and Hellegers surveyed the editors of the 138 core medical journals listed on the Selected List of Books and Journals for the Small Medical Library for 1997 [11,12]. While most editors reported that they believed that the observance of ethical standards in research is a precondition for publication and that editorial responsibilities include ethical responsibilities, most had no policy with respect to ethical review. In response to Brackbill and Hellegers, Arnold Relman, then editor of the New England Journal of Medicine, expressed skepticism about routine requirements for inclusion of statements about informed consent and IRB approval because it would not by itself screen out unethical research and because enforcement would raise problems [13].

Others believe that it is the function of the journal editor to require that authors sign appropriate declarations and disclosures about authorship, conflict of interest, and ethical treatment of research subjects. This is important because requiring formal statements ‘reminds the research community of the standards that they should observe’ [14]. But Calleigh still believes that this is not sufficient, that only when funding agencies and home institutions link these declarations to their own policies and procedures will they become important enough to deter scientific fraud and ensure the enforcement of ethical procedures in scientific research and publication.

Currently the Council of Science Editors (formerly the Council of Biology Editors) maintains its Editorial Policy Statements on its Website. The council believes that because young scientists are rarely subject to the long-term mentoring by senior scientists that formerly had provided unwritten guidance on science publishing, journal editors are now expected to supply explicit expectations for communicating science in their journals [15]. Editors are responsible for clearly defining and implementing the journal’s ethical standards regarding duplicate publication, ethical standards in research, etc., and are responsible for monitoring possible failures to meet these standards. Henry R. Cowell, now editor emeritus of the Journal of Bone and Joint Surgery, claims that the editorial process is now widely accepted as the control mechanism for preventing scientific misconduct and preventing the publication of material that evidences scientific misconduct [16].

Other papers have reviewed instructions for authors looking for guidelines on specific ethical issues. Krimsky and Rothenberg determined the extent to which scientific and biomedical journals have adopted conflict of interest policies and whether the journals that have such policies publish their authors’ financial interest disclosure statements [17]. They found that in 1997, 16% of 1,396 highly ranked scientific and biomedical journals had such policies in effect, but that less than 1% of the articles published that year by those journals included any disclosures of author personal financial interest.

Amdur and Biddle determined whether the instructions to authors in the 102 English-language biomedical research journals listed in the 1995 Abridged Index Medicus required that manuscripts being considered for publication indicate that the studies that involved human subjects had institutional review board (IRB) approval [18]. They found that just under half (47%)
of the journals required a statement of IRB approval as a prerequisite for publication and that 24% did not make any reference to human research ethics. The presentation of guidelines for ethical standards for human research other than IRB approval was extremely variable, as were the methods of documenting IRB approval.

Asai and Singu examined eleven English-language journals from the Anesthesiology section of the 1995 Science Citation Index Journal Citation Report to see whether the instructions to authors of these journals included ethical considerations [19]. They found that all 11 addressed issues concerning avoidance of redundant publication and unjustifiable authorship; 10 required institutional approval of studies and signatures from all authors; 8 mentioned informed consent; and 7 required the disclosure of any conflict of interest and protection of patients’ privacy. A comparison of the instructions appearing in 1998 to those printed in 1995 showed that the instructions had become more comprehensive and that more of the journals addressed ethical points.

Informed consent in studies involving the aged was also reviewed [20]. Olde Rikkert and colleagues examined 586 articles that reported research on humans. They selected articles from the 1993 and 1994 issues of the four journals with the highest impact in the category Geriatrics and Gerontology from the 1995 Science Citation Index. The authors looked for whether informed consent procedures and approval of an ethics committee were mentioned. They found that the frequency with which information on informed consent and approval of an ethics committee was given was low, 29% and 21% respectively. None of the four journals specifically included such requirements in their instructions for authors.

Olson and Jobe determined how frequently reports in the literature about human cardiopulmonary resuscitation mention approval of a research ethics committee and address subjects’ consent [21]. Of the 47 studies reviewed, 51% mentioned committee approval and 26% addressed subjects’ consent. They concluded that authors were more likely to report consent, committee approval, or both when journal instructions require that approval be mentioned. The next year, the same authors wrote that inclusion of IRB approval and subjects’ consent in journals is improving, as more journals require it [22]. Olson and Jobe believe that journal editors and reviewers can and should ensure compliance with the requirements of their journals.

Probyn and Asch found the opposite, that editors cannot or do not enforce authors’ compliance with the rules of their journals. In November 1997, the journal Radiology revised its guidelines for authors so that each author was required to identify those parts of the manuscript for which he or she was responsible. Probyn and Asch determined whether these changes in guidelines for authors affected the number of authors per article by analyzing number of authors per article for eleven issues of the journal before the changes were made and eleven after [23]. Since the number of authors per article did not significantly decrease, Probyn and Asch concluded that authors continue to take credit for articles in which they have very little involvement.

The frequency of obtaining IRB approval and informed consent in critical care research was examined by Matot and colleagues [24] in a one-year retrospective review of original critical care research published in seven journals. The instructions to authors in all of the journals reviewed included a requirement that submitted manuscripts must state that the study was approved by the authors’ institutional human investigation committee or IRB and that informed consent be obtained from all subjects. In 24% of the 279 studies examined there was no evidence of IRB review or informed consent approval; in 13% IRB approval was obtained but the method of consent not specified. The authors of that study cited earlier work that reported that 89% [25] and 55% [26] of studies of emergency medical research lacked evidence of IRB approval and noted the improvement in reporting in their study. They believe that further increases could be achieved by including more precise criteria in instructions for authors, specifically addressing the types of studies or research protocols that require IRB approval and informed consent.

Karlawash and colleagues investigated whether published articles complied with four common standards for research involving nursing home residents or the cognitively impaired: justification of the use of this population; IRB review; nursing home committee review; and informed consent [27]. They found that while these basic standards of research ethics were not reported consistently, the requirements contained in a journal’s instructions for authors or other features of peer review and editing did affect the quality of reporting research ethics. Their study revealed that compliance with research ethics was reported more often when it was specifically required by the publishing journal’s instructions for authors.

The ethical issues included in instructions to authors in Brazilian medical journals have also been examined [28]. Out of 29 journals, 79% contained no recommendations related to ethics. Only 15 wanted the required ethical information to be included in the text, and 2 wanted a letter from the authors about how ethical standards were followed. Sardenberg and colleagues concluded that Brazilian scientific journals showed little concern for the ethical aspects of scientific research in human subjects and that the ethical recommendations of those few journals that do require them are very different from other recommendations.

The frequency of reporting informed consent and IRB approval in all reports of clinical trials published between 1993 and 1995 in the New England Journal of Medicine, Lancet, JAMA, and BMJ was also assessed [29]. Of reports on 767 clinical trials, 70.8% included a statement of IRB approval, and 79.8% reported that informed consent had been obtained from participants. This survey shows higher rates of compliance with ethical guidelines than others. To the authors
these results suggest that even the most prominent medical journals need to pay closer attention to the conduct of clinical research, as well as to the reporting of its ethical aspects.

Scheetz, with the Office of Research Integrity, performed a content analysis for research integrity issues in “Instructions to Authors” of 41 journals that had published articles between 1992 and 1999 that were subject to findings of misconduct. She found that the journals provided minimal guidance on these issues. Thirty-two “content themes” found in the instructions were grouped into ten primary categories: copyright practice, authorship, reference practices, publishing practices, financial disclosure, peer review, human research, animal research, correcting literature, and research misconduct. Only three (7%) of the journals included all ten categories in the instructions, most (58%) contained four or fewer of the categories, and four did not include any of them [30].

An editorial in JAMA by Rennie and Yank discussed the relationship between the guidelines of the Declaration of Helsinki and the “Uniform requirements” [31]. The Declaration of Helsinki provides rules for the ethical conduct of studies with human studies and requires that articles that do not conform to these rules not be published. The authors believe that this implies that journals have a duty to confirm that research was conducted accordingly and it also suggests that they have a strong interest in promoting ethical research practices. However, the uniform requirements do not state that journals have an ethical imperative to publish only research consistent with Helsinki or that the researcher must have abided by ethical rules. The uniform requirements focus on what the researcher should write about ethical rules: “When reporting experiments on human subjects, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration.” So, it simply mandates that authors’ state whether or not their procedures were in accordance; there is no attempt to tell authors how to design, implement, or report on safeguards for human subjects.

Rennie and Yank agree with Amdur and Biddle that editors should standardize their ethical requirements for publication and make these requirements very explicit. Journals should explicitly state in their instructions to authors that manuscripts will be considered for publication only if the research described meets the ethical standards for human experimentation laid out in the Declaration of Helsinki.

Drummond Rennie, who has been associated with the editorial boards of both JAMA and the New England Journal of Medicine, said, “The fact is that if editors demand strict standards of reporting as a condition of acceptance, investigators will meet those standards, and the standards will become the norm for how science is conducted” [32].

**Current status of ethical considerations**

On the basis of impact factor (Table 1), 124 journals were selected from the 1999 Journal Citation Reports (JCR) Science Edition. The Institute for Scientific Information, publisher of JCR, designed the impact factor as a measure of the frequency with which the “average article” in a journal has been cited in a particular year. The impact factor was created to help evaluate a journal’s relative importance, especially when compared to others in the same field. Impact factor is calculated by dividing the number of current citations to articles published in the two previous years by the total number of articles published in the two previous years.

During the month of April 2001, the Websites of all 124 journals were checked for their instructions to authors. The instructions were read for references to ethical standards or requirements. Thirty-one different items were identified as being ethical issues raised in the instructions for authors. Table 2 shows these issues grouped in six broad categories.

Four of the 124 high-impact journals made no reference to ethical guidelines in their instructions to authors: Brain Pathology, Genes to Cells, Journal of Cognitive Neuroscience, and Nature Medicine (see Figure 1). A requirement to follow the “Uniform Requirements” was included in 27 of the journals. Of the 124 journals, 61 included some type of guideline concerning the protection of patients’ rights, and 40 included some type of guideline concerning the protection of experimental animal subjects. Guidelines on professional cooperation (depositing materials in appropriate databases/databases and sharing research materials) were given by 64 of the journals. Guidelines on author conflict of interest were specified in 66 of the journals. Ethical issues regarding publication included prohibition of prior publication and simultaneous submission; prohibition of fragmentation of research; requirement that only original research material and data be submitted; and requirement that authorships be verified and publication permissions obtained. At least one of these areas of ethical concern was included in the instructions to authors of 109 of the 124 journals.

**DISCUSSION OF CURRENT STATUS**

This paper attempts to determine whether current interest in the maintenance of ethical standards in the conduct of scientific research and its publication is reflected in the specific requirements for authors for manuscript preparation as stated in the instructions to authors for articles being prepared for submission to “high impact” journals. A review of the Web-based instructions for authors for 124 high impact biomedical journals found interest in many areas of ethical concerns. The area of ethical concern that more of the journals, 87.2%, included in their instructions to authors was publication ethics. Human rights and animal welfare issues were covered by a significantly smaller percentage, 48.8% and 32% respectively. Even as publicly visible a topic as conflict of interest was covered by only 58.8% of the journals investigated. Only 51.2%, of the journals, encouraged their contributing authors to act collegially and share unique research materials and
these results raise the question of whether editors and publishers of the biomedical literature are more concerned about the image of their journals, that they be perceived as untainted by conflicts of financial and professional interest, plagiarism, and priority of publication than they are about protecting and promoting the rights of the subjects of the experiments for which they publish the methods and results. Perhaps is it simply a matter of where we currently stand in the development and expression of public concerns about ethical issues in research and publishing as expressed in instructions to authors.

In September 2001, twelve prominent medical journals, including *Annals of Internal Medicine*, the *New England Journal of Medicine*, *Lancet*, and *JAMA*, issued a joint editorial announcing a uniform policy of rejecting manuscripts submitted by authors who do not have control over either the data or the decision to publish. The editorial expressed concern that “the current intellectual environment in which some clinical research is conceived, study subjects are recruited, and the data analyzed and reported (or not reported) may threaten this precious objectivity” [33]. The Association of American Universities and the Association of American Medical Colleges also announced new guidelines on financial conflicts of interest in clinical research in late 2001 [34,35].

With the recent questions raised about freedom of information in the context of the anthrax bioterrorism incident of fall 2001, we see that the ethical issues in science, including those found in instructions to authors in major biomedical journals, continue to occupy a significant place in the public’s perception of the role of the scientist researcher. To ensure that this role con-
Emerging ethical issues

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<td><strong>2. Protecting patient rights</strong></td>
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<td>a. NIH Guide for the Care and Use of Laboratory Animals (NIH Pub. No. 85-23 revised 1985)</td>
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<td>d. Authorship</td>
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<td>e. Original data or material only</td>
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<td>f. Complete studies only, no fragments</td>
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<td><strong>6. Professional cooperation</strong></td>
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Continues to be perceived in a positive light, as a profession of people concerned with the improvement of the welfare of their fellows, journals and their editors must continue to improve and, more importantly, enforce the ethical guidelines published in the instructions to authors contributing to their journals.

However, scrutiny by editors and publishers may not be enough. In December 2001, the U.S. government’s General Accounting Office (GAO) issued a report that found that federal rules on conflicts of interest in biomedical research are inadequate [36]. Specifically, the GAO investigated how five universities that are among the top recipients of federal research funds are implementing Department of Health and Human Services (HHS) regulations governing investigators’ financial interests, policies, and procedures concerning institutional financial conflicts of interest, and how implementation of HHS regulations is affecting the integrity of research and the safety of human research subjects. The GAO found that universities do not systematically monitor how investigators comply with conflict-of-interest policies, do not keep well-organized records about conflicts of interest, are confused about when to report conflicts of interest, and do not consistently inform institutional review boards (IRBs) about conflict-of-interest disclosures or how such conflicts have been resolved.

While the GAO report did not address the role of journals and their editors, they found that the federal regulations that give universities much of the responsibility for monitoring conflicts of interest involving biomedical researchers must be strengthened and recommended additional legislation to resolve these issues [37]. One of the first actions of the Bush Administration in 2002 was to issue proposed new guidelines that govern the quality and objectivity of scientific information released by federal agencies [38]. These guidelines could mandate “additional quality checks beyond peer review” of federally funded research [39]. This action reflects the sense of responsibility for reassuring the public that scientific research, especially that funded by the federal government, is indeed, of high quality, objective, useful, and accomplished and published with integrity.

The results of this survey of the ethical issues included in the instructions to authors suggest that both commercial and nonprofit journal publishers, their editors, and their editorial boards have not sufficiently responded to the public concern with scientific integrity and publicity about scientific misconduct. Journals
should be more proactive in their attempts to influence standards of scientific conduct and publication by giving high visibility to publishing ethical guidelines for research in their instructions to authors. It is imperative that they do so in order to maintain the integrity of their publications and to ensure that enforcement of the proper conduct of science remains within the scientific community.

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