

Editorial policy in reporting ethical processes: A survey of ‘instructions for authors’ in International Indexed Dental Journals

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Abstract

Background: The International Committee of Medical Journal Editors expects authors to report if their studies were carried out in accordance with the International Ethical Guidelines and Declaration of Helsinki; and inform readers regarding the same. **Aims:** To determine the proportion of International Indexed Dental Journals reporting on ethical clearance for human and animal research, obtaining of informed consent and / or assent, and the conduction of research in accordance with the Declaration of Helsinki and International Medical Research, 2006. **Settings and Design:** A cross-sectional survey of ‘instructions for authors,’ for analysis of editorial policy on ethical processes, was done. **Materials and Methods:** One hundred and twenty-six dental journals (which included 50 general and 76 specialties) were reviewed for reporting, with regard to the Ethical Committee Approval for human and animal researches, obtaining of informed consent / assent from the research participants, and research in accordance with the Declaration of Helsinki as well as International Medical Research 2006 were analyzed. **Statistical Analysis Used:** Descriptive statistics was used and results were expressed in percentages. **Results:** Of the 126 dental journals, 57 (45.23%) reported having obtained approval from the Ethics Committee, 33 (26.19%) were instructed about the Animal Ethics Committee approval, and 38 (30.15%) insisted on obtaining and reporting informed consent / assent. 41 (32.53%) journals expected authors to mention the research being conducted according to Declaration of Helsinki and 3 (2.38%) journals required researches to be conducted in accordance with International Medical Research, 2006. **Conclusions:** A significant proportion of international indexed dental journals did not provide instructions to authors to report on the ethical approval, informed consent and / assent, and research conduction according to the Declaration of Helsinki as well as the International Medical Research, 2006.

Keywords: Authors, ethics, publication, research

Introduction

“Reports of experimentations not in accordance with the principles laid down in this Declaration should not be accepted for publication.” From Principal 27, Declaration of Helsinki

The horrifying inhuman activities in the Nazi Concentration Camps and Nuremberg Trial during Hitler’s regimen, Buchenwald Concentration Camp during World War II, Tuskegee Syphilis Trial in Alabama, Thalidomide Tragedy are some of the events which spurred the world to lay down a certain code of conduct for undertaking research. The first

global document was ‘the Nuremberg code,’ which formed the foundation for researches to be conducted in a scientifically and ethically correct manner. In 1964, the first body of doctors under the World Medical Association (WMA) geared researchers through its Declaration of Helsinki (DoH),^[1] the three principles to be implemented on the research subjects. First being respect for the research subject, second principle stresses on beneficence, and the third on justice.

Under subsequent amendments and updates, the two protection measures that are concentrated upon during research involving human subjects are, providing informed consent after having understood the risks and benefits associated with the study; and the study protocol has to be evaluated and sanctioned by a disinterested body termed as the Institutional Ethics Committee (IEC) or Independent Review Board (IRB); and the Declaration of Helsinki expects publishers not to publish reports of experimentation that do not follow the principles laid down in the declaration.^[2] In countries like Australia and the USA, there is a Scientific Affairs Committee on Animal Research and Ethics (CARE) that endeavors humane consideration for the well-being of animals incorporated into the study design and conduction of all experiments, keeping in mind the primary goal of experimental procedures — the acquisition of sound, replicable data. Therefore, requisite of clearance report from the Animal Ethical Committee (AEC) of the institution / National Research Council / any national law, on the care and use of laboratory animals involved in studies is mandatory.

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Access this article online	
Quick Response Code:	Website: www.contempclindent.org
	DOI: 10.4103/0976-237X.83066

In fact, the International Committee of Medical Journal Editors (ICMJE)³¹ expects the authors to indicate whether the procedures followed were in accordance with the ethical standards laid out by the responsible committee on human experimentation (institutional or national) and with the DoH as well as the AEC, for animal experiments. Hence, a study was carried out to determine the editorial policy in reporting ethical processes for research studies in international indexed journals, by surveying the 'Instructions to authors'.

Materials and Methods

The study protocol was submitted to the Institutional Ethics Committee for clearance. The committee opined that its permission was not necessary as it did not constitute biomedical research. A cross-sectional survey of the International Indexed Dental Journals was done on the website of the Science Citation Index Expanded Journal List, Science Direct, Cochrane Library, Directory of the Open Access Journal, and Pubmed, between the calendar year June and October 2010. The Print and online contents of 'instructions to authors' were searched for, to ascertain the policy of the journal requiring acceptance of trails on human as well as animal subjects. Descriptive statistics were used to refer the following and results were expressed as percentages.

- Obtaining ethical clearance from the Institutional Ethics Committee or the Independent Review Board
- Obtaining informed consent and assent from parents / guardian of the research participants⁴¹
- Obtaining ethical clearance from the Animal Ethics Committee / National Law
- Research in accordance with the Declaration of Helsinki and / the International Medical Research, 2006

Results

A total of 126 journals were indexed in the above-mentioned citations. Out of these 50 were General Dentistry Journals and 76 were Specialty Dental Journals.

Ethics committee's approval

Ethics committee approval (ECA) either from the IEC/IRB was considered. As shown in Table 1, 57 / 126 (45.23%) reported ethical approval. The corresponding figures for the General and Specialty Dental Journals were 24 / 57 (42.10%) and 33 / 57 (57.89%), respectively. The author was instructed to mention the approval in the manuscript.

Animal ethics committee's approval

As shown in Table 1, 33 / 126 (26.19%) insisted on obtaining approval from the animal ethics committee (AEC); 14 / 33(42.42%) of the general and 19 / 33 (57.57%) of Specialty Dental Journals instructed the authors to report the approval in their publication.

Informed consent / assent

Thirty eight out of one hundred and twenty six (30.15%) dental journals instructed the authors to obtain informed consent from the participating subjects and assent from the parents or lawful guardians of children aged seven years or above. However, the instructions did not clarify whether the consent had to be verbal or written. Although, it is preferred to document written consent forms. As shown in Table 1, 27 / 38 (71.05%) Specialty and 11 / 38 (28.94%) General dental journals made it mandatory to report the Informed Consent / Assent.

Perhaps, one general journal, that is, the 'Dental Update,' demanded the copy of the written permission letter of the subject to be provided to the editorial board in case of publication of a photograph.

Reporting Declaration of Helsinki / International Medical Research 2006

Forty four out of one hundred and twenty-six (34.92%) journals expected the research to be conducted in accordance with the DoH (41 / 126) and International Medical Research 2006 (3 / 126). As shown in Table 1, 29 / 41 (70.73%) Specialty and 12 / 41 (29.26%) General dental journals instructed authors to report the relevant statement regarding the same.

Research conduction according to the International Medical Research 2006 was preferred in 2 / 3 (66.6%) of Specialty and 1 / 3 (33.3%) of the General Dental journals.

Discussion

The International Committee of Medical Journal Editors (ICMJE)³¹ recommends authors to mention about the experimentation being done in accordance with standard ethical procedures and DoH.¹¹ It is observed in this study that a vast majority (one-third) of indexed international dental journals do not mention the ECA and approximately three-fifth did not refer to AEC, IC / Assent procedures.

Table 1: Number of Indexed International Dental Journals following ICMJE* requirements

Total Indexed International Dental Journals	126		General	50	39.68%
			Specialty	76	60.31%
Ethical Committee Approval	57	45.23%	General	24	42.10%
			Specialty	33	57.89%
Animal Ethics Committee Approval	33	26.19%	General	14	42.42%
			Specialty	19	57.57%
Informed Consent and Assent	38	30.15%	General	11	28.94%
			Specialty	27	71.05%
Declaration of Helsinki	41	32.53%	General	12	29.26%
			Specialty	29	70.73%
International Medical Research 2006	3	2.38%	General	1	33.33%
			Specialty	2	66.66%

*ICMJE — International Committee of Medical Journal Editors

Although these dental journals are internationally indexed, the importance of its signatory to the ICJME policy cannot be neglected.

The responsibility to ensure that research is conducted ethically rests with a number of individuals, including investigators, sponsors, Research Ethics Committees (RECs), journal editors, participants, and the public. A particularly powerful mechanism to encourage ethical research is the requirement stipulated by leading international bodies of journal editors^[3] that authors include in their manuscripts submitted for publication, written statements confirming that REC approval and informed consent has been obtained before commencement of the research.

All and any research on humans must be preceded by permission from an Ethics Committee. The type of research could be prospective or retrospective, could be an invasive experimental study involving a new drug or new device (or even an old drug or device) or a 'simple' questionnaire-based study, in normal subjects or in patients, a study looking at a histopathology specimen or serum samples, a company-sponsored project or a Government-sponsored one, an academic project or a student's thesis. Unfortunately, it has been found in this study that only 45.23% of various dental journals mentioned about ECA; significantly less often in General (42.10%) and Specialty (57.89%) dental journals.

The World Medical Association recommends that greater care be taken while enrolling a population for research study and advocates the provision of additional safeguards.^[1] Our study unearthed a relatively less reported fact (30.15%) of the published journals informing readers about informed consent / assent. Informed consent implies that discussions are taking place about the basic elements, including the nature of the decision / procedure; reasonable alternative to the proposed intervention; the relevant risk, benefit and uncertainties related to each alternative, an assessment of the patient's understanding; and the acceptance of intervention by the patient.^[5] There is also emphasis on reporting the assent from child participants, who are not a homogeneous population. Older children and adolescents, depending upon their cognitive abilities, might be able to understand important aspects of research, and hence, their assent is required to be taken.

The Declaration of Helsinki ensures protection of patient's rights and privacy; and only 32.53% of the dental journals stressed on the conduction of the research in its accordance. However, it must be conceded that the situation is unique and even a majority of the international indexed journals demonstrate lacunae.^[6,7] It is the editor's duty to ensure that reports of clinical trials state that research has been conducted in accordance with the Declaration of Helsinki or International Medical Research 2006 (which reports to be

only 2.38% in this study) or such other guidelines, and that research has been carried out after ECA and enrollment has been done after obtaining IC.^[8] Reporting on these crucial issues should be considered as a minimum requirement, as it serves to assure readers and the general public that research is being carried out in conformity with basic principles, namely, respect for individuals, beneficence, and justice. These findings raise interesting questions regarding the responsibility of journal editors in the chain of ethical protections, that is, should journal editors be the final arbitrators of ethical research and is the existing focus on documentation of informed consent and REC approval a reasonable and adequate reflection of important ethical concerns facing international biomedical research?

Surprisingly, the growing literature in the dental field illustrates [Table 1] low levels of documentation of basic ethical safeguards, namely, ECC approval, AEC approval, informed consent, and DOH Guidelines by the editorial board. Importantly, as the authors' caution, failure to document the ethical section in a journal article does not necessarily imply that the research was unethical, nor is it evident that researchers failed in their ethical obligations or that participants were put at risk, but it is a clear reflection of the actual failure of compliance during the conduction of a study.

As the instructions provided by several journals are deficient, editors could first concentrate on updating them by asking authors to include an 'ethics section' under 'Material and Methods'. This section can be used to describe ECA, provision for IC, and conformity to the DoH and guidelines of the International Medical Research 2006 on Human Participants and Animal Ethics Committee on animal study designs. Other measures such as providing checklists for authors and reviewers to ensure compliance with reporting of ethical processes could also help. The journals could consider providing links to the Declaration of Helsinki, AEC Guidelines, and so on, from the journal website.

Perhaps, if editors believe they have a meaningful role in promoting ethical research, they should look at extending the existing yet narrow reporting requirements to include other equally important indicators of ethical research, especially in a time of globalization of clinical research.^[8] Editors need to identify ethical indicators specifically relevant to international research, and alternatively if appropriately operationalized as current benchmarks,^[9] it might serve this purpose for real. Finally, to be effective gatekeepers, editors must ensure consistent and uniform application of reporting guidelines for ethical research outlined in their instructions to authors, underlined by the international governing bodies. Only once the authors know for sure that publication is conditional on documentation of the basic ethical practices, are they likely to comply fully with the journals' reporting requirements.

In conclusion, this study suggests that journals improve on these aspects by ensuring that reporting these procedures is made mandatory and included in the 'Instructions to Authors.' A checklist could be devised that would remind authors, reviewers, and editors about reporting the ethical procedures. There may also be a need to educate researchers and reviewers regarding the importance of reporting on these issues. Journals could also provide links to sites providing national and international guidelines concerning the conduct and reporting of research. Indeed, if publications were conditional on such compliance, editors would become the ultimate gatekeepers of ethical research.

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How to cite this article: Navaneetha C. Editorial policy in reporting ethical processes: A survey of 'instructions for authors' in International Indexed Dental Journals. *Contemp Clin Dent* 2011;2:84-7.

Source of Support: Nil. **Conflict of Interest:** None declared.