

Reporting of Ethical Issues in Indian Physiotherapy Journals

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INTRODUCTION

Reporting of ethics related issues during publication not only gives credibility to the study but also increases the confidence of the readers and public. The first guideline of the Nuremburg code makes it clear that voluntary consent of the human subject is absolutely essential for research.¹ Principle B-15 of the Helsinki Declaration (2008) emphasizes that a research study should be submitted for consideration, comment, guidance and approval of an ethics committee. Principle B-30 of the Helsinki Declaration (2008) also mentions that the author is responsible for the completeness of the report. It also mentions that studies which have not been conducted in accordance with the Helsinki Declaration should not be accepted for publication.² Editors have a large responsibility ensuring that only research conducted in the most ethical manner is published.

ABSTRACT

Background: Reporting of ethical issues in published articles not only improves the credibility of the journal and its published articles but also increases the confidence of the readers and general public.

Purpose: The current study aimed to determine the current prevalence of reporting ethical issues in Indian Physiotherapy journals.

Materials and methods: Two physiotherapy journals, the *Journal of Indian Association of Physiotherapists* (JIAP) and *Indian Journal of Physiotherapy and Occupational Therapy* (IJPOT) were searched for articles on human participants. The ethical issues expected to be reported were; ethical committee clearance, informed consent, photograph consent, and acknowledgements. Out of total 73 studies identified, 53 studies were from IJPOT (2007-2008) and 20 studies were from JIAP (2005-2008) and were included for final analysis. Analysis was done descriptively using percentiles for each of the four ethical issues.

Results: Ethical committee clearance was mentioned in 14/73 studies (19.17%); informed consent in 38/68 studies, assent in 3/6 studies (50%), picture consent in 1/5 studies (20%), parent/guardian consent in 4/8 studies (50%) and acknowledgements in 8/73 studies (10.95%).

Conclusion: The poor status of ethical reporting and lack of proper guidelines were evident in our findings. There is an immediate need for improving the situation considering the international reporting guidelines for research ethics.

Key words: Physiotherapy, Publication, Ethical issues, Reporting.

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Key points and pre-publication history of this article is available at the end of the paper.

Short Communication

The International Committee of Medical Journal Editors (ICMJE), in their "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication", have mentioned that when informed consent has been taken, it has to be reported in the published article.³ The same can be applicable for ethics committee clearance. The guidelines also go on to mention that anyone who has assisted in the study design, data collection, analysis of data and manuscript preparation but have not qualified for authorship, should be acknowledged in the publication. The ethical guidelines for biomedical research on human participants published by the Indian Council of Medical Research (ICMR) in 2006 mentions that if photographs are used in published articles, appropriate consent should have been obtained.⁴

The ethical guidelines for social science research in health published by the Center for Enquiry into Health and Allied Themes (CEHAT), Mumbai, India also mention that the publication should mention how ethical guidelines were followed.⁵

In other studies considering whether these standards have been met, we found variable results. Olsen *et al.*⁶ reviewed 43 articles related to interventional research in human cardiopulmonary resuscitation and reported that 51% mentioned ethical committee

approval and 26% addressed subjects' consent. Miguel Ruiz-Canela *et al.*⁷ studied 767 clinical trials and found that the proportions of not reporting informed consent and ethics committee clearance was 19.8% and 29.2% respectively. Another study by Bauchner *et al.*⁸ reviewed articles related to child health research from five leading journals and reported that 340 articles out of 560 (61%) reported ethic committee approval. Veronica Yank *et al.*⁹ reviewed 300 articles published before 1997 and 300 articles published after 1999. They found that informed consent was not mentioned in 26% of articles published before 1997 and in 18% published after 1997. In the same study, ethics committee clearance was not mentioned in 31% before 1997 and 18% published after 1997. Meschia *et al.*¹⁰ found that out of 41 articles related to genetics studies of stroke, 29% did not report informed consent and 37% did not report ethics committee clearance. A study by S. Schroter *et al.*¹¹ conducted in March 2003 found that only 31% of the manuscripts mentioned ethics committee approval and only 47% mentioned consent. A previous study by Henley *et al.*¹² reviewed 806 articles in six physiotherapy journals published between 1996 and 2001 and found that only 48% documented ethics committee approval and informed consent. Bavdekar *et al.*¹³ studied 132 manuscripts in two Indian pediatric journals and found that only 29.53% reported ethics committee

clearance and only 8% reported informed consent and assent. Chaturvedi *et al.*¹⁴ reviewed 157 articles from the *Indian Journal of Psychiatry* and reported that 64% mentioned obtaining informed consent and only 15% mentioned ethics committee permission.

The *Indian Journal of Physiotherapy and Occupational Therapy* started publishing physiotherapy research from 2007 onwards in its quarterly journal. The *Journal of the Indian Association of Physiotherapists* has been publishing physiotherapy research since 2005 and is a biannual journal. Whether the ethical issues are reported in the Indian physiotherapy journals is not clear and to date, there is no research, study or documentation available in this regard. Hence, this study aims to determine the incidence of reporting of ethical issues in Indian physiotherapy journals and discover if editorial policies mandate the submission and publication of ethics related information.

METHODOLOGY

This study protocol was submitted for ethics committee review and was exempted from review since human participants were not involved and the published articles were in the public domain.

A total of 73 articles were reviewed from both the *IJPOT* and *IAP* journal. Articles were included if they involved human participants

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and their information in the form of case records or databases. Reviews and studies that did not involve human participants were excluded from the study. All types of study designs were included in the study.

The authors distributed the articles among themselves and reviewed them against a check list which included the mention of ethics committee clearance, informed consent or parent/guardian consent, assent, picture consent and acknowledgements. Reporting for the above ethical issues was accepted if it was mentioned anywhere in the article.

Reporting Ethics Committee Clearance

This was accepted as reported if the words "ethics committees" were mentioned.

Reporting Informed Consent

Informed consent was understood to have been reported if it was mentioned in the article.

Reporting Assent

Studies which involved participation of children were expected to report if "assent" had been taken from the children or not.

Reporting Parental/Guardian Consent

Studies which involved research on infants and others who were not in a position to give consent or assent were expected to have reported "consent from parents or guardians".

Reporting Photograph Consent

Covering the eyes of the participant was not accepted as that does not satisfy the confidentiality of the participant. Informed consent should have been taken from the participants and it should be mentioned in the article. The manuscript should have been shown to the participant before sending for publication.

Reporting Acknowledgement

It is the opinion of all the authors of this study that it is not possible to conduct research without the assistance of other research personnel and technical staff and this contribution should be acknowledged even if these contributors do not qualify for authorship. Many study participants suffer loss of time and work hours while participating in research. We felt that it would always be worthwhile to acknowledge all the study participants.

RESULTS (figure-1)

Excluding reviews and studies that did not involve human participants, 53 articles, published during the years 2007 and 2008, were reviewed. All 53 studies involved human participants and required reporting of ethics committee clearance. However, only 11 (20.75%) of the articles mentioned that they obtained ethics committee clearance (Table-1).

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Excluding reviews and studies that did not involve

human participants, 20 articles, published between 2005 and 2008 were reviewed. One study that included animal experimentation was included; 19 studies involved human participants and required reporting of ethics committee clearance. However, only three (15.78%) of the articles mentioned that they obtained ethics committee clearance. The study involving animals required mentioning animal ethics committee clearance but it was not reported.

From the 19 studies that required informed consent, it was reported in only five (26.4%) of the studies. There were two studies where children were research participants and neither of these studies reported obtaining this assent. Four studies were conducted on infants and required parental consent but none of these mentioned that parental consent was obtained. Photographs of study participants appeared in one study and that study did not report obtaining photograph consent. Out of the 20 studies reviewed, only four (16%) mentioned acknowledgement of any kind (Table-2).

DISCUSSION

The results of this study are similar to other studies of similar nature conducted in the past,⁶⁻¹³ Of the 73 articles included in this study, which needed ethics committee approval, only 19.17% of the articles reported approval. Informed consent was required in 68 of these studies

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Table-1. Comparison of reporting ethical issues between the two Indian Physiotherapy journals

Ethical issues	Indian Journal of Physiotherapy and Occupational Therapy N = 53			Journal of Indian Association of Physiotherapists N = 20		
	Required	Mentioned	Percentage	Required	Mentioned	Percentage
Institutional ethics committee	53	11	20.75	20	3	15
Informed consent	49	33	67.34	19	5	26.4
Assent	4	3	75	2	0	0
Picture consent	4	1	25	1	0	0
Parent/guardian consent	4	4	100	4	0	0
Acknowledgement	53	4	7.5	20	4	20

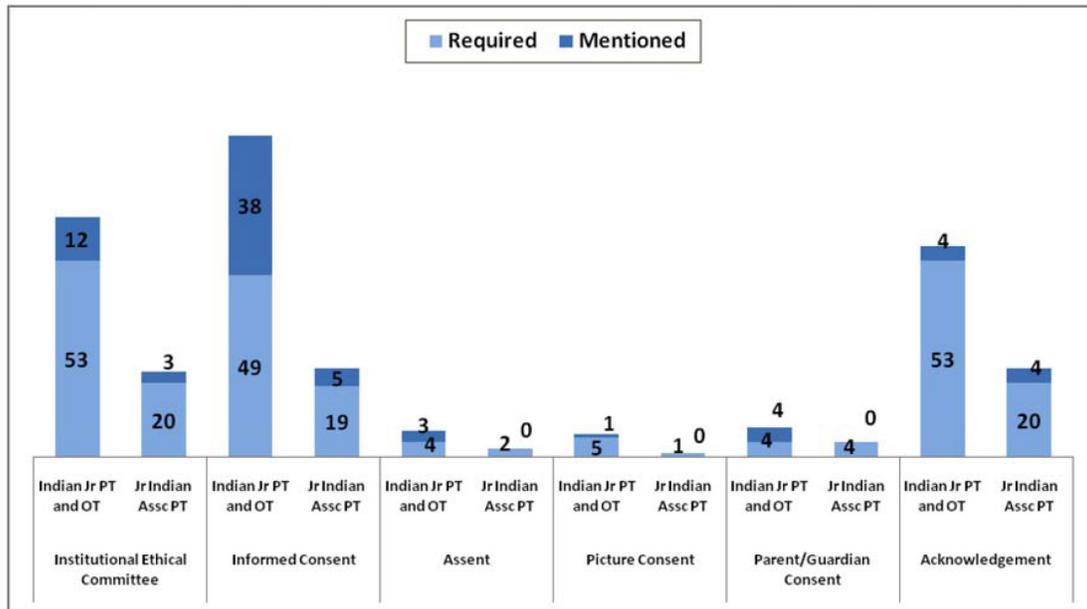
Table-2. Reporting of ethical issues in the both Indian journals (combined).

Ethical issues	Both Indian Physiotherapy Journals (Combined) N = 73		
	Required	Mentioned	Percentage
Institutional ethics committee	73	14	19.17
Informed consent	68	38	55.88
Assent	6	3	50
Picture consent	5	1	20
Parent/guardian consent	8	4	50
Acknowledgement	73	8	10.95

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Figure-1. Comparison of reporting ethical issues between the two Indian Physiotherapy journals- *Indian Journal of Physiotherapy and Occupational Therapy* (Indian Jr PT and OT) and *Journal of Indian Association of Physiotherapists* (Jr Indian Assc PT)



but was reported only in 55.88% of articles; assent was required in six studies and reported in 50% of studies; picture consent was required in five studies and reported in 20% of articles; parental or guardian consent was required in eight studies and only 50% reported it; and acknowledgements of any kind were mentioned in only 10.95% of the 73 articles. The results of this study are similar to other studies of similar nature conducted in the past.⁶⁻¹³

One article analysed in our study mentioned that permission was obtained from a "University Committee" and another mentioned that the "research committee" approved the study. Both these studies were assumed not to have reported ethics

committee review since it is not known if the review process involved ethics related issues.

Some terminologies that were reported in the articles and that were considered as having not reported obtaining informed consent are: (a) Willing to give consent; (b) Volunteers participated in the study; (c) Volunteered to participate; (d) Subjects option to participate or not; and (e) If they could not give informed consent they were excluded from the study. The abovementioned reporting methods do not state clearly if informed consent was obtained or not and were included in the analysis as not having reported obtaining informed consent. A patient may volunteer to be a study

participant for fear of being denied care, under duress or due to coercion. It is also not clear from these statements if participants were fully informed about the study and consent was obtained. Another study reported "Blanket consent" which was not acceptable by the authors as equivalent to informed consent as we felt that informed consent should have been taken from the parents or guardians. Some published studies had photographs of study participants but did not mention obtaining consent for using the photographs in the manuscript.

A large number of the articles published did not mention ethics related issues. Instructions to authors and editorial guidelines play an

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important role in authors reporting ethics related issues. When the authors started the study in December 2008, *IJPOT* had an "instruction to authors section" in which there was clear mention that no study would be published without ethics committee clearance. However, the instructions have been removed from the website and an attempt was made, by emailing the Executive Editor, to obtain the latest copy of instructions to authors. The Executive Editor responded that they no longer have a set of guidelines as it obstructs creativity.

The *Journal of the Indian Association of Physiotherapy* has published a proposed editorial draft in the April 2006 issue which states that if informed consent is taken, it should be reported in the published article. It also mentions that when reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human research. This guideline could be assumed as the study should have been subjected to ethics review and the same should be reported.

Apart from the responsibility on the part of authors to report ethics related issues, the onus also lies with editors and the editorial policy to ensure that such issues are reported in their journals and discourage articles which have not mentioned them. The

argument that the researchers might have obtained ethics committee clearances, informed consent and other ethics related issues but did not mention this because the journal did not require stating so in the body of the article that ethic committee approval is required, is weak. Some publication guidelines clearly require these statements. If there was uniformity of instructions to authors and authors' guidelines, it would be apparent that studies have been conducted in an ethical manner. Such decisions by editors would create a ripple effect where researchers would be careful and honest in reporting and institutions, presently without ethics committees, would be motivated to create such functioning bodies. Instructions to authors should also mention that where there are institutional ethics committees, these should be identified by name and authors should mention clearly if written informed consent or assent was obtained.

The authors of this study would like to conduct a survey of the authors of the articles reviewed to discover if they had, in fact, followed ethical guidelines and did not merely report them. We agree that there is an urgent need for stringent editorial guidelines, with authors considering it their responsibility to follow and report ethical issues related to their research.

CONCLUSION

It can be concluded from the current study that despite the presence of international and specific journal publication guidelines, a large number of articles did not report ethical issues related to their research. We also found that one journal did not have any editorial guidelines requiring reporting of ethical issues.

We also conclude that ethical issues related to research are not considered important issues for publication by these two Indian physiotherapy journals and do not necessitate formulation of stringent editorial guidelines. The authors of this study are disturbed by this lack of interest and feel that it would be important for research if they changed their position and mandated strict reporting of ethical issues.

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Key points:

Past- The *Uniform requirements for manuscripts submitted to biomedical journals* were proposed by International Committee of Medical Journal Editors (ICMJE) and the standards of ethical reporting were given by Nuremberg code and Declaration of Helsinki.

Present- The standards of reporting ethical issues in two Indian physiotherapy journals were too low to warrant interpretation of ethical conduct and ethical reporting of research. Indian journals did not have mandatory instructions for authors towards ethical reporting.

Future- The International Society of Physiotherapy Journal Editors (ISPJE) and World Confederation of Physical Therapy (WCPT) should ensure thorough quality check on physiotherapy journals on a periodical basis if we realize our dearth to improve research in Physical Therapy. Training on medical writing for the authors may also provide some assistance in this aspect.