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Abstract

Ethics reporting practices in clinical research publications: A review of four Indian journals

Background: Manuscript authors of scientific journals are expected to report if their studies were conducted according to international and national ethical guidelines and inform readers regarding ethics approval and informed consent obtained from participants and/or their legally acceptable representative/s. In the present study we assessed the reporting practices of ethics approval and informed consent (assent in case of pediatric studies) in four Indian journals. **Materials and Methods:** Original research articles published over a period of 4 years (2009-2012) in four major national clinical journals, viz. Journal of Association of Physicians of India (JAPI), Indian Journal of Surgery (IJS), Journal of Obstetrics and Gynecology of India (JOGI), and Indian Journal of Orthopedics (IJO) were reviewed with regard to documentation of ethics approval and written informed consent and assent in case of pediatric participants. **Results:** We reviewed 673 research articles and found that, overall ethical approval was mentioned in 163 (24.2%) and informed consent or assent was mentioned in 179 (26.5%) articles in all four journals. Individually we found, in JAPI of the 174 manuscripts reviewed, 74 (42.5%) reported having obtained approval from the ethics committee and 68 (39.1%) reported taking written informed consent from participants. In IJS of 123 manuscripts, 18 (14.6%) reported ethics committee approval and 20 (16.2%) reported informed consent from participants. In JOGI of 152 manuscripts, 21 (13.8%) reported ethics committee approval while 49 (32.2%) reported informed consent from participants. In IJO, of 224 manuscripts, 50 (22.3%) reported ethics committee approval and 42 (18.7%) reported obtaining informed consent. **Conclusion:** Majority of the publications did not provide information regarding compliance to ethical guidelines in spite of the availability of various guidelines. Thus, there is a need for awareness and training on bioethics for authors, reviewers, and editors of biomedical journals.

Key words: Ethical approval, ethics committee, informed consent

Access this article online

Quick Response Code:



Website:

www.picronline.org

DOI:

10.4103/2229-3485.134316

INTRODUCTION

There has been increased focus on human subject protection and documentation of ethical review in clinical research in the last few years.^[1] Ethical considerations have changed from no rules to very strict regulations in clinical trials as well as in epidemiological research. It is a well-recognized principle in medical ethics that the consent of a participant

should be obtained before performing any trial-related procedure whatsoever, whether invasive or not, for the purpose of research or for treatment. To conform with ethical and legal requirements, obtaining consent should involve providing participants, at their level of understanding and comprehension, with information regarding the purpose/rationale for the study, trial-related procedures, benefits and risks, inconveniences and discomforts, rights and responsibilities, and possible outcomes of the research (including the likelihood and form of publication of research results); and allow the participant to make an informed voluntary decision of whether or not to participate.

The Nuremberg Code makes it clear that voluntary consent of the human subject is absolutely essential for research.^[2] Declaration of Helsinki (DoH) (2008) principle B-15 emphasizes that a research study should be submitted for consideration, comment, guidance, and approval of an ethics committee. DoH (2008) principle B-30 mentions that the author is responsible for the completeness and accuracy of reports of their research. It also mentions that studies which have not been conducted in accordance with DoH should not be accepted for publication.^[3] The six main sources of relevant international guidelines on conducting, reporting, and editing research are the Council of International Organizations for Medical Sciences (CIOMS),^[4] World Medical Association (WMA),^[5] Consolidated Standards of Reporting Trials (CONSORT),^[6] International Committee of Medical Journal Editors (ICMJE),^[6] World Association of Medical Editors (WAME),^[7] and Committee on Publication Ethics (COPE).^[8] Journal editors can verify whether articles submitted and published in their journals follow these instructions for ethical approval and written informed consent or not. Also the ICMJE expects authors to indicate whether the procedures followed were in accordance with the ethical standards laid out by the responsible committee on human experimentation and with the DoH.^[9]

The Journal of Association of Physicians of India (JAPI), Indian Journal of Surgery (IJS), Journal of Obstetrics and Gynecology of India (JOGI), and Indian Journal of Orthopedics (IJO) are four peer-reviewed national journals widely read by many clinicians. Whether ethical processes followed by authors during clinical research are reported in these journals is not clear and till date there is no study or documentation available in this regard. Hence, this study was planned with the objective of documenting the informed consent or assent in case of pediatric studies and ethics committee approval of research manuscripts published over a period of 4 years (2009-2012) in the above mentioned four prominent Indian journals.

MATERIALS AND METHODS

Ethics committee approval

As this study assessed the reporting of ethical practices in four Indian journals that are already available in public domain, an informed consent waiver was obtained from the Institutional Ethics Committee (IEC) when obtaining approval for the study.

Design

A retrospective observational study of 673 research articles published in JAPI, IJS, JOGI, and IJO over a period of 4 years (2009-2012). The authors reviewed them for the documentation of ethics committee clearance, informed consent, and assent in case of pediatric population. The authors reviewed only those prospective studies wherein obtaining ethics approval and informed consent were considered mandatory. However, articles were not segregated and analyzed based on their study designs.

Reporting ethics committee clearance

This was accepted as reported if the words “ethics committee approval” were mentioned.

Reporting informed consent

Informed consent was understood to have been reported if it was mentioned in the article. In case a waiver of consent was mentioned, this too was documented.

Reporting assent

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

Eligibility criteria

Inclusion criteria

1. Clinical research articles (including original research articles and short communications) published over a period of 4 years (2009-2012) in JAPI, IJS, JOGI, and IJO.

Exclusion criteria

1. Retrospective observational or epidemiological studies
2. Meta-analyses and case reports (as it is not mandatory to obtain the consent if identity is not disclosed)
3. Reports of studies done using data available in public domain (ethics approval not mandatory)
4. Editorials, review articles, letters to the editor, and book reviews (informed consent not required).

Statistical analysis

The number of research articles mentioning about ethical clearance, informed consent, and assent in case of children were expressed in terms of descriptive statistics.

Data is expressed as proportions with 95% confidence interval (CI).

RESULTS

In the present study, 673 research articles satisfying the inclusion criteria across the four Indian journals were reviewed.

Reporting of ethical approval

Ethical approval was mentioned in 163 (24.2%) articles out of 673 articles reviewed. In JAPI of 174 manuscripts reviewed, 74 (42.5%, 95% CI: 35.2-49.9) reported having obtained approval from the ethics committee. In IJS of 123 manuscripts, 18 (14.6%, 95% CI: 8.4-20.9) reported receiving ethics committee approval. In JOGI of 152 manuscripts, 21 (13.8%, 95% CI: 8.3-19.3) reported obtaining ethics committee approval; while in IJO, of 224 manuscripts, 50 (22.3%, 95% CI: 16.9-27.8) reported ethics committee approval.

Reporting of consent

Documentation of informed consent was reported in 179 (26.5%) articles out of 673 articles. In JAPI of 174 manuscripts reviewed, 68 (39.1%, 95% CI: 31.8-46.7) reported taking written informed consent from participants. In IJS of 123 manuscripts 20 (16.3%, 95% CI: 9.7-22.8) reported obtaining informed consent. In JOGI of 152 manuscripts, 49 (32.2%, 95% CI: 24.8-40.3) reported informed consent; while in IJO, of 224 manuscripts, 42 (18.8%, 95% CI: 14.2-24.4) reported obtaining informed consent. Out of 16 pediatric studies published in these journals, although parental consent was taken, whether assent was obtained or not was not mentioned.

For year-wise reporting of ethical approval and informed consent please refer to Tables 1-4.

DISCUSSION

The aim of this study was to identify current state of reporting of ethical approval and informed consent in four Indian journals. Although ICMJE recommends that authors mention about human experimentation being done in accordance with standard ethical procedures and DoH,^[9] we observed that a majority of articles from these journals did not mention ethical approval and/or informed consent. Out of 673 research articles reviewed; only 163 (24.2%) articles mentioned about ethical approval and 179 (26.5%) articles mentioned about informed consent as shown in Figure 1.

International studies of similar nature conducted in the past, showed better results when compared with the

Table 1: Year 2009

Journal	Number of manuscripts	EC approval (%)	Informed consent/ assent (%)
JAPI	38	18 (47.4)	14 (36.8)
IJS	35	05 (14.3)	03 (8.5)
JOGI	47	07 (14.9)	12 (25.5)
IJO	50	10 (20.0)	08 (16.0)
Total no. of manuscripts	170	40 (23.5)	37 (21.8)

JAPI = Journal of Association of Physicians of India, IJS = Indian Journal of Surgery, JOGI = Journal of Obstetrics and Gynecology of India, IJO = Indian Journal of Orthopedics, EC = Ethics committee

Table 2: Year 2010

Journal	Number of manuscripts	EC approval (%)	Informed consent/ assent (%)
JAPI	37	12 (32.4)	13 (35.1)
IJS	33	03 (9.1)	02 (6.1)
JOGI	34	03 (8.8)	07 (20.5)
IJO	40	09 (22.5)	03 (7.5)
Total no. of manuscripts	144	27 (18.8)	25 (17.4)

JAPI = Journal of Association of Physicians of India, IJS = Indian Journal of Surgery, JOGI = Journal of Obstetrics and Gynecology of India, IJO = Indian Journal of Orthopedics, EC = Ethics committee

Table 3: Year 2011

Journal	Number of manuscripts	EC approval (%)	Informed consent/ assent (%)
JAPI	46	20 (43.5)	18 (39.1)
IJS	46	08 (17.4)	12 (26.1)
JOGI	61	07 (11.5)	26 (42.5)
IJO	58	13 (22.4)	15 (25.9)
Total no. of manuscripts	211	48 (22.7)	71 (33.6)

JAPI = Journal of Association of Physicians of India, IJS = Indian Journal of Surgery, JOGI = Journal of Obstetrics and Gynecology of India, IJO = Indian Journal of Orthopedics, EC = Ethics committee

Table 4: Year 2012

Journal	Number of manuscripts	EC approval (%)	Informed consent/ assent (%)
JAPI	53	24 (45.3)	23 (43.4)
IJS	09	02 (22.2)	03 (33.3)
JOGI	10	04 (40.0)	04 (40.0)
IJO	76	18 (23.7)	16 (21.1)
Total no. of manuscripts	148	48 (32.4)	46 (31.1)

JAPI = Journal of Association of Physicians of India, IJS = Indian Journal of Surgery, JOGI = Journal of Obstetrics and Gynecology of India, IJO = Indian Journal of Orthopedics, EC = Ethics committee

present study. Schroter *et al.*, (2006) had analyzed research papers published in five general medical journals viz., the Annals of Internal Medicine, British Medical Journal, The Journal of the American Medical Association, Lancet, and The New England Journal of Medicine; and found that ethical approval was mentioned in 69% and consent was mentioned in 53% of manuscripts, respectively.^[10] Myles

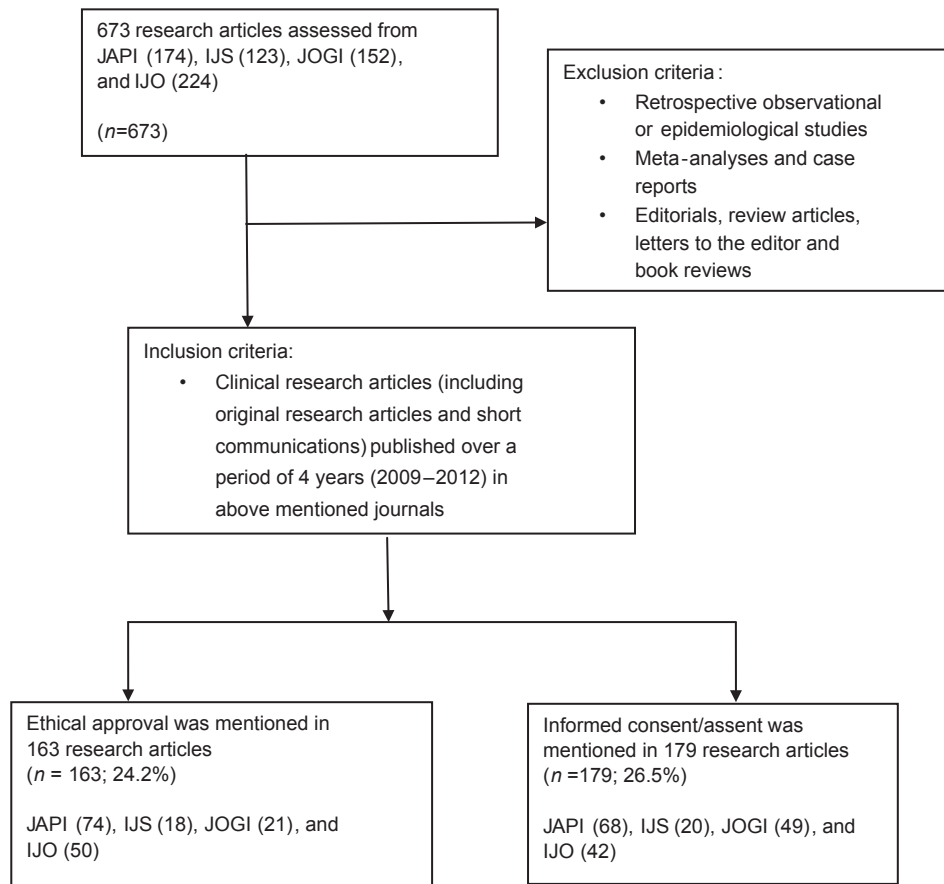


Figure 1: The number of research articles with ethical approval and informed consent

et al. studied reporting of ethical approval and informed consent in clinical research published in leading anesthesia journals and found that ethical approval was documented in 71% of publications and consent was obtained in 66% of publications.^[11] Munung *et al.*, had analyzed publications from Cameroon (west central Africa) and found that 57.53% reported ethics approval, 70.78% informed consent, and 50.68% both ethics approval and informed consent.^[12] Matot *et al.*, studied seven critical care journals and found that in 76% studies mentioned about institutional review board (IRB) and informed consent approval.^[13]

Indian studies of similar nature showed varied results. Bavdekar *et al.*, (2008) studied 132 manuscripts in two Indian pediatric journals and found that in 29.5% studies reported ethics committee approval and in 46.9% studies informed consent was obtained from parents or lawful guardians.^[14] Chaturvedi *et al.* (2009) reviewed 157 articles from the Indian Journal of Psychiatry and reported that, informed consent was mentioned in 51% of studies in 2000, which gradually rose to 82% in the year 2007 and ethics committee approvals were mentioned in 2% of studies in 2000, which rose to 28% in the year 2006 and 25% of reports in 2007.^[15] Sabapathy *et al.*, had assessed reporting ethical issues in Indian physiotherapy journals

and found that ethics committee clearance was mentioned in 19.17% of studies, informed consent in 55.8% studies, and assent in 50% of the studies.^[16]

The high proportion of articles lacking in reporting of ethical approval in our study suggests the presence of potential ethical flaws which should be discussed and overcome. It was observed that over the 4 years reporting of ethics approval and informed consent remained almost unchanged, contrary to growing international awareness of the value of incorporating these ethical issues into the execution and reporting of health research.^[10-13] We also observed that ethical approval was mentioned in 42.5% of studies and informed consent in 39.1% studies in JAPI. This is almost twice when compared with other three journals and this may be due to better peer review practices of JAPI as compared to the other three journals.

Most journals require properly documented review and approval from a formally constituted review board (national or institutional review board or ethics committee) for all studies involving humans, medical records, and human tissues/organs. This study gives evidence of the need for stronger direction on bioethical issues in publication. Journal editors are important for

the publication of scientific documents. They should encourage authors to meet the standards as stated in guidelines and should reject research not meeting these requirements. Editors should explain the importance of ethical protection to reviewers, readers, and researchers and publish those papers that show them as important criteria in research. Though many journals including those in the study provide guidance on information to be provided regarding ethical approval and informed consent in their Instructions to Authors, it appears that these requirements are not always adhered to by authors. Journal editors should introduce effective mechanisms to ensure that this information is reported for all research conducted on human participants. Authors use a range of statements to indicate that consent was obtained from patients. More precise use of language would help the reader understand whether the participant simply agreed to participate in the study or gave fully 'informed' consent. In our opinion, there is a need to train journal reviewers by editors themselves; so that, the reviewers can guide the authors at the time of review of their research articles.

Thus, the results of this study demonstrate that the rate of reporting of ethical practices in four Indian journals is not up to the expected standards. The high proportion of articles failing in the reporting of ethical practices suggests the presence of potential ethical publication flaws which needs to be discussed and overcome.

CONCLUSION

We found poor reporting practices of ethics committee approval and informed consent. There is an urgent need to improve the situation considering the international reporting guidelines for research ethics.

REFERENCES

1. Perkins AC, Choi JM, Kimball AB. Reporting of ethical review of clinical research submitted to the Journal of the American Academy of Dermatology. *J Am Acad Dermatol* 2007;56:279-84.
2. Nuremberg Code. Available from: <http://ohsr.od.nih.gov/guidelines/nuremberg.html> [Last accessed on 2012 Dec 22].
3. World Medical Association. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. *J Postgrad Med* 2002;48:206-8. Available from: <http://www.wma.net/e/policy/b3.htm> [Last accessed on 2013 Jan 12].
4. Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for biomedical research involving human subjects. Geneva; 2002. Available from http://www.cioms.ch/publications/layout_guide2002.pdf [Last assessed on 2013 April 15].
5. Moher D, Schulz KF, Altman DG. CONSORT. The CONSORT Statement: Revised recommendation for improving the quality of reports of parallel group randomized trials. *BMC Med Res Method* 2001;1:2. Available from: <http://www.biomedcentral.com/1471-2288/1/2> [Last accessed on 2013 Apr 16].
6. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. Available from: <http://www.icmje.org> [Last accessed on 2013 Apr 16].
7. World Association of Medical Editors-WAME. Recommendations on Publication Ethics Policies for Medical Journals. Available from: <http://www.wame.org/pubethicrecom.htm> [Last accessed on 2013 Apr 16].
8. Committee on Publication Ethics-COPE. Guidelines on good publication and the Code of Conduct. Available from: <http://www.publicationethics.org.uk/guidelines> [Last accessed on 2013 Apr 16].
9. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to Biomedical Journals: Writing and Editing Biomedical Publications. (Updated February 2006). Available from: <http://www.icmje.org> [Last accessed on 2013 Apr 16].
10. Schroter S, Plowman R, Hutchings A, Gonzalez A. Reporting ethics committee approval and patient consent by study design in five general medical journals. *J Med Ethics* 2006;32:718-23.
11. Myles PS, Tan N. Reporting of ethical approval and informed consent in clinical research published in leading anesthesia journals. *Anesthesiology* 2003;99:1209-13.
12. Munung NS, Che CP, Ouwe-Missi-Oukem-Boyer O, Tangwa GB. How often are ethics approval and informed consent reported in publications on health research in Cameroon? A five-year review. *J Empir Res Hum Res Ethics* 2011;6:93-7.
13. Matot I, Pizov R, Sprung CL. Evaluation of Institutional Review Board review and informed consent in publications of human research in critical care medicine. *Crit Care Med* 1998;26:1596-602.
14. Bavdekar SB, Gogtay NJ, Wagh S. Reporting ethical processes in two Indian Journals. *Indian J Med Sci* 2008;62:134-40.
15. Chaturvedi SK, Somashekar BS. Reporting ethical aspects in published research articles in the Indian Journal of Psychiatry. *Indian J Psychiatry* 2009;51:34-7.
16. Sabapathy SS, Janakiraman K, Swarnalatha CC, Ayyanar M. Reporting of ethical issues in Indian Physiotherapy Journals. *J Phys Ther* 2010;1:25-31.

How to cite this article: Belhekar MN, Bhalerao SS, Munshi RP. Ethics reporting practices in clinical research publications: A review of four Indian journals. *Perspect Clin Res* 2014;5:129-33.

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