

Authorship criteria and reporting of ethical compliance in Indian biomedical journals

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Abstract

The "instructions to authors" of a total of 55 PubMed/MEDLINE-indexed Indian biomedical journals were evaluated to assess the authorship criteria and guidance on reporting of research ethics including incorporation of recent updates. Thirty-seven (67.3%) journals recommended the ICMJE guidelines for manuscript preparation. Thirty-two of 55 (58.2%) journals defined authorship; only two journals defined authorship as per the latest (2013) ICMJE criteria. The journals' recommendations which indicated ethical compliance in articles were– the conduct of a study in accordance with the Declaration of Helsinki(n=39); ethical approval (n=37); consent (n=26); assent (n=10); and consent for identifiable information (n=31).The majority of the journals (n=27) referred to the 1975 version of the Declaration of Helsinki and the revisions of 2000 (n=25). None of them mentioned the latest (2013) Declaration of Helsinki amendment. Overall, the results showed that the international recommendations and latest updates have not been completely incorporated into the "instructions to authors"of Indian biomedical journals.

Background

A journal's "instructions to authors" are specific instructions that guide authors on what they must include in their manuscript while submitting an article. The instructions cover the structure, format and reference style as well. These instructions reflect the editorial processes and ethics being followed or endorsed by the journal, how far it conforms to the existing publication guidelines (International Committee of Medical Journal Editors [ICMJE](1), Committee on Publication Ethics [COPE](2), etc., and educates the scientific community. Ethical approval by an independent review board or institutional ethics committee and written informed consent provided by research participants are foundations of ethical research. Global publication guidelines expect journals to include these requirements in their instructions to authors and guide authors to report them (1,3).

Publication guidelines are brought up to date from time to time with a view to making them more robust

and transparent, and journals are expected to adhere to these recommendations. The Declaration of Helsinki was developed by the World Medical Association (WMA) as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The recent revision of the Declaration of Helsinki (October 2013 amendment) highlights the need to disseminate the results of research and states that: "Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects ...all parties should adhere to accepted guidelines for ethical reporting" (3). In addition, it specifies that "all previous versions have been replaced and should not be used or cited except for historical purposes" (3).

The ICMJE recommendations are a set of guidelines for standardising the ethics, preparation and formatting of biomedical publications. These recommendations, including the definition of authorship, are widely used by most biomedical journals (and most leading journals), although membership of the ICMJE is limited to a very small number of top journals. Since the first version of the guidelines came out, they have been updated many times, most recently in 2015. In 2013, the name of these guidelines was changed from "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (URMs) to "Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals," also known as "ICMJE recommendations"(1). In 2013 ICMJE also updated its authorship criteria. The four authorship criteria are (i) substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; (ii) drafting the work or revising it critically for important intellectual content; (iii) final approval of the version to be published; and (iv) agreement to be accountable for all aspects of the work by ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The ICMJE recommends that all the listed authors meet the four criteria for authorship, and all who meet these criteria be listed as authors.

Though there are several resources to guide authors on what is to be included in a manuscript, a particular journal's instructions to authors play a critical role. This analysis was aimed to assess the authorship criteria of Indian biomedical journals and their guidance to authors on the reporting of research ethics. This included exploring whether recent updates had been incorporated in the instructions to authors.

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Methods

This was a cross-sectional analysis of the instructions to authors of Indian biomedical journals, conducted between June 2015 and July 2015. A total of 55 PubMed/MEDLINE-indexed Indian biomedical journals from different therapeutic areas and specialties were included in the analysis. A list of Indian biomedical journals was culled from MedIND (<http://medind.nic.in/>) and the journals were included if they were listed in PubMed. Additional journals were searched for manually on Google and included if they were indexed in PubMed/MEDLINE. Ethical approval was not required for this analysis since it did not constitute biomedical research involving human participation. All the information used in this analysis was available in the public domain.

The journals' instructions to authors were read carefully and note was taken of whether they required manuscript preparation and authorship criteria to conform to the ICMJE guidelines, the principles originating in the Declaration of Helsinki or applicable local ethical standards. Data were also collected on whether the journals required authors to report if they obtained consent and assent from those participating in a study, and whether consent was obtained for the inclusion of identifiable personal information. In addition, the journals' stance regarding the investigation of suspicious misconduct; recommendation on using reporting checklists; statement of inclusion of no or only essential identifying information; requirement for suggesting potential reviewers (while submitting manuscript); and requirements for registration in trials were assessed. The data were summarised using descriptive statistics.

Results

Overall, 37 (67.3%) of 55 journals mentioned that the manuscript should be prepared in accordance with the ICMJE (Table 1). Of these 37 journals, 34 (91.9%) were referring to older versions of the ICMJE, ie the URM's (Table 2). Only one journal mentioned the latest version of the ICMJE (*Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*). The remaining two journals did not specify which version was being used. Twenty-one (56.8%) of the 37 journals advised authors to check the latest ICMJE guidelines before submitting their work, instead of specifying the latest version for easy reference.

Thirty-two (58.2%) of the 55 journals defined authorship; however, the majority (30/32) of journals did not incorporate the fourth authorship criterion specified by the ICMJE in 2013. Twenty-seven journals mentioned the first three criteria, one journal mentioned the first two, while two journals made only a brief mention of authorship. Only two journals incorporated the fourth ICMJE authorship criterion. Among 37 journals which recommended that the manuscript should be prepared in accordance with the ICMJE guidelines, 28 (75.7%) defined authorship on the basis of 4 (n=2), 3 (n=24) or only 2 (n=1) ICMJE criteria, or made just a brief mention of authorship (n=1).

A total of 42 (76.4%) journals mentioned that a study must

Table 1
Summary of observations

Parameters (n=55)	n (%)
Manuscript preparation in accordance with ICMJE	37 (67.3)
Conduct of study in accordance with Declaration of Helsinki or applicable local requirements	42 (76.4)
Defined authorship	32 (58.2)
Recommendation to indicate in the manuscript that study has been conducted in accordance with the Declaration of Helsinki	39 (70.9)
Reporting ethics committee approval	37 (67.3)
ICMJE, International Committee of Medical Journal Editors	

Table 2
Various ICMJE (URM) versions mentioned by journals for manuscript preparation

ICMJE version (n=34)	n (%)
April 2010	3 (8.8)
October 2008	4 (11.7)
February 2006	3 (8.8)
October 2006	6 (17.6)
October 2004	2 (5.9)
October 2001	5 (14.7)
2006	2 (5.9)
2004	1 (2.9)
Article published in <i>Ann Intern Med</i> ¹	2 (5.9)
Not specified	6 (17.6)
Total	34 (100)
¹ Uniform Requirements for Manuscripts Submitted to Biomedical Journals. International Committee of Medical Journal Editors. <i>Ann Intern Med</i> 1997;126:36-47.	
ICMJE, International Committee of Medical Journal Editors; URM, Uniform Requirements for Manuscripts Submitted to Biomedical Journals	

be conducted in accordance with the Declaration of Helsinki or applicable local requirements. However, only 39 (70.9%) recommended that this should be indicated in the manuscript. Most journals referred to the Declaration of Helsinki as updated in 1975 (n=27). Those referring to the 1964 version were 9, those referring to the revisions of 2000 were 25, and those to later amendments were 8 (Table 3). None of the journals mentioned the latest (2013) Declaration of Helsinki amendment. Reporting of ethical conduct or approval by an ethics committee was recommended by 37 (67.3%) journals, while reporting whether consent was obtained for enrolment in a study was recommended by 26 (47.3%). The phrases used for written informed consent were "consent" (n=1), "informed consent" (n=23) and "written consent" (n=2). Ten (18.18%) journals mentioned obtaining assent from children less than 7 years of age. However, only one journal mentioned that the consent of a guardian/parent should be obtained together with that of the child.

A total of 32 journals recommended the use of various reporting guidelines or checklists (Table 4). The CONSolidated Standards of Reporting Trials (CONSORT) statement was the most commonly (n=32) recommended reporting guideline. A statement of the inclusion of no identifying information or only essential identifying information was mentioned in 39 journals.

Table 3 Summary of guidance on study conduct in accordance with Declaration of Helsinki or local ethical requirements			
Declaration of Helsinki (n=39)	n (%)	Mention of its amendments	n (%)
1964	9 (23.1)	Its later amendments	8 (20.5)
		Subsequent amendments till 2004	1 (2.6)
1975	27 (69.2)	1983	1 (2.6)
		2000	25 (64.1)
		Not specified	1 (2.6)
Not specified	3 (7.7)		
Total	39 (100)		

The requirement to register trials was found in 20 (36.4%) journals (Table 4).

Thirty-seven journals specified that written permission should be obtained from patients for using identifiable information and 31 of these 37 mentioned that if consent was obtained, it should be indicated in the article. However, only 11 journals specified that the patient/person should see the manuscript before its publication. Overall, 32 (58.2%) journals mentioned that they followed a double-blind peer-review process, 2 (3.6%) stated that they followed a single-blind peer-review process, while the remaining 21 (38.2%) did not specify anything. Sixteen journals asked authors to suggest potential reviewers; of these, 15 specified that these should not be from the same institution and 12 specified that the selection of reviewers would be at the editor's/journal's discretion. Five journals ask their authors to suggest reviewers who can be excluded from the review process.

Discussion

Instructions to authors not only guide authors in the preparation of their manuscripts, but also position the journal in terms of ethical policies, on the basis of which authors can feel confident that their research will be handled and published by an ethically compliant or good journal. There is significant evidence that the instructions to authors of Indian journals lack comprehensive ethical requirements (4). Global publication policies and recommendations are updated from time to time, and it is expected that everyone involved in publication, especially those who endorse the recommendations, should adhere to them. The October 2013 amendment of the Declaration of Helsinki particularly focuses on transparent dissemination of trial data and ethical publication practices. Similarly, journals should adhere to recently added fourth authorship criterion of the ICMJE

All authors may not be aware of publication guidelines and their frequent updates. However, they may learn of some of these if the journal revises its instructions. While preparing a manuscript, authors check if the journal expects them to fulfil any particular requirement. If something is not mentioned or recommended in the journal's instructions, authors may

Table 4 Summary of other observations	
Parameters	n (%)
Endorsement of reporting guidelines (n=32)	
CONSORT	18 (56.3)
CONSORT, STARD, MOOSE, QUOROM, STROBE	10 (31.3)
CONSORT, STARD, MOOSE, PRISMA, STROBE	1 (3.1)
CONSORT, STARD, MOOSE, QUOROM	1 (3.1)
CONSORT, PRISMA	1 (3.1)
CONSORT, STROBE	1 (3.1)
Journals' strategy to investigate in case of suspicious misconduct (n=55)	8 (14.5)
Trial registration requirement (n=55)	20 (36.4)
CONSORT, CONSolidated Standards of Reporting Trials; MOOSE, Meta-analysis of Observational Studies in Epidemiology; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; QUOROM, Quality of Reporting of Meta-Analyses; STARD, Standards for Reporting of Diagnostic Accuracy; STROBE, STrengthening the Reporting of OBServational studies in Epidemiology	

assume that the information is not necessary and there is no need to provide it, hence unknowingly deviating from ethical publication practices. Therefore, it is important that journals provide comprehensive instructions to authors and update them regularly, thus encouraging scientific integrity.

Several studies have analysed journals' instructions to authors, focusing particularly on publication ethics and reporting guidelines (4–15); however, there is not much literature on the regular update of instructions. One follow-up study by Smith et al (16) evaluated whether there was any improvement in surgery journals that insist on reporting in accordance to CONSORT and PRISMA. The findings of the present analysis show that few Indian biomedical journals regularly update their instructions according to the global recommendations. It was observed that only two journals updated their authorship criteria in keeping with the ICMJE updates (ie fourth criterion). In a previous study, Jaykaran et al (4) reported that the authorship criteria were mentioned by 64.5% of Indian journals and the authorship criteria according to ICMJE were mentioned by 59.3%. However, these data were obtained before the 2013 ICMJE update, in which the fourth authorship criterion was added. A previous study by Mathur et al, which covered 10 Indian dental journals, reported that all journals (100%) specified authorship or contributorship criteria. The present study found that 58.2% of journals define authorship. This is not the case only in India; studies conducted outside India have made similar observations. Authorship criteria were not mentioned in 32.4% of Pakistani journals (17), 41% of journals from the membership list of the World Association for Medical Editors (WAME) and from Medline (18), 48% of journals in Central and East Europe (19), 85% in Brazil (20), 85% in Iran (10) and 86% of Croatian open-access journals (11).

The recommendation to indicate in an article that the study has been conducted in accordance with the Declaration of Helsinki was mentioned by 70.9% journals, which was consistent with the finding of Jayakaran et al (70.1%)(4) and higher than the figure reported by Bavdekar et al (40%)(21).

Overall, the majority of journals referred to the Declaration of Helsinki 1975 (n=27) and its revisions of 2000 (n=25). None of them recommended reporting according to the latest 2013 amendment.

In the present study, 67.3% of journals specified that manuscripts be prepared according to the ICMJE recommendations. In a previous report (13), 58.5% of journals made some mention of the ICMJE requirements in the instructions for authors. Of these, 21% mentioned the ICMJE guidelines only in the context of the style of references or units of measurement, and the remaining 78.9% recommended that manuscripts follow all ICMJE requirements.

The authorship criteria recommended by the ICMJE are widely accepted and referred to most commonly by journal editors worldwide. However, there are journals that do not follow the ICMJE criteria to define authorship (eg *Neurology*). According to the ICMJE guidelines, to qualify as an author, a researcher has to contribute substantially in all aspects of the study to be able to take responsibility and recognition for the work, and should meet all four authorship criteria (1). In the present study, around 40% of journals did not mention authorship. Among the 37 journals which recommended the preparation of the manuscript according to the ICMJE guidelines, only 26 defined authorship criteria and only two updated their authorship criteria. This shows a lack of adherence to global recommendations.

The study of Bavdekar et al (21) reported that ethical approval and written informed consent were mentioned in 62% and 43% of journals, respectively. The corresponding figures in a study by Jayakaran et al (4) were 72.8% and 74.5%, respectively. In the present study, 67.3% of journals mentioned reporting of ethics committee approval and 47.3% mentioned reporting of consent. These results show that instructions to authors have not been updated to any considerable extent since 2009, after Bavdekar et al (21) published their findings.

A study by Mathur et al (5) reported that 80% of journals mentioned obtaining approval from the ethics committee as well as informed consent. Tharyan et al (13) reported that 55.4% of journals required approval by an institutional or national ethics committee, or required that research be conducted in accordance with the Declaration of Helsinki. According to the study of Navaneetha et al (6), 45.2% of journals required reporting of approval by the ethics committee, and 13.2% required mention of informed consent and assent. Another international study, which covered 126 journals, made similar observations.

Assent is a form of consent obtained from participants/minors who are too young to give written informed consent, but can understand the proposed research. In cases in which a person's assent is obtained, the researcher is expected to also obtain written informed consent from the participants' parents or legal guardians. Two previous studies (21,4) have reported that 3% and 15.2% of journals, respectively, mentioned obtaining the assent of minors. However, in the present study, 18.2%

of journals mentioned that assent should be obtained from minors. The relatively low number of journals requiring the mention of assent may be attributed to the scope of the journals, ie not all journals may expect manuscripts from studies involving the paediatric population.

Peer-review is one of the most important components of the publication process and plays a key role in validating the quality of research. However, recently, several papers have been retracted because fabricated details of potential peer-reviewers were provided during manuscript submission. These cases are alarming and to avoid such peer-review scams, rigorous selection of reviewers must be ensured and the relevant systems put in place.

The author acknowledges that this report has several limitations. The journals included in this analysis were selected randomly, using PubMed, MedIND and Google search, which could have introduced a selection bias. In addition, journals listed on other indexing databases and non-indexed journals were not included. Hence, the overall number of journals in India has been underestimated and this may affect the overall outcome of the analysis. However, though our sample may not be representative of all Indian journals, it provides insights into the current practices followed by journals with respect to reporting requirements. Despite the fact that the analysis included journals indexed only in PubMed/Medline, on the basis of this study, it can be hypothesised that the situation of Indian journals not indexed in these databases may not be significantly different. Further studies are needed to confirm this.

Another limitation of this study was the process of reviewing the "instructions to authors" of each journal. The review was done by just one author, which leaves room for errors. In the case of some journals which mentioned appendices, we did not assess the latter to ascertain whether they contained any forms requesting information. It was out of the scope of this analysis whether any additional information is requested during online submission or how editorial policies are being followed. In addition, a journal's instructions to authors may not reflect its actual ethical practices. Further research is needed on this subject. The instructions to authors were reviewed from June 2015 to July 2015 and they might have been updated by the time of the publication of this study.

Conclusion

Despite the limitations mentioned above, the results of this cross-sectional study indicate that international recommendations and the latest updates for improving publication practices have not been completely incorporated into the Indian biomedical journals' instructions to authors. A significant proportion of journals need to update their instructions to authors. Instructions for manuscript development, authorship, ethical conduct and transparent reporting should be updated appropriately and regularly.

Competing interest: During this analysis, PB was an employee of

SIRO Clinpharm Pvt. Ltd, Mumbai and is currently an employee of Tata Consultancy Services, Thane.

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