

**Absolute risk reduction (ARR)** or the risk difference is the difference between the risk of an event in the control group and the risk of an event in the treatment group. The advantages of ARR are that it is easy to compute; the confidence interval obtained is easy to interpret; it reflects both the underlying risk without treatment and risk reduction associated with treatment; and it has a clear meaning that makes it appealing to the practitioner. Absolute risk measures overcome the drawbacks of RRR because they reflect the baseline risk and are better at discriminating between small and large treatment effects. Despite the obvious advantages of absolute risk measures, because they are dependent on baseline risk, they are of limited generalisability. It would, for example, be inappropriate to extrapolate published absolute risk measures from one population to another population with a different baseline risk.

The number needed to treat (NNT) is the reciprocal of ARR. The meaning of this measure is the number of patients that need to be treated to obtain the desired outcome in one patient who would not have benefited otherwise. NNT takes into account the absolute benefit and is meaningful because it addresses both statistical and clinical significance. It is also worth noting

that the numerical value of NNT is a function of the disease, the intervention, and the outcome.

An **intention to treat (ITT)** analysis is generally interpreted as an analysis including all patients, regardless of whether they actually satisfied the criteria of assignment, the treatment was actually received, or they subsequently withdrew or deviated from the protocol. ITT helps retain the benefit of randomisation in that it helps in making comparisons between groups. ITT may benefit effectiveness regardless of clinical efficacy. ITT also minimises bias with respect to dropouts related to outcome and simplifies the task of dealing with suspicious outcomes, all of which can protect against attempts to drive the results in a desirable direction. ITT reflects the way treatments will be performed in the population by ignoring adherence when the data are analysed.

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## Survey of “instructions to authors” of Indian medical journals for reporting of ethics and authorship criteria

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### Abstract

*This study looked at information on ethics reporting and authorship in the “instructions to authors” section of Indian medical journals. Instructions to authors in 59 Indian medical journals were examined for guidance on ethics reporting and authorship. Guidance regarding ethics was mentioned in 43 (72.8%) journals; assent from minors was mentioned in 9 (15.2%) journals; approval from an animal ethics committee was mentioned in 10 (16.9%) journals; authorship criteria were mentioned in 38 (64.5%) journals. Authorship criteria according to the International Committee of Medical Journal Editors were mentioned in 35 (59.3%) journals. Guidance regarding contributors’ details was mentioned in 30 (50.8%) journals. These findings suggest that many editors of Indian medical journals must upgrade their instructions to authors to include ethical requirements.*

### Introduction

Instructions to authors provided by journals are useful for the effective preparation of manuscripts. Two important

components of these instructions are “guidance regarding reporting of ethics” and “authorship criteria”.

Ethical approval by an independent or institutional review board and evidence of informed consent are considered to be important components of any research project (1). Studies in the Indian context have found that reporting of ethics of research in manuscripts is less than satisfactory, though this reporting has improved (1,2).

Journal articles include a list of the paper’s authors in order to give them credit for the research. This also holds the authors responsible for the authenticity of the research (3). Disputes over authorship are a global phenomenon and “ghost authorship” and “gifted authorship” are not uncommon (4). As publications are important for appointments and promotions in teaching institutions, fairness and accuracy in deciding authorship are important (3).

A study done in the Indian context found that the faculty in an Indian medical institution had poor awareness of authorship

criteria (5). Another study found guidance regarding authorship criteria in the "instructions to authors" section of medical journals to be inadequate (6).

Various guidelines are available in the literature regarding the reporting of ethics and authorship criteria. Since authors prepare manuscripts on the basis of a journal's instructions to authors, the information given in this section is very important.

We examined Indian medical journals for the guidance provided in the "instructions to authors" section, on reporting of ethics and authorship criteria.

## Materials and methods

A list of 354 Indian medical publications was compiled from Google, Pubmed, Indmed and the National Informatics Centre. The following types of journals were excluded from analysis: journals of unani, ayurvedic and siddha medicine; dentistry and pharmacy science journals; those whose instructions to authors could not be located; and newsletters, periodicals and journals that published only reviews. The remaining 59 journals were examined.

The instructions to authors were read to determine whether ethical aspects were mentioned. We looked at the following:

1. Did they require a mention of: approval from the (human) research ethics committee and the animal ethics committee?
2. Did they require informed consent and assent from research subjects?
3. Did they require a statement that the research was carried out in accordance with the ethical guidelines of the Indian Council of Medical Research, 2006, or the Declaration of Helsinki?

Concerning authorship criteria, we looked at the following questions:

1. Was there a mention of criteria for authorship?
2. Was there a reference to the guidelines of the International Committee of Medical Journals Editors (ICMJE) or other guidelines?
3. Did the journal require a statement on the contribution of each author to the submission?

Data were expressed in frequencies and percentages.

## Results

From a list of 354 Indian medical periodicals, 59 fulfilled the inclusion criteria. Instructions regarding ethics were mentioned in 43 (72.8%) journals. Permission from an ethics committee was mentioned in 45 (76.2%) articles. The need for informed consent was mentioned in 44 (74.5%) journals and "assent" was mentioned in 9 (15.2%) journals. Approval from an animal ethics committee and the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) was mentioned in 10 (16.9%) and 24 (40.6%) journals respectively. In the case of authorship criteria guidance according to ICMJE guidelines was mentioned in 35 (59.3%) journals; a statement of the authors' contributions was required in 30 (50.8%) journals; ghost or gifted authorship was mentioned in 23 (38.9%) journals. Other results are summarised in Tables 1 and 2.

## Discussion

Instructions to authors in many Indian medical journals lack clear-cut and comprehensive guidelines regarding certain ethical issues and authorship criteria. Similar findings were also observed in other studies done for western journals (7-9).

Permission from an IRB/ethics committee was mentioned in 45 (76.2%) journals. Some journals mentioned guidance with reference to the "Declaration of Helsinki" and a few journals mentioned "ICMR guidelines". As these guidelines are based on similar principles, mentioning either one is sufficient.

Only 44 (74.5%) of the journals required a statement that informed consent was taken from the research participants.

"Assent" is a term used to express willingness to participate in research by persons who are by definition too young to give informed consent but old enough to understand the proposed research and the activities expected of them as subjects. If assent is given, informed consent must still be obtained from the subject's parents or guardian (7-9).

Only 9 of the 59 journals (15.2%) mentioned the reporting of assent. It is possible that many of the journals surveyed do not expect to receive articles related to children. In a similar study done for Indian medical journals by Bavdekar et al (1) it was observed that reporting of assent was mentioned in only three journals.

Guidance regarding the CPCSEA was mentioned in 24 (40.6%) journals and guidance regarding animal ethics committees was mentioned in 10 (16.9%) journals. It is possible that many of the journals surveyed did not expect to receive articles related to animals.

We found that while guidelines regarding authorship criteria, in the instructions to authors of Indian medical journals, were less than satisfactory, they were better than those in some foreign journals. In 21 (35.5%) journals authorship criteria were not mentioned. In a similar study done on journals indexed by the Pakistan Medical and Dental Council (PMDC), it was observed that authorship criteria were not mentioned in 32.4% journals (3). In two other international studies, authorship criteria were not mentioned in 41% and 85% journals respectively (6,10).

Details on the contributions of authors were required in 30 (50.8%) journals. This can reduce the chances of ghost authorship and guest authorship and educate authors about authorship criteria. In the study of journals in Pakistan just 2.7% of journals indexed by the PMDC required these details and none of the 20 journals in a similar study in Brazil required the contributors' details. (3,10).

The ICMJE guidelines for authorship were mentioned in 35 (59.3%) journals. This is more than was found in other studies (3,10). The ICMJE guidelines were developed to improve the quality of manuscripts submitted to medical journals (11). They specify criteria for authorship: 1. either conception, or design or acquisition of data; 2. analysis or interpretation of data, drafting or revising the article for important intellectual content; and 3.

**Table 1: Guidance on ethics in instructions to authors of Indian medical journals**

| S.No. | Observation (n=59)                                                            | Frequency  | 95% CI         |
|-------|-------------------------------------------------------------------------------|------------|----------------|
| 1     | Ethics mentioned as a heading in the instructions                             | 43 (72.8%) | 60.4% to 82.5% |
| 2     | Instruction regarding mention of ethical approval by an independent committee | 45 (76.2%) | 64.0% to 85.3% |
| 3     | Guidance regarding mention of "written informed consent"                      | 44 (74.5%) | 62.2% to 83.9% |
| 4     | Guidance regarding mention of "assent"                                        | 9 (15.2%)  | 8.2% to 26.5%  |
| 5     | Guidance regarding the Declaration of Helsinki                                | 42 (71.1%) | 58.6% to 81.1% |
| 6     | Guidance regarding an animal ethics committee                                 | 10 (16.9%) | 9.4% to 28.4%  |
| 7     | Guidance regarding CPCSEA                                                     | 24 (40.6%) | 29.0% to 53.4% |
| 8     | Mention of the ICMR guidelines                                                | 18 (30.5%) | 20.2% to 43.1% |

**Table 2: Guidance on authorship criteria in instructions to authors of Indian medical journals**

| S. No. | Instruction (n=59)                          | Journals   | 95% CI         |
|--------|---------------------------------------------|------------|----------------|
| 1      | Guidance according to ICMJE                 | 35 (59.3%) | 46.5% to 70.9% |
| 2      | Guidance (own criteria)                     | 3 (5%)     | 1.9% to 13.9%  |
| 3      | No guidance                                 | 21 (35.5%) | 24.6% to 48.3% |
| 4      | Requiring details of authors' contributions | 30 (50.8%) | 38.4% to 63.1% |
| 5      | Statement on ghost/gifted authorship        | 23 (38.9%) | 27.5% to 51.7% |

final approval of the version to be published. The author should have substantial contributions in all three areas.

Our study indicates that a significant proportion of Indian medical journal editors need to update their instructions to authors regarding ethics reporting and authorship criteria. They should require authors to include information on the ethics of their research in their manuscripts. This includes information on IRB/ethics committee permissions, and information on consent and assent of participants. In the case of authorship, we suggest that the guidelines of the ICMJE be followed.

These requirements given in the "instructions to authors" of medical journals will be informative to readers and also encourage ethical research and publication practices.

**References**

- Bavdekar SB, Gogtay NJ, Chavan R. Reporting ethical processes: Survey of "instructions to authors" provided by Indian journals. *Indian J Med Sci.* 2009 Jun;63 (6):260-2.
- Jaykaran, Gohiya S, Gohiya V, Sharma G, Saurabh MK, Yadav P. Reporting of the methodological quality and ethical aspects in clinical trials published in Indian journals: a survey. *Journal of Pharmacy Research.* 2010,3(2):307-9.
- Samad A, Khanzada TW, Siddiqui AA. Do the instruction to authors of Pakistani Medical Journals convey adequate guidance for authorship criteria?. *Pak J Med Sci.* 2009;25(6):879-82.
- Wilcox LJ. Authorship: the coin of realm, the source of complaints. *JAMA.* 1998 Jul 15;280(3):216-7.
- Dhaliwal U, Singh N, Bhatia A. Awareness of authorship criteria and conflict: Survey in a medical institution in India. *MedGenMed.* 2006;8(4):52.
- Wager E. Do medical journals provide clear and consistent guidelines on authorship? *MedGenMed.* 2007;9(3):16.
- Rowan-Legg A, Weijer C, Gao J, Fernandez C. A comparison of journal instructions regarding institutional review board approval and conflict-of-interest disclosure between 1995 and 2005. *J Med Ethics.* 2009 Jan;35(1):74-8.
- Freeman SR, Lundahl K, Schilling LM, Jensen JD, Dellavalle RP. Human research review committee requirements in medical journals. *Clin Invest Med.* 2008;31:E49-54.
- Atlas MC. Emerging ethical issues in instructions to authors of high-impact biomedical journals. *J Med Lib Assoc.* 2003 Oct;91(4):442-9.
- Pellizzon Rde F, Montero EF, Problacion DA, Monteiro R, Castro RC. Brazilian scientific journals in surgery. III: analysis of the instructions for authors based on Vancouver uniform requirements. *Acta Cir Bras.* 2007;22:511-8.
- ICMJE International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publications [Internet]. [place unknown]: International Committee of Medical Journal Editors; 2009 [cited 2010 Dec 2]. Available from: <http://www.icmje.org/>

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