Original Article

An audit of reporting of conflict of interest policies among three stakeholders in Indian biomedical journals

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Abstract

Background: A conflict of interest (COI) in publication exists when the primary interest of publication is influenced by a secondary interest (financial or non-financial). International guidelines are available that can be used by journal editors to formulate their own COI policies. The present study was carried out with the objective of evaluating COI policies existing among Indian biomedical journals.

Materials and Methods: MEDLINE/PubMed and MedIND/IndMed databases were searched. Inclusions were journals that were active and indexed. Outcome measures were proportion of journals: (a) mentioning COI disclosure statement for authors, reviewers, and editors, (b) adequately explaining COI, (c) referring to three international guidelines, and (d) the proportion of PubMed/other than PubMed indexed journals mentioning COI policy for authors, reviewers, and editors and providing an adequate explanation for COI. Apart from descriptive statistics, associations between indexing and COI Policy for all three stakeholders were evaluated.

Results: A total of $n = 106$ journals formed the final sample. Among them, 82 (77%) were PubMed and 24 (23%) were MedIND/IndMed indexed. COI disclosure statement was mentioned in 93 (87.7%) journals for authors, 10 (9.4%) for reviewers, and 06 (5.6%) for editors. Only 35 (33%) journals adequately explained COI. A total of 61 (57.5%) journals endorsed all the three international guidelines. PubMed indexing was found to be associated with approximately 19 times the odds of COI policies being present on the journal's home page relative to the journals indexed with other indexing agencies (crude odds ratio - 18.8, 95% confidence interval [4.6, 77], $P < 0.0001$).

Conclusion: Very few Indian biomedical journals have COI policies for reviewers and editors and most did not explain it adequately. Nearly, a fifth of the journals we evaluated did not follow any guideline for disclosing COI.

Keywords: Authors, editor, medical journals, reviewer

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INTRODUCTION

Publications in Biomedical Journals generate evidence to influence practice guidelines and health policies. Most publications require authors to declare their conflict of interest (COI) as part of the journal's requirements. COI is said to exist when the primary interest of the publication is influenced by a secondary interest.[1] Secondary interests may include personal financial profit or non-financial

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advantages.[2] COIs have the potential to affect the quality of healthcare by influencing decision-making.[3]

Organizations such as the International Committee of Medical Journal Editors (ICMJE), the World Association of Medical Editors (WAME), and the Committee on Publication Ethics (COPE) have laid down guidelines to address COI. ICMJE guidelines all participants in the peer-review and publication process — not only authors but also peer reviewers, editors, and editorial board members of journals — must consider their conflicts of interest when fulfilling their roles in the process of article review and publication and must disclose all relationships that could be viewed as potential COI.[4] Both COPE and WAME guidelines address COI in cases of submissions to the journal from the editorial board members.[5,6] The most recent [2018] ICMJE's "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals," provides a more explicit statement on COI for authors.

Indian Council of Medical Research [ICMR] Ethical Guidelines for Biomedical and Health Research involving Human Participants [2017] mentions COI in research and publication.[7] However, as yet, India does not have a national policy to specifically address COI. Gauging the extent of the problem across Indian Biomedical Journals may help any national policy that will be formed. Against this backdrop, the present study was envisaged with the objective to assess COI policies among Indian biomedical journals.

MATERIALS AND METHODS

Ethics

The study was exempted from review by the Institutional Ethics Committee as the data were available in the public domain [EC/OA-33/2019].

Study design, selection criteria, databases, and search strategy

This audit included journals that were currently active and published from India. MEDLINE/PubMed and MedIND/IndMed databases were searched. The search strategy used was – (India* AND medicine [Mesh] OR "Specialities, Surgical" [Mesh]).

Study procedure

Instructions to authors and editorial policy of the identified journals were hand searched for "COI"/"Competing interest" disclosure policy. The journals were subsequently classified based on the nature of indexing (PubMed/Other than PubMed indexed journals) and nature of discipline (Medical, Surgical, Multidisciplinary, and Miscellaneous). The COI policy was reviewed for three stakeholders – authors, peer reviewers, and editor/editorial team. The explanation provided for COI by the journals was classified as adequate or inadequate, depending on whether the journals provided an explanation for both financial and non-financial COI. A clear explanation was defined as one that gave at least one example each of both financial and non-financial COI.

Outcome measures

These were: (1) the proportion of Indian Biomedical journals – (a) mentioning COI policy for each of the three stakeholders, (b) providing an adequate explanation of COI, and (c) endorsing ICMJE, WAME and COPE guidelines, (2) the proportion of PubMed/other than PubMed indexed journals (a) mentioning COI policy for all three stakeholders and (b) providing an adequate explanation for COI, (3) the proportion of journals from various disciplines (a) mentioning COI policy for all three stakeholders and (b) providing an adequate explanation for COI.

Statistical analysis

Both descriptive and inferential statistics were used. Categorical data were presented as proportions. Chi-square or Fisher's exact test was used to measure the association between the nature of indexing and nature of disciplines with statement of COI Policy for all three stakeholders and its explanation. Crude odds ratio (cOR) with 95% confidence intervals (CIs) was calculated to measure the strength of association between the nature of indexing and disciplines with the COI policy and its explanation. Binary associations of two types evaluated were: (a) Miscellaneous journals versus all journals from other disciplines and (b) surgical journals versus medical journals or surgical journals versus miscellaneous category. All analyses were performed at 5% significance using Microsoft Excel 2016, Microsoft Corporation, Redmond, Washington, USA.

RESULTS

Demographics

A total of n = 228 journals were found across PubMed/MEDLINE, IndMed and MedIND databases. A total of 60 journals were duplicates and thus excluded. One hundred and sixty-eight journals were screened to shortlist n = 106 that finally satisfied the selection criteria.

Nature of indexing

Among the n = 106 journals, 82 (77%) journals were PubMed indexed and the remaining 24 (23%) journals were

indexed with IndMed/MedIND. Among these journals, majority (47, 44.3%) of the journals were both PubMed and IndMed indexed followed by 30 (28.3%) journals that were PubMed indexed only and 15 (14.1%) journals that were IndMed indexed only. Only 08 (7.5%) journals were IndMed and MedIND indexed, 04 (3.7%) journals were PubMed, IndMed and MedIND indexed, only 01 (0.9%) journal was both PubMed and MedIND indexed and one journal (0.9%) was only MedIND indexed.

Nature of disciplines

Among the *n* = 106 journals, 63 (59.4%) journals were medical, 17 (16%) journals were surgical, 11 (10.4%) were multidisciplinary journals, and 15 (14.2%) journals were classified in the miscellaneous category.

Conflict of interest disclosure policy among the three stakeholders [Table 1]

a. Authors: Among the *n* = 106 journals, 93 (87.7%) journals had COI disclosure policy for authors
b. Reviewers: Among these *n* = 106 journals only 10 (9.4%) journals had COI disclosure policy for reviewers
c. Editors: Out of *n* = 106 journals, only 06 (5.6%) journals had COI disclosure policy for editors.

Adequate explanation of conflict of interest

Out of *n* = 106 journals, majority (71, 66.9%) of the journals did not explain COI clearly.

Endorsement of international guidelines for conflict of interest

Among the *n* = 106 journals, 19 (17.9%) journals did not endorse any guideline. Majority (61/106, 57.5%) of the journals endorsed all the three guidelines, 12/106 (11.3%) journals endorsed ICMJE guideline alone, 09/106 (8.4%) journals endorsed COPE guideline, 03/106 (2.8%) journals endorsed both COPE and ICMJE guidelines and 02/106 (1.9%) journals endorsed both WAME and COPE guidelines.

Conflict of interest disclosure policy among stakeholders based on nature of indexing

Among the *n* = 82 PubMed indexed journals, majority of the journals had COI disclosure policy for authors (79/82, 96.3%) and very few journals for reviewers (07/82, 8.5%) or editors (03/82, 3.7%). Similarly, out of the *n* = 24 journals indexed with IndMed/MedIND, majority of the journals (14/24, 58.3%) journals had COI disclosure policy for

Table 1: Conflict of interest disclosure policy and explanation of conflict of interest of the journals

Nature of Indexing (*n*=106)	PubMed Indexed (82/106; 77%)	Other than PubMed Indexed (24/106; 23%)		
COI disclosure policy (Present/absent, percent)		**COI disclosure policy (*n*/*N* [percent])**		
Authors				
Present (93/106, 87.7)	79/82 (96.3)	14/24 (58.3)		
Absent (13/106, 12.3)	03/82 (3.7)	10/24 (41.7)		
Reviewers				
Present (10/106, 9.4)	07/82 (8.5)	03/24 (12.5)		
Absent (96/106, 90.6)	75/82 (91.5)	21/24 (87.5)		
Editors				
Present (06/106, 5.6)	03/82 (3.7)	03/24 (12.5)		
Absent (100/106, 94.4)	79/82 (96.3)	21/24 (87.5)		
Explanation of COI (present/absent, percent)		**Explanation of COI (*n*/*N* [Percent])**		
Explanation of COI				
Present (35/106, 33.1)	29/82 (35.4)	06/24 (25)		
Absent (71/106, 66.9)	53/82 (64.6)	18/24 (75)		
Nature of disciplines	**Medical (63/106; 59.4%)**	**Surgical (17/106; 16%)**	**Multidisciplinary (11/106; 10.4%)**	**Miscellaneous [15/106; 14.2%)**
COI disclosure policy (present/absent, percent)		**COI disclosure policy (*n*/*N* [Percent])**		
Authors				
Present (93/106, 87.7)	56/63 (88.9)	17/17 (100)	11/11 (100)	09/15 (60)
Absent (13/106, 12.3)	07/63 (11.1)	0/17 (00)	0/11 (00)	06/15 (40)
Reviewers				
Present (10/106, 9.4)	04/63 (6.3)	01/17 (5.8)	01/11 (9.1)	04/15 (26.6)
Absent (96/106, 90.6)	59/63 (93.7)	16/17 (94.2)	10/11 (90.9)	11/15 (73.4)
Editors				
Present (06/106, 5.6)	02/63 (3.1)	01/17 (5.8)	00/11 (00)	03/15 (20)
Absent (100/106, 94.4)	61/63 (96.9)	16/17 (94.2)	11/11 (100)	12/15 (80)
Explanation of COI (present/absent, percent)		**Explanation of COI (*n*/*N* [percent])**		
Explanation of COI				
Present (35/106, 33.1)	18/63 (28.5)	11/17 (64.7)	04/11 (36.4)	2/15 (13.3)
Absent (71/106, 66.9)	45/63 (71.5)	06/17 (35.3)	07/11 (63.6)	13/15 (86.7)

COI: Conflict of interest

authors but very few for reviewers (03/24, 12.5%) or editors (03/24, 12.5%).

Explanation of conflict of interest and nature of indexing

Among the $n = 82$ PubMed indexed journals, 29/82 (35.4%) journals provided a clear explanation for COI, whereas, among the journals ($n = 24$) indexed with IndMed/MedIND, only 06/24 (25%) journals had a clear explanation for COI.

Conflict of interest disclosure policies among stakeholders and nature of disciplines

Among the $n = 63$ medical journals, most journals (56/63, 88.9%) had COI disclosure policy for authors, very few for 04 (6.3%) reviewers and only 02 (3.1%) for editors. Among the $n = 17$ surgical journals, all (17/17, 100%) had COI disclosure policy for authors and one journal (5.8%) each for reviewer and editor (5.8%). Among the $n = 11$ multidisciplinary journals, all had [11/11, 100%] COI disclosure policy for authors, only one (9.1%) journal for reviewers and none for editors. Among the $n = 15$ miscellaneous journals, most of the journals (09/15, 60%) had COI disclosure policy for authors and very few 4 (26.6%) for reviewers and only 3 (20%) for editors.

Explanation of conflict of interest disclosure and nature of disciplines

Among the $n = 63$ medical journals, 18 (28.5%) journals provided clear explanation for COI. Out of $n = 17$ surgical journals, majority of the journals (11, 64.7%) provided clear explanation for COI. Among the $n = 11$ multidisciplinary journals, 04 (36.4%) journals provided a clear explanation for COI. Out of $n = 15$ journals, only 02 (13.3%) journals provided a clear explanation for COI.

Associations

Conflict of interest policy and nature of indexing

PubMed indexing was associated with approximately 19 times the odds of COI policies being present for authors on the journal's home page relative to the journals indexed with IndMed/MedIND (cOR – 18.8, 95% CI [4.6, 77], $P < 0.0001$) There was no association between the COI policies being present for reviewers, editors with the nature of indexing.

Explanation of conflict of interest and nature of indexing

Nature of indexing was not associated with explanation of COI.

Conflict of interest policy and nature of disciplines

Journals from Medical, Surgical and Multidisciplinary category were associated with eight times the odds of COI policies being present for authors relative to journals from miscellaneous category (cOR – 8.0, 95% CI [2.2, 29.03], $P = 0.001$). There was no association between the medical, surgical, multidisciplinary journals and journals from other disciplines with regard to disclosure of COI for authors ($P > 0.05$).

Medical journals were associated with five times the odds of COI policies being present for authors relative to journals from miscellaneous category (cOR – 5.3, 95% CI [1.4, 19.6], $P = 0.01$). Surgical journals were associated with approximately 11 'times the odds of COI policies being present for authors relative to the journals from miscellaneous category (cOR – 10.6, 95% CI [1.1, 103], $P = 0.04$).

Associations were not done for COI policies among reviewers and editors as the number of journals that had policies for these categories were very few.

Explanation of conflict of interest and nature of disciplines

Surgical journals were associated with approximately four times the odds of providing a clear explanation for COI relative to journals from other disciplines (cOR – 4.2, 95% CI [1.4, 12.5], $P = 0.009$). There was, however, no association between the journals from the miscellaneous category, medical and multidisciplinary journals and journals from other disciplines with respect to clarity of explanation of COI ($P > 0.05$).

Surgical journals were associated with four times the odds of providing clear explanation for COI relative to the medical journals (cOR– 4.5, 95% CI [1.4, 14.2], $P = 0.008$). Surgical journals were associated with four times the odds of providing a clear explanation for COI relative to journals from miscellaneous category (cOR – 11.9, 95% CI [1.9, 71.4], $P = 0.006$). There was no association between medical, multidisciplinary, and miscellaneous journals with respect to clarity of explanation of COI. Similarly, there was no association between surgical and multidisciplinary journals ($P > 0.05$).

DISCUSSION

Our audit on reporting of COI policies among Indian biomedical journals found that COI disclosure policy for authors was described in nearly 90% of the journals. However, very few journals had COI policies in place for reviewers and editors. PubMed indexing was associated with higher odds of having a COI policy for authors and surgical journals had higher odds of providing an adequate explanation of the COI policy relative to journals from other disciplines.

We noted that a majority of journals had COI disclosure policy only for authors compared to COI policies for reviewers and editors. This indicates that COI is not associated with the latter which is erroneous as authors are not the only stakeholders in the publication process. Anraku *et al*. found that nearly 80% of the Ophthalmology journals had COI policies for authors, and only 7% for reviewers and 5% for editors.[8] Similarly, Smith *et al*., found that among the ten top medical journals, only four had accessible COI policies for editors.[9] Availability of COI policies in the public domain for peer reviewers and editors will help assess whether a journal truly has an all-encompassing COI policy in place.

We found that more than two-thirds of the journals did not provide an adequate explanation for COI. Ancker and Flanagin also similarly noted that more than half of journals studied by them did not have COI disclosure policy with clear definitions and examples.[10] There are two possible reasons for this – (a) an assumption by the journal editors that all stakeholders have a clear understanding of what COI means and entails and (b) lack of awareness that submissions come from a wide range of authors not all of whom may be knowledgeable. Thus, merely having a COI policy is not adequate. Clear cut examples (both financial and nonfinancial) must be detailed on the website.

Nearly a fifth of the journals did not endorse any international guideline for addressing COI. This could reflect lack of awareness about their existence. It also indicates that a national guideline would help journal editors to formulate their own policies.

The finding of PubMed indexing being associated with a greater likelihood of the presence of a COI policy may stem from the fact that having a COI policy is needed for indexing. The MEDLINE website promotes an appropriate disclosure of COI so that users may assess the credibility of the findings.[11]

A higher proportion of surgical, medical and journals from other disciplines (surgical, medical and multidisciplinary combined) had COI disclosure policy for authors (relative to the journals in the miscellaneous category). Bhandari *et al*. reported that pharmaceutical industry funded surgical trials had eight times the odds of reporting statistically significant pro-industry findings relative to investigator-initiated studies. They also reported that pharmaceutical industry funded drug trials had five times the odds of reporting positive outcomes relative to investigator-initiated studies.[12] Therefore, transparency in reporting COI is vital in this specialty and our finding of surgical journals having COI policies is encouraging.

A significantly higher proportion of surgical journals clearly explained the COI. Surgical trials are conducted often in collaboration with large multinational pharmaceutical companies or device manufacturers. If these publications are not written by the surgeon (investigator), but by the industry funding the trial, there will be a declaration of COI due to a greater appreciation of its need by the industry. This is more relevant when the outcome is positive as COI is a metric of the risk of bias.

Our study is limited by the fact that we have evaluated only the home page of the all included journals. A study has found that COI policies for editors are less likely to be present in the "Instructions for Authors" and are usually circulated internally to the editorial members.[13] We could not access their manuscript management system designed for reviewers and editors, did not confirm the COI disclosure policy for editors and reviewers by directly writing to them and evaluated only PubMed and IndMed indexed journals.

CONCLUSION

Most of the journals stated COI disclosure policy for authors but only few journals had COI disclosure statement for reviewers and editors and nearly one fifth of the journals did not endorse any international guidelines for addressing COI. There should be greater awareness among the editors and mandate for all the journals to display COI disclosure policy on the Journals' home page for all the stakeholders, irrespective of their indexing status and nature of discipline.

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Conflicts of interest

There are no conflicts of interest.

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