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Competing-interest disclosure at medical journals in Japan: a nationwide survey

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Competing-interest disclosure at medical journals in Japan: a nationwide survey

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Original Research

Key Words: conflict of interest, editorial secretariats, education and training, publication ethics

Abstract

Objectives:
Medical journals in Japan have appropriate policies regarding disclosure of competing interests (henceforth COI). However, COI management depends on the staff members of each journal's editorial secretariat. This study's objectives were to find out (a) whether COI disclosure and the journal's role in it are clearly understood, (b) how much experience the editorial secretariat has in actually handling issues related to disclosure, and (c) what kind of help or support they need.

Setting & Design:
Questionnaires were sent to the editorial secretariats of journal-publishing societies belonging to the Japanese Association of Medical Sciences (JAMS).

Participants:
At the time of the study, the JAMS comprised 118 academic medical societies, publishing 121 journals that report original research. The editorial secretariats of all 121 journals participated in this study.

Primary and secondary outcome measures:
Information was collected on the history of COI policies and on how those policies were implemented. At the end of the questionnaire there was an open-ended call for comments.

Results:
Compulsory COI disclosure began between 2010 and 2013 for 60.3% of the journals (73/121). Handling of COI issues was not uniform: 17.4% (21/121) of respondents do not pursue cases of dubious disclosure, and 47.9% (58/121) do not require COI disclosures from editorial board members. Very few of the editorial secretariats had clearly-stated consequences for violations of COI-disclosure policy (33/121, 27.3%), and only 28.9% offered COI education (35/121). Respondents' comments indicated that uniform, indexed guidance regarding COI policies and implementation would be welcome.

Conclusions:
Although commitment is widespread, policy implementation is inconsistent and COI experience is lacking. Clear, easy-to-use guidelines are desired by

many societies. The JAMS is to be commended for supporting this country-wide investigation: other countries and regions are encouraged to perform similar investigations to respond to needs regarding COI management.

Strengths and limitations of this study

- This is the first-ever international report of a nationwide survey on COI management among Japanese medical societies.
- The response rate was 100%, and the respondents represented all 121 member societies (as of December 2014) of the Japan Association of Medical Sciences (JAMS).
- The findings should not be generalized outside Japan, so additional nationwide surveys such as this one will be needed to facilitate obtaining a grasp of COI management in various countries and regions.

Introduction

In publishing medical research, competing interests are "almost inevitable."[1] Of course they should be disclosed, but who ensures that they are? Editors and authors can avail themselves of training materials on publication ethics[2], and senior researchers are encouraged to teach good publication practices to their juniors[3]. Anyone with an Internet connection can easily access clear statements of positions on this topic that have been endorsed by groups of journal editors[4, 5, 6]. Such education and official declarations are essential, but we suspect that they are not enough, because policies on disclosure of competing interests are implemented by the staff members of each journal's editorial secretariat. We believe that their role is crucial. They are a journal's first point of contact with potential conflicts of interest (COI), and at later stages of the process too, those staff members translate policies into practice.

To illuminate the realities of COI management, we began close to home. The Japan Association of Medical Sciences (JAMS) is a group comprising 118 academic medical societies[7]. The 118 member societies publish 121 journals with original research in basic medical sciences, clinical medicine, laboratory medicine, public health, etc. The COI Subcommittee of the JAMS requested one of its members (one of the authors, JPB) to report on COI management by JAMS members. The official guidelines of the JAMS with regard to disclosure of competing interests[8] are generally consistent with the positions of the International Committee of Medical Journal Editors (ICMJE), the World Association of Medical Editors (WAME), and the Council of Science Editors (CSE), but we were interested in the *implementation* of those policies at each journal's editorial secretariat. Here we report information provided by the JAMS member societies with regard to (a) whether there is a clear understanding of COI disclosure and of the journal's role, (b) how much experience the editorial secretariat has in actually handling issues related to disclosure, and (c) what kind of help or support they need[9].

Materials and Methods

We compiled a questionnaire of 8 questions, and 1 question was added by

the JAMS office. The questions concerned the history of COI policies of each journal, and how those policies were implemented. At the end there was an open-ended call for comments on the topic. English versions of the questions that were given in Japanese are in Table 1.

Table 1. Questions included in the COI questionnaire

1. Has your journal made any effort to positively prove the credibility of COI disclosure or declaration (especially when "No COI to declare" is reported)? How do you corroborate this statement?
2. In your journal, if the COI disclosure by the author has not been made or is incomplete at submission, does the secretariat request an explanation? If yes, how many times a year?
3. When did you start posting the liability of COI disclosure in the Instructions to Authors of your journal?
4. Does your journal investigate when dubious cases regarding COI declaration arise?
5. Do you make it obligatory for members of the editorial committee of your journal to make COI disclosures when they are appointed?
6. Do the reviewers and editorial board members understand the significance and importance of COI disclosure? What kind of education or training do you carry out to ensure the above?
7. Do you have a system of regulations for sanctions regarding those who contravene COI disclosure policy? (Paper withdrawal, embargo on paper submission etc.)
8. How often does your office receive questions about COI and COI disclosure?
9. Please list any problems or unclear points concerning COI management regarding submitted manuscripts.

The questionnaire was distributed by the JAMS central office to editorial secretariats of its 118 premier journal-publishing member societies, which are called "Bunkakai" of the JAMS (4 Bunkakai were added after this survey was done, so that as of December 15, 2014 the JAMS had 122 Bunkakai)[10]. The completed forms were returned to the JAMS office, which then collected and sent them to one of the authors (JPB), who was responsible for collating and tabulating the data. All 118 Bunkakai returned their forms. A total of 121 forms were returned, because 3 of the Bunkakai returned 2 forms each, 1 for their Japanese-language journal and 1 for their English-language journal. For each of those 3 Bunkakai, it is clear that the 2 journals had separate editorial secretariats, because the contact information and the responses to the questions were different. Thus there was no duplication of respondents.

Results

All 118 Bunkakai returned their forms. A total of 121 forms were returned, because 3 of the Bunkakai returned 2 forms each, 1 for their Japanese-language journal and 1 for their English-language journal. For each of those 3 Bunkakai, it is clear that the 2 journals had separate editorial secretariats, because the contact information and the responses to the questions were different. Thus there was no duplication of respondents. Because of missing data on some questions, the tabulated responses reported here sum to less than 100%. All totals and percentages are in the Appendix.

The first question asked if the journals made any efforts to positively corroborate the credibility of COI disclosures, especially when the authors of a paper stated that they had no COI to declare. Approximately 77% of the societies do not make any effort to corroborate statements regarding the absence of COI, and only 19.8% stated that they did attempt to confirm COI statements.

In response to the next question, 42.9% of the journals stated that they did not check with the author in cases in which the COI disclosure statement is incomplete. More than 75% of journals either had no such clarification issues, or had fewer than 4 cases per year.

Regarding the period in which societies began to require COI disclosure, there was a clear peak (60.3%) in the 4-year period of 2010-2013. When asked about investigations of dubious cases of COI declaration, almost 70% stated that they did investigate suspicious cases but 21 of the respondents revealed that they did not (about 13% did not respond to this question). Comments made by the societies concerning this aspect included statements suggesting that their investigational system had not been fully determined and that the societies consider themselves to be in a kind of trial period. There were also some comments indicating that while some journal secretariats believe such matters to be in the province of the COI committee, others consider it is not the duty of the editorial committee to act on such issues. There was also a comment from a single journal that a suspicious case would be discussed with the publisher.

In response to the question on whether editorial board members are asked to disclose any personal COI on their appointment as board members, almost half (47.9%) stated that they do not make such disclosure obligatory. Those journals that did make it obligatory constituted just under half (49.6%) of the total number of journals, suggesting that journals may not be aware of the fact that all persons related to the publication of the paper, including authors, reviewers, medical editors, and all those named in the acknowledgement section, should disclose any potential COI.

One question was a composite, inquiring whether the reviewers and the editorial board members understood the significance and importance of COI disclosure and also whether the society carried out any education or training regarding COI disclosure. From the responses to this question we found that COI education was given by only 35 of the editorial secretariats (28.9%). With regard to sanctions or obligations imposed on those who contravene COI disclosure policy, such as enforced retraction, embargoes on paper submission, etc., only 27.3% of journals had a regulation system in place.

In response to our request for comments regarding COI management and related problems, it became clear that some journals had not experienced a single case of COI disclosure problems. An overall lack of confidence on the suitability of their own system was expressed in comments by many journals. There were also repeated comments on the lack of a sufficient surveillance mechanism and systems that would allow for reliable and transparent implementation of COI management.

Questions were also raised by editorial secretariats concerning present policies of holding documentation for only 1-2 years after publication of a paper. The feeling was also expressed that, since university and research institutes usually have ethics committees, regulation of researchers' ethical behavior should be left up to the authors themselves or their institutions, and should not be the responsibility of the journal or the editorial secretariats.

In general, the comments highlighted a lack of a uniform system of COI management implementation and the need for more convenient and easy-to-refer-to guidelines in Japanese for the use of the journals' secretariats.

Discussion

We set out to determine how COI-disclosure policies were being implemented at medical journal-publishing societies in Japan. Only half of the journals requested an explanation if a COI-disclosure statement were missing or incomplete, which shows that having a policy is not enough, as implementation can be lacking or inconsistent.

More than 1 in 6 journals in Japan in our study did not investigate cases in which non-disclosure of COI was suspected, which threatens the viability of the entire system. This could be both a cause and an effect of the current situation in Japan in which many staff members at editorial secretariats lack confidence in implementing COI-related policies, although they are given those responsibilities. Staff members of editorial secretariats were uncertain about the implementation of COI-disclosure policies at their journals. In addition, practices such as sanctioning violators of journal policy, COI disclosure by editors and reviewers, and education about COI were implemented inconsistently among the journals.

As pointed out by Smith in his 1998 BMJ editorial and reaffirmed by Irwin in his comments 20 years later, expectations for transparency and accountability of research are increasing, so COI needs constant attention and this appears to be a common worldwide situation[3, 11]. In a randomised trial, “BMJ readers reported that data showing the impact of pain from herpes were less interesting, important, relevant, valid and believable when the authors were employees of a fictitious pharmaceutical company compared with an ambulatory care centre.”[12]
This indicates that the task of those who educate authors and implement COI-related policies is complicated further because of the belief that readers will discount the results of a study if the authors of that study had a potential COI. That belief is justified.

Although some of the societies in this survey consider that COI education and policy implementation is the province of universities and research institutes, we would submit that the societies or journals themselves are the ultimate gatekeepers of scientific integrity. Journals and academic societies are thus obligated educate their officers and members concerning COI and COI disclosure. As necessary as it is, education concerning COI does have

its challenges. Therefore, creating uniform guidelines on COI that can be easily used, regardless of the level of awareness the author has, could provide a solution to this problem. Regarding this, many international journals and institutions, such as the BMJ and AMA have sought to explain how to deal with COI problems in an open, fair, and transparent manner. Attitudes towards COI have become more strict and definitions more narrow worldwide. In Japan, journal-publishing medical societies first adopted COI policies around 2010, at about the same time the ICMJE introduced its COI Disclosure Form in 2009. Several modifications of the latter were made based on feedback regarding the form, after piloting it and making it publicly accessible among ICMJE member journals[13]. Modifications included elimination of the necessity of including authors' spouses, minor dependents, relatives, and nonfinancial competing interests[14]. However, many Japanese societies and journals still specify that these be included in COI disclosures. This situation emphasizes the need for authors to consult Instructions to Authors before submission, but even more importantly, it suggests the need for at least national, if not international policies, and in all fields of medical research.

Approximately half of all society journals in this study do not require their editorial board members to make COI disclosures, and thus they contravene ICMJE Recommendations, which state that all those involved in the publishing process should disclose any potential COI[15]. Furthermore, not only authors, but reviewers and editors, and all editorial secretariat members, as well as anyone mentioned in Acknowledgement sections must be given education on the significance of COI and on how to make appropriate, transparent statements. In addition, we feel that there should be detailed information on COI, separate from the Instructions to Authors, perhaps preceding the COI disclosure formats, clearly specifying the nature of the situation, and requiring individual agreement from all coauthors, before consideration for publication. The results of our survey point to a lamentable lack of education in this field, which involves all of medical publishing in Japan, and which we suspect is a problem facing many other countries as well.

Regardless of whether non-disclosure of COI is intentional or an honest mistake, the author, as a member of the scientific community, cannot plead ignorance of the rules. There is, therefore, a need for sanctions to enforce COI policy. Sanctions of course can be determined by the individual society or journal, e.g. embargo on future submissions for a certain period

of time. While these do not need to be spelled out by the individual journal, it should be made absolutely clear to all concerned that there will be a serious penalty to be paid for any transgression.

In this regard, and with a mind to the desirability of uniformity and international harmonization of policies, it may be necessary to strengthen and increase recognition of organizations such as the International Society for Medical Publication Professionals[16] and the Committee on Publication Ethics (COPE). In particular, the COPE has produced flowcharts that are freely available in several languages, providing advice and steps to follow for journals in cases of suspected or definite undisclosed COI[17]. They also make it clear to authors what process will be followed in such cases. National bodies such as the JAMS could also play an important role.

Limitations:

We could not be sure whether the respondent was a staff member working in the editorial office, or the editor, or a representative of the COI committee for that society, and respondents in different positions could differ in their understanding of COI-related issues and in their experience implementing COI policies. This limitation emphasizes the need for an easily comprehensible transparent system of guidelines and procedures consistently evaluable by all staff. The strongly hierarchical nature of the Japanese medical world may prevent editorial-secretariat staff from contributing fully to the development and implementation of processes for managing COI-related issues, and that would also be true in similarly hierarchical workplaces worldwide.

Despite the increasing concern regarding various aspects of COI, Japanese medical societies (and, we suspect, academic societies in many other nations) lack uniform understanding, despite great sincerity and effort, and are also lacking in many aspects of COI education. The confusion in the editorial offices of Japanese medical societies about COI management clearly shows that greater and more thorough emphasis should be placed on education in scientific communications ethics.

Conclusion

On the basis of these findings we recommend that Japanese medical societies adopt common guidelines on how to manage COI. Furthermore, providing a form such as the ICMJE COI form in Japanese to all Japanese medical societies could help their editorial secretariats standardize their education for staff, reviewers, and editors. The AMA, among other societies, now requires that all authors submitting to JAMA submit the ICMJE COI Disclosure Form[18], and the JAMS member societies too would do well to require that form or a similar document. However, we also believe that COI disclosure should include all interests that might affect the perception of the behavior of the author(s), and therefore should include non-financial competing interests. Hamilton states that personal COI, such as COI with a family member, religious, cultural, ethnic, or political COI, is potentially as detrimental as financial COI[2]. Therefore, we recommend that a standard form be developed in Japanese for non-financial COI, which could be used in addition to the ICMJE COI form.

Creating simple guidelines on COI disclosure and management in Japanese can help the staff of editorial secretariats enforce their journals' policies. We recommend that the JAMS societies use a Japanese-language version of the ICMJE's COI disclosure form. This standardized COI disclosure form would help both authors and editorial offices to clearly understand what information they should disclose when submitting to any member journal of the JAMS. The measures outlined here could also enable focused education on COI, and improve the overall situation of COI management.

In closing, we would like to compare the situation in Japan with that in other parts of the world, but we are unable to do so because, to the best of our knowledge, no comparable study has been published. We hope that others will follow the JAMS in honest self-examination of the translation of policy into practice.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Contributors: The questionnaire was composed by all authors (TK, JG, JPB) together. Tabulation of the data was the responsibility of JPB. The manuscript was written collaboratively by TK, JG and JPB. All authors agreed to submission.

Data sharing: no additional data available.

All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Appendix

Question 1 Has your journal made any effort to positively prove the credibility of COI disclosure or declaration (especially when "No COI to declare" is reported)? How do you corroborate this statement? Yes: 24 (19.8%) No: 93 (76.9%) No response: 4 (3.3%)
Question 2 In your journal, if the COI disclosure by the author has not been made or is incomplete at submission, does the secretariat request an explanation? If yes, how many times a year? Yes: 63 (51.7%) Up to 3: 41 (33.8%) 4-10: 12 (9.9%) 11-25: 5 (4.1%) 26 and over: 5 (4.1%) No: 52 (42.9%) No response: 6 (5.0%)
Question 3 When did you start posting the liability of COI disclosure in the Instructions to Authors of your journal? 2005-2009: 26 (21.5%) 2010-2013: 73 (60.3%) 2014- : 9 (7.4%) *1 responded "from 2001" No response: 13 (10.7%)
Question 4 Does your journal investigate when dubious cases regarding COI declaration arise? Yes: 84 (69.4%) No: 21 (17.5%) No response: 4 (3.3%) Other: 12 (9.9%), e.g. Have not had any dubious cases so far; will consider the investigational system after rules have been implemented; Editorial Committee and COI Committee will decide if it occurs

Question 5 Do you make it obligatory for members of the editorial committee of your journal to make COI disclosures when they are appointed? Obligatory: 60 (49.6%) Not obligatory: 58 (47.9%) No response: 3 (2.5%)
Question 6 Do the reviewers and editorial board members understand the significance and importance of COI disclosure? What kind of education or training do you carry out to ensure the above? Education given: 35 (28.9%) No education given: 82 (67.8%) No response: 4 (3.3%)
Question 7 Do you have a system of regulations for sanctions regarding those who contravene COI disclosure policy? (Paper withdrawal, embargo on paper submission etc.) Regulation system in place: 33 (27.3%) No sanction system: 85 (70.2%) No response: 3 (2.5%)
Question 8 How often does your office receive questions about COI and COI disclosure? 1-5: 42 (34.7%) 10-30: 8 (6.6%) None: 53 (43.8%) "Almost none" or no response: 18 (14.9%)
Question 9 Please list any problems or unclear points concerning COI management regarding submitted manuscripts. Selected responses: ● We have not a single case of COI disclosure. ● We lack confidence in the suitability of our present system. ● What should be done concerning paper acceptance and publication if commercial sponsoring appears involved? ● Although COI disclosure is made for the entire manuscript on submission, its clarification requires confirmation. ● It appears that some journals destroy disclosure documentation after 1-2 years, but there is no problem in destroying documentation concerning accepted manuscripts? ● The method of investigating the background of COI disclosure contents is

unclear.

- Are investigations and sanction systems common in foreign journals?
- We do not fully comprehend the extent to which COI management should be implemented. We would appreciate concrete instructions from JAMS.
- Many universities and research institutes have ethics committees, COI committees and other committees regulating the behavior of investigators, and as a result journals tend to leave ethical questions up to the submitting author.
- How COI disclosure conditions are decided on is unclear.

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Original Research

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Abstract

Objectives:
Medical journals in Japan generally have appropriate policies regarding disclosure of conflicts of interest (COI). However, COI management depends on the staff members of each journal's editorial secretariat. This study's objectives were to find out (a) whether COI disclosure and the journal's role in it are clearly understood by the journals' secretariat staff, (b) how much experience the editorial secretariat has in actually handling issues related to disclosure, and (c) what kind of help or support they need.

Setting & Design:
In January 2014, questionnaires were sent to the editorial secretariats of journal-publishing societies belonging to the Japanese Association of Medical Sciences (JAMS).

Participants:
The response rate was 100%, and the respondents represented 121 journals published by the 118 JAMS member societies (at the time of the survey).

Primary and secondary outcome measures:
Information was collected on the history of COI policies and on how those policies were implemented. At the end of the questionnaire there was an open-ended call for comments.

Results:
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Conclusions:
Although commitment is widespread, policy implementation is inconsistent and COI experience is lacking. Clear, easy-to-use guidelines are desired by many societies. The JAMS is to be commended for supporting this country-wide investigation: other countries and regions are encouraged to

perform similar investigations to respond to needs regarding COI management.

Strengths and limitations of this study

- This is the first-ever international report of a nationwide survey on COI management among Japanese medical societies.
- The response rate was 100%, and the respondents represented 121 journals published by the 118 member societies (as of the time of the survey, January 2014) of the Japanese Association of Medical Sciences (JAMS).
- The findings should not be generalized outside Japan, so additional nationwide surveys such as this one will be needed to facilitate obtaining a grasp not only of policies but also of actual COI-management practices in various countries and regions.

Introduction

In publishing medical research, conflicts of interest (COI) are "almost inevitable."[1] Of course they should be disclosed, but research on COI disclosure indicates that journals' policies vary widely[2]. Editors are interested in standardizing disclosure, although doing so may be difficult[2]. There is also some evidence that repeated auditing might improve COI-disclosure practices.[3]

Our focus was on the people who ensure that COI are disclosed. Editors and authors can avail themselves of training materials on publication ethics[4], and senior researchers are encouraged to teach good publication practices to their juniors[5]. Anyone with an Internet connection can easily access clear statements of positions on this topic that have been endorsed by groups of journal editors[6, 7, 8]. Such education and official declarations are essential, but we suspect that they are insufficient, because policies on COI disclosure are implemented by the staff members of each journal's editorial secretariat. We believe that their role is crucial. They are a journal's first point of contact with authors who may have COI, and at later stages of the submission and publication process too, those staff members translate policies into practice.

To continue illuminating the realities of COI management, we began close to home. The Japanese Association of Medical Sciences (JAMS) is a group that comprised 118 academic medical societies[9] at the time of the survey, January 2014. The member societies publish journals with original research in basic medical sciences, clinical medicine, laboratory medicine, public health, etc. The COI Subcommittee of the JAMS requested one of its members (one of the authors, JPB) to report on COI management by JAMS member societies. The official guidelines of the JAMS with regard to COI disclosure [10] are generally consistent with the positions of the International Committee of Medical Journal Editors (ICMJE), the World Association of Medical Editors (WAME), and the Council of Science Editors (CSE), but we were interested in the *implementation* of those policies at each journal's editorial secretariat. Here we report information provided by the JAMS member societies with regard to (a) whether there is a clear understanding of COI disclosure and of the journal's role, (b) how much experience the editorial secretariat has in actually handling issues related to disclosure, and (c) what kind of help or support they need[11].

Materials and Methods

We compiled a list of 8 questions. All authors contributed ideas as to what questions to ask, based on a total of more than 80 person-years of experience in medical editing and publishing. As a native speaker of Japanese, one of the authors (TK) revised and edited the questions for language suitability. One question was added by the JAMS office. The questions concerned the history of COI policies of each journal, and how those policies were implemented. At the end there was an open-ended call for comments on the topic. English versions of the questions that were given in Japanese are in Table 1.

Table 1. Questions included in the COI questionnaire, and tabulated responses

Question 1 Has your journal made any effort to positively prove the credibility of COI disclosure or declaration (especially when "No COI to declare" is reported)? How do you corroborate this statement? Yes: 24 (19.8%) No: 93 (76.9%) No response: 4 (3.3%)
Question 2 In your journal, if the COI disclosure by the author has not been made or is incomplete at submission, does the secretariat request an explanation? If yes, how many times a year? Yes: 63 (51.7%) Up to 3: 41 (33.8%) 4-10: 12 (9.9%) 11-25: 5 (4.1%) 26 and over: 5 (4.1%) No: 52 (42.9%) No response: 6 (5.0%)
Question 3 When did you start posting the requirement for COI disclosure in the Instructions to Authors of your journal? 2005-2009: 26 (21.5%) 2010-2013: 73 (60.3%) 2014- : 9 (7.4%) *1 responded "from 2001" No response: 13 (10.7%)
Question 4 Does your journal investigate when dubious cases regarding COI declaration arise? Yes: 84 (69.4%) No: 21 (17.5%) No response: 4 (3.3%) Other: 12 (9.9%), e.g. Have not had any dubious cases so far; will consider the investigational system after rules have been implemented; Editorial Committee and COI Committee will decide if it occurs

Question 5 Do you make it obligatory for members of the editorial committee of your journal to make COI disclosures when they are appointed? Obligatory: 60 (49.6%) Not obligatory: 58 (47.9%) No response: 3 (2.5%)
Question 6 Do the reviewers and editorial board members understand the significance and importance of COI disclosure? What kind of education or training do you carry out to ensure the above? Education given: 35 (28.9%) No education given: 82 (67.8%) No response: 4 (3.3%)
Question 7 Do you have a system of regulations for sanctions regarding those who contravene COI disclosure policy? (Paper withdrawal, embargo on paper submission etc.) Regulation system in place: 33 (27.3%) No sanction system: 85 (70.2%) No response: 3 (2.5%)
Question 8 How often does your office receive questions about COI and COI disclosure? 1-5: 42 (34.7%) 10-30: 8 (6.6%) None: 53 (43.8%) “Almost none” or no response: 18 (14.9%)
Question 9 Please list any problems or unclear points concerning COI management regarding submitted manuscripts. (See the Appendix)

The questionnaire was distributed in January 2014 by the JAMS central office to editorial secretariats of its 118 *bunkakai*, which are its member societies, all of which publish journals. Other *bunkakai* were added to the JAMS after this survey was done. As of May 17, 2015, 5 *bunkakai* had been added, making a total of 123[12]. The completed forms were returned to the JAMS office, which then collected and sent them to one of the authors (JPB), who was responsible for collating and tabulating the data.

Results

All 118 *bunkakai* returned their forms. A total of 121 forms were returned, because 3 of the *bunkakai* returned 2 forms each, 1 for their Japanese-language journal and 1 for their English-language journal. For each of those 3 *bunkakai*, it is clear that the 2 journals had separate editorial secretariats, because the contact information and the responses to the questions were different. Thus it was clear that there was no duplication of

respondents. Because of missing data on some questions, the tabulated responses reported here sum to less than 100% (Table 1).

The first question asked if the journals made any efforts to positively corroborate the credibility of COI disclosures, especially when the authors of a paper stated that they had no COI to declare. Approximately 77% of the societies do not make any effort to corroborate statements regarding the absence of COI, and only 19.8% stated that they did attempt to confirm COI statements.

In response to the next question, 42.9% of the journals stated that they did not check with the author in cases in which the COI disclosure statement is incomplete. More than 75% of journals either had no such clarification issues, or had fewer than 4 cases per year.

Regarding the period in which societies began to require COI disclosure, there was a clear peak (60.3%) in the 4-year period of 2010-2013. When asked about investigations of dubious cases of COI declaration, almost 70% stated that they did investigate suspicious cases but 21 of the respondents revealed that they did not (about 13% did not respond to this question). Comments made by the societies concerning this aspect included statements suggesting that their investigational system had not been fully determined and that the societies consider themselves to be in a kind of trial period. There were also some comments indicating that while some journal secretariats believe such matters to be in the province of the COI committee, others consider it is not the duty of the editorial committee to act on such issues. There was also a comment from a single journal that a suspicious case would be discussed with the publisher. That "publisher" referred to a company, which, we suspect, might not respond as a scholarly society would to cases of undisclosed COI.

In response to the question on whether editorial board members are asked to disclose any personal COI on their appointment as board members, almost half (47.9%) stated that they do not make such disclosure obligatory. Those journals that did make it obligatory constituted just under half (49.6%) of the total number of journals, suggesting that journals may not be aware that all persons related to the publication of the paper, including authors, reviewers, medical editors, and all those named in the acknowledgement section, should disclose any potential COI.

One question was a composite, inquiring whether the reviewers and the editorial board members understood the significance and importance of COI disclosure and also whether the society carried out any education or training regarding COI disclosure. From the responses to this question we found that COI education was given by only 35 of the editorial secretariats (28.9%). With regard to sanctions or obligations imposed on those who contravene COI disclosure policy, such as enforced retraction, embargoes on paper submission, etc., only 27.3% of journals had a regulation system in place.

In response to our request for comments regarding COI management and related problems, it became clear that some journals had not experienced a single case of COI disclosure problems. An overall lack of confidence on the suitability of their own system was expressed in comments by many journals. There were also repeated comments on the lack of a sufficient surveillance mechanism and systems that would allow for reliable and transparent implementation of COI management.

Questions were also raised by editorial secretariats concerning present policies of holding documentation for only 1-2 years after publication of a paper. The feeling was also expressed that, since university and research institutes usually have ethics committees, regulation of researchers' ethical behavior should be left up to the authors themselves or their institutions, and should not be the responsibility of the journal or the editorial secretariats.

In general, the comments highlighted a lack of a uniform system of COI management implementation and the need for more convenient and easy-to-refer-to guidelines in Japanese for the use of the journals' secretariats.

Discussion

We set out to determine how COI-disclosure policies were being implemented at medical journal-publishing societies in Japan. Only half of the journals requested an explanation if a COI-disclosure statement were missing or incomplete, which shows that having a policy is not enough, as implementation can be lacking or inconsistent.

More than 15% of journals in Japan in our study did not investigate cases in which non-disclosure of COI was suspected, which threatens the viability of the entire system. This could be both a cause and an effect of the current situation in Japan in which many staff members at editorial secretariats lack confidence in implementing COI-related policies, although they are given those responsibilities. Staff members of editorial secretariats were uncertain about the implementation of COI-disclosure policies at their journals. In addition, practices such as sanctioning violators of journal policy, COI disclosure by editors and reviewers, and education about COI were implemented inconsistently among the journals.

As pointed out by Smith in his 1998 BMJ editorial and reaffirmed by Irwin in his comments 20 years later, expectations for transparency and accountability of research are increasing, so COI needs constant attention and this appears to be a common worldwide situation[5, 13]. In a randomised trial, "BMJ readers reported that data showing the impact of pain from herpes were less interesting, important, relevant, valid and believable when the authors were employees of a fictitious pharmaceutical company compared with an ambulatory care centre."[14]
This indicates that the task of those who educate authors and implement COI-related policies is complicated further because of the belief that readers will discount the results of a study if the authors of that study had a potential COI. That belief is justified.[14]

Although some of the societies in this survey consider that COI education and policy implementation is the province of universities and research institutes, we would submit that the societies or journals themselves are the ultimate gatekeepers of scientific integrity. Journals and academic societies are thus obligated educate their officers and members concerning COI and COI disclosure. As necessary as it is, education concerning COI does have its challenges. Therefore, creating uniform guidelines on COI that can be easily used, regardless of the level of awareness the author has, could provide a solution to this problem. Regarding this, many international journals and institutions, such as the BMJ and AMA have sought to explain how to deal with COI problems in an open, fair, and transparent manner. Attitudes towards COI have become more strict and definitions more narrow worldwide. In Japan, journal-publishing medical societies first adopted COI policies around 2010, at about the same time the ICMJE introduced its COI Disclosure Form in 2009. Several modifications of the latter were made based on feedback regarding the form, after piloting it and

making it publicly accessible among ICMJE member journals[15]. Modifications included elimination of the necessity of including authors' spouses, minor dependents, relatives, and nonfinancial COI[16]. However, many Japanese societies and journals still specify that these be included in COI disclosures. This situation emphasizes the need for authors to consult Instructions to Authors before submission, but even more importantly, it suggests the need for at least national, if not international policies, and in all fields of medical research.

Approximately half of all society journals in this study do not require their editorial board members to make COI disclosures, and thus they contravene the ICMJE Recommendations, which state that all those involved in the publishing process should disclose any potential COI[17]. Journals might protect their credibility by applying such recommendations not only to staff members who make day-to-day decisions, but also to the editorial advisory board, as the latter's guidance on matters of a journal's focus, direction, and priorities could be adversely affected by COI. Furthermore, not only authors, but reviewers and editors, and all editorial secretariat members, as well as anyone mentioned in Acknowledgement sections should be given education on the significance of COI and on how to make appropriate, transparent statements. In addition, we feel that there should be detailed information on COI, separate from the Instructions to Authors, perhaps preceding the COI disclosure formats, clearly specifying the nature of the situation, and requiring individual agreement from all coauthors, before consideration for publication. The results of our survey point to a lamentable lack of education in this field, which, given the coverage and response rate of the present survey, likely involves nearly all of medical publishing in Japan, and which we suspect is a problem facing many other countries as well.

Regardless of whether non-disclosure of COI is intentional or an honest mistake, authors, as members of the scientific community, cannot plead ignorance of the rules. But authors are in a difficult situation, because the understanding of what constitutes COI can itself differ among individuals, institutions, and countries. Editors' too are in a difficult position, as the time and resources they can devote to handling ethical issues are limited. Also complicating the situation is the fact that editors have a variety of opinions on COI management. For example, arduous though the task may be, perhaps editors of medical journals worldwide could strive to find areas of consensus regarding responses to violations of COI-disclosure policies.

In this regard, and with a mind to the desirability of uniformity and international harmonization of policies, it may be necessary to strengthen and increase recognition of organizations such as the International Society for Medical Publication Professionals[18] and the Committee on Publication Ethics (COPE). In particular, the COPE has produced flowcharts that are freely available in several languages, providing advice and steps to follow for journals in cases of suspected or definite undisclosed COI[19]. They also make it clear to authors what process will be followed in such cases. National bodies such as the JAMS could also play an important role.

Limitations:

We could not be sure whether the respondent to a given questionnaire was a staff member working in the editorial office, or the editor, or a representative of the COI committee for that society, and respondents in different positions could differ in their understanding of COI-related issues and in their experience implementing COI policies. This limitation emphasizes the need for an easily comprehensible transparent system of guidelines and procedures consistently evaluable by all staff. The strongly hierarchical nature of the Japanese medical world may prevent editorial-secretariat staff from contributing fully to the development and implementation of processes for managing COI-related issues, and that would also be true in similarly hierarchical workplaces worldwide.

Despite the increasing concern regarding various aspects of COI, Japanese medical societies (and, we suspect, academic societies in many other nations) lack uniform understanding, despite great sincerity and effort, and are also lacking in many aspects of COI education. The confusion in the editorial offices of Japanese medical societies about COI management clearly shows that greater and more thorough emphasis should be placed on education in scientific communications ethics.

Conclusion

On the basis of these findings we recommend that Japanese medical societies adopt common guidelines on how to manage COI. Furthermore,

providing a form such as the ICMJE COI form (at least until a more widely accepted form is developed) in Japanese to all Japanese medical societies could help their editorial secretariats standardize their education for staff, reviewers, and editors. A Japanese translation of the form is freely available, together with explanations in Japanese of the issues it addresses [20]. The AMA, among other societies, now requires that all authors submitting to JAMA submit the ICMJE COI Disclosure Form[21], and the JAMS member societies too would do well to require such a document. However, we also believe that COI disclosure should include all interests that might affect the perception of the behavior of the author(s), and therefore should include non-financial COI. Hamilton states that personal COI, such as COI with a family member, religious, cultural, ethnic, or political COI, is potentially as detrimental as financial COI[4]. Therefore, we recommend that a standard form be developed in Japanese for non-financial COI.

Creating simple guidelines on COI disclosure and management in Japanese can help the staff of editorial secretariats enforce their journals' policies. We recommend that the JAMS societies use a standardized Japanese-language COI disclosure form, to help both authors and editorial offices understand clearly what information they should disclose when submitting a paper to any member journal of the JAMS. The measures outlined here could also enable focused education on COI, and improve the overall situation of COI management.

In closing, we note that diversity such as we found in Japan has also been seen in some Western countries[2, 3]. Still, without comparable studies of practices at journal secretariats in other parts of the world, the status of COI management globally remains unclear. We hope that others will follow the JAMS' example of honest self-examination of the translation of policy into practice.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Contributors: The questionnaire was composed by all authors (TK, JG, JPB) together. Tabulation of the data was the responsibility of JPB. The manuscript was written collaboratively by TK, JG, and JPB. All authors agreed to submission.

Data sharing: no additional data available.

All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Appendix

Question 9 Please list any problems or unclear points concerning COI management regarding submitted manuscripts.
Selected responses:

- We have not yet had even one case of COI disclosure, so we worry that there might be something really inadequate about the present system.
- What should be done concerning paper acceptance and publication if commercial sponsoring appears involved?
- Although COI disclosure is made for the entire manuscript on submission, its clarification requires confirmation.
- It appears that some journals destroy disclosure documentation (whether paper or electronic) after 1-2 years, but in fact is there not a problem in destroying documentation, even concerning accepted manuscripts?
- The method of investigating the background of COI disclosure contents is unclear.
- Are investigations and sanction systems common in foreign journals?
- We do not fully comprehend the extent to which COI management should be implemented. We would appreciate concrete instructions from JAMS.
- Including the university with which the head of our editorial committee is affiliated, many universities and research institutes have ethics committees, etc. that have been properly regulating the behavior of investigators internally for the past 2-3 years. With those organizations in place, regarding submissions and also editorial board members, our journal now does not have any specific policy [in those matters], and entrusts them to the submitting author.
- How COI disclosure conditions are decided on is unclear.

BMJ Open

Conflict-of-interest disclosure at medical journals in Japan: a nationwide survey of the practices of journal secretariats

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Keywords:	conflict of interest, editorial secretariats, education and training, publication ethics

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Original Research

Key Words: conflict of interest, editorial secretariats, education and training, publication ethics

Abstract

Objectives:
Medical journals in Japan generally have appropriate policies regarding disclosure of conflicts of interest (COI). However, COI management depends on the staff members of each journal's editorial secretariat. This study's objectives were to find out (a) whether COI disclosure and the journal's role in it are clearly understood by the journals' secretariat staff, (b) how much experience the editorial secretariat has in actually handling issues related to disclosure, and (c) what kind of help or support they need.

Setting & Design:
In January 2014, questionnaires were sent to the editorial secretariats of journal-publishing societies belonging to the Japanese Association of Medical Sciences (JAMS).

Participants:
The response rate was 100%, and the respondents represented 121 journals published by the 118 JAMS member societies (at the time of the survey).

Primary and secondary outcome measures:
Information was collected on the history of COI policies and on how those policies were implemented. At the end of the questionnaire there was an open-ended call for comments.

Results:
Compulsory COI disclosure began between 2010 and 2013 for 60.3% of the journals (73/121). Handling of COI issues was not uniform: 17.4% (21/121) of respondents do not pursue cases of dubious disclosure, and 47.9% (58/121) do not require COI disclosures from editorial board members. Very few of the editorial secretariats had clearly-stated consequences for violations of COI-disclosure policy (33/121, 27.3%), and only 28.9% offered COI education (35/121). Respondents' comments indicated that uniform, easily-searchable guidance regarding COI policies and implementation would be welcome.

Conclusions:
Although commitment is widespread, policy implementation is inconsistent and COI experience is lacking. Clear, easy-to-use guidelines are desired by many societies. The JAMS is to be commended for supporting this country-wide investigation: other countries and regions are encouraged to

perform similar investigations to respond to needs regarding COI management.

Strengths and limitations of this study

- This is the first-ever international report of a nationwide survey on COI management among Japanese medical societies.
- The response rate was 100%, and the respondents represented 121 journals published by the 118 member societies (as of the time of the survey, January 2014) of the Japanese Association of Medical Sciences (JAMS).
- The findings should not be generalized outside Japan, so additional nationwide surveys such as this one will be needed to facilitate obtaining a grasp not only of policies but also of actual COI-management practices in various countries and regions.

Introduction

In publishing medical research, conflicts of interest (COI) are "almost inevitable."[1] Of course they should be disclosed, but research on COI disclosure indicates that journals' policies vary widely[2]. Editors are interested in standardizing disclosure, although doing so may be difficult[2]. There is also some evidence that repeated auditing might improve COI-disclosure practices.[3]

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We compiled a list of 8 questions. All authors contributed ideas as to what questions to ask, based on a total of more than 80 person-years of experience in medical editing and publishing. As a native speaker of Japanese, one of the authors (TK) revised and edited the questions for language suitability. One question was added by the JAMS office. The questions concerned the history of COI policies of each journal, and how those policies were implemented. At the end there was an open-ended call for comments on the topic. English versions of the questions that were given in Japanese are in Table 1.

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Question 4 Does your journal investigate when dubious cases regarding COI declaration arise? Yes: 84 (69.4%) No: 21 (17.5%) No response: 4 (3.3%) Other: 12 (9.9%), e.g. Have not had any dubious cases so far; will consider the investigational system after rules have been implemented; Editorial Committee and COI Committee will decide if it occurs

Question 5 Do you make it obligatory for members of the editorial committee of your journal to make COI disclosures when they are appointed? Obligatory: 60 (49.6%) Not obligatory: 58 (47.9%) No response: 3 (2.5%)
Question 6 Do the reviewers and editorial board members understand the significance and importance of COI disclosure? What kind of education or training do you carry out to ensure the above? Education given: 35 (28.9%) No education given: 82 (67.8%) No response: 4 (3.3%)
Question 7 Do you have a system of regulations for sanctions regarding those who contravene COI disclosure policy? (Paper withdrawal, embargo on paper submission etc.) Regulation system in place: 33 (27.3%) No sanction system: 85 (70.2%) No response: 3 (2.5%)
Question 8 How often per annum does your office receive questions about COI and COI disclosure? 1-5: 42 (34.7%) 10-30: 8 (6.6%) None: 53 (43.8%) “Almost none” or no response: 18 (14.9%)
Question 9 Please list any problems or unclear points concerning COI management regarding submitted manuscripts. (See the Appendix)

The questionnaire was distributed in January 2014 by the JAMS central office to editorial secretariats of its 118 *bunkakai*, which are its member societies, all of which publish journals. Other *bunkakai* were added to the JAMS after this survey was done. As of May 17, 2015, 5 *bunkakai* had been added, making a total of 123[12]. The completed forms were returned to the JAMS office, which then collected and sent them to one of the authors (JPB), who was responsible for collating and tabulating the data.

Results

All 118 *bunkakai* returned their forms. A total of 121 forms were returned, because 3 of the *bunkakai* returned 2 forms each, 1 for their Japanese-language journal and 1 for their English-language journal. For each of those 3 *bunkakai*, it is clear that the 2 journals had separate editorial secretariats, because the contact information and the responses to the questions were different. Thus it was clear that there was no duplication of

respondents. Because of missing data on some questions, the tabulated responses reported here sum to less than 100% (Table 1).

The first question asked if the journals made any efforts to positively corroborate the credibility of COI disclosures, especially when the authors of a paper stated that they had no COI to declare. Approximately 77% of the societies do not make any effort to corroborate statements regarding the absence of COI, and only 19.8% stated that they did attempt to confirm COI statements.

In response to the next question, 42.9% of the journals stated that they did not check with the author in cases in which the COI disclosure statement is incomplete. More than 75% of journals either had no such clarification issues, or had fewer than 4 cases per year.

Regarding the period in which societies began to require COI disclosure, there was a clear peak (60.3%) in the 4-year period of 2010-2013. When asked about investigations of dubious cases of COI declaration, almost 70% stated that they did investigate suspicious cases but 21 (17.5%) of the respondents revealed that they did not (about 13% did not respond to this question). Comments made by the societies concerning this aspect included statements suggesting that their investigational system had not been fully determined and that the societies consider themselves to be in a kind of trial period. There were also some comments indicating that while some journal secretariats believe such matters to be in the province of the COI committee, others consider it is not the duty of the editorial committee to act on such issues. There was also a comment from a single journal that a suspicious case would be discussed with the publisher. That "publisher" referred to a company, which, we suspect, might not respond as a scholarly society would to cases of undisclosed COI.

In response to the question on whether editorial board members are asked to disclose any personal COI on their appointment as board members, almost half (47.9%) stated that they do not make such disclosure obligatory. Those journals that did make it obligatory constituted just under half (49.6%) of the total number of journals, suggesting that journals may not be aware that all persons related to the publication of the paper, including authors, reviewers, medical editors, and all those named in the acknowledgement section, should disclose any potential COI.

One question was a composite, inquiring whether the reviewers and the editorial board members understood the significance and importance of COI disclosure and also whether the society carried out any education or training regarding COI disclosure. From the responses to this question we found that COI education was given by only 35 of the editorial secretariats (28.9%). With regard to sanctions or obligations imposed on those who contravene COI disclosure policy, such as enforced retraction, embargoes on paper submission, etc., only 27.3% of journals had a regulation system in place.

In response to our request for comments regarding COI management and related problems, it became clear that some journals had not experienced a single case of COI disclosure problems. An overall lack of confidence on the suitability of their own system was expressed in comments by many journals. There were also repeated comments on the lack of a sufficient surveillance mechanism and systems that would allow for reliable and transparent implementation of COI management.

Questions were also raised by editorial secretariats concerning present policies of holding documentation for only 1-2 years after publication of a paper. The feeling was also expressed that, since university and research institutes usually have ethics committees, regulation of researchers' ethical behavior should be left up to the authors themselves or their institutions, and should not be the responsibility of the journal or the editorial secretariats.

In general, the comments highlighted a lack of a uniform system of COI management implementation and the need for more convenient and easy-to-refer-to guidelines in Japanese for the use of the journals' secretariats.

Discussion

We set out to determine how COI-disclosure policies were being implemented at medical journal-publishing societies in Japan. Only half of the journals requested an explanation if a COI-disclosure statement were missing or incomplete, which shows that having a policy is not enough, as implementation can be lacking or inconsistent.

More than 15% of journals in Japan in our study did not investigate cases in which non-disclosure of COI was suspected, which threatens the viability of the entire system. This could be both a cause and an effect of the current situation in Japan in which many staff members at editorial secretariats lack confidence in implementing COI-related policies, although they are given those responsibilities. Staff members of editorial secretariats were uncertain about the implementation of COI-disclosure policies at their journals. In addition, practices such as sanctioning violators of journal policy, COI disclosure by editors and reviewers, and education about COI were implemented inconsistently among the journals.

As pointed out by Smith in his 1998 BMJ editorial and reaffirmed by Irwin in his comments 20 years later, expectations for transparency and accountability of research are increasing, so COI needs constant attention and this appears to be a common worldwide situation[5, 13]. This was particularly highlighted in the findings by Alfonso et al.[2]. In a randomised trial, "BMJ readers reported that data showing the impact of pain from herpes were less interesting, important, relevant, valid and believable when the authors were employees of a fictitious pharmaceutical company compared with an ambulatory care centre."[14]
This indicates that the task of those who educate authors and implement COI-related policies is complicated further because of the belief that readers will discount the results of a study if the authors of that study had a potential COI. That belief is justified.[14]

Although some of the societies in this survey consider that COI education and policy implementation is the province of universities and research institutes, we would submit that the societies or journals themselves are the ultimate gatekeepers of scientific integrity. Journals and academic societies are thus obligated educate their officers and members concerning COI and COI disclosure. As necessary as it is, education concerning COI does have its challenges, which agrees with the findings of Alfonso et al. Therefore, creating uniform guidelines on COI that can be easily used, regardless of the level of awareness the author has, could provide a solution to this problem. Regarding this, many international journals and institutions, such as the BMJ and AMA have sought to explain how to deal with COI problems in an open, fair, and transparent manner.
Attitudes towards COI have become more strict and definitions are receiving more attention worldwide. In Japan, journal-publishing medical societies first adopted COI policies around 2010, at about the same time the

ICMJE introduced its COI Disclosure Form in 2009. Several modifications of the latter were made based on feedback regarding the form, after piloting it and making it publicly accessible among ICMJE member journals[15]. Modifications included elimination of the necessity of including authors' spouses, minor dependents, relatives, and nonfinancial COI[16]. However, many Japanese societies and journals still specify that these be included in COI disclosures. This situation emphasizes the need for authors to consult Instructions to Authors before submission, but even more importantly, it suggests the need for at least national, if not international policies, and in all fields of medical research.

Approximately half of all society journals in this study do not require their editorial board members to make COI disclosures, and thus they contravene the ICMJE Recommendations, which state that all those involved in the publishing process should disclose any potential COI[17]. Journals might protect their credibility by applying such recommendations not only to staff members who make day-to-day decisions, but also to the editorial advisory board, as the latter's guidance on matters of a journal's focus, direction, and priorities could be adversely affected by COI. Furthermore, not only authors, but reviewers and editors, and all editorial secretariat members, as well as anyone mentioned in Acknowledgement sections should be given education on the significance of COI and on how to make appropriate, transparent statements. In addition, we feel that there should be detailed information on COI, separate from the Instructions to Authors, perhaps preceding the COI disclosure forms, clearly specifying the nature of the situation, and requiring individual agreement from all coauthors, before consideration for publication. The results of our survey point to a lamentable lack of education in this field, which, given the coverage and response rate of the present survey, likely involves nearly all of medical publishing in Japan, and which we suspect is a problem facing many other countries as well.

Regardless of whether non-disclosure of COI is intentional or an honest mistake, authors, as members of the scientific community, cannot plead ignorance of the rules. But authors are in a difficult situation, because the understanding of what constitutes COI can itself differ among individuals, institutions, and countries. Editors' too are in a difficult position, as the time and resources they can devote to handling ethical issues are limited[2]. Also complicating the situation is the fact that editors have a variety of opinions on COI management. For example, arduous though the task may

be, perhaps editors of medical journals worldwide could strive to find areas of consensus regarding responses to violations of COI-disclosure policies.

In this regard, and with a mind to the desirability of uniformity and international harmonization of policies, it may be necessary to strengthen and increase recognition of organizations such as the Committee on Publication Ethics (COPE), as the study by Graf et al. points out that some editors of COPE member journals, are even sometimes unaware of COPE[3]. In particular, the COPE has produced flowcharts that are freely available in several languages, providing advice and steps to follow for journals in cases of suspected or definite undisclosed COI[18]. They also make it clear to authors what process will be followed in such cases. National bodies such as the JAMS could also play an important role.

Limitations:

We could not be sure whether the respondent to a given questionnaire was a staff member working in the editorial office, or the editor, or a representative of the COI committee for that society, and respondents in different positions could differ in their understanding of COI-related issues and in their experience implementing COI policies. This limitation emphasizes the need for an easily comprehensible transparent system of guidelines and procedures consistently evaluable by all staff. The strongly hierarchical nature of the Japanese medical world may prevent editorial-secretariat staff from contributing fully to the development and implementation of processes for managing COI-related issues, and that would also be true in similarly hierarchical workplaces worldwide.

Despite the increasing concern regarding various aspects of COI, Japanese medical societies (and, we suspect, academic societies in many other nations) lack uniform understanding, despite great sincerity and effort, and are also lacking in many aspects of COI education. The confusion in the editorial offices of Japanese medical societies about COI management clearly shows that greater and more thorough emphasis should be placed on education in scientific communications ethics.

Conclusion

On the basis of these findings we recommend that Japanese medical societies adopt common guidelines on how to manage COI. Furthermore, providing a form such as the ICMJE COI form (at least until a more widely accepted form is developed) in Japanese to all Japanese medical societies could help their editorial secretariats standardize their education for staff, reviewers, and editors. A Japanese translation of the form is freely available, together with explanations in Japanese of the issues it addresses [19]. The AMA, among other societies, now requires that all authors submitting to JAMA submit the ICMJE COI Disclosure Form[20], and the JAMS member societies too would do well to require such a document. However, we also believe that COI disclosure should include all interests that might affect the perception of the behavior of the author(s), and therefore should include non-financial COI. Hamilton states that personal COI, such as COI with a family member, religious, cultural, ethnic, or political COI, is potentially as detrimental as financial COI[4]. Therefore, we recommend that a standard form be developed in Japanese for non-financial COI.

Creating simple guidelines on COI disclosure and management in Japanese can help the staff of editorial secretariats enforce their journals' policies. We recommend that the JAMS societies use a standardized Japanese-language COI disclosure form, to help both authors and editorial offices understand clearly what information they should disclose when submitting a paper to any member journal of the JAMS. The measures outlined here could also enable focused education on COI, and improve the overall situation of COI management.

In closing, we note that diversity such as we found in Japan has also been seen in some Western countries[2, 3]. Still, without comparable studies of practices at journal secretariats in other parts of the world, the status of COI management globally remains unclear. We hope that others will follow the JAMS' example of honest self-examination of the translation of policy into practice.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Contributors: The questionnaire was composed by all authors (TK, JG, JPB) together. Tabulation of the data was the responsibility of JPB. The manuscript was written collaboratively by TK, JG, and JPB. All authors agreed to submission.

Data sharing: no additional data available.

All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Appendix

Question 9 Please list any problems or unclear points concerning COI management regarding submitted manuscripts.

Selected responses:

- We have not yet had even one case of COI disclosure, so we worry that there might be something really inadequate about the present system.
- What should be done concerning paper acceptance and publication if commercial sponsoring appears involved?
- Although COI disclosure is made for the entire manuscript on submission, its clarification requires confirmation.
- It appears that some journals destroy disclosure documentation (whether paper or electronic) after 1-2 years, but in fact is there not a problem in destroying documentation, even concerning accepted manuscripts?
- The method of investigating the background of COI disclosure contents is unclear.
- Are investigations and sanction systems common in foreign journals?
- We do not fully comprehend the extent to which COI management should be implemented. We would appreciate concrete instructions from JAMS.
- Including the university with which the head of our editorial committee is affiliated, many universities and research institutes have ethics committees, etc. that have been properly regulating the behavior of investigators internally for the past 2-3 years. With those organizations in place, regarding submissions and also editorial board members, our journal now does not have any specific policy [in those matters], and entrusts them to the submitting author.
- How COI disclosure conditions are decided on is unclear.

BMJ Open

Conflict-of-interest disclosure at medical journals in Japan: a nationwide survey of the practices of journal secretariats

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Keywords:	conflict of interest, editorial secretariats, education and training, publication ethics

Conflict-of-interest disclosure at medical journals in Japan: a nationwide survey of the practices of journal secretariats

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Original Research

Key Words: conflict of interest, editorial secretariats, education and training, publication ethics

Abstract

Objectives:
Medical journals in Japan generally have appropriate policies regarding disclosure of conflicts of interest (COI). However, COI management depends on the staff members of each journal's editorial secretariat. This study's objectives were to find out (a) whether COI disclosure and the journal's role in it are clearly understood by the journals' secretariat staff, (b) how much experience the editorial secretariat has in actually handling issues related to disclosure, and (c) what kind of help or support they need.

Setting & Design:
In January 2014, questionnaires were sent to the editorial secretariats of journal-publishing societies belonging to the Japanese Association of Medical Sciences (JAMS).

Participants:
The response rate was 100%, and the respondents represented 121 journals published by the 118 JAMS member societies (at the time of the survey).

Primary and secondary outcome measures:
Information was collected on the history of COI policies and on how those policies were implemented. At the end of the questionnaire there was an open-ended call for comments.

Results:
Compulsory COI disclosure began between 2010 and 2013 for 60.3% of the journals (73/121). Handling of COI issues was not uniform: 17.4% (21/121) of respondents do not pursue cases of dubious disclosure, and 47.9% (58/121) do not require COI disclosures from editorial board members. Very few of the editorial secretariats had clearly-stated consequences for violations of COI-disclosure policy (33/121, 27.3%), and only 28.9% offered COI education (35/121). Respondents' comments indicated that uniform, easily-searchable guidance regarding COI policies and implementation would be welcome.

Conclusions:
Although commitment is widespread, policy implementation is inconsistent and COI experience is lacking. Clear, easy-to-use guidelines are desired by many societies. The JAMS is to be commended for supporting this country-wide investigation: other countries and regions are encouraged to

perform similar investigations to respond to needs regarding COI management.

Strengths and limitations of this study

- This is the first-ever international report of a nationwide survey on COI management among Japanese medical societies.
- The response rate was 100%, and the respondents represented 121 journals published by the 118 member societies (as of the time of the survey, January 2014) of the Japanese Association of Medical Sciences (JAMS).
- The findings should not be generalized outside Japan, so additional nationwide surveys such as this one will be needed to facilitate obtaining a grasp not only of policies but also of actual COI-management practices in various countries and regions.

Introduction

In publishing medical research, conflicts of interest (COI) are "almost inevitable."[1] Of course they should be disclosed, but research on COI disclosure indicates that journals' policies vary widely[2]. Editors are interested in standardizing disclosure, although doing so may be difficult[2]. There is also some evidence that repeated auditing might improve COI-disclosure practices[3].

Our focus was on the people who ensure that COI are disclosed. Editors and authors can avail themselves of training materials on publication ethics[4], and senior researchers are encouraged to teach good publication practices to their juniors[5]. Anyone with an Internet connection can easily access clear statements of positions on this topic that have been endorsed by groups of journal editors[6, 7, 8]. Such education and official declarations are essential, but we suspect that they are insufficient, because policies on COI disclosure are implemented by the staff members of each journal's editorial secretariat. We believe that their role is crucial. They are a journal's first point of contact with authors who may have COI, and at later stages of the submission and publication process too, those staff members translate policies into practice.

To continue illuminating the realities of COI management, we began close to home. The Japanese Association of Medical Sciences (JAMS) is a group that comprised 118 academic medical societies[9] at the time of the survey, January 2014. The member societies publish journals with original research in basic medical sciences, clinical medicine, laboratory medicine, public health, etc. The COI Subcommittee of the JAMS requested one of its members (one of the authors, JPB) to report on COI management by JAMS member societies. The official guidelines of the JAMS with regard to COI disclosure [10] are generally consistent with the positions of the International Committee of Medical Journal Editors (ICMJE), the World Association of Medical Editors (WAME), and the Council of Science Editors (CSE), but we were interested in the *implementation* of those policies at each journal's editorial secretariat. Here we report information provided by the JAMS member societies with regard to (a) whether there is a clear understanding of COI disclosure and of the journal's role, (b) how much experience the editorial secretariat has in actually handling issues related to disclosure, and (c) what kind of help or support they need[11].

Materials and Methods

We compiled a list of 8 questions. All authors contributed ideas as to what questions to ask, based on a total of more than 80 person-years of experience in medical editing and publishing. As a native speaker of Japanese, one of the authors (TK) revised and edited the questions for language suitability. One question was added by the JAMS office. The questions concerned the history of COI policies of each journal, and how those policies were implemented. At the end there was an open-ended call for comments on the topic.

The questionnaire was distributed in January 2014 by the JAMS central office to editorial secretariats of its 118 *bunkakai*, which are its member societies, all of which publish journals. Other *bunkakai* were added to the JAMS after this survey was completed. As of May 17, 2015, 5 *bunkakai* had been added, making a total of 123[12]. The completed forms were returned to the JAMS office, which then collected and sent them to one of the authors (JPB), who was responsible for collating and tabulating the data.

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Table 1. English versions of the questions included in the COI questionnaire, and tabulated responses

Question 1 Has your journal made any effort to positively prove the credibility of COI disclosure or declaration (especially when "No COI to declare" is reported)? How do you corroborate this statement?
Yes: 24 (19.8%)
No: 93 (76.9%)
No response: 4 (3.3%)

Question 2 In your journal, if the COI disclosure by the author has not been made or is incomplete at submission, does the secretariat request an explanation? If yes, how many times a year? Yes: 63 (51.7%) Up to 3: 41 (33.8%) 4-10: 12 (9.9%) 11-25: 5 (4.1%) 26 and over: 5 (4.1%) No: 52 (42.9%) No response: 6 (5.0%)
Question 3 When did you start posting the requirement for COI disclosure in the Instructions to Authors of your journal? 2005-2009: 26 (21.5%) 2010-2013: 73 (60.3%) 2014- : 9 (7.4%) *1 responded “from 2001” No response: 13 (10.7%)
Question 4 Does your journal investigate when dubious cases regarding COI declaration arise? Yes: 84 (69.4%) No: 21 (17.5%) No response: 4 (3.3%) Other: 12 (9.9%), e.g. Have not had any dubious cases so far; will consider the investigational system after rules have been implemented; Editorial Committee and COI Committee will decide if it occurs
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The first question asked if the journals made any efforts to positively corroborate the credibility of COI disclosures, especially when the authors of a paper stated that they had no COI to declare. Approximately 77% of the societies do not make any effort to corroborate statements regarding the absence of COI, and only 19.8% stated that they did attempt to confirm COI statements.

In response to the next question, 42.9% of the journals stated that they did not check with the author in cases in which the COI disclosure statement is incomplete. More than 75% of journals either had no such clarification issues, or had fewer than 4 cases per year.

Regarding the period in which societies began to require COI disclosure, there was a clear peak (60.3%) in the 4-year period of 2010-2013. When asked about investigations of dubious cases of COI declaration, almost 70% stated that they did investigate suspicious cases but 21 (17.5%) of the respondents revealed that they did not (about 13% did not respond to this question). Comments made by the societies concerning this aspect included statements suggesting that their investigational system had not been fully determined and that the societies consider themselves to be in a kind of trial period. There were also some comments indicating that while some journal secretariats believe such matters to be in the province of the COI committee, others consider it is not the duty of the editorial committee to act on such issues. There was also a comment from a single journal that a suspicious case would be discussed with the publisher. That "publisher" referred to a company, which, we suspect, might not respond as a scholarly society would to cases of undisclosed COI.

In response to the question on whether editorial board members are asked to disclose any personal COI on their appointment as board members, almost half (47.9%) stated that they do not make such disclosure obligatory. Those journals that did make it obligatory constituted just under half

(49.6%) of the total number of journals, suggesting that journals may not be aware that all persons related to the publication of the paper, including authors, reviewers, medical editors, and all those named in the acknowledgement section, should disclose any potential COI.

One question was a composite, inquiring whether the reviewers and the editorial board members understood the significance and importance of COI disclosure and also whether the society carried out any education or training regarding COI disclosure. From the responses to this question we found that COI education was given by only 35 of the editorial secretariats (28.9%). With regard to sanctions or obligations imposed on those who contravene COI disclosure policy, such as enforced retraction, embargoes on paper submission, etc., only 27.3% of journals had a regulation system in place.

In response to our request for comments regarding COI management and related problems, it became clear that some journals had not experienced a single case of COI disclosure problems. An overall lack of confidence on the suitability of their own system was expressed in comments by many journals. There were also repeated comments on the lack of a sufficient surveillance mechanism and systems that would allow for reliable and transparent implementation of COI management.

Questions were also raised by editorial secretariats concerning present policies of holding documentation for only 1-2 years after publication of a paper. The feeling was also expressed that, since university and research institutes usually have ethics committees, regulation of researchers' ethical behavior should be left up to the authors themselves or their institutions, and should not be the responsibility of the journal or the editorial secretariats.

In general, the comments highlighted a lack of a uniform system of COI management implementation and the need for more convenient and easy-to-refer-to guidelines in Japanese for the use of the journals' secretariats.

Discussion

We set out to determine how COI-disclosure policies were being implemented at medical journal-publishing societies in Japan. Only half of the journals requested an explanation if a COI-disclosure statement were missing or incomplete, which shows that having a policy is insufficient, as implementation can be lacking or inconsistent.

More than 15% of journals in Japan in our study did not investigate cases in which non-disclosure of COI was suspected, which threatens the viability of the entire system. This could be both a cause and an effect of the current situation in Japan in which many staff members at editorial secretariats lack confidence in implementing COI-related policies, although they are given those responsibilities. Staff members of editorial secretariats were uncertain about the implementation of COI-disclosure policies at their journals. In addition, practices such as sanctioning violators of journal policy, COI disclosure by editors and reviewers, and education about COI were implemented inconsistently among the journals.

As pointed out by Smith in his 1998 BMJ editorial and reaffirmed by Irwin in his comments 20 years later, expectations for transparency and accountability of research are increasing, so COI needs constant attention and this appears to be a common worldwide situation[5, 13]. This was particularly highlighted in the findings by Alfonso et al.[2]. In a randomised trial, "BMJ readers reported that data showing the impact of pain from herpes were less interesting, important, relevant, valid and believable when the authors were employees of a fictitious pharmaceutical company compared with an ambulatory care centre."[14] This indicates that the task of those who educate authors and implement COI-related policies is complicated further because of the belief that readers will discount the results of a study if the authors of that study had a potential COI. That belief is justified[14].

Although some of the societies in this survey consider that COI education and policy implementation is the province of universities and research institutes, we would submit that the societies or journals themselves are the ultimate gatekeepers of scientific integrity. Journals and academic societies are thus obligated to educate their officers and members concerning COI and COI disclosure. As necessary as it is, education concerning COI does have its challenges, which agrees with the findings of Alfonso et al.

Therefore, creating uniform guidelines on COI that can be easily used, regardless of the level of awareness the author has, could provide a solution to this problem. Regarding this, many international journals and institutions, such as the BMJ and AMA have sought to explain how to deal with COI problems in an open, fair, and transparent manner.

Attitudes towards COI have become more strict and definitions are receiving more attention worldwide. In Japan, journal-publishing medical societies first adopted COI policies around 2010, at about the same time the ICMJE introduced its COI Disclosure Form in 2009. Several modifications of the latter were made based on feedback regarding the form, after piloting it and making it publicly accessible among ICMJE member journals[15]. Modifications included elimination of the necessity of including authors' spouses, minor dependents, relatives, and nonfinancial COI[16]. However, many Japanese societies and journals still specify that these be included in COI disclosures. This situation emphasizes the need for authors to consult Instructions to Authors before submission, but even more importantly, it suggests the need for at least national, if not international policies, and in all fields of medical research.

Approximately half of all society journals in this study do not require their editorial board members to make COI disclosures, and thus they contravene the ICMJE Recommendations, which state that all those involved in the publishing process should disclose any potential COI[17]. Journals might protect their credibility by applying such recommendations not only to staff members who make day-to-day decisions, but also to the editorial advisory board, as the latter's guidance on matters of a journal's focus, direction, and priorities could be adversely affected by COI. Furthermore, not only authors, but reviewers and editors, and all editorial secretariat members, as well as anyone mentioned in Acknowledgement sections should be given education on the significance of COI and on how to make appropriate, transparent statements. In addition, it may be advisable for journals to provide detailed information on COI, separate from the Instructions to Authors, perhaps preceding the COI disclosure forms, clearly specifying the nature of the situation, and requiring individual agreement from all coauthors, before consideration for publication. The results of our survey point to a lamentable lack of education in this field, which, given the coverage and response rate of the present survey, likely involves nearly all of medical publishing in Japan, and which we suspect is a problem facing many other countries as well.

Regardless of whether non-disclosure of COI is intentional or an honest mistake, authors, as members of the scientific community, cannot plead ignorance of the rules. But authors are in a difficult situation, because the understanding of what constitutes COI can itself differ among individuals, institutions, and countries. Editors' too are in a difficult position, as the time and resources they can devote to handling ethical issues are limited[2]. Also complicating the situation is the fact that editors have a variety of opinions on COI management. For example, arduous though the task may be, perhaps editors of medical journals worldwide could strive to find areas of consensus regarding responses to violations of COI-disclosure policies.

In this regard, and with a mind to the desirability of uniformity and international harmonization of policies, it may be necessary to strengthen and increase recognition of organizations such as the Committee on Publication Ethics (COPE), as the study by Graf et al. points out that even some editors of COPE member journals are unaware of the COPE[3]. In particular, the COPE has produced flowcharts that are freely available in several languages, providing advice and steps to follow for journals in cases of suspected or definite undisclosed COI[18]. They also make it clear to authors what process will be followed in such cases. National bodies such as the JAMS could also play an important role.

Limitations:

We could not be sure whether the respondent to a given questionnaire was a staff member working in the editorial office, or the editor, or a representative of the COI committee for that society, and respondents in different positions could differ in their understanding of COI-related issues and in their experience implementing COI policies. This limitation emphasizes the need for an easily comprehensible transparent system of guidelines and procedures consistently evaluable by all staff. The strongly hierarchical nature of the Japanese medical world may prevent editorial-secretariat staff from contributing fully to the development and implementation of processes for managing COI-related issues, and that would also be true in similarly hierarchical workplaces worldwide.

Despite the increasing concern regarding various aspects of COI, Japanese medical societies (and, we suspect, academic societies in many other nations) lack uniform understanding, despite great sincerity and effort, and are also lacking in many aspects of COI education. The confusion in the

editorial offices of Japanese medical societies about COI management clearly shows that greater and more thorough emphasis should be placed on education in scientific communications ethics.

Conclusion

On the basis of these findings we recommend that Japanese medical societies adopt common guidelines on how to manage COI. Furthermore, providing a form such as the ICMJE COI form (at least until a more widely accepted form is developed) in Japanese to all Japanese medical societies could help their editorial secretariats standardize their education for staff, reviewers, and editors. A Japanese translation of the form is freely available, together with explanations in Japanese of the issues it addresses [19]. The AMA, among other societies, now requires that all authors submitting to JAMA submit the ICMJE COI Disclosure Form[20], and the JAMS member societies too would do well to require such a document. However, we also believe that COI disclosure should include all interests that might affect the perception of the behavior of the author(s), and therefore should include non-financial COI. Hamilton states that personal COI, such as COI with a family member, religious, cultural, ethnic, or political COI, is potentially as detrimental as financial COI[4]. Therefore, we recommend that a standard form be developed in Japanese for non-financial COI.

Creating simple guidelines on COI disclosure and management in Japanese can help the staff of editorial secretariats enforce their journals' policies. We recommend that the JAMS societies use a standardized Japanese-language COI disclosure form, to help both authors and editorial offices understand clearly what information they should disclose when submitting a paper to any member journal of the JAMS. The measures outlined here could also enable focused education on COI, and improve the overall situation of COI management.

In closing, we note that diversity such as we found in Japan has also been seen in some Western countries[2, 3]. Still, without comparable studies of practices at journal secretariats in other parts of the world, the status of COI management globally remains unclear. We hope that others will follow the JAMS' example of honest self-examination of the translation of policy into practice.

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All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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Appendix

Question 9 Please list any problems or unclear points concerning COI management regarding submitted manuscripts.
Selected responses:

- We have not yet had even one case of COI disclosure, so we worry that there might be something really inadequate about the present system.
- What should be done concerning paper acceptance and publication if commercial sponsoring appears involved?
- Although COI disclosure is made for the entire manuscript on submission, its clarification requires confirmation.
- It appears that some journals destroy disclosure documentation (whether paper or electronic) after 1-2 years, but in fact is there not a problem in destroying documentation, even concerning accepted manuscripts?
- The method of investigating the background of COI disclosure contents is unclear.
- Are investigations and sanction systems common in foreign journals?
- We do not fully comprehend the extent to which COI management should be implemented. We would appreciate concrete instructions from JAMS.
- Including the university with which the head of our editorial committee is affiliated, many universities and research institutes have ethics committees, etc. that have been properly regulating the behavior of investigators internally for the past 2-3 years. With those organizations in place, regarding submissions and also editorial board members, our journal now does not have any specific policy [in those matters], and entrusts them to the submitting author.
- How COI disclosure conditions are decided on is unclear.