Authorship issues in multi-centre clinical trials: the importance of making an authorship contract

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ABSTRACT

Discussions about authorship often arise in multi-centre clinical trials. Such trials may involve up to hundreds of contributors of whom some will eventually co-author the final publication. It is, however, often impossible to involve all contributors in the manuscript process sufficiently for them to qualify for authorship as defined by the International Committee of Medical Journal Editors. Therefore, rules for authorship in multi-centre trials are strongly recommended. We propose two contracts to prevent conflicts regarding authorship; both are freely available for use without pay but with reference to the original source.

SPECIAL ARTICLE

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Discussions about authorship often arise in multi-centre trials where numerous contributors are involved [1-3]. Some multi-centre trials may run over an extensive period of time with several participating departments, and local investigators may change during the study period. It is difficult, and in many instances impossible, for all participating persons to be involved in the manuscript process. One manner in which conflicts about authorship may be prevented is by agreeing on an authorship contract at a very early stage of the research process, e.g. before the first patient is included in the trial.

The aim of this paper is to discuss the handling of authorship issues in multi-centre trials and to provide an example of an authorship contract.

AUTHORSHIP CRITERIA

Authorship definitions and traditions are different in biomedicine compared with other scientific fields and disciplines [4]. In general, a tendency towards a growing number of authors per article is seen, but averages vary across disciplines [4-6]. In the humanities, articles have relatively few authors, whereas articles in e.g. high-energy physics can have hundreds or even thousands of authors [7]. The definition of authorship and the use of authorship criteria also differ. In biomedicine, the majority of journals have implemented the authorship criteria defined by the International Committee of Medical Journal Editors (ICMJE) [8] (**Table 1**). These criteria have undergone several changes since the first edition was launched in 1985 [9]. In 2013, the criteria were updated to include a fourth authorship criterion concerning responsibility in multi-authored publications if questions related to the accuracy or integrity of the work should arise. The remaining three authorship criteria are the same as in the previous version, where authorship criterion one concerns data acquisition and interpretation; authorship criterion two concerns drafting of the manuscript and critical revision; and criterion three concerns final approval of the version to be submitted to a journal; see Table 1.

Author order, byline formats and indexing issues

It can be a great challenge to determine the order of author names, including deciding who should be first and last author, respectively. There are no firm rules on this; but the first author is typically the person who drafts the first version of the manuscript and the last author is typically the senior person in the research group (but still fulfilling all four authorship criteria). Placing the remaining author names in the byline can be done by using scoring systems [10-13] or by quantifying contributions in less formal ways. Alphabetical listing is also an option, although rather uncommon in biomedicine. A recent review looked at different methods of determining authorship in multi-centre trials and recommended that if the byline would contain more than ten authors, guidelines should be developed for authorship for the trial in question, e.g. based on scoring systems [14].

Besides listing each author in the byline, different variants of group authorship can also be considered

TABLE 1

The authorship criteria defined by the International Committee of Medical Journal Editors (ICMJE) [8]. The ICMJE recommends that authorship be based on these four criteria.

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; *and*
2. Drafting the work or revising it critically for important intellectual content; *and*
3. Final approval of the version to be published; *and*
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

(e.g., "author aa, author bb, author cc *and* research group xx", or "… author cc *on behalf of* research group xx"). All authors must meet the criteria for authorship regardless of the byline format, and the use of group names in the byline may therefore be confusing. Some journals have restrictions on the number of authors in the byline, but this is actually against the ICMJE recommendations since all authors who meet the authorship criteria should be listed as authors [8]. Individuals who do not meet all four authorship criteria should not be listed as authors, but instead as contributors in the acknowledgements section. As noted in the revised ICMJE recommendations [8], the National Library of Medicine (PubMed) has stated that regardless of the byline wording, and thus regardless of the use of a group name, they will index individual authors and contributors provided that their individual roles are listed elsewhere. This will typically imply that the acknowledgements section clearly lists who should be regarded and indexed as authors and who should be regarded and indexed as contributors. Other terminology such as protocol committee, writing committee, etc., may be misleading for the indexing process, and it is recommended only to use the terms authors and contributors stating exact names for the persons involved. When using these simple rules, the use of a group name in the byline actually seems redundant.

Special problems and solutions in multi-centre trials

The typical authorship-related problem in multi-centre trials regards individuals who fulfil the first authorship criterion, e.g. those who have participated in data acquisition at a local investigating centre. In large-scale trials, this may be hundreds of persons, and it can be very difficult to include all in the manuscript process (authorship criteria two and three). Authors may also become ill, go on retirement, move to another department or get a leave of absence. These situations are difficult to foresee, and may therefore be dealt with on a case-by-case basis. At a very early phase, the researchers involved in the trial should agree on the persons who are going to take part in the drafting and revising of the manuscript. These persons are obviously those who will ultimately qualify for authorship.

A practical solution could be to decide, before study initiation, that each participating centre provides a number of named potential co-authors for the final paper. Typically, one or two potential authors would be selected per centre, but the number of selected authors depends on the size of the study and the number of centres. Another way of defining the number of author candidates could be by number of included patients; e.g. if a person includes more than xx patients, then he/she will be involved in the manuscript process and thereby qualify for authorship. Such a limit follows the ICMJE criteria in that a person should have made "substantial" contributions to e.g. data acquisition (criterion one, Table 1). It is important to discuss and define these provisions in detail before embarking on the study so that expectations may be fulfilled and conflicts avoided.

The authorship contract

In order to avoid conflicts about authorship, it may be advisable to use a formal authorship contract that should be signed by at least one local investigator per study site as well as by all other persons in the initiating study group. Preferably, this should be done before the first patient is included in the trial. We have given an example of an authorship contract in Appendix A. The coordinator for such a contract would be the lead author (most often the first author) on the paper. It is his or her responsibility to obtain all the signatures and to ensure communication to all involved persons in the trial about the agreements on authorship.

It is also important to define rules about the manuscript workflow in the writing process. Otherwise, this may also give rise to conflicts in the author group. An author may prevent publication of the final manuscript, for instance by holding back a reply to manuscript changes. In order to facilitate publication, it is therefore important to define time limits for the revision process. We have given an example of such rules in Appendix B.

These rules (Appendix A and Appendix B) have been adapted from a similar set of rules that we developed for the Scandinavian Surgical Outcomes Research Group (SSORG), a group running multi-centre studies typically involving 10-20 hospitals in Denmark and Sweden [15, 16]. Thus, we have experience with these rules from a few other studies, but further improvements can probably be made when more experience has been gathered. It is advisable that both contracts (Appendix A and Appendix B) are signed by all potential authors of the final publication, as well as by at least one local investigator from each participating centre.

Change of byline

If previous agreements on authorship need to be changed, then it is be advisable to seek written approval from all authors. This applies both to the addition and to the deletion of an author. If the paper is already written and submitted, then there are certain procedures that are followed by most journals. They have been developed by the Committee of Publication Ethics and can be followed by simple flow charts [17].

CONCLUSION

Multi-centre clinical trials can involve up to hundreds of contributors of whom some will eventually co-author

the final publication. It is, however, often practically impossible to involve all contributors in the manuscript process to the extent that they will fulfil the ICMJE criteria for authorship, e.g. give feedback during critical manuscript revision. Therefore, to avoid conflicts, some rules for authorship in multi-centre trials are strongly recommended. We propose two contracts to prevent conflicts regarding authorship (Appendix A and Appendix B).

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