

CRITERIA FOR AUTHORSHIP FOR STATISTICIANS IN MEDICAL PAPERS

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SUMMARY

We organize a statistician's potential scientific and intellectual contributions to a medical study into three types of activities relating to design, implementation and analysis. For each type, we describe high-level, mid-level and low-level contributions. Using this framework, we develop a point system to assess whether authorship is justified. Although we recommend discussion and resolution of authorship issues early in the course of any project, our system is especially useful when this has not been done. © 1998 John Wiley & Sons, Ltd.

The making of many books is without limit
And much study is a wearying of the flesh
ECCLESIASTES: 12:12

1. INTRODUCTION

Publications are not solely a source of personal satisfaction. In academia, they are the currency of success. Much as we deplore the phenomenon of 'publication counting', career decisions are often based, at least in part, on the number of publications listed in the curriculum vitae. For example, faculty members promoted at Johns Hopkins University School of Medicine had approximately twice as many publications as those faculty members not promoted.¹ Similarly a survey of 366 academicians found that the number of publications and the quality of the journals were the most important considerations in tenure decisions.² Publications also are used to evaluate departments within a university.³

The International Committee of Medical Journal Editors has specified criteria for authorship in medical publications. Their criteria are 'substantial contributions to (a) conception and design,

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or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met.⁴ Criterion (c) implies that each author accepts responsibility for the article. Having sufficient expertise to judge the adequacy of contributions made by others in most multi-disciplinary papers is virtually impossible for any single author. Thus, we interpret criterion (c) to mean that the statistician is willing to take responsibility for the study design and data analysis in the paper, and believes that the co-authors are equally responsible and competent in their individual specialities.

Several papers have been published presenting guidelines for assigning authorship.^{5–8} These are usually based on the International Committee of Medical Journal Editors' criteria, often with modifications to make them less stringent. Some journals ask all authors to certify that these criteria are met as part of the submission process (for example, *Journal of the American Medical Association*).⁹ Other journals specify these requirements in their 'Information for Authors' (for example, *New England Journal of Medicine*).¹⁰ If there are many authors on a paper, the *New England Journal of Medicine* requires that each author certify that the criteria are met.¹¹ Many other journals have similar requirements.^{12,13}

In this paper we focus on authorship questions as they relate to statisticians and statisticians' activities in a study. We assume throughout this paper that the statistician would meet the common responsibilities of all authors: the critical review of the manuscript and accepting responsibility for the manuscript. We limit our discussion to studies and publications of substantive medical issues, not statistical techniques. Although issues of authorship arise in papers about statistical research and methodology, we do not address those problems here. We first outline the 'primary activities' for a statistician involved in a study and rank them by importance of intellectual content (Section 2). In Section 3, we provide a simple formula to estimate the overall importance of the statistician's intellectual contributions to a specific study. In Section 4 we provide several examples and make a recommendation about authorship in each case. Although others might disagree with our decisions, we offer specific advice anticipating that such an approach will provoke discussion of the issues raised. We discuss some additional conditions that may modify our recommendations on authorship in Section 5, and end with a general discussion of other issues involved in authorship in Section 6.

2. DESCRIPTION OF PRIMARY ACTIVITIES

Ideally, a scientific collaborator should be actively involved in all phases of a study, including the design, implementation, analysis of the specific results, assisting in interpreting these results in the context of the general scientific area, and in the preparation of the manuscript. As mentioned above, we do not discuss 'drafting the article or revising it critically for important intellectual content'⁴ as a specific activity in this paper, since we assume that every author routinely does this on every paper. We have attempted to divide the remaining items into three discrete primary activities specifically for a statistician: design, implementation, and analysis of the specific study.

Within each phase, the activities are listed with the most intellectual involvement first and with the least involvement third. Note that the time spent on an activity is not considered in our ordering. For example, doing an analysis will usually take far longer than developing the analysis plan, but the amount of intellectual investment in the study is far greater when designing the analysis plan. We discuss our rationale for this ordering after presenting the activities.

Phase I: Design

1. Substantive input into the overall design of the study and protocol development, which may be thought of as 'thinking through a study'.
2. Writing one or more sections of the research protocol or grant application (for example, data analysis and/or data management).
3. Overall critical review to sharpen a grant application before submission, without major substantive changes.

Phase II: Implementation

1. Regular (ongoing) participation in study meetings with the other investigators.
2. Implementation of data collection and data management activities.
3. Advising only on specific issues when requested by the principal investigator.

Phase III: Analysis

1. Planning and directing the analyses. This is usually based on the analysis plan described in the grant but now includes exact model specification, resolution at decision points, etc.
2. Preparing written material summarizing the results of the analyses for the other investigators and/or preparing formal reports.
3. Doing the analyses.

Each of these specific items covers a range of contributions. For example, the intellectual contribution involved in 'writing one or more sections for a grant' differs between a single paragraph justifying a sample size for a two-group comparison and an analysis plan for extensive modelling of the data. Despite this variability, the organization above provides a useful framework for determining the appropriateness of authorship, based on intellectual contribution and work during the study.

2.1. Rationale for order given

In phase I, the most important contribution is extensive input into the overall design of the study ('thinking through a study'). This implies at least substantial refinement and usually substantial modification of the original study design or aims, and modification of the protocol so that these aims can be achieved. In contrast, helping a colleague sharpen a grant application, without substantial revision, is unlikely to influence substantially the study design or the chance of funding. As such, this activity, although beneficial, is more a service than a major intellectual contribution to a study. Thus, we view preparing actual material for the grant application as more important than a general review of the whole grant application. When major changes are made to the grant based on the overall review, however, we consider this extensive input into the overall design of the study, the highest level activity.

During the implementation phase, regular participation in study meetings with other investigators reflects the greatest involvement. The term 'participation' implies an active role in these meetings, since mere attendance does not constitute involvement. Even without assigned responsibilities, because of the number and extent of the meetings, the statistician is likely to provide multiple small contributions to the study, often to ensure that the study continues to follow the original design criteria. Over time, these contributions will constitute substantial intellectual input. Implementation of data collection and data management activities, including supervision of data management personnel, is another single large activity. Although the contribution made by providing this service is important, it is limited to a single aspect of study implementation. The

third activity listed, responding to specific issues when raised by the investigator, is likely to provide the least opportunity for substantive intellectual input, since the investigator will predefine and limit the questions and issues.

Finally, planning the appropriate analysis and directing its execution is the major contribution, while doing the analysis under someone else's direction, although the most time consuming, is the least intellectually challenging task. Although we have sympathy with the view that interpreting results to investigators sometimes is more challenging than planning an analysis, determining the right analytic approach to use is technically more demanding and is the greatest intellectual input into this phase of the study. This is particularly true when the project requires innovative analytic methodology.

3. PROPOSED SCORING SYSTEM FOR AUTHORSHIP

We believe that a simple scoring system, with four points for the highest level '1' activities, two points for the mid-level '2' activities, and one point for the low-level '3' activities adequately reflects the relative importance of the categories. A statistician involved in every possible activity would have a maximum of 20 points, since one cannot be both 'involved in all aspects' and 'answer only specific questions' during study implementation. Clearly, such a statistician should be an author on any paper involving data collected from the study. In the more general case, we believe that 6–8 points on our scale represents an adequate level of involvement to warrant authorship. One could achieve this score with a high level of participation in at least one phase of the study, and equal lower levels in the order phases. Although one could also attain it by several low-level activities, usually we would expect that the statistician would participate at the highest level in at least one phase. We note that not all combinations are likely. The Appendix contains a form that summarizes the scoring system for use with collaborators when discussing authorship issues. We strongly recommend discussion of these issues at the initiation of a project so that misunderstandings do not arise later.

4. EXAMPLES

The examples, summarized in Table I, are illustrative and are not an exhaustive listing of all possibilities. All the examples below assume a project leading to a single paper. We discuss additional considerations affecting the appropriateness of authorship in Section 5. Within each group, we place the clearest case first.

4.1. Examples in which the statistician should be an author

4.1.1. Example 1

A statistician is involved in overall development of the protocol, is regularly involved with investigators during the study, and plans the analysis. Others, however, do all the detailed work. This yields a total of 12 points on our scale. This statistician has clearly made a substantive intellectual contribution to the study and authorship is appropriate.

4.1.2. Example 2

A statistician is involved in two of the three highest level activities and does one (or more) other activities involved in the implementation or analysis. Thus, the statistician has a total of nine or more points on our scale and authorship is appropriate.

Table I. Summary of illustrative examples

Phase	Activity	Points	Example											
			1	2*	3*	4	5*	6*†	7	8*	9*			
Study design	Thinking through a study	4	X					X						
	Writing grant material	2								X				
	Reviewing grant application	1				X	X	X						
Implementation	Involved in all aspects	4	X	X	X									
	Managing data management	2					X			X				
	Answers only specific questions when asked	1				X	X							
Analysis and presentation	Plans overall analysis	4	X	X	X						X	X		
	Interprets results	2								X	X	X		
	Performs analysis	1		X	X	X						X		
	Total points		12	9	8	3	5	5	5	6	6	7		
Authorship		Y	Y	Y	N	N	N	N	N?	N?	Y			

* Sample case. Other similar patterns (in terms of major/mid-level/minor activities) would also be possible
 † For Example 6, we believe that these combinations would not occur in practice

4.1.3. Example 3

A statistician is involved only in two of the three highest level activities but nothing else. This happens, for example, when a statistician is heavily involved in the implementation and analysis of a study, but the design is developed by others, often years before the arrival of the statistician. This gives a total of eight points. These two major contributions are adequate for authorship.

4.2. Examples in which being an author is not appropriate

4.2.1. Example 4

A statistician is involved in all the low-level activities, that is, overall review of the protocol, response to specific issues when requested by the investigator, and doing the analysis (planned primarily by other statisticians, or at the direction of the investigator). This gives a total of three points. Although these activities may be extremely time consuming, and meticulously done, authorship is not appropriate for a study that produces a single publication. We consider this example further in Section 5.3.

4.2.2. Example 5

In addition to the low-level activities in Example 4, the statistician is also involved in one mid-level contribution for a total of five points. This situation occurs, for example, if the statistician has done all the lower level activities, and: (a) prepared data management plans for the grant application; or (b) has supervised data management; or (c) has summarized the results of the analysis for the other investigators. Authorship is not appropriate for this level of involvement for an individual publication.

4.2.3. *Example 6*

A statistician could conceivably earn five points by participating in a major activity and a minor activity or participating in two mid-level activities and one minor activity. We have difficulty in imagining a statistician actually fulfilling either role, however. For example, it seems unlikely that a statistician could have a major impact on the study design and review the protocol without also writing text for it. Similarly, it seems unlikely that a statistician would have a major impact on the study design and analyse the data, but is not heavily involved in planning the analyses. We have similar difficulty with the plausibility of other such combinations that lead to five points.

4.3. Examples in which it is not clear whether authorship is appropriate

4.3.1. *Example 7*

A statistician makes mid-level contributions in all three areas of the study, for a total of six points. The statistician has prepared part of the grant, has implemented data management, and helps interpret results for the other investigators, although the analysis is primarily planned and implemented by others. We feel that this is not quite enough to merit authorship.

4.3.2. *Example 8*

The statistician does the two more important activities in a single phase of the study, for example, plans and interprets the analysis. Although the intellectual contribution may be relatively small in the activity not included, doing only two activities in one area, without involvement in either of the other areas, is not quite adequate for authorship.

4.3.3. *Example 9*

A statistician is involved in all three activities involving either the study design or the data analysis, but has no involvement in either of the other functions of a statistician. This provides a total of seven points. For example, a statistician may join a study as data collection nears completion. The statistician has clearly made a major contribution in one area of the study, which is adequate for authorship.

5. SPECIAL CONSIDERATIONS

In this section we consider several factors that may modify the decision about authorship.

5.1. Statistician involved only in the initial phases of the study

As a special case of Examples 8 and 9, a statistician may be heavily involved in the early phases of a study, but not involved in its completion either because of changing positions, retirement, or death. This frequently occurs in large, long-term collaborative studies. When a statistician has strongly influenced the planning and start of a study, even if no longer participating in the project, we feel that authorship is appropriate for the major publication(s) arising from the study. Thus, two or more statisticians may be authors, one with primary involvement in planning and the other with primary involvement in analysis.

When a statistician has died before the completion of the study, posthumous authorship, with a note indicating such, is appropriate.

5.2. Rescuing a study

Another special case of Examples 8 and 9 is when the statistician is brought into a study after the study is completed because of major problems in the design or implementation of the study. In such circumstances, one often finds it necessary to redefine the goals of the study or to become heavily involved in data management to resolve data problems. Although these issues should have been resolved earlier, this would still be design and implementation activity no matter when done. As such, a statistician involved in rescuing a study often contributes substantially to all three areas of the study, even though becoming involved only after the study is completed, and the point score should reflect all areas of involvement.

5.3. Staff contributions to multiple publications

A statistician may be one of a group in a large scale, long-term collaborative study that produces many papers. Many statisticians in the group may be involved only in one or two mid-level or lower level activities, usually data management and data analyses under the direction of a more senior person, as described in Example 4. Such work would be done over a long period and would contribute to many publications. We believe that co-authorship on some papers is appropriate for the statistician, particularly those in which the statistician has had the most involvement, to recognize the overall contribution, although the statistician does not reach the formal point criterion. This recommendation reflects that such studies often have relatively long lists of authors, so that the rigorous application of our 6–8 point criterion for authorship may adversely harm statisticians involved in the study. We recommend that such groups develop a formal policy specifying when authorship is appropriate.^{5,14} Appearance on a list of the study team is not authorship.

A similar problem might arise in a consulting service, in which staff work on multiple unrelated publications. One would hope, over time, that staff would develop their skills so that they could be able to provide the substantive intellectual contribution necessary to justify authorship. Again, we recommend that such groups develop a formal policy specifying when authorship would be appropriate.

5.4. Long-term involvement with a research group

On occasion, a statistician may work with a research group over a long period, making major contributions to the first in a series of similar projects. For example, a statistician might provide advice on the design and analysis of a single class of study, that is then repeated many times with minor modifications, for example, testing new antibiotics in a specific assay. In such a situation, collaborators may feel that the statistician deserves authorship on all publications that arise from the experimental programme. Although the statistician's contribution to a specific experiment might be relatively small, the long-term involvement with the group, and the statistician's initial involvement in both planning the design and the analysis of the basic experiment, would be marginally adequate for authorship.

5.5. Authorship in response to referees

On occasion, we have been offered authorship to rebut a referee's criticism of a manuscript with which we had no previous involvement. By being an author, we show that a 'real statistician' approves of the methods in the manuscript, and that the referee's comments are incorrect.

Although we are happy to help our colleagues with a written rebuttal to the journal editor when appropriate, becoming an author in such a circumstance is inappropriate.

A separate case is when the referee is correct and a statistician is brought into a project for additional analyses and revision of a manuscript. Such circumstances need to be judged in terms of the intellectual content provided by the statistician to the revised analysis and manuscript.

5.6. Institutional pressure to be an author

Independent of intellectual contribution, 'institutional considerations' (politics) might be cited for listing a statistician as an author on a manuscript on which the statistician would not normally consider it appropriate to be an author. In such circumstances one might be prepared to accept authorship even though one's contribution does not warrant it. None the less, authorship implies general responsibility for the paper as a whole. Thus, one should never agree to authorship on a paper unless one is prepared to accept public responsibility for the conclusions in it. If the paper does meet such a standard, however, it is not clear to us why such 'institutional considerations' would need to be placed on the statistician. Fortunately, we have never faced such a dilemma ourselves.

5.7. Relationship of authorship and financial compensation

Financial support and authorship are independent for everyone involved in a study, including both the principal investigator and the statistician. Financial compensation is intended to recover expenses (including salary support) associated with providing service, and is necessary for the long-term viability of both the statistician and of the investigator. As such, it is based on the time and effort spent on a project. In contrast, authorship is related to the scientific contribution to a study, independent of the time involved on a project. Thus, we view financial support and scientific collaboration as independent features of our interaction with an investigator. One cannot substitute one type of support for the other. Similarly, one type of support does not require, or preclude the other. The basis of financial support should be the time/effort spent on a project and the basis for authorship should be whether the statistician has made a scientific contribution to the project.

6. DISCUSSION

We believe that issues of authorship need resolution early in every project to avoid unpleasant surprises during manuscript preparation. Note that these unpleasant surprises are not solely on the statistician's side; when the statistician indicates surprise at not being offered authorship, the investigator might also be surprised that the statistician anticipates authorship. This problem is not unique to statisticians; 48 per cent of respondents in a survey of a university medical faculty had not been included as authors when they felt their authorship was deserved.¹⁵ The same article reported that most respondents (70 per cent) felt that the criteria of the International Committee of Medical Journal Editors were too restrictive and more than half of the respondents felt that the criteria were not usually met. This feeling was also noted in an accompanying editorial¹⁶ and by other authors.^{8,17,18}

In this paper, we have presented guidelines for statisticians on what constitutes a 'substantial contribution to a study'. This is an attempt to define standards for the first of the criteria

customarily given for authorship 'substantial contribution to conception and design, or analysis and interpretation of data'.⁴ We defined our guidelines operationally. It is important to note that our guidelines are not rules. As indicated in Section 5, there are many additional factors which affect the decision whether a statistician merits authorship.

We have assumed throughout that the statistician will participate in the writing of the manuscript, will review the final version, and will accept responsibility for the work. Thus, we have not focused on what makes a substantial contribution to 'drafting the article or revising it critically for important intellectual content'.⁴

To some extent, authorship relates to whether one is (and is viewed as) a 'collaborator' or a 'consultant'. We recognize that a rigorous distinction between 'collaboration' and 'consultation' is virtually impossible. This is reflected in the *Encyclopedia of Statistical Sciences*, where statistical consulting includes both 'a statistician who worked for years with a chemical engineer' and 'the response of a statistician to a telephone query on how to compute a standard deviation'.¹⁹ None the less, we believe that the two differ, even though we recognize that an absolute distinction is probably impossible. Despite the fuzziness of these terms, there are clear implications involved in these names, since a collaborator is usually considered a 'scientific partner' in the study, while a consultant is often viewed as a 'technical advisor'. Although the name given the relationship should not determine the appropriateness of authorship, we have tried to separate statistical activities into higher level activities, usually associated with collaboration, and lower level activities associated more with consulting. Our idea is that a collaborator generally merits authorship while a consultant generally does not. This distinction is particularly apparent in implementation activities, with the high-level activity ('involved in all aspects') likely to suggest a collaborator and the low-level activity ('answers only specific questions when asked') more typical of a consultant.

In summary, we believe that authorship issues require resolution soon after one becomes involved in a study. Although there often may be some ambiguity in determining whether the statistician merits authorship, we hope other statisticians find our guidelines useful.

APPENDIX: CHECKLIST OF STATISTICAL CONTRIBUTIONS TO STUDY

Activity	Points	Involved	
<i>Study design</i>			
Substantive input into the overall design of the study and protocol development ('thinking through a study')	4	Yes	No
Writing one or more sections of the grant application (data analysis, data management)	2	Yes	No
Overall review of grant application prior to submission	1	Yes	No
<i>Implementation</i>			
Regular (ongoing) participation in study meetings with the other investigators	4	Yes	No
Implementation of data collection and data management activities, including monitoring and supervision of data collection staff	2	Yes	No
Advising only on specific issues when requested by the principal investigator ('answers only specific questions')	1	Yes	No

APPENDIX: (Continued)

Activity	Points	Involved	
<i>Analysis</i>			
Planning and directing the analyses; this is usually based on the analysis plan described in the grant but now includes exact model specification, resolution at decision points, etc.	4	Yes	No
Preparing written material summarizing the results of the analyses for the other investigators and/or preparing formal reports	2	Yes	No
Doing the analyses	1	Yes	No
Total points	<hr/>		
Do special circumstances apply?	Yes	No	
Authorship criterion (without special circumstances)			
8 or more points: Yes			
6–7 points: Possibly			
5 or fewer points: No			

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