Research article

Adherence to the CONSORT guideline in papers written by professional medical writers

by Adam Jacobs

Abstract

Background

Many papers in the biomedical literature are drafted not by those who did the research, but by professional medical writers. CONSORT guidelines give specific recommendations for items that should be included in publications of randomised controlled trials. This study investigated whether papers written by professional medical writers were more compliant with the CONSORT guidelines than other papers.

Findings

All randomised clinical trials published in the journal *Current Medical Research and Opinion* between October 2004 and August 2009 were included in this study. Data were abstracted by two researchers, both of whom were blind to the objectives of the study; one recorded whether each CONSORT item was absent, present but incompletely described, or completely described and the other checked each paper for whether a medical writer had been acknowledged and whether the paper had industry sponsorship. The mean number of completely described guidelines was compared between papers written by a medical writer and those written by others. The secondary analysis was to compare industry-sponsored papers with those that did not declare industry sponsorship. 241 papers were included, 93% of which were industry sponsored; 63% acknowledged assistance from a medical writer. Papers that acknowledged medical writers complied with more CONSORT items (17 of 22) than those that did not (16 of 22; difference between groups 0.75 items completed, 95% CI 0.07 to 1.43, P = 0.03). Too few non-industry-sponsored papers were found to allow a meaningful comparison of industry and non-industry-sponsored papers.

Conclusions

Papers that acknowledged assistance from professional medical writers were more likely to comply with the CONSORT guidelines than papers that did not. However, the difference was small, and the practical importance of the difference is unknown.

Introduction

Many papers in the biomedical literature are drafted not by those who did the research, but by professional medical writers. Many professional medical writers receive training in how to write papers, and write papers and other medical documents as a full-time job. It might therefore be hypothesised that they are better qualified to write papers than most researchers, for whom writing the paper is often simply an unfortunate extra chore that needs to be done at the end of a piece of research.

However, despite the theoretical benefits of assistance from professional medical writers, there are almost no data to show whether those benefits are realised in practice. In a systematic review in 2003, Lagnado only found anecdotal evidence that professional medical writers improve the quality and readability of papers, and concluded "I did not find firm evidence to support these reported benefits." [1]

Measuring the writing quality in published papers is hard to do, as many aspects of writing quality are subjective. However, the CONSORT guidelines give specific recommendations for items that should be included in publications of randomised controlled trials, with a 22-item checklist [2]. The extent to which papers of randomised trials comply with the CONSORT guidelines could be considered a measure of the completeness with which the research is documented, which is one measure of writing quality, albeit a measure of only one dimension of a complex multi-dimensional concept. The aim of this study was to determine whether papers written by professional medical writers were more compliant with the CONSORT guidelines than other papers. An updated version of the CONSORT guidelines has recently been published [3]; however, this research pre-dates the publication of those guidelines and therefore used the 2001 version.

Methods

The primary objective of this study was to determine whether papers written by professional medical writers are more likely to comply with the recommendations of the CONSORT guideline than papers that were not written by professional medical writers. A secondary objective was to determine whether industry sponsorship of papers was associated with compliance with the CONSORT guideline. Involvement of professional medical writers and industry sponsorship are often considered as a single issue, although in reality they are two quite distinct concepts.

All randomised clinical trials published in the journal *Current Medical Research and Opinion* between October 2004 and August 2009 were included in this study. That journal was selected because it has a high proportion of papers written by professional medical writers and was therefore expected to yield a sufficient number of such papers for

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analysis. A previous pilot study (unpublished) in a wider range of journals failed to yield useful results because the number of papers acknowledging professional medical writers was too small to allow meaningful comparisons. The date range was chosen for pragmatic reasons, as we had had a subscription to the journal since October 2004 and therefore had full text articles available since that date. The instructions to authors of *Current Medical Research and Opinion* had recommended that manuscripts of randomised controlled trials comply with the CONSORT guideline since April 2005.

Data were abstracted by two interns, both of whom were blind to the objectives of the study to avoid any bias in collecting the data. Both interns were science graduates and received brief training in the methods of the study. One intern (VM), who was not aware that the study was designed to compare papers written by professional medical writers with those that were not, compared each paper with each item in the CONSORT checklist, and recorded whether the item was absent, present but incompletely described, or completely described. The other intern (AM), who was not aware that the study was designed to assess compliance with the CONSORT checklist (or indeed any other measure of quality), checked each paper for whether a professional medical writer had been acknowledged (rated as yes, no, or unclear), and whether the paper had industry sponsorship. Although it was not always easy to infer the nature of any writing assistance from often vague statements in acknowledgements, we attempted to define the involvement of a professional medical writer as someone who had had a role in drafting the manuscript, and if it was clear that only editing of an already complete manuscript was being acknowledged, we did not count that as writing assistance.

A total score was calculated for each paper as the sum of the items that were completely described (minimum = 0, maximum = 22). If an item was not completely applicable, a full point was awarded if the paper described the parts that were applicable and contained sufficient information to be sure other parts were not applicable. The primary analysis was a t-test of the difference in those scores between papers written by a professional medical writer and those that either were not or were unclear. A secondary analysis was done to compare industry-sponsored papers with those that did not declare industry sponsorship. As a sensitivity analysis, the total score was recalculated with the addition of half a point for each item that was present but incompletely described.

As a further sensitivity analysis, the odds of completion of CONSORT items were investigated by logistic regression. Because items within a specific paper would be expected to be correlated, a random effects logistic regression model was used in which the paper was included as a random effect, and acknowledgement of a professional medical writer and the number of the CONSORT item were included as fixed effects.

Exploratory analyses were done to calculate the odds ratios and their confidence intervals for completion of each CONSORT item individually.

Table 1. Characteristics of the included papers

Source of funding	No medical writer acknowledged	Acknowledgement unclear	Medical writer acknowledged	Total
Industry	60 (27%)	17 (8%)	147 (66%)	224 (100%)
Other	9 (53%)	3 (18%)	5 (29%)	17 (100%)
Total	69 (29%)	20 (8.3%)	152 (63%)	241 (100%)

Results

241 papers were included in the study. Details of industry sponsorship and acknowledgement of professional medical writers are shown in Table 1. As expected for a journal that focuses on industry-sponsored research, the overwhelming majority of papers were industry sponsored, and a little over half clearly acknowledged assistance from a professional medical writer.

Most CONSORT items were at least partially described in almost all papers, although some were less well described (Figure 1). Items that were particularly poorly described by both groups of writers were items 9 (concealment of random allocation), 10 (implementation of randomisation), and 14 (dates of recruitment and follow up periods). The frequency of reporting of each CONSORT item by medical writers and other writers is given in Table 2.

Papers that acknowledged professional medical writers complied with more CONSORT items than those that did not (Table 3). The difference between groups was statistically significant for the primary measure of counting only complete CONSORT items (difference between groups 0.75 items completed, 95% CI 0.07 to 1.43, P = 0.03) but not for the secondary measure in which half points were counted if items were present but incompletely described (difference between groups 0.53 items completed, 95% CI –0.02 to 1.07, P = 0.06).

Figure 1. Overall compliance with CONSORT items

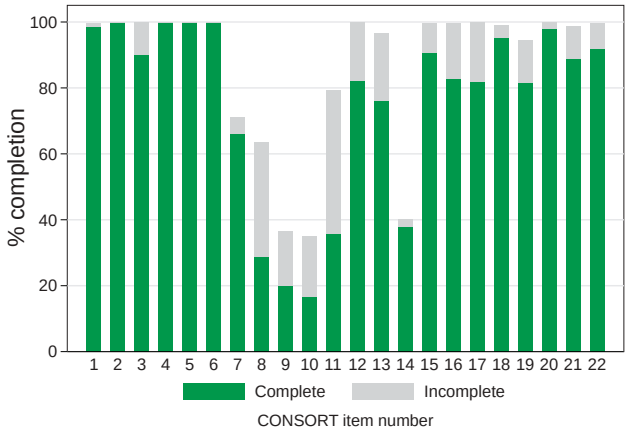

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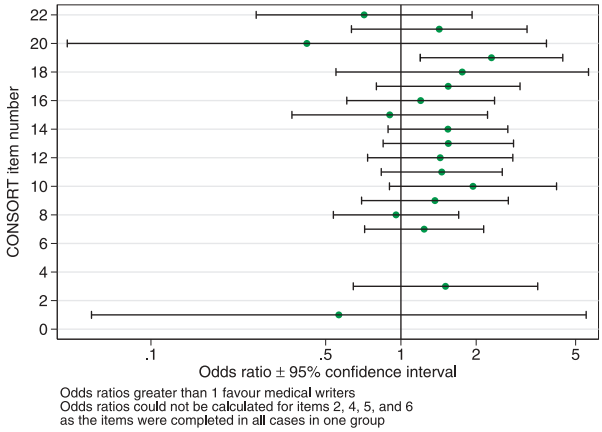
Figure 2. Odds ratios for completion of each CONSORT item



Odds ratios greater than 1 favour medical writers
Odds ratios could not be calculated for items 2, 4, 5, and 6 as the items were completed in all cases in one group

Table 3. Number of CONSORT items completed

	Papers probably written by medical writers (N= 152)		Other papers (N = 89)	
	Mean	SD	Mean	SD
Number of CONSORT items completed	16.9	2.5	16.1	2.7
Items completed with half marks for incomplete items	18.0	2.0	17.5	2.1

Table 2. Frequency of reporting of CONSORT items

CONSORT item	Paper section	Topic	Description	Frequency of reporting n (%)	
				Medical writer	Other writer
1	Title & abstract	Title and abstract	How participants were allocated to interventions	149 (98.03)	88 (98.88)
2	Introduction	Background	Scientific background and explanation of rationale	151 (99.34)	89 (100.00)
3	Methods	Participants	Eligibility criteria and the settings and locations where the data were collected	139 (91.45)	78 (87.64))
4		Interventions	Precise details of the interventions intended for each group; how and where they were administered	151 (99.34)	89 (100.00)
5		Objectives	Specific objectives and hypotheses	151 (99.34)	89 (100.00)
6		Outcomes	Clearly defined primary and secondary outcome measures; any methods used to enhance the quality of measurements	152 (100.00)	88 (98.88)
7		Sample size	How sample size was determined and explanation of any interim analyses and stopping rules	103 (67.76)	56 (62.92)
8		Randomisation, sequence generation	Method used to generate the random allocation sequence, including any restrictions	43 (28.29)	26 (29.21)
9		Randomisation, allocation concealment	Method used to implement the random allocation sequence, clarifying whether the sequence was concealed until interventions were assigned	33 (21.71)	15 (16.85)
10		Randomisation, implementation	Who generated the allocation sequence, enrolled participants, and assigned participants to their groups	30 (19.74)	10 (11.24)
11		Blinding	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated	59 (38.82)	27 (30.34)
12		Statistical methods	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses	127 (84.11)	70 (78.65)
13	Results	Participant flow	Flow of participants through each stage. Describe protocol deviations from study as planned, together with reasons	120 (78.95)	63 (70.79)
14		Recruitment	Dates defining periods of recruitment and follow-up	63 (41.45)	28 (31.46)
15		Baseline data	Baseline demographic and clinical characteristics of each group	137 (90.13)	81 (91.01)
16		Numbers analysed	Number of participants (denomination) in each group included in each analysis and whether the analysis was by “intention-to-treat”	127 (83.55)	72 (80.90)
17		Outcomes and estimation	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision	128 (84.21)	69 (77.53)
18		Ancillary analyses	Address multiplicity by reporting any other analyses performed	146 (96.05)	83 (93.26)
19		Adverse events	All important adverse events or side effects in each intervention group	131 (86.18)	65 (73.03)
20	Discussion	Interpretation	Interpretation of the results	148 (97.37)	88 (98.88)
21		Generalisability	Generalisability (external validity) of the trial findings	137 (90.13)	77 (86.52)
22		Overall evidence	General interpretation of the results in the context of current evidence	138 (90.79)	83 (93.26)

The logistic regression analysis also showed that CONSORT items were significantly more likely to be completed in papers with a clear acknowledgement of a medical writer (odds ratio 1.44, 95% CI 1.04 to 2.00, P = 0.03).

In the exploratory analysis of the odds ratio for each individual CONSORT item, most 17 of 22 odds ratios were greater than 1, showing that the item was more likely to be completed in papers with a clear acknowledgment of a medical writer (Figure 2). However, the difference was statistically significant only for item 19 (reporting of adverse events) (odds ratio 2.30, 95% CI 1.19–4.44, P = 0.01).

No significant differences were noted between industry-sponsored and independent publications on any measure. The ability of this study to determine the effect of industry sponsorship was severely hampered by the small number of papers without industry sponsorship.

Discussion

There are very few existing data on whether professional medical writers improve the quality of publications. This study has shown that papers that acknowledged professional medical writers were more compliant with the CONSORT guideline than papers that did not. The difference was small but statistically significant and although this is only one proxy measure of article quality, the result is important as it provides evidence towards a much discussed but seldom answered question. Unfortunately, there were too few non-industry-sponsored publications to allow meaningful comparison with industry-sponsored publications, so this study was unable to meet its secondary objective.

It has been suggested that randomisation, avoidance of exclusions after trial entry, and blinding are the most important methodological components of controlled trials [4]. It has also been reported that trials that used inadequate allocation concealment compared with those that used adequate concealment had larger estimates of effect [4,5]. Therefore, it could be proposed that the most important CONSORT items to include as markers of study quality are items 9 (concealment of random allocation), 10 (implementation of randomisation), 11 (blinding), and 13 (participant flow); items 9 and 10 were poorly reported by both groups in this study. However, items 9, 10, 11, and 13 were all more frequently reported in papers that acknowledged professional medical writers than those that did not. It therefore appears that professional medical writers do better than other writers on items that make important contributions to the quality of reporting, although reporting of these items was far from perfect even in the articles that acknowledged medical writers.

Some limitations need to be borne in mind when considering the results of this study. The most important is that if a paper does not acknowledge a medical writer, that is not proof that no medical writer was involved, as it is possible that an unacknowledged medical writer (or ghostwriter) assisted with the paper. A substantial proportion of papers written by medical writers do not contain an acknowledgement of the medical writer's contribution [6], although that proportion is decreasing, probably as a result of recent guidelines that have emphasised the importance of acknowledgement of medical writers. However, as 2 of those guidelines [7, 8] were published in *Current Medical Research and Opinion*, and that journal has been keen to engage constructively with professional medical writers, it seems likely that the proportion of unacknowledged contributions by medical writers would be lower than in biomedical publishing as a whole.

It is likely, therefore, that most of the papers that did not acknowledge medical writers were written by the researchers, but some misclassification bias could have affected this study. In this context, misclassification bias could result either from papers that were truly written by medical writers being classified as having been written without their assistance, or vice versa. The effects of such misclassification bias are hard to determine and could act in either direction. On the one hand, it is possible that such misclassification bias could have diluted the effect seen in this study, as a result of the involvement of medical writers in some of the papers classified as having been written without their assistance. If that were the dominant effect of misclassification bias, then the true benefit of professional medical writers would be greater than suggested by the results shown here.

However, it is also possible that medical writers who are not acknowledged simply lack the professionalism of their acknowledged colleagues and do not keep sufficiently well informed about current guidelines, which would make them less likely to insist on acknowledgement as well as less likely to adhere to the CONSORT guidelines. If that is the dominant effect, then it is possible that this study may over-estimate the benefit of medical writers.

This study was not a randomised trial and papers written by professional medical writers may differ from the others in other ways. However, as all papers were taken from the same journal, any differences between the papers should be reduced, but systematic differences between the groups of papers cannot be ruled out. Data were extracted by only one person, and it is therefore likely that there were some errors in data collection. However, any such errors would have the effect of adding random noise to the data, which would tend to obscure any difference between the two groups of papers, and therefore be likely to bias the results towards the null hypothesis. If such errors were common, then the true difference between the groups may be greater than reported here. Importantly, neither of the researchers extracting data was aware of the study hypothesis, so it is unlikely that any systematic bias could have affected the results.

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A further limitation is that this study was only able to examine the final published manuscripts. We do not know whether medical writers were responsible for including items in the CONSORT checklist. It is possible that a medical writer may have initially included some items which were subsequently deleted, or have initially omitted some items which were subsequently added, as many changes would be made to a medical writer's first draft both by the named authors and in response to requests from peer reviewers.

In conclusion, papers that acknowledged assistance from professional medical writers were more likely to comply with the CONSORT guidelines than papers that did not. However, the difference, although statistically significant, was small, and the practical importance of the difference is unknown.

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