

Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers

by Adam Jacobs and Cindy W Hamilton

Introduction

Ghostwriting, defined as undisclosed contributions by medical writers to manuscripts for publication in medical journals, is unethical and undermines the integrity of the authorship system [1]. The International Committee of Medical Journal Editors (ICMJE) [2], American Medical Writers Association (AMWA) [3], European Medical Writers Association (EMWA) [4], and other organisations [1, 5, 6] agree that substantial contributions to manuscripts should be disclosed with either a byline (authorship or contributorship) or an acknowledgement. In addition, many organisations recommend disclosure of potential conflicts of interest by medical writers, in particular their source of funding [1, 2, 3, 4].

Ghostwriting is believed by some to be common practice [7], but the prevalence of undisclosed contributions in medical journals is unknown because of a lack of specific research [8]. Estimates are often based on the survey by Flanagin and colleagues [9] in which 11% of 809 articles published in 1996 had evidence of ghost authors. Similarly, 9% of 141 reviews published in 1999 had evidence of ghost authors [10]. Ghost authorship, however, should be distinguished from ghostwriting. Ghost authorship is defined as failure to identify all authors meeting each of the following authorship criteria: (1) conceive and design the work or analyse and interpret the data, (2) write at least part of the manuscript or revise it to make important content changes, and (3) approve the final version [2]. Medical writers and editors can make substantial contributions without meeting all 3 authorship criteria. Such contributions, if unacknowledged, constitute ghostwriting. Only 1% of the 809 articles in Flanagin's survey [9] had an undisclosed medical writer or other undisclosed individual who participated in writing the article. A paper published in 2007 by Gøtsche et al [11] has been widely cited as evidence of the prevalence of ghostwriting, but in fact looks specifically at whether statisticians are listed as authors, and provides no evidence on the role of professional medical writers. It is therefore clear that there is an important gap in the literature on how common ghostwriting is.

To evaluate the prevalence of ghostwriting among papers written by professional medical writers (ie, those whose main job is writing, as opposed to researchers who write their own papers), we conducted 2 surveys of members of AMWA and EMWA. Our primary objective was to determine the proportion of substantial contributions by medical writers that were undisclosed in submitted manuscripts (ie,

ghostwriting; hereafter, undisclosed contributions). Secondary objectives were to determine the proportion of participants who request acknowledgement of their contributions and disclosure of their potential conflicts of interest, and effect of familiarity with guidelines [2, 3, 4, 5, 6] and other factors on disclosure. Our original survey was done in October 2005. To investigate changes over time, specifically after the EMWA guidelines [4] were published, we repeated the survey in November 2008.

Methods

Our first survey of AMWA and EMWA members was done from October 12 to 28, 2005, using an internet survey tool, Survey Monkey (www.surveymonkey.com). We developed the survey instrument using repeated rounds of pilot testing among groups of medical writers. All members of AMWA and EMWA were invited by e-mail to participate in the survey; 1 e-mail reminder was sent. No incentives were offered. To encourage participation, we promised that it would be anonymous and would take only 5 minutes.

The survey instrument comprised 13 multiple-choice questions and 1 open-ended question about the practices and experiences of medical writers who make substantial contributions to manuscripts intended for submission to biomedical journals. See the EMWA website [www.emwa.org] for the full version of the survey used.

We repeated the survey from 13 to 25 November, 2008. The survey was identical to the 2005 survey, apart from the addition of one question asking whether participants wrote mainly primary manuscripts, review manuscripts, or a mixture of both.

Some questions allowed for internal validation of responses. For example, participants were considered to have invalid data if they indicated that 90% or 100% of manuscripts did not disclose their substantial contributions (question 3), that they always or usually requested acknowledgement when they made substantial contributions (question 7), and that this request was always or usually granted (question 8), as if the answers to questions 7 and 8 were true, then it should also be true that most of their contributions were disclosed. Participants with invalid data were excluded from the analyses. If participants answered any parts of question 5 about familiarity with relevant guidelines, but did not answer whether or not they were familiar with any specific guideline, then we assumed that they were not familiar with that guideline. Otherwise, missing data were ignored with no attempt at imputation.

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All statistical analyses were done using Stata (StataCorp, College Station, Texas). The primary analysis was calculation of mean percentage of manuscripts containing undisclosed contributions in the last year (question 3) weighted in proportion to the number of manuscripts to which participants had made substantial contributions and that were intended for submission to biomedical journals during an average year (question 2). The response category >20 manuscripts/year was assumed to be 25 manuscripts/year. The 95% confidence interval (95% CI) was calculated assuming that responses were normally distributed. An unweighted mean and CI were also calculated similarly.

Secondary analyses were done to test the null hypothesis that familiarity with relevant guidelines (question 5) was not associated with frequency of undisclosed contributions (or, in subsequent analyses, participants' requests for acknowledgement [question 7] and disclosure of pertinent professional or financial relationships [question 9]). Linear regression analysis was used to test whether the percentage of undisclosed contributions was associated with the number of guidelines with which the participant was familiar, (maximum 5, minimum 0). Ordinal logistic regression was used for analogous analysis of frequency of request for acknowledgement or disclosure of potential conflicts of interest in the following 3 categories: always, usually, and rarely or never (including both "rarely or never, but I am not opposed to the practice" and "rarely or never, because I am opposed to the practice" in the case of request for acknowledgement).

Further exploratory analyses investigated other potential predictors of these outcomes, namely percentage of manuscripts with undisclosed contributions and participants' requests for acknowledgement and disclosure. Predictor variables to be evaluated were number of manuscripts to which participants had made substantial contributions during an average year, familiarity with each of the 5 guidelines specifically, type or place of employment, number of years of experience in biomedical communication, and membership in professional organisations. These were investigated in both univariate and multivariate analyses.

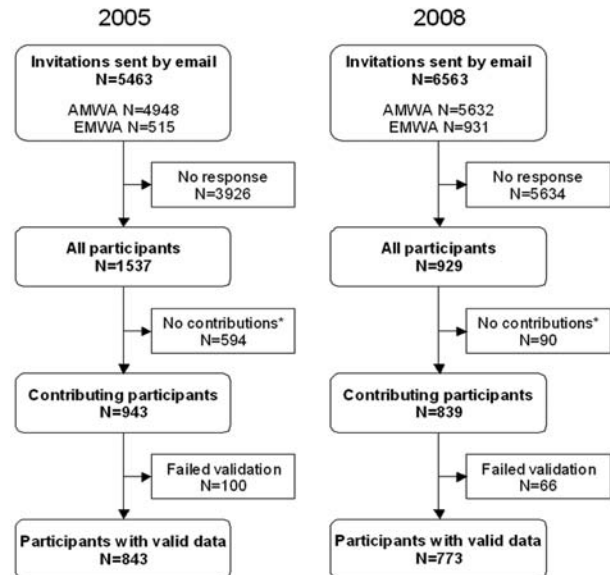
Results were analysed in an identical manner for the 2005 and 2008 surveys, except that the proportion of review papers was included in the multivariate analyses as an extra independent variable in the 2008 data, and different versions of Stata were used (version 8.2 in 2005 and version 9.2 in 2008). No formal statistical comparisons were made between the 2005 and 2008 results, as this was not a pre-specified objective at the time the 2005 survey was planned.

Results

The response rate was 28% in 2005 and 14% in 2008 (the invitation to the survey explained more clearly in 2008 than in 2005 that the survey was only relevant to those writers who made substantial contributions to manuscripts intended for publication). After excluding participants who did not contribute substantially to manuscripts and those

who failed the internal validation check, 843 and 773 participants contributed data for analysis in 2005 and 2008 respectively (Figure 1).

Figure 1 Flowchart of respondents to survey



* No substantial contributions to writing or editing manuscripts

Characteristics of the participants are shown in Table 1, and were similar in both years. The most common type of employment in both years was freelance, followed by pharmaceutical, biotech, or medical device companies. In both years, most participants had at least 6 years of experience in medical writing. Consistent with the relative sizes of the organisations, AMWA members greatly outnumbered EMWA members in both years.

Familiarity with guidelines was greater in 2008 than in 2005. In both years, the AMWA position statement and the ICMJE guidelines were the most familiar (Table 2).

The mean, weighted percentage of manuscripts with undisclosed contributions decreased from 62% in 2005 to 42% in 2008, in other words acknowledgement of medical writers' contributions became more common over the 3 year interval. In both years, the unweighted percentage of manuscripts with undisclosed contributions was slightly lower (Table 3).

Consistent with the observed fall in the proportion of undisclosed contributions, the majority of respondents in 2008, although not in 2005, replied that the frequency of undisclosed contributions had decreased in the last 5 years in their experience (Table 4). Also consistent with the fall in the proportion of undisclosed contributions, the percentage of writers who always requested acknowledgement and the percentage of respondents reporting that their requests were always granted increased substantially from 2005 to 2008.

In both years, there was a highly significant negative correlation between the number of guidelines with which participants were familiar and the frequency of their undisclosed

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Table 1 Characteristics of the participants

	Total responses		n (%)	
	2005	2008	2005	2008
Employment:	746	662		
<i>Self-employed or freelance</i>			289 (39%)	260 (39%)
<i>Pharmaceutical, biotech, or medical device company</i>			208 (28%)	154 (23%)
<i>Medical communications, medical education, or PR</i>			112 (15%)	131 (20%)
<i>Hospital, university, or medical school</i>			77 (10%)	57 (9%)
<i>CRO</i>			32 (4%)	32 (5%)
<i>Other</i>			28 (4%)	28 (4%)
Years of experience	737	657		
0–2			85 (12%)	87 (13%)
3–5			158 (21%)	157 (24%)
6–10			208 (28%)	160 (24%)
11–15			106 (14%)	115 (18%)
16–20			71 (10%)	55 (8%)
> 20			109 (15%)	83 (13%)
Number of manuscripts per year	776	691		
0–2			169 (22%)	131 (19%)
3–5			275 (35%)	229 (33%)
6–10			184 (24%)	188 (27%)
> 10			148 (19%)	143 (21%)
AMWA member	736	647	631 (86%)	500 (77%)
EMWA member	736	647	127 (17%)	166 (26%)

Table 2 Familiarity with position statements and guidelines

	n / total responses (%)	
	2005	2008
AMWA position statement [3]	317/625 (51%)	497/654 (76%)
EMWA guidelines [4]	198/735 (27%)	298/641 (46%)
GPP guidelines [6]	317/730 (43%)	377/646 (58%)
ICMJE guidelines [2]	399/735 (54%)	498/661 (75%)
PhRMA guidelines [5]	206/719 (29%)	229/632 (36%)

Table 3 Percentage of papers with undisclosed contributions

	N	Mean	95% CI
2005			
<i>Weighted mean*</i>	774	62%	59–65%
<i>Unweighted mean</i>	750	59%	56–62%
2008			
<i>Weighted mean*</i>	678	42%	39–45%
<i>Unweighted mean</i>	684	39%	36–42%

* The weighted mean was weighted in proportion to the number of manuscripts the respondent wrote per year

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Table 4 Experience of and practice in requesting acknowledgement

	Total responses		n (%)	
	2005	2008	2005	2008
Change in last 5 years in frequency of undisclosed contributions in participants' experience	688	651		
Decreased to none			20 (3%)	72 (11%)
Decreased but still occurs			250 (36%)	340 (52%)
No change			360 (52%)	198 (30%)
Increased			58 (8%)	41 (6%)
Request acknowledgement of substantial contributions	747	665		
Always			187 (25%)	288 (43%)
Usually			183 (24%)	168 (25%)
Rarely or never, but I am not opposed to the practice			354 (47%)	194 (29%)
Rarely or never because I am opposed to the practice			23 (3%)	15 (2%)
Requests for acknowledgement granted	365	466		
Always			127 (35%)	224 (48%)
Usually			177 (48%)	185 (40%)
Rarely or never			61 (17%)	57 (12%)

contributions, in other words participants familiar with more guidelines were more likely to have their contributions acknowledged. Similarly, there was a strong positive relationship between the number of familiar guidelines and requests for acknowledgement (Table 5).

Results of univariate analyses of other potential predictors on the frequency of undisclosed contributions were mostly similar in 2005 and 2008, although there were some small differences (Table 6). In both years, familiarity with each individual guideline was associated with fewer undisclosed contributions, and participants contributing to > 10 papers a year having a greater proportion of undisclosed contributions than less prolific writers. In 2005, employees of medical communication companies were most likely to have undisclosed contributions, whereas in 2008 freelance writers had more undisclosed contributions. There appeared to be a substantial change in the practices of those working for medical communication companies between 2005 and 2008. In 2005, employees of medical communication companies were highly significantly more likely to have unac-

knowledged contributions than those working in academia (the reference category), whereas in 2008 this difference was small and non-significant. Although it is often assumed in the popular media that ghostwriting is driven by pharmaceutical companies, it is interesting to note that employees of pharmaceutical companies were the least likely to have unacknowledged contributions in both years. In 2008, participants who wrote review papers were more likely to have undisclosed contributions than those who wrote primary manuscripts (this question was not asked in 2005). Most of these results were similar in the stepwise multivariate analyses (data not shown), the final models in both years including the number of papers, familiarity with specific guidelines, and type of employing organisation as significant predictors. In addition, writing review papers or primary manuscripts remained a significant predictor in the 2008 model.

Similar results were obtained for predictors of requests for acknowledgement (data not shown).

Discussion

Our data, based on a survey of medical writers, fills an

Table 5 Regression analysis of effect of number of familiar guidelines

	N	Estimate*	95% CI	P value*
2005				
<i>Proportion of undisclosed contributions</i>	750	-6.6%	-8.5 to -4.8%	< 0.001
<i>Frequency of request for acknowledgement</i>	747	1.41	1.29 to 1.55	< 0.001
2008				
<i>Proportion of undisclosed contributions</i>	684	-7.7%	-9.6 to -5.8%	< 0.001
<i>Frequency of request for acknowledgement</i>	665	1.57	1.41 to 1.74	< 0.001

* Estimate is the regression coefficient (change in proportion of undisclosed contributions for each extra familiar guideline) for proportion of undisclosed contributions or odds ratio from ordinal logistic regression for increasing frequency of acknowledgement. P value tests null hypothesis of no effect, ie regression coefficient of 0 or odds ratio of 1

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important gap in the literature on the extent to which medical writers are ghostwriters. It is often assumed that ghostwriting is common among professional medical writers, although there has up to now been little evidence on which to base that assumption. Ghostwriting was common practice in 2005, although the frequency decreased substantially over the following 3 years, such that our results show that acknowledged contributions were more common than ghostwriting in 2008.

The strengths of our survey are that it obtained results from a large number of professional medical writers from a variety of working environments in several countries, answering under conditions of anonymity. We used the same survey methods in both years, so comparisons between 2005

and 2008 should be valid. In addition, we included an internal validation step that allowed exclusion of participants who may not have answered the questionnaire sufficiently carefully.

Nonetheless, our survey also has important limitations that should be considered in interpreting the results. It is important to realise that our survey was aimed only at professional medical writers. Many papers are written without the aid of professional medical writers, and any conclusions from our survey cannot be extrapolated to those articles. Our survey provides information about the acknowledgement of writing assistance by professional medical writers, but the extent to which this is representative of biomedical publications in general is unknown. Our survey therefore

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Table 6 Regression analysis of other predictors of proportion of undisclosed contributions

	2005			2008		
	Est.	95% CI	P	Est.	95% CI	P
Specific guidelines						
<i>AMWA</i>	-9.0	-15.1 to -2.8	0.004	-10.4	-17.2 to -3.6	0.003
<i>EMWA</i>	-13.0	-19.9 to -6.1	< 0.001	-15.6	-21.8 to -9.4	< 0.001
<i>GPP</i>	-14.5	-20.5 to -8.5	< 0.001	-21.3	-27.3 to -15.2	< 0.001
<i>ICMJE</i>	-22.3	-28.1 to -16.5	< 0.001	-24.3	-30.9 to -17.6	< 0.001
<i>PhRMA</i>	-13.0	-19.7 to -6.3	< 0.001	-13.4	-19.9 to -6.8	< 0.001
Type of employment			< 0.001			< 0.001
<i>Academic</i>	Reference category					
<i>Freelance</i>	28.2	18.2-38.3		12.3	0.4 to 24.2	
<i>Medcom</i>	36.7	25.1 to 48.3		3.3	-9.6 to 16.2	
<i>Pharma</i>	0.0	-10.5 to 10.4		-7.0	-19.5 to 5.6	
<i>Other</i>	13.9	0.2 to 27.6		1.7	-13.2 to 16.7	
Number of papers/year			0.134			0.042
0-2	Reference category					
3-5	4.3	-4.0 to 12.5		-2.1	-11.2 to 6.9	
6-10	4.2	-4.8 to 13.1		-9.6	-18.9 to 0.3	
> 10	11.3	1.8 to 20.8		2.7	-7.2 to 12.6	
Experience (years)			0.425			0.407
0-2	Reference category					
3-5	11.7	0.2 to 23.1		3.0	-8.0 to 14.1	
6-10	11.4	0.4 to 22.4		1.2	-9.8 to 12.2	
11-15	10.6	-1.9 to 23.2		9.2	-2.5 to 21.0	
16-20	11.2	-2.6 to 24.9		4.3	-9.8 to 18.4	
> 20	10.1	-2.3 to 22.5		10.1	-2.7 to 22.9	
Reviews or primary manuscripts	Question not included in survey					< 0.001
<i>Mostly primary</i>				Reference category		
<i>Some reviews</i>				10.0	2.5 to 17.6	
<i>Mostly reviews</i>				16.0	7.1 to 24.8	

* No substantial contributions to writing or editing manuscripts

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does not allow an estimate to be made of the prevalence of ghostwriting in biomedical publications in general, only in the subset of papers written with the assistance of professional medical writers. While the proportion of that subset is unknown, a study by Woolley et al published in 2005 [12] sheds some light on this question with the finding that 6% of a sample of publications in high-ranking journals declared medical writing assistance.

The most important limitation of our survey is selection bias, in that the respondents in our survey may not be representative of the entire community of medical writers. Our survey was sent only to those medical writers who belong to AMWA or EMWA, and our response rate was, while respectable for e-mailed surveys, still low enough that it is likely that our respondents are not even representative of AMWA or EMWA members. It could reasonably be hypothesised that AMWA and EMWA members are more likely to follow latest guidelines than medical writers who are not members, and also that those who take the trouble to respond to surveys about ghostwriting are more likely to take an interest in ethical practices and comply with guidelines. For those reasons, we believe it is likely that our results underestimate the prevalence of ghostwriting.

Nonetheless, although our estimate of the prevalence of medical writing may be inaccurate, we believe some conclusions can be drawn from our results with reasonable confidence. One such conclusion is that ghostwriting, while still common among medical writers, is now less common than it was 3 years ago. Another conclusion is that medical writers who are familiar with guidelines on ethical medical writing practices are less likely to have undis-

closed contributions. Consistent with this is the finding that medical writers who are familiar with the guidelines are more likely to request acknowledgement, which is presumably the reason why their contributions are more likely to be acknowledged. Although the cross-sectional nature of our surveys precludes making causal inferences from that association, it seems reasonable to postulate that the publication of guidelines has had at least some effect in helping to reduce the prevalence of ghostwriting.

In conclusion, there is no room for complacency in the fight against ghostwriting, as the prevalence remains unacceptably high among EMWA and AMWA members. Nonetheless, this survey shows, for the first time, that ghostwriting became less common between 2005 and 2008, giving way to disclosure of medical writing assistance. Organisations such as AMWA and EMWA have a duty to continue their educational efforts to help ensure ghostwriting becomes ever closer to extinction. We, together with other medical writers, have recently published a checklist designed to ensure medical writers fulfil their role ethically when contributing to publications [13], and hope that that checklist will assist in those efforts.

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Definitions box

Side effect

There are at least two meanings for this term. To the layman, side effects are serious, unwanted and undesirable actions of drugs or medicines, a usage especially beloved of the media. A better term for these properties of drugs or medicines is 'adverse effects'. However, because no drug can ever be specific (i.e. have only one action), all drugs have properties that lead to effects other than those for which the drug was developed or by which the drug is normally classified. These actions of the drug may be undesirable or useful—there are many drugs, for example, that are particularly useful because they have more than one pharmacological action. Side effects should not be confused with adverse events, which are events reported during a clinical study, whether or not they can be attributed to the preparation or preparations under evaluation in the study.

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