Mythbusting Medical Writing: Goodbye Ghosts, Hello Help

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Abstract

To meet ethical and scientific obligations, authors should submit timely, high-quality manuscripts. Authors, however, can encounter ethical (eg, authorship designation) and practical (eg, time and resource limitations) challenges during manuscript preparation. Could professional medical writers—not ghostwriters—help authors address these challenges? This essay summarizes evidence countering three myths that may have hindered authors from considering the use of professional medical writers. Authors with sufficient time, writing expertise, and reporting guideline knowledge may meet their obligations without writing assistance. Unfortunately, not all authors are in this position. Decisions about writing support should be based on evidence, not myths.

Introduction

All authors should be aware of their ethical and scientific obligations to share the results from their research. The Declaration of Helsinki (World Medical Association, 2013) highlights principles that authors should follow when preparing manuscripts.

Researchers, authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication (World Medical Association, 2013, clause 36).

Manuscript preparation, however, can be a daunting challenge—not only for first-time authors but also for experienced authors. Regardless of the level of experience, authors often lack the time needed to adequately research the literature, prepare a first draft, and make the many revisions required to produce a submission-worthy manuscript. To make matters worse, many authors are not aware of reporting guidelines and other author resources. Similarly, many authors are not familiar with authorship criteria. Even when familiar with the criteria, authors may disagree with the criteria or become confused because the criteria are not necessarily intuitive and have evolved over time.

While there is no simple way to overcome all of the barriers to publishing, professional medical writers can help authors meet their obligations to prepare manuscripts. Misinformation, however, has impeded the dialogue about the use of appropriate medical writing support for decades. In fact, it has been 20 years since the editors of the *Journal of the American Medical*

Association (JAMA) published a provocative editorial about authorship issues (Rennie and Flanagin, 1994). Despite clarification of authorship criteria, confusion continues to muddle the pages of medical literature, especially about individuals who make substantial contributions but do not fulfill authorship criteria. Over time, this misinformation has eroded perceptions about the role of professional medical writers in the medical community—constraining potentially beneficial collaboration among authors, professional medical writers, and other parties responsible for disseminating research findings.

"There are ghosts as well as guests lurking in the bylines.... Who can object to deposing the guests, substantiating the ghosts, and excommunicating the grafters?" —Rennie and Flanigan (1994, 470)

The need to address this misinformation inspired the formation of the Global Alliance of Publication Professionals (GAPP) in 2012, which has prepared approximately 25 articles, letters to the editor, editorials, and other publications (www.gappteam.org). In this essay, we counter three common myths about the role of professional medical writers (Table 1). After reviewing the evidence, we summarize recommendations for aspiring authors who want to produce timely, well-written, ethical manuscripts that are ready for submission to a medical journal.

Myth #1: Medical writers are ghostwriters.

Myth: "Authors need to actually write every word of their papers."

— Ghaemi (2003, 229-30)

Confusion about authorship requirements is at least partly attributable to the plethora of definitions and variations in authorship criteria used by different journals and publishers. A comprehensive review of authorship models is beyond the scope of this essay, but a brief historical overview provides relevant insight. The International Committee of Medical Journal Editors (ICMJE) began to define authorship in the late 1970s. Although the ICMJE increased the number of criteria over time and made them more specific, strict interpretation can inadvertently permit some of the unethical behavior that the criteria were designed to prevent (Moffatt, 2013; Matheson, 2011). To better promote transparency, journal editors proposed a contributorship model in the late 1990s; advantages of the contributorship model were recently reviewed in this journal (Borenstein and Shamoo, 2015). Nevertheless, the ICMJE criteria continue to be frequently used in medical publication—having been adopted by more than 600 medical journals. In a discussion of the limitations of the ICMJE criteria and benefits of the contributorship model, Moffatt (2013, 59) noted, "the ICMJE criterion is the leading contender for a universal standard of authorship in the biosciences." Therefore, this essay focuses on the ICMJE criteria with considerations for improving transparency.

The ICMJE definition of authorship differs from that in the humanities. Unlike traditional definitions in which the writer and the author are synonymous, authors of medical publications must fulfill each of four distinct criteria (Table 2).

Medical writers fulfill the first part of the second criterion, "drafting the work..."; however, they usually do not fulfill the remaining three criteria. The first criterion, "substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work," is consistent with the ICMJE's aim to ensure that contributors making substantive intellectual contributions are given credit as authors. Writers are

generally not involved early enough in the research project (eg, at the concept, design, dataacquisition stage) and may not have sufficient statistical or clinical expertise to interpret the data. The third criterion, "final approval of the version to be published," was included in the first ICMJE authorship guidelines in 1979. Writers may prepare the final version of the manuscript but may not be asked to approve it. The fourth criterion, "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," was recently added to reinforce the responsibilities that come with authorship. Writers may be responsible for documenting author input (eg, for compliance and audit purposes), checking the accuracy of the data against source documents, and helping authors respond to editor queries in a timely, transparent, and robust manner; however, writers are rarely able to take full accountability for all aspects of the work, particularly the conduct of the research and data collection. Authors are also responsible for ensuring that all individuals fulfilling all four criteria are named as authors (International Committee of Medical Journal Editors, 2014). In an effort to improve integrity and transparency, other guidelines, including corporate policies, have begun to specify that authors should be accountable for the work and that authors, not pharmaceutical sponsors, should independently approve the final draft (Dowsett et al., 2010; Camby et al., 2014; Battisti et al., 2015).

If an individual makes a substantial contribution but does *not* satisfy all four criteria, that individual should be acknowledged along with disclosure of any potential conflicts-of-interest. The addition of this disclosure is noteworthy because of the implications for improving transparency. The ICMJE (2014) specifically identifies writing assistance, if performed without fulfilling other requirements, as an example of an activity that does not justify authorship. If this activity is substantial, then the individual should be acknowledged. Like authorship criteria, the

definition of substantial is another source of confusion that has been debated in the medical literature. Flanagin (2007) hypothesized that the choice of this adjective might have been intentional to allow for wider application. In a respected guide for authors, she defined substantial contribution as "an important intellectual contribution, without which the work, or an important part of the work, could not have been completed or the manuscript could not have been written and submitted for publication contribution" (Flanagin, 2007, 128). In addition, all individuals acknowledged should grant permission, in writing, for that acknowledgement prior to manuscript submission. This eliminates any question about whether all participants support the study interpretations and conclusions.

Certain terms have been coined to denote violations of these authorship principles.

Rennie and Flanagin (1994) were among the first to define ghostwriting, ghost authorship, and honorary or guest authorship. Unacknowledged writers who make substantial contributions (falling short of authorship) are ghostwriters. Individuals who satisfy authorship criteria but are not credited as authors are ghost authors; examples might include statisticians (Gøtzsche et al., 2007) and writers. Authors who do not satisfy authorship criteria but appear in the author byline are honorary or guest authors; examples include department heads and opinion leaders whose names are added to a manuscript in a misguided attempted to increase the likelihood of publication (Rennie and Flanagin, 1994). Inappropriate authorship practices can involve collusion, and egregious, high-profile examples of ghost authors working with ghostwriters have been documented (Ross et al., 2008; McHenry and Jureidini, 2008; Steinman et al., 2006; Singer, 2009). Regardless of how authorship is defined, such practices are clearly unacceptable.

Myth #2: Ghostwriting is common.

Myth: "Studies and commentaries suggest 11-50% of studies are ghost-written."

—Langdon-Neuner (2008)*

Much of the data used to paint a narrative of rampant ghostwriting relies on case studies, quotes taken out of context, or misinterpreted definitions of authorship. Stretton (2014) systematically reviewed cross-sectional surveys and descriptive analyses to unveil the prevalence of ghostwriting in the medical literature. Of 848 publications screened for eligibility, only 16 reported original, quantitative estimates and were considered to be primary publications; 32 cited other evidence and were considered to be secondary publications. Beginning with these secondary publications, Stretton traced a 2004 quote by a prominent psychiatrist who estimated that 57% (55/96) of articles about a new antidepressant, published from 1998 to 2000, were coordinated through a medical information company, but only two of these articles acknowledged medical writing assistance. Generalizing from his experience with one antidepressant and ignoring the problem of having obtained his numerator and denominator data from different sources, the psychiatrist testified to a government hearing that 50% of articles about drug therapeutics published in leading medical journals were ghostwritten (Select Committee on Health; UK Parliament, 2004). After scouring the literature, Stretton (2014) found that only two of nine subsequent secondary publications correctly interpreted his quote, illustrating this domino effect on perceptions about medical writing.

Turning to the primary literature, Stretton identified a series of well-designed surveys (Flanagin et al., 1998; Wislar et al., 2011) that offer evidence-based insight about authorship

^{*} Question for editors: How should this quotation be designated when the page numbers are not indicated in the monograph? The quotation is the second sentence under "Examples of ghost-writing in the literature."

practices over time (Figure 1). The survey was sent to corresponding authors who had published in six prestigious, peer-reviewed journals that followed ICMJE guidelines—first in 1996 (n = 1179) and again in 2008 (n = 896). The prevalence of honorary authorship was 19.3% in 1996 and 17.6% in 2008, a nonsignificant change. The prevalence of ghost authorship decreased from 11.5% to 7.9% (*P* = .023). The corresponding prevalences of ghostwriting were 1.4% and 0.16% (*P* value not stated); only one unnamed individual participated in writing an article in the second survey (Flanagin et al., 1998; Wislar et al., 2011). Another well-designed survey (Mowatt et al., 2002) investigated authorship practices in reviews published by the Cochrane Library in 1999 (n = 577). The prevalence of honorary authorship was 39%; this high rate of honorary authorship was largely attributable to authors who did not draft or revise (24%) or did not approve the final submission (27%). This survey did not distinguish between ghost authorship and ghostwriting; the combined prevalence was 9% (Mowatt et al., 2002).

The American and European Medical Writers Associations (AMWA and EMWA) conducted identical surveys in 2005, 2008, and 2011 to determine the prevalence of ghostwriting in manuscripts to which its members had made substantial contributions (Hamilton and Jacobs, 2011). Each survey had approximately 700 to 1500 respondents and represented 12% to 28% of members (and excluded those who did not contribute to manuscripts). The percentage of ghostwritten manuscripts decreased with each successive survey, for an overall decrease of 47% over time. These changes coincided with efforts to increase awareness of evolving authorship guidelines among AMWA and EMWA members, including specification of the need to disclose contributions made by medical writers around the time of the first survey. Awareness of ICMJE guidelines was a predictor of transparency in a multivariate regression analysis. The mean, weighted percentage of ghostwritten manuscripts, however, remained unacceptably high at

33.0% (95% confidence interval [CI], 29.7–36.3) in 2011 (Hamilton and Jacobs, 2011). This finding should not be equated with the overall prevalence of ghostwriting in published articles because the surveys were limited to manuscripts to which AMWA and EMWA members had made substantial contributions. While the proportion of that subset to the overall prevalence is unknown, it is possible to make an estimate based on the finding that only 6% of publications in 1000 high-ranking journals declared medical writing assistance (Woolley et al., 2006). Assuming that 67% (100% – 33%) of medical writers' contributions are declared and that the ratio of declared to undeclared contributions is 2:1, findings from the AMWA-EMWA survey (Hamilton and Jacobs, 2011) suggest that the overall prevalence of ghostwriting is approximately 3%. This estimate is closer to that reported in previous surveys (Flanagin et al., 1998; Wislar et al., 2011), although this figure should be treated with caution as it combines data from different sources. Of course, survey participants may have underreported the incidence of ghostwriting and other unethical practices; however, this type of bias should have been relatively consistent in serial surveys and should not affect trends seen over time. Despite the inherent limitation of surveybased research, we believe that evidence from surveys is more compelling than that from case studies lacking the perspective (i.e., denominator) needed to estimate the frequency of ghostwriting.

Collectively, these evidence-based findings indicate that the prevalence of ghostwriting in the peer-reviewed literature is low and decreasing (Stretton, 2014).

Myth #3: Researchers should not need medical writing support.

Myth: "Most of us are capable of stringing a few sentences together without help from an industry funded assistant." —Yates (2012, last paragraph)

Preparing a manuscript is not as easy as some may think. Indeed, the failure to publish findings is a well-documented, persistent problem in medical research. In a cross-sectional analysis, only 46% of clinical trials funded by the US National Institutes of Health (NIH) were published in peer-reviewed journals within 30 months after trial completion. When the duration of follow-up was extended to a median of 51 months, 32% remained unpublished (Ross et al., 2012). Similarly high failure rates have been reported for research supported by other funding agencies (Scherer et al., 2015). Authors have identified lack of time as the most common and most important reason for failing to publish research presented at medical conferences (Scherer et al., 2015). Even when research findings are reported, they are often delayed for years. The median time to publication of the NIH-funded trials was 23 months (range, 14 to 36 months) after trial completion (Ross et al., 2012).

Another frequent problem is failure to adhere to reporting guidelines, which has been documented in a variety of therapeutic categories (Adie et al., 2013; Augestad et al., 2012; Peron et al., 2013; Smith et al., 2012). For example, the mean quality of adverse event reporting on a 16-point scale was only 10.1 in 325 randomized controlled trials designed to evaluate systemic cancer therapy. Sadly, quality did not improve over time and was no better in articles published in journals with high-impact factors (Peron et al., 2013).

Clearly, authors could benefit from being given more time and training on how to write. Proponents of good publication practices have recognized that "authors have insufficient training in the range of issues related to reporting of research, such as use of reporting guidelines, publication ethics, and research integrity" (Glasziou et al, 2014, 274). Another legitimate, complementary, and pragmatic approach for improving compliance with reporting research findings in a timely manner is to provide authors with medical writing assistance (Global

Alliance of Publication Professionals et al., 2012). Evidence from seven observational studies (Jacobs, 2010; Gattrell et al., 2015; Bailey, 2011; Woolley et al., 2005; Breugelmans and Barron, 2008; Manring et al., 2014; Woolley et al., 2011) and five surveys (Marušić et al., 2014; Wager et al., 2014; Camby et al., 2014; Marchington and Burd, 2014; Lang, 1997) indicate that professional medical writers can and do provide valuable services shown to assist authors in their efforts to publish. In the interest of full disclosure, we were involved in many of these studies.

Articles acknowledging professional medical writers were associated with desirable and quantifiable outcomes compared with articles lacking such acknowledgment. For example, articles that disclosed medical writing involvement were associated with better compliance with reporting guidelines (P < .05) (Jacobs, 2010; Gattrell et al., 2015), acceptable written English as rated by peer reviewers (P < .01) (Gattrell et al., 2015), a trend toward a shorter time to manuscript acceptance (Bailey, 2011; Woolley et al., 2005), an increased rate of publication over time (Breugelmans and Barron, 2008; Manring et al., 2014), and a lower risk of publication retraction due to misconduct (Woolley et al., 2011). In contrast, Gattrell and colleagues (2015) reported that medical writing support was associated with longer time to manuscript acceptance (P < .01), which may be attributable to confounding factors. In this study, the articles with medical writing support had more authors, were based on studies with much larger sample sizes, and were more likely to be sponsored by industry. In our experience, the quality control (eg, data verification) and review procedures (eg, legal, medical, intellectual property) required by industry sponsors can be more detailed and lengthy than those from non-industry sponsors. While these observational studies cannot prove cause and effect, the evidence generated does challenge opinions that may be outdated, unfounded, or confused with perceptions of

ghostwriting. Further, the evidence from these studies can be used to generate hypotheses that merit further evaluation.

Evidence is also emerging that professional medical writers are aware of relevant guidelines, which may facilitate their ability to provide services of value to authors and other stakeholders. For example, the Medical Publishing Insights and Practices Initiative (MPIP) recently published survey findings on the familiarity with and reliance on authorship guidelines by different stakeholders (Marušić et al., 2014). This collaborative research project collected qualitative data through an online survey regarding confidence in authorship decisions, frequency of case situations, and other opinions on authorship issues. Target enrollment was at least 96 participants from each of four stakeholder groups; the final tally was 498 participants with good distribution among groups. Medical writers (88%), publication professionals (97%), and journal editors (89%) had similarly high awareness of ICMJE authorship criteria. In contrast, only 49% of clinical investigators were familiar with these authorship guidelines. Similarly, medical writers (51%), publication professionals (70%), and journal editors (59%) were more likely to rely on these guidelines than clinical investigators (28%) (Marušić et al., 2014).

Similar to MPIP, the Global Publication Survey aimed to gather information about current practices and implementation of publication guidelines among different stakeholders (Wager et al., 2014). Of 469 participants, 238 (51%) worked for medical communication agencies and 144 (30%) worked for pharmaceutical or device companies. Notably, 93% of both agency and industry participants routinely referred to ICMJE for guidance on ethical practice. Moreover, the survey provided evidence that participants enforced guidelines. For example, 99% of agency and 96% of industry participants reported having departmental policies to ensure acknowledgment of medical writing support (Wager et al., 2014).

Survey findings also indicate that authors value the assistance provided by professional medical writers. In a survey sent to clinical investigators and researchers, 88% of respondents (364/415) agreed that professional medical writers added value to publication development, including compliance with relevant guidelines and awareness of target journal requirements, sequence of action items, timelines, and submission and post-submission status (Camby et al., 2014). In another survey sent to academic authors and clinicians who had worked with a medical communications company, 84% of respondents (63/75) valued medical writing assistance. The services most valued were editing and journal styling, conformity with reporting guidelines, and assistance with manuscript submission (Marchington and Burd, 2014). In an older survey (Lang, 1997), authors who used a hospital-based editing service agreed that editorial comments were helpful, appropriate, and timely. These participants valued substantive editing (18%), copyediting (17%), queries (16%), adherence to scientific reporting requirements (10%), and publication advice (10%) (Lang, 1997).

Recommendations

"The problem of poor research documentation ... is long-standing, worldwide, pervasive potentially serious, and not at all apparent to many readers." —Lang and Secic (2006, ix)

Failure to publish has many negative repercussions—not only for authors but also for others. Scientists and clinicians rely on timely publication to make informed decisions about the need for future research and the choice of treatment for patients. Meta-analyses and clinical guidelines are only as valuable as the availability of published literature. Funding, investigation, and analysis are wasted unless research findings are thoroughly and accurately reported—

including both positive and negative findings. Nondisclosure erodes public trust by clinical trial participants and, in the case of publicly funded trials, taxpayers. Authors rely on publications for professional advancement. Consequently, the entire community suffers when research findings are not published.

In view of these implications, we recommend that aspiring authors consider collaborating with professional medical writers to produce submission-ready manuscripts (Figure 2). Survey findings suggest that many types of authors are likely to benefit from such assistance. For example, authors who are unfamiliar with resources may wish to partner with professional medical writers who advocate compliance with ethical guidelines and best-reporting practices. Busy authors and those who do not enjoy writing can delegate time-intensive tasks such as expanding a pre-approved outline to text that is clear, concise, credible, accurate, and grammatically correct; preparing figures and tables; tracking and incorporating author changes; formatting the manuscript to journal standards (eg, word count, formatting references); and finalizing the documents for on-line submission (Woolley, 2006). Authors whose first language is not English are likely to benefit from working with professional medical writers who have English-language expertise.

For authors choosing to work with professional medical writers, we recommend planning ahead to ensure the availability of and financial support for medical writing assistance (Global Alliance of Publication Professionals et al., 2012). Ideally, medical writing assistance should be included in the budget at the time of grant preparation. In a perfect world, grant application forms would include a line item reminding researchers to request funding for medical writing services similar to the way that funding is requested for laboratory technicians who help generate the data and for statisticians who help analyze the data. Some academic institutions, journals, and

publishers offer medical writing and editing assistance. For example, Taylor & Francis offers English-language editing, translation, and manuscript formatting or figure preparation. Authors at institutions not offering such support can encourage administration to consider the cost of failure to publish, the relative salaries of faculty compared with medical writers, and publications from institutions that have reported the benefits of in-house medical writing assistance (Manring et al., 2014; Breugelmans and Barron, 2008; Lang, 1997). Independent medical writers can be identified though AMWA (www.amwa.org), EMWA (www.amwa.org), International Society of Publication Professionals (www.ismpp.org), and other professional associations. A number of these not-for-profit professional associations have robust certification programs to help authors and editors identify writers who have had to pass an exam on their knowledge of ethical and best-reporting requirements.

Regardless of the source of medical writing assistance, authors should clearly define their needs and requirements. They should refuse to work with writers who do not know or do not commit to follow ethical or best-reporting practices. They should also refuse invitations to place their names on prewritten reviews (i.e., refuse to become guest authors) and to participate in any other project that interferes with their ability to fulfill authorship criteria and other ethical obligations.

For all authors, we recommend relevant resources from authoritative organizations and institutions (Table 3). Along with authorship criteria, ICMJE offers information about other ethical considerations; practical tips for preparing manuscripts, tables, and graphs; and links to relevant documents. These documents provide valuable insight about the history of ICMJE and how the recommendations have changed over time, as well as useful suggestions such as how to determine the order of authorship. Enhancing the Quality and Transparency of Health Research

(EQUATOR, http://www.equator-network.org) provides a comprehensive, user-friendly database of reporting guidelines, such as Consolidated Standards of Reporting Trials (CONSORT), good publication practice (GPP) guidelines for communicating company-sponsored medical research, and MPIP. In addition, EQUATOR provides links to other resources, such as ethical guidelines, books about scientific writing, and author toolkits. Despite the tsunami of information on this website, it is easily searchable.

Many of these resources emphasize the need for a stepwise process to minimize confusion and streamline the publishing process. Before writing begins, all involved parties (eg, potential authors, research sponsor) should be identified, agree on the collaborative process and actively participate in it, and become familiar with the journal's instructions for authors. Early in the research project, these parties should agree on how authorship (including the order of authorship) will be determined and on who should be acknowledged. When the manuscript is ready for submission, the lists of authors and acknowledged contributors should be reviewed and adjusted as needed to accommodate any changes that may have occurred during manuscript preparation. For example, most professional medical writers should be acknowledged. If, however, a professional medical writer fulfills all four authorship criteria, then that writer should be identified as an author. To better promote transparency, authors may wish to adopt aspects of the contributorship model by indicating the exact contributions made by each author (Battisti et al., 2015) as shown at the end of this article. The use of a checklist may serve as a helpful reminder of how to comply with best practices and how to avoid ghostwriting and other unethical practices (Gøtzsche et al., 2009).

Conclusions

"Most of us are not born authors.... It is unfortunate that almost all universities, and other centres of higher learning, appear to have abdicated their responsibilities regarding formally teaching [publication science]." —Moher (2014, 215)

Well-intentioned authors encounter many different types of barriers to publishing (see Figure 2). While no single action can overcome all of these barriers, aspiring authors should not allow confusion about authorship criteria or myths about medical writers to preclude the use of professional medical writing support. In contrast with ghostwriters, whose contributions have impugned the good name of others, professional medical writers are aware of ethical guidelines, comply with them, and fully disclose their substantial contributions and any potential conflicts of interest. Professional medical writers can and do provide services that are associated with desirable, quantifiable outcomes and that are valued by authors. As such, professional medical writers are positioned to assist authors who are concerned about the shameful waste that transpires when publication of research findings is delayed or, worse, fails to occur. Of course, not all authors will, or need to, collaborate with professional medical writers. For those desiring assistance, professional medical writers can help authors identify relevant resources and help authors meet their ethical and scientific obligations to prepare timely and high-quality manuscripts.

Disclosures: All authors except SW declare that: 1) all authors have provided or do provide ethical medical writing services to academic, biotechnology, or pharmaceutical clients,

2) KW's husband is also an employee of Proscribe – Envision Pharma Group and AG's wife

works for Johnson & Johnson; all other authors' spouses, partners, or children have no financial

relationships that may be relevant to the submitted work; and 3) all authors are active in national

and international not-for-profit associations that encourage ethical medical writing practices. SW

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References

- Adie, S., Harris, I. A., Naylor, J. M., and Mittal, R. (2013). CONSORT compliance in surgical randomized trials: are we there yet? A systematic review. *Annals of Surgery* 258 (6):872-878. doi: 10.1097/SLA.0b013e31829664b9.
- Augestad, K. M., Berntsen, G., Lassen, K., Bellika, J. G., Wootton, R., Lindsetmo, R. O., Study Group of Research Quality in Medical, Informatics, and Decision, Support. (2012). Standards for reporting randomized controlled trials in medical informatics: a systematic review of CONSORT adherence in RCTs on clinical decision support. *Journal of the American Medical Informatics Association* 19 (1):13-21. doi: 10.1136/amiajnl-2011-000411.
- Bailey, M. (2011). Science editing and its effect on manuscript acceptance time. *American Medical Writers Association Journal* 26 (4):147-152.
- Battisti, W. P., Wager, E., Baltzer, L., Bridges, D., Cairns, A., Carswell, C. I., Citrome, L., Gurr, J. A., Mooney, L. A., Moore, B. J., Pena, T., Sanes-Miller, C. H., Veitch, K., Woolley, K. L., and Yarker, Y. E. (2015). Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Annals of Internal Medicine*: epub ahead of print. doi: 10.7326/M15-0288.
- Borenstein, J., and Shamoo, A. E. (2015). Rethinking authorship in the era of collaborative research.

 *Accountability in Research 22 (5):267-283. doi: 10.1080/08989621.2014.968277.
- Breugelmans, R., and Barron, J. P. (2008). The role of in-house medical communications centers in medical institutions in nonnative English-speaking countries. *Chest* 134 (4):883-885. doi: 10.1378/chest.08-1068.
- Camby, I., Delpire, V., Rouxhet, L., Morel, T., Vanderlinden, C., Van Driessche, N., and Poplazarova, T. (2014). Publication practices and standards: recommendations from GSK Vaccines' author survey. *Trials* 15:446. doi: 10.1186/1745-6215-15-446.
- Chipperfield, L., Citrome, L., Clark, J., David, F. S., Enck, R., Evangelista, M., Gonzalez, J., Groves, T., Magrann, J., Mansi, B., Miller, C., Mooney, L. A., Murphy, A., Shelton, J., Walson, P. D., and

- Weigel, A. (2010). Authors' Submission Toolkit: a practical guide to getting your research published. *Current Medical Research and Opinion* 26 (8):1967-1982. doi: 10.1185/03007995.2010.499344.
- Dowsett, S. A., Van Campen, L. E., and Bednar, L. A. (2010). Developing good scientific publishing practices: one pharmaceutical company's perspective. *Current Medical Research and Opinion* 26 (6):1249-1254. doi: 10.1185/03007991003748880.
- Flanagin, A. 2007. Ethical and legal considerations. In *AMA Manual of Style. A Guide for Authors and Editors*, edited by C. Iverson, S. Christiansen, A. Flanagin, P. B. Fontanarosa, R. M. Glass, B. Gregoline, S. J. Lurie, H. S. Meyer, M. A. Winker and R. K. Young, 125-300. New York: Oxford.
- Flanagin, A., Carey, L. A., Fontanarosa, P. B., Phillips, S. G., Pace, B. P., Lundberg, G. D., and Rennie,
 D. (1998). Prevalence of articles with honorary authors and ghost authors in peer-reviewed
 medical journals. *Journal of the American Medical Association* 280 (3):222-224.
- Gattrell, W., Hopewell, S., Young, K., Lang, S., Farrow, P., White, R., Wager, E., and Winchester, C. 2015. Professional medical writing support improves the quality but not the speed of reporting randomized controlled trials (poster 10). European Meeting of the International Society for Medical Publication Professionals, London, Jan 20-21.
- Ghaemi, S. N. (2013). Postmodern medicine: an analysis of the pharmaceutical industry and its critics.

 *Perspectives in Biology and Medicine 56 (2):223-235. doi: 10.1353/pbm.2013.0018.
- Glasziou, P., Altman, D. G., Bossuyt, P., Boutron, I., Clarke, M., Julious, S., Michie, S., Moher, D., and Wager, E. (2014). Reducing waste from incomplete or unusable reports of biomedical research.

 *Lancet 383 (9913):267-276. doi: 10.1016/S0140-6736(13)62228-X.
- Global Alliance of Publication Professionals, Woolley, K. L., Gertel, A., Hamilton, C., Jacobs, A., and Snyder, G. (2012). Poor compliance with reporting research results we know it's a problem ... how do we fix it? *Current Medical Research and Opinion* 28 (11):1857-1860. doi: 10.1185/03007995.2012.739152.

- Gøtzsche, P. C., Hrobjartsson, A., Johansen, H. K., Haahr, M. T., Altman, D., and Chan, A. (2007). Ghost authorship in industry-initiated randomised trials. *Public Library of Science and Medicine* 4 (1):0047-0051.
- Gøtzsche, P. C., Kassirer, J. P., Woolley, K. L., Wager, E., Jacobs, A., Gertel, A., and Hamilton, C. (2009). What should be done to tackle ghostwriting in the medical literature? *Public Library of Science and Medicine* 6 (2):e23.
- Hamilton, C. W., and Jacobs, A. (2011). Evidence of decreased ghostwriting in a series of three surveys of medical communicators conducted between 2005 and 2011 (abstract). *American Medical Writers Association Journal* 27 (3):115.
- International Committee of Medical Journal Editors. (2014). Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Available at http://www.icmje.org/index.html. Last accessed Feb 23, 2015.
- Jacobs, A. (2010). Adherence to the CONSORT guideline in papers written by professional medical writers. *Write Stuff* 19 (3):196-200.
- Lang, T. A. (1997). Assessing the productivity and value of a hospital-based editing service. *American Medical Writers Association Journal* 12 (1):6-14.
- Lang, T. A., and Secic, M. 2006. *How to Report Statistics in Medicine. Annotated Guidelines for Authors, Editors, and Reviewers*. 2nd ed. Philadelphia, PA: American College of Physicians.
- Langdon-Neuner, E. (2008). Medical ghost-writing. *Mens Sana Monographs* 6 (1):257-273. doi: 10.4103/0973-1229.33006.
- Manring, M. M., Panzo, J. A., and Mayerson, J. L. (2014). A framework for improving resident research participation and scholarly output. *Journal of Surgical Education* 71 (1):8-13. doi: 10.1016/j.jsurg.2013.07.011.
- Mansi, B. A., Clark, J., David, F. S., Gesell, T. M., Glasser, S., Gonzalez, J., Haller, D. G., Laine, C., Miller, C. L., Mooney, L. A., and Zecevic, M. (2012). Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and

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- pharmaceutical industry perspective. *Mayo Clinic Proceedings* 87 (5):424-429. doi: 10.1016/j.mayocp.2012.02.009.
- Marchington, J. M., and Burd, G. P. (2014). Author attitudes to professional medical writing support.

 *Current Medical Research and Opinion 30 (10):2103-2108. doi: 10.1185/03007995.2014.939618.
- Marušić, A., Hren, D., Mansi, B., Lineberry, N., Bhattacharya, A., Garrity, M., Clark, J., Gesell, T., Glasser, S., Gonzalez, J., Hustad, C., Lannon, M.-M., Mooney, L. A., and Pena, T. (2014). Five-step authorship framework to improve transparency in disclosing contributors to industry-sponsored clinical trial publications. *BioMed Central Medicine* 12:197-206.
- Matheson, A. (2011). How industry uses the ICMJE guidelines to manipulate authorship--and how they should be revised. *Public Library of Science Medicine* 8 (8):e1001072. doi: 10.1371/journal.pmed.1001072.
- McHenry, L. B., and Jureidini, J. N. (2008). Industry-sponsored ghostwriting in clinical trial reporting: a case study. *Accountability in Research* 15 (3):152-167. doi: 10.1080/08989620802194384.
- Moffatt, B. (2013). Orphan papers and ghostwriting: the case against the ICMJE criterion of authorship. 20 (2):59-71. doi: 10.1080/08989621.2013.767115.
- Moher, D. (2014). Along with the privilege of authorship comes important responsibilities. *BioMed Central Medicine* 12:214.
- Mowatt, G., Shirran, L., Grimshaw, J. M., Rennie, D., Flanagin, A., Yank, V., MacLennan, G., Gotzsche,
 P. C., and Bero, L. A. (2002). Prevalence of honorary and ghost authorship in Cochrane reviews.
 Journal of the American Medical Association 287 (21):2769-2771.
- Peron, J., Maillet, D., Gan, H. K., Chen, E. X., and You, B. (2013). Adherence to CONSORT adverse event reporting guidelines in randomized clinical trials evaluating systemic cancer therapy: a systematic review. *Journal of Clinical Oncology* 31 (31):3957-3963. doi: 10.1200/JCO.2013.49.3981.

- Rennie, D., and Flanagin, A. (1994). Authorship! Authorship! Guests, ghosts, grafters, and the two-sided coin. *Journal of the American Medical Association* 271 (6):469-471.
- Ross, J. S., Hill, K. P., Egilman, D. S., and Krumholz, H. M. (2008). Guest authorship and ghostwriting in publications related to rofecoxib: a case study of industry documents from rofecoxib litigation. *Journal of the American Medical Association* 299 (15):1800-1812.
- Ross, J. S., Tse, T., Zarin, D. A., Xu, H., Zhou, L., and Krumholz, H. M. (2012). Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis. *British Medical Journal* 344:d7292. doi: 10.1136/bmj.d7292.
- Scherer, R. W., Ugarte-Gil, C., Schmucker, C., and Meerpohl, J. J. (2015). Authors report lack of time as main reason for unpublished research presented at biomedical conferences: a systematic review.

 **Journal of Clinical Epidemiology 68 (7):803-810. doi: 10.1016/j.jclinepi.2015.01.027.
- Select Committee on Health; UK Parliament. (2004). Examination of witnesses (questions 180-199).

 Available at

 http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/4101414.htm. Last accessed December 18, 2014.
- Singer, N. (2009). "Medical papers by ghostwriters pushed therapy." The New York Times, August 5.
- Smith, S. M., Chang, R. D., Pereira, A., Shah, N., Gilron, I., Katz, N. P., Lin, A. H., McDermott, M. P., Rappaport, B. A., Rowbotham, M. C., Sampaio, C., Turk, D. C., and Dworkin, R. H. (2012).
 Adherence to CONSORT harms-reporting recommendations in publications of recent analgesic clinical trials: an ACTTION systematic review. *Pain* 153 (12):2415-2421. doi: 10.1016/j.pain.2012.08.009.
- Steinman, M. A., Bero, L. A., Chren, M. M., and Landefeld, C. S. (2006). Narrative review: the promotion of gabapentin: an analysis of internal industry documents. *Annals of Internal Medicine* 145 (4):284-293.

- Stretton, S. (2014). Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature. *British Medical Journal Open* 4 (7):e004777. doi: 10.1136/bmjopen-2013-004777.
- Wager, E., Woolley, K., Adshead, V., Cairns, A., Fullam, J., Gonzalez, J., Grant, T., and Tortell, S. (2014). Awareness and enforcement of guidelines for publishing industry-sponsored medical research among publication professionals: the Global Publication Survey. *British Medical Journal Open* 4 (4):e004780. doi: 10.1136/bmjopen-2013-004780.
- Wislar, J. S., Flanagin, A., Fontanarosa, P. B., and Deangelis, C. D. (2011). Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey. *British Medical Journal* 343:d6128. See also Web extra table 6125 and correction BMJ 2011;6343:d7677.
- Woolley, K., Ely, J., Woolley, M., Lynch, F., McDonald, J., Findlay, L., and Choi, Y. 2005. Declaration of medical writing assistance in international, peer-reviewed publications and effect of pharmaceutical sponsorship (abstract). Fifth International Congress on Peer Review and Biomedical Publication, Chicago, Sept 16-18.
- Woolley, K. L. (2006). Goodbye Ghostwriters! How to work ethically and efficiently with professional medical writers. *Chest* 130 (3):921-923.
- Woolley, K. L., Ely, J. A., Woolley, M. J., Findlay, L., Lynch, F. A., Choi, Y., and McDonald, J. M. (2006). Declaration of medical writing assistance in international peer-reviewed publications.

 *Journal of the American Medical Association 296 (8):932-934.
- Woolley, K. L., Lew, R. A., Stretton, S., Ely, J. A., Bramich, N. J., Keys, J. R., Monk, J. A., and Woolley,
 M. J. (2011). Lack of involvement of medical writers and the pharmaceutical industry in publications retracted for misconduct: a systematic, controlled, retrospective study. *Current Research and Medical Opinion* 27 (6):1175-1182. doi: 10.1185/03007995.2011.573546.
- World Medical Association. (2013). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Journal of the American Medical Association* 310 (20):2191-2194. doi: 10.1001/jama.2013.281053.

Yates, T. (2012). Response to "a defense of professional medical writers". Forbes Available at http://www.forbes.com/sites/larryhusten/2012/02/14/a-defense-of-professional-medical-writers/. Last accessed October 23, 2014.

Table 1. Common myths about professional medical writers

Myth	Truth
1. Medical writers are	Unlike ghostwriters, professional medical writers disclose
ghostwriters.	their substantial contributions and potential conflict of
	interest. They are familiar with reporting guidelines and
	other best practices, and can help busy authors ethically
	and efficiently achieve publishing goals.
2. Ghostwriting is common.	Evidence-based findings indicate that the prevalence of
	ghostwriting is low and decreasing.
3. Researchers should not need	Failure to publish is a widespread problem that is often
writing support.	attributable to lack of time. Survey findings confirm that
	busy authors value medical writing assistance.

Table 2. Definitions (International Committee of Medical Journal Editors 2013; Rennie and Flanagin 1994)

Authors: "The ICMJE recommends that authorship be based on the following 4 criteria:

- "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."
- Ghostwriters: writers whose substantial contributes to manuscripts are not disclosed in an acknowledgment
- **\$\forall\$** Ghost authors: contributors who meet authorship criteria but are not identified as authors
- Honorary or guest authors: individuals identified as authors who do not meet authorship criteria

ICMJE, International Committee of Medical Journal Editors.

Table 3. Author resources

Resource (URL or reference)	Description
Organizations and Institutions	
International Committee of Medical	Recommendations for conducting, reporting, editing, and
Journal Editors (ICMJE)	publishing scholarly work (eg, authorship criteria,
(http://icmje.org)	publishing and editorial issues, and practical tips on
	manuscript preparation and submission)
Equator Network (www.equator-	Comprehensive list of reporting guidelines (eg,
network.org)	Consolidated Standards of Reporting Trials [CONSORT])
	intended to enhance the quality and transparency of health
	research
Guidelines	
Good publication practice (GPP3) for	Recommendations to help maintain ethical practices and
communicating company-sponsored	comply with current requirements when individuals
medical research (Battisti et al., 2015)	contribute to the communication of company-sponsored
	medical research
Medical Publishing Insights and Practices	Compilation of best practices for manuscript preparation and
Initiative (MPIP; www.mpip-	submission, with emphasis on industry-sponsored trials,
initiative.org) (Chipperfield et al., 2010;	developed through a collaboration of MPIP co-sponsors
Mansi et al., 2012; Marušić et al., 2014)	and journal editors

Figure 1. Prevalence of unacceptable authorship practices in articles published in peer-reviewed medical journals (Flanagin et al., 1998; Wislar et al., 2011)

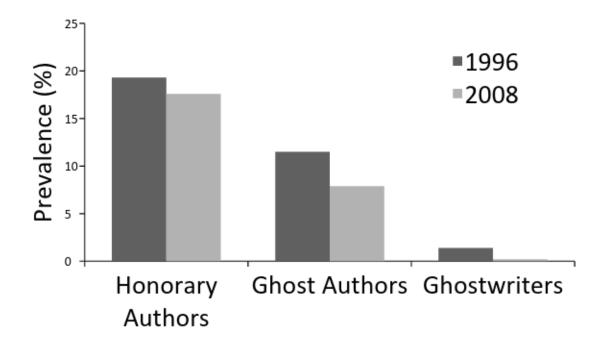


Figure 2. Algorithm for aspiring authors

