Arch. Immunol. Ther. Exp. (2010) 58:255–261
DOI 10.1007/s00005-010-0080-3

VARIA – ETHICS IN SCIENCE

Don't Get Spooked! How to Collaborate with a Professional Medical Communicator (And Avoid Ghostwriting)

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Received: 22 April 2010 / Accepted: 4 May 2010 / Published online: 28 May 2010

Abstract Substantial confusion exists about the role of medical writers and editors (hereafter, medical communicators) in medical publication. Much of the confusion is due to the failure to recognize the difference between terms. Ghostwriting is unethical, whereas professional medical communication refers to legitimate writing and editing services provided by individuals who comply with ethical guidelines. The purpose of this article is to shed light on this subject by reviewing relevant guidelines and by providing practical tips for authors interested in collaborating with medical communicators. Specifically, this article addresses a series of questions, such as what to expect from medical communicators, how to evaluate them, and how to collaborate ethically and efficiently with them. To ensure that the process is ethical, authors should begin collaborating with the medical communicator early in the process, continue doing so throughout manuscript development, and control manuscript content. In addition, authors should disclose substantial contributions and funding sources of the medical communicator and all other individuals not meeting authorship criteria. To ensure that the process is efficient, authors should delegate time-consuming technical writing and editing tasks to the medical communicator.

Keywords Interprofessional relations · Medical education · Professional ethics · Writing standards

Abbreviations

AMWA	American Medical Writers Association
BELS	The Board of Editors in the Life Sciences
CONSORT	*Con*solidated *S*tandards *o*f *R*eporting *T*rials
COPE	Committee on Publication Ethics
CSE	Council of Science Editors
EMWA	European Medical Writers Association
EQUATOR	*E*nhancing the *Qua*lity and *T*ransparency *o*f Health *R*esearch
GPP2	Good Publication Practice (GPP2) for Communicating Company-Sponsored Medical Research
ICMJE	International Committee of Medical Journal Editors
ISMPP	The International Society for Medical Publication Professionals
MOOSE	Meta-analysis of Observational Studies in Epidemiology
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SOP	Standard operating procedure
STARD	*Sta*ndards for the *R*eporting of *D*iagnostic Accuracy Studies
STROBE	*S*trengthening *t*he *R*eporting of *Ob*servational Studies in *E*pidemiology
WAME	World Association of Medical Editors

Introduction

Case Study

Aleksy receives an invitation to collaborate with a medical writer on a manuscript for submission to a prestigious

Based on a lecture delivered at an international conference "Current challenges in medical communication: diagnosing and curing unethical practices" organized by the Polish Academy of Sciences on October 7, 2010 in Warsaw.

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medical journal. He recently completed a clinical research fellowship and was one of the highest enrollers in a double-blind randomized multicenter study designed to evaluate the activity and safety of a new antibiotic. This phase III study was sponsored by a pharmaceutical company. He has presented many research posters, including one on the current study, but has been too busy to complete a manuscript for submission to a medical journal. Should Aleksy be flattered by the invitation or should he decline the opportunity?

Substantial confusion exists about the role of medical writers and editors in medical publication. At one end of the spectrum, ghostwriters have been characterized as shadowy figures hiding in the background (Rennie and Flanagin 1994) who ultimately violate authors' personal integrity and threaten the foundation of science (Gøtzsche et al. 2009). At the other end of the spectrum, professional medical writers have been characterized as being ideal for providing services such as preparing an overview of a meeting, writing the findings of large studies, and helping authors whose first language is not English (Daskalopoulou and Mikhailidis 2005). Much of the confusion is due to the failure to recognize the difference between terms. Specifically, ghostwriting is an unethical practice, whereas professional medical communication refers to legitimate writing and editing services provided by individuals who comply with ethical guidelines.

The purpose of this article is to shed light on this subject by reviewing relevant guidelines and by providing practical tips for authors interested in collaborating ethically and efficiently with medical communicators. This article will address a series of questions, such as what to expect from medical communicators, how to evaluate them, and how to collaborate ethically and efficiently with them.

What Is the Difference Between Ghostwriting and Professional Medical Communication?

Ghostwriting refers to a concealed, substantial writing contribution to a manuscript, often before the authors become involved. Substantial contribution refers to "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 (Flanagin 2007)." Failing to disclose that contribution is unethical. Unlike ghostwriters, professional medical writers and editors (hereafter, medical communicators) collaborate with authors and comply with ethical guidelines by ensuring that their substantial contributions are disclosed along with any financial or other pertinent relationships.

Disclosure of substantial contributions by medical communicators and other contributors is now specified by guidelines from many organizations representing journal editors, medical communicators, and authors (Table 1). For example, the International Committee of Medical Journal Editors (ICMJE) is a group of editors who developed the uniform requirements for manuscripts submitted to biomedical journals to aid authors and editors in their mutual task of "creating and distributing accurate, clear, easily accessible reports of biomedical studies (ICMJE 2008)." Established in 1979, ICMJE meets annually and has compiled a wealth of practical information on the technical aspects of preparing manuscripts for submission to medical journals. In addition, ICMJE has gradually expanded its mission to include ethical principles. One change made within the last decade was to identify individuals who provide writing assistance as examples of those who should be listed in an acknowledgments section. In addition to disclosing the contribution, the authors should disclose the

Table 1 Organizations with guidelines on preparing manuscripts for submission to medical journals

Organization	URL
Journal editors and publishers	
*C*ommittee *o*n *P*ublication *E*thics (COPE)	http://www.publicationethics.org
*C*ouncil of *S*cience *E*ditors (CSE)	http://www.councilscienceeditors.org
*I*nternational *C*ommittee of *M*edical *J*ournal *E*ditors (ICMJE)	http://www.icmje.org
*W*orld *A*ssociation of *M*edical *E*ditors (WAME)	http://www.wame.org
Medical communicators	
*A*merican *M*edical *W*riters *A*ssociation (AMWA)	http://www.amwa.org
*E*uropean *M*edical *W*riters *A*ssociation (EMWA)	http://www.emwa.org
*I*nternational *S*ociety for *M*edical *P*ublication *P*rofessionals (ISMPP)	http://www.ismpp.org
Other stakeholders	
*E*nhancing the *Qua*lity and *T*ransparency *o*f Health *R*esearch (EQUATOR)	http://www.equator-network.org

source of financial support for writing assistance. There is a high level of consensus among organizations about the need for full transparency, including disclosure of both the contribution and associated funding (COPE 1997; Hamilton and Royer 2003; ICMJE 2008; Jacobs and Wager 2005; Norris et al. 2007; Scott-Lichter 2009; WAME 1995).

What Could a Professional Medical Communicator Do for Aleksy?

Professional medical communicators provide many different types of services that could be helpful to Aleksy, especially the time-intensive tasks required to prepare a manuscript suitable for publication. For example, medical communicators can draft text that is clear, concise, credible, and grammatically correct, which is valuable to authors whose first language is not English. Medical communicators can prepare figures and tables, which is beneficial to authors who are not familiar with computer software. They can input references into bibliographic software and style the output for the target journal. Medical communicators can coordinate revisions from multiple authors. They can ensure that the manuscript meets journal requirements, which can be challenging if the journal requires special formatting or limits the number of allowable words. Perhaps most important of all, medical communicators help ensure that manuscripts are prepared ethically by being familiar with available guidelines (Woolley 2006).

The results of a survey of 809 authors who had published in six high-circulation journals provide insight about the perceived value of these services. When the survey was conducted in 1996, 309 (38%) survey respondents were willing to use medical communicators. In this subset, the most common reasons for working with medical communicators were to improve writing (52%), quality (45%), and chance of publication (16%). In addition, 38% of survey respondents were willing to work with medical communicators because writing is too time-consuming. Smaller percentages of respondents did not enjoy writing (9%), did not write well in English (5%), and did not write well (4%). Interestingly, 35% of those unwilling to work with medical communicators felt that such collaboration would be unethical; this is not surprising because this survey preceded expansion of guidelines to provide a mechanism for ethical collaboration through disclosure of medical communicators' contributions and funding. Other common reasons for not working with medical communicators were ability to write better than a medical communicator (65%) and writer's inability to understand or interpret data (60%) (Phillips et al. 2001).

Shouldn't Professional Medical Communicators Be Authors?

Aleksy might wonder whether the services listed in the previous section qualify the medical communicator for authorship. The answer depends on the exact contribution(s), the journal's criteria for authorship, and type of manuscript. According to ICMJE, an author is generally considered to be an individual who has made substantial intellectual contributions to a publication. Specifically, each author should meet all of the following conditions:

1. "substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data";
2. "drafting the article or revising it critically for important intellectual content"; and
3. "final approval of the version to be published (ICMJE 2008)".

Medical communicators who contribute to original research articles usually meet the second and third conditions, but they do not necessarily meet the first condition. In contrast, some medical communicators who contribute to review articles meet all three conditions, especially if they are willing to take public responsibility for relevant portions of the content and if they helped to define the scope of the review by performing an extensive literature search and summarizing the literature (Graf et al. 2009). All individuals who make substantial contributions but do not meet all three conditions of authorship should be acknowledged with their permission and with disclosure of their funding. Written permission is needed because readers may infer endorsement of data and conclusions (ICMJE 2008).

More than 500 journals follow ICMJE's uniform requirements. In addition, some journals require that authors specify their exact contributions. For example, *Arch Immunol Ther Exp* requires that an author's contribution to the paper be indicated on the title page as follows: A, study design; B, data collection; C, statistical analysis; D, data interpretation; E, manuscript preparation; F, literature search; or G, funds collection. This contributorship model helps editors and readers understand how each author met authorship criteria. Even if the journal does not require these details, authors are encouraged to specify their contributions (Graf et al. 2009).

How Should Aleksy Evaluate a Medical Communicator?

In deciding whether to collaborate with a medical communicator, Aleksy should rely on criteria similar to those

used for evaluating other professional consultants and should request a résumé, writing sample(s), and letter(s) of recommendation. He should not expect the résumé to include specific education at the university level because few institutions of higher learning offer a dedicated degree in medical communication. The educational background for medical communicators is approximately evenly divided between liberal arts (e.g. technical communication, English literature and composition) and science; the latter is approximately evenly divided between clinical and basic science. Aleksy may be surprised by the diversity of professional experience among medical communicators. Some are independent freelance writers and work in their homes, whereas others work at pharmaceutical companies or at medical communication companies that offer services to pharmaceutical companies.

Aleksy should carefully review writing samples for evidence of accurate content, good writing technique, and adherence to ethical principles. If the sample is a published article, he should ensure that the medical communicator and associated funding have been disclosed. If the sample reflects a collaborative effort, he may have difficulty discerning exactly which services were provided by the medical communicator. In this situation, a letter of recommendation can provide valuable insight.

The medical communication profession is not yet licensed or regulated, but some organizations offer certification that requires work experience and a passing grade on a written, validated examination. For example, The Board of Editors in the Life Sciences (BELS; http://www.bels.org) offers an examination to evaluate the proficiency of manuscript editors who have at least 2 years of experience and a bachelor's degree or equivalent from an accredited academic institution. The International Society for Medical Publication Professionals (ISMPP; http://www.ismpp.org) offers an examination on best practices in medical publication. After passing these examinations, individuals may add "ELS" or "CMPP", respectively, after their names. Lastly, some organizations offer certificates that require successful completion of relevant educational workshops but do not require examination per se.

Another way to evaluate a medical communicator is to request his or her standard operating procedure (SOP) for manuscript preparation. Large companies often have detailed SOPs, whereas a freelance writer might have a simple SOP (Fig. 1). Regardless of the level of detail, the SOP should identify the stepwise process for ethical and efficient collaboration. To ensure that the authors are responsible for the main messages and data to be conveyed, the SOP should indicate that the authors become involved at the earliest stages of manuscript development and remain involved throughout the process (Woolley 2006).

What Is the Process for Manuscript Preparation?

The process for manuscript preparation should be ethical and efficient, which requires collaboration among authors, contributors not meeting authorship criteria, and the sponsor. The new Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP2) recommends a written publication agreement to describe the roles and responsibilities of the authors, medical communicator and other contributors who do not meet authorship criteria, and sponsor. This agreement should be established at the earliest opportunity, preferably upon finalization of the protocol, and should confirm that the manuscript will conform to recognized standards. In addition, the agreement should confirm that authors and contributors will have access to data, that authors will be free to report or publish study results, and that these results will be reported or published in a timely and responsible manner. The agreement should also include the definition of authorship criteria, the requirement that premature and duplicate publication be avoided, and the process for resolving differences in study interpretation or presentation (Graf et al. 2009).

Authors should not expect the agreement to indicate an honorarium or other reimbursement for being an author of a peer-reviewed article (Graf et al. 2009). On the other hand, reimbursement for travel or other reasonable expenses is acceptable; however, financial details must be disclosed in the appropriate place in the manuscript.

Another early step is to define the process for preparing the manuscript, which usually includes the following: literature search, outline, first draft, multiple reviews and revisions, submission to the journal, responding to reviewers' comments, and reviewing page proofs, with frequent communication by teleconference and email throughout the process. Many sequences are possible. Defining the preferred sequence for a given manuscript, assigning responsibility for each task, and setting deadlines generally require a live meeting or at least a telephone conversation involving all authors, the medical communicator and other contributors who do not meet authorship criteria, and the sponsor. This step helps each stakeholder understand his or her responsibilities and the schedule for performing them.

The medical communicator should refer authors to the instructions for authors for the target journal and other relevant guidelines about ethical and efficient preparation of manuscripts. For example, the *Con*solidated *S*tandards *o*f *R*eporting *T*rials (CONSORT) guidelines should be used in the preparation of manuscripts about randomized controlled trials (Schulz et al. 2010), whereas other guidelines are available for systematic reviews, meta-analyses, and other types of articles (Table 2). Although a complete list

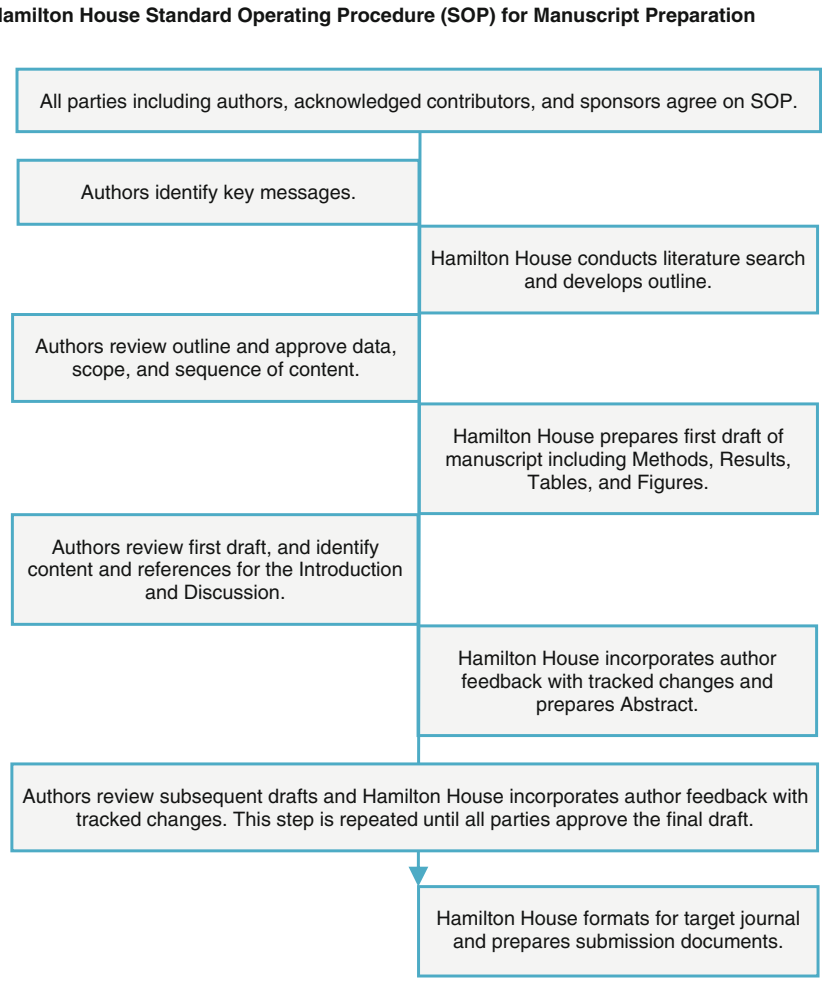

Fig. 1 Example of a simple SOP. © Copyright Hamilton House 2007 (used with permission)

is beyond the scope of this article, a catalogue was recently published (Simera et al. 2010). The EQUATOR Network, an international organization seeking to improve reliability and value of medical research literature by promoting transparent and accurate reporting of research studies, also maintains a comprehensive list (http://www.equator-network.org/resource-centre/authors-of-research-reports/authors-of-research-reports).

To ensure that authors determine content, they must remain engaged throughout manuscript development. As a first step, the authors should determine the main message and outline the overall content. A skilled medical communicator can expand the information into a detailed outline (Woolley 2006). Another way for authors to control content is to recommend articles to be cited in the manuscript. A skilled medical communicator can perform a search to identify additional articles.

After the authors have reviewed the outline, I recommend a two-stage approach to the first draft, especially for original research articles. The Methods, Results, and tables and figures should be prepared first because they determine the content of other sections. The protocol should be used to guide preparation of the Methods section. Potential tables and figures should be prepared early, preferably at the time of the outline and based on author input from the first teleconference. Preparing detailed working tables will facilitate note-taking about potential articles to be cited and help to identify trends that should be addressed in the Discussion of an original research article or in the text of a review (Hamilton 2009). These working tables can be edited later in manuscript development. In this first stage, the medical communicator may include queries about the remaining sections. For example, the medical communicator may ask about articles that should be cited to provide background information, about the rationale for the study design, and the hypothesis, all of which should be included in the Introduction. Answers to these and other queries are used to guide development of the Introduction and Discussion during the second stage.

Multiple revisions are usually required to ensure that each author is satisfied with the manuscript. While reviewing each draft, authors should avoid the temptation to microedit. If the writing contains grammatical errors or is unsatisfactory for any reason, authors should delegate

Table 2 Frequently used guidelines for reporting health research

Guideline	URL
*Con*solidated *S*tandards *o*f *R*eporting *T*rials (CONSORT)	http://www.consort-statement.org
*G*ood *P*ublication *P*ractice (GPP2) for Communicating Company-Sponsored Medical Research	http://www.bmj.com/cgi/reprint/339/nov27_1/b4330
*M*eta-analysis *o*f *O*bservational *S*tudies in *E*pidemiology (MOOSE)	http://jama.ama-assn.org/cgi/reprint/283/15/2008
*Sta*ndards for the *R*eporting of *D*iagnostic Accuracy Studies (STARD)	http://www.stard-statement.org
*S*trengthening *t*he *R*eporting of *Ob*servational Studies in *E*pidemiology (STROBE)	http://www.strobe-statement.org
*P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses (PRISMA)	http://www.prisma-statement.org

editorial corrections to the medical communicator. If the text is well written, authors should not be complacent. Dr. Marvin Moser, Editor-in-Chief Emeritus of *The Journal of Clinical Hypertension*, can recognize involvement by a medical communicator because the data are usually clear and correct and references are numerous and complete; however, these manuscripts often suffer from omission bias (Moser et al. 2010). Authors should make intellectual contributions by critically reviewing the content for completeness and fair balance, especially in the Discussion. Authors should ensure that the Discussion begins with a brief summary of the main findings, compares and contrasts current findings to all published findings that are relevant, explains the implications of current findings and how they add to the literature, discloses study limitations, and provides conclusions. By the time the Discussion is prepared, another literature search may be needed to ensure that all relevant studies are included.

The medical communicator should manage the authors' and other reviewers' comments in a way that ensures each author is fully aware of all changes, such as by tracking changes and explaining the rationale for them. Teleconferences should be scheduled as needed to facilitate manuscript development, and the medical communicator should prepare written reports with details on changes made, reasons for making changes, other decisions, and action items. Authors should not hesitate to request the reports or to ask why certain changes were made.

Professional medical communicators can facilitate the final stages of manuscript development by ensuring that the document is properly formatted for the target journal and ready for online submission. They can oversee preparation of required text and graphics files. They can also circulate conflict-of-interest and other journal-specific forms that require authors' signatures (Woolley 2006).

Fewer than half of manuscripts are accepted for publication, and most require revisions. If revisions are requested, the medical communicator can help by tabulating reviewers' comments to facilitate preparation of point-by-point responses to each comment along with cross-references to revisions in the manuscript. If the manuscript is rejected, authors should consider resubmitting to a different journal because more than half of rejected manuscript are published within 2 years (Woolley and Barron 2009). The medical communicator can help authors use reviewers' comments to improve the manuscript and reformat it for an appropriate journal. After the manuscript has been accepted, the medical communicator can also help authors meet the deadline for reviewing page proofs.

Conclusions

The answer to the question about whether Aleksy should be flattered or should decline the opportunity depends on many factors. Aleksy is the best person to determine whether a medical communicator can add value to his project. If the answer is "yes", he should review the candidate's resume, letter(s) of recommendation, writing sample(s), and SOP. If these materials are satisfactory, he should expect manuscript preparation to be ethical and efficient. To ensure that the process is ethical, Aleksy should begin collaborating with the medical communicator early in the process, continue doing so throughout manuscript development, control manuscript content, and disclose substantial contributions and funding sources of all individuals not meeting authorship criteria. To ensure that the process is efficient, he should delegate time-consuming technical writing and editing tasks to the medical communicator.

Acknowledgments The author received no specific funding for this article. The author has published and presented papers on ethical medical communication practices, is a member of professional associations for medical communicators, and provides professional medical communication services to authors from academic, biotechnology, medical device, and pharmaceutical organizations. I thank Anne K. Derbes for editing this manuscript.

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