

Volume 25 Number 1
March 2016

Medical Writing



Authors and Authorship

Also in this issue...

- Returning to full-time employment after freelancing
- Freelance business survey



EUROPEAN MEDICAL WRITERS ASSOCIATION



EUROPEAN
MEDICAL
WRITERS
ASSOCIATION

Medical Writing is the official journal of the European Medical Writers Association (EMWA). It is a quarterly journal that publishes articles on topics relevant to professional medical writers. Members of EMWA receive Medical Writing as part of their membership. For more information, contact mew@emwa.org

Submissions:

For instructions to authors, go to the journal section of EMWA's website (www.emwa.org). All manuscripts should be submitted to mew@emwa.org.

Editor-in-Chief

Phillip Leventhal

Co-Editor

Stephen Gilliver

Associate Editors

Joselita T Salita
Raquel Billiones
Anuradha Alahari
Barbara Grossman
Katharine Webb

Section Editors

Kathryn White
Alison McIntosh
Karin Eichele
Greg Morley
Alistair Reeves
Wendy Kingdom
Lisa Chamberlain-James
Barry Drees
Maria Koltowska-Haggstrom
Laura Collada-Ali
Beatrix Dörr
Hervé Maisonneuve

Copy editor/reviewer

Amy Whereat

Editor Emeritus

Elise Langdon-Neuner



Authors and authorship	1
Phillip Leventhal	
Letter from the editor:	3
A step - no a leap - forward	
Phillip Leventhal	

President's Message	4
----------------------------	---

Feature Articles

Ghostwriting prevalence among AMWA and EMWA members (2005 to 2014)	6
---	---

Cindy Hamilton and Adam Jacobs

The sun never sets on transparency	13
---	----

Kim Pepitone and Brian Sharkey

GPP3 - what is it, why is it necessary and what is new?	21
--	----

Keith Veitch

Attribution, advocacy, disposable authors, corporate ghosts and cultural assimilation: new themes in the ethical critique of commercial medical literature	25
---	----

Alastair Matheson

Perspective from a leading scientific author: An interview with Professor Ruth Roberts on authors and authoring	30
--	----

Andrew Walker

Authorship of clinical trial documents	33
---	----

Raquel Billiones

Project management in medical publication writing: A less explored avenue in pharmaceutical companies and clinical research organisations	36
--	----

Prashant Auti and colleagues

Never say never! - Returning to full-time employment after freelancing	44
---	----

Alison McIntosh

Fifth EMWA freelance business survey	47
---	----

Johnathan Edwards and colleagues

Regular Features

Journal Watch	54
• The COMPARE project	
• Journals should publish referee reports and respond to well-founded concerns about papers after publication	
• Are meta-analysis simple works, office-based, cheap, time-efficient with chances to be highly cited?	

- First data on the reproducibility of research published in Science
- The HAP score for granting authorship of large multi-center trials
- Restoring study 329: reanalysis of a paroxetine trial with the same data with opposite conclusions

In the Bookstores	36
--------------------------	----

- The Elements of English Editing: A Guideline to Clear Writing
- Visual Complexity: Mapping Patterns of Information

The Webscout	58
---------------------	----

Authors and authorship

Regulatory Matters	59
---------------------------	----

- Authorship issues in regulatory documents

English Grammar & Syntax	61
-------------------------------------	----

- Good Writing Practice:
- Writing abstracts for congresses

Medical Communication	62
------------------------------	----

- Poacher turned gamekeeper

Lingua franca and beyond	64
---------------------------------	----

- Choosing a collaborator

Gained in Translation	65
------------------------------	----

- Authoring medical translations - to MD or not MD?
- Which background makes a better medical translator?

Medical Writing Teaching	70
---------------------------------	----

- A novice's experiment with a wiki on a writing course

Profile	72
----------------	----

- Phil Leventhal, Editor-in-Chief of *Medical Writing*

EMWA News	72
------------------	----

- EMWA's 2016 Webinar Programme

Out on Our Own	73
-----------------------	----

- Editorial
- The start of a year in Germany as a freelance medical writer
- Medical translation - a dead-end job or a gateway to opportunity? Part 1
- Are you having the impact you want with your clients?

Medical Writing

Authors and Authorship

Phil Leventhal, Editor-in-Chief

Authorship of medical journal articles has been and continues to be a complicated subject. The unethical practices of guest, honorary, and ghost authorship and incomplete or biased disclosure of clinical trial data have led to guidelines meant to eliminate these practices. The International Committee of Medical Journal Editors (ICMJE) Recommendations,¹ first published in 1979, and Good Publication Practice (GPP) guidelines, first published in 2003,² have led the way.

The current ICMJE guidelines¹ stipulate that authors of medical journal articles should make substantial contributions to:

- The conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- 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.

These authorship criteria mean that adding an author after the fact – a guest or honorary author – is not acceptable. The third and fourth criteria are meant to prevent authors from denying responsibility for any of the article's content. In their current state, the ICMJE authorship criteria also generally preclude medical writers from being authors because they usually cannot (or are unwilling to) satisfy criteria 3 and 4. Finally, the ICMJE guidelines state, "Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged." This means that the contributions of medical writers and editors should be transparently and clearly stated in the acknowledgments.

As explained by **Keith Veitch** in this issue of *Medical Writing*, GPP, first published in 2003, was designed to reinforce the ICMJE guidelines and "establish clear guidelines and standards for industry-

sponsored biomedical research publications." GPP2, in 2009,³ and GPP3, just published in 2015,⁴ were designed to further clarify some of the grey areas. They also introduced the contributorship model of authorship, where authors need to specifically state how they satisfied the criteria for authorship. A main goal of GPP3 is to eliminate the practices of guest authorship and ghostwriting. It also discusses in detail the valid role of medical writers and provides recommendations on how authors of publications should work with a medical writer.

By the way, EMWA's position on ghostwriting is articulated in its Ghostwriting Position Statement.⁵ It insists that "medical writers have a legitimate role in assisting named authors" and should not be referred to as ghostwriters because our contributions, and funding for our work, should not be secret and should instead be openly acknowledged. The American Medical Writers Association (AMWA) takes a similar stance in their position statement.⁶

Most journals now require that authors meet at least the first three of the ICMJE authorship criteria, and most companies require their employees to follow GPP guidelines, but that does not necessarily mean that the practice of ghost authorship has disappeared. Based on the results of surveys of EMWA and AMWA members conducted between 2005 and 2014, **Cindy Hamilton** and **Adam Jacobs** report in this issue that although the practice has decreased, approximately one-third of respondents were aware of ghostwriting as a continuing problem. Clearly, unethical authorship practices continue and more work needs to be done to wipe them out.

Alastair Matheson argues that even if these guidelines, recommendations, and position statements were followed perfectly, they do not go far enough – that we should be discussing not just authorship but *attribution*, which he defines as "what the article communicates to readers about its stakeholders, origins, and development." In particular, he says that



CONTACT



Phillip Leventhal
editor@emwa.org

in industry-sponsored publications, there is a systematic over-emphasis on academic recruits and downplaying of the sponsoring companies, with the specific intent of using “key opinion leaders” that had nothing to do with the study as product advocates. He says that this unethical practice should be eliminated but that it is consistent with existing guidelines and recommendations. In his article, he suggests specific steps to ensure that companies are assigned the “dominant authorial role” in industry-financed publications.

Thanks to increasing awareness of the potential for unethical advocacy practices and bias, the US enacted the Sunshine Act in 2010. The Sunshine Act, and its European equivalents, require disclosure of transactions or “transfers of value” between industry and healthcare practitioners. **Kim Pepitone**

A main goal of GPP3 is to eliminate the practices of guest authorship and ghostwriting. It also discusses in detail the valid role of medical writers and provides recommendations on how authors of publications should work with a medical writer.

writes about the effects of this legislation on medical writers and authors. She explains that, unfortunately, whether industry support for medical writing and editorial services should be reported remains unclear. She says that requiring authors to report it may scare away potential study investigators or result in refusal of authorship by someone who should receive it, surely not the intent of the legislation.

Although most conversation about authorship focuses on publications, **Raquel Billiones** explains that authorship of clinical trial documents also deserves scrutiny. It turns out that authorship of these documents is far less well defined for clinical trial documents than for publications. Little guidance is available in current ICH (International Committee for Harmonization) guidelines. This will hopefully change following publication of the recommendations of the CORE (Clarity and Openness in Reporting: E3 based) Reference project,⁷ which is led by EMWA President Sam Hamilton and will be co-published this spring here in *Medical Writing* and in the journal *Implementation Science*.

Finally, two articles in this issue of *Medical Writing* provide practical advice on how medical writers can best work with authors on publications. In the first of these, **Andrew Walker** interviews Professor Ruth Roberts, who has published over 130 peer-reviewed research articles and reviews. In the interview, Professor Roberts describes some of the main challenges when working with co-authors including determining who will and will not be listed as a byline author. In the second of these two articles, **Prashant Auti and colleagues** discuss project management in publications writing. Their article describes a specific project management approach that can simplify and speed the delivery of publication writing projects.

Also in this issue

Last but not least, long-time EMWA member **Alison McIntosh** talks about her return from freelancing to full-time employment. This should be interesting to the many full-time medical writers who fantasize about the independence of freelancing, as well as the many freelancers who are considering sacrificing self-determination for stability.



References

1. International Committee of Medical Journal Editors. The New ICMJE Recommendations (August 2013). 2015 [cited 2016 Jan 21] Available at: http://www.icmje.org/news-and-editorials/new_rec_aug2013.html.
2. Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin* 2003;19(3):149–54.
3. Graf C, Battisti WP, Dan Bridges D, et al. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009;339:b4330.
4. Battisti WP, Wager E, Baltzer L, et al. Good Publication Practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med* 2015;163(6):461-4.
5. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin* 2005;21: 317-21.
6. Hamilton CW, Royer MG. AMWA position statement on the contributions of medical writers to scientific publications. *AMWA Journal* 2003;18:13-16.
7. Hamilton S., Seiler W., Gertel A. The EMWA Budapest Working Group: a 2-year collaboration to make recommendations for aligning the ICH E3 guideline with current practice and developing clinical study protocol guidance. *Medical Writing* 2014;23(4):281-8.

Letter from the Editor

A step – no a leap – forward

In 2012, the journal's precursor, *The Write Stuff*, became *Medical Writing* under the guidance of then Editor-in-Chief Elise Langdon-Neuner. *The Write Stuff* had been managed almost single-handedly by Elise, and the shift to a publishing house was designed to simplify operation while bringing the journal to a wider international audience that included subscribers outside of EMWA. As part of this, the journal adopted a more academic look, style, and name.

Later the same year, Elise stepped down, handing the editorship over to me. The last three and a half years has presented a variety of challenges but also many rewards. I feel strongly that we have added to the depth, quality, and usefulness of the articles.

Over the years, I have had informal discussions with many EMWA members about what they would like from the journal. Some of the main suggestions were to move away from the academic look and feel of the journal, make the journal open access, and eliminate copyright. We worked hard to address some of these issues, but most were unattainable due to the limitations of our contract with and the operations of our publisher.

On January 1, we shifted *Medical Writing* to a printing house, moved control of the journal in-house, and added an Editorial Assistant to help handle management of the journal. This created the opportunity to seriously consider the suggestions I have received over the years.



Copyright

As part of our contract with our former publisher, copyright for all content had to be assigned to EMWA. Elise and the EMWA Executive Committee worked hard to ensure that copyright remained at least with EMWA and not the publisher. However, this still created an awkward and complicated situation, not to mention a lot of concern, especially by our freelance members.

Copyright assignment is no longer necessary as of January 1. Copyright will now remain with the authors. This means that

authors can now reuse or republish all or part of their text without asking for permission. We only ask that if text is used verbatim, authors cite the original publication in *Medical Writing* and state that it was first published there.

New look

You might have noticed the new look of this issue. I hope that you like it. Every issue will now have a different cover. We also selected fonts and formatting, not to mention colour images, to give the journal a more magazine-like look. Our aim is to better reflect that *Medical Writing* is a combination of a journal, magazine, and professional newsletter and not an academic journal.

Open access

The idea of making *Medical Writing* open access had been tossed around for several years, but each time the issue was raised, it was voted down out of concerns that it would cause EMWA to lose members. Following a discussion on LinkedIn, we decided to let EMWA members vote on it. Based on the responses to that survey and considering practical issues in running the journal website, we have decided to make all feature articles available open access. Regular sections, however, will remain limited to EMWA members. In addition, the journal will now appear on Google Scholar and therefore also on Google, which should increase the international profile of EMWA, our members and contributors to the journal.

New journal website

Access to *Medical Writing*, and *The Write Stuff* archive, is now available at journal.emwa.org and will no longer be available via the publisher's website. New versions of the instructions for authors and the template for writing feature articles can also be found there. The website features a nice search option as well as author bios, with the eventual goal of linking them to Google Scholar profiles.

How to contact *Medical Writing*

All requests for information about *Medical Writing* and article submissions should now be sent to our Editorial Assistant at mew@emwa.org. Our Editorial Assistant is housed at EMWA's Head Office, which will improve communication between the journal and other parts of EMWA's operations.

Tell us what you think

We hope that you like these changes to *Medical Writing*. If you have any comments or suggestions, or if you are interested in getting involved or contributing an article, please write to us at mew@emwa.org.

Phil Leventhal
Editor-in-Chief

President's Message

Dear EMWA Members,

It is my very great pleasure to 'speak' to you from the pages of the very first issue of *Medical Writing* of 2016, with our new printer, Hastings. I am particularly excited that our feature articles are now open-access – a progressive and forward-thinking move for EMWA and its journal. Not only will authors benefit from an expanded audience, but EMWA will also increase its global reach and ability to influence the medical writing industry.

Our Munich spring conference is just around the corner and your Executive Committee (EC) and an army of volunteers have been working hard these past 10 months to put together another stimulating programme.

If we look back on the past 22 months, we see that our spring conference content has flourished from a sound offering of workshops with Symposium Day back in May 2014, into the complex multi-layered programme that we offer you in May 2016. We should all be proud of EMWA's maturation.

As usual, foundation and advanced workshops, the Freelance Business Forum and the buzz of medical writers networking will underpin the conference. The 4th Symposium Day on 'Scientific and Medical Communication Today' will bring us together with cross-industry speakers, panellists and regulators for lively debate on our ever-changing professional landscape. Experienced members will enjoy the 2nd Expert Seminar Series, covering topics as diverse as clinical trial disclosure; referencing software; running medical writing groups in India, China and Japan; artificial intelligence and adaptive study design.

Special Interest Groups (SIGs) will provide EMWA's very own 'talking shops' on hot topics that are expected to develop and endure. The Pharmacovigilance Special Interest Group (PV SIG) will delve into issues that impact the PV documents that we write, and with the direct involvement of regulators, you can ask the questions that matter to you. As EMWA and AMWA (American Medical Writers Association) publish the open-access resource CORE (Clarity and Openness in Reporting: E3-based) Reference in May 2016, we will launch the Regulatory Public Disclosure SIG (RPD SIG), a natural

The SIGs allow EMWA and its members to contribute to important conversations around topics that we know will impact our industry in the coming years.

follow-up to CORE Reference. RPD SIG will focus on public disclosure of clinical regulatory documents, with the expectation that their content and structure will be impacted; that their range will increase; and that public disclosure will create the need for new documents, which the medical writer will support. The SIGs allow EMWA and its members to contribute to important conversations around topics that we know will impact our industry in the coming years.

We will also trial an internship forum, where potential internees new to medical writing and companies seeking interns can network.

With something for everyone – from entry-level right through to experienced members – I invite you to join us in lively Munich from 10th to 14th May 2016 for another memorable conference.

Best wishes,
Sam Hamilton



EMWA

EMWA is an association committed to representing, supporting and training medical communication professionals. EMWA has over 1,000 members from 39 different countries (including 12 countries outside Europe), and comprises academics and professionals working in-house or freelance for the pharmaceutical industry, medical communications companies, research institutes, and in the field of scientific journalism.

Social Media Team

We promote standards of excellence in medical writing by furthering the professional development of members and increasing awareness of medical writing throughout Europe.

pr@emwa.org

PR Officer



Beatrix

Laura

Facebook Manager



Sally



913



followers

LinkedIn Managers



Maria



Simon



Carola



2000

EMWA Discussion Group

591

EMWA Company Page

2014

members

2015

3623

1335

Twitter Managers



Juliane



Jen



1156



followers

1924



tweets

"Logos and brand identifiers of other companies are the property of those companies and may be registered trademarks. The use of brand logos does not imply any form of partnership, endorsement, or sponsorship. The European Medical Writers Association logo is a registered trademark of EMWA."

Ghostwriting prevalence among AMWA and EMWA members (2005 to 2014)

Cindy W. Hamilton¹ and Adam Jacobs²

¹ Virginia Commonwealth University School of Pharmacy, Richmond, VA, USA and Hamilton House Medical and Scientific Communications, Virginia Beach, VA, USA

² Premier Research, Wokingham, UK

Correspondence to:

Cindy W. Hamilton, 844 Quail Point Cove, Virginia Beach VA 23454 USA; Phone: (757) 481-2799; Email: cindy@hamiltonhouseva.com

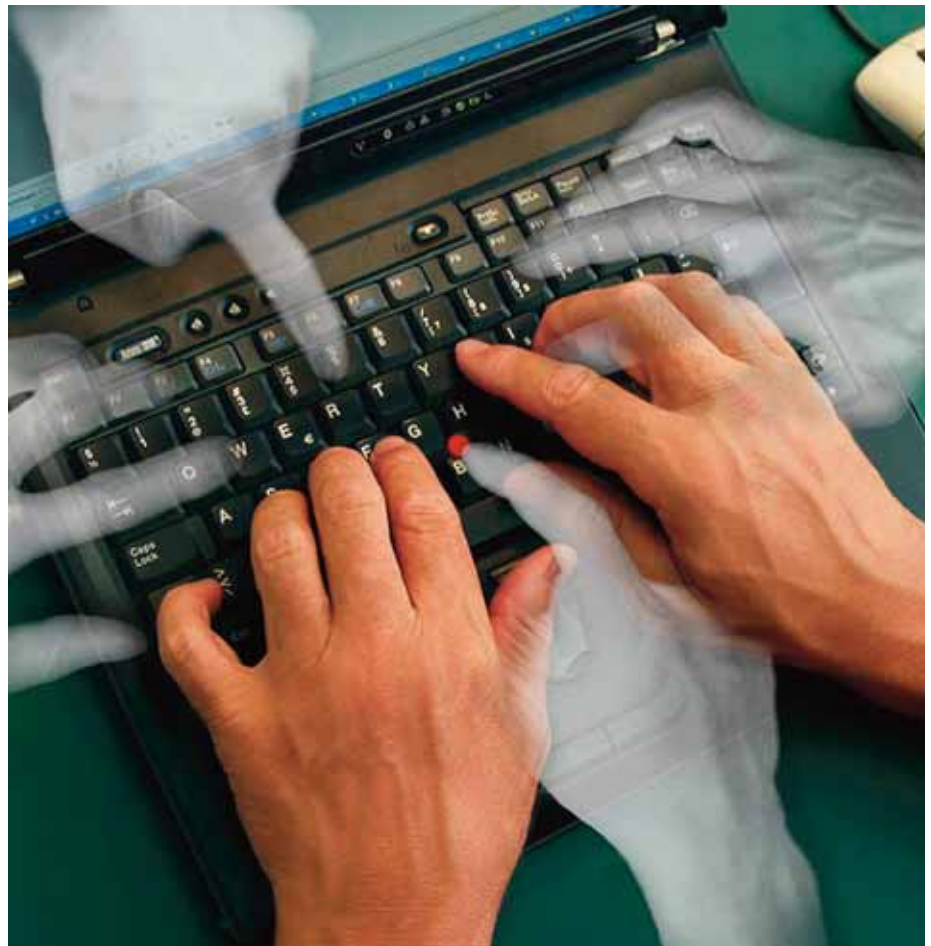
This article is being co-published in the Spring 2016 issue of the *AMWA Journal* (Volume 31, Issue 1).

Abstract

Introduction: Ghostwriting, defined as undisclosed substantial contributions by medical writers, is considered to be unethical by the American Medical Writers Association (AMWA), EMWA, and other professional associations.

Methods: To determine the prevalence of ghostwriting among medical writers coincident with educational campaigns, we initiated a Web-based, self-administered, confidential survey of AMWA and EMWA members in 2005 and repeated it in 2008, 2011, and 2014. We focused on manuscripts to which survey participants had made substantial contributions and now report final findings from all surveys.

Results: The number of participants with valid data was 843 in 2005, 773 in 2008, 620 in 2011, and 410 in 2014. The mean weighted percentage of manuscripts with undisclosed contributions was 61.8% (95% confidence interval [CI], 59.0 to 64.6) in 2005, 41.7% (95% CI, 38.6 to 44.7) in 2008, 33.0% (95% CI, 29.7 to 36.3) in 2011, and 34.4% (95% CI, 30.2 to 38.5%) in 2014. In univariate analyses, participants familiar



with more authorship guidelines were less likely to have undisclosed contributions; regression coefficients ranged from -6.6 (95% CI, -8.5 to -4.8) in 2005 to -10.6 in 2014 (95% CI, -13.1 to -8.0; all *P* values <0.001).

Conclusions: The 44% decrease in the rate of manuscripts with undisclosed contributions between 2005 and 2014 is encouraging, but the 34% rate of ghostwriting among medical writers remains unacceptable. While these findings should *not* be generalised to the overall prevalence of ghostwriting in the literature (because survey participation was restricted to AMWA and

EMWA members who made substantial contributions to manuscripts), our findings suggest the need for further collaborative efforts to promote transparency and to conduct research about how to achieve best practices in medical publication.

Introduction

“A lack of transparency results in distrust and a deep sense of insecurity.”

– Dalai Lama

Ghostwriting, defined as undisclosed substantial contributions by medical writers to manuscripts published in medical journals,

has long been recognised as unethical.¹ Without transparency, readers are denied the opportunity to judge the potential influence by groups with special interests and other conflicts. Allegations of bias and other transgressions have a domino-like effect and tarnish not only the reputations of medical communicators but also the entire profession of medical communication as well as their sponsors.²⁻⁴

During the last 10 to 15 years, professional and trade organisations representing medical writers, journal editors, and the pharmaceutical industry have attempted to clarify and expand authorship guidelines, including how to distinguish the legitimate role of professional medical writers from that of ghostwriters. For example, the American Medical Writers Association (AMWA) adopted a position statement on the contributions of medical writers to scientific publications in 2002,⁵ and the European Medical Writers Association (EMWA) published more detailed guidelines in 2005.⁶ In 2005, the International Society of Medical Publication Professionals (ISMPP) was founded to enhance medical publication integrity and transparency and to improve standards and best practices. Recently, ISMPP supported the development and publication of the third version of the Good Publication Practice (GPP3) for the International Committee of Medical Journal Editors (ICMJE) increased the number of authorship criteria and made them more specific.⁸⁻¹² The Pharmaceutical Research and Manufacturers of America (PhRMA)¹³ also updated their guidelines. These professional organisations now agree that medical writing assistance is acceptable provided that both substantial contributions to manuscripts and any potential conflicts of interest are disclosed.

Coincident with efforts to clarify guidelines, medical writing organisations launched campaigns to educate stakeholders about transparency and other best practices. For example, AMWA appointed a task force in 2001,¹⁴ which recommended a stepwise process beginning with publications and presentations to educate the medical community about the contributions of

medical writers to scientific communications.¹⁵ To further improve awareness among members, AMWA subsequently developed new ethics workshops and, in 2010, began requiring an ethics workshop for completion of each AMWA certificate. EMWA and ISMPP also undertook educational campaigns.

Ghostwriting is presumed to be widespread, but a recent systematic review has shown that estimates have often been based on anecdotal evidence, statements taken out of context, and confusion about authorship criteria.¹⁶ Furthermore, the prevalence was unknown among medical writers in the early 2000s. To determine the prevalence of ghostwritten manuscripts among AMWA and EMWA members before, during, and after implementation of educational initiatives, we initiated a series of surveys in 2005. Our secondary objective was to determine the prevalence of medical writers' requests for acknowledgment and variables associated with acknowledgment. The preliminary results from each survey have been previously presented, usually as conference posters or presentations.¹⁷⁻²⁰ The purpose of this article is to report complete and final findings from all four surveys.

Methods

The methods have been reported previously¹⁸ and are reproduced with modifications as needed to accommodate more recent surveys. A series of surveys was conducted over 3-week periods in October or November of 2005, 2008, 2011, and 2014, using an Internet survey tool (Survey Monkey; www.surveymonkey.com). Survey methods were identical, apart from the addition of a single question from 2008 onward as described in the next paragraph. All AMWA and EMWA members were invited by email to participate in the survey; one or two email reminders were sent. No incentives were offered. To encourage participation, we promised that responses would be anonymous and the survey would take only 5 min to complete.

We developed the survey instrument using repeated rounds of pilot testing among

groups of medical writers. The 2005 survey instrument comprised 13 multiple-choice questions and one open-ended question about the practices and experiences of medical writers who make substantial contributions to manuscripts intended for submission to medical journals (see Supplementary Material). Subsequent surveys were identical to the 2005 survey, except for the addition of a question about the type of manuscript to which participants had made substantial contributions (question 11). 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 acknowledgment when they made substantial contributions (question 7), and that this request was always or usually granted (question 8). In other words, contradictory responses to question 3 compared with questions 7 and 8 were considered to be invalid. 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.

All statistical analyses were done using Stata version 8.2 or later (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 medical 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 95% CI were also calculated similarly. The assumption behind the calculation of



95% CIs was checked by calculating bootstrap confidence intervals as a sensitivity analysis. Because there was good agreement between the normal distribution CIs and the bootstrap CIs, the bootstrap CIs are not presented here.

Secondary analyses were done to test the null hypothesis that familiarity with relevant guidelines (question 5) was not associated with frequency of undisclosed contributions. 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).

Further exploratory analyses investigated the potential association between undisclosed contributions and other variables (i.e., number of manuscripts to which participants had made substantial contributions during an average year, familiarity with each of the five guidelines specifically, type or place of employment, number of years of experience in medical communication, and membership in professional organisations). These associations were investigated in an exploratory sense in both univariate and stepwise multivariate analyses, with thresholds of $P > 0.1$ for removing variables and $P < 0.05$ for re-entry.

Results were analysed in an identical manner for all surveys, except that the

proportion of review papers was included in the multivariate analyses as an extra independent variable in the 2008, 2011, and 2014 data. No formal statistical comparisons were made between surveys because this was not a pre-specified objective when the 2005 survey was planned.

Results

The survey participation rate ranged from 28% (1537 participants/5463 email invitations) in 2005 to 8% (464/5664) in 2014, which suggests that both the percentage and number of survey participants decreased over time (Table 1). Participants represented a wide variety of types of employment, years of experience, and numbers of manuscripts – with no obvious changes over time (Table 2). In each survey year, the largest single employment category was freelance. Consistent with the relative

sizes of the organisations, more participants were members of AMWA than EMWA. In 2014, 52 participants reported that they were not members of either organisation and were excluded from further analysis.

The mean, weighted percentages of manuscripts with undisclosed contributions were 61.8% (95% CI, 59.0% to 64.6%) in 744 participants in 2005 and 34.4% (95% CI, 30.2% to 38.5%) in 354 participants in 2014, for an overall decrease of 44.3% (Figure 1). The mean, unweighted percentages of manuscripts with undisclosed contributions were 58.8% (95% CI, 55.8% to 61.8%) in 750 participants in 2005 and 26.4% (22.4% to 30.4%) in 355 participants in 2014.

Survey participants' experience of and practice in requesting acknowledgment were generally consistent with trends in the percentages of manuscripts with un-

Participants	Number (%)			
	2005	2008	2011	2014
Invitations sent by email	N = 5,463	N = 6,563	N = 6,084	N = 5,664
All participants	1,537 (28)	929 (14)	725 (12)	464 (8)
Contributing participants	943 (17)	839 (13)	658 (11)	437 (8)
Participants with valid data	843 (15)	773 (12)	620 (10)	410 (7)
Member of AMWA or EMWA ^a	843 (15)	773 (12)	620 (10)	358 (6)

^a Participants could be a member of both AMWA and EMWA.

Table 1. AMWA and EMWA members who participated in the surveys

Our survey findings provide unique insights into the prevalence of ghostwriting among medical writers during the last decade.

disclosed contributions (Table 3). For example, the percentage of participants who reported a decreased prevalence of ghostwriting was 39% (270/688) in 2005 and 64% (217/339) in 2014. The percentage of participants who requested disclosure of their contributions was 50% (370/747) in 2005 and 79% (282/357) in 2014. The percentage whose requests for disclosure were granted was 83% (304/365) in 2005 and remained high in 2014 (95% [267/281]). The percentage of participants who encouraged authors and other contributors to follow ICMJE guidelines was 55% (332/609) in 2005 and 81% (276/341) in 2014.

Reported familiarity with guidelines appeared to increase over time (Figure 2). For example, the percentage of participants who were familiar with ICMJE guidelines was 54% (399/735) in 2005 and 85% (304/356) in 2014.

In univariate analyses of data from each

survey year, participants who were familiar with more guidelines were less likely to have undisclosed contributions. Specifically, the regression coefficients for the change in percentage of undisclosed contributions for familiarity with each additional guideline was -6.6% (95% CI, -8.5% to -4.8%) in 2005, -7.7% (95% CI, -9.6% to -5.8%) in 2008, -7.7% (95% CI, -9.5% to -5.8%) in 2011, and -10.6% in 2014 (95% CI, -13.1% to -8.0%; all *P* values <.001; data not shown in tables). This means that writers made, on average, 10.6% fewer undisclosed contributions for each guideline with which they were familiar in 2014, and the interpretation of the regression coefficients is similar in other years.

In the stepwise multivariate analyses, ghostwriting or disclosures were associated with eight variables in at least two survey years (Table 4). Ghostwriting was associated with making substantial contributions to more than 10 papers per year (relative to

only one to two papers per year; *P* < 0.05 in 2005, 2011, and 2014) and to review-type articles (relative to original-research articles; *P* < 0.05 in 2008 and 2011). Similarly, ghostwriting was associated with being a freelance writer (relative to being employed by a hospital, university, or medical school; *P* ≤ 0.01 in 2005 and 2008). Disclosure was associated with familiarity with guidelines from AMWA, EMWA, GPP, ICMJE, and PhRMA. Of these, ICMJE was significant in all four survey years (*P* < 0.001), with regression coefficients ranging from -14.0% (95% CI, -20.4% to -7.6%) in 2005 to -20.5% (95% CI, -31.5% to -9.4%) in 2014.

Discussion

Our survey findings provide unique insights into the prevalence of ghostwriting among medical writers during the last decade. The mean, weighted percentage of manuscripts with undisclosed contributions was 62% in 2005, fell sequentially in the next two

Characteristic	Number of Responses (%)			
	2005	2008	2011	2014
Employment	N = 746	N = 662	N = 523	N = 358
Self-employed or freelance	289 (39)	260 (39)	240 (46)	158 (44)
Pharmaceutical, biotech, or medical device company	208 (28)	154 (23)	106 (20)	69 (19)
Medical communication, medical education, or PR ¹² (15)	131 (20)	67 (13)	52 (14)	
Hospital, university, or medical school	77 (10)	57 (9)	62 (12)	49 (14)
Contract research organization	32 (4)	32 (5)	21 (4)	14 (4)
Other	28 (4)	28 (4)	27 (5)	16 (4)
Years of experience	N = 737	N = 657	N = 514	N = 350
0–2	85 (12)	87 (13)	49 (10)	41 (12)
3–5	158 (21)	157 (24)	88 (17)	66 (19)
6–10	208 (28)	160 (24)	117 (23)	77 (22)
11–15	106 (14)	115 (18)	99 (19)	56 (16)
16–20	71 (10)	55 (8)	61 (12)	42 (12)
>20	109 (15)	83 (13)	100 (19)	68 (19)
Number of manuscripts in an average year	N = 776	N = 691	N = 559	N = 356
1–2	169 (22)	131 (19)	95 (17)	41 (12)
3–5	275 (35)	229 (33)	189 (34)	133 (37)
6–10	184 (24)	188 (27)	154 (28)	93 (26)
>10	148 (19)	143 (21)	121 (22)	89 (25)
Membership	N = 736	N = 647	N = 520	N = 358
AMWA	631 (86)	500 (77)	424 (82)	252 (70)
EMWA	127 (17)	166 (26)	110 (21)	121 (34)
PR, public relations				

Table 2. Characteristics of participants with valid data across survey years

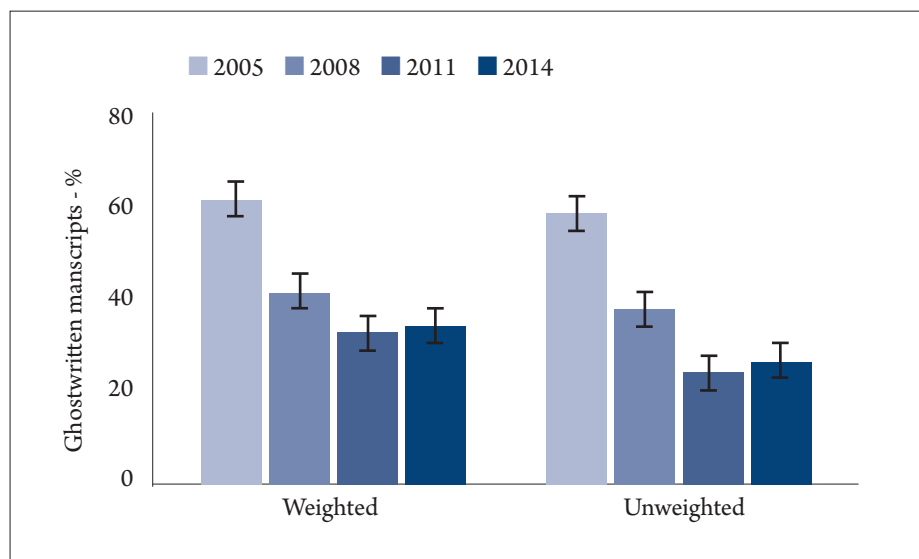


Figure 1. Prevalence of ghostwriting across survey years. Error bars represent 95% CIs.

surveys to a low of 33% in 2011, and persisted at 34% in 2014. While the rate remained unacceptably high in 2014 and failed to sustain the improvement seen in the first three surveys, the overall decrease was 44% between the first and last surveys. This drop is noteworthy, particularly when combined with the results of regression analyses. There were strong correlations between disclosures and familiarity with guidelines in both univariate and stepwise multivariate analyses, some of which persisted throughout the four surveys. For example, disclosure was associated with familiarity with ICMJE guidelines, with

regression coefficients suggesting that participants familiar with ICMJE guidelines had 14% to 21% fewer undisclosed contributions compared with those who were not familiar with these guidelines. Decreases in the rates of undisclosed contributions between 2005 and 2008 and again between 2008 and 2011 coincided with international efforts to clarify publication guidelines^{5, 6, 8-11, 15, 21} and increase awareness of them.^{14, 15, 22}

The high level of guideline awareness in our 2014 survey is consistent with that in other recently reported surveys.^{23, 24} For example, the Medical Publishing Insights

and Practices Initiative (MPIP) evaluated familiarity with and reliance on authorship guidelines among four stakeholder groups.²³ Nearly 500 people, with good representation in each group, participated in the online survey. Most medical writers (88%), publication professionals (97%), and journal editors (89%) were aware of ICMJE authorship criteria; however, only 49% of clinical investigators were familiar with these guidelines. Also, medical writers (51%), publication professionals (70%), and journal editors (59%) were more likely to rely on these guidelines than clinical investigators (28%).²³ Like MPIP, the Global Publication Survey studied current practices and implementation of publication guidelines among nearly 500 stakeholders,²⁴ especially employees at medical communication agencies (51%) and at pharmaceutical or device companies (30%). Again, the majority of both agency and industry participants routinely referred to ICMJE for guidance on ethical practice (93%).²⁴ In 2014, 85% of our survey participants were familiar with ICMJE guidelines. Also in our 2014 survey, 79% of participants requested disclosure of their contributions and 95% reported that their requests for disclosure

Type of experience or practice

	Number (%)			
	2005	2008	2011	2014
Perceived change in prevalence of ghostwriting in last 5 years	N = 688	N = 651	N = 526	N = 339
Decreased to none	20 (3)	72 (11)	95 (18)	51 (15)
Decreased but still occurs	250 (36)	340 (52)	275 (52)	166 (49)
No change	360 (52)	198 (30)	137 (26)	107 (32)
Increased	58 (8)	41 (6)	19 (4)	15 (4)
Request acknowledgment	N = 747	N = 665	N = 533	N = 357
Always	187 (25)	288 (43)	309 (58)	205 (57)
Usually	183 (24)	168 (25)	118 (22)	77 (22)
Rarely or never, but I am not opposed	354 (47)	194 (29)	99 (19)	73 (20)
Rarely or never because I am opposed	23 (3)	15 (2)	7 (1)	2 (1)
Requests for acknowledgment granted	N = 365	N = 466	N = 424	N = 281
Always	127 (35)	224 (48)	257 (61)	173 (62)
Usually	177 (48)	185 (40)	142 (34)	94 (33)
Rarely or never	61 (17)	57 (12)	25 (6)	14 (5)
Encourage others to follow ICMJE guidelines	N = 609	N = 598	N = 495	N = 341
Yes	332 (55)	426 (71)	401 (81)	276 (81)
No	277 (45)	172 (29)	94 (19)	65 (19)

Table 3. Experience of and practice in requesting acknowledgment

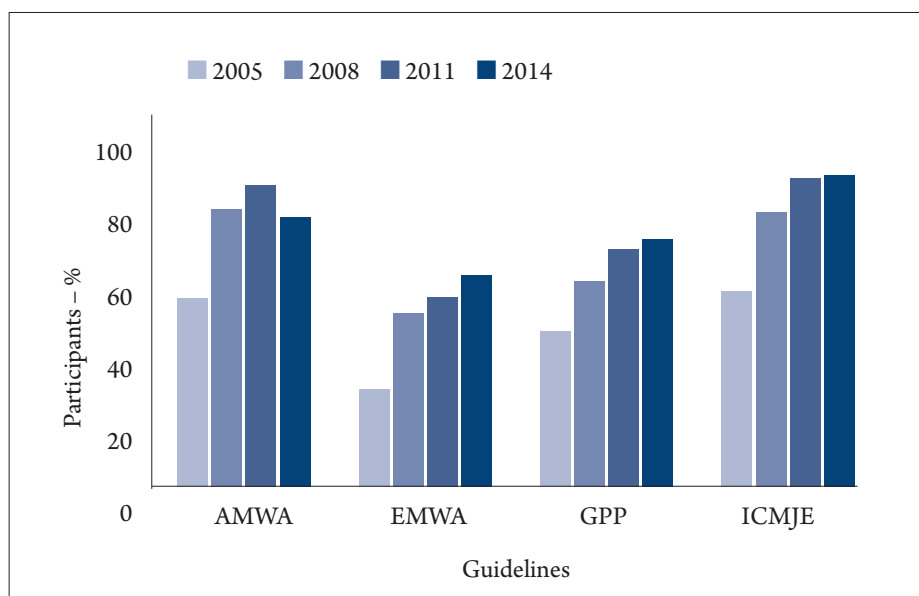


Figure 2. Increased familiarity with guidelines across survey years^a
^a Survey question: “Are you familiar with the content of the following guidelines? Check all that apply.”

were granted.

It is intriguing that writers who contributed to larger numbers of manuscripts were more likely to have undisclosed contributions than less prolific writers. This explains why the weighted proportion of undisclosed contributions was slightly higher than the unweighted proportion, as participants’ responses were weighted in proportion to the number of manuscripts. It is possible that some contributions made by prolific writers contributing were not

substantial and, for example, were limited to copy editing. As such, those contributions may have been less deserving of acknowledgement than more substantial contributions and perhaps may not have met the traditional definition of ghostwriting. Substantial contribution, however, is undefined in most guidelines, so interpretation can often be a grey area. Alternatively, contributing to larger numbers of manuscripts may indeed be correlated with ghostwriting.

While our survey findings do not prove

cause and effect, the evidence can be used to generate hypotheses that merit further evaluation and that might have practical implications. For example, a recent survey²⁵ indicates that the Certified Medical Publication Professional (CMPP) credential is a surrogate marker for broader and more current knowledge of medical publication guidelines. This is not surprising because medical writers would be expected to be aware of guidelines if they had invested in the certification examination, achieved a passing score, and maintained the credential. If future research confirms that certification and other variables are associated with transparency and other types of ethical behavior, then employers, contractors, and authors could use these findings to enhance their criteria for selecting medical writers. In addition, these findings may inspire companies to encourage or even require their writers to take advantage of educational opportunities and to audit freelance writers for awareness of and compliance with best practices.²⁶

Our findings have additional implications for different stakeholders. Professional organisations should escalate their efforts to educate members about the dangers of

Variable	2005		2008		2011		2014	
	PE (95% CI)	P value	PE (95% CI)	P value	PE (95% CI)	P value	PE (95% CI)	P value
>10 papers/year ^b	11.4 (2.2 to 20.5)	0.02	9.6 (-0.6 to 19.7)	0.06	26.2 (16.4 to 36.1)	<0.001	23.9 (10.5 to 37.2)	<0.001
Mostly reviews ^c	Not included ^d	NA	14.1 (5.0 to 23.1)	0.002	12.0 (2.2 to 21.8)	0.02	Not included	NA
Freelance ^e	27.8 (17.6 to 38.0)	<0.001	14.9 (3.2 to 26.6)	0.01	5.3 (-4.3 to 15.0)	0.28	10.0 (-1.7 to 21.7)	0.09
Familiarity with the following guideline								
AMWA	Not included	NA	-8.8 (-16.0 to -1.6)	0.02	Not included	NA	-8.7 (-16.9 to -0.5)	0.04
EMWA	-8.2 (-15.0 to -1.4)	0.02	-6.5 (-13.4 to 0.4)	0.07	-7.5 (-13.6 to -1.5)	0.02	Not included	NA
GPP	Not included	NA	-14.0 (-21.6 to -6.4)	<0.001	Not included	NA	-18.4 (-27.2 to -9.6)	<0.001
ICMJE	-14.0 (-20.4 to -7.6)	<0.001	-17.1 (-24.7 to -9.5)	<0.001	-15.7 (-23.6 to -7.9)	<0.001	-20.5 (-31.5 to -9.4)	<0.001
PhRMA	-7.3 (-14.4 to -0.1)	<0.05	Not included	NA	-15.4 (-21.8 to -9.0)	<0.001	Not included	NA

NA, not applicable; PE, probability estimate, where positive values indicate the variable is associated with ghostwriting and negative values indicate the variable is associated with disclosure.

^a $P < 0.05$ in at least two surveys.

^b Relative to one to two papers/year.

^c Relative to contributions to manuscripts conveying original data; this question was not included in the 2005 survey.

^d Not included in multivariate analysis usually because not significant ($P > 0.1$) in univariate analysis (see footnote c).

^e Employment type with hospital, university, or medical school as the reference value.

Table 4. Stepwise multivariate linear regression analysis^a

ghostwriting and other unethical practices that can damage the entire profession and can embroil authors and funders in controversy and potential legal action. Members should commit to lifelong learning practices as guidelines are likely to continue evolving. Medical writers who refuse to ghostwrite can take heart in knowing that their requests for acknowledgment are likely to be granted.

Our findings should *not* be generalised to the overall prevalence of ghostwriting in the medical literature because survey participation was restricted to AMWA and EMWA members who had made substantial contributions to manuscripts. Although the proportion of this subset to the overall prevalence is unknown, we can make an estimate based on another survey in which medical writing assistance was declared in 6% of publications in 1000 high-ranking journals.²⁷ If we assume that medical writers do not disclose one-third of their contributions and that the ratio of undisclosed to disclosed contributions is therefore 1:2, then the combined findings from our survey and the previous survey²⁷ suggest an overall ghostwriting prevalence of approximately 3% (9% – 6%). This estimate, however, should be interpreted with caution because it is based on data from different sources. On the other hand, this estimate is closer to that reported in previous, well-designed, serial surveys of authors who had published in six prestigious, peer-reviewed journals; the prevalence was 1.4% in 1996 and 0.16% in 2008.^{28,29}

Our survey had additional limitations. The most important limitation is the potential for selection bias of both participants (e.g., self-selection) and their survey responses. Although respectable for an email survey without incentives, our response rate was low enough that participants might not be representative of all AMWA and EMWA members, who in turn might not be representative of all medical writers. The low response rate is partly attributable to the previously mentioned restriction to a subset of AMWA and EMWA members. The proportion of AMWA and EMWA members who make

substantial contributions to manuscripts is unknown; however, 26.8% (108/403) of AMWA members reported that their primary area of work was scientific publications in a recent survey (data on file). If this proportion is generalisable to EMWA and is extrapolated to the entire sample, then 1518 medical communicators (5664 x 26.8%) were eligible for our survey in 2014. This estimate suggests a participation rate of 28.8% (437/1518 x 100%), which is better than the rate derived from the entire membership of AMWA and EMWA (see Table 1). The large decrease between 2005 and 2008 is probably due to clarification of the survey invitation to better define target participants. We cannot explain further decreases in response rates in 2011 and 2014. The number of participants probably would have been higher if ISMPP members had been invited, but our first survey predated that organisation. To maintain consistency and allow for comparison across survey years, we did not invite ISMPP to participate in subsequent surveys. As the survey was anonymous, we do not know how many respondents in more recent surveys had also participated in previous surveys. Therefore, it is not possible to know whether the observed decrease in ghostwriting represents individual writers changing their practices, a new cohort of writers who are less likely to make undisclosed contributions than writers working in earlier years, or a combination of both.

Another limitation is that data were self-reported and based on recall. As such, participants familiar with ethical guidelines may have been tempted to answer survey questions in way suggesting ethical practices, or participants may have forgotten times when they did not observe ethical practices. It is possible that AMWA and EMWA members are more likely to follow guidelines than medical writers who are not members of these organisations and that those who devote time to survey participation are also more likely to devote time to learning ethical guidelines and complying with them. These hypotheses suggest that our results might underestimate the

prevalence of ghostwriting.

Another limitation is the deliberate avoidance of the word “ghostwriting”, which was excluded from the survey invitation to prevent being trapped by email security filters. Another reason for avoiding this word was an attempt to prevent confusion because the term is frequently misunderstood and potentially ambiguous. Unfortunately, these efforts necessitated the use of lengthy, often awkward wording, which might have led to unintended answers to survey questions about the prevalence of ghostwriting. At the same time, our survey included questions designed to identify inconsistent responses; fewer than 2% of participants were eliminated because of invalid responses.

Author comments

Our survey findings are bittersweet. The 44% decrease in the rate of manuscripts with undisclosed contributions between 2005 and 2014 is encouraging, but the 34% rate of ghostwriting remains unacceptably high. Furthermore, the failure to sustain the improvement seen in the first three surveys is not only disappointing but also perplexing. Clearly, there is no room for complacency. We challenge our medical writer colleagues and professional organisations to intensify collaborative efforts to promote transparency and to conduct research about how to achieve best practices in medical publication.

References

1. Rennie D, Flanagan A. Authorship! Authorship! Guests, ghosts, grafters, and the two-sided coin. *JAMA*. 1994;271(6):469-471.
2. Sharp D. A ghostly crew. *Lancet*. 1998;351(9109):1076.
3. Smith R. Beyond conflict of interest. Transparency is the key. *BMJ*. 1998;317(7154):291-292.
4. Lanier WL. Bidirectional conflicts of interest involving industry and medical journals: who will champion integrity? *Mayo Clin Proc*. 2009;84(9):771-775.

5. Foote MA, Hamilton C, Royer MG. Contributions of medical writers to scientific publications. *AMWA J.* 2002;17(4):48.
6. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin.* 2005;21(2):317-321.
7. Battisti WP, Wager E, Baltzer L, et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Intern Med.* 2015: epub ahead of print.
8. Huth EJ, Case K. The URM: twenty-five years old. *Science Editor.* 2004;27(1):17-21.
9. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: writing and editing for biomedical publication. 2006. http://www.icmje.org/recommendations/archives/2006_urm.pdf. Accessed August 21, 2015.
10. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: writing and editing for biomedical publication. 2007. http://www.icmje.org/recommendations/archives/2007_urm.pdf. Accessed August 21, 2015.
11. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: writing and editing for biomedical publication. 2008. http://www.icmje.org/recommendations/archives/2008_urm.pdf. Accessed August 21, 2015.
12. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. 2014. <http://www.icmje.org/index.html>. Accessed Feb 23, 2015.
13. Pharmaceutical Research and Manufacturers of America. Principles on conduct of clinical trials and communication of clinical trial results. 2014. http://phrma.org/sites/default/files/pdf/042009_clinical_trial_principles_final_0.pdf. Accessed Feb 23, 2015.
14. Royer MG, Hamilton CW. The story behind the AMWA Task Force on the Contribution of Medical Writers to Scientific Publications. *AMWA J.* 2002;17(3):5-6.
15. Hamilton CW, Royer MG. AMWA Position Statement on the Contributions of Medical Writers to Scientific Publications. *AMWA J.* 2003;18(1):13-15.
16. Stretton S. Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature. *BMJ Open.* 2014;4(7):e004777.
17. Hamilton CW, Jacobs A. Survey of AMWA and EMWA members who make substantial contributions to manuscripts (abstract 3). *AMWA Journal.* 2006;21(2):50.
18. Jacobs A, Hamilton CW. Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers. *Write Stuff.* 2009;18(2):118-123.
19. Hamilton CW, Jacobs A. Evidence of decreased ghostwriting in a series of three surveys of medical communicators conducted between 2005 and 2011 (abstract). *AMWA J.* 2011;27(3):115.
20. Hamilton C, Peña T, Platt M, Gertel A. Transforming perceptions of medical writers from coal to diamonds – If Superman can do it, so can we! (open session 24). American Medical Writers Association Annual Conference. San Antonio, TX; 2015.
21. Graf C, Battisti WP, Bridges D, et al. Research Methods & Reporting. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ.* 2009;339:b4330.
22. Hamilton CW, Hudson S, Gegeny T. AMWA Code of Ethics added to membership application and renewal forms. *AMWA J.* 2008;23(4):177-179.
23. Marušić A, Hren D, Mansi B, et al. Five-step authorship framework to improve transparency in disclosing contributors to industry-sponsored clinical trial publications. *BMC Med.* 2014;12:197-206.
24. Wager E, Woolley K, Adshead V, et al. Awareness and enforcement of guidelines for publishing industry-sponsored medical research among publication professionals: the Global Publication Survey. *BMJ Open.* 2014;4(4):e004780.
25. Woolley KL, Dickson T, Seth A, Stretton S. The Certified Medical Publication Professional (CMPP) credential: more than a knowledge test? (poster 30). 11th Annual Meeting of the International Society for Medical Publication Professionals. Arlington, VA; 2015.
26. Woolley KL, Feeny S, Ralston J, Marchington J, Palmisano SM, McMurray B. For the greater good... Can agency competitors cooperate to advance medical publication practices? *Med Writing.* 2015;24(3):124-127.
27. Woolley KL, Ely JA, Woolley MJ, et al. Declaration of medical writing assistance in international peer-reviewed publications. *JAMA.* 2006;296(8):932-934.
28. Flanagin A, Carey LA, Fontanarosa PB, et al. Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. *JAMA.* 1998;280(3):222-224.
29. Wislar JS, Flanagin A, Fontanarosa PB, DeAngelis CD. Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey. *BMJ.* 2011;343:d6128. See also Web extra table 6125 and correction *BMJ* 2011;6343:d7677.

Declarations

Both authors declare that we: 1. have provided or do provide ethical medical writing services to academic, biotechnology, or pharmaceutical clients, 2. have no financial relationships that may be relevant to the submitted work; and 3. are active in national and international not-for-profit associations that encourage ethical medical writing practices. No external sponsors were involved in the preparation of this manuscript, and no external funding was used.

Author information

A medical writer since 1982, Cindy Hamilton, PharmD, ELS was President of AMWA from 2008 to 2009. She has promoted ethics within the profession by developing and leading ethics workshops, conducting research, and being a founding member of the Global Alliance of Publication Professionals (GAPP; www.gappteam.org).

Supplementary Material Survey Instrument

1. Do you contribute substantially to the writing or editing of manuscripts prepared on behalf of authors and intended for submission to medical journals? yes no

[If the answer to question 1 is yes, the participant will be routed to question 2. If the answer is no, the participant will be routed to question 14.]

2. During an average year, to how many manuscripts intended for submission to medical journals do you make substantial contributions? _____ (1, 2, 3 0. 0. >20)

3. In the last year, what percentage of manuscripts submitted for publication did not contain disclosure of your substantial contribution as a medical writer or editor, either in a byline, as an author, or in an acknowledgment? _____ % (0% – 100%, increments of 10)

4. In your experience, how has the frequency of undisclosed substantial contributions changed during the last 5 years?
- decreased to none
 decreased but still occurs
 no change
 increased

5. Are you familiar with the content of the following guidelines?
- American Medical Writers Association's (AMWA's) Position Statement (www.amwa.org)
 yes no
- European Medical Writers Association's (EMWA's) Guidelines (www.emwa.org/Mum/EMWAGuidelines.pdf)
 yes no
- Good Publication Practice (GPP) for Pharmaceutical Companies (<http://www.gpp-guidelines.org/>)
 yes no
- ICMJE Uniform Requirements (www.icmje.org)
 yes no
- PhRMA's Guidelines (<http://www.phrma.org/publications/publications/2004-06-30.1035.pdf>)
 yes no

6. Do you encourage authors and other contributors to follow these guidelines?
- | | | |
|----------------------------------|------------------------------|-----------------------------|
| AMWA's Position Statement | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| EMWA's Guidelines | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| GPP for Pharmaceutical Companies | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| ICMJE's Uniform Requirements | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| PhRMA's Guidelines | <input type="checkbox"/> yes | <input type="checkbox"/> no |

7. Do you request acknowledgment when you make substantial contributions to manuscripts submitted to medical journals?
- always
 usually
 rarely or never, but I am not opposed to the practice
 rarely or never, because I am opposed to the practice
- [If the answer to question 7 is always or usually, the participant will be routed to question 8. If the answer is rarely or never, the participant will be routed to question 9.]*

8. How often is your request granted for acknowledgment of your substantial contributions to manuscripts submitted to medical journals?
- always
 usually
 rarely or never

9. Do you disclose your pertinent professional or financial relationships (e.g., receipt of funding from a manufacturer or other organisation associated with the product mentioned in the manuscript) when you are acknowledged for substantial contributions to manuscripts submitted to medical journals?
- always
 usually
 rarely or never
- [If the answer to question 9 is always or usually, the participant will be routed to question 10. If the answer is rarely or never, the participant will be routed to question 11.]*

10. How often is your request granted for disclosure of your professional or financial relationships?
- always
 usually
 rarely or never

11. During an average year, how many of your manuscripts convey original data?^a
- Most manuscripts convey original data.
 Most manuscripts are review-like articles.
 Manuscripts are approximately evenly divided between original data and review-like articles.

12. By what kind of organisation are you employed? (Select only one.)
- medical communication, medical education, or public relations company
 contract research organisation (CRO)
 hospital, university, or medical school
 journal office or publisher
 pharmaceutical, biotech, or medical device company
 professional society or association
 self-employed or freelance
 other _____

13. How many years have you been employed in medical communication? (Insert the number of years as a whole numeric value, not as a fraction or decimal.) _____ years

14. To which organisations do you belong? (Check all that apply.)
- American Medical Writers Association (AMWA)
 Board of Editors in the Life Sciences (BELS)
 Council of Science Editors (CSE)
 Drug Information Association (DIA)
 European Medical Writers Association (EMWA)
 International Society for Medical Publication Professionals (ISMPP)
 National Association of Science Writers (NASW)
 Other (please specify) _____

15. Please use the space below to add comments and to elaborate on any of your answers to this questionnaire.

^a Question 11 was added in 2008 (i.e., not included in the 2005 survey).

The sun never sets on transparency

Kim Pepitone¹ and Brian P. Sharkey²

¹ Cactus Communications, Trevoze, PA, USA;

² Porzio Life Sciences, Morristown, NJ, USA

Correspondence to:

Kim Pepitone
Cactus Communications Inc.
2 Neshaminy Interplex, Suite 100
Trevose, PA 19053 USA
(267) 332-0051 (ext. 125)
kim.pepitone@cactusglobal.com

Abstract

The financial relationships between the pharmaceutical and device industries and healthcare practitioners appear frequently in the spotlight because of their potential to create bias and influence prescribing choices. Public disclosure of these transactions may help patients make informed choices about their healthcare practitioners and may help reduce healthcare costs. The US Sunshine Act, a Federal law that requires disclosure of transactions between industry and healthcare practitioners, was passed in 2010. Similar disclosure laws and codes now exist globally. Unfortunately, none of the current requirements are clear about the reportability of industry support for medical writing and editorial services. Regardless, medical writers should be aware of these requirements, which can help them as they forge relationships with authors.

Introduction

The public continues to be made aware of the financial relationships between industry and healthcare practitioners (HCPs) and the role that these transactions may play in creating bias and influencing prescribing choices. Current best practice guidelines, such as Good Publication Practice 3 (GPP3) and the International Committee for Medical Journal Editors (ICMJE) criteria for authorship support integrity and transparency in the publication of industry-sponsored clinical trials' data.^{1,2} A HCP-industry specific transparency law, known as the US Federal Sunshine Act, was passed in 2010.³ Its main goal is to help reduce potential conflicts of interest that could harm clinical integrity and patient care and increase healthcare costs.⁴ Other countries have followed suit (Figure 1).

HCPs. Despite this lack of clarity, medical writers should be aware of the current landscape and should be able to discuss the various aspects of the global transparency requirements.

The US Sunshine Act

Overview

In brief, the Sunshine Act requires that applicable manufacturers and group purchasing organisations make public certain financial relationships between themselves and certain HCPs, known as covered recipients, and teaching hospitals (see Table 1 for a list of terms and definitions). The granular details of the requirements of the Sunshine Act were published in February 2013 in a document called the Rules for Implementation.⁴ According to the Rules for Implementation, the financial relation-

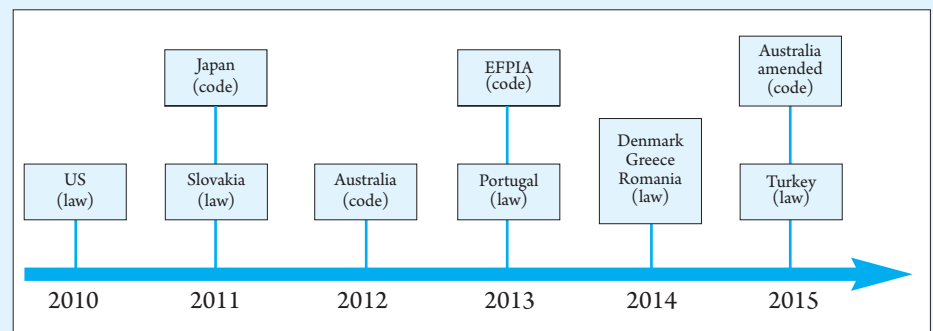


Figure 1. Timeline for passage of transparency laws and codes^{3,11} The US Sunshine Act, passed in 2010, is a transparency law requiring public disclosure of financial transactions between the pharmaceutical and device industries and healthcare practitioners. Many other countries have followed suit, with either laws or codes. It is anticipated that this trend will continue in 2016 and beyond.

Unfortunately, the global transparency reporting requirements have little detail about non-monetary support for medical writing and editing, and whether or not it constitutes a transfer of value (TOV) to

ships that must be reported can be in the form of direct payment or TOV, and include payment or TOV of 10 USD or more. Employees of sponsoring companies who meet the definition of covered

Term	Definition
Applicable manufacturers	Manufacturers of covered drugs, devices, biologicals, and medical supplies covered under Medicare, Medicaid, or the Children’s Health Insurance Program
Group purchasing organisations	An entity that helps healthcare providers, such as hospitals, nursing homes and home health agencies, save money by purchasing large volumes and use that as leverage to negotiate discounts with manufacturers, distributors and other vendors.
Covered recipients	Licensed medical doctors, doctors of osteopathy, dentists, optometrists, podiatrists, and chiropractors
Teaching hospitals	All hospitals that receive direct or indirect graduate medical education payments from Medicare
Transfer of value (TOV)	Anything of value given by an applicable manufacturer or group purchasing organisation to a covered recipient or physician owner/investor that does not fall within one of the excluded categories under the Sunshine Act Rules for Implementation
Healthcare organisations (HCO)	A legal person whose business address, place of incorporation, or primary place of operation is in Europe that is involved in the provision of healthcare services (e.g., hospital, learned society, association of HCPs).
Healthcare provider (HCP)	Any licensed healthcare practitioner who provides patient care

Table 1. Specific terms and definitions related to the Sunshine Act

recipient are excluded.

The public database that contains the financial transaction data is known as Open Payments, and is administered by the US Centers for Medicare and Medicaid Services. The first financial transaction data were released on September 30, 2014, and within 24 hours, there were reportedly 11 million hits.⁵ On October 1, 2015, the *BMJ* released a feature article detailing the types of payments made, the top five companies making payments, the top five drugs to which payments were attributed, and the five most highly paid physicians. The article also included the following quote from a 2014 article published in the *Annals of Internal Medicine*:⁶

“There were ~ 11 million hits within the first 24 hours following release of the first Open Payments data set”

“One may presume that the public may have difficulty distinguishing between donated drugs for research and transfers of financial value to physicians. Such confusion frustrates the purpose of [the Act], casting shadows where bright light had been promised.”

And in fact, this may be the case. For example, the reporting of funding for a clinical trial, which would likely include administrative costs for conducting the trial as well as the cost of the drug, might be recorded in the database as a large payment made to an individual physician investigator.

Updates and Changes to the Sunshine Act

Since the initial publication of the Rules for Implementation in February 2013, we have seen some changes intended to help clarify

the reporting requirements. For example, the exemption for reporting payment to physician speakers at accredited or certified continuing medical education (CME) events was deleted.⁷ According to the Centers for Medicare and Medicaid Services,

this was done to create consistency in the reporting of payments to speakers at certain accredited or certified CME events, and to give clarity to consumers who will ultimately have access to the reported data. Thus:

“Starting in 2016, when an applicable manufacturer provides an indirect payment or other [TOV] to a continuing education organization for a continuing education event to physicians, and knows or finds out the identity of the physician attendees/speakers within the reporting year or by the end of the second quarter of the following reporting year, that payment must be reported to the Centers for Medicare and Medicaid Services in 2017.”

Under the Rules for Implementation, reprints and textbooks provided by applicable manufacturers to covered recipients is a reportable TOV.⁴ In November 2013, 23 members of the US House of Representatives communicated their disagreement to the Centers for Medicare and Medicaid Services regarding classification of these items as a reportable TOV, as this type of information promotes good medical care and, ultimately, supports

patients. The Centers for Medicare and Medicaid Services did not agree, and declined to change the classification of these items.⁸ There continues to be widespread disagreement with the decision made by the Centers for Medicare and Medicaid.

In July of 2015, the US House of Representatives overwhelmingly voted in favour of the 21st Century Cures Act.⁹ The major purpose of this act is to increase the speed with which new medicines reach patients. It also includes a provision to exempt certified CME events and the acceptance medical texts and journal reprints by covered recipients from Sunshine reporting. The proposed changes to the Rules for Implementation include the following:

“In the case of a [covered recipient] who is a physician, an indirect payment or TOV to the [covered recipient] for speaking at, or preparing educational materials for, an educational event for physicians or other health care professionals that does not commercially promote a covered drug, device, biological, or medical supply” [would be exempt from reporting under the Act].

The US Senate has declined to vote on the bill as a single entity. Instead, they are addressing the legislation as smaller, individual bills. It is unclear at this time whether they

will address the above-mentioned proposed Sunshine Act exemptions for reprints and textbooks.

“It is unclear as to whether the US Senate will address proposed Sunshine Act exemptions for reprints and textbooks.”

In October 2015, the US Senate proposed legislation that would broaden the Sunshine Act to include the reporting of financial transactions between applicable manufacturers and physician assistants, nurse practitioners, and other advanced practice nurses, all of whom are licensed to prescribe covered products.¹⁰ If passed, reporting for this expanded group of covered recipients would begin in 2017.

Global Transparency

Focus on France

Other countries and regions of the world have joined the transparency movement. Europe has experienced the most activity on the transparency front, but it has also extended to places like Australia and Japan. Unlike the US, where transparency reporting requirements have been established in Federal and State laws, in Europe the transparency requirements have been created either by governments through laws and regulations or by self-regulatory bodies in the form of voluntary industry codes.

The first, best-known, and most compre-

hensive law was enacted in France in December 2011, *LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé*, also known as the French Act.¹¹ The French Act, and its implementing decrees, requires broad disclosure by pharmaceutical and medical device companies of agreements with and benefits provided to HCPs and various entities. Under the French Act, there are two main types of disclosure requirements:

1. All agreements, except for commercial sales agreements of goods and services, that companies have with specified individuals, including HCPs, and entities, must be reported within 15 days of signing;
2. Certain benefits given to those individuals and entities, must be reported biannually. Companies must report the required information about benefits and agreements to the French government via a web

portal, and the information is made publicly available on a governmental website (www.transparence.sante.gouv.fr).

Initially, only the existence of an agreement – but not the amount – had to be reported. An update is now pending that will require details on the amount of payment to be reported.

Beyond France: Laws and Codes

A number of other European countries have introduced laws requiring or codes recommending reporting requirements (Figure 1).

¹¹ It is important to understand the distinction between the two: laws are governmental or legislative requirements whereas codes are only binding on companies that are members of the particular

industry group. For example, in Denmark, pharmaceutical and medical device companies are required by law to report certain details about their relationships with HCPs but not the amounts paid.

“It is important to understand the distinction between transparency laws and transparency codes.”

SCHEDULE 2 - TEMPLATE												Date of publication:	
	Full Name (Art. 1.01)	HCPs: City of Principal Practice HCOs: city where registered (Art. 3)	Country of Principal Practice (Schedule 1)	Principal Practice Address (Art. 3)	Unique country identifier OPTIONAL (Art. 3)	Donations and Grants to HCOs (Art. 3.01.1.a)	Contribution to costs of Events (Art. 3.01.1.b & 3.01.2.a)			Fee for service and consultancy (Art. 3.01.1.c & 3.01.2.c)		TOTAL OPTIONAL	
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract		
INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)													
HCPs	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02						N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs		Optional
Number of Recipients in aggregate disclosure - Art. 3.02						N/A	N/A	number	number	number	number		Optional
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02						N/A	N/A	%	%	%	%		N/A
INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up; itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)													
HCOs	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02						Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs		Optional
Number of Recipients in aggregate disclosure - Art. 3.02						number	number	number	number	number	number		Optional
% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Art. 3.02						%	%	%	%	%	%		N/A
AGGREGATE DISCLOSURE													
R & D	Transfers of Value re Research & Development as defined - Article 3.04 and Schedule 1											TOTAL AMOUNT	OPTIONAL

Figure 2. An example of the EFPIA template for reporting TOV. Source: <http://transparency.efpia.eu/>

Instead, it is the Danish HCPs that must report such financial support. Portuguese law requires companies to report support and sponsorship provided to HCPs that exceeds € 60. Other European countries with financial transparency reporting laws include Slovakia, Romania, Greece, and Turkey. In the Pacific Rim, industry groups in Japan and Australia have also introduced code-based transparency requirements. Although the specifics of the requirements may differ by individual country, the message is clear: global transparency is here.

EFPIA: Industry driven approach to transparency

The European pharmaceutical industry has been proactive in seeking to develop and implement an industry-driven approach to transparency. This effort has been led by the European Federation of Pharmaceutical Industries and Associations (EFPIA), which includes 33 national member associations and 40 corporate members. The EFPIA adopted a Disclosure Code in June 2013, which was slightly amended in 2014. The EFPIA Disclosure Code requires individual-level reporting of TOVs to HCPs and healthcare organisations (HCOs) by its members.¹²

EFPIA’s goal in adopting its Disclosure Code was to create a uniform approach to transparency reporting across Europe for the pharmaceutical industry. In contrast to the pharmaceutical industry’s

“The goal of EFPIA’s Disclosure Code is to create a uniform approach to transparency across Europe.”

aggressive approach to transparency, Eucomed, which represents the medical device industry in Europe, has chosen to not impose reporting requirements on its members.

Under EFPIA’s Disclosure Code, the first year of data collection was 2015, and first reports are due in 2016. The Code includes three individual-level categories for companies to report their direct payments and TOV provided to HCPs and HCOs (Table 2).¹³

According to EFPIA’s Disclosure Code, disclosures must be made on an annual basis, with each reporting period covering a full calendar year. Companies must make their disclosure within 6 months of the end of the preceding reporting period, and the disclosed information must remain in the public domain for 3 years, unless local laws require a shorter time or a recipient withdraws his or her previously granted consent relating to a specific disclosure. Companies must document all payments and TOV required by the code and maintain records for at least 5 years, unless local law requires a shorter period.

The Disclosure Code provides two options for disclosure: 1. on the reporting company’s website; or 2. on a central platform, which can be developed by the national member association. The disclosures must be made in the local language, although companies are encouraged to also make the disclosures in

English. The EFPIA provides a reporting template that lists the types of data that companies must disclose. (see Figure 2 for example of the template).

Individual vs aggregate reporting

Although EFPIA wants as much individual-level reporting as possible, there are two instances in which companies will report at the aggregate level.¹²

1. When legal reasons prevent certain information from being disclosed. The Disclosure Code is not a law and is superseded by data privacy laws, so companies must obtain the consent of a recipient to publicly disclose individual information. If consent is not provided, individual-level data cannot be reported.
2. Research and development. This includes TOV to HCPs or HCOs for the planning or conduct of clinical trials or non-interventional studies that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

For instances in which legal reasons prevent individual-level disclosure, for each reported category, the aggregate disclosure must identify the number of recipients covered by the disclosure (on both an absolute basis and as a percentage of all recipients) and the aggregate amount attributable to the TOV. In contrast, when companies report research and development TOV at the aggregate level, they simply disclose a single monetary figure that encompasses all such transfers in a jurisdiction,

Category	Description
1	Donations and grants (HCOs only)
2	Contributions to costs related to events, including registration fees; travel and accommodation, to the extent permissible; and, for HCOs only, sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event
3	Fees for service and consultancy. In contrast to the US, companies do not have to report the details of every single transaction that they have with a HCP or HCO; instead, they are permitted to aggregate all their TOV to a HCP or HCO on a category-by-category basis
Exclusions	<ol style="list-style-type: none"> 1. Transfers that are solely related to over-the-counter medicines 2. Transfers that are not explicitly identified in the Code, including, for example, items of medical utility, meals/drinks, and medical samples 3. Transfers that are part of ordinary course purchases and sales of medicinal products by and between a member company and a HCP or HCO

Table 2. EFPIA Disclosure Code Reporting Categories

without having to provide any accompanying details.

Bringing EFPIA home

The Disclosure Code requires EFPIA’s national member associations to integrate the disclosure requirements into their own national codes, except when the reporting requirements are inconsistent with national laws or regulations.¹² Such inconsistencies exist in France, Denmark, and Portugal. In these cases, EFPIA permits deviations from the Disclosure Code, so that companies are not required to report under both the governing law and a national industry code.

EFPIA’s approach to transparency should produce some consistency across Europe, although it is impossible to achieve absolute consistency for two main reasons. First, the various national disclosure laws, which may have different reporting requirements, take precedence over industry’s self-regulatory approach. Second, although EFPIA’s member associations have almost uniformly adopted the categories of TOV that must be reported at the individual or aggregate levels, some have taken slightly different approaches to some issues. For example, a handful of jurisdictions, including Spain, the Netherlands, and Belgium, require companies to disclose a unique country identifier for each recipient on their reports. As noted previously, under the Disclosure Code national associations have the option of either creating a central registry for

reports or having companies place their reports on their own corporate websites. Most national member associations have chosen to have companies simply place the reports on their websites instead of creating a central registry.

Global Sunshine and medical writing: what do we know?

One area of the Sunshine Act that continues to lack clarity is whether providing non-monetary medical writing and editorial support constitutes a TOV. Interpretation of the Rules for Implementation has varied between industry companies, with some reporting it as a TOV and others not (Table 3).¹⁴

As noted by Toroser and colleagues, we still lack definitive guidance in this area.¹⁵ The support provided to covered recipient authors is intended to ensure that applicable manufacturers can meet their ethical obligations to publish clinical trial data in as timely a manner as possible. This benefits the applicable manufacturer. Ascribing TOV to this support for an author could undermine the credibility of the authors, the study sponsor, and the results of the research, because the support may be misconstrued as payment for authorship.¹⁶

Medical writers need to know the nuances around the reportability of non-monetary medical writing support.”

Similar to the US experience with the Sunshine Act, the EFPIA Disclosure Code does not explicitly address the reportability of TOV associated with medical writing and editorial support. A Frequently Asked

Questions document issued by EFPIA does address the topic, although the comments are somewhat ambiguous.¹³ Accordingly, companies will have to determine whether and how they report TOV associated with medical writing and editorial support, and they will have an opportunity to publicly explain their rationale for their decisions. The Disclosure Code requires companies to publicly disclose a note that summarises the methodologies they used to prepare their disclosures and to identify TOV for each category.¹² Although companies are not obligated to address how they treated medical writing and editorial support in their methodology notes, they can explain their decision and rationale. As with the US, this lack of clarity may likely lead to inconsistencies among companies and could lead to confusion among authors who work with different companies.¹⁷ There could also be a chilling effect on industry-HCP relationships.^{15,17} The potential negative impact may be in the form of investigators declining to work with industry on clinical trials and clinicians declining to participate as authors of clinical-trial publications. The latter example may lead to the loss of critical real-world clinical-practice interpretation of clinical trial results, which could, ultimately, harm patient care.

Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect the opinions of their employers. The authors have no financial conflicts of interest to declare.

<p>No, the support does not need to be reported</p> <p>The support is of value to applicable manufacturers because it helps them meet their ethical obligations to publish their data in as timely a manner as possible. In this case, the support is of no value to the covered recipient authors.</p>	<p>Yes, the support must be reported</p> <p>The support is of value to the covered recipient authors because they would have had to either do the work or pay for the support had the applicable manufacturer not provided the support.</p>	<p>Maybe</p> <p>Whether the support needs to be reported depends on the circumstances. For example, there is no TOV for clinical study manuscripts, but there is a TOV for authors who request support from the applicable manufacturer for publication of data from an investigator-initiated study.</p> <p>Source: International Society for Medical Publication Professionals¹⁴</p>
--	--	--

Table 3. Reporting Scenarios for Publication Support Under the Sunshine Act

References

1. Battisti WP, Wager E, Baltzer L, *et al.* Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3 Good Publication Practice for Company-Sponsored Research (GPP3). *Annals of Internal Medicine.* 2015;163(6): 461-464.
2. ICMJE. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. 2013; www.ICMJE.org
3. United States 111 Congress HR 3590. Patient protection and affordable care act. 2010:111-148.
4. Centers for Medicare and Medicaid Services. Federal register. Department of Health and Human Services; 2013:9457-9528.
5. Jarvies D, Coombes R, Stahl-Timmins W. Open Payments goes live with pharma to doctor fee data: first analysis. *BMJ (Clinical research ed.).* 2014-10-01 16:46:40 2014;349.
6. Morain SR, Flexner C, Kass NE, Sugarman J. Forecast for the Physician Payment Sunshine Act: Partly to Mostly Cloudy? Forecast for the Physician Payment Sunshine Act. *Annals of Internal Medicine.* 2014;161(12): 915-916.
7. Centers for Medicare and Medicaid Services. CMS implements final rule change for open payments. In: *Services CfMaM*, ed. Vol Public law no. 111-152: Centers for Medicare and Medicaid Services; 2014.
8. Andrews RE, Schwartz AY, Meehan P, *et al.* Final Sunshine Act letter to Marilyn Tavenner. 2014.
9. Upton F. HR6-21st century cures act. 2015.
10. Grassley C. S.213-Provider Payment Sunshine Act. 2015.
11. Campbell DJ, Sharkey BP. Ready or not, full speed ahead for the global transparency movement. 2015; <http://porziolifesciences.com/resources/publications>.
12. European Federation of Pharmaceutical Industries and Associations. EFPIA HCP/HCO disclosure code. 2014:1-15.
13. European Federation of Pharmaceutical Industries and Associations. EFPIA code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations: Frequently asked questions. 2014; http://transparency.efpia.eu/countries/download/11/document_2/faq-disclosure-code.pdf. Accessed November 22, 2015.
14. The International Society for Medical Publication Professionals. ISMPP Sunshine Act information update. 2014; http://www.ismpp.org/assets/docs/Inititives/Sunshine_Act/sunshine%20act%20interpretation%20update_february%202014_final.pdf. Accessed November 22, 2015.
15. Toroser D, DeTora L, Cairns A, *et al.* The Sunshine Act and medical publications: Guidance from professional medical associations. *Postgrad Med.* 2015/11/04 2015;127(7):752-757.
16. Wechsler R, Hauser RA, French J, the Clinician Investigator C. Who is helping whom? Manuscript support and transfer of value. *Annals of Neurology.* 2015;77(2):353-355.
17. Ratain MJ. Forecasting unanticipated consequences of "the Sunshine Act": mostly cloudy. *JCO.* 2014;32(22): 2293-2295.

Author Information

Kim Pepitone, CMPP, is a Scientific Director at Cactus Communications, specialising in education about good publication practices. Ms Pepitone is the Vice Chair of the ISMPP Sunshine Act Task Force. She has published and lectures frequently on the topic. Brian P. Sharkey is Vice President of Porzio Life Sciences, a subsidiary of the law firm Porzio, Bromberg & Newman, where he specialises in counselling life sciences companies on a variety of compliance-related issues, most significantly those relating to ex-US marketing disclosure, gift limitation laws, and industry codes. Mr. Sharkey is also an attorney with Porzio, Bromberg & Newman.

GPP3 – what is it, why is it necessary and what is new?

Keith Veitch

keithveitch communications
Amsterdam, The Netherlands

Correspondence to:

keith.veitch@gmail.com

Abstract

The good publication practice for pharmaceutical companies (GPP) guidelines were first published in 2003, then revised in 2009 (GPP2) and most recently in 2015 (GPP3). The latest version reflects the changes that have occurred in legislation concerning dissemination of data from clinical trials, mainly focussed on the pharmaceutical industry. These guidelines are intended to serve as a basis for publication professionals to establish transparent and ethical working practices within the pharmaceutical industry. The need for such guidance and the main differences in the latest version are introduced.

Background

The term *Medical Writing* encompasses a wide field of diverse forms of written communication that seemingly only medical writers themselves can understand and distinguish. The different demands and requirements for writing regulatory documents, clinical study reports, grant applications, and publications mean that medical writers usually become specialised in one or two areas. For example, a writer may have the background, skill set, and familiarity with the legislative requirements to work on both regulatory and clinical documents but may have little or no knowledge about the intricacies of narrative writing or publications. Due to increasing legislation and control in almost all aspects of medical writing, medical

writers have continued to become more specialised over the past two decades, as reflected in the specific training certificates offered by the EMWA Professional Development Programme.

Most facets of medical writing have always been regulated by legislation, and training can be focussed on meeting those needs. However, one area where it has been assumed that training is not needed is that of medical communications, namely, manuscripts for peer-reviewed journals, abstracts, posters, and slide presentations for conferences. The prevailing belief is medical writers learn how to write these documents during their university education through expertise passed on by their PhD or Master's supervisor, who in turn had learned from their peers. This belief persists in academia, where despite the need to publish the results of scientific projects to add to one's curriculum vitae or support grant proposals, little or no consideration is given to how such publications should be written.

The same situation existed in the pharmaceutical industry in the 20th century, with publication being the final uncontrolled, unregulated stage of a process that generated clinical results through a strictly controlled process, from

protocol to regulatory submission. The simple view was that scientists would run their experiments and publish the data, driven by the need of academics to have papers to secure tenure and further grants, and by the need for industry to promote their products. The interface between the two was a grey area that few understood and most never questioned. However, as negative headlines about the pharmaceutical industry became increasingly frequent, public trust rapidly dissipated, leading to increasing demands from many stakeholders to increase and enforce data dissemination and transparency for industry-sponsored clinical trials.

Regulation of publications

The result of demands for increased data dissemination and transparency was a sequential increase in legislated requirements for public reporting of clinical trials. This



began with voluntary registration of clinical trials on internet sites such as the US-based ClinicalTrials.gov and EudraCT in Europe. Editors of major scientific and medical journals immediately supported these requirements and added punctual registration of clinical trials as a criterion for the acceptance of manuscripts based on clinical trials. As companies realised they would no longer be able to publish their studies in the top journals without registering their trials, they rapidly accepted this requirement. When this was followed by the requirement to report the results of those trials on the same sites, it was also quickly accepted by industry. Currently, the final stage of public disclosure is becoming established, giving qualified researchers access to patient-level data from company-sponsored clinical trials through internet sites.

This leaves the final form of data sharing, the writing and publishing of scientific and medical papers in peer-reviewed journals, as the last area for which there is no legislation. Publication is still a voluntary exercise – there is no legal obligation to publish – driven only by the ethical commitment inherent in the International Conference on Harmonization (ICH) to make all data public and in the knowledge that an unpublished study is a wasted opportunity to demonstrate not only full transparency but also the benefits of a product.

Failure to publish all clinical trial data has been waved in the face of the industry as evidence of malpractice. Accusations that poor or *negative* data are being hidden are common. Furthermore, compliance with the requirement to register clinical studies on ClinicalTrials.gov has exacerbated this situation. Even though there are many reasons for which a study may never be published (e.g. it may never have been conducted or was never completed), industry is being held to account when a paper does not appear. This ignores the published evidence that company-sponsored research is more widely reported than academic trials.¹

One of the problems is that industry may not always control publication of results from clinical trials that they sponsor. Of course, even scientists who do not need additional publications for their curricula vitae may still want to publish, but industry-sponsored clinical trials often involve dozens of academic investigators, not to mention *in-house* experts who are equally valid contributors to the research, so who owns the data and is therefore responsible for its publication can be unclear. Another limitation to publishing everything is that corporate enthusiasm – and therefore budget support – to publish relies on the novelty or interest in the data, and something that is not particularly novel or beneficial for a product may not obtain the resources needed to generate and submit a manuscript punctually.

Good Publication Practice – 2003

It was against this background and the lack of regulations that a meeting of academics, journal editors, and industry representatives was organised in 1998 by the Council of Biology Editors. The aim was to establish clear guidelines and standards for industry-sponsored biomedical research publications. It took another 5 years for the results of that first meeting to come to fruition, with the publication in 2003 of Good publication practice for pharmaceutical companies (GPP).² This document was the first to provide standards for industry-based manuscripts, but it was restricted to a relatively small set of issues: the obligation to publish everything, the role of professional medical writers in assisting with

As
with the original
guidelines, GPP2
resulted in numerous
unanswered
questions and
requests to include
more detail and
additional topics.

manuscripts, and a first brief approach to a major issue for all manuscripts, authorship. Although GPP was rapidly taken up by medical writers as guidance within their companies, even at its inception it was evident that many topics had not been considered and that a more comprehensive guidance document was required.

GPP2 – 2009

The next iteration of GPP – GPP2 – was published six years later, in 2009.³ GPP2 was a more complete document written by a larger author panel (12 vs. 3 in the original GPP) representing pharmaceutical companies, publishers, communication agencies, and independent medical writers. Before submission, the guidelines were also reviewed by a wide review panel that included representatives from academia and journal editors. GPP2 was more comprehensive than GPP and introduced or supported new concepts, including written publication agreements, publication steering committees, checklists, and the contributorship model, while reinforcing the authorship guidelines proposed by the International Committee of Medical Journal Editors (ICMJE) and adherence to trial registration and results posting requirements.

As a more detailed document with many concepts more precisely covered, GPP2 was ideal for helping publication professionals establish internal guidelines and ways of working. Having such externally written guidance also lent credence to the idea that publication professionals brought value to their employers and reinforced the ability of writers to insist on ethical working practices.

GPP3 – 2015

As with the original guidelines, GPP2 resulted in numerous unanswered questions and requests to include more detail and additional topics. The most recent version, GPP3, published in late 2015, has therefore continued to build on the original guidelines.⁴ It focusses on the core values of GPP and GPP2 and also adds further detail and an improved organisation to enhance clarity and eliminate redundancy. Sections already present in GPP2 have been built upon and updated, taking into account the evolution of publication and data dissemination practices. GPP3 starts with a list of 10 key publication principles, which are intended to support the six core principles of GPP: integrity, transparency, completeness, accuracy, accountability and responsibility. These 10 principles can also serve as a checklist for authors and medical writers.

Authorship

Notable changes in publication practice occurred following revisions to the ICMJE requirements for authorship in 2010 and 2013 (and which have been further revised in December 2015). These include addition of a fourth criterion to the original three criteria for authorship:⁵

“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.”

Authorship is a grey area that seems to generate more disputes and problems in manuscript preparation than any other – despite the ICMJE criteria and the extensive attention it gives to the subject of authorship.⁵ GPP3 therefore also addresses authorship, with the intent of clearly identifying and defining authorship. A specific intention is to eliminate, once and for all, the practices known as guest authorship and ghostwriting. Publication professionals are aware of these concepts and avoid them, but having them defined in GPP3 makes it easier to communicate this knowledge to colleagues and ensures that they are recognised as unacceptable practices.

Another authorship issue that frequently arises is the question of payment and reimbursement of an author’s time for their role in manuscript development. GPP3 provides additional guidance and clarity on this divisive issue – even the authors of GPP3 had differing perspectives. Other authorship issues, such as author number, author order, deceased authors, and authors no longer with the company, are specifically addressed in a table.

Role of professional medical writers

Two common questions for publication professionals are how they justify their role in manuscript preparation and why they are not then themselves authors? GPP3 attempts to address both questions, notably by presenting published data supporting the importance of medical writers in improving the quality of submitted manuscripts. In defining the need for professional writers,

GPP3 also provides recommendations on how they should work with authors. A key recommendation is to clearly establish defined roles and responsibilities before writing starts. Also discussed is how the role of the medical writer may, in certain circumstances, result in authorship. As in GPP2, GPP3 recommends written agreements for authors, medical writers, and agencies, as well as establishing publication steering committees. GPP3 also recommends that, for transparency, any writing contribution must be acknowledged along with the source of funding for such support.

GPP3 supports use of the contributorship model of authorship, wherein each author’s role in the work is clearly defined and potential conflicts of interest, financial or otherwise, are disclosed, even if the target journal does not request such information. GPP3 recommends calling such information *Disclosures* because this term carries no negative connotation and is more likely to encourage greater disclosure of both financial and non-financial sources of potential conflict of interest. Use of the contributorship model may also identify gaps in contributions that should be covered by the author panel. For example, if no one is identified as having performed statistical analyses, who was responsible for ensuring the accuracy of the data or the appropriateness of the analytical methods employed? Finally, GPP3 discusses the use of author groups for large trials.

Types of articles

Noting the impact that data posting may have on publications, some guidance is given on appropriate timing. GPP3 establishes the principle that the primary publication must be published before secondary articles, which themselves must clearly identify and refer to the primary article. GPP3 briefly touches on the different types of scientific article that may be written, with some indication of the

Typical comments have included “make it for academics too!,” “send it to universities,” and “maybe the next step for GPP3 could be guidelines for non-company-sponsored medical research?”

guidance already available for different types (e.g. PRISMA guidelines for systematic reviews). This section also covers encore presentations at different congresses.

Data sharing

Important areas of evolution since GPP2 have included clinical trial data dissemination following trial registration with data posting and data sharing with researchers.

GPP3 recognises and fully endorses all aspects of clinical trial reporting, while noting that it does not substitute for publication as a means of presenting and explaining the data in context. More importantly, data posting does not constitute prior publication, nor does it cover the ethical obligation to publish, as the researcher has an obligation to present the work in the context of current knowledge and note the contribution that the work makes.

An important point raised in GPP3 is that any publication of clinical trial data – abstract, poster or paper – should include the appropriate trial registration identifier to allow readers to identify the study. This also helps ensure that data are not published in duplicate, even unintentionally. Having mentioned duplicate publication, GPP3 does note that certain exceptions can be made for encore presentations of abstracts and posters at scientific congresses in different specialties or geographies. Equally, GPP3 advises that every effort be made to minimise plagiarism, including self-plagiarism, a concept addressed for the first time in GPP3.

Towards GPP4

GPP3 is just the latest evolution of an established process. Undoubtedly, there will be a GPP4, which will take into account further evolution in the fields of data dissemination and publication. The timing and content of GPP4 are yet to be determined. In the meantime, the GPP3 Steering Committee acknowledges that



questions will arise in the interim; so the committee, in conjunction with the International Society for Medical Publication Professionals (ISMPP), has established an online repository of questions and answers and relevant resources on publication practice (<http://www.ismpp.org/gpp3>). Further questions about GPP3 can be submitted to its authors at gpp3@ismpp.org. In future, the ISMPP-GPP3 website may serve not only as a resource but also as a platform for recruiting new members to the GPP team to work on GPP4.

What will GPP4 bring? That remains to be seen, but the feedback from reviewers of GPP3 and subsequent comments from users gives a strong hint. Typical comments have included “make it for academics too!”

“send it to universities,” and “maybe the next step for GPP3 could be guidelines for non-company-sponsored medical research?” GPP3 is endorsed by an increasingly wide range of organisations concerned with scientific communication and medical writing, including EMWA, the American Medical Writers Association, the Committee on Publication Ethics, the European Association of Science Editors, and the Japan Medical and Scientific Communicators Association. Perhaps, with the support of such organisations, GPP4 will become the go-to model for all writers of medical communications, not only of industry-sponsored studies, for increasing transparency and the quality of clinical trial reporting.

References

1. Anderson ML, Chiswell K, Peterson ED, *et al.* Compliance with results reporting at ClinicalTrials.gov. *N Engl J Med* 2015;372:1031–9.
2. Wager E, Field EA, Grossman L. Good publication practice for pharmaceutical companies. *Curr Med Res Opin* 2003;19(3):149–54.
3. Graf C, Battisti WP, Dan Bridges D, *et al.* Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009;339:b4330.
4. Battisti WP, Wager E, Baltzer L, *et al.* Good Publication Practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med.* 2015;163(6):461–4.
5. International Committee of Medical Journal Editors. Recommendations [cited January 5, 2016] Available at: <http://www.icmje.org/recommendations/>.

Author information

Keith Veitch is a biochemist who moved from research into publication writing, originally with GSK in Belgium, almost 20 years ago. He subsequently headed publication groups in Sanofi Pasteur (Lyon, France) and Novartis Vaccines (Amsterdam, the Netherlands). He is now a freelance consultant in publications and medical writing, particularly for infectious diseases and vaccines.

Keith served in EMWA as President and as Editor of *The Write Stuff* (forerunner of *Medical Writing*). He has worked with various organisations concerned with ethical reporting of clinical trials, including ISMPP and TIPPA, and was a member of the Steering Committee and author for GPP3.

Attribution, advocacy, disposable authors, corporate ghosts and cultural assimilation: new themes in the ethical critique of commercial medical literature

Alastair Matheson
Toronto, Canada

Correspondence to:
amatheson@outlook.com

Abstract

To clarify the ethical difficulties surrounding authorship in industry-financed medical journal articles, one must consider their overall attribution rather than authorship alone. Correctly understood, attribution involves not only authorship but everything an article communicates to readers about its stakeholders, origins, and development. Proper attribution requires that the most important aspects of the origins and development of an article are brought most prominently to the attention of readers, rather than disclosed in inconspicuous small print. An important ethical problem arises when, for marketing reasons, attribution including authorship is spun to exaggerate the role of academic recruits and downplay that of the companies themselves. This practice is unethical but consistent with medicine's current editorial recommendations. Here, I introduce new themes and concepts in the ethical analysis of commercial practices, and propose changes to editorial guidelines to ensure that companies, not their contingent academic recruits, are assigned the dominant authorial role in industry-financed journal literature.

To understand the ethical challenges surrounding authorship in industry-financed medical journal articles, one must look beyond authorship alone and examine their attribution considered as a whole. I argue in this essay that the attribution of industry literature including authorship is routinely spun for marketing purposes to exaggerate the role of academics and downplay that of companies. Furthermore, I argue that this practice is not merely misleading but part of a pernicious cultural transformation of science and medicine that should be resisted by everyone concerned for scientific integrity.

Attribution

The attribution of journal articles is sometimes thought to be synonymous with authorship, but in fact, everything an article relates to readers about its provenance, stakeholders and development should be considered part of its attribution (Table 1 overleaf). Individual aspects of attribution, such as authorship, contributorship and disclosure, have been addressed by medicine's editorial community over the decades,¹⁻⁴

but attribution *per se*, considered as the sum and balance of all the information communicated about the article, has received scant attention. The current International Committee of Medical Journal Editors (ICMJE) Recommendations exceed 13,000 words,⁴ but the term "attribution" appears not once.

Proper attribution requires clear communication with the reader. It is determined not merely by what is documented but also by what is brought to readers' attention. Proper attribution requires key information to be related fully, in clear language and for the most salient information to be made prominent at the head of articles, not buried in small print (Table 1). Articles failing to do this may be misattributed if they give a misleading overall impression of the article's development. In my experience, this is an enduring problem in pharma's journal literature.



Definition

- The sum and balance of everything an article or presentation communicates to its audience about its stakeholders and contributors, their roles and their interests.

Components

- Authorship including number of authors and corporate authorship
- Author sequence
- Contributor listings
- Acknowledgements and footnotes
- Labeling and advisory statements
- Textual descriptions of stakeholder roles
- Disclosures, including interest disclosures
- Title (if group, company etc. identified in Title)

Role of perception

- Attribution depends on what the reader notices, not merely what is disclosed.
- An article with comprehensive “transparent” disclosures, but which places key facts about its provenance and development in the small print while letting secondary details capture reader attention, is poorly attributed.

Testing attribution

- Does the attribution of an article actively bring to the reader’s attention the truth about its provenance and development?
- Salience – are the most important facts isolated and presented to the reader?
- Conspicuity – Are the most important features brought prominently to the reader’s attention at the outset of articles?
- Clarity – are facts presented to readers in clear, unambiguous, non-euphemistic language?
- Inclusiveness – are any key facts omitted?

Table 1. Understanding attribution

Advocacy marketing, content steerage, and attributional spin

Advocacy marketing (Table 2) is in my opinion the single greatest ethical problem in contemporary industry publications. Advocacy marketing occurs in numerous retail sectors, when products are promoted by members of the public or respected personas rather than by salespeople. This encourages consumers both to trust and to respect product messages – two key marketing objectives. In pharmaceutical marketing, advocacy occurs when commercial data and argument are presented to customers – chiefly, practicing clinicians – by respected academics rather than by the company itself. Many academic “advocates” are recruited by pharma for their status as “key opinion leaders” also known as “KOLs”.⁵⁻⁸ Others are “rising stars”, with whom companies cultivate longstanding relationships beneficial to the company and academic alike.⁸

In publications, advocacy involves two steps. Firstly, companies shape the content of literature to deliver the company’s

intended messages. Secondly, this literature’s attribution is assigned primarily to academic recruits.⁹ In rare cases, content is simply written by a company, then “authored” without modification by a KOL. More generally, in my experience however, when marketing influences scholarly literature, content is developed with academic participation but subtly steered by the company to incorporate commercial perspectives, after which its attribution is subtly spun to exaggerate its academic credentials, while the company that is the true master is credited with mere “support” or “sponsorship”.

With respect to article content, the GPP3 guidelines illustrate many points at which it can be commercially guided. These include publication planning, which may propose themes, provisional titles, authors, journals and messages;^{5,10-12} author selection, either directly by companies or indirectly by committees initiated by companies; inclusion of company co-authors on most industry trials;¹³ company analysis of data;

Attribution of industry literature commonly emphasises academic leadership.

the use of editorial teams and writers; and company review. Collectively, these devices provide extensive opportunities for content steerage. Of note, GPP3 requires that authors “control” manuscript development and make “final” decisions, but the wording is subtle: GPP3 does *not* require that authors should have *sole* control or make *all* decisions.¹² Authors do not; and in any case, most are the company’s trusted academic recruits or its employees.

Attribution of industry literature commonly emphasises academic leadership. It is common practice to place academics and their institutions conspicuously at the head of author bylines, whereas industry employees are generally placed inconspicuously in the middle or towards the rear of bylines, and are often fewer in number than academic recruits.^{9,14} There is rarely any prominent identification of the company, for instance in the title of the article or as a corporate co-author. Where it is identified – for instance at the foot of abstracts – it is misleadingly

Term	Definition
Advocacy marketing	Presentation of marketing-related data or argument to potential customers through their peers and opinion leaders, not company representatives.
Corporate authorship	When a company considered as an entity plays an authorial role.
Corporate ghost authorship	When corporate authorship is not given an appropriately frank and prominent attribution.
Disposable author	Academic author recruited into a commercial project who could readily be exchanged for another without significant impact on the project or publication.
Content spin	Subtle steering of content through planning, message formulation, research design, results analysis, author selection, manuscript development or review.
Attribution spin	Subtle spinning of attribution through authorship, author sequence, vague language, euphemism, omission, poor labeling and small print.
Cultural corruption	State in which the norms of conduct and ethics within culturally linked institutions and discourses are distorted by cultural change – typically involving money or power.
Commercial-academic assimilation	Blending and merger between commerce and academia, such that the distinction between what is commercial and what is academic becomes progressively less apparent and less important.

Table 2. Terminology used in this analysis

credited with mere “funding” or “support.” Contributor listings generally do not distinguish company from academic co-authors and are presented in small print. Interest disclosures typically bury academic relationships with the company amid a mass of small print disclosures. Writers are usually denied co-authorship and acknowledged only in small print. Textual descriptions of the company’s role generally omit key facts, such as company instigation or private data ownership, and indeed GPP3’s recommendations for disclosure omit these facts. The collective effect of these practices is to position senior academic authors as leaders of publications planned, financed and drafted substantially by companies who analyse and secretly own the data. Such attributional practices provide academic endorsement, and as Hirsch has noted, may increase the likelihood of publication in prestigious journals, whose editors and readers may prefer to see academics at the head of bylines.¹⁴

Disposable authors and corporate ghosts

This picture of content steering and attributional spin leads to further new concepts in commercial publication ethics. Firstly, ghostwriting remains controversial in industry publications, but in my opinion, the greater ethical problem is *corporate ghost authorship* (Table 2). This occurs when a corporate entity plays an authorial role but is not assigned a commensurate attribution in the published article. Secondly, the chief

ethical problem for academic recruits is, in my opinion, not that they are “guest authors” – most are not – but rather that they are positioned as leaders when their involvement is a contingent detail. If they or their institutions had been unavailable, or if the company’s choice had been different, alternative institutions and academic authors could and would have been selected. The *actual* academic who is recruited is not decisively important. What is vital – as much to marketing as science – is that academics *per se* are recruited. The individual academics who happen to sign on are therefore what may be termed *disposable authors*.⁹ (Table 2) Regardless of the scale of their contribution, they are conditions of possibility for a company project that would proceed regardless of their particular involvement. It is therefore unethical for such participants to head the attribution of this literature.

Editorial guidelines support advocacy

Medical journal editors have taken many valuable steps to uphold scientific and ethical standards in journal literature. These include improved documentation of individual contributions, through contributor listings and acknowledgements; enforcement of author accountability; securing author access to

company data; promoting compliance with research guidelines; enforcing trial registration; and improving interest disclosures.^{1-4,15,16} Yet none of these measures challenges the exaggeration of academic roles and understatement of commercial ones upon which advocacy marketing depends. Rather, the ICMJE *Recommendations* assist these practices – they exclude writers from byline authorship of research articles; set no requirements for corporate authorship; permit omission and euphemism in descriptions of industry’s role, for instance in recommending terms such as “funding”, “support” and “sponsor”; and provide no advice on what information should be brought more actively to readers’ attention.⁴ Consequently, articles planned, financed, and drafted by companies and reporting their secretly held data continue routinely to be published under supposed academic leadership.

Medical journal editors have taken many valuable steps to uphold scientific and ethical standards in journal literature. Yet none of these measures challenges the exaggeration of academic roles and understatement of commercial ones upon which advocacy marketing depends.

Cultural corruption and commercial assimilation

All the practices I have described – advocacy marketing, misattribution of commercial literature, corporate ghost authorship and disposable authorship – require the participation of drug companies, marketing companies, publishers, journals and

recruited academic authors. These stakeholders all benefit according to their interests – indeed, the culture of contemporary industry publications could not endure were not the interests of all stakeholders met. Thus, academics gain prominent authorial credit, and their careers benefit from the research and publishing opportunities they find in industry partnership. Drug companies obtain publications and endorsements to promote their products. Marketers secure lucrative publications contracts with the corporations; journals receive copy for their pages; and publishers receive substantial reprint revenues. All of them benefit – and yet are able to claim that their conduct is fully ICMJE-compliant, meticulously transparent and ethical.

Lessig has defined “institutional corruption” as a state in which “there is a systemic and strategic influence which is legal ... that undermines the institution’s effectiveness by diverting it from its purpose or weakening its ability to achieve its purpose.”¹⁷ Insofar as medical research and publishing can be considered as “institutions”, then they are vulnerable to institutional corruption as Lessig has defined it, due to the systematic and strategic influence of pharmaceutical marketing.

I want here, however, to place the notion of “institutional corruption” within a more generalised framing. The drug industry, biomedical science, medicine, marketing and the publishing industry – Foucauldians would refer to the interconnected whole as a “dispositif”^{5,18} – is composed of a mesh of institutions, practices, discourses, traditions and cultures that are in a process of continual interaction and evolution. What Lessig would term “institutional corruption” occurs when commercial drives within this setting deflect the scientific, clinical and publishing domains from their traditional goals. Because commercial forces reach across many institutions and discourses, the term “cultural corruption” is to be preferred to “institutional corruption”, although the latter term remains valid within individual institutions and discourses. Yet the term “corruption” does not capture the full range

and subtlety of change wrought within science and medicine, and editorial opinions differ over whether industry’s presence is harmful or beneficial.^{19,20} Perhaps the most troubling trend is best characterised not so much as a deflection, deception or corruption of traditional academic discourse but rather a gradual *merger* between the domains of commerce and medical science, generating a hybrid research culture in which the distinction between what is scientific and what is commercial is by slow decrements becoming less apparent and less important. Such commercial-academic *assimilation* is occurring on many levels: institutions and the geographical organisation of research; universities, research groups, research personnel and academic appointments; clinical research; and publications, whose webs of small print disclosure function more to integrate than differentiate the contributions of commerce and academia. The practices described in this essay are pernicious not only in respect of advocacy marketing but also because they too subvert the boundary between what is commercial and what is not. Once commerce becomes so blended into academia that its presence becomes a mere detail, routine in nature and giving little pause for thought, then marketing’s campaign for access into the soul of medicine is won.

Policy proposals

In this essay I have argued that attribution is a poorly developed concept in medical editorial thought; that the attribution of industry literature frequently exaggerates its academic and downplays its commercial credentials, in the service of advocacy marketing; that companies are frequently corporate authors, such that corporate ghost authorship is an important problem; and that academics who make honest contributions are nonetheless contingent, “disposable authors” who

Recommendations

For any article financed by a company and reporting on its product, in which the company, its employees or hirelings have participated at any stage, the first author should be the company itself. Alternatively, the company should be named at the beginning or end of the title.

For all articles financed by industry, the Abstract and Introduction should state the article’s commercial provenance and marketing functions.

Research articles should include a dedicated “Commercial Considerations” section in the Methodology, explaining the commercial rationale and how this influenced the study design.

There should be joint measures by journals, societies, and academic institutions to ban physician advocacy from medicine.

should not front this literature. I have argued that the ICMJE *Recommendations* facilitate these practices, and that biomedical science is threatened not merely by commercial corruption, but by creeping merger between the worlds of science and commerce.

To address these issues, the medical editorial community must develop a more sophisticated conceptualisation of attribution. Editors must understand that while transparency, disclosure and documentation are vital, they do not equate with good attribution if readers are not actively presented with the most salient facts about the material they are reading. Academic lead authorship should never be allowed to

dominate attribution; and there should be vigorous measures, conducted in collaboration with academic institutions, to ban physician advocacy from medicine.

The problems of misattribution in commercial literature could be solved by taking corporate authorship seriously.

For any article financed by a company and reporting on its product, and in which the company has participated in research or manuscript development, I recommend that *the first author should be the company itself* – for example, Merck, Inc. Other authors could remain unchanged, although in my opinion writers should be co-authors. An alternative would be to begin

The problems of misattribution in commercial literature could be solved by taking corporate authorship seriously.

or end the *title* of the article with “A Merck, Inc. Trial”. In addition, for all articles financed by industry, including review articles and consensus statements, the abstract and the introduction should state: “This article has been planned and financed by Company X with assistance from YZ Medical Communications, in connection with the marketing of Drug D, a Company X product.” There should also be a dedicated “Commercial Considerations” section within the Methodology section, explaining the commercial rationale and how this influenced the review themes or study design. For instance:

“The study proprietors, XY Pharma, chose to measure 24-hour blood pressure control rather than absolute blood pressure reduction in this study in part because the investigational product they manufacture, *votasartan*, has a long elimination half-life, and is therefore likely to perform favorably according to 24-hour assessment. The proprietors chose the comparator drug, *plodipine*, in part because *votasartan* is competing for its market share, and in part because while *plodipine* yields greater absolute blood pressure reductions than *votasartan*, it has a shorter elimination half-life, offering potential advantages for *votasartan* with respect to the selected assessment criteria. The proprietors conducted the study at 35 centres rather than a small number of centres, because while statistically less robust, this enabled them to familiarise more physicians with the use of *votasartan*, which may lead to higher sales.”

These or similar measures should have been enforced by journals decades ago, but that would have been incommensurate to advocacy marketing, to academic authors, to the vanities and anxieties of professional medical culture, and to publishers eager to fill journals with literature and coffers with reprint sales. The only beneficiaries of truthful attribution and a true description of commercial considerations would be scientific integrity, the scientific record, journal readers, and their patients, whose

bodies are the ultimate target of the marketing enterprise. Measures such as these would not only prevent misattribution and reduce advocacy but would bolster the distinction between commercial and noncommercial science and combat cultural blending. To support this goal and assist research on industry practices, the US National Library of Medicine should introduce an obligatory new publication category, “Commercial”, for all industry-financed literature.

Conclusion

I end with an appeal to my friends in the pharmaceutical and publications trades. There is much to celebrate in mercantile science, as pharma’s own traditions of scientific research and discovery demonstrate. Likewise, collaboration between commerce and science can be beneficial, and whether welcome or not, increasing commercial-academic interaction is the reality we must live with. The challenge then is to maintain scientific rigor, frankness, freedom from bias, and intellectual independence in a world of growing commercial partnership. Much of today’s commercially financed medical publications culture is an exemplar for how *not* to achieve this: its output is vulnerable to bias in framing and content, may incorporate subtle commercial positioning into scientific text, and may report or discuss research that is designed to sell rather than discover; whose patient-level data are secret; and their attribution is commonly spun the better to impress readers. Many trade writers are former scientists, who understand the importance of absolute truthfulness and frankness in the way science is done, and who, I believe, know that whatever the ICMJE might allow, the published output of the pharmaceutical, marketing and publications trade too often falls short of the standards science should attain. Not only do science, medicine and patients deserve better, but the trade deserves better – to have the frankness to call itself a trade, to be open with readers about the commercial objectives of publications, to abhor euphemism, omission, understatement,

vagaries and small print in reporting industry roles, and to respect and vigorously defend the distinction between commercial and noncommercial science. In my opinion the publications trade needs new guidelines, a new trade association, and new leadership to realise these goals.

Conflicts of Interest and Disclaimers

Between 1994 and 2012 the majority of my income came from consultancy and writing services provided to pharmaceutical corporations, either directly or via marketing agencies. In 2015 I acted as a paid expert witness on behalf of the plaintiffs in a US federal legal action against a pharmaceutical corporation.

I received no support, remuneration or benefits of any kind for researching and writing this article.

I consider myself a supporter of *bona fide* scientific research including for-profit industry research but an opponent of marketing practices in the setting of scientific research and publication.

References

1. Huth EJ, Case K. The URM: twenty-five years old. *Science Editor* 2004; 27: 17-21.
2. Rennie D, Yank V, Emanuel L. When authorship fails. A proposal to make contributors accountable. *JAMA* 1997; 278: 579-585.
3. Rennie D. Integrity in scientific publishing. *Health Serv Res* 2010; 45: 885-896.
4. International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations). Available: <http://www.icmje.org/recommendations/>. Accessed November 30, 2015.

5. Matheson A. Corporate science and the husbandry of scientific and medical knowledge by the pharmaceutical industry. *BioSocieties* 2008; 3: 355–382.
6. Sismondo S. Key opinion leaders and the corruption of medical knowledge: what the Sunshine Act will and won't cast light on. *J Law Med Ethics*. 2013;41:635-43.
7. Moynihan R. Key opinion leaders: independent experts or drug representatives in disguise? *BMJ*. 2008;336:1402-3.
8. White Paper: Key Opinion Leader Identification and Selection. A Pharma Matters Report. Thomson Reuters, January 2009. Available: <http://www.slideshare.net/driceman/kol-management?related=1> Accessed November 10 2015.
9. Matheson A. The disposable author: how pharmaceutical marketing is embraced within medicine's scholarly literature. *Hastings Center Report* 2016; 10.1002/hast.576.
10. Wittek MR, Williams MJ, Carlson AM. Evidence development and publication planning: strategic process. *Curr Med Res Opin*. 2009;25:2723-7.
11. Sismondo S. Ghost management: how much of the medical literature is shaped behind the scenes by the pharmaceutical industry? *PLoS Medicine* 2007; 4: e286.
12. Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CL, *et al*. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Intern Med*. 2015;163:461-4.
13. Hoekman J, Frenken K, de Zeeuw D, Heerspink HL. The geographical distribution of leadership in globalized clinical trials. *PLoS One* 2012; 7: e45984.
14. Hirsch LJ. Conflicts of interest, authorship, and disclosures in industry-related scientific publications: the tort bar and editorial oversight of medical journals. *Mayo Clin Proc*. 2009;84: 811-21.
15. Davidoff, F, C.D. DeAngelis, J.M. Drazen, M.G. Nicholls, J. Hoey *et al*. 2001. Sponsorship, authorship, and accountability. *New England Journal of Medicine*. 345:825-826.
16. DeAngelis CD, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, *et al*. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *JAMA*. 2004 Sep 15;292(11):1363-4
17. Lessig L. "Institutional corruption" defined. *J Law Med Ethics* 2013; 41: 2-4.
18. Foucault, M. (1980). The confession of the flesh. In M. Foucault (C. Gordon, Ed.), *Power/knowledge: Selected interviews and other writings*, 194–228. Brighton: Harvester Press. P 195.
19. Horton R. The Dawn of McScience. *New York Review of Books*. March 11 2004.
20. Drazen JM. Revisiting the commercial-academic interface. *N Engl J Med* 2014;372;19:1853-4.

Author information

Alastair Matheson, PhD, worked as an independent consultant and writer specialising in product analysis, publications planning, and manuscript development in the pharmaceutical, marketing, and publications industries from 1994-2012. He has worked with over 20 medical communications agencies and most of the major pharmaceutical corporations. He retains friendships and contacts in these trade sectors.



Andrew Walker

Clinical Information Science Director
AstraZeneca
Alderley Park, UK

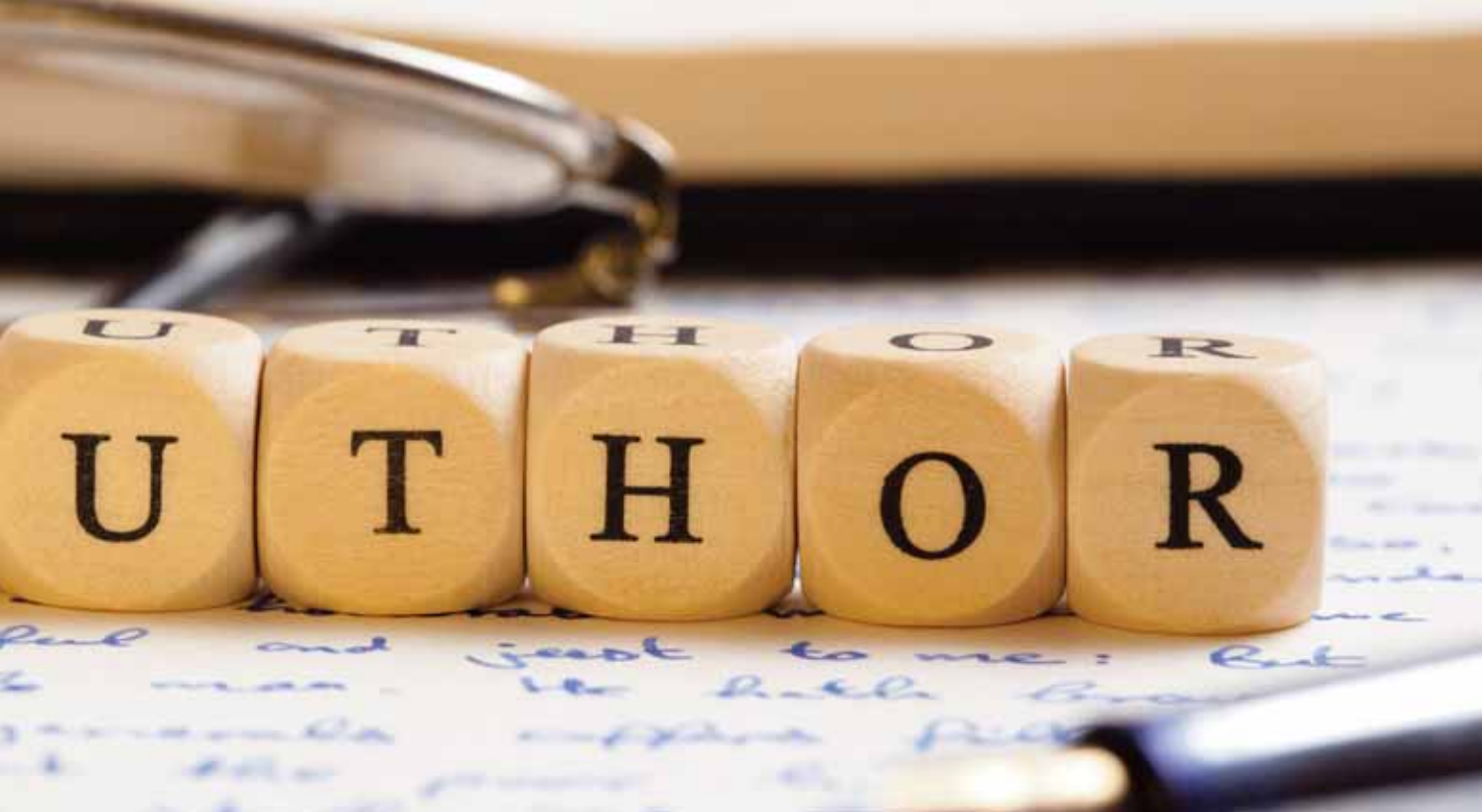
Correspondence to:

Andrew Walker
Clinical Information Science Director
AstraZeneca
Alderley Park
UK
andrew.walker@astrazeneca.com

Abstract

This interview provides solutions to some of the common pitfalls that face medical writers when working with large teams. Practical tips are provided on key topics including manuscript planning, agreeing on key messages and the use of figures, tables and other contents, deciding on the criteria for authorship, and dealing with contributors who fall short of their commitments.

Professor Ruth Roberts is founder and director of ApconiX, a pre-clinical consultancy and ion-channel expertise company based in the UK. In the last 20 years, she has published over 130 peer-reviewed research articles and reviews as well as numerous scientific posters, several book chapters and two books. In addition, she has been chief editor for several authoritative text books.



Perspective from a leading scientific author: An interview with Professor Ruth Roberts on authors and authoring

As expected, most of these publications have had multiple authors and input from large multi-disciplinary teams.

The author's questions (Q) and Professor Roberts's answers (A) provide tips for driving collaborative manuscript production including resolving authorship issues and other challenges that face anyone involved in such work.

Q: You have an impressive publication record with one article produced every couple of months. How do you find the time and inspiration?

A: I don't consider a research project or other piece of work to be finished unless it is published. In addition to analysing the data, starting work on the draft manuscript is something I really look forward to. I have to be very efficient with my time and that includes the need to set aside the time to work on papers. Because I'm so busy I look at my schedule for the coming weeks and identify time periods where I can concentrate on drafts or outlines or arrange meetings with collaborators and co-authors. Many of my outlines and initial drafts have

been put together on aeroplanes somewhere over the Atlantic whilst everyone else is watching a film.

If you're working on a manuscript with a key opinion leader or a subject matter expert, remember that they are usually busy people. It's essential to plan well ahead in order to get their input.

Q: What are the biggest challenges that you face when working with co-authors?

A: One of the perennial challenges is getting agreement on the key messages of the work. The analysis itself can be problematic but framing those messages in a way that best meets the needs of the primary audience can generate lots of discussions. Consequently, as an author, that's one of the things that I prioritise with the team at a very early stage. That said, there can also often be disagreement around identifying the primary audience. From my experience, a good paper will often span several disciplines which provide different perspectives and context. Working with such a diverse team brings about its own complications as each member usually has his or her own specific

viewpoint on key messages and the rank of importance. For example, an experimental pathologist will want to position the pathology data centrally, whereas a toxicologist might want the general toxicology data to take centre stage.

It's essential that the key messages and their priorities are discussed as early as possible and agreed at the outline stage, and certainly before proceeding with the first draft.

Q: When you're leading the development of a manuscript, how do you decide who will be an author on the paper? Are they all equal or do some contribute more than others? We're all familiar with the order of authors but what do they mean to you?

A: The first and somewhat easiest criterion I use is the contribution of data. Anyone who has contributed data during the project will be included as an author. That's the easiest one to deal with. After that it gets more complicated. People who have taken an active part in shaping the paper or who may have taken the lead in writing specific,

technical or expert sections are also included as a rule. Occasionally I may get a request to include someone's boss or co-worker because they reviewed an early draft. The political situation can be a minefield but I try to be as fair and consistent as possible. However, having said that, I find that on many occasions it's reasonable to acknowledge people who have been kind enough to review the draft and provide editorial comments. Unfortunately, they don't always see it that way and feel that such a minor contribution warrants an authorship.

Q: Indeed, sometimes inter-departmental politics can be very problematic. You must have struggled with such authorship issues and it'd be interesting to hear your tips for resolution. For example, have you had to deal with a colleague who received an acknowledgement rather than an authorship and wasn't happy with that decision?

A: I haven't struggled personally because I try to be as fair and consistent as possible but others have struggled with my decision! Usually, the problem lies around the perception of the level of contribution by an individual; it's a difficult area. I consider that reviewing the document and offering editorial comment qualifies for an acknowledgement. On the other hand, engaging with the data and offering reasoned, substantial changes to their interpretation is worthy of inclusion as an author.

With experience, it's often apparent from the outset where and with whom these issues may arise. In order to prevent derailing the process at a later stage, I distribute the International Committee of Medical Journal Editors (ICMJE) guidelines to the authoring team whilst we are agreeing on the outline for the manuscript.

On one paper earlier this year, several people who received acknowledgements for editorial comments on a recent manuscript protested that they should be authors; I responded that they were welcome to set out how their comments had altered or contributed significantly to the scientific conclusions of the paper. In the end none of them came back to challenge my decision!

Q: Having agreed who the authors are, how do you agree as a team on contents and how do you resolve any issues?

A: I usually get the team to start with a blank sheet of paper and build a story board from scratch. After the initial brain-storming session, we usually end up with bits of paper pinned all over the wall and spread over the floor. We then go through the story and determine how the proposed data or key message described on each piece of paper contributes to the manuscript. Anything superfluous to the main story gets put in 'back up' for later consideration!

One of the most challenging parts of this approach is to try and keep the story as clear and simple as possible. Quite often there is a desire from a team member to include a piece of data solely because the work has been done, as opposed to it contributing to the story. In one recent extreme case, a potential author tried to argue for inclusion of data solely on the basis that he had spent hours generating statistics and beautiful graphics. It took a while to convince him that the data, whilst wonderfully presented, weren't relevant to the paper that we were trying to construct.

It's easy to get lost in the details of the data so start with a 'rough sketch' story board – what are the key points or messages and how does one assemble them into a logical order? Use a 'straw man' to get the creativity going and be controversial to engage your team in discussion.

A good, functional storyboard may be nothing more than a sketch of the results section so resist the urge to start generating elaborate diagrams or detailed tables until you have agreed the message.

Be prepared to ditch data sets that don't add anything to the story, or even better, consider how they may contribute to the next manuscript!

Q: As a lead author, how do you deal with collaborators who don't fulfill their obligations?

A: Firmly! Like any project, developing a manuscript quickly and efficiently requires good leadership skills. Once the storyline is agreed and the authors are aware of their

responsibilities, a firm hand is needed to drive the project forward and to keep to the planned schedules. However, when dealing with co-authors, I always ensure my decisions leave me with a way forward. After all, collaboration or networking is the lifeblood of good science. In practical terms, I'll always follow up on difficult decisions with a phone call and then follow up with an email that confirms, in writing, what has specifically been agreed.

If people lose interest or don't deliver on their commitments, I will escalate the issue (usually by email so providing a written record) and state that if there has been no response by a specific date, it's assumed that they no longer want to be part of the paper. This is the ultimate sanction but no one really wants to go there.

Q: Is there one particular paper that stands out as being difficult to get into print?

A: There have been a few. A difficult one recently came from a consortium of some 40 scientists from academia, industry, and regulators that I was leading. Each of the 40 contributed to the work of the consortium to some extent but not all contributed to the paper so we had to tease apart authorship, acknowledgement, and 'no part played'. Layered on top of this was the approval to publish processes from 40 different institutions. I nearly gave up on this one but in the end dogged determination paid off! As with any project, early discussion and agreement of the story, the authorship, and good project management paved the way for a successful, if somewhat drawn out outcome.

Author information

Andrew Walker, PhD began his medical writing career in 1996 and has worked as a freelancer, as an agency writer and also in-house for AstraZeneca. In this time he has worked extensively on regulatory documents, publications and training materials.



Authorship of clinical trial documents

Raquel Billiones
Clinipace Worldwide
Zurich, Switzerland

Correspondence to:
medical.writing@billiones.biz

Abstract

Authorship of publications has been the subject of much public debate; however, authorship of clinical trial documents such as clinical study protocols, clinical study reports, investigator's brochures and informed consent forms has not really been given much attention. This article looks at the common practices of authorship attribution and signing off on these documents and examines what the ICH guidelines, on which their contents are based, say about these issues. The implications of the EMA Policy 0070 on clinical trial disclosure are discussed.

Introduction

Clinical study protocols (CSPs), clinical study reports (CSRs), investigator's brochures (IBs) and informed consent forms (ICFs) are among the most common documents that regulatory medical writers author as professionals. Unlike publications where authorship has been under scrutiny in recent years, authorship of CSPs, CSRs, and other clinical trial documents has not really been a topic of discussion. This is probably because these documents have traditionally been hidden behind the shroud of confidentiality.

However, with increasing requirements for transparency having reached the realms of regulatory documents, it is about time that authorship attribution of these documents should be considered. As we move towards posting some of these documents in the public domain, it is also important to see the implications of disclosure on the authors and signatories of these documents.

Clinical Study Protocol (CSP)

The contents of a CSP are based on ICH E6 (Guidelines for Good Clinical Practice, 1996)¹ and the ICH E6 integrated addendum (2015)². The protocol is frequently written by a regulatory medical writer who receives input from other functional groups. Contributors to the document will include, but are not limited to, a biostatistician and a medical expert. In some cases, investigators or clinical research scientists also draft a CSP with or without the support of a medical writer.

The ICH E6 guideline does not provide guidance with respect to authorship attribution of the CSP. However, it does indicate the individuals and institutions who should be signatories of the final protocol, namely, the *'investigator/institution and the sponsor'*. In signing off the protocol (*'or an alternative contract'*), these individuals and institutions thereby declare their commitment to follow the protocol and abide to the principles of Good Clinical Practice (GCP).

The CSP eventually ends up as part of appendix 16.1.1 of the CSR, which is

expected to be posted in the public domain under the EMA Policy 0070 Publication of Clinical Data for Medicinal Products for Human Use^{3,4}. Only the names of investigators may be disclosed. If other names appear in the protocol, these may need to be redacted or the concerned individuals may need to sign a waiver to disclose their personal data. Moving forward, it might be advisable for the signatories to sign off on an *alternative contract* that is not part of the main document, an option that is provided for in ICH E6.

Clinical Study Report (CSR)

CSRs are more often than not written by regulatory medical writers. The CSR has a dedicated ICH guideline (ICH E3 Structure and Content of Clinical Study Reports 1997⁵ and Q and A update 2012⁶), thus belying its importance. It is also the centrepiece of the EMA Policy 0070³ and its implementation.

Authorship is mentioned in two sections of ICH E3.

In Section 6 *Investigators and Study Administrative Structure*, the guideline recommends that a list of people ‘whose participation materially affected the conduct of the study should also be provided in appendix 16.1.4.’ This listing should include ‘...the author(s) of the report, including the responsible biostatistician(s).’

Authorship is also touched upon in appendix 16.1.5 *Signatures*. In the sample signature form provided in Annex II of ICH E3, the term *study author(s)* is used (Figure 1) but the authors are not necessarily the signatories of the CSR. The distinction between *report author* and *study author* (if any) is not clearly specified in ICH E3.

The CSR and CSP are the two most important clinical trial documents impacted by disclosure through the EMA Policy 0070. ICH E6 does not provide any guidance on authorship of CSPs. ICH E3 provides somewhat unclear recommendations for authorship of CSRs. The CORE Reference may provide much needed clarity.

Assuming that these two terms of authorship are used interchangeably, in theory, the medical writer(s) who drafted the text sections of the CSR would qualify as author(s) of the report. The biostatistician(s) who provide the statistical outputs would qualify as well. Other roles that would be considered for authorship or contributorship are the site staff (investigators and subinvestigators) as well as the sponsor and the contract research organisation (CRO) staff (if used).

In practice, attribution of authorship is usually dependent on company policy. Below are a few scenarios that I have encountered over the years.

1. Authorship of CSRs is, by default, attributed to sponsor personnel. If CSR writing is outsourced, the medical writing company, consultant or CRO will be listed in appendix 16.1.4 as being responsible for writing the CSR. However, the title page of the report would only list the name(s) of the sponsor’s responsible person(s) and one, some or all of these people will be the CSR signatories.
2. There is no authorship attribution to any individual. In many CSRs I

have written for clients, an institutional author (company name) is provided on the title page and the synopsis. A responsible medical officer on the sponsor side will sign off on the report. Appendix 16.1.4 may or may not list individuals or institutions responsible for CSR development.

3. A CSR is a shared endeavour and responsibility is across the functional groups. I have had clients who insisted on naming the medical writer, the biostatistician and the medical officer as authors of the document. Furthermore, they usually expected these authors to be signatories in appendix 16.1.5.

It is important to clarify that the authors and the signatories of a CSR are not necessarily the same people, as in scenarios #1 and #2. For the signature page in appendix 16.1.5, the minimum requirement is for the sponsor’s responsible medical officer to sign off on the document. In European studies, the signature of the coordinating investigator is also required.⁷

Scenario #3 is especially controversial as some medical writers do not feel comfortable in signing off on such an important document. With the requirement to disclose CSRs in the public domain, the reluctance to sign has increased. It should be noted that, based on the EMA policy 0070^{3,4} on CSR disclosure, sections 16.1.4 and 16.1.5 will not be posted publicly. Hence, based on the current disclosure policy, attribution of

authorship to individuals in these sections does not amount to disclosing their personal data. However, even this argument cannot allay concerns of possible legal implications.

If we argue that the terms *report author(s)* and *study authors(s)* are not synonymous, we might have to go down the road of defining metrics for an individual’s level of involvement and contribution to a clinical study. This, however, would be a discussion that is

beyond the scope of this article.

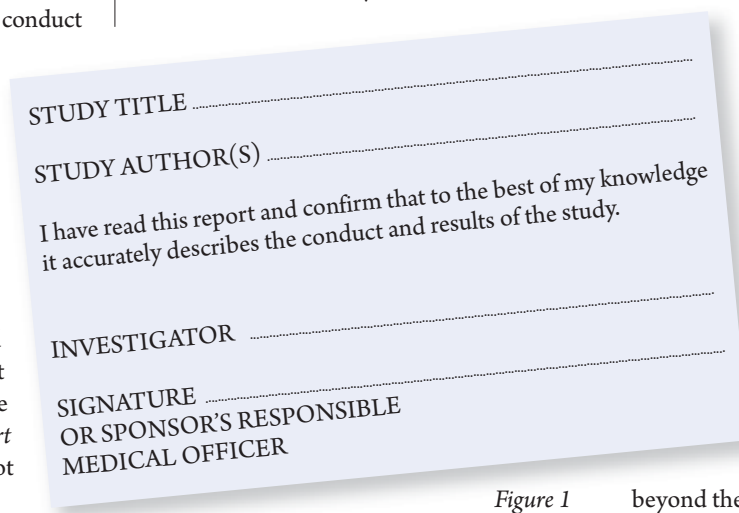


Figure 1

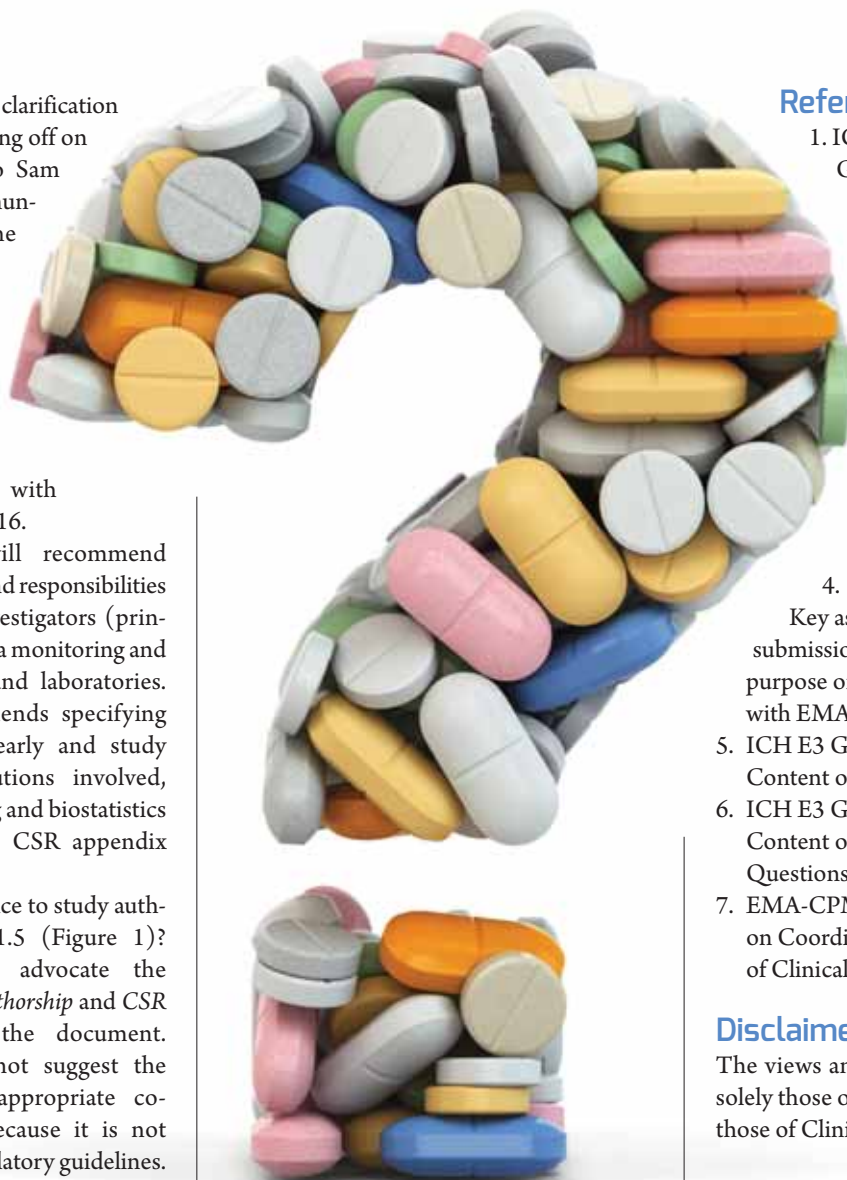
In my search for further clarification on authorship of and signing off on a CSR, I reached out to Sam Hamilton (personal communication), chair of the Budapest Working Group (BWG). This group is developing the CORE (Clarity and Openness in Reporting: E3 based) Reference as an open access user manual for CSR authors, with planned release in May 2016.

CORE Reference will recommend inclusion of a list of roles and responsibilities in Section 6 detailing investigators (principal or coordinating), data monitoring and evaluation committees, and laboratories. The BWG also recommends specifying study responsibilities clearly and study activities of the institutions involved, including report authoring and biostatistics with details provided in CSR appendix 16.1.4.

What about the reference to study authorship in appendix 16.1.5 (Figure 1)? CORE Reference will advocate the consistent use of *report authorship* and *CSR authorship* throughout the document. CORE Reference will not suggest the medical writer as an appropriate co-signatory for a CSR, because it is not mandated by existing regulatory guidelines. In reality, CSR signatories over and above those required according to ICH (or the relevant country or regional guidelines) remain a matter for individual sponsor consideration or policy.

Investigator's Brochure (IB) and Informed Consent Form (ICF)

ICH E6 also covers the contents of the IB and the ICF. As in the case of the CSP, no authorship attribution for these documents is specified in the guideline. But, unlike the CSR and CSP, these documents will not be posted publicly but will remain filed in the Trial Master File. Hence, the authorship attribution of these documents is less likely to become an important issue in the future.



Summary

In summary, regulatory medical writers continue to create key regulatory documents for clinical trials. The CSR and CSP are the two most important clinical trial documents impacted by disclosure through the EMA Policy 0070. ICH E6 does not provide any guidance on authorship of the CSP, IB and ICF. ICH E3 provides somewhat unclear recommendations for authorship of CSRs; CORE Reference may provide the much needed clarity. If handled appropriately, authorship attribution of and signing off on CSRs need not be impacted by public disclosure.

References

1. ICH E6 (R1) Guideline 1996. Guideline for Good Clinical Practice.
2. ICH E6 (R2) Guideline 2015. Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice.
3. EMA Policy 0070 02 October 2104. Policy on Publication of Clinical Data for Medicinal Products for Human Use.
4. EMA 07 September 2015. Key aspects related to the submission of clinical reports for the purpose of publication in accordance with EMA Policy 0070.
5. ICH E3 Guideline 1997. Structure and Content of Clinical Study Reports.
6. ICH E3 Guideline 2012. Structure and Content of Clinical Study Reports Questions & Answers (R1).
7. EMA-CPMP 2001. Note for Guidance on Coordinating Investigator Signature of Clinical Study Reports.

Disclaimer

The views and opinions in this article are solely those of the author and do not reflect those of Clinipace Worldwide.

Author Information

Raquel is a Senior Director for Regulatory and Medical Writing at Clinipace Worldwide. She has more than 25 years' experience as a life scientist and regulatory medical writer and is an advocate of transparency and disclosure in clinical trials. She is currently serving as Honorary Secretary on the EMWA Executive Committee.



Project management in medical publication writing: A less explored avenue in pharmaceutical companies and clinical research organisations

**Prashant Auti, Rishabh Pandey,
Vatsal Shah**
SIRO Clinpharm Private Limited,
Thane (W), India

Correspondence to:

Prashant Auti,
SIRO Clinpharm Pvt Ltd,
Kalpataru Prime, 1st floor,
Unit Nos. 3 & 4, Plot no. D-3,
Road no. 16, Wagle Industrial Estate,
Thane (W) - 400 604,
Maharashtra, India.
Tel: +91 22 6108 8145
bd@siroclinpharm.com
prashantauti23@gmail.com

Abstract

Drug development forms the core of the pharmaceutical industry. Medical writing is a key function in pharmaceutical companies and clinical research organisations that works on scientific publications and regulatory dossiers. Regulatory writing steers the drafting and submission of regulatory dossiers and safety reports to health authorities; medical publication writing on the other hand deals with scientific publications such as manuscripts, abstracts, presentations, and posters. Project management is essential for the expedited execution and seamless delivery of publication writing projects with a quick turnaround time. End-to-end project management of publication writing projects on the lines of five-stage process of the Project Management Body of Knowledge (PMBOK) is discussed in this article.

Introduction

Medical writing is a diverse field originated from the need of pharmaceutical companies to have a support function that works exclusively on regulatory submissions and commercial scientific communications.¹ This function is responsible for the analysis, interpretation, and dissemination of scientific information.² Regulatory writing steers the drafting and submission of regulatory dossiers and safety reports for health authorities; publication writing (PW) on the other hand deals with scientific publications, such as manuscripts, abstracts, presentations, and posters and falls under commercial writing.³ PW is regulated by many publication-specific guiding principles, such as good publication practice (GPP), recommendations of the international council of medical journal editors (ICMJE), consolidated standards on reporting trials (CONSORT), the committee on publication ethics (COPE) guidelines, and many others.^{1,3,4,5}

With new stringent trial disclosure policies and an industry-wide obligation to submit trial results with medical importance for publication, the importance of manu-

script publication has increased. The publication of drug research in reputed journals and at congresses increases the impact of the results in the scientific community and is a major channel of communication of scientific advances to a wide range of healthcare providers.^{1,2} A staggering number of scientific publications are published each year, with scientific output doubling every nine years.⁶ Many well-known universities across the globe, such as the John Hopkins University,⁷ the University of Chicago Graham School,⁸ and the Massachusetts Institute of Technology⁹ to name a few, have already launched courses and curriculum on medical publication/science writing and editing. Many universities even have a department dedicated to scientific publishing that keeps track of all publications and supports their drafting and editing. Nowadays various international research institutes and government agencies fund academic research with potential, with a component of the grant allocated for publication support.^{1,2}

McGuigan and Russell¹⁰ noted that the scientific, technical, and medical segment of the academic journal publishing industry generates more than US\$19 billion revenue globally. Scientific publication has increased

rapidly with the advent of highly sophisticated publication planning tools such as PubSTRAT™ (from Sylogent) and DataVision™ (from Envision pharma group). Publication planning tools have revolutionised the publication industry by accelerating the planning and execution of publication projects.^{1,2,3,6}

All these particulars illustrate that medical PW is emerging as one of the most important departments in pharmaceutical companies, publication houses, and clinical research organisations (CROs). Due to the huge expenditure of time and money in addition to regular expenses such as research and manufacturing, many pharmaceutical companies outsource PW work to CROs or pharma knowledge processing and outsourcing (KPO) companies. Irrespective of the type of company, there is always a requirement to have set processes in place for the seamless execution of a project, which brings the principles of project management into the picture. Challenges faced in the execution of PW projects are unique and different than those faced in conventional regulatory medical writing. In this article, we discuss project management in the PW department of a pharmaceutical company or a CRO/KPO.

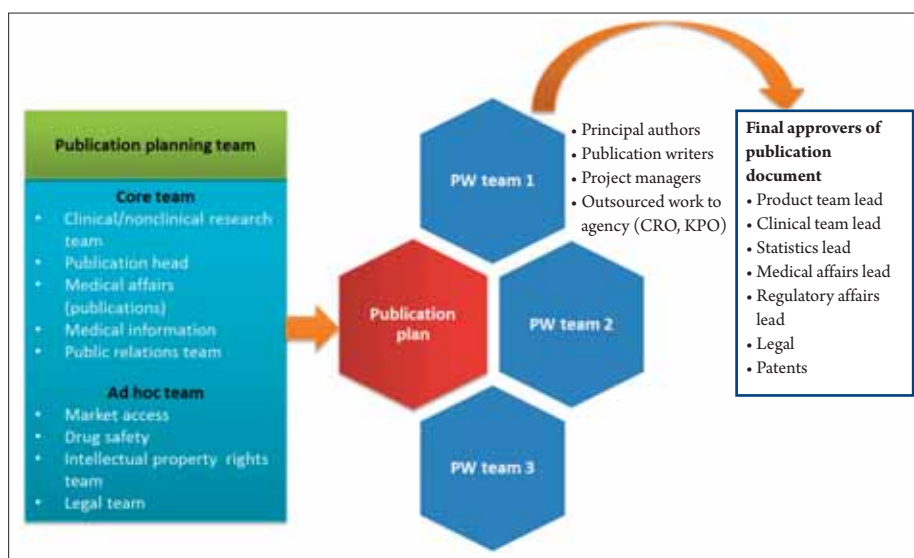


Figure 1: Publication writing team structure Abbreviations: PW, Publication writing; CRO, Clinical research organisation; KPO, Knowledge processing and outsourcing Note: PW team 1, 2, 3 represents PW teams working on various deliverables/projects.

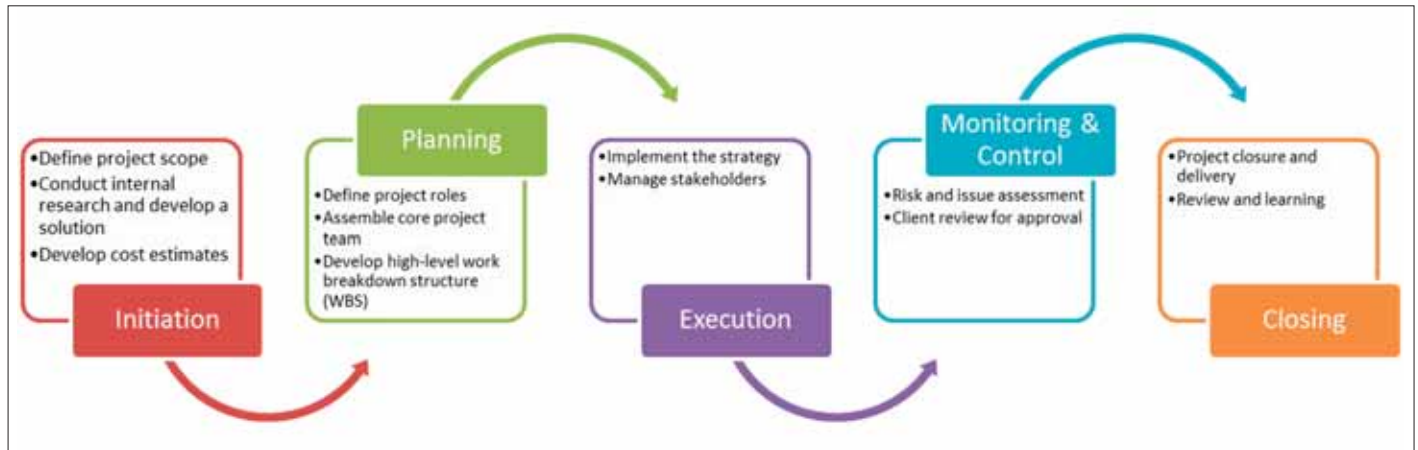


Figure 2: Implementation of project management based on PMBOK framework

Project Management in Medical Publication Writing in line with the PMBOK Framework

Before discussing the actual process of project management in PW, let us first understand the structure and function of a PW team in a pharmaceutical company or CRO. A PW team comprises trained professionals who have higher degrees in the life science domain, including, but not limited to, pharmacy, medicine, and clinical research. The schematic depiction of the working of a PW team is shown in Figure 1. The structure of a PW team may however vary depending on the functionality and size of the organisation.^{1,2,3}

We propose a process of managing a PW project in line with the five process groups recognised in the Project Management Body of Knowledge (PMBOK) published by the Project Management Institute (PMI).¹¹ Among the many different deliverables in PW projects, most frequently encountered are abstracts, posters, and manuscripts. Development of any medical publication document can be divided into five process groups: Initiation, Planning, Execution, Monitoring and Control, and Closing (Figure 2).¹¹

Initiation

Publication planning is a key aspect in the project management of PW. A publication plan is developed by the publication steering committee and scientific publication team, with the involvement of the publication lead and writers. The publication plan is developed in line with the drug development and product life-cycle by considering

evaluations such as the needs assessment, and internal and external gap analyses. The publication planning team plans publications at every stage of drug development and also based on the medical queries they receive at the medical information management department.^{12,13}

Project management in medical PW begins with the definition of the objectives and scope of the project. While pharmaceutical companies have a publication plan¹² ready as part of a drug's development, project management of a PW project in a CRO varies in the processes followed. In the case of CROs, the project is understood by communicating with the client (usually a pharmaceutical company or other service provider agency) and the drafting of a statement of work or a project charter. This is often achieved by conducting a kick-off meeting following a formalised handover from business development to operations. The very first step to initiate the project is requirement gathering, where open-ended questions are asked to determine the project specifications. For example, to develop a manuscript, the following particulars can clarify project specifications: author documentation (debarment, legal agreements with external authors, authorship invitation), availability of data sources (reports, existing publications, study protocol, statistical plan, or any other data source), the need for a comprehensive literature search (important for reviews and meta-analyses), quality control (data and editorial checks), and the number of review cycles.^{14,15} In the case of a CRO project, the scope should be discussed in great detail

with the client so that the expectations of both parties are aligned. For example, if the CRO is requested to use the client's standard operating procedures (SOPs), they should be analysed to see if they will affect the time management aspects of the project. After the scope is defined and understood, internal research and discussion are conducted and a solution is devised. Internal team meetings are arranged where the project manager and medical writers discuss how to proceed with the project. The strategies and processes to be followed for the timely delivery of the project are defined, i.e. the project is set up in a publication planning tool where timelines and stakeholders for each draft stage (initial draft, first draft, second draft, and final draft) of the deliverable (manuscript/poster/abstract) are defined.¹⁶ After the requirement gathering, internal research and preparatory activities are carried out to determine the deadline for each milestone. This includes the sharing of a content outline and getting its approval from the client. Cost estimates for publication planning in pharmaceutical companies are prepared by the publication steering committee and the finance department. In CROs, they are usually prepared during the business development phase while negotiating with the client. Estimated project hours and billable hours per resource are taken into consideration to develop a cost estimate.^{11,12,13}

Planning

The planning stage begins once all project specifications are defined and a unique solution has been proposed. The first step is

Pharma company	Brand Name	Study ID (Generic name)	Deliverable	Write	Subject matter expert reviewer	Quality reviewer	Start date	End date	Actual project hours
A	X	1A	Manuscript	P	CD	DE	1-Jun-15	12-Aug-15	105
B	Y	1B	Congress poster	Q	GH	HI	7-Jun-15	28-Jun-15	64
C	Z	1C	Scientific abstract	R	LM	MN	2-Jun-15	11-Jun-15	18

Table 1: An example of a project tracker sheet

Tasks	Technical Assistant	Project Manager	Publication Writer	Review Team	Authors	Approvers	Graphic Designer
Requirement gathering and project set up	R	R, A	C, I	O	C	O	O
Kick-off and author documentation	R	R, A	R, I	O	R, C, I	O	O
Drafting and comment addressing	O	A	R	O	C	O	O
Review of the first draft	O	A	I	R	R	O	O
Design work; creating tables, figures, layout, etc	O	A	R, C	I	C, I	O	R
Review of the final draft	O	A	I	R	R	O	O
Final approval	O	A	R	O	I	R	O
Submission	R	A	A	O	I	I	O

Adapted from: Dubois B. Fostering collaboration. *The Write Stuff*. 2011;20(4):219-21.

Abbreviations: R, Responsible; A, Accountable; C, Consulted; I, Informed; O, Omitted from the loop.

Note: the lead statistician is generally listed as an author; this matrix may change as per organisation structure and its requirements

Table 2: An example of a responsibility assignment matrix for writing a manuscript

the assignment of project roles, which can be achieved based on the skills documented in the work profile of the writer and the writer's position in the organisation. A writer's work profile should be well categorised with regard to their competencies, prior experience, and their therapeutic area expertise. Tasks such as complex manuscripts, manuscripts, or posters with limited data sources, review articles, and primary manuscripts can be handed over to a senior publication writer who has ability to interpret statistical data whereas the task of drafting an encore abstract or poster can be given to a junior publication writer.¹⁷ In the case of CROs where there are no dedicated project managers, the publication lead might work as a writer-cum-project-manager and manage internal and external communications. He/she also has to ascertain if the contribution of assistant teams, such as publication technical support (handling the publication tracking tool and other technicalities) or the graphic design team, is needed, and if yes, to what extent. The availability of resources with the required skills at a given time can be tracked using

online time management tools and a common project tracker sheet.^{11,17} An example of a project tracker sheet is provided in Table 1.

The availability of full-time employees should be assessed quarterly as to whether there is a need to allocate work to freelancers, other agencies, or vendors.¹⁷ Overall availability is calculated based on the number of project and non-project hours. Non-project hours include employee leave and activities such as skillset training, self-learning, corporate activities, SOP training, and the maintenance of the staff training folders. While assigning project roles, the project manager should always pay heed to the requirement of a back-up writer as part of the risk mitigation strategy. A back-up writer can do "fire-fighting" in cases where the primary writer is unavailable due to ill-health or other emergent work. Meticulous resource planning is important to the successful implementation of the project, since the definition of the project roles and the formation of the project team are based on this. A responsibility assignment matrix¹⁸ is one such tool to define project roles in

cross-functional/inter-departmental business/project processes. An example of responsibility assignment matrix in a PW project for writing a manuscript is given below (Table 2).¹⁹

Once the project roles have been assigned, a work breakdown structure²⁰ is created where an activity is divided into smaller tasks and these tasks are assigned to team members. An example of a work breakdown structure for writing a manuscript is given in Figure 3 overleaf.

Execution

The execution phase in medical writing includes working in accordance with SOPs to complete a particular task. For PW, it basically involves the drafting of the document, review cycles, performing quality checks, and addressing comments provided by internal and external stakeholders. Sometimes project managers also have to deal with external agencies, giving rise to vendor management. In the case of CROs, vendors could include translation agencies, printing and publishing support vendors, or freelance service providers.

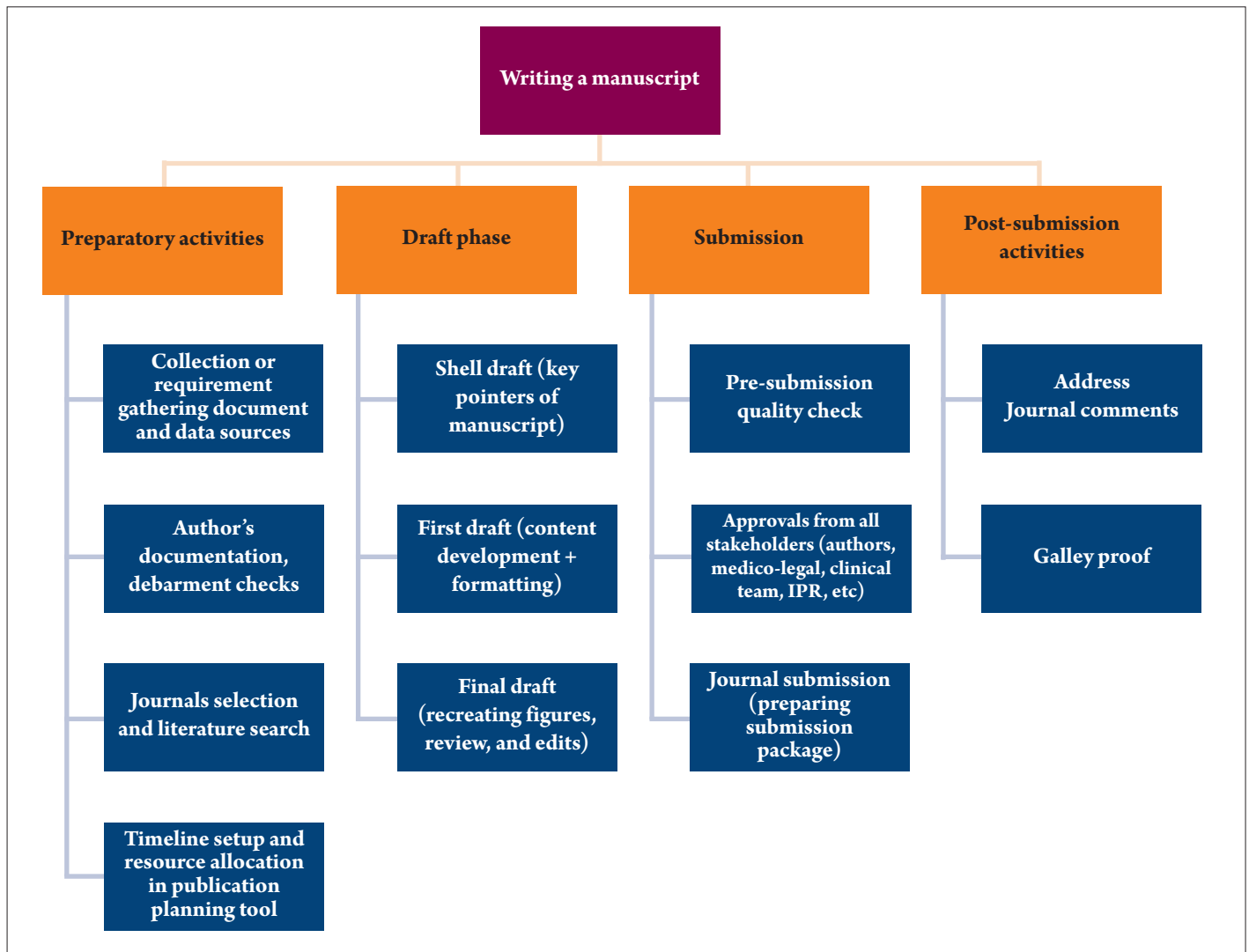


Figure 3: Work breakdown structure for drafting a manuscript. Abbreviations: IPR, Intellectual property rights

Offshore operations management is important for CROs working in different geographical locations all over the globe. Offshore operations are carried out through a global hybrid delivery model considering geographical, cultural, and chronological variations. The project manager drives execution against the plan and has to communicate regularly and openly with the sponsor.^{14,17,21}

We shall now review the important steps in the drafting of a manuscript. Initially, a shell draft is written that includes all important subject matter points in the form of bulleted text for the introduction and discussion sections and text paragraphs for the methods and results sections. Comments requesting input or suggestions to researchers or authors are put in the shell draft. Once the shell draft is approved, the

first draft of the manuscript is written with input from researchers and authors. Once the first draft is written, the scientific content of the entire manuscript is reviewed by the core publication planning team and comments are provided in case of inconsistencies, which are then addressed by the publication writers. Once the first draft is approved, the writers prepare the second draft in accordance with the journal guidelines. The second draft is generally considered to be the final draft; however additional drafts can be made depending on the number of review cycles and project requirements. Stakeholders involved in final approval are the researchers, medico-legal team, intellectual property team, regulatory team, statistics head, and the clinical team head.^{14,17,21}

The line of reviews includes an in-house

review by an internal subject matter expert (SME) and an editor. SME review involves a diligent check of the scientific content, the correct interpretation of the data, important discussion points, tone of the overall message (language should not sound promotional), and the proper citation of references. In the case of CROs, points of contact (POCs) from the sponsor (i.e. the client) will review the content from their perspective. Editorial review is done by the medical editors to check grammar and language. The writer-cum-project manager acts as a bridge during such reviews as they communicate and address comments, meticulously check content, propose solutions, and involve the statistician or main author regarding any queries.

Submission of the manuscript to the journal or conference involves a mock

Deliverable	Risk	Impact	Action Plan
Conference abstract or oral presentation or poster	Difficulties updating results from ongoing clinical trials or late-breaking clinical trial results	Failure to disseminate key results of trial during conference	<ul style="list-style-type: none"> • Publication team should plan pre-presentation meeting with clinical lead to incorporate final data/results
Poster and oral presentation for medical conference	Failure to capture important data due to limits on word count, slide count, or poster size	Poster with no scientific impact, poster does not convey the intended scientific message	<ul style="list-style-type: none"> • Prepare ancillary (back-up) slides in case of presentation • In case of poster, prepare handouts or generate a QR code linked with additional information
Manuscript writing	Minimal data sources provided by study sponsor	Manuscript may lack impact	<ul style="list-style-type: none"> • Ask for credible sources, especially the CSR of the study and arrange a kick-off meeting with the authors to discuss future directions and flow of manuscript
Manuscript writing	Targeting high-tier journal with high rejection rate	Manuscript might be rejected or major revisions suggested by journal leading to delayed publication	<ul style="list-style-type: none"> • Prepare a list of preferred journals with their specifications (impact factor, rejection rate, circulation) from publication planning tools and discuss with authors • Draft a pre-submission query to journals regarding their interest to publish particular research work • Be ready with back-up journals and their submission guidelines <p>Abbreviations: CSR, clinical study report; QR, quick response.</p>

Table 3: Example of a risk register for publication writing projects

submission with the help of the publication technical expert, preparation of a submission package, and communicating with the journal or conference secretariat.

Monitoring and Control

The monitoring and control phase of a project consists of risk management measures and review by the stakeholders. As Murphy's Law says 'Anything that can go wrong will go wrong' and risks are associated with every project. Risk management is one of the most critical aspects of project management. Hence the risk identification and mitigation plan should always be at the disposal of the project manager. It is important to list all possible risks that may be encountered in the project and have an action plan ready so that the risks do not become issues. An example of a risk register is shown in Table 3.^{11,16,22}

Corrective action and preventive action (CAPA) is another approach for managing risks.²³ Corrective action aims at correcting

an existing non-conformity and to avoid recurrence of the same non-conformity. Corrective action comes into the picture when issues have been logged or risks have been identified during audit findings, major client reviews, etc. Preventive action on the other hand aims to avoid the initial occurrence of non-conformity by proactively implementing improvements. In brief, CAPA acts as a solution to the issues or risks encountered in the light of integrated quality management. Gantt charts can be used to note employee engagement and to track the timelines of the project. One more way of tracking deviation in the process and keeping corrective measures ready is by employing a fishbone analysis (Ishikawa diagram). A fishbone analysis for deviations and their proposed solutions for a PW project are given in Figure 4.

Closure

Project closure involves close-out documentation and review meetings. Close-out

documentation is a final information dossier and includes all the relevant project-related logs, minutes-of-meeting reports, business emails, etc. These documents contain all important project specifications, decisions made, and measures employed, as well as information on the overall course of the project. Important aspects captured in the close-out dossier include risks and issues, project quality, lessons learnt, and an overall analysis underlining achievements made and pitfalls encountered during the execution. From the kick-off meeting to project delivery, many lessons are learnt in each phase of the process, which can be discussed and shared as a group. The mistakes made in the execution of the project and solutions offered therein go into a knowledge base to be used for future reference. Special lessons learnt meetings are arranged to broaden the knowledge and troubleshooting experience of the resources involved in the project.

Preparing a data sheet comprising all

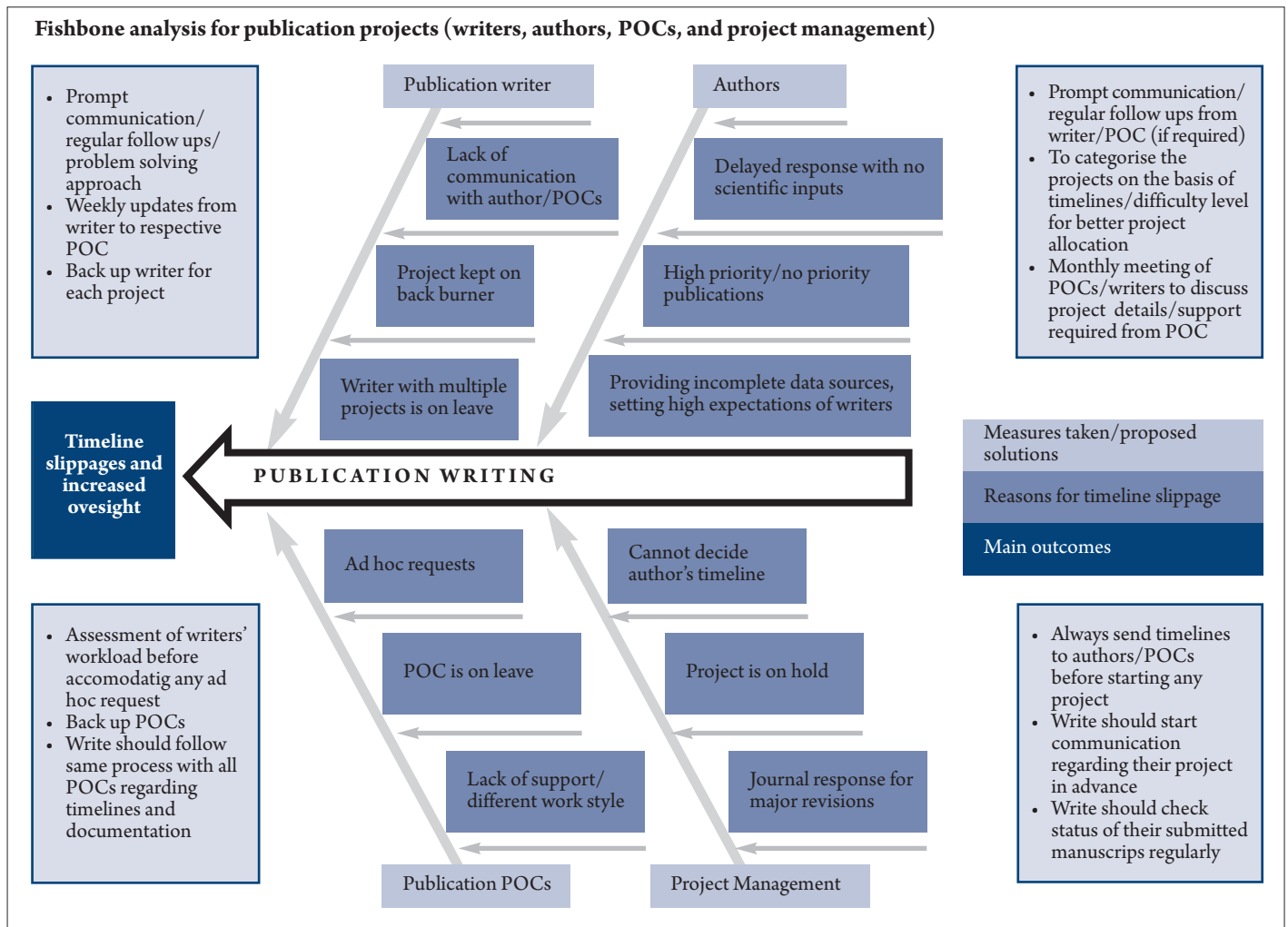


Figure 4: Risk mitigation fishbone analysis. Abbreviations: POC, Point of contact (Acts as a bridge between medical writer and authors and other stakeholders)

detailed information about a project compound (drug), such as the molecule ID, history, generic term, drug class, and pharmacology, safety, and efficacy studies of that molecule, creates a knowledge base, which can be utilised in the future. Closure also involves keeping all documents in an inventory, such as issue logs, logs of project risks and mitigation strategies, and the archiving of the published deliverable.

We have discussed how projects are executed in medical writing organisations. Let us now see the various issues faced in project management. Barriers to effective project management include communication hurdles, a lack of status-reporting measures, a low accountability culture, and conflicts in decision-making. Communication hurdles include language barriers or different interpretations of the intended message. Working with non-English speakers

can pose significant problems due to the incomprehension of or misunderstandings regarding requirements. Services of translation agencies and interpreters can help overcome these issues. The project manager should communicate clearly while interacting with the POCs. The project manager needs to be able to negotiate effectively with vendors and should be endowed with good interpersonal skills. Each resource working on the project should be given ample freedom as well as accountability for the seamless execution of the project. There should be an efficient risk reporting system so that the risks do not become issues. In addition, the project manager should be able to manage resources and resolve conflicts. The behavioural and communication aspects of a manager are instrumental to the progress of the project.^{24,25}

Project Management in Medical Publication Writing: Future Directions

The success of the project lies in the several process improvement methods and diligent contribution of the assigned resources promoting quick and smooth functioning. Process improvement methods can further help expedite project delivery timelines and reduce costs. Capability maturity model integration²⁶ is a sophisticated process improvement plan that can be implemented by pharmaceutical companies as well as CROs in medical affairs or medical writing departments. In the case of CROs, capability maturity model integration appraisal additionally wins the confidence of the client and can help attract new projects and business for service industries. The global hybrid delivery model, a relatively new approach to carrying out project work in

accordance with client specifications in CROs, enables the seamless execution and delivery of a project. It basically involves two working teams, one offshore and the other onsite, which coordinate with the client and each other to give effective output. The lean six sigma initiative is a business improvement strategy that aims to improve team performance by integrated efforts and removing redundancy. This business strategy improves cross-functional teamwork in any process driven service industry and also reduces the cost of poor quality resulting from late delivery, customer complaints, costs associated with misdirected problem solving, etc.²⁷ There have been attempts at harmonising and implementing lean six sigma and PMBOK principles in pharmaceutical organisations.^{28,29} The future of any product, process, or service lies in innovation. Novel and innovative approaches that minimise process hurdles and make project execution smooth and error free are the future ideals of project management.

Conflicts of Interest and Disclaimers

The authors declare no conflict of interest. The opinions expressed here are solely those of the authors and not necessarily those of SIRO Clinpharm Pvt Ltd.

References

1. Wager E. Publishing clinical trial results: The future beckons. *PLoS Clin Trials*. 2006 Oct 27;1(6):e31.
2. Pakes GE. Writing manuscripts describing clinical trials: a guide for pharmacotherapeutic researchers. *Ann Pharmacother*. 2001;35(6):770-9.
3. Sharma S. How to become a competent medical writer? *Perspect Clin Res*. 2010;1(1):33-7.
4. Norris R, Bowman A, Fagan JM, Gallagher ER, Geraci AB, Gertel A, et al. International Society for Medical Publication Professionals (ISMPP) position statement: the role of the professional medical writer. *Curr Med Res Opin*. 2007;23(8):1837-40.
5. Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CL, et al. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med*. 2015;163(6):461-4.
6. Van Noorden R. Global scientific output doubles every nine years. 2014 [cited 2015 Nov 27]. Available from: <http://blogs.nature.com/news/2014/05/global-scientific-output-doubles-every-nine-years.html>.
7. John Hopkins University. Science writing at Hopkins. 2015 [cited 2015 Nov 27]. Available from: <http://advanced.jhu.edu/academics/graduate-degree-programs/writing/the-experience/science-writing-at-hopkins/>.
8. University of Chicago Graham School. Medical writing and editing. 2015 [cited 2015 Nov 27]. Available from: <https://grahamschool.uchicago.edu/noncredit/certificates/medical-writing-editing/index>.
9. Massachusetts Institute of Technology. MIT graduate program in science writing. 2015 [cited 2015 Nov 27]. Available from: <http://sciwrite.mit.edu/>.
10. McGuigan GS, Russell RD. The business of academic publishing: a strategic analysis of the academic journal publishing industry and its impact on the future of scholarly publishing. *E-JASL*. 2008, 9(3). [cited 2015 Nov 27]. Available from: http://southernlibrarianship.icaap.org/content/v09n03/mcguigan_g01.html.
11. Project Management Institute. A Guide to the Project Management Body of Knowledge (PMBOK® Guide). 5th ed. Newtown Square, Pennsylvania USA: Project Management Institute, Inc.; 2013.
12. Fugh-Berman A, Dodgson SJ. Ethical considerations of publication planning in the pharmaceutical industry. *Open Med*. 2008;2(4):e121-4.
13. Sismondo S, Nicholson SH. Publication planning 101. *J Pharm Pharm Sci*. 2009;12(3):273-9.
14. Armstrong JS. Peer review for journals: Evidence on quality control, fairness, and innovation. *Science and engineering ethics*. 1997;3(1):63-84.
15. Johnson C, Green B. Submitting manuscripts to biomedical journals: common errors and helpful solutions. *J Manipulative Physiol Ther*. 2009;32(1):1-12.
16. Atkinson R. Project management: cost, time and quality, two best guesses and a phenomenon, its time to accept other success criteria. *Int J Project Man*. 1999;17(6):337-42.
17. De Looze S. Are we nearly there? Resource planning – step by step. *The Write Stuff*. 2008;17(3):127–32.
18. Melnic AS, Puiu T. The management of human resources within projects: the structures of the project team, the responsibility assignment matrix. *Economy Transdisciplinarity Cognition*. 2011;14(1):476-84.
19. Dubois B. Fostering collaboration. *The Write Stuff*. 2011;20(4):219-21.
20. Globerson S. Impact of various work-breakdown structures on project conceptualization. *Int J Project Man*. 1994;12(3):165–71.
21. Pololi L, Knight S, Dunn K. Facilitating scholarly writing in academic medicine. *J Gen Intern Med*. 2004;19(1):64-8.
22. Williams TM. Using a risk register to integrate risk management in project definition. *Int J Project Man*. 1994;12(1):17-22.
23. Motschman TL, Moore SB. Corrective and preventive action. *Transfus Sci*. 1999;21(2):163-78.
24. Matthews JR, Matthews RW. Successful scientific writing: a step-by-step guide for the biological and medical sciences. 4th ed. Cambridge, UK: Cambridge University Press; 2014.
25. El-Sabaa S. The skills and career path of an effective project manager. *Int J Project Man*. 2001;19(1):1-7.
26. Team CMMI Product. Capability Maturity Model® Integration (CMMI SM), Version 1.1. CMMI for Systems Engineering, Software Engineering, Integrated Product and Process Development, and Supplier Sourcing (CMMI-SE/SW/IPPD/SS, V1. 1) (2002).

27. Antony J. Six Sigma in the UK service organizations: results from a pilot survey. *Managerial Auditing Journal*. 2004;19(8):1006–13.
28. Herskovitz M. The harmonization of DMAIC and the PMBOK® guide for pharmaceutical lean six sigma projects. 2011 [cited 2015 Nov 27]. Available from: <http://www.projectmanagement.com/articles/283581/The-Harmonization-of-DMAIC-and-the-PMBOK-Guide-for-Pharmaceutical-Lean-Six-Sigma-Projects>.
29. Swanson SA. Winning pair: Integrating six sigma and PMBOK guide at an organizational level. 2011 [cited 2015 Nov 27]. Available from: <http://www.projectmanagement.com/articles/285914/Winning-Pair-Integrating-Six-Sigma-and-PMBOK-Guide-at-an-Organizational-Level>.

Author information

- **Prashant Auti**, MS (Pharm) has experience of working in the medical communications, HEOR, and medical publication writing groups of various organisations. He has supported scientific writing activities for several pharmaceutical giants. Prashant is currently associated with the scientific writing and communications team of SIRO Clinpharm Pvt Ltd, India.
- **Rishabh Pandey**, PhD is associated with the scientific writing and communications team at SIRO Clinpharm Pvt Ltd, India. He has more than 20 publications to his credit in numerous peer reviewed journals and experience as a journal reviewer. As a publication writer he has supported the publication groups of various pharmaceutical companies.
- **Vatsal Shah**, MD has vast experience in medical writing. He has been involved in establishing and managing medical writing departments across different pharmaceutical companies in India. He is currently working as chief operating officer at SIRO Clinpharm Pvt Ltd, India.

Never say never! Returning to full-time employment after freelancing

Alison McIntosh

ICON Clinical Research UK Ltd
Chandlers Ford
Eastleigh, Hants
United Kingdom

Correspondence to:

Dr Alison McIntosh
ICON Clinical Research UK Ltd
6 Stonecroft Rise
Chandlers Ford
Eastleigh, Hants
United Kingdom, SO53 3LD
Tel +44 (0)2380 688713
Alison.McIntosh@iconplc.com

Abstract

Alison McIntosh successfully operated as a freelance medical writer for 14 years and gave up the 'flexible lifestyle' of a self-employed freelance medical writer to become a full time employee. She has joined a growing band of 'decentralised' office workers and has become an employee of ICON Clinical Research, a full service, world-wide clinical research organisation (CRO). She has stepped from one end of the medical writing spectrum to the other in terms of working arrangement and organisational structure. The skills needed to work for a large CRO align well with those of a freelance medical writer. Whilst major benefits of joining a large organisation have included colleagues to share the workload, and well defined department structures, new company jargon together with the number of standard operating procedures have been a more challenging experience.

I have been a medical writer for the pharmaceutical industry for 20 years. My



medical writing career began when, after working as a postdoc, I became a full time employee with Wellcome (now Glaxo-SmithKline). After 5 years as an employee, I made the momentous decision to become a freelance medical writer and found gainful employment in this capacity for 14 years.

Most of my freelance years were during what I like to refer to as the 'pre-blog era.' As such, I documented my medical writing journey in articles published in the EMWA journal. My first ever EMWA article was entitled "Medical Writing at Home" and covered my significant change in direction, relaying important first steps along the road of a freelance medical writing career.¹ Alongside this, I documented my first attendance at an EMWA conference,² my experience of developing an EMWA workshop,³ and how my years as a freelance medical writer progressed and my medical writing experience developed.^{4, 5}

Setting off on a New Medical Writing Journey

A new episode in my medical writing journey began in June 2014 when I gave up the "flexible lifestyle" of the self-employed, freelance medical writer to become a full

time employee again. My employer is ICON Clinical Research, a full service, world-wide clinical research organisation (CRO). This change in status allowed me to truly step from one end of the medical writing spectrum to the other in terms of my employment arrangement and organisational structure.

At first glance, joining a large CRO may have seemed like a strange move for someone who had worked as a sole trader for such a long time, but for some time previous to making the move, I had felt that I needed new challenges. When I considered what I wanted to achieve, working for a CRO seemed to me like a natural progression as I thought the freelance skills that I had built up were ideally suited to this environment.

During my 14 years as a freelance medical writer I had essentially operated as a CRO in miniature (Table 1 overleaf). I had a broad client base, and I had learned how to provide a service to these clients that met their requirements and needs. I was adept at meeting tight deadlines and being flexible in terms of working arrangements. Through the years I had gained the ability to transform client requirements into well written

documents of a high standard. Since I had also been exposed to a variety of different document types, for me it was also important that I maintained an exposure to regulatory writing whilst also continuing to have the opportunity to write medical communications documents.

I have now joined a growing band of 'decentralised' office workers working from home on a permanent basis. When I first became a freelance medical writer the opportunity to pursue this type of working arrangement was limited, not least because of the lack of reliable home internet facilities. In 2000 these were primitive to say the least. Who among us remembers the long cables that were originally needed to connect a computer to the phone line for dial up internet services using AOL as a service provider? These limited internet connections made downloading a document bigger than 1 or 2 pages an impossibility – and sometimes even 1 or 2 pages took hours! This limitation is definitely a thing of the past. Working from home nowadays means you have access to everything you would have in the office, including all the servers and back-up systems you expect from working for a large

Individual Skill	Large CRO	Freelance MW (mini CRO)
Broad client base	X	X
Interaction with many different clients	X	X
Understand the individual needs of clients	X	X
Developing new clients	X	X
Understand what is required to meet agreed deadlines	X	X
Project management skills	X	X
Awareness of budgets	X	X
Awareness of time required to completed writing tasks	X	X
Different types of medical writing ^{a, b}	X	X
Regulatory	X	X
Medical Communications	X	X

^a This skill is based on the medical writer’s personal experience and the different documents they have written or audiences they have written for.

^b Not all clinical research organisation offer the ability to write both regulatory and medical communications documents.

Table 1 Matched Skill Set of Freelance Medical Writer and Clinical Research Organisation

company. Everything is completed online with only an occasional visit to the office required.

Has the Change been Positive?

Of course, there are pros and cons associated with making what many might consider a ‘giant leap’. Major positives are friendly colleagues with whom I can discuss challenges and share the workload. The problem of conducting independent quality control of documents has also disappeared as there is a distinct process in place to achieve and verify these important stages of document development. There are well defined department structures and for the first time in around 15 years I found myself looking at an organogram with my name on it. Joining a large organisation also exposes you to company jargon and many, many standard operating procedures (SOPs). The sheer number of SOPs was one of the most challenging features of joining a large CRO, but after more than 1 year in the job this aspect has become routine in nature.

Continuous professional development (CPD) is something that we all have to be aware of and pursue. As a freelance medical writer you are responsible for organising and paying for your own CPD, and committing to regularly attending EMWA conferences over the years has allowed me to keep abreast of new developments in the pharmaceutical industry. I now have an employer that ensures there are on line

learning facilities available to me in the workplace together with other CPD opportunities. There is just not enough time in the working day to avail myself of all the possibilities on offer.

Advice to Others?

My main advice to all medical writers, and not just those who are working in a freelance capacity, is to always keep your options open, and do your utmost to grow professionally. As a freelance medical writer, regularly attending EMWA conferences to keep up to date with advances and changes in the industry was of enormous importance to me. Playing an active part in EMWA, the organisation, can pay huge dividends not only when looking for opportunities as a freelancer, but also if you decide to change direction at a later stage in your career.

Overall, my change in career direction has provided me with new challenges as a medical writer and increased my professional experiences. I understand that it is not a direction that all freelance medical writers will choose to follow and is heavily dependent on factors that are specific to the person concerned. However, for me it has been the right move at the right time. Although I have fewer holidays, and may have a little less flexibility in the work I undertake, I had my first paid holiday in over 14 years and I think it was all the more relaxing because of this.

Conflicts of Interest and Disclaimers

Alison McIntosh is an employee of ICON Clinical Research UK. She is also a workshop leader for EMWA, a section editor of *Medical Writing* and has served on the EMWA Professional Development Committee.

References

- McIntosh A. Medical Writing at Home. *The Write Stuff*. 2001;10(4):82-83 (available from http://www.emwa.org/documents/journal/TWS/The%20Write%20Stuff_Vol%2010_No%204_2001.pdf).
- McIntosh A. CTD Seminar in Brighton. *The Write Stuff*. 2002;11(1):9-10 (available from http://www.emwa.org/documents/journal/TWS/The%20Write%20Stuff_Vol%2011_No%201_2002.pdf).
- McIntosh A. Developing a Workshop for the EPDP. *The Write Stuff*. 2002;11(3):64-65 (available from <http://www.emwa.org/documents/journal/TWS/TWS%202002%203%2011.pdf>).
- McIntosh A. Round Robin. *The Write Stuff*. 2005;14(1):19-20 (available from <http://www.emwa.org/documents/journal/TWS/TWS%202005%201%2014.pdf>).
- McIntosh A. Broad-Spectrum Medical Writer: Nature or Nurture? *The Write Stuff*. 2009;18(1):7-8 (available from <http://www.emwa.org/documents/journal/TWS/TWS%202009%201%2018.pdf>).

Author information

Alison McIntosh has been a medical writer for 20 years. She was initially employed by Wellcome (formerly GlaxoWellcome, now GlaxoSmithKline) for 5 years, before becoming a freelance medical writer and trading as AAG Medical Writing for 14 years. Her broad medical writing experience covers both regulatory writing and medical communications.

Fifth EMWA freelance business survey

Jonathan Edwards¹, Alistair Reeves² and Adam Jacobs³

¹ Macclesfield Medical Writing Ltd, Macclesfield, UK

² Ascribe Medical Writing and Translation, Wiesbaden, Germany

³ Premier Research, Wokingham, UK

Correspondence to:

Jonathan Edwards
Macclesfield Medical Writing Ltd.
Macclesfield, UK
jonathanedwards2718@gmail.com

Abstract

Following surveys in 2003, 2007, 2010 and 2012, the fifth EMWA Freelance Business Survey was conducted in 2015. 181 respondents, most based in Europe, completed the survey. The findings indicate that freelance medical writing and related activities continue to offer a varied and potentially lucrative business opportunity. The responses received indicate a wide range of types of work and client, from niche opportunities to more traditional medical writing activities. In addition, freelancing offers unique flexibility, as indicated by the range of hours worked. Chargeable rates have been stable since the first survey in 2003, and it appears that the freelance environment remains a healthy place within which to operate.

Introduction

This fifth survey follows those conducted in 2003, 2007, 2010 and 2012.^{1,2,3,4}

The survey has developed considerably, from the initial paper-based questionnaire distributed at the Freelance Business Forum held at the EMWA spring conference in 2003, to an online system shared with all potential respondents via SurveyMonkey. The number of respondents has grown almost three-fold, from 63 for the first survey in 2003 to 181 in 2015.



Methods

Questionnaire design and distribution

The EMWA Freelance Team developed the 2015 web-based survey, based on the 2012 instrument. Individual questions were revised to reflect feedback from EMWA freelancers, to take account of an interim survey on types of regulatory documents worked on by freelance writers, and changes in the medical writing field. The resulting questions differed considerably from previous years, so historical comparisons were generally not possible. To enable comparison across surveys, the questions on chargeable rates were not changed.

The 10-question survey was produced on SurveyMonkey and was available online from mid-January 2015 to mid-March 2015. EMWA sent an email with the survey web link to all members and an announcement was posted on EMWA's LinkedIn page and social media, with reminders sent out using the same channels. The survey was open to anyone conducting freelance medical writing activities in Europe, including non-members of EMWA.

Statistical methods

Data were analysed using Stata version 13.1.

All data are presented using descriptive statistics only.

For the analysis of hourly rates, part-

icipants were classified as doing mainly regulatory work, mainly med comms work, or a mixture of the two, as follows. The percentage of time spent working on documents that were clearly regulatory (summary documents, protocols, CSRs, other regulatory documents, and SOPs) or clearly med comms (journal articles, marketing materials, presentations, or product information) were summed to give a total for each type. If the percentages of each type were within 10% of each other, participants were classified as doing both kinds of work, otherwise they were classified as doing the type of work with the larger percentage. Where participants had given rates in British pounds, these were converted to euros at the rate prevailing on 27 September 2015 (£1 = €1.35).

Results and Discussion

Number of responses and geographical location of respondents and their clients

181 respondents participated in the 2015 survey, an increase of almost 50% compared with 123 in the previous survey in 2012. Almost two-thirds (115, 63.5%) were based in a European country and undertook work for clients in different countries. A smaller proportion (54, 29.8%) of respondents were based in Europe and worked only with clients in their own country. Few (12, 6.6%)

respondents were based outside Europe and had European clients.

Employment status and EMWA membership

Almost two-thirds (110, 62.5%) of respondents were full-time freelancers, and most of the remainder (57, 32.4%) were part-time freelancers (Figure 1). Only a small proportion (9, 5.1%) of respondents were employed by a company and also undertook some freelance work. All employment categories were well represented by EMWA members and non-members.

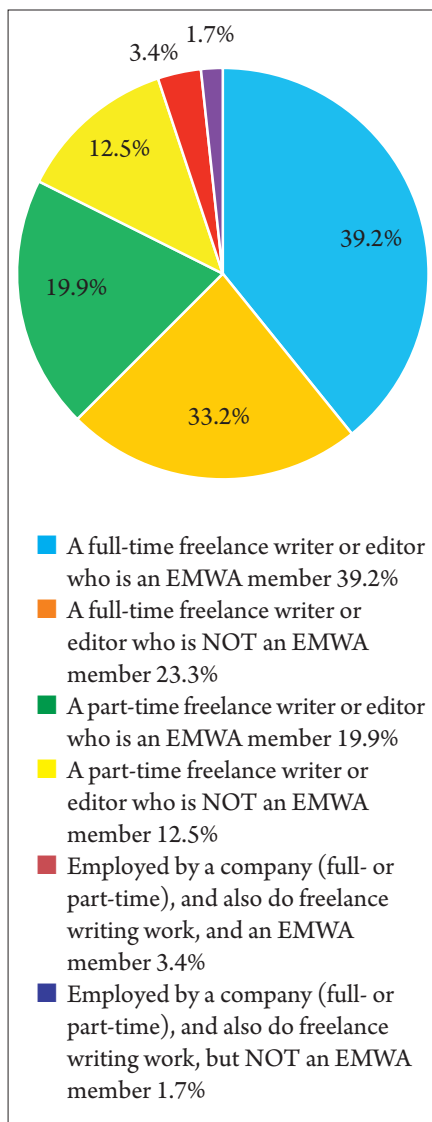


Figure 1. Employment status and EMWA membership (N=176)

Number of hours worked

Respondents were asked how many hours they worked per week, based on typical workload over the last 3 years (Table 1). It is interesting to note that slightly less than half (81, 46.3%) of respondents worked for more than 30 hours per week, but almost two-thirds (62.5%) of respondents consider themselves to be full-time freelancers. In the context of a standard working week of approximately 40 hours as an employee, it appears that freelancing may offer a favourable work-life balance compared with the ‘employed’ sector.

Hours per week ^a	Response count (%)
1–10	8.6
11–20	16.6
21–30	28.6
31–40	30.3
41–50	13.1
>50	2.9

^a Average number of hours, based on typical workload over the last 3 years

Table 1. Number of hours worked (N=175)

Sources of work and work providers

Respondents categorised sources of work (Table 2) and providers (Table 3).

By a considerable margin, the most significant source of work (56.5%) came

Sources of work	Response average (%) ^a
Longstanding customers	56.5
Referrals from colleagues	17.2
Referrals from customers	14.5
Professional or social networking sites	11.6
Own advertising, including own website	6.1
EMWA Freelance Directory	2.3
Other	9.4

^a Average percentage of total work undertaken, based on typical workload over the last 3 years

Table 2. Sources of work (N=163)

from long-term customers. Referrals from colleagues and customers also provided for a large proportion (31.8%) of work undertaken. The pattern of sources of work has been similar in all surveys so far. These findings are not surprising, as interpersonal relationships are the building block of any service business. However, other more ‘virtual’ approaches, including websites and professional and social networking sites, provided for approximately 20% of work on average, and therefore are also of considerable value when building a broad and stable client base.

The most significant providers of work

Work providers	Response average (%) ^a
Medical communications agencies	43.2
Research-based pharmaceutical companies	27.9
CROs on behalf of any of the above	13.4
Academic institutions or academia-based individuals	12.2
Publishing companies	10.3
Medical device companies	6.9
Medical writing companies	3.9
Biotech companies	3.5
Non-profit organisations	3.0
Generic companies	2.8
Work placement agencies	2.4
Any other sponsor (eg, investigator-led research groups)	1.9
Other	3.6

^a Average percentage of total work undertaken, based on typical workload over the last 3 years

Table 3. Work providers (N=157)

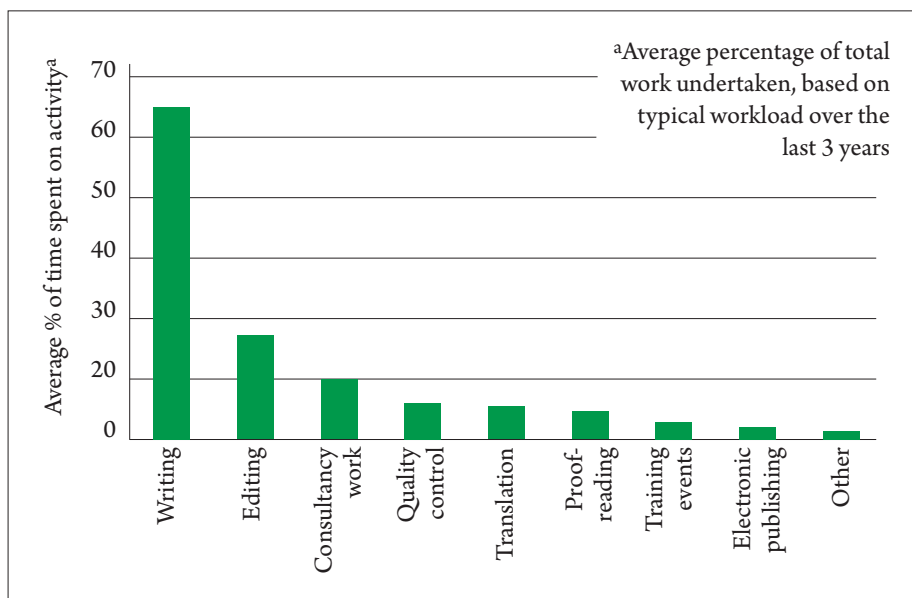


Figure 2. Types of work undertaken (N=156)

were medical communications agencies (43.2%), research-based pharmaceutical companies (27.9%). Contract research organisations (CROs), academia and publishing companies each provided for more than 10% of work on average. Opportunities

also exist in the biotech, generics and medical device fields. This was the first survey where the proportion of providers working mostly in the area of medical communications (56.4%) exceeded those doing mostly regulatory work (22.1%). This

may reflect that this survey was more widely publicised on LinkedIn and social media.

Types of work undertaken

Respondents categorised their work by broad ‘type’ (Figure 2) and also more specifically by document type (Table 4).

Writing constituted the most significant portion of work (62.3%), with editing (19.1%) and consultancy work (10.3%) also providing significant amounts of work. Opportunities also exist in the fields of quality control, translation, proof-reading and training.

Slightly over half of all work can be categorised under the general headings of ‘medical communications’ and ‘publications’, including articles for scientific journals and congresses, product information and educational materials for patients and healthcare professionals. Approximately one quarter of work fell under the heading of ‘regulatory writing’, including work for regulatory submissions, clinical and non-clinical study reports and protocols, and patient safety documentation and other annual updates. ‘Presentations’ also comp-

Type of document

Type of document	Response average (%) ^a
Articles for scientific journals and the scientific press	32.2
All other (non-protocol-related) supporting documentation contributing to non-clinical and clinical study reports, and the reports themselves	9.8
Marketing materials, including congress materials and proceedings	9.7
Presentations	9.7
Summary documentation for regulatory submissions, eg, clinical overviews and summaries of efficacy and safety (including non-clinical), including regulatory prescribing information (eg, SmPCs)	8.1
Educational materials for patients and health professionals, including audiovisual media	6.8
Preparatory documents for non-clinical and clinical trials including study protocols and supporting documentation	5.3
Product information for marketing purposes, including product monographs	3.9
Consultancy documentation	2.2
Training documentation	2.0
Other regulatory documents, eg, variations, PBRERs, RMPs, Annual Reports, responses to authority questions	1.9
Websites	1.9
Medical and scientific textbooks	1.5
Standard operating procedures	1.0
User manuals for devices	0.3
Other	5.4

^aAverage percentage of total work undertaken, based on typical workload over the last 3 years.

Abbreviations: PBRER Periodic benefit-risk evaluation report; RMP Risk management plan; SmPC Summary of product characteristics

Table 4. Types of documents authored (N=148)

Type of work activity	N	Minimum	25th percentile	Median	75th percentile	Maximum
Writing (total)	134	0	68	78	90	384
Med Comms writing	90	0	66	75	82	384
Regulatory writing	39	48	69	90	104	160
Editing	108	0	55	70	83	384
Translation	37	0	30	60	80	160
Proof reading	53	0	40	60	87	384
Quality control	51	0	50	70	83	139
Consultancy	63	0	66	83	110	186
Electronic publishing	21	0	0	62	79	139
Other	21	0	0	45	71	139
Training	16	50	70	84	125	150
Training preparation	12	55	68	95	115	150
Training (half day rate)	14	200	280	385	500	800
Training (whole day rate)	21	350	560	840	1000	1750

^aAll rates are in euros per hour

Table 5. Chargeable rates in euros, by type of work activity

rised about 10% of work undertaken, by ‘document’ type.

Hourly rates

Respondents provided hourly rates in euros, which are summarised by the type of work activity undertaken in Table 5. Whilst minimum and maximum values can be misleading, presentation of 25th, 50th and 75th percentile values provides a more useful overview of rates charged.

Unsurprisingly, training work demands the highest premium, with daily rates in excess of €840 (50th percentile) not uncommon, and with rates rising up to €1750. Of course, this high rate is likely to be offset by the fact that opportunities for such work may be more sporadic than other activities. Writing work also tends to be charged at higher rates than most other types of activities, with regulatory writing commanding a higher median hourly rate at €90 than med comms work at €75. The median rate for consultancy work was €83 per hour.

It is of note that hourly rates have remained stable during the 12 years since the first survey in 2003 (Figure 3). Consultancy work appears to be the exception, with rates consistently lower than the 2003

peak, but this may reflect there being fewer respondents in previous surveys.

Differential charging by client type

Data were also summarised for hourly rates by type of client, with respondents indicating whether they charged a particular type of client more, less or the same as their ‘regular’ rate (Figure 4). Overall, it appears that most writers charge most types of clients the same rate. The main exception to this observation is that almost half (40/90, 44.4%) of respondents indicated that they charged research-based pharmaceutical companies a higher-than-usual rate. Conversely, some types of clients were offered lower rates by some respondents, most notably academic clients, non-profit organisations and publishing companies, although the difference was much less pronounced than for the pharma companies.

Conclusion

Our survey shows that freelance medical writing and related activities continue to offer a varied and potentially lucrative business opportunity. The responses received indicate a wide range of types of work and clients, including niche opportunities in addition to more traditional activities. In

addition, freelancing offers unique flexibility, indicated by the range of hours worked. Chargeable rates remain stable, and it appears that the freelance environment remains a healthy place within which to operate.

We hope that these data will allow you to assess your own business model, client profile and chargeable rates, so you can make the most of your own freelancing in the future.

EMWA would like to thank all respondents for taking the time to contribute to this survey.

References

1. Reeves A, Drees B. EMWA Freelance and Small Business Survey 2003. TWS 2004;13(1):11-13.
2. Reeves A, Hamilton S. EMWA Freelance Business Survey 2007. TWS 2007;16(3):138-140.
3. Reeves A. Third EMWA Freelance Business Survey 2010. TWS 2010;19(2):147-149.
4. McDonough A, Billiones R, Hamilton S. Fourth EMWA freelance business survey 2012. Medical Writing 2013;22(1):67-77.

Author information

Jonathan Edwards: after 13 years working as an ‘employed’ medical writer in a med comms agency and more recently in large pharmaceutical company, Jonathan has recently set up a UK-based freelance medical writing business. (jonathanedwards2718@gmail.com)

Alistair Reeves is a freelance author’s editor, translator and trainer based in Germany. (a.reeves@ascribe.de)

Adam Jacobs is a senior principal statistician with Premier Research and used to be a medical writer. You can find him on Twitter at @statsguyuk.

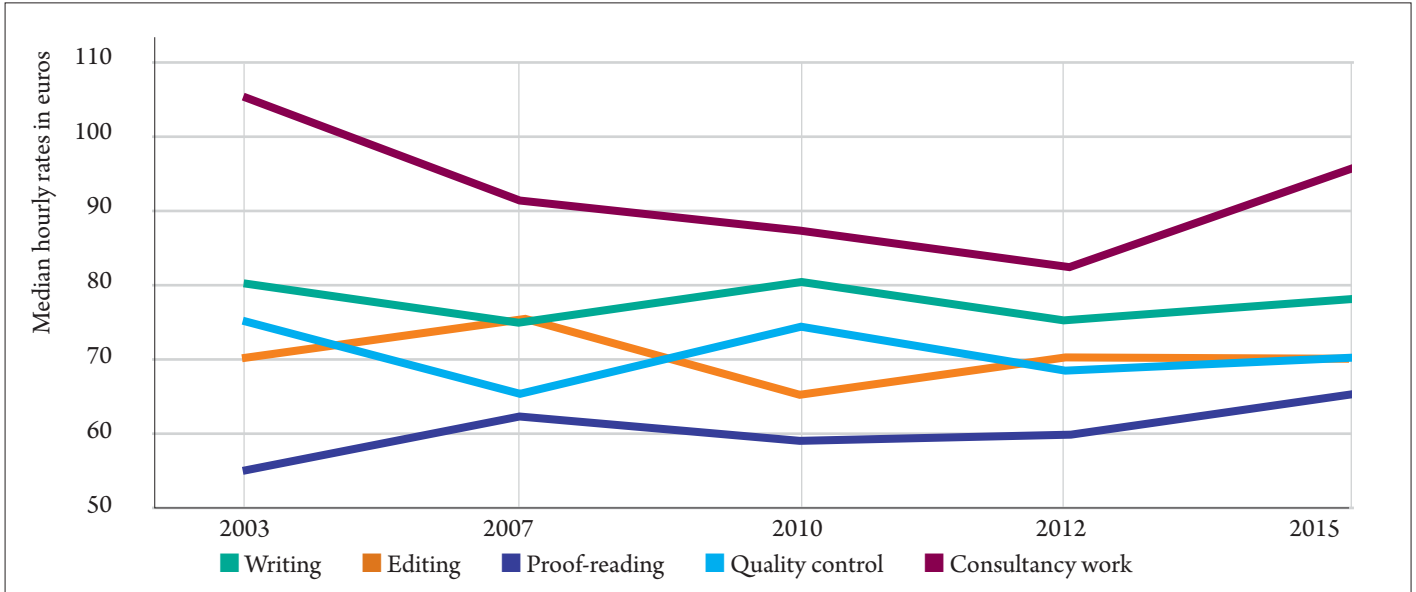


Figure 3. Median hourly rates 2003–2015 in euros

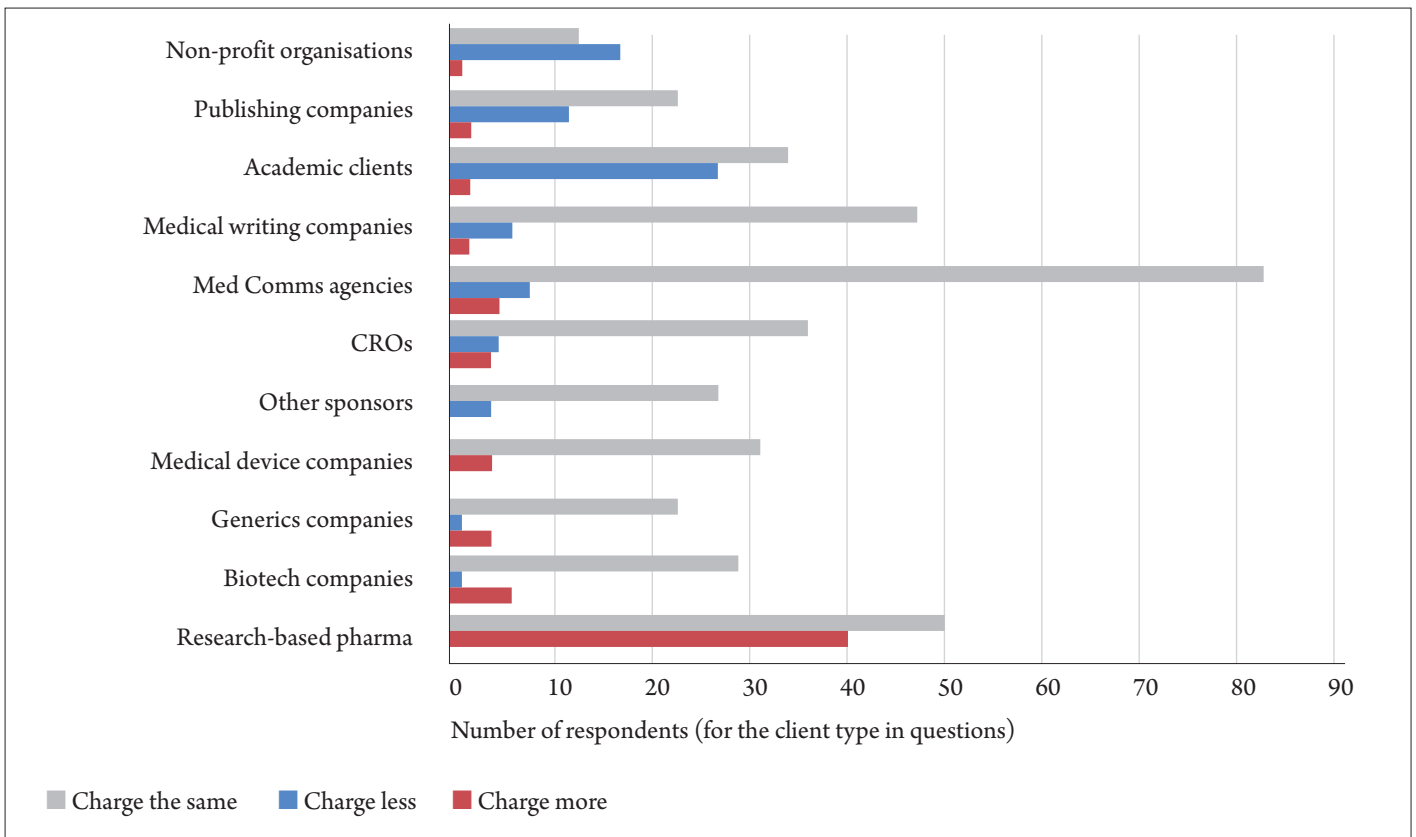


Figure 4. Differential charging by client type (N=141)



EUROPEAN
MEDICAL
WRITERS
ASSOCIATION

The 42nd EMWA Conference

Tuesday 10 to Saturday 14 May 2016

Sheraton Arabellapark Hotel, Munich, Germany

Visit: www.emwa.org or
email for further information: info@emwa.org

Approximately 50 foundation and advanced-level workshops will underpin the conference, complemented by special events including:

- Welcome Event and Networking Reception
- Conference Dinner and a range of evening social events
- Expert Seminar Series (ESS) **see details opposite**
- Symposium Day **see details opposite**
- Industry-sponsored lunch symposium
- Freelance Business Forum
- Update session from the Pharmacovigilance Special Interest Group
- Update on May launch of **CORE** (**C**larity and **O**penness in **R**eporting: **E3**-based) Reference
- **NEW:** Launch of the Regulatory Public Disclosure Special Interest Group
- **NEW:** Poster session
- **NEW:** Internship Forum.

The ESS will be held either side of Symposium Day to provide a 3-day content package suited to senior and experienced delegates.

New Member Offer for 2016

Why not take advantage of our *New Member Offer priced at €90 for the year and valid for new members joining between 01 April and 30 June 2016?

As an EMWA member you will benefit from our extensive webinar programme and growing range of member offers.

**New Member means no EMWA membership in the last 3 years. To take advantage of the New Member Offer, email info@emwa.org with 'New Member Offer 2016' in the subject line, and quote discount code "NM_EMWA2016".*

2nd Expert Seminar Series - 11 and 13 May 2016

The ESS is for experienced medical writers, heads of medical writing departments, and industry leaders from other disciplines interested in the latest developments affecting the medical writing industry and in shaping the world of medical writing. International experts will lead lectures with either a panel or participant discussion or demonstration:

Tracy Farrow PPD: The Impact of Clinical Trial Data Disclosure on Trial-related Documents: Redaction Requirements and Future Document Structure

Margaret Mathes RTI Health Solutions: Saying Goodbye to Manual Referencing: Embracing EndNote

Joanne Hilton Kinapse: Working with India as a Partner for Medical Writing – Expectations and Best Practices

Roselynn Tien Parexel: How to Build a Medical Writing Group in the Asia Pacific Region, Focusing on China and Japan

Keith Kleeman Clingenuity: Artificial Intelligence and Automated Authoring – Current State of Affairs

Susanne Herzig ICON: Medical Writing for Studies with Adaptive Design.

4th Symposium Day - 12 May 2016

Symposium Day will focus on the ever-changing field of medical communications, and the importance of medical writers as medical communicators. The evolved role from regulatory, medical and scientific writer to the role of medical communicator, specialising in a specific therapeutic area or field of communication will be explored with reference to:

- What 'communication' actually means
- The different ways of communicating medical issues effectively
- How to 'communicate' with the patient, parent and caregiver
- Scientific communication and non-scientific media
- Effective means of translating scientific communications
- Regulator (EMA) perspective on how to communicate medical research and findings
- Industry-driven research and its communication to healthcare professionals and non-medical audiences
- Medical communications agencies – *in medias res* ('in the thick of it')
- Publishing scientific and clinical research – past, present and future trends
- The role of publication professionals in medical communication.

Journal Watch

SECTION EDITOR



Hervé Maisonneuve

herve@h2mw.eu

From the Editor-in-Chief: Journal Watch is the re-birth of a previous column edited by Nancy Milligan. We are happy to welcome Hervé Maisonneuve, MD as the new Section Editor for Journal Watch. Hervé is a contributing editor for several scientific journals and regularly teaches medical writing in hospitals and universities in France. The new version of Journal watch will be based on his French-language blog *Rédaction Médicale et Scientifique*, available at <http://www.redactionmedicale.fr>.

Journals should publish referee reports and respond to well-founded concerns about papers after publication

According to an article by Nicolair Slavov published in the November 11 issue of *eLife*, referee reports are helpful and hiding them is an enormous waste. The author encourages post-publication debates and for journals to take the lead in considering non-anonymous comments posted on electronic platforms. Three controversial reports—one that a bacterial DNA sample contained arsenic instead of phosphorous, one that RNA sequences contain widespread edits or changes from the corresponding DNA sequences, and one on stimulus-triggered acquisition of pluripotency — have shown that post-publication comments offer a fast and efficient method for raising concerns about potential problems in published papers. **Reference:** Slavov N. Making the most of peer review. *eLife* 2015;4:e12708.

Are meta-analysis simple works, office-based, cheap, time-efficient with chances to be highly cited?

In an article recently published in *Medical Hypothesis*, Giovanni Tebala, a surgeon, warned about a trend in current research for researchers to move from performing randomised clinical trials to systematic reviews and meta-analysis. He warned that “If we are unable to invert this trend, in the future we will have a growing number of synthetic studies utilising someone else’s original data and fewer raw data to base our knowledge upon.”

Reference: Tebala GD. What is the future of biomedical research? *Medical Hypothesis* 2015;85(4):488-490.



The COMPARE Project

The COMPARE project is an Oxford-based group (<http://compare-trials.org/>) that is tracking “switched outcomes”. They are systematically checking every trial published in the top five medical journals (*Annals of Internal Medicine*, *BMJ*,

JAMA, *Lancet*, and *New England Journal of Medicine*) to see if the findings have been misreported by comparing each clinical trial report with its registry entry. Results are updated weekly, and as of January 6, 2016, they had checked 66 trials. Only 9

trials were considered “perfect”, while the remaining had a total of 355 outcomes not reported and 336 new outcomes that were silently added. Unreported or added outcomes are reported to the journal so that readers are aware of the problems.

First data on the reproducibility of research published in *Science*

A huge effort is under way to reproduce 100 experiments published by three prestigious American psychological journals (<https://osf.io/ezcu/>). The effort, supervised by the Center for Open Science at the University of Virginia (US), is supported by 250 researchers at 125 foundations in the US. As reported in the August 28th issue of *Science*, although 97% of original studies had statistically significant results, only 36% had statistically significant results when they were reproduced. In 47% of the cases, the original effect sizes were in the 95% confidence interval of the replication effect size, and only 39% of effects were subjectively rated to have replicated the original result. The authors concluded that “if no bias in original results is assumed, combining original and replication results left 68% with statistically significant effects.”

A similar same effort is being carried out for cancer biology (<https://osf.io/e81xl/wiki/home/>), although results have not yet been published.

Reference: Open Science Collaboration. Estimating the reproducibility of psychological science. *Science* 2015 (28 August);349:6251.



Restoring study 329: re-analysis of a paroxetine trial with the same data with opposite conclusions

Study 329 was a randomised, controlled trial on the efficacy and harms of paroxetine and imipramine in the treatment of adolescent major depression published in the *Journal of the American Academy of Child and Adolescent Psychiatry* in July 2001. The original paper concluded that “Paroxetine is generally well tolerated and effective for major depression in adolescents” and found that “The response to imipramine was not significantly different from placebo for any measure.” The article was ghostwritten and largely criticised, with a variety of anomalies spotted by researchers. A reanalysis of the original study, recently published in *BMJ*, was carried out under the Restoring Invisible and Abandoned Trials initiative “to see whether access to and reanalysis of a full dataset from a randomised controlled trial would have clinically relevant implications for evidence based medicine.” The authors of the re-analysis concluded, “Neither paroxetine nor high dose imipramine showed efficacy for major depression in adolescents, and there was an increase in harms with both drugs.”

Reference:

Keller *et al.* Efficacy of paroxetine in the treatment of adolescent major depression: a randomised, controlled trial. *J Am Acad Child Adolesc Psychiatry*. 2001 Jul;40(7):762-72.

Doshi *et al.* Restoring invisible and abandoned trials: a call for people to publish the findings. *BMJ*. 2013;346:f2865.

Le Noury. Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence. *BMJ*. 2015;351:h4320.

The HAP score for granting authorship of large multi-center trials

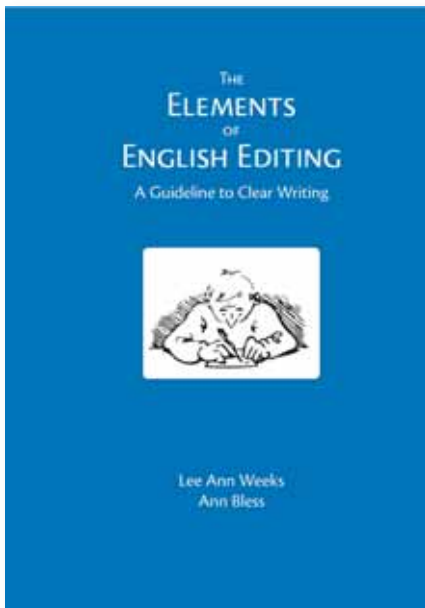
In an article relevant to the current issue of *Medical Writing*, David Whellan describes a new system for attributing authorship, the HF-ACTION Authorship and Publication (HAP) score. The HF-ACTION study was a randomised clinical trial that examined the efficacy of exercise training as a supplement to standard care in heart failure patients. The score assigns points according to “investigators’ participation in trial

enrolment, follow-up, and adherence, as well as participation in committees and other trial activity” and “was designed to enhance rate of dissemination, recognise investigator contributions to the successful conduct of the trial, and harness individual expertise in manuscript generation.” They admit that although it is not without limitations, the system may be useful as a starting point for authorship decisions in multisite trials.

Reference:

Whellan DJ *et al.* Authorship in a multicenter clinical trial: The Heart Failure – A controlled trial investigating outcomes of exercise training (HF-ACTION) authorship and publication (HAP) scoring systems results. *Am Heart J* 2015;169:457-463.e6.

In the Bookstores



In *The Elements of English Editing: A Guideline to Clear Writing*, authors Lee Ann Weeks and Ann Bless have combined their 50 years of experience to create a concise, 71-page book which introduces readers to the language editing process. This book is divided into six chapters covering topics such as substantive editing, translational editing, copy editing, proof-reading and on-screen editing. It provides practical information to anyone entering or currently in the editorial profession, as well as a useful tool for medical writers and writers who translate text on a regular basis.

Chapter 1 introduces the reader to the rationale behind the book, references various institutes, societies and other organisations approach to editing and outlines the authors' approach and what to expect from the subsequent chapters.

Comprising of 28 pages, chapter 2 forms the major part of this book and provides a general overview of substantive editing, whether it is at the text, paragraph, or sentence level. At the text level, the role of editor is to check for a main topic statement which has logic and cohesion followed by a concluding statement. The authors cover a range of common errors which require substantive editing. These include, but are not limited to, unfulfilled announcements and missing markers, where writers fail to discuss a topic that they claim they are going

The Elements of English Editing: A Guideline to Clear Writing

by Lee Ann Weeks and Ann Bless;

Scientific Editing Service, 2013.

ISBN: 978-90-820504-0-0.

€10.50. 71 pages.

to; and insufficient differentiation of unfamiliar information, where writers mistakenly assume the reader is familiar with information that is not yet been introduced. It also highlights the muddled use of singular and plural, mixed use of positive and negative statements, inconsistent terminology, insufficient repetition, and unclear pronouns, all of which can contribute to cumbersome and ambiguous reading.

Substantive editing at the paragraph level ensures that each paragraph presents a single cohesive idea. The authors highlight errors that writers are particular prone to, including incorrect distinction of paragraphs, not defining the topic of the paragraph in the first line, misuse of transitional statements to improve the flow between multiple points within a single paragraph, and incorrect ordering of information within the paragraph. Lastly, the authors explain how the use of parallel terminology, where writers use different words to describe the same thing within a single paragraph, increases the complexity of the text and can affect its readability.

Substantive editing at the sentence level is similar to editing at the paragraph level. Here, the editor checks for a multitude of features including incorrect use of pronouns, incorrect ordering of information, correct presentation of parallel ideas, inappropriate use of connective words, empty wording, passive wording and ambiguity in the text, to name but a few. In the final section of this chapter the authors discuss each feature of editing at the paragraph level and provide practical advice to ensure the flow of the text is logical, coherent, and unambiguous.

Overall this chapter is well-structured and informative; throughout the chapter the authors provide relevant examples of problematic text which requires revision. These examples are described in a logical

SECTION EDITORS



Alison McIntosh

Alison.McIntosh@iconplc.com



Stephen Gilliver

scgilliver@yahoo.co.uk

step-by-step way; the authors provide an example text, indicate the problem, and provide a solution to the problem followed by a revised text. A valuable feature of this chapter is that the advice given is broad and not limited to a single document type. Thus, the problems covered have implications for regulatory and medical communication documents.

Chapter 3 looks at editing text which has been translated, in particular the need to ensure that sentences are accurate and complete and that the correct wording is used. The chapter concludes with four helpful approaches to revising translated text: 1) setting the document aside before self-editing, 2) checking the translated text against the source, 3) having someone else check the translated text against the source, and 4) having someone else edit. For writers whose first language is not English, or who regularly translate text, reading this chapter is particularly worthwhile.

Chapter 4 discusses the need for copy editing and the distinction between copy editing and proof-reading. The authors define copy editing as the process by which the text is checked for accuracy and consistency but also whether the text layout conforms to specific guidelines. In particular, it relates to the visual characteristics of the text and includes reviewing headings, bullet points, spelling, punctuation, parentheses, references, figures, tables and appendices. This chapter discusses each characteristic and highlights some basic writer errors with more examples of problematic text and suggested revisions.

Chapter 5 discusses the role of the proof-reader in reviewing documents. The proof-reader reviews the final version of the text, which can either be compared against a preceding version or without reference to the previous version and as such is a "blind" review of the document. The proof-reader

provides an essential role in highlighting formatting error, inconsistencies, omissions or typos that may have arisen after multiple editorial review stages and typically uses a set of symbols to denote changes; which are presented in this chapter. It also provides information on how to effectively edit a document “on-screen” using track changes and comments, as well as the benefit of using macros and comment codes.

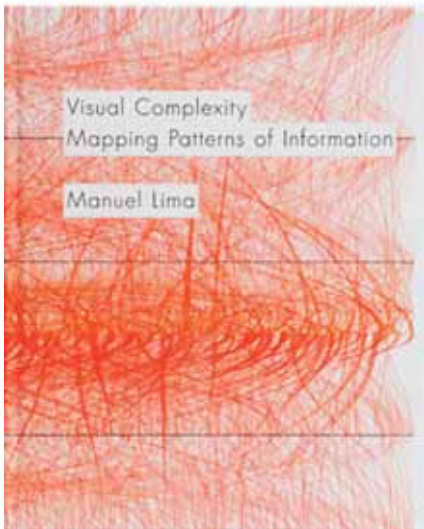
This book concludes with some final remarks in chapter 6, a reference section,

and a useful editor’s checklist consisting of 30 key points an editor needs to check at the text, paragraph and sentence levels.

Other reviewers have complimented this book on its practicality and I would echo that sentiment. From a writer’s perspective, it is a useful guide to prevent unnecessary last-minute editing of documents. Admittedly, many of the topics covered are basic and are by no means dealt with comprehensively. Thus, a seasoned medical writer may consider the content second

nature. However, at €10.50, it does offer value for money as a useful reference book. You may not find this book in bookstores, but you can get it from the following websites: www.sciencewriting.nl/book/ and www.annbless.com.

Reviewed by Nicholas Churton
Medical Writer
Clinical Research Services,
ICON, Eastleigh, UK
Nicholas.Churton@iconplc.com



Making a pool of knowledge available to lay audiences can be challenging and often invites the following question: How is information understood, processed, and presented? Manuel Lima, the New York-based founder of the network visualisation platform visualcomplexity.com, investigates this question in his book *Visual Complexity: Mapping Patterns of Information*. *Visual Complexity* provides a collection of essays and 100 examples of information visualisation from the field’s leading professionals. It becomes obvious that information visualisation has evolved in recent years and now goes far beyond the standard line charts, pie charts, and box plots that many of us routinely produce.

Manuel Lima’s aim with this book was to decode trends and technologies of data representation so that readers can understand and appreciate this fast evolving field, which emerged with the rise of the information age. Since we now have to represent considerably more data than

Visual Complexity: Mapping Patterns of Information

by Manuel Lima

Princeton Architectural Press, 2013.

ISBN: 9781616892197 (paperback).

21.99 GBP; 272 pages.

before, the aim of data visualisation has changed from simple data presentation to the representation of multi-dimensional relationships. Computer scientists, artists, and writers often work hand in hand to find ways to represent relationships between more dimensions of data than is possible with two-dimensional displays such as bar charts and scatter plots.

Although Lima shows that the standard graphical language, which consists of points, lines, and curves, can be found in novel information visualisation techniques, he also points out that aesthetics and contemporary design features have in recent years become a major aspect of data visualisation. To illustrate this, he highlights 15 basic types of network diagrams, ranging from arc diagrams to flow charts and spheres. While Lima explores how different strategies to map information work, he does not provide insights into new visualisation techniques. For those interested in actual visualisation techniques, *The Visual Display of Quantitative Information* by Edward Tufte provides sophisticated guidance on this topic.

Visual Complexity focuses on the beautification of big data through an innovative mix of art and design. Lima argues that information visualisation has become the modern language of data representation in the twenty-first century. Whereas data visualisation is widely used as a tool to present data, Lima suggests using visualisation techniques in order to

understand big data. In this way, visual representations can facilitate the perception of patterns, connections, and structures.

Interestingly, *Visual Complexity* reveals that besides aiming for efficiency and clarity, information visualisation designers aim to communicate their ideas about data, making statements and evoking particular emotions in the viewer.

Whereas this is clearly a no-go for regulatory writing, it might be an interesting consideration for communication with lay audiences. Actually, as a medical writer, you might already have been using the new graphical visualisation language without knowing it. Think about it: An integral part of medical communication is the visualisation of complex data through (flow) charts, pictograms, and infographics. Communication with lay audiences is often facilitated by visual aids and representation of large data sets through multi-dimensional visualisations should clearly be considered for this purpose.

As Lev Manovich, author of the book *The Language of New Media*, sums it up in the foreword to *Visual Complexity*: ‘We seek to represent, in order to understand.’

Reviewed by Carola Krause
Freelance Medical Writer
codeX
Carola.Krause@codex-biomed.com

The Webscout

Authors and Authorship

This issue of *Medical Writing* focuses on authors and authorship, but where, in fact, did the term “authorship” come from? The term first appeared in the early 18th century. In a paper presented at the Annual Meeting of the National Council of Teachers of English and available online at <http://files.eric.ed.gov/fulltext/ED266481.pdf>, Lisa Ede describes the historical perspective and development of the concept of authorship. She explains that authorship is a complex construct and reflects the contemporary culture.

Apropos history: Did you know that it is a matter of debate that Shakespeare really is the author of the works accredited to him? According to the Shakespearean Authorship Trust (www.shakespeareanauthorshiptrust.org.uk), whether he is the true author of his works has been debated for hundreds of years.

According to a presentation entitled “A Visual History of Authorship” (<http://prezi.com/wd7yqxxkl-qw/visual-history-of-authorship/>), the history of authorship can be split into three cultures: the pre-print, the

SECTION EDITOR



Karin Eichele
info@mediwiz.de

print and the digital culture. This fits perfectly with Lisa Ede’s explanation that common understanding of what authors and authorship mean changes as culture evolves. Of course, the meanings can differ between literary works and academia. Wikipedia defines the term “academic authorship” as the way “by which academics communicate the results of their scholarly work” (http://en.wikipedia.org/wiki/Academic_authorship).

In 2011, Google created a special web feature named “authorship”, connecting each piece of content to an author profile with individual biographical information and photograph. The idea was to influence page rankings based on the reputation of its authors using digital signatures. Because of a lack of success and the sinking prominence of G+, Google cancelled the authorship

programme in autumn 2014. As explained in the blogs Web Engine Land (<http://searchengineland.com/authorship-dead-long-live-authorship-217209>) and Buzzsumo (<http://buzzsumo.com/blog/author-authority-influence-content-marketing-interview-j-d-metz/>), this initiative could have helped authors build their “author authority”, which aims to help authors generate credibility and awareness so that their content is read.

Modern communication allows not only spreading of your ideas but also interaction between you and your community, who can leave you comments and messages or add their own ideas. So what about the authorship of user-generated content on, for example, your webpage or blog? What looks like a simple issue turns out to be much more complex. Do you want to reuse content posted by your community? What do you have to consider in terms of liability? Who is responsible for the content? If you declare that you own all content posted on your page including those of your followers, than you might also be liable, for example, for copyright infringement. Some information and guidance can be found on the blog Legal to English (<http://outsourcedassociate.com/owns-user-generated-content-site/>).

Finally, what do social networks have to say? Instagram (www.instagram.com/explore/tags/authorship), for example, gives an idea of how people are visualising the term “authorship”. This can be a source of inspiration. Different pictures of reading, writing or books from daily life might encourage you to further explore and stumble over interesting people and interesting ideas.

Did you like this Webscout article? Do you have any questions or suggestions? Please feel free to get in touch and share your thoughts.

Karin Eichele and Marc Briele
mediwiz
info@mediwiz.de



Regulatory Writing

SECTION EDITOR



Greg Morley
greg.morley@docuservicio.com

Authorship issues in regulatory documents



When medical writers discuss authors and authorship – the theme of this issue of medical writing – they are usually referring to documents in the public domain such as journal articles or maybe congress abstracts. The primary purpose of such publications is to communicate the results of the study to the scientific community and wider world. The investigators who appear as authors of an article about a clinical trial should rightly take responsibility for the content. Thus, all authors should have been

involved in the drafting process, and have critically reviewed and approved a manuscript prior to publishing. They may have requested additional outputs to be generated or suggested that certain conclusions are toned down or changed. They should also have had access to the data to verify the presentation of the results and the conclusions. But large volumes of outputs are generated and in the real world where investigators are busy clinicians, only the most diligent will have gone through

the source data in detail. Potential conflicts of interest should be declared and the involvement of a medical writer should be acknowledged. Given that drug development takes place in a competitive environment and that the temptation to present results in a favourable light is strong, the aim of the above is to prevent ghost-written articles. In the past, such articles have used the veneer of peer-reviewed respectability for marketing ends. Greater awareness of these issues,

combined with stringent public disclosure requirements, giving readers access to the results pertaining to the main efficacy endpoints and safety, have no doubt reduced the extent of these dubious practices, though there is always room for improvement.

Realities of clinical research

Although the investigators named as authors take public responsibility for the article content, there is a tacit recognition (perhaps not always addressed in discussions about journal authorship) that the study design and analysis is largely done by the drug company. So although the investigators will have been the ones who actually administered the study drug to the patients, in terms of the big picture, a team within the company, involving many employees with expertise in many different areas (biostatistics, clinical science, clinical pharmacology, and so on) will have been responsible for study design and administrative aspects. The company will have drafted the protocol (although investigators may have provided input to study design through participation in steering committees and advisory boards). Likewise, the statistical outputs will be produced within the company, and drafting the clinical study report (and public disclosure of the results on a clinical trial registry if appropriate) will also be the responsibility of the company.

Authorship of regulatory documents

Unlike journal articles, regulatory documents are generally prepared for submission to the health authorities and are not available in the public domain (although this may be changing with the current shift towards greater transparency). Companies will have well defined Standard Operating Procedures that describe exactly who is responsible for reviewing and/or approving a document or sections of a document. The medical writer assigned to the project is not an intellectual author in the sense that authors of journal articles are (or should be), but rather has a more technical role. The responsibility of the medical writer is mainly to compile and present data from a wide range of sources and ensure that regulatory documentation requirements are met. As a result, there is usually no need to name a medical writer as an author, or explicitly acknowledge his or her participation in the document, which if the appropriate review and approval cycles

have been followed should reflect a consensual company position.

The target audience, the health authority reviewers, is aware of the conflict of interest (the company will ultimately want to see the drug approved) and so the documents will generally be read with a critical eye. Audits can ensure the accuracy of the data and health authorities have the option of asking further questions in many types of interactions. If it transpires that the company has attempted to mislead the health authorities, the consequences both financially and in terms of loss of faith and credibility can be severe. From my experience, companies take their interactions with the health authorities very seriously and “we can’t be seen to be hiding anything” is a common sentiment in discussions about data presentation to the health authorities. Certainly (and again I am speaking about my personal impression), companies nowadays show plenty of apprehensive respect to the regulators who can make life very difficult for a company.

Investigator conformity in regulatory documents

Although most regulatory documents are authored and approved internally, a company must sometimes seek the signature or approval of someone external to the company. For example, as per International Conference on Harmonisation (ICH) guidance, clinical study reports (CSRs) must be accompanied by the signature of the principle investigator (for a single-centre trial) or the coordinating investigator (in the case of multicentre trials). The regulations are rather vague as to who should be designated the coordinating investigator. For example, ICH E3 states that the figure of the coordinating investigator will usually be designated by the protocol. However, the wording does not make this obligatory and, in practice, the protocol is often silent on this matter. If the study has a Data Safety Monitoring Board (DSMB) or some other study oversight body, then one common practice is for the DSMB chair to be made coordinating investigator. Another approach might be to ask the investigator who has recruited most patients. Either way, the final decision often has a political dimension. For example, if a publication is planned from the results of the study, then the lead author and the coordinating investigator may be one and the same.

The investigator signature page essent-

ially confirms that to the best of his or her knowledge, the trial was conducted according to Good Clinical Practice and that the results presented reflect those obtained. Unlike the author of a publication, the investigator doesn’t necessarily have to fully agree with the interpretation of the results to sign the investigator signature page, just acknowledge that the study was appropriately conducted and that the results themselves are accurate. In any case, detailed interpretation of the results is not usually included in the discussion section of a CSR. Although decisions about which results are highlighted and how they are presented in the text of the CSR may influence the readers’ perception of the study, the most important outputs are appended to the document and will be available to reviewers. Thus, CSRs are essentially factual documents with limited opportunity for spin.

Higher level documents do of course include company interpretation of the data. The clinical overview, for example, may aim to convince the regulators that the company’s product should be approved. The regulators, for their part, have extensive access to supporting data and can make up their own minds. Indeed, the Food and Drug Administration takes a bottom-up approach, paying relatively little attention to the higher level documents anyway and performing their own analyses of the raw data.

Journal articles and regulatory documents – two different worlds

In short, clinical development is a complex, collaborative process involving many company employees, hired external workers, and of course the investigators and other medical staff. Journal articles describing an interventional trial generally aim to disseminate the results. The limited number of authors who take public responsibility for the article content may not accurately reflect the extent of the effort or the real intellectual input. Regulatory documents, in contrast, if authored and reviewed according to company guidelines, with input from the relevant departments, should provide an accurate and detailed description of the clinical development process and represent the company position. The role of the regulatory medical writer is a technical one, and there is usually no need to acknowledge his or her input.

Gregory Morley

English Grammar and Syntax

Good Writing Practice

Writing abstracts for congresses (2)

Tables and Figures

Unlike manuscript abstracts, congress abstracts may often include tables or figures, or both. Many congresses allow these to be submitted alongside the abstract text, and this is often the most concise and clear way to present large amounts of data.

Limitations of tables and figures

Including a table or figure may reduce the available character or word count of the abstract. Consult the congress abstract guidelines to see if this is the case; some congresses count each table or figure as equivalent to 250 characters of body text. If more than one table or figure is to be included, one way to reduce the impact of this on the overall word count is to upload a single multipanel image containing a number of tables or figures. Depending on the congress and stipulated file size limits, this may count as one figure overall. All table and figure titles and footnotes should be included in the image file to save additional characters or words.

Unlike manuscripts, there is no opportunity to see proofs of congress abstracts, therefore it is crucial to ensure that any tables or figures will be clear and readable when published in the final abstract book. Why

overload a table with data if the end product is illegible in the abstract book? To ensure that tables and figures are published clearly, check the minimum resolution and size requirements for the congress. Many congresses provide little guidance here; if the congress abstract book will be printed, aim for the standard print resolution of 300 dpi.

Tables

If supplying tables in table format (as opposed to uploading as a figure), these will usually be transcribed and copyedited by the congress in the abstract book. While this may seem the preferred option for tables, this may introduce errors, which may disturb the message and clarity of complex tables. Incorrect, or non-translation of row indenting can make the table harder to follow, as can failure to embolden important category headings. When the contents of an individual cell contain a lot of data, these will invariably spill onto two rows and the most appropriate position for the line break may not be used. Using additional columns can also resolve this problem; for example, instead of including the value and upper and lower confidence intervals in the same column, add a separate column for the intervals. Consider the risk of an

SECTION EDITORS



Wendy Kingdom

infor@wendykingdom.com



Alistair Reeves

a.reeves@ascribe.de

erroneously translated table and whether supplying it as a figure would be preferable.

When supplying tables as a figure, a number of additional details must be considered. Special care should be taken when using superscript footnotes. In our experience, these are sometimes not published clearly in the congress book, whereas using square brackets for footnotes prints well (ie. [a] instead of a). Avoid over-compartmentalising data with grids and excessive row and column borders. Tables should be simple and clean; lines and shading should be thoughtful and should aid in the comprehension of the data presented (Figure 1).

Figures

Many congresses have no specific rules against supplying coloured figures. Colour may be inherent to the figure, eg. photographic material or imaging scans. Otherwise, if colour will improve the understanding of the figure (graphs and charts), its use should be encouraged. When developing figures in colour, consider colourblind users by avoiding red-green and blue-yellow contrasts.

Graphs and charts should clearly focus on the data. Figures may be resized and loss in quality may occur. Gridlines should generally be avoided: include only major lines in a narrow width and lighter shade.

Consistency is key in figures. Consistent shading must be used for each data series and text sizes should be aligned for axes titles, data labels and other on-figure text (keeping in mind the final size of the figure in the abstract book). Inconsistency is more noticeable than consistency, therefore a well-presented figure will draw attention to the data in part by not drawing attention to other less important aspects of the figure.

Including the title in the image will conserve characters

Restrict the use of horizontal borders

Explanatory rows spanning entire table width may be helpful

in-line footnotes appear clearer than superscript

Use shading carefully to enhance data protection

		Apples with prior pesticide exposure (N=106)			Apples without prior pesticide exposure (N=287)		
		Day 0	Day 5	Day 10	Day 0	Day 5	Day 10
Data shown as n/N (%), unless stated otherwise							
Bugs	Present	31/106 (28.7)	17/99 (17.2)	9/95 (9.5)	182/287 (63.4)	51/252 (20.2)	29/248 (11.7)
	Mean (SD) [a]	3.2 (1.1)	1.5 (0.8)	1.2 (0.7)	5.9 (2.2)	2.4 (1.9)	1.1 (1.4)
Holes	Present	8/107 (7.5)	10/99 (10.1)	9/94 (9.6)	10/287 (3.5)	16/250 (6.4)	19/248 (7.7)
	Mean (SD) [b]	0.1 (1.6)	0.5 (2.1)	0.6 (1.9)	0.2 (2.2)	0.4 (2.5)	0.5 (2.1)
Bruises	Present	9/108 (8.3)	10/99 (10.1)	12/95 (12.6)	16/286 (5.6)	17/251 (6.8)	19/248 (7.7)
	Mean (SD) [b]	0.2 (1.8)	0.8 (1.3)	0.8 (1.6)	0.3 (1.8)	0.6 (1.1)	0.7 (1.2)

[a] Mean number of bugs per apple affected; [b] Mean number of holes or bruises per apple.

Figure 1. Example of a well-presented congress abstract table

Sana Eljamel

Costello Medical Consulting,
Cambridge, UK

sana.eljamel@costellomedical.com

Medical Communications

SECTION EDITOR



Lisa Chamberlain James

lisa@trilogywriting.com

Editorial

Dear all,

A very warm welcome to the first issue of *Medical Writing* in 2016!

This issue is dedicated to authors and authorship, so I'm delighted to have an article for this section from one of EMWA's authorities on all things authoring and ghost writing – Adam Jacobs.

In this issue Adam discusses the roles of reviewers in the collaborative process of

producing well-written documents. Adam is now in the role of statistician, but having been an accomplished medical writer himself, he is perfectly placed to give us some excellent insights into the review process from the reviewer's side as well as from the writer's side.

Adam's thoughts and tips are particularly useful for anyone sending out their first document for review, but I think even 'old hands' can learn something from his experiences as a reviewer – particularly as a

statistical reviewer. As we all know, so much time and energy can be wasted in poor review cycles, with non-specialists offering their 'wisdom' on sections outside of their remit, and it's in everyone's interest to make review cycles as efficient and useful as possible.

As for whether Adam is now a 'poacher turned gamekeeper' or a 'gamekeeper turned poacher' – I'll leave that for you all to decide!! Bestest.

Lisa



Poacher turned gamekeeper

Medical writing is a collaborative process. Medical writers seldom write about their own research. Typically other people do the research, and the medical writer writes

about it. Whether the writing is for a study report for regulatory purposes, a peer-reviewed journal article, a conference abstract, or something intended for a lay

audience, the collaborative process is broadly similar. The medical writer must collaborate with researchers to make sure that the end product accurately describes

the research, is suitable for the target audience, and is clearly written.

I have been fortunate enough to have experienced this process from both sides. I used to be a medical writer, and I am now a statistician: one of the researchers with whom medical writers need to collaborate. I'm not entirely sure if that makes me a "poacher turned gamekeeper" or a "gamekeeper turned poacher". Make your own mind up about that.

But either way, I think my experience of medical writing was fantastically useful in helping me to make sure that my collaboration with medical writers is as efficient as possible. Having been a medical writer myself, I know what kinds of contributions medical writers find helpful and what kind of things piss them off.

Probably top of the list of things that piss



medical writers off is gratuitous nitpicking. It is not only annoying, it is a waste of everyone's time. So if I come across a sentence that the medical writer wrote one

way that makes perfect sense, then I will not change it, even if I would have written it differently. That's not my job. It's the medical writer's job to decide how to phrase things. Maybe there was a good reason for writing it that way that I wasn't aware of, such as complying with a client's style guide. Maybe my idea of how it should be phrased is a bit odd and the medical writer's version is clearer anyway. And even if my way of writing it is better, then so what? No drug ever got rejected by the FDA because they didn't like the way a sentence was phrased in a study report.

What I *do* focus on is the sort of thing that was the reason why the medical writer wanted a statistician to review the document in the first place. So, for example, does the statistical methods section accurately describe the analyses that we actually did? Have statistical results described in the results section been properly interpreted? Do the conclusions as written by the medical writer follow from the results?

There can, of course, be a fine line between commenting on what is written and how things are written. Some statistical concepts do require a certain amount of precision in the way they are expressed. I will comment on the way a sentence is written if I feel it is missing some statistical subtlety. For example, if a medical writer were to write (and I'm sure no EMWA members would ever do this!) that treatment A was superior to treatment B when in fact we have just done a non-inferiority analysis that only shows that treatment A is not inferior to treatment B, then I would correct them. And if text is unclear or misleading, then I will comment on that as well.

So what can medical writers do to help their reviewers be efficient in their reviews? First, I think it is always helpful if a medical writer tells me which parts of a document I need to review, or, if I am expected to read the whole thing, then at least which parts I should pay particular attention to. If someone sends me a 150 page clinical study report to review, it is not a good use of time for me to review the whole document in great detail. It is far better that the clinical project manager spends time looking in detail at what was written in the visit schedule part of the methods section than that I do. And if the adverse events section contains substantial discussion of the clinical relevance of the adverse events

observed, then that's a job for the medic more than it is for me.

It is also helpful if I know whereabouts the document is in its quality control process. If I see a typo or misplaced comma in the first draft of a document that I know is going to have a couple of rounds of editing and proofreading before it sees the light of day, then I'm not going to waste everyone's time by telling you about it. If the document is supposedly a final version, then perhaps it would be more helpful to point out things like that.

Often medical writers will have questions for me in a draft document, often inserted as comments. That's great. If there are specific things you need to know from your statistician reviewer, then ask me. And it's helpful if the questions can be made as specific as possible. "What do you think of this?" is less helpful than "Is my interpretation of the relevance of the upper limit of the 95% confidence interval correct here?" If you are not sure what to write about something and need some help, then please be clear about whether you need me to explain to you what's going on so that you can write something appropriate or whether you want me to supply a ready made paragraph of text.

Adam Smith, the influential 18th century Scottish economist, explained at some length the benefits of division of labour. He described the example of pin making, in which some workers drew out the wire, others cut it, others sharpened the point, and so on, and how this was more efficient than single workers making entire pins by themselves, as it allowed for specialisation.

So it is in writing about clinical research. Statisticians have expertise in statistics, medics have expertise in medicine, and medical writers have expertise in communication. If we all stick to our own areas of expertise and recognise the expertise of others, then we will find that research is written up more efficiently.

Disclaimer

This article represents my own personal views and does not necessarily represent the views of Premier Research.

Adam Jacobs

Senior Principal Statistician, Premier Research Ltd. Twitter: @statsguyuk

Lingua Franca and Beyond

Authors and co-authors

This issue of *Medical Writing* is about Authors and Authorship, a topic, which – despite stringent rules and regulations – is sensitive, culturally-dependent and often full of emotion. I guess that we could have endless discussions as to why papers from some regions have close to 20 co-authors, while those from other regions are authored by just a few researchers. We could also, for hours, share different strategies on how to handle heads of departments who hardly know the title of a paper yet insist on being if not the first author then at least the last, senior author. I am sure that a glass (or two) of wine would make our discussions even more vivid and creative.

We, medical writers, frequently witness situations that fall far from the ICMJE guidelines and put us in a rather uncomfortable position. We also quite often have

SECTION EDITOR



Maria Koltowska-Hägström
maria.koltowska-haggstrom@
propermedicalwriting.com

to explain what the rules are and why we do not meet the authorship criteria. This, however, is not what I would like to address in this issue of *Lingua Franca and Beyond*, although if you would like to tell us about your own authorship-related experience, how you manage such situations and what your approach is, you are more than welcome. We will publish it in one of the forthcoming *Medical Writing* issues.

In this issue of *Lingua Franca and Beyond*, I would like to introduce Professor Stephen M Shalet from Manchester in the UK. He is one of the leading endocrinologists in the world and an author of numerous articles (PubMed search of 23 November 2015

yielded 427 hits), many of them published in such prestigious journals as *The Lancet*, the *New England Journal of Medicine* and the *British Medical Journal*. He was also a co-editor of the first edition of the *Oxford Textbook of Endocrinology*. Professor Shalet writes not only scientific papers but also Hotspur's stories, many of which were published in *The Endocrinologist*. But now Steve describes for us his early lesson on how to select co-authors. This lesson resulted in the formulation of his own guidelines for future collaborations. Is it something to be shared with your co-authors or perhaps you can use his advice to establish a trustful relationship with your clients? ☺

Have fun reading it!

Maria Koltowska-Hägström

Choosing a Collaborator

The project looked a promising one. We planned to determine, using a rat model, if chemotherapy-induced damage to an endocrine gland could be modified by endocrine manipulation induced before and during the period of time that chemotherapy was given. We had an excellent team and everyone was making a significant contribution; there were four of us, Gerry, Ian, me (Steve) and Barry. From a personal perspective, this was my first real attempt to be involved in research studies, which tested a hypothesis as opposed to more clinically orientated observational studies. I felt that potentially it represented a genuine step forward in my research profile and subsequently my hopes were raised further by the fact that within less than 2 years the results of the study supported the initial hypothesis. Thus, it was time to publish our findings and, as a mere clinician involved in basic science experimentation for the first time, I chose to rely on the experience of my senior colleague from the medical school. He chose an American journal with a high impact factor, the referees made

complimentary remarks and the article was duly accepted without any fuss. The only slightly unusual aspect was the request by the journal for the first names of all authors. Previously, I had only published in journals that used authors' surnames and initials but I could not see any problem with the additional use of first names. The proofs were sent to the senior scientist for checking and, therefore, I was not aware of the disaster about to unfold until the article actually appeared in print. This article was going to be the big one, big enough to make my reputation! After months of waiting I sat at my desk and scanned the title page, and authorship: Gerry – Ian – Steve – and Barrington – Barrington! I was scarcely able to take in the full horror of what lay in front of me. Barrington, what a name – everyone called him Barry. Why, oh why, did he have to be called Barrington? I knew immediately my chance of glory had gone. Who on earth is going to pay any attention to a Steve, when there is a Barrington on the team sheet?

It was in the wee hours of the morning following the discovery of my collaborator's real name that I formulated certain absolute resolutions regarding future collaborations.

These guidelines have been as follows: if you do not want unfair competition, never work with anyone with a double-barrelled name, or with the second, third or fourth or even junior placed after their name. In fact never work with anyone with a first name that contains more than five letters!

When you come to consider collaborative research and are thinking about possible collaborators, do not worry about intellect, motivation, capacity to see a project through to completion, writing skills or even the grandeur of their CV. Just demand to see their birth certificate!

Whatever the various contributions of different authors, a 'Steve' will never be noticed in the close vicinity of a 'Sebastian Montmorency' or a 'Montague Kingsley the fourth, junior'. The only alternative, apart from giving up, is a name change, which provides you with an unforgettable moniker, but that is really risky and lays you open to the possibility that the majority of potential collaborators will not choose to work with you!

Stephen Shalet
stephen.m.shalet@manchester.ac.uk

Gained in Translation

SECTION EDITOR



Laura C Collada Ali

laura.collada@teksema.com

Editorial

Welcome to the Translation Section editorial!

Who is qualified to author a medical translation? This is one of those topics that we often read about on professional translation forums and discussion groups. It is, indeed, a never ending discussion. On the IMIA Guide on Medical Translation, Rocío Txabarriaga says: “The real indicators of proficiency in translation are knowledge of the subject matter, knowledge of relevant terminology, the ability to discern meaning

in context and transfer it within the target language constraints, i.e., accurately (all meaning has been transferred), precisely (all nuances of the language, tone, intent, style have been preserved in the target language), correctly (grammar, syntax, orthography rules have been observed), completely (no part of the original was omitted and nothing has been added to the target text), and consistently (specific terms, stylistic elements and language-specific norms have been consistently used throughout).”¹ Yet, the discussion which has gone on for so long is about who does a better job, a medical

doctor (MD) or a linguist.

With this article, we hope to shed some light on this and to demystify some clichés.

Enjoy the article!

References

1. Txabarriaga R. January 2009. IMIA Guide on Medical Translation. Retrieved from: <http://www.imiaweb.org/uploads/pages/438.pdf>

Laura C Collada Ali

Authoring medical translations – to MD or not MD?

Of all the translation specialisations, medical translation is one which constantly attracts an enormous amount of interest. Translation forums are full of posts from translators asking how to get started in this field: at the same time, it is also considered – fairly universally – as one of the most difficult areas to translate successfully, for a variety of reasons. Due to the particular nature of medical translation, and the difficulties associated with it, the debate on who makes the better medical translator – a physician trained in languages, or a translator trained in medicine – is one which has been raging for many years. And it shows no signs of abating. This debate is sparked by many factors – the increasing “accessibility” of translation as a profession, the bewildering number of qualifications and accreditations available, and the increasing regulation of the healthcare profession.

The purpose of this article is two-fold. Based on a survey we conducted through professional associations, discussion groups and social media, and the 332 responses received, we hope to shed some light on what makes a translator truly “qualified” to succeed in the medical field. And in doing so, we hope to demystify some of the aspects of the profession that aspiring medical translators may be curious about, such as the particular difficulties associated with this



type of work, how established professionals entered the profession and gained experience, and what medical translators consider to be the necessary traits for a “good” medical translator.

One survey, eight questions

The survey asked medical translators about

their experience and background:

1. Are you a specialised medical translator?
2. Are you a medical doctor who has become a translator or a translator who has specialised in medicine?
3. Which of these two professional figures do you feel is best qualified to work as a medical translator? An MD,

a translator, or other.

4. If a translator, how have you specialised in medicine?
5. Do you work full-time or part-time?
6. How many years of experience in the field do you have?
7. What kind of texts do you feel comfortable translating?
8. What do you consider to be the particular difficulties related to medical translation?

One obvious limitation of the survey is that it was self-reported, and some discrepancies show that the actual number of “specialised medical translators” could be higher or lower than the result shown. That said, the survey was directed at those working in medical translation, therefore it is probably safe to assume that this number is reasonably accurate.

The identikit of a medical translator

So what are the overall characteristics of medical translators? According to Andriesen¹, six out of seven translators are women, and their background “is most often in the study of languages or translation, but quite a few (approximately 20%) have a medical background.” According to our survey, the vast majority of respondents [86%] identified themselves as specialised medical translators – the 9% who checked “other” [29 respondents] included a teacher of medical translation, who lists medical translation as one of their areas of expertise: another whose medical and medical-related translations ran into the hundreds) (Table 1).

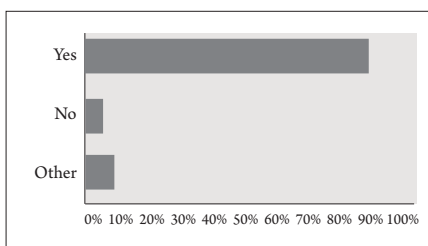


Table 1: Q1 – Are you a specialised medical translator?

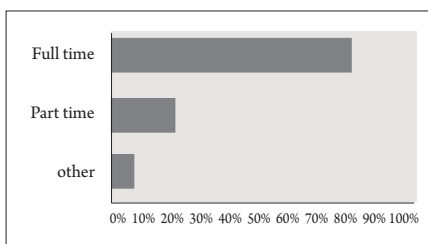


Table 2: Q5 – Do you work full-time or part-time?

As the overwhelming majority of respondents (73%) show, **medical translators normally work full-time** in the field; just under 20% were part-time (Table 2). Some were full-time freelancers who engaged in other medical writing activities, others translated part-time while doing other healthcare activities such as interpreting, work as doctors, or other healthcare professionals.

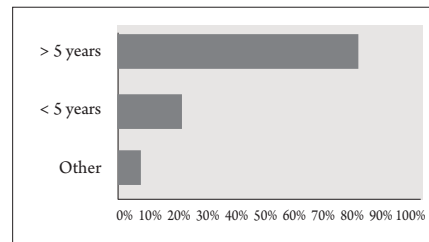


Table 2: Q6 – How many years of experience in the field do you have?

The vast majority of respondents had **over five years hands-on experience** in the field (73%) and many specified that they had been in the field much longer, with responses ranging from ten to fifty-five years of experience (Table 3): these figures agree with Andriesen’s observation that “good medical translators have many years of experience and are usually involved in medical translation most or all of their time.”¹

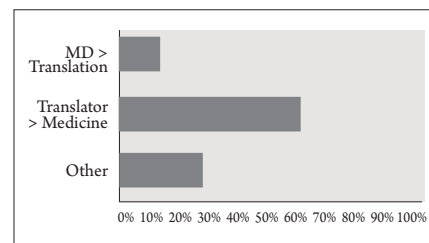


Table 4: Q2 – Are you a medical doctor who has become a translator or a translator who has specialised in medicine?

Respondents were not only **MDs or translation-based professionals**, but also nurses, biologists, veterinarians, chemists, pharmacists, and many other scientific professionals. (Table 4). Of the 90 “other” responses shown in Table 2, only 22 had no medical or scientific background whatsoever. If we add these other scientific professions – including, as declared by the respondents, biologist, nurse, veterinary surgeon, biochemist, physicist and others – to the (A) category, the numbers look a little different:

- 34% medical doctor or other science or health professional who has become a translator
- 59% translator who has specialised in medicine
- 6% other

Which background makes a better medical translator?

So who did respondents feel was “best qualified” to undertake medical translation? On the surface, it seems to be the eternal dilemma: as one respondent remarked, “the doctor knows the subject matter, but may not have the linguistic skills. The translator has the linguistic skills, but lacks the knowledge the doctor has acquired during their training and practice.” If we delve a little deeper, however, some interesting insights emerge.

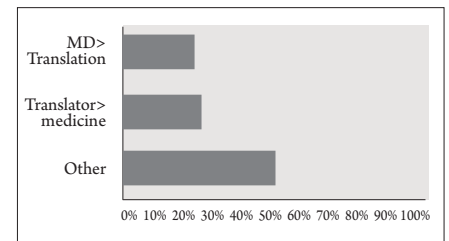


Table 5: Q3 – Which of these two professional figures do you feel is best qualified to work as a medical translator?

Half of respondents (50%) checked “other”. Of those who chose option A or B, respondents were divided almost equally, just slightly in favour of translators specialising in medicine, with 26%, versus 23% favouring MDs specialising in translation (Table 5).

“An MD or other health professional is more qualified.”

A number of respondents felt MDs or other health professionals were more suited to the task of medical translation. In general, such participants felt that medical translation requires a body of knowledge that translators who have specialised in medicine do not – or cannot – have. Some felt that the sheer breadth of the medical field meant that translators specialising in medicine would take a long time to achieve the necessary proficiency, and that CPD alone would be unable to give the same level of expertise, except in rare cases. Another recurring opinion was that a translator specialising in medicine does not have the background to

know what is correct or not, or to understand the complexity of medical texts, or is simply unaware of the gaps in their knowledge, making them more prone to errors.

“A translator specialising in medicine is preferable”

Other respondents felt a translator specialising in medicine was more desirable for a number of reasons. The sensitivity needed to adapt the text to the target audience and a consideration of its overall comprehensiveness and readability was felt by some to be lacking in many linguistic medics: one respondent felt that translators are much more keen to learn about medical topics than MDs are to learn about language and its use, and many felt that it was easier to acquire specialist knowledge than it was to gain the translation and linguistic skills necessary to produce an effective target document, prompting one participant to note: “we can all study and acquire knowledge in specific fields... a translator is bound to have a set of skills (grasp of grammar, style, syntax) that an MD does not necessarily have”. Another said: “I have worked with many doctors over the years; their technical terminology is correct, but they often lack a strong command of the target language”. Another opinion voiced by many is that being a physician is useful but not absolutely necessary, since it is impossible to translate all fields of medicine, and that no MD has sufficient knowledge across all medical specialities.

“Both can do an excellent job”

Many were of the opinion that both categories could perform equally well, and that excellent results could be achieved by translators in both groups, provided they have acquired the necessary knowledge and skills in both areas to do a good job: they were simply seen as two different paths to arrive at the same goal. Of course there is also the other side of the coin: various participants expressed opinions such as “both figures can be excellent, or very poor medical translators”, and that they had seen good and bad in both groups. The criteria seen as fundamental for a good medical translator were relevant experience in the subject matter and appropriate research skills: “whichever category a translator belongs to”, one respondent remarked, “they will always need to do research”. Another

essential attribute voiced by many was the ability and willingness to continuously learn more – indeed a strong theme underpinning the entire survey was the need to continue studying and to acquire the knowledge that is lacking. “Both start with key knowledge”, one participant noted, “but also have much to learn.”

What kind of texts were participants comfortable with?

Table 6 shows the number of respondents who expressed their comfort at translating the various text types in the medical field.

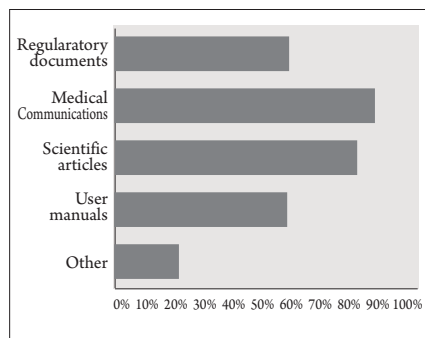


Table 6: Q7 – What kind of texts do you feel comfortable translating?

The fact that respondents were less at ease with regulatory documents and user manuals, compared to medical communications and scientific translations, may be due to the fact that the former two categories require a knowledge of the particular restrictions governing these text types (such as EMA templates), or the fact that user manuals often require technical as well as medical and scientific knowledge.

The “other” text types declared by respondents were many, however the overriding sentiment expressed by participants was that they would only take on texts they were comfortable with and capable of concluding successfully.

What makes medical translation different from other types of translation?

Shortcomings or ambiguities in the source text and use of non-standard abbreviations and acronyms were the two most serious problems, cited by 61% and 59% of respondents respectively.

Identical acronyms with various meanings was another problem, cited by 48% of respondents (e.g. “aha” > acquired haemolytic anemia or autoimmune haemolytic anemia; “ist” > insulin shock therapy or insulin stress test; “and” > axillary node dissection or the conjunction meaning in addition to²).

Other related problems mentioned by respondents were **poor handwriting**, as well as complex language and unclear writing styles, by doctors and medical writers alike. Others observed that the authoring of texts by non-native speakers often made them difficult to understand, and that **poor quality control processes** often led to errors. These factors conflict with the “distinctive features of scientific language”, as observed by Lucia Ruiz Rosendo³, who describes these as “universal nature, accuracy, objectivity, lack of expressiveness and emotion, clearly defined meaning and connotation in order to avoid

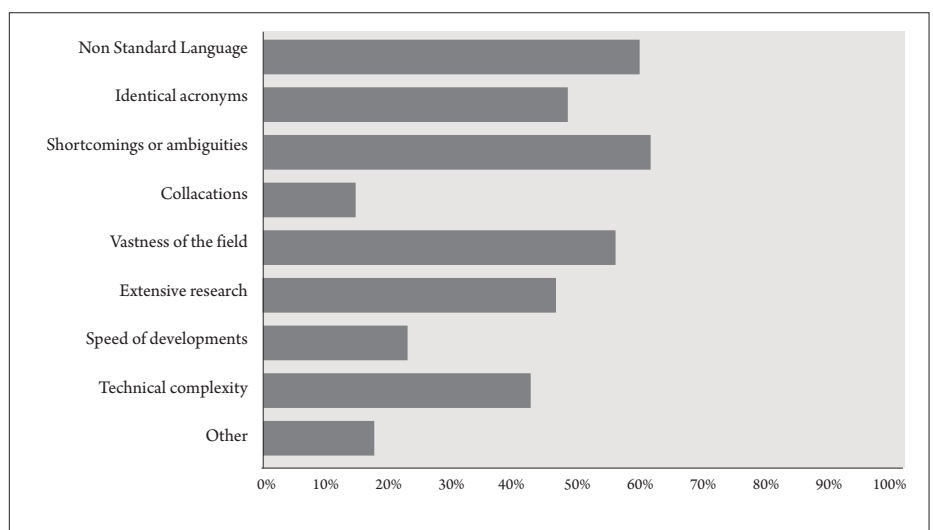


Table 7: Q8 – What do you consider to be the particular difficulties related to medical translation?

any kind of confusion and allow universal communication, lexical monosemic, appropriateness and correction, and clarity and precision.”

Other language-related issues raised by participants were the use of “anglicised Latin”, or “two levels” in certain languages such as English, with the existence of an erudite Greco-Latin term and a more popular name, which is more commonly used, such as *coagulation* (erudite) and *clotting* (popular), or *myopia* (erudite) and *shortsightedness* (popular)^{3,4} – one participant notes that “this is not always evident and requires careful evaluation”. **False friends** and new terms without translations or equivalents in the foreign language (related to the speed at which the medical field is evolving) were also mentioned, while **collocations**, some of which are described by Peter Newmark⁵ as being “among some of the translator’s biggest pitfalls”, were not seen as particularly problematic, cited by just 15% of participants in the survey.

The “**vastness**” of the **medical translation field** was the next most-cited problem (by 55% of respondents, followed by **the need for extensive research** (46%), **technical complexity** (41%) and **the speed of new developments in medicine and technology** (22%). While obviously seen as a major issue for many (almost one in two respondents), others saw terminological and other research as positive, a form of continuing professional development that keeps translators up to date, a way of learning new techniques, methods and terminology. One participant noted: “A specialised translator needs to learn how to learn – how to locate accurate, reliable information and get up to speed with a particular specialised topic quickly. It’s the translator’s job to read and understand background material well, no matter how complex.” Of course a medical translator always has the possibility – indeed the ethical obligation, it might be said – to decline a text they do not feel proficient to handle. Hence the “vastness” is not seen as a problem by some, since translators should simply decline a text they are not able to translate.

Other points not covered by the survey options included the regulatory standards governing certain types of translations, and the fact that many translators (from both groups) are unaware of these regulations. Others lamented a lack of documentation in

certain languages, as well as a lack of educational programmes or courses.

How do medical translators specialise?

So how do translators specialise in medicine? The following table shows the responses from the participants in our survey.

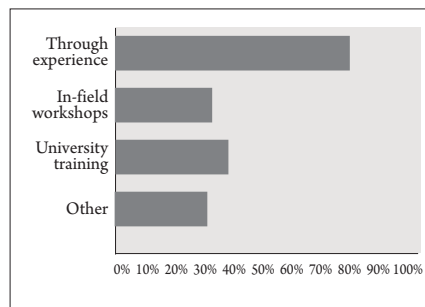


Table 8: Q4 – How have you specialised in medicine?

What is the “best” way to specialise? American anthropologist and folklorist Ruth Fulton Benedict famously wrote: “The trouble with life isn’t that there is no answer, it’s that there are so many answers”. And perhaps we could apply the same sentiment here – the striking feature of the information provided by respondents in their comments was just how many different backgrounds medical translators have: indeed there seem to be almost as many roads into medical translation as translators themselves.

Formal medical education

Perhaps the most obvious, but by no means the most common. The fact that we limited formal medical education to that of doctors when writing the questionnaire, meant that many of the respondents, as shown in the comments to the previous questions, come from a variety of medical backgrounds, including nursing, veterinary medicine, pharmacy, biomedicine and life sciences. Some have been, or are currently, involved in medical and clinical research: other medicine or science-related professions and backgrounds include lab technician, medical secretary or transcriptionist, experience in the medical devices industry, medical billing and insurance, and regulatory affairs. Voluntary work was also mentioned, with some respondents working as hospital interpreters and translators; others found that their experience in administrative positions, and the access this provided to

medical records and their terminology, proved to be an invaluable training ground.

The “Accidental” Specialist

The overwhelming majority (75%) reported **specialising in medicine through experience**, although this took different forms. One aspect of specialisation that many translators will be able to relate to is that “you do not choose your specialisation – it chooses you”, in the sense that at a certain point in their careers, translators are offered work in a certain field, and slowly build up experience this way. One participant reported doing their final internship in a medical translation agency, and being hired at the end; another began doing veterinary translations part-time before starting to do medical translations, and deciding to concentrate full-time on these, while another contract law specialist began translating contracts for clinical trials, continuing their CPD via courses in other branches of medicine.

Personal interest, research and self-study

Another strong theme running throughout the entire survey was a **love of the subject matter**. One respondent in particular recalls reading medical and scientific books as a child, and drawing anatomical figures in her teenage years; this may be an atypical experience, however many respondents have gained experience through their own research and self study, both in the form of the more traditional books and journals, as well as the more interactive and modern resources now available, such as conferences, workshops, webinars and MOOC courses, such as those run by Coursera. While four or perhaps five respondents reported having undertaken formal medical translation courses, this was by no means a typical experience.

Family members and professional contacts

Some respondents reported having one or more family members who work in the medical sector and who can be called upon for help and advice, others report close cooperation, consultation and discussion with health professionals and medical experts as being an invaluable source of help and a way to increase their knowledge and experience, or to polish their translations. Another reported proofreading of their work by senior proofreaders as having been

very helpful, as were reference materials provided by clients. While not all of us are lucky enough to have doctors in the family, the plethora of online help sources, such as the ProZ.com KudoZ feature and online glossaries – provided these are used critically and wisely – are available to everyone.

The traits of a successful medical translator

Given that the purpose of any translation is to convey a message, the skill that emerges – almost unanimously – from our survey as essential, is the **ability to write well**. Fischbach⁶ writes: “Good translating is the *rewriting* in the foreign language of the *ideas* contained in the original. Indeed, we might say that a good translator ought to be as good a writer as the one who wrote the original.” One respondent wrote: “The key to being a good translator in any field is a desire to create a target text with the reader in mind. The translator must be interested in both the subject matter and the language used.” Understanding and knowing how to translate the terminology in the native language was seen to go hand-in-hand with the need to a good writer, to be able to convey ideas simply and directly. Other traits seen as necessary for medical translators included patience, curiosity, attention to detail and an ability and a desire to learn, together with humility and the willingness to check (and double-check!) facts, not taking for granted that “they know better”. In her excellent blog post, Dr Sarai Pahla urges medical translators to “be humble enough to admit that we are all human and all err...”

Conclusions

To MD or not MD? At the end of this article, there is still no clear consensus, but plenty of points for reflection. What does emerge – and what makes this profession so unique – is that translators are individuals, each bringing with them their own particular experience and know-how. While this may sound trite, it is crucial when considering the question in hand. Translation proficiency, indeed, is not merely a result of training, but of many other factors, evident in the wide number of routes taken by medical translators to arrive where they are now. We have seen that medical translation has its own set of challenges, but participants were divided

here too. The difficulties listed were not considered such by many respondents, but rather as a natural part of the medical translation process: the very factors which drive, stimulate and challenge them. And as one participant pointed out: while these challenges exist, there is always someone to call on for clarification. Some expressed the view that these challenges were no more extreme than in other very specialised fields (a view shared by Newmark who writes “this form of translation may be no more challenging than that of poetry”), while one respondent felt that medical translation is actually easier than other fields, noting that better conditions in terms of factors such as source text quality, deadlines and support actually made this one of the easier areas of translation to work in. One current running through our body of data was a call for **teamwork**, proposing the combination of a qualified MD and a qualified translator as being the ideal solution, a “medical-linguistic tandem” so to speak, collaborating and revising each others’ work. “I think both of them are qualified to work as medical translators”, one participant wrote, “BUT when they work together.” Sarai Pahla again: “So let’s spend less time comparing and more time collaborating – if you’re a medical linguist, find a doctor who has studied languages and get them on your side... and if you’re a doctor who has figured out how to work your way through this jungle of an industry, make friends with the right linguists and help each other out!”².

And one nurse said something particularly apposite: “Medical translation must be open to all who either have experience or are willing to learn. Why confine this huge field to a relatively small group of people?”

Acknowledgements

We thank all the professional translation associations who helped us by distributing the survey to fellow translators and to all the colleagues who kindly took time to answer and comment on the questionnaire.

References

1. Andriesen, S (2006) Medical Translation: What Is It, and What Can The Medical Writer Do to Improve Its Quality? *AMWA Journal*, Vol. 21, no. 4, 2006, pp 157-159.
2. Jules J. Berman (2004) Pathology Abbreviated: A Long Review of Short Terms. *Archives of Pathology & Laboratory Medicine*: March 2004, Vol. 128, No. 3, pp. 347-352. Available on: [http://www.archivesofpathology.org/doi/10.1043/1543-2165\(2004\)128%3C347:PAALRO%3E2.0.CO;2?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed&Accessed on 20/11/2015](http://www.archivesofpathology.org/doi/10.1043/1543-2165(2004)128%3C347:PAALRO%3E2.0.CO;2?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed&Accessed on 20/11/2015).
3. Lucía Ruiz Rosendo (2008). English and Spanish Medical Languages: A Comparative Study from a translation point of view. *TRANS* 2008: 12, pp 231-246
4. Van Hoof, H. (1999). Manual práctico de traducción médica. Diccionario básico de términos médicos (inglés-francés-español). Granada: Comares.
5. Newmark, P (1979) A layman’s view of medical translation. *British Medical Journal*. December 1 ; 2(6202): pp 1405-1407.
6. Fischbach, H (1962) Problems of Medical Translation. *Bulletin of the Medical Library Association*. July 1962; Vol. 50, No. 3, pp 462–472.
7. Pahla S. Medical Linguists vs Linguistic Medics. *Loving Language Blog*. Available on: <http://polyglotaholic.blogspot.it/2014/01/medical-linguists-vs-linguistic-medics.html> Accessed on: 15/11/2015.
8. Van Hoof, H. (1999). Manual práctico de traducción médica. Diccionario básico de términos médicos (inglés-francés-español). Granada: Comares.

Fiona Peterson

fiona@traduzioni-mediche.com

Laura C Collada Ali

laura.collada@teksema.com

Medical writing teaching

A novice's experiment with a wiki on a writing course

A wiki? What is that?

The name 'wiki' was probably what attracted me most about using this e-learning tool in my teaching. As a New Zealander, I associated the word with the Maori terms 'waaka' (canoe) and 'tiki' (wooden carving) and of course just an odd way of spelling 'kiwi'. I thought that at the very least, I would feel some affinity for the wiki, even it proved challenging to use.

How wrong I was! At least for a good while, before I had experimented with the wiki on two writing courses. I am not the most technologically literate person, but I found it more difficult than expected to delve into the world of e-learning and to appear knowledgeable when explaining the wiki task to my students – and to feel confident that it would work.

A wiki is a series of linked pages on a website, where selected users can write freely and also edit and comment on other users' texts (it is the basis of Wikipedia). I used a wiki exercise as part of my lecturer's training course at the University of Southern Denmark in Odense. The university has made e-learning a priority within a framework of "active teaching and learning", where students are stimulated to be active in a way that generates in-depth learning and motivates both students and lecturers. During our one-year training course, we were to choose an e-learning tool and develop a project for our students that would facilitate their learning. The choice range was wide and included not just wikis but also podcasts, flipped learning, student-response systems, blogs, discussion forums, etc.

I teach academic writing to undergraduate students and PhD students, aiming to help them develop their writing skills to produce effective, scientifically sound, and ethical journal articles. One of the learning objectives is that the students can critically assess their own and other people's

manuscripts. This calls for an understanding of the required academic content, and format of a scientific journal article as well as the ability to present ideas and findings logically using common reporting standards and ethical publishing principles.

I thought it would be interesting to see if a collaborative wiki exercise could help the students to develop a list of items that should be checked before a manuscript is shared with others or submitted for publication. The aims of the task were to strengthen the individual student's ability to reflect on the quality and content of their text and to support them in identifying key elements of scientific manuscripts.

Creating a wiki on an e-learning platform

It took me quite a while to understand how to set up the wiki and give others the opportunity to write in it, and indeed to see how to structure it. The encouragement and technical assistance from the IT consultants for the lecturer's training course were invaluable here! But then it was relatively easy to set it up in a format that gave the students a quick overview of the wiki structure and the freedom to add new items. I chose to use the wiki homepage to describe the purpose of the exercise and then created four new pages for different aspects of a manuscript (General layout, Language, Content, and Tables and figures). Each student was to add new items to the pages.

I was surprised at how much explanation was needed to describe the wiki exercise. Most of my students had never used a wiki, so I needed to:

- explain the purpose of the wiki exercise and how it related to the learning objectives
- give some examples of relevant items that could be added
- describe how to open and add wiki pages, and how to add items and comments
- provide deadlines for adding items and describe how we would work with the wiki during the course.

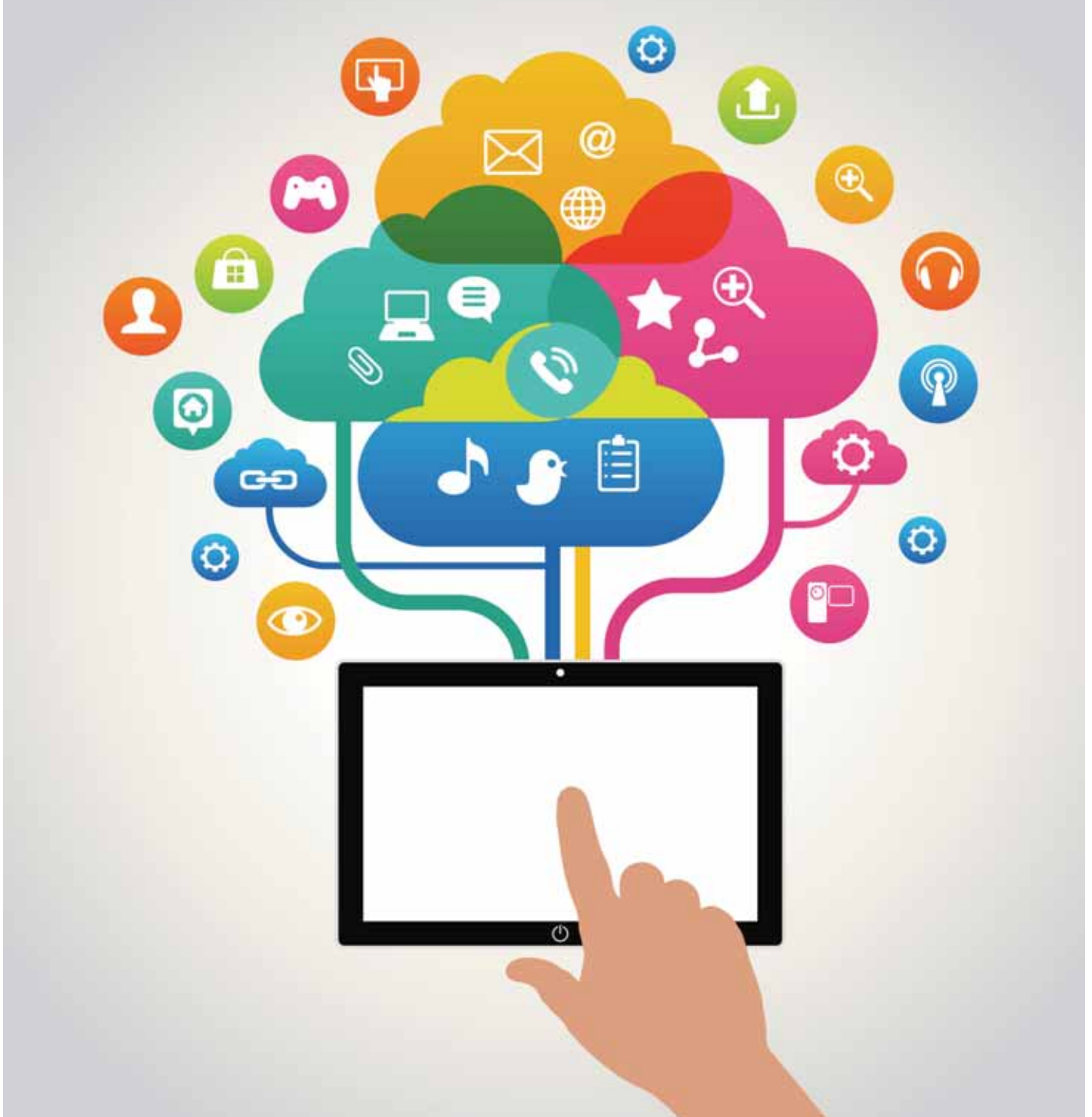
Although the students in the first writing course all added useful items to the wiki, there was little online discussion of each other's items and the students did not appear to actively use the checklist when reviewing one another's manuscripts in the final class session. I think the students hesitated to alter other students' items because they did not know each other before the course and came from different scientific backgrounds.^{1,2} Although most students thought the exercise had been useful, and two said they had been inspired to create their own wiki checklist, it was also noted that the wiki checklist was too general. I realised that more class time should be spent on the wiki to utilise the students' varying scientific backgrounds and writing experiences.

In the second writing course, I explicitly asked the students to use the checklist while preparing their own manuscripts and then the final class session started with the students discussing the wiki checklist in small groups. This resulted in a much more lively discussion about the meaning and use of the wiki items and their relevance for different types of scientific manuscripts, and I think the students took greater ownership of the product. The written feedback from these students showed that the wiki exercise had been useful in assessing the quality of their own and others' manuscripts, and would be useful for their future manuscripts.

SECTION EDITOR



Claire Gudex
claire.gudex@rsyd.dk



Conclusion

The wiki exercise helped open my eyes to the potential of e-learning activities. It was definitely harder than I expected, though. Not just because of the practicalities in understanding and setting up the exercise, but also because it requires you to think carefully about what you want to achieve with the activity. I spent much thought on how to inspire the students to participate actively in the exercise and thus benefit from the collaborative learning.

I think that in the end I succeeded in encouraging the students to reflect more critically and systematically over their own and others' manuscripts. In future classes though, I might experiment with a different

approach where small groups of students use an online discussion forum to jointly develop the wiki checklist, and then have the results discussed in class.

So perhaps my initial thoughts about the wiki were not so wrong after all. The approach can be tricky to handle effectively (like a canoe) and requires patience (like locating the shy, nocturnal kiwi) but after some practice, it can be mastered and used successfully as a learning tool. If others have any experience using wikis or other e-learning activities to teach (scientific) writing skills, I would very much like to hear about it.

References

1. Carr N. Wikis, knowledge building communities and authentic pedagogies in pre-service teacher education. In: Hello! Where are you in the landscape of educational technology? Melbourne: Proceedings of the Australasian Society for Computers in Learning in Tertiary Education, 2008. Available from: <http://www.ascilite.org.au/conferences/melbourne08/procs/carr-n.pdf>
2. Wheeler S, Wheeler D. Using wikis to promote quality learning in teacher training. *Learning, media and technology* 2009;34(1):1-10.

Claire Gudex



An interview with Phil Leventhal Editor-in-Chief of *Medical Writing*

How and why EMWA members should contribute to the journal

At the beginning of this year, *Medical Writing* (MEW) changed from Maney Publishing to Hastings Printing Company. This has allowed the journal to dispense with the need for copyright transfer and to consider open access. The idea of open access was brought up several times, and a LinkedIn discussion last spring, coupled with the pending change in publishers, encouraged EMWA to launch a member survey about it. The results of the survey led to EMWA's new policy of open access for feature articles.

In the light of these changes and considering the theme of this issue (Authors and Authorship), we thought that we should ask Phil Leventhal, Editor-in-Chief of MEW, to discuss what authors need to publish in MEW and why they should do it.

Phil has been a medical writer since 2003, when he transitioned from pharmaceutical research. Phil is originally from the US and has a PhD in Bio-molecular Chemistry from the University of Wisconsin. In addition to serving as the Editor-in-Chief of MEW since 2012, he has been an instructor at the Medical University of Innsbruck and is an Adjunct Associate Professor at New York University. Phil has also led workshops on medical writing for EMWA and various institutions in Europe since 2011.

MEW: Many medical writers may ask themselves if their level of experience is good enough to submit an article to MEW. Who can submit an article? Is there a specific level of experience contributors need?

Phil Leventhal (PL): Of course, we love receiving contributions from experts, but

any medical writer, irrespective of experience level, can publish an article in MEW. Your personal experiences will be relevant to someone, no matter what your experience level. Even if you are inexperienced, the information you collect as you learn and the process you go through as you master new subjects will be helpful to someone. You can write about something you know about or even something you don't know yet but want, or need, to learn. For example, you might be asked by your employer or client to prepare a kind of document you know nothing about, and your research about the topic could end up as an article.

MEW: So if junior writers can submit articles, how do you ensure that the quality is sufficient?

PL: When we receive an article, I or another member of the Editorial Board will critically review the content and writing and then work with the author to make sure that the quality is sufficient for publication. This can include several rounds of revision by the editor and the contributors. We only ask that contributors remain open to having their writing edited and, if necessary, reworked.

MEW: What about non-native speakers who might not be confident about their English?

PL: All of our editors have excellent English skills, and they are asked to work with the contributors to perfect the English as part of the standard review and revision process.

MEW: What is the process of preparing and submitting a paper, and where can I find the author's instructions?

PL: The best way to start is to contact the Editorial Assistant (mew@emwa.org) and propose an idea for an article. Assuming that we agree on the overall theme, I will ask the Editorial Assistant to send you the feature article template and the instructions for authors. The feature article template is a Microsoft Word file that contains all of the formatting needed to prepare the article. The specifics are also given in the instructions for authors, but the template simplifies the process and makes the Editorial Board's job easier. You can download the feature article template and instructions for authors from the journal website (<http://journal.emwa.org>) or request them from our Editorial Assistant (mew@emwa.org).

MEW: A frequent cause of frustration in medical writing is the rejection of an article. Could you explain how articles for MEW are selected?

PL: Most of the time, articles are solicited by me or a member of the Editorial Board, but more and more articles are coming in unsolicited. Except for the rare original research article, articles do not go through a formal peer-review process. The decision to accept the article is up to me and the Editorial Board member assigned to the article. Honestly, it's rare for us to reject an article. I think that I have rejected about three articles in the last 3 years. Even in the worst cases, we would rather work with the contributor to develop an article so that everyone is satisfied with and that will be of practical use to our readers. The rare

cases of rejection happen when the subject is not appropriate for our readers, it is clearly advertising for a company, or the contributor refuses to make changes we consider essential.

MEW: What other advice can you provide to authors who would like to submit an article?

PL: The most important thing to remember when writing for MEW is to think about your target audience – professional medical writers of varying experience levels. The article should be practically useful and include examples, and it should be written in a professional but conversational tone. We are not looking for a boring, academic style but rather a more dynamic magazine or newsletter style. We strongly encourage that you include tables, figures, and pull-quotes (key bits of text that appear in large, highlighted text) to help maintain interest and emphasise key points.

MEW: Why should I write an article for MEW?

PL: Writing an article for MEW is an excellent way to advance your career and to improve your visibility within the medical writing field. It establishes that you are an expert in your area, someone to turn to when other medical writers have questions. This is even the case for junior writers, and it is especially true now that feature articles will appear on Google and Google Scholar and will be available open access. Because of open access, you will be able to post your articles on any website and share them with potential employers or clients. For companies and freelancers, this means improved visibility, so it's essentially free advertising.

Another benefit of writing an article for MEW is that it is a great way to learn and add to your professional expertise. Every time you prepare an article, you will need to do some research, even if you are already an expert. This will expand your

knowledge about medical writing. For example, when I started at my current company, I wondered "What are the most common reasons that articles are rejected?" The research I did answering this question not only became an article but also added to my understanding of the peer-review process, which has helped make me a better publications writer.

A third benefit of publishing in MEW is that the article is concrete evidence of your expertise that can be shared with a prospective client or employer. As with peer-reviewed articles that you may have published during graduate studies, your articles can (or should) be listed on your cv, and thanks to open access, they can be distributed freely, either in print or electronically.

MEW: Once I publish in MEW, don't I relinquish the rights to the writing?

PL: Since switching to the new printer, contributors no longer have to assign copyright to us or the publisher. Contributors retain full ownership of the material, although if you want to provide or re-use the full article or substantial portions of it, we ask that you state that it was originally published in MEW and give at least the volume, issue, and page numbers.

MEW: If someone wants to participate more or become a member of the Editorial Board, what experience do they need, and who should they contact? For that matter, how did you become Editor-in-Chief?

PL: We definitely welcome volunteers – there's always room for additional Associate or Section Editors. We need people with excellent English writing skills and an interest in writing and editing magazine-type articles, something that most medical writers don't get to do.

We definitely welcome volunteers – there's always room for additional Associate or Section Editors.

Usually, I ask people interested in joining our board to write or to edit an initial article or two so that I can judge their abilities. Anyone interested in volunteering for the board can simply send me an email.

How I became Editor-in-Chief is a good illustration of how volunteering for EMWA is an amazing opportunity. Back in 2007, I volunteered to write an article called "Freelance or employee: Which is better?" for MEW's precursor, *The Write Stuff*. I really liked this magazine-style of writing, so I pitched the idea of a regular column on my specialty, manuscript writing, which I ended up writing for two years. That, in turn, led to my guest editing two issues of *The Write Stuff* and agreeing to serve as an Associate Editor. When MEW's first Editor-in-Chief, Elise Langdon-Neuner stepped down in 2011, it was natural for me to take the reins. It's been challenging but fulfilling, and I am happy to continue during our transition to a new printer and new format.

MEW: Thank you for taking the time to share this important "insider" information with us. Publishing in MEW is obviously a great way for medical writers to advance their careers and increase their visibility within the medical writing field.

Phil Leventhal can be contacted at editor@emwa.org.



EMWA's 2016 Webinar Programme

In 2015 EMWA launched its webinar programme, providing members with an online training resource. Your feedback has been valuable in helping us to shape an exciting and extended programme for 2016, presented by inspirational speakers, all highly experienced in their field.

What is a webinar?

A webinar is 'a seminar or other presentation that takes place on the internet, allowing participants in different locations to see and hear the presenter, ask questions, and sometimes answer polls.'¹

Why is EMWA offering this?

What's the purpose of a webinar and of the webinar series?

EMWA webinars allow for distance learning and for updating and refreshing basic medical communications skills and knowledge, for newcomers and old hands alike. This is especially useful for subjects that might not be practical or possible to be presented during EMWA conferences. Webinars also allow for timely training for specific issues as they arise, although this means that the schedule may be adapted as the year progresses.

How are the webinars selected?

Several factors go into selecting webinar topics. First, we select webinars based upon the feedback received from the audience of previous webinars. Additionally, we judge from attendee numbers the topics that are of special interest to medical writers. Second, we try to cover a wide range of topics specifically related to medical writing as well as universal topics such as statistics and project management. We also intend to provide updates on the latest guidelines, such as the new risk management plan summary template, which is expected to be published in mid-2016. Lastly, we plan for one disease-specific webinar per year. All presentations are peer-reviewed, and we ensure that the speakers are experts in their fields.

The current webinar programme can be accessed at www.emwa.org/webinars, and the preliminary webinar programme for 2016 is summarised in the table.

How do the webinars work?

How do I access live webinar

platforms and the webinar archive?

Webinars usually last 1 hour, with time reserved for a short question and answer

session at the end. Webinars are free for EMWA members. Attendees use the Citrix GoTo Webinar platform. The technology is best-in-class and does not require a phone or complicated installation or permissions. Registration will open at least 2 weeks prior to each webinar and will be announced via LinkedIn, Facebook, and Twitter. Once open for registration, you can register for any webinar simply by following the green "Register here" button found at www.emwa.org/webinars.

Once registered, reminders are adapted to the user's time zone. The system allows for sharing of handout material, polls, and surveys as needed.

If you missed a webinar, you can still access it via the webinar's archive. Simply click the respective "View the archive" link at the bottom of www.emwa.org/webinars. Webinars are posted approximately 2 weeks after broadcast.

We wish you a good and joyful learning experience and welcome your feedback at pr@emwa.org.

The webinar team

- Beatrix Doerr, Public Relations Officer
- Patrick Bohan, Webinar Manager
- Gail Zona, Editor

References

1. Dictionary.com. Definition for webinar. [Accessed on December 30, 2015] <http://dictionary.reference.com/browse/webinar?s=t>

Beatrix Doerr

Clinical Research and Management
Consultant, Medical Writer
Beatrix.doerr@gmail.com

Patrick Bohan

PharmaMar
pbohan@pharmamar.com

Emwa's 2016 Webinar Programme

Month	Webinar Title	Speaker	Webinar Description
January*	Practical tips for effective project management and communication	Alison Rapley	Alison will share her experience of over 20 years in the medical writing department of a large CRO
February*	Introduction to statistics	Magda Joana Silva	This webinar is intended for medical writers who want to understand more from statistics. It will include basics such as mean and median, p-value, confidence intervals, and risk ratios.
March	First steps into freelancing –	Jonathan Edwards	Jonathan will reflect on his initial experiences, including initial experience considerations during the pre-freelancing 'set-up' period; approaches to contacting and winning clients; and how hopes and expectations met with reality during his first few months as a freelancer. He will also comment briefly on aspects of business set-up (such as tax status), but by necessity this part of the presentation will be UK-specific.
April	Linguistic panel	Amy Whereat, Alistair Reeves, and Laura C. Collada Ali	We will discuss linguistic topics such as sentence building, introductory phrases and link words, comparing and contrasting, as well as some 'language myths'. If you have any questions regarding grammar and style, please send them to pr@emwa.org and we will endeavour to answer them during the webinar.
June	Introduction to MedDRA coding	Ursula Oestringer	This webinar will provide an overview of Medical Dictionary for Regulatory Activities (MedDRA); an introduction to MedDRA coding; and some practical "how to" tips for those who might already have preliminary experience with MedDRA.
July	New risk management plan summary template	Inga Abed	The EMA's Inga Abed will discuss the outcome of the EMA pilot on RMP summaries which began in March 2014 and the updated template of the RMP summary, highlighting the main changes and guidance for completing it.
August	Make Word behave as it should	Gail Zona	This webinar shows Word users how to solve some of the most common formatting problems that occur when working in a Word document, how to use Word's formatting styles, how to deal with table of contents problems, and how to create internal and external links.
September	Practical guide for writing clinical study protocols for medical devices	Beatrix Doerr	This webinar will give practical, step-by-step guidance on how to write a clinical study protocol for a medical device.
October	Client management	Kathryn White	In this webinar, Kathryn addresses several questions she received during her time as EMWA Freelance Advocate, such as points to address at a first interview with a potential new client. She will also offer tips on gaining and retaining clients.
December	The cardiovascular system	Monica Meyer	This webinar will focus mostly on the heart, its anatomy, physiology, and associated diseases such as aortic stenosis and coronary heart disease.

* Available in the webinar archive.

**European
Association of
Science
Editors**

EASE



Photo: Yves Nato-Campanella

Scientific integrity: editors on the front line

THIRTEENTH EASE GENERAL ASSEMBLY AND CONFERENCE

Strasbourg, France

10-12 June, 2016

Strasbourg is the capital and principal city of the Alsace region in eastern France and is the official seat of the European Parliament. The historic city centre, the Grande Île (Grand Island), was classified a World Heritage site by UNESCO in 1988. The University of Strasbourg is currently the second largest in France and the conference will take place in the superb facilities of the University's School of Medicine. For more information, visit www.ease.org.uk/ease-events/13th-ease-conference-strasbourg-france

Plenary Speakers

Surgery: from research to training and publishing – Jacques Marescaux, IRCAD, Strasbourg

Role of institutions and editors – Lex Bouter, VU University Amsterdam

Plagiarism – Michelle Bergadaà, University of Geneva

PubPeer: implications for editors – Boris Barbour, PubPeer, Paris

Organising committee

Hervé Maisonneuve, Alison Clayson, Evelyne Decullier,

Joan Marsh, Chris Sterken, Liz Wager

Out On Our Own

SECTION EDITORS



Kathryn White

kathryn@cathean.co.uk



Alistair Reeves

a.reeves@ascribe.de



Sam Hamilton

sam@samhamiltonmwservices.co.uk

Editorial

This is the last OOOO edited by Kathryn White and Alistair Reeves, with Sam Hamilton in the background. After many years all three stepped down from their freelance advocate activities at the conference in The Hague, and have handed the torch over to Julie Charlesworth and Satyendra Shenoy, who will be running the Freelance Business Forum and will also be looking after this journal section in the future.

Of interest in how fellow freelancers set up business and acquire work is always high, and in this issue we include Lizzie Sharpe's story about her experiences in Germany.

We also include Part 1 of Marion Alzer's account of how she reluctantly became a medical translator but then found that it actually opened up many unexpected doors for her, including becoming a freelancer and also taking on medical writing jobs.

Are you having the impact you want to build the business you truly deserve? This is

the question pursued by Dawn Bentley, an executive coach, who feels that creating the right impact on clients is something that freelancers often neglect. But since you alone are responsible for your impact, this is something to consider very carefully.

Please contact Julie (julie@atreeoflifesciences.com) or Satyen (ssheno@describescientific.de) if you would like to contribute to OOOO

The start of a year in Germany as a freelance medical writer

"I'm moving to Germany."

"What?"

"Yes" I repeated, "Moving to Germany."

"And what are you going to do there?"

"I'm going freelance." I said – the thought of which was scarier to me than moving to a country where I didn't even speak the language.

So went the majority of conversations with friends, family, and colleagues as I broke the news that I would soon be moving to Munich.

In theory, all a writer needs is their laptop, a few industry contacts, and a reasonable WiFi connection. And that's it; you're free to work wherever you choose.

In reality, nothing prepared me for the barriers that would crop up on the other side of the UK border.

Challenge 1: Getting ready to go

Leaving a stable job at an agency I'd loved working at for the past 3 years was by far the most difficult decision. After that, I had to try to get to grips with what it meant to be a freelancer. Not just a freelancer, but a *freelancer in Germany*.

Being a complete newcomer to the game, I sought advice wherever I could. Calls with umbrella agencies, recruiters, tax advisors. Chats with freelance colleagues proved



invaluable, but no one could really tell me what steps I would need to take to work as a freelancer in Germany. I even rang the German consulate in one moment of desperation.

Before moving out here, I contacted various recruiters to see if they could help find me work and even got in touch with a few Munich-based agencies myself. A few got back to me and I secured a couple of interviews before boarding the plane.

Challenge 2: The interview stage

I come from healthcare advertising and – in Germany at least – it seems that scientific and creative writing are kept very separate. Luckily, I'd worked at an agency in the UK where I was given the chance to develop both skill-sets.

Being able to be both a medical writer and copywriter therefore seemed to be a rare and valuable quality to my German interviewers; and the fact that my portfolio spanned both creative and scientific work

really seemed to work in my favour.

Given my limited German capacities, I niched myself as a native English speaker, which I hoped might give me the edge over in-house German writers on global accounts. This, however, didn't always work to my advantage.

Challenge 3: Ich spreche kein Deutsch (I don't speak German)

When working in-house for German agencies, this was never really an issue. Germans are incredibly helpful people and I found that most were more than willing to go out of their way to accommodate my linguistic deficits.

For example, agencies would have freelance contracts translated into English for me before I looked over them. And I was grateful to find that my multi-lingual colleagues all switched to English for my benefit whenever I joined them on conference calls.

The language barrier only presented real problems when setting myself up as a freelancer.

Challenge 4: Making friends with the tax man

As I moved into freelancing, the hardest part for me to grasp was who was going to take care of my taxes. I would be working for both UK and German agencies, but carrying out the work entirely from Munich meant that all my taxes would have to be paid to the German government.

Most umbrella agencies are only able to support you for up to 3 months if you are living in another country. And if you are set up as a limited company then you're only able to invoice through this for up to 6 months while living abroad.

But I needed someone to process my UK and German invoices for a whole year. I had a few leads on some umbrella agencies who specialised in leasing out freelancers in European markets; but generally these were not willing to take me on unless I was contracted to work for at least a couple of months at a time.

The solution I found was to register as a 'Freiberufler' (self-employed person) – meaning I could invoice my clients directly using my tax and VAT numbers – and I hired a German tax advisor to take care of my German taxes.

To do this I first had to fill out a form from the Finanzamt (the 'Fragebogen zur steuerlichen Erfassung') – this is long, and

entirely in German. I had a German friend help me decipher the different sections and even she found it difficult to understand.

My biggest concern with becoming a Freiberufler was that this might close a lot of doors to me in England. It's not uncommon for many UK agencies to have a policy whereby they only work with freelancers who are registered as a limited company or otherwise working through an umbrella organisation.

After explaining that this was the most compliant way for me to operate as a freelancer in Germany, some of my UK clients were happy to work with me under my Freiberufler status, but others weren't.

Challenge 5: Getting down to business

After the first couple of interviews, which I'd set up before leaving the UK, I was optimistic that it wouldn't be long before I was hit by a tidal wave of work that would soon come flooding through my door.

At each interview I was greeted enthusiastically, complemented on my portfolio, and received great feedback. Then ... nothing.

I waited and waited for the call but it was almost 2 months after I moved before I got stuck into my first piece of work at a German agency.

Remote medical writing from old industry contacts in the UK tided me over while I waited to get started. I began to cast my net wider by applying for work in different sectors, and in doing so sought out jobs in places I'd never thought to look before. Even, at one point, branching out beyond pharmaceuticals into health and wellbeing for a Munich-based fitness brand.

Now, I'm mostly brought in to work for German companies on a project-by-project basis, which means my contracts are short term. The majority of my income still comes from remote work, and I'm not busy all of the time.

But I'm ok with that. This year is more about giving me a chance to explore life in another country; learn how to live as a freelancer; and hopefully pick up more than a bit of German along the way. Tschüß!

Correspondence to:

Elizabeth Sharpe

Munich, Germany

lizziejanesharpe@gmail.com

<https://elizabeth-sharpe-dglu.squarespace.com>

Medical translation – a dead-end job or a gateway to opportunity? Part 1

When I was a teenage student studying English as a foreign language, I used to think translating was boring; utterly boring to be precise. So, why did I follow a career as a professional translator and what made me change my mind?

Dreams and aspirations

It was during my first trip to England at the age of 13 that I fell in love with the English language. Three years later, in 1980, my German school offered a 3-month student exchange programme in Vancouver and I was selected as one of the fortunate candidates. I realised that the ability to communicate with people in other countries opened the door to the rest of the world for me.

By the time I returned from Canada, I was determined to teach foreign languages when I left school. Unfortunately, job prospects for teachers were far from brilliant in Germany at that time. I had to face the fact that the career I had dreamed of was not a realistic option if I wanted to avoid becoming an unemployed university graduate. Being a conference interpreter sprang to mind and it seemed like an exciting alternative. I

Are you having the impact you want with your clients?

As a freelancer, or 'entrepreneur' you are the leader in your business. You are the one who makes things happen, so whatever happens in your business is down to you. Good client relationships are the key to your success. *You* are responsible for setting the tone of each interaction and standards of behaviour for those around you. This may sound scary, however, as the leader in your business you are on show all of the time. People are always watching you and making assessments, so it's not good enough to just show up and hope for the best. Whether you like it or not, you and your business are judged by the impact you have on others.

So, the question is, are you having the

imagined myself travelling from one international conference to another, helping people communicate with one another. I applied to the “Department of Applied Linguistics” at the University of Mainz in Germersheim to study English and Spanish and I was accepted.

Change and choice

What seemed fascinating in theory turned out to be disappointing in practice. I just couldn't get the hang of sitting in a booth, listening to someone speak in one language and conveying what was being said in another language. After umpteenth attempts to master the challenges of simultaneous interpreting, I eventually got to grips with the fact that all those international conferences would have to take place without me.

This experience did not discourage me from wanting to pursue a career in languages. Fortunately, my university offered translation studies as a suitable option and despite my earlier reservations I switched over to translation. The course was structured to include two foreign languages and an additional subject such as law, economics, engineering or medicine. I chose medicine and thoroughly enjoyed this subject. I attended medical lectures that focussed on the various body systems and

later completed medical translations specific to each body system to gain competence in medical terminology and how to convey the meaning of medical texts. The examining board consisted of professional translators, a physician and a pharmacist and ensured that after nine semesters I was proficient in “medicalese” and worthy of the degree “Diplom-Übersetzerin”.

Work experience

To gain work experience in the real world, I applied for internships in the Medical Department of a pharmaceutical company while I was still studying. I was introduced to drug research and development at a time when the company was granted marketing authorisation for a new drug which later became a blockbuster product. My responsibilities included translating regulatory documents and correspondence with authorities, medical and marketing materials as well as press releases.

Language proficiency

To improve my command of English, I decided to live in an English-speaking country and so I participated in exchange programmes with the University of North Carolina at Charlotte (UNCC) and Louisiana State University (LSU) at Baton Rouge. At LSU, I also completed a Master's

programme in linguistics with a focus on second language teaching. To finance these studies, I taught German in the Department of Foreign Languages.

When I returned to Germany in 1991 I applied for a position in the pharmaceutical industry. Fortunately, the headquarters of a German pharmaceutical company with affiliates all over the world were looking for a medical translator. The company's Foreign Language Services group formed part of the Scientific Documentation Department and consisted of six people who worked in four different languages. Our group was responsible for translating and coordinating translations mainly in the following areas: pre-clinical, clinical and regulatory; drug manufacturing; corporate affairs and international relations. Other tasks also included review and correction of translations done by external translators as well as terminology work.

In Part 2, I will describe how I became freelance.

Correspondence to:

Marion Alzer
Pharma Communications GmbH
Erding, Germany
info@marion-alzer.de
www.marion-alzer.de

impact you want to build the business you truly deserve? Have you even considered the impact you want to have?

In my experience most people haven't!

How do I create impact with my clients?

There are two principles to have in mind when you are considering your personal impact with clients:

1. Your intention
2. Your attention

Principle 1: Intention

Let us start by looking at intention. There's a phrase I often use which is 'we judge ourselves by our intention and we judge others by their impact.' Being really clear about your intention helps you focus your mind and your energy. To be effective your actions must match your intention. This

portrays a clear message, if you are thinking one thing but saying another, people will pick this up.

How often do you go into a meeting with a clear intention of what you want to achieve from it?

Leadership is about connection, so you need to make sure you connect in some way with everyone you meet – and yes I did say everyone. Of the people you come into contact with, you never know who could introduce you to a potential new client or perhaps they know one of your existing clients.

So, how do you create that connection? To connect you have to take the other person into account and should be part of your consideration when thinking about your intention. Before any meeting or interaction with a client, some good

questions to ask yourself are:

- What is your current relationship with them?
- What is the history between you both (or between you and their department)?
- How do you want this relationship to develop?

Once you have thought about these you can then think about what you want from a meeting with them – whether this is in person or remotely by telephone. What outcome do you want to achieve?

Case study

Here's a case study from my coaching practice to give you an example of how considering your intention can make a difference:

Carol was a newly appointed Operations



Director and very experienced in her field. In a relatively short space of time she had mastered how to lead her team effectively so that they were aligned with her vision.

However, she realised she hadn't been giving her customers (i.e., her stakeholders) the attention they deserved in order to engage with them and 'get them on board'. This was particularly important if she wanted the changes she was implementing to work.

Together, we explored what her intentions were and what became clear was that she was 'just' going through the motions. She was using all the right words when she spoke with her customers, but she didn't sound as though she meant them. I sensed that her mind was on other things so she was working with her customers out of a sense of duty rather than to build relationships.

We went on to explore how she wanted the relationships to develop. By being focused on her intention, in just a few months, she'd built strong relationships and trusted allies.

So, before you have any contact with your clients, really think through what it is you want and how you want to be seen.

Here are a few examples of things you could consider as intentions to get you started before any client interaction:

- Do you simply want to connect and build rapport with the person? At the start of a relationship this is critical.
- Is there a particular result you want from this interaction?

- Is there something you want to learn?
- If there is a topic you're discussing with the client, do you simply want to understand it or learn more about it?
- If so, what is it about that topic that you want to learn/understand?
- Is there an idea you want to share with the client to get some feedback on it?

Principle 2: Attention

'Energy flows where attention goes'

Where do you put your attention? When you are in a meeting or with a client how often are you waiting to speak rather than actually listening with an intention to understand what the other person is saying?

If personal impact means aligning your intention to how you act, then you *have* to be attentive to those you are working with. That means that you are fully present in that moment. I am sure you have been with someone and thought that they were not really with you, their mind was somewhere else. When someone seems distracted like this, say in a meeting, you notice it. So, it will come as no surprise to you that people will notice it too when *you* are not paying attention!

Case study

This principle was a real light bulb moment for one of my clients as shown by the following case study.

When I'm coaching I encourage my clients to bring real situations they are facing into the session. On one coaching occasion I picked up that my client Paul, seemed to be rushing ahead and not necessarily

connecting with me as he described a situation he wanted help with. After some feedback from me, and some practise at improving his attention, we replayed the situation. There was a marked difference. He had slowed down, he was making eye contact, his breathing had slowed down and I felt he was really listening to me. Now, he was working with me at my pace and was fully present and engaged with me.

After the session he applied these principles at work and found his team became more engaged, he developed a deeper connection with his customers and as a consequence got better results.

What can I do to create impact with my clients?

To help you create more impact during your business interactions, I've listed a few things to consider before any client meeting:

- Set an intention for every interaction or meeting you go to.
- Consider how you want to be seen and adjust the tone of your voice and body posture to support this. The more relaxed you are, the deeper your vocal tone and this will be reflected in your body language too, thus giving you a greater air of confidence.
- If you are having a conversation with someone focus your full attention on that person and the conversation – really listen to what they are saying.
- If it's a meeting you are in, do the same and focus on every person as they speak.

Personal impact is what others feel when they are with you and this will be reflected in the quality of the relationships you build. If you want to take your business to a new level, practice these skills regularly and feel the difference it makes!

Dawn Bentley is an Executive Coach working with leaders to be authentic in their style and develop powerful teams. If you'd like to follow her posts please connect with her on LinkedIn Facebook, Twitter or sign up for her monthly newsletter here.

Correspondence to:

Dawn Bentley
Aurora Business Coaching and Consulting UK
Dawn@aurora4success.co.uk
www.aurora4success.co.uk

Themes of forthcoming issues of **Medical Writing**



June 2016: **'Medical Communication'**

This will include articles on careers in medical communications, evolving best practices, continuing medical education, communication strategy, and medcomms agencies.

Guest Editor: Amy Whereat.

This issue is now closed to new submissions.



September 2016: **'Statistics'**

This will include articles on presenting and understanding basic statistics for medical writers.

The deadline for feature articles is June 13, 2016



December 2016: **'Medical Education'**

This will include articles on running advisory boards and preparing slide kits, conference presentations, and other learning resources.

The deadline for feature articles is September 12, 2016

If you have ideas for themes or would like to discuss any other issues, please write to editor@emwa.org.

