

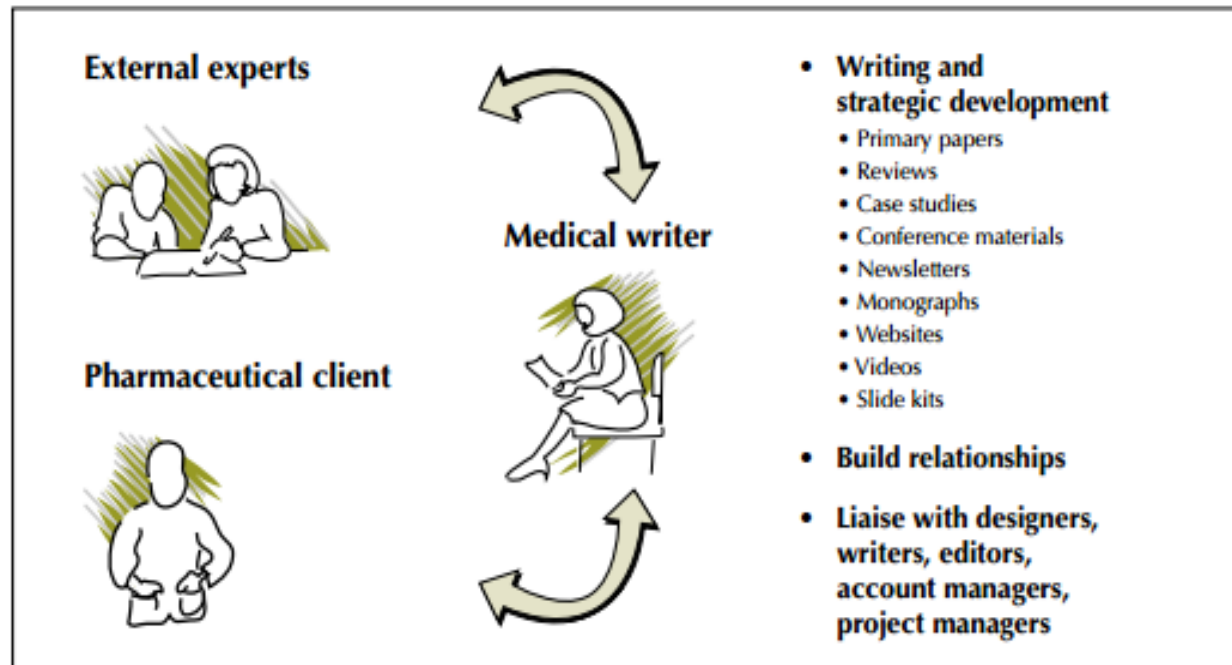
**Publishing, medical writing and authorship:  
Is more transparency needed?  
The Publisher perspective**

Sandra Lê, PhD  
Dove Medical Press

Thursday 8 December 2016

**Dove**press

# What do medical writers do?



From academic to medical writing – a guide to getting started in medical communications, by Dr Annick Moon, 2016, Published by NetworkPharma

<http://medcommsnetworking.com/careersguide.pdf>

# Who are ghostwriters?

- A person whose job it is to write material for someone else who is the named author (English Oxford Dictionary online)
- Medical ghostwriters are employed by pharmaceutical companies and medical-device manufacturers to produce apparently independent manuscripts for peer-reviewed journals, conference presentations and other communications. Physicians and other scientists are paid to attach their names to the manuscripts as though they had authored them. The named authors may have had little or no involvement in the research or writing process (Wikipedia)



# So that we're clear

- Few ghostwriting scandals in the late 90's, early 2000's
- Ghostwriting is unacceptable and unethical (COPE, ISMPP, EMWA, AMWA, GPP3)
- **Medical writers are NOT ghostwriters unless they are not acknowledged**
- Medical writing support improves the timeliness and quality of the reporting of RCTs as well as the written English (Gattrell *et al.*, *BMJ Open*, 2016; 6:e010329)
- Medical writers are trained to provide appropriate assistance and insist on disclosure. They can be valuable allies in the efforts to tackle ghostwriting (Gøtzsche PC *et al.* *PLoS Med* 6(2): e1000023)



# Authorship in medicine

According to ICMJE, designation as an author must satisfy four conditions. The authors must have:

- Contributed substantially to the conception and design of the study, the acquisition of data, or the analysis and interpretation

**AND**

- Drafted or provided critical revision of the article

**AND**

- Provided final approval of the version to publish

**AND**

- Agreed 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

# And...

- **Anyone else who contributed to the study in some way (e.g. medical writers) but does not meet all four criteria for authorship should be mentioned in the Acknowledgements section**
- **However, solely writing or editing a manuscript does not warrant authorship**

# **Contributorship**

- **Many journals now encourage or require authors to describe each person's contribution to the study. This is generally added at the end of the manuscript**

# Guarantorship

- **Some journals, like *The BMJ* or *Diabetes*, require an author to serve as a guarantor of the paper**
  - **The guarantor will be held responsible for the overall integrity of the work including ethics, data handling, reporting of the results etc.)**



# Medical writers as authors

The *Neurology* journal requires medical writers to be included in the author byline:

***Author:*** *Neurology* defines an author as a person who has made a substantive **intellectual contribution** to the submitted manuscript. A substantive contribution includes **one or more** of the following:

*Design or conceptualization of the study*

**OR** *analysis or interpretation of the data*

**OR** *drafting or revising the manuscript for intellectual content*

**Professional writers employed by pharmaceutical companies or other academic, governmental, or commercial entities who have drafted or revised the intellectual content of the paper must be included as authors.**

# Editorial Policies

Biomedical journals with authorship editorial policies generally follow the ICMJE guidelines but many journals still do not have authorship policies (41% in 2007\*) or give guidance for authorship criteria (33% in 2012\*\*)

\*Wager E. *MedGenMed*. 2007; 9:16

\*\* Marchington J., ISMPP poster, 2012

# **Editorial Policies to ensure honesty and transparency**

*“Biomedical publishers large and small and editors' groups have taken concerted action to confront the rising incidence (...) of ghostwriters and the failure to accurately report the roles and contributions of authors, sponsors, and others who are assigned credit for involvement in the research effort. Such action has, in large part, focused on the establishment of editorial policies pertaining to authorship criteria and financial disclosures”*

Catherine M. Nancarrow, BA. *JAMA Intern Med.* 2013;173(10):921-922.

# **Editorial Policies to ensure honesty and transparency**

Bosch X. *et al.* performed a cross-sectional study of 399 peer-reviewed biomedical journals:

- 17% mentioned ghostwriting
- 10% provided an explicit definition
- Less than 6% had detection and response procedures

Bosch X, Hernandez X, Pericas JM, Doti P. *JAMA Intern Med.* 2013;173(10): 920-921.

# Ghostwriting – still a problem?

- A 2009 *New York Times* article estimated that 11% of *New England Journal of Medicine* articles, 8% of *JAMA*, *Lancet* and *PLoS Medicine* articles, 5% of *Annals of Internal Medicine* articles and 2% of *Nature Medicine* articles were ghostwritten

(Wilson D, Singer N. 2009. *Ghostwriting Is Called Rife in Medical Journals*. *The New York Times*)

- In 2014, Stretton wrote that there is no clear evidence that the prevalence of ghostwriting is as high as that which certain reports suggest

(Stretton S. Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature. *BMJ Open* 2014;4:e004777. doi:10.1136/bmjopen-2013-004777)

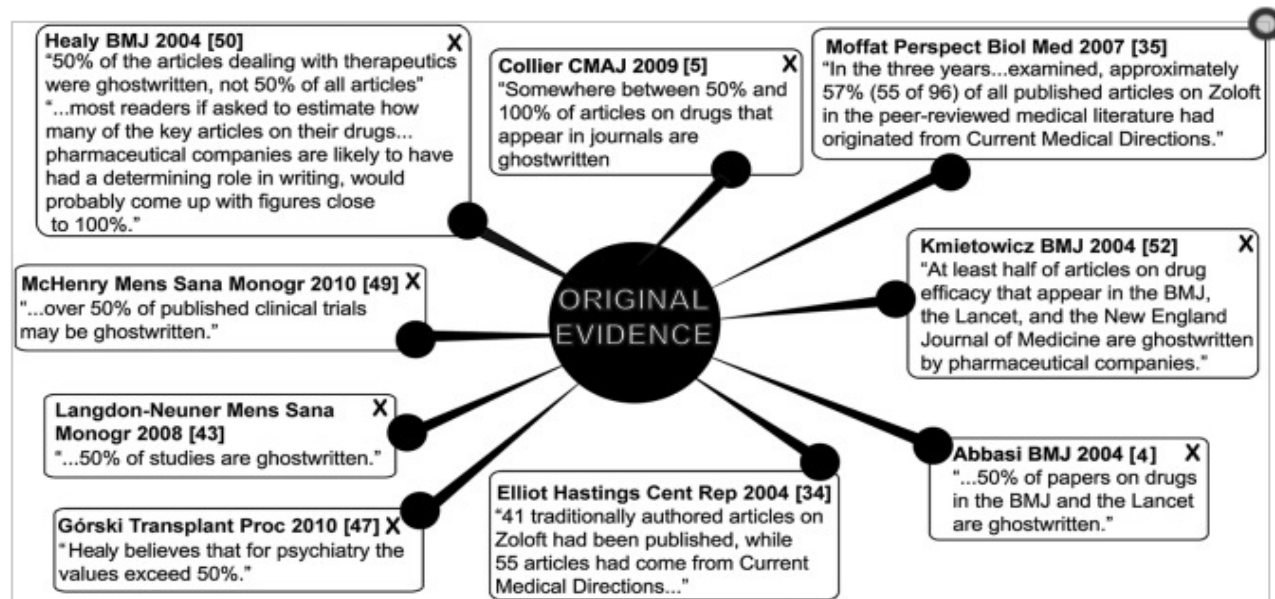
# Ghostwriting – still a problem?

- Stretton performed a systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature and didn't find much in terms of evidence. In fact, she states that “evidence that ghostwriting is pervasive is often misleading, misguided and mistaken”. In her opinion, the most robust evidence indicates that the prevalence of ghostwriting is low and decreasing.

Stretton S. Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature. *BMJ Open* 2014;4:e004777. doi:10.1136/bmjopen-2013-004777

# Ghostwriting – still a problem?

Figure 2



Case study of original versus cited evidence of ghostwriting prevalence. Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell<sup>6</sup> showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the 'possible extent of ghostwriting based on a single drug'. Inaccurate reporting from the cited source is marked with a cross.

Stretton S. Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature. *BMJ Open* 2014;4:e004777. doi:10.1136/bmjopen-2013-004777

# **Ghostwriting – still a problem?**

Stretton concludes that researchers should not inflate estimates using non-standard definitions of ghostwriting nor conflate ghostwriting with other unethical authorship practices.

Editors and peer reviewers should not accept articles that incorrectly cite or interpret primary publications that report the prevalence of ghostwriting.



# **The question is....**

- Do we/can we do anything else to enable readers to assess a study's validity and credibility?
- Or is stating the involvement of medical writers in the Acknowledgments enough?

# What else could Publishers do?

- Should journals have policies clarifying that involvement with ghostwriting is a serious and punishable breach of publication ethics?
- Should authors, who failed to declare the involvement of medical writers at the point of submission, be sanctioned by the journal and their misconduct reported to their institution?
- Should medical writers be banned from writing Review articles?
- Should journals request that drug companies, if they wish to publish articles that they fund, release the data upon which those articles are based?
- Should medical writers be included in the author byline?

# What else could Publishers do?

- Should journals implement a mandatory checklist that editors could use to spot ghostwriting and authors to avoid ghostwriters?

Question	Answer	
	No	Yes
1 (a) Did the medical writer meet the three criteria for authorship, as specified by the ICMJE ? (b) If not, has the writer been identified in the acknowledgments or as directed by the journal?		
2 Has the source of funding for the medical writer's services been identified in the acknowledgments or as directed by the journal?		
3 Did the author(s) make the final decision on the main points to be communicated in the manuscript, particularly in the conclusion?		
4 Did the author(s) make the final decision on the primary and secondary outcomes and relevant data to be reported in the manuscript?		
5 If requested by the journal, can the medical writer provide evidence that the manuscript was prepared in accordance with international guidelines for ethical medical writing (e.g., Uniform Requirements for Manuscripts Submitted to Biomedical Journals [10]; Good Publication Practice for Pharmaceutical Companies [9]; Position Statements from the European or American Medical Writers Associations or the International Society for Medical Publication Professionals [21])?		

This checklist is available as an MS Word document in Table S1.  
doi:10.1371/journal.pmed.1000023.t001

Gøtzsche PC, Kassirer JP, Woolley KL, Wager E, Jacobs A, et al. (2009) What should be done to tackle ghostwriting in the medical literature? PLoS Med 6(2): e1000023. doi: 10.1371/journal.pmed.1000023

# What else could Publishers do?

- Should the Acknowledgements section include:
  - The name of the person/company/organisation who paid for the writing assistance
  - The name of the person who wrote the first draft
  - The names of the people who approved the final draft
  - The names of the people who approved the final draft could, for example, include the publication manager in a drug company or communication agency and would be in line with the World Association of Medical Editors (WAME) statement  
(Langdon-Neuner E. “Medical Ghost-Writing”. *Mens Sana Monogr.* 2008)

# What else could Publishers do?

- Should authors use digital badges to credit contributors in their papers?
  - A pilot using contributorship badges started in 2014 and is still at development stage
  - This project was initiated by a group of open access publishers, funders, software and technology companies, and the registry of unique researcher identifiers (ORCID)
- Should authors use the contributor roles taxonomy (CRediT) developed by CASRAI in their papers?
  - High-level classification of the diverse roles performed in the work leading to a published research output in the sciences. Its purpose is to provide transparency in contributions to scholarly published work
  - CASRAI is an international nonprofit membership initiative led by research institutions and their partners



**Thank you!**