

12TH ANNUAL MEETING OF ISMPP

**Myth busters: Separating fact from
fiction in our profession**

MedComms Networking Event 4 May 2016

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Director of Global Operations, Caudex, UK**





Disclosures

- The opinions expressed are my own and do not necessarily represent those of my employer or of ISMPP
- My co-presenters' presentations have been condensed from their original form



Let's start at the beginning...

- How can we make ISMPP members aware of the evidence used to defend our profession?
- GAPP had recently published on several of the most common myths, due out just before ISMPP

ACCOUNTABILITY IN RESEARCH
2016, VOL. 23, NO. 3, 178-194
<http://dx.doi.org/10.1080/08989621.2015.1088788>



Taylor & Francis
Taylor & Francis Group

Mythbusting Medical Writing: Goodbye, Ghosts! Hello, Help!

Cindy W. Hamilton, Pharm.D., E.L.S.^{a,b}, Art Gertel, M.S.^c, Adam Jacobs, Ph.D.^d,
Jackie Marchington, Ph.D., C.M.P.P.^e, Shelley Weaver, Pharm.D.^f
and Karen Woolley, Ph.D., C.M.P.P.^{g,h,i}



Selected myths

1

Professional medical writers are ghosts!

2

Professional medical writers introduce bias

3

Researchers should not need medical writing support

4

Half of all clinical trials remain unpublished

5

Damned if you do; damned if you don't



Introducing the panel

Our “Mythbusters”:

- Karen Woolley
- Santosh Mysore
- Jackie Marchington






Our “Evaluators”:

- Jocalyn Clark
- Richard Smith





Setup

- 5 minutes for each presenter to bust a myth, using evidence
 - Hard stop, claxon at 5 mins!
- Evaluation: was the myth
 - Confirmed 
 - Plausible 
 - Busted? 
- 3 minutes for evaluators to explain their verdict
 - Evaluators not shown evidence in advance



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Professional medical writers are ghosts!

Karen Woolley

- Google gives about 6½ million hits for ghostwriter – there are a lot out there
- Acknowledged that medical ghostwriting has taken place in the past
 - Grassley report, 2010
- Ghostwriters and Professional Medical Writers are the same thing. Right? NO, Wrong!



Professional medical writers are ghosts!

- Ghostwriting and professional medical writing are mutually exclusive because of
 - Disclosure
 - Professional and ethical guidelines
- Evidence

	Global Publication Survey		ISMPP member research (subanalysis)	
	Agency	Industry	CMPP	Non-CMPP
Disclosure of writing support	99%	95%	N/A	N/A
Routine use of GPP2	91%		99%	87%
Routine use of ICMJE	93%		98%	91%



Professional medical writers are ghosts!

- Anyone could claim to be a medical writer, but amongst the medical writing community:

Ghostwriters are decreasing



Professional medical writers are increasing

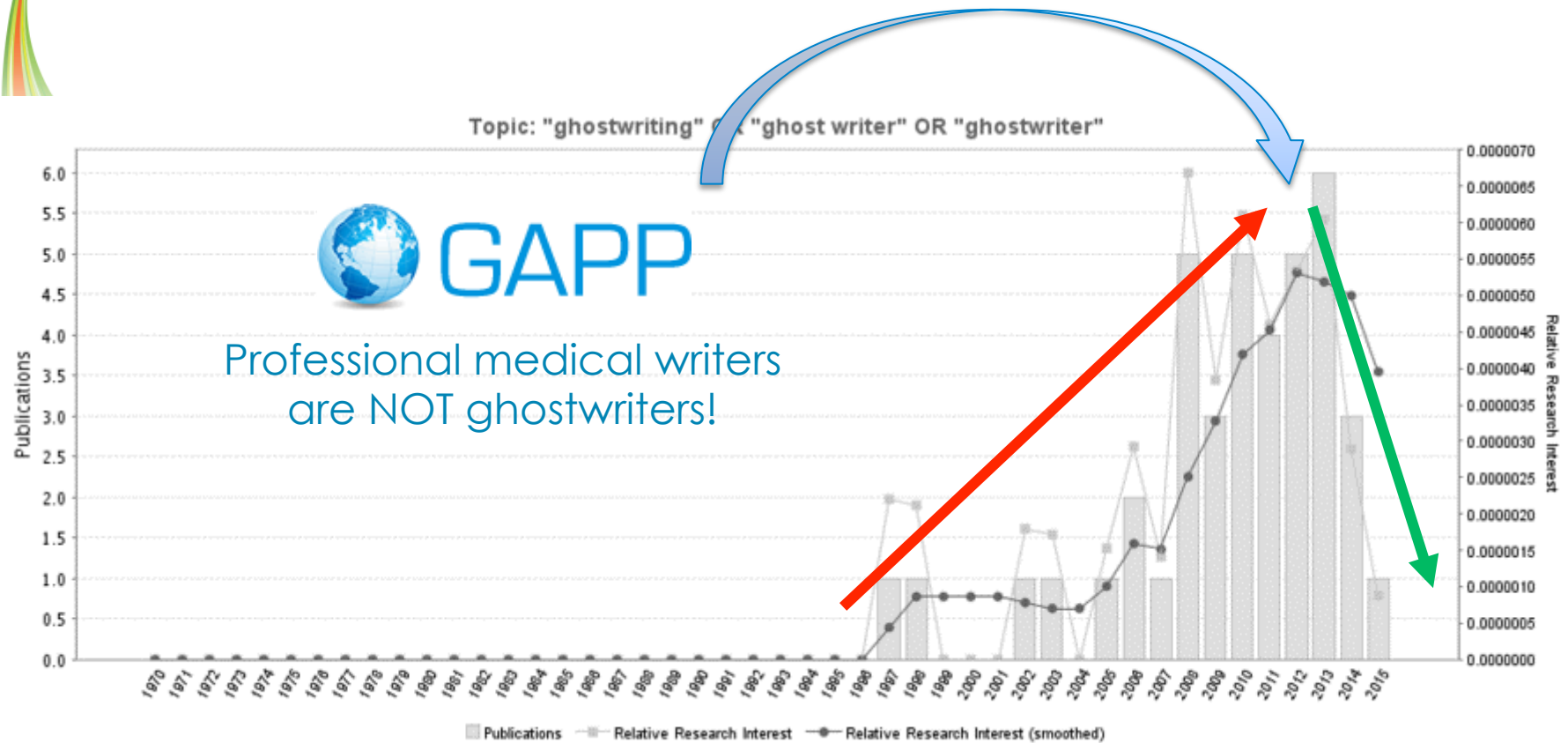


Hamilton CW, Jacobs A. Ghostwriting prevalence among AMWA and EMWA members (2005 to 2014). *Medical Writing* 2016;25:6-14.



Professional medical writers are ghosts!

- Correlation \neq causation, but





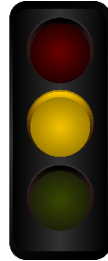
Professional medical writers are ghosts!

- Expert opinion from
 - Academics (Association of American Medical Colleges)
 - Journal editor groups (ICMJE, WAME)
 - Say we are legitimate contributors
- Position statements
 - Industry (IFPMA, EFPIA, JPMA, PhRMA)
 - Say we should be used
- Actions
 - Professional associations (ISMPP, AMWA, EMWA, GAPP)
 - Are fighting the ghosts



Evaluation

- Plausible



Professional medical writers are ghosts

- Great progress in terms of disclosure, guidelines development and evidence of ethical behaviours

BUT

- No control of unethical behaviours outside the professional groups
- No way to measure non-disclosure



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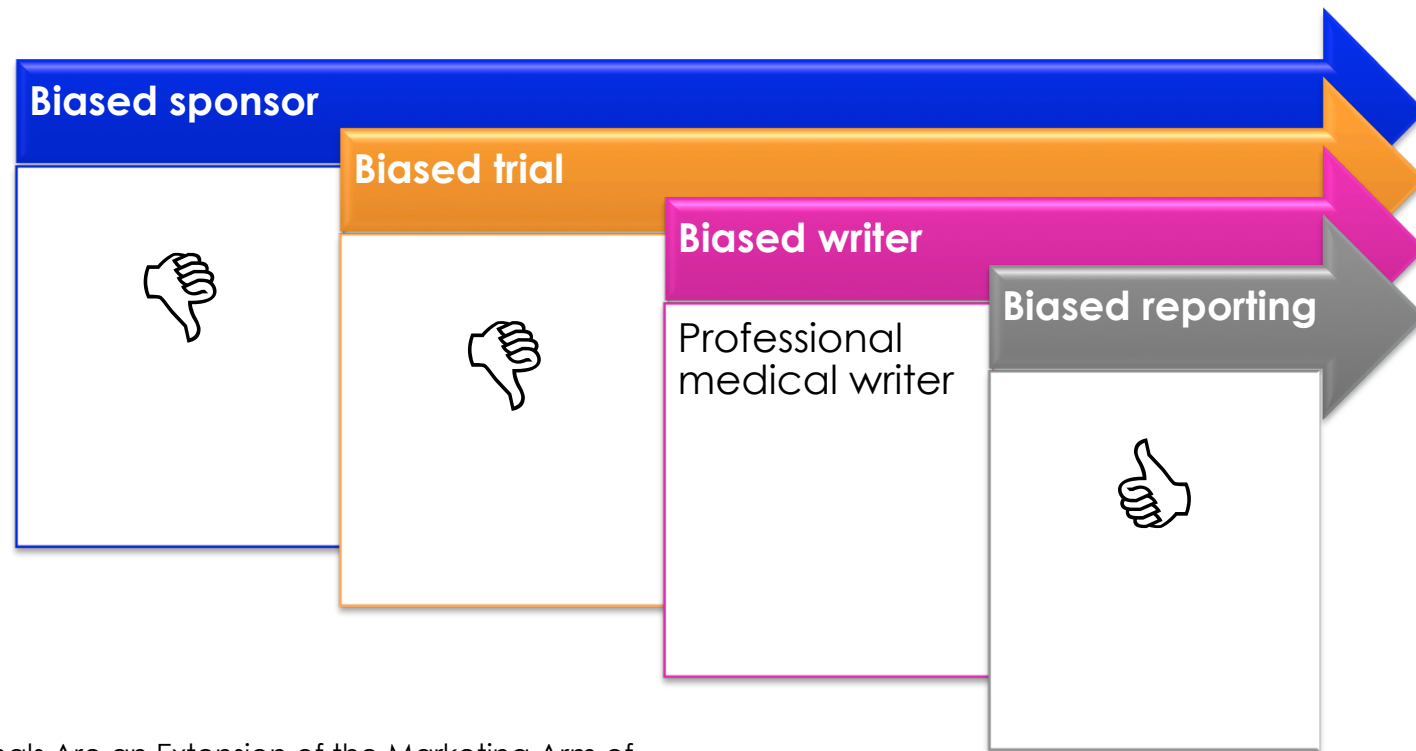


2

Professional medical writers introduce bias

Karen Woolley

- Structured argument around a Richard Smith editorial





2

Professional medical writers introduce bias

- ISMPP code of ethics

B. Publication Preparation Principles

When preparing or developing publications (ie, abstracts, posters or manuscripts), members should:

1. Ensure accuracy, completeness and fair balance and avoid commercial product promotion
2. Recognize the authors' responsibility for a publication's content, including its references.
3. Identify appropriate trial protocols clearly, if available, when publishing clinical trial results (eg, clinical trial registry number).
4. Report primary results of a multi-center clinical trial first, and thereafter issue secondary publications from the same trial, when appropriate citing the primary publication.
5. Identify and report clinical trial results that are inconclusive or inconsistent with the hypothesized outcome.
6. Never misrepresent or fabricate clinical research and/or clinical trial results.
7. Prevent duplicate submission of manuscripts, consistent with accepted professional standards.
8. Apply appropriate standards, guidelines, and position statements of professional organizations including, but not limited to:



2

Professional medical writers introduce bias

- Do medical writers introduce bias?
 - BMJ Open 2015;5:e007961 doi:10.1136/bmjopen-2015-007961
 - Of 12 outcomes with potential for the writer to introduce bias, there were no significant differences between industry and non-industry manuscripts
 - BMJ Open 2016;6:e010024. doi:10.1136/bmjopen-2015-010024
 - Of 9 “players” identified with the potential to introduce bias, professional medical writer was not on the list (authors were...)



2

Professional medical writers introduce bias

- Do medical writers commit misconduct?
 - *Curr Med Res Opin.* 2011;27(6):1175–82. doi: 10.1185/03007995.2011.573546.
 - Only 1.4% (3/213) of misconduct retractions involved medical writer support



2

Professional medical writers introduce bias

- Do medical writers reduce the risk of bias?
 - Papers involving professional medical writers are more compliant with CONSORT
 - Jacobs A. *Medical Writing* 2010; 19(3):196-200.
 - Gattrell W et al. *BMJ Open* 2016; 6:e010239
 - But still room for improvement!
- “Many journal editors recognize that help from a **professional writer** can **raise reporting** standards, **improve compliance** with guidelines, and elevate overall **editorial quality**”
 - Chipperfield L, Citrome L, Clark J, et al. *Curr Med Res Opin.* 2010;26(8):1967–82. doi: 10.1185/03007995.2010.499344.



2

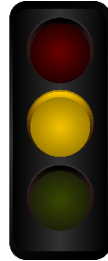
Professional medical writers introduce bias

- Do professional medical writers have to please marketing departments?
 - Rare for marketing to be involved in publication budgets
 - Global publication survey (5%)
 - Funding source not a high concern for COPE editors
 - Hames I et al., COPE European Seminar, Brussels, 14 March 2014



Evaluation

- Plausible



Professional medical writers introduce bias

- Medical writers are not the only source of bias
- Not all medical writers follow the practices outlined
- Not all medical writers are up to date with guidelines



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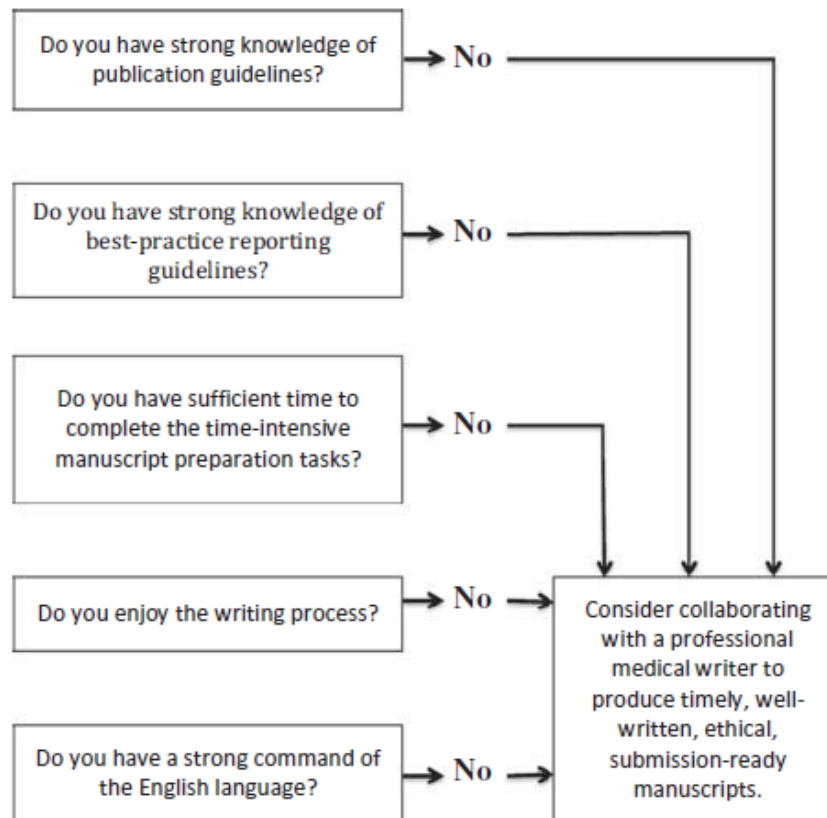


3

Researchers should not need medical writing support

Santosh Mysore

- Authors should be able to string two words together without assistance



Hamilton CW, Gertel A, Jacobs A, Marchington J, Weaver S, Woolley K. Mythbusting Medical Writing: Goodbye Ghosts, Hello Help. *Account Res.* 2016; 23:3, 178-194. doi: 10.1080/08989621.2015.1088788.



3

Researchers should not need medical writing support

- Can all researchers do those things?
 - Poor adherence to reporting guidelines
 - Adie S, et al. *Ann Surg* 2013;258:872–8.
 - Peron J, et al. *J Clin Oncol* 2013;31:3957–63.
 - Smith SM, et al. *Pain* 2012;153:2415–21.
 - Incomplete or delayed data disclosure
 - Chen R, et al. *BMJ* 2016;352:i637.
 - Ross JS, et al. *BMJ* 2012;344:d7292.
 - Scherer RW, et al. *J Clin Epidemiol* 2015;68:803–10.



3

Researchers should not need medical writing support

- Can all researchers do those things?
 - Lack of time
 - Scherer RW et al., J Clin Epidemiol 2015;68:803–10.
 - Language fluency
 - Improved publication rates once publication professionals are involved
 - Breugelmans R, Barron JP. Chest 2008;134:883-885.
 - Manring MM, Panzo JA, Mayerson JL. J Surg Edu 2014;71:8-13.
 - Lack of training
 - Glasziou P, et al. Lancet 2014;383:267–76.
 - van Lent M, et al. BMJ Open 2015;5:e007961.





3

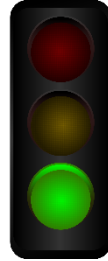
Researchers should not need medical writing support

- Authors familiar with professional medical writing support appreciate it
 - Camby I, Delpire V, Rouxhet L, et al. *Trials* 2014;15:446. doi:10.1186/1745-6215-15-446
 - Marchington JM, Burd GP. *Curr Med Res Opin* 2014;30(10):2103–8. doi:10.1185/03007995.2014.939618.



Evaluation

- Busted



Researchers should not need medical writing support

- Manuscripts produced with professional writing support, appropriately disclosed, are welcomed by journal editors





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Half of all clinical trials remain unpublished

- **Half**
 - Most prominently (at least in recent years) the AllTrials campaign
 - Casual (usually unsupported) statements in publications about clinical trial disclosure
- **All**
 - Defined trial subsets
 - Time periods and selection criteria
- **Unpublished**
 - Conference abstracts vs publications vs results postings

4

Half of all clinical trials remain unpublished

- Song F, Parekh S, Hooper L, Loke YK, Ryder J, Sutton AJ, *et al.* Dissemination and publication of research findings: an updated review of related biases. *Health Technol Assess* 2010;**14**(8).
- Song F, Eastwood AJ, Gilbody S, Duley L, Sutton AJ. Publication and related biases. *Health Technol Assess* 2000;**4**(10).
- Neither of these Cochrane reviews make an overall estimate of publication rates
- Most recent study included was 2003
- Publication rates vary in the studies included, but so do the methodologies

The logo for AllTrials, featuring a red folder icon with a white plus sign and the text '+ AllTrials' in white. Above the folder is a purple circle containing the number '4'. To the left of the folder is a decorative graphic of colorful, flowing ribbons in shades of blue, green, and orange.

+ AllTrials



4

Half of all clinical trials remain unpublished

- Mis-citation **of** research

OPEN ACCESS Freely available online

PLOS MEDICINE

Timing and Completeness of Trial Results Posted at ClinicalTrials.gov and Published in Journals

Carolina Riveros^{1,2,3}, Agnes Dechartres^{1,2,3*}, Elodie Perrodeau^{1,3}, Romana Haneef^{1,3},
Isabelle Boutron^{1,2,3,4}, Philippe Ravaud^{1,2,3,4,5}

- Widely cited as supporting “50% publication rate” which is correct in terms of journal publications, but amongst a random sample of 600 trials with results disclosed on clinicaltrials.gov



4

Half of all clinical trials remain unpublished

- Mis-citation *in* research

Benefits and harms in clinical trials of duloxetine for treatment of major depressive disorder: comparison of clinical study reports, trial registries, and publications

BMJ 2014 ; 348 doi: <http://dx.doi.org/10.1136/bmj.g3510> (Published 04 June 2014)

Cite this as: *BMJ* 2014;348:g3510

Introduction

About half of all randomised clinical trials are never published,¹ and the other half is often published selectively,² in both cases depending on the direction of the results.

Introduction presented in abstract form up to 2003

one third ~~of~~ all randomised clinical trials ~~are~~ never published, ~~and~~ the other half is often published selectively,² in both cases depending on the direction of the results. ~~as a full journal article~~



4

Half of all clinical trials remain unpublished

- Mechanisms for clinical trial data disclosure now include
 - Publication (abstracts, articles)
 - Registries (clinicaltrial.gov, EudraCT)
 - Clinical study data request website (<https://www.clinicalstudydatarequest.com/>)
 - Company websites
 - Institutional websites
 - Dryad, Figshare etc
- What does “publication” mean in the digital age?



Evaluation

- Plausible



Half of all clinical trials remain unpublished

- Agree that it is impossible to quantify the statistic, but it is plausible that the disclosure rate of clinical trial data could be this low, despite recent improvements
- Academia and industry both contribute to the statistic



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5

Damned if you do; damned if you don't

- “Damned if you do” is not so much a myth, as an unintended consequence
 - Articles discounted as inherently biased if industry sponsorship is disclosed
 - Articles rejected without review because of medical writer involvement



- “Damned if you don't” is taken as given
 - Non-disclosure of medical writing assistance or other support is not an option



Damned if you do; damned if you don't

- Reader bias
 - Evidence¹
 - Fictional abstracts assessed for rigour of trial design, confidence in results and willingness to change prescribing behaviour
 - Industry funding disclosure decreased all ratings
 - Anecdote
 - Richard Lehman's BMJ blog²

Just how much of this paper was written by the named authors is unclear. "Professional medical writers who were paid by Bristol-Myers Squibb contributed to the preparation of the manuscript and are not listed as authors."

- MedPage today article³

¹ Kesselheim et al. *N Engl J Med*. 2012;367(12):1119–27.

² <http://blogs.bmj.com/bmj/2015/06/08/richard-lehmans-journal-review-8-june-2015>

³ <http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/53057>



Damned if you do; damned if you don't

- Reviewer bias
 - Evidence
 - Survey of peer reviewers. Author disclosure of industry support increased time spent reading, decreased credibility and affected the recommendation for publication¹
 - Articles with disclosed medical writing support spend an additional 31 days in peer review²
 - Anecdote

—Original Message—

From: [REDACTED]
To: [REDACTED]
Sent: Tue, 28 Sep 2010 21:24
Subject: [REDACTED] paper

Hi- I am sorry but we only consider original papers written by the researchers.
BG

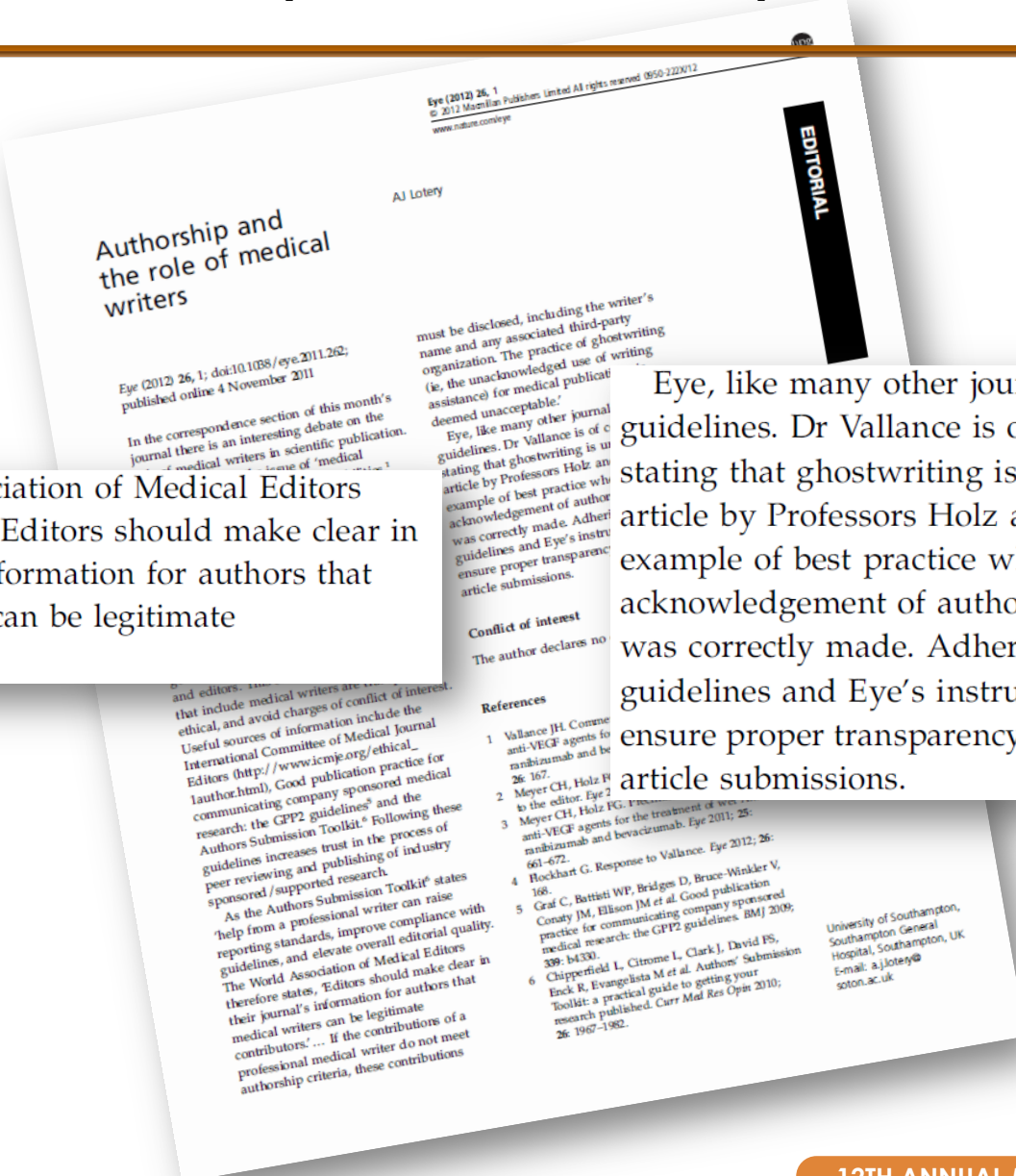
¹ Lippert et al. PLoS ONE 2011; 6(11): e26900
² Gattrell W et al. BMJ Open. 2016; 6:e010239



5

Damned if you do; damned if you don't

The World Association of Medical Editors therefore states, 'Editors should make clear in their journal's information for authors that medical writers can be legitimate contributors.' ...



Authorship and the role of medical writers

Eye (2012) 26, 1, doi:10.1038/eye.2011.262; published online 4 November 2011

In the correspondence section of this month's journal there is an interesting debate on the role of medical writers in scientific publication.

AJ Lotery

must be disclosed, including the writer's name and any associated third-party organization. The practice of ghostwriting (ie, the unacknowledged use of writing assistance) for medical publications is deemed unacceptable.

Eye, like many other journals, has clear guidelines. Dr Vallance is of course correct in stating that ghostwriting is unacceptable. The article by Professors Holz and Meyers is an example of best practice where all appropriate acknowledgement of authors and contribution was correctly made. Adhering to these guidelines and Eye's instructions ensure proper transparency in article submissions.

Conflict of interest

The author declares no conflict of interest.

References

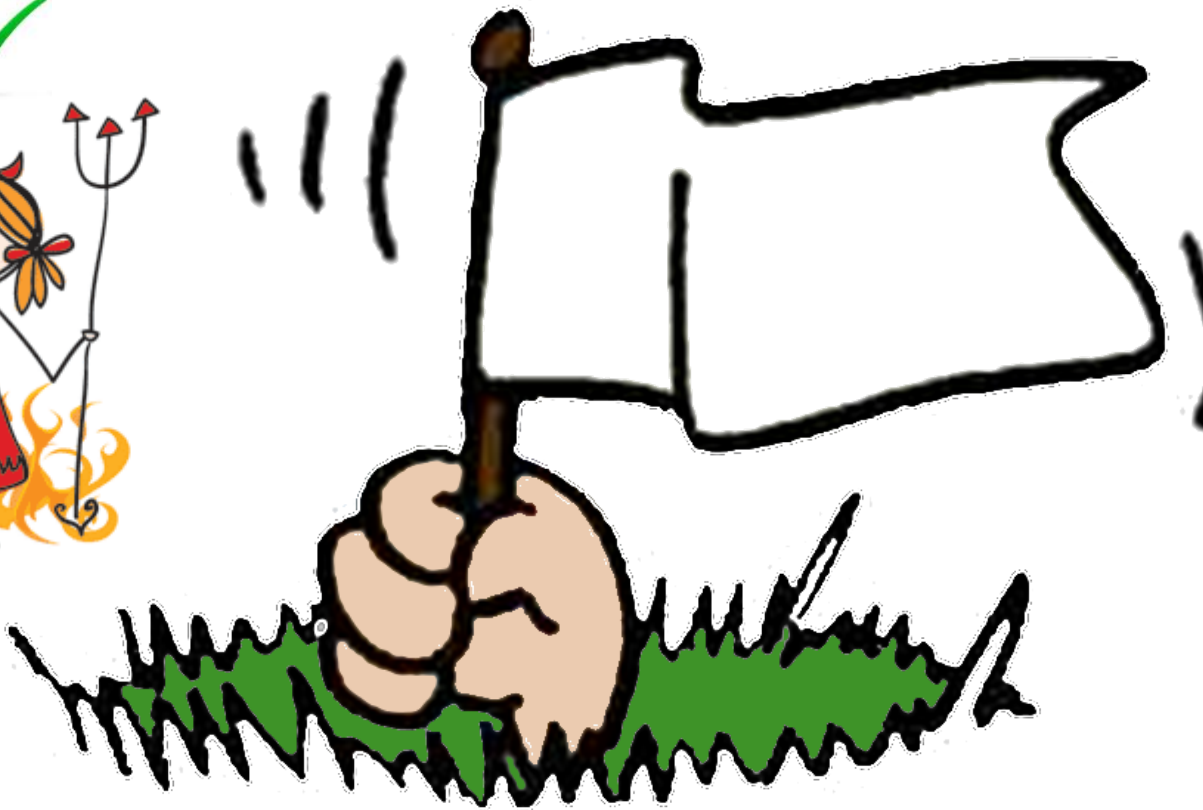
- 1 Vallance JH. Comments on anti-VEGF agents for the treatment of wet age-related macular degeneration. *Eye* 2011; 25: 1667-1672.
- 2 Meyer CH, Holz FG. Response to Vallance. *Eye* 2011; 25: 1661-1672.
- 3 Meyer CH, Holz FG. Response to Vallance. *Eye* 2011; 25: 1661-1672.
- 4 Hockhart G. Response to Vallance. *Eye* 2012; 26: 168.
- 5 Graf C, Battisti WP, Bridges D, Bruce-Winkler V, Conaty JM, Ellison JM et al. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009; 339: b4330.
- 6 Chipperfield L, Citrome L, Clark J, David FS, Enck R, Evangelista M et al. Authors' Submission Toolkit: a practical guide to getting your research published. *Curr Med Res Opin* 2010; 26: 1967-1982.

EDITORIAL

Eye, like many other journals works to these guidelines. Dr Vallance is of course correct in stating that ghostwriting is unacceptable. The article by Professors Holz and Meyers is an example of best practice where all appropriate acknowledgement of authors and contribution was correctly made. Adhering to these guidelines and Eye's instruction to authors ensure proper transparency and best practice in article submissions.

5

Damned if you do; damned if you don't





Evaluation

- Confirmed



Damned if you do,
damned if you don't

- Peer reviewers *should* examine industry sponsored work more closely

But

- Unfair that openness seemed to invite criticism, but don't stop doing it!
- There is far more danger in not disclosing



AUDIENCE QUESTION

- Which of the below do we still need to work on and provide more evidence to counter?
 1. Medical writers are ghosts
 2. Medical writers introduce bias
 3. Researchers should not need medical writing support
 - 4. Half of all clinical trials remain unpublished**
 5. Damned if you do, damned if you don't



Links

- Full slide decks for the myth presentations are available to ISMPP members on the 12th Annual Meeting archive (www.ismpp.org)
- Monty Python logic to identify ghostwriters
 - <https://www.youtube.com/watch?v=k3jt5ibfRzw>
- Grassley report
 - <http://www.grassley.senate.gov/sites/default/files/about/upload/Senator-Grassley-Report.pdf>
- Additional supporting references can be found at www.gappteam.org

THANK YOU

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