Myth busters: Separating fact from fiction in our profession

MedComms Networking Event 4 May 2016

Jackie Marchington PhD, CMPP™
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

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

Cindy W. Hamilton, Pharm.D., E.L.S.\textsuperscript{a,b}, Art Gertel, M.S.\textsuperscript{c}, Adam Jacobs, Ph.D.\textsuperscript{d}, Jackie Marchington, Ph.D., C.M.P.P.\textsuperscript{e}, Shelley Weaver, Pharm.D.\textsuperscript{f} and Karen Woolley, Ph.D., C.M.P.P.\textsuperscript{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 Half of all clinical trials remain unpublished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
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 Half of all clinical trials remain unpublished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
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!
• Ghostwriting and professional medical writing are mutually exclusive because of
  – Disclosure
  – Professional and ethical guidelines

• Evidence

<table>
<thead>
<tr>
<th></th>
<th>Global Publication Survey</th>
<th>ISMPP member research (subanalysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Agency</td>
<td>Industry</td>
</tr>
<tr>
<td>Disclosure of writing support</td>
<td>99%</td>
<td>95%</td>
</tr>
<tr>
<td>Routine use of GPP2</td>
<td>91%</td>
<td></td>
</tr>
<tr>
<td>Routine use of ICMJE</td>
<td>93%</td>
<td></td>
</tr>
</tbody>
</table>

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

- **Ghostwriters** are decreasing
- **Professional medical writers** are increasing

Professional medical writers are ghosts!

- Correlation ≠ causation, but

GAPP

Professional medical writers are NOT ghostwriters!
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
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
Karen Woolley

• Structured argument around a Richard Smith editorial

Smith R. Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies
PLOS Medicine 2005 http://dx.doi.org/10.1371/journal.pmed.0020138
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 (e.g., 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.
• Do medical writers introduce bias?
    • Of 12 outcomes with potential for the writer to introduce bias, there were no significant differences between industry and non-industry manuscripts
    • Of 9 “players” identified with the potential to introduce bias, professional medical writer was not on the list (authors were...)
• Do medical writers commit misconduct?
  • Only 1.4% (3/213) of misconduct retractions involved medical writer support
• 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”
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
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
Researchers should not need medical writing support

Santosh Mysore

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

• Can all researchers do those things?
  – Poor adherence to reporting guidelines
  – Incomplete or delayed data disclosure

Researchers should not need medical writing support
Researchers should not need medical writing support

- Can all researchers do those things?
  - Lack of time
  - Language fluency
    - Improved publication rates once publication professionals are involved
  - Lack of training
• Authors familiar with professional medical writing support appreciate it
Evaluation

• Busted

Researchers should not need medical writing support

• Manuscripts produced with professional writing support, appropriately disclosed, are welcomed by journal editors
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
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
Half of all clinical trials remain unpublished


- 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.
Half of all clinical trials remain unpublished

- What are these studies actually reporting?

Jacobs A. http://www.statsguy.co.uk/zombie-statistics-on-half-of-all-clinical-trials-unpublished/
Half of all clinical trials remain unpublished

- Mis-citation of research

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

Carolina Riveros¹,²,³, Agnes Dechartres¹,²,³, Elodie Perrodeau¹,³, Romana Haneef¹,³, Isabelle Boutron¹,²,³,⁴, Philippe Ravaud¹,²,³,⁴,⁵

- 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

http://zombiestatistics.co.uk/blog3.php/seriously-that-quot-50-of
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.

One third were presented in abstract form up to 2003 as a full journal article
• 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
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
“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
• Reader bias
  – Evidence\(^1\)
    • 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 blog\(^2\)

\(^3\) [http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/53057](http://www.medpagetoday.com/PublicHealthPolicy/HealthPolicy/53057)
• Reviewer bias
  – Evidence
    • Survey of peer reviewers. Author disclosure of industry support increased time spent reading, decreased credibility and affected the recommendation for publication\(^1\)
    • Articles with disclosed medical writing support spend an additional 31 days in peer review\(^2\)
  – 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
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.’ …

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.
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
• Additional supporting references can be found at www.gappteam.org
THANK YOU

JACKIE MARCHINGTON
DIRECTOR OF GLOBAL OPERATIONS
CAUDEX, OXFORD, UK
JACKIE.MARCHINGTON@CAUDEX.COM