Unpacking the evidence behind the AMWA–EMWA–ISMPP Joint Position Statement

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MedComms Networking Brunch Club
5 April 2017
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- Communications Director at Oxford PharmaGenesis
  - More than 11 years of experience in medical communications
  - ISMPP Certified Medical Publications Professional
  - Former contract Global Publications Lead for a top-10 pharma company
  - Good Publication Practice 3 reviewer
  - Head of the PharmaGenesis Publications Ethics, Planning and Research group
  - Guest lecturer on good publication practice at the University of Oxford, UK
Professional medical writing support helps authors and sponsors to disclose their research in peer-reviewed journals and at scientific congresses in an ethical,\textsuperscript{14} accurate,\textsuperscript{15,16} and timely\textsuperscript{17} manner, with the ultimate aim of advancing patient care. Professional medical writers have extensive knowledge of ethical publication guidelines.\textsuperscript{18,19}

AMWA–EMWA–ISMPP Joint Position Statement on the Role of Professional Medical Writers. Released January 2017
Building an evidence base for the value of medical writing support

Adherence to the CONSORT guideline in papers written by professional medical writers

by Adam Jacobs

Abstract
Background
Many papers in the biomedical literature are drafted not by those who did the research, but by professional medical writers. CONSORT guidelines give specific recommendations for items that should be included in publications of randomised controlled trials. This study investigated whether papers written by professional medical writers were more compliant with the CONSORT guidelines than other papers.

Findings
All randomised clinical trials published in the journal Current Medical Research and Opinion between October 2004 and August 2005 were included in this study.

Hypothesised that they are better qualified to write papers than most researchers, for whom writing the paper is often simply an unfortunate extra chore that needs to be done at the end of a piece of research.

However, despite the theoretical benefits of assistance from professional medical writers, there are almost no data to show whether those benefits are realised in practice. In a systematic review in 2003, Lagnado only found anecdotal evidence that professional medical writers improve the quality and readability of papers, and concluded “I did not find firm evidence to support these reported benefits.” [1]

Measuring the writing quality in published papers is hard to do, as many aspects of writing quality are subjective.

Study of medical writing support and compliance with reporting guidelines

Medical writing support (n = 152)

Current Medical Research and Opinion articles between October 2004 and August 2009 describing RCTs (n = 241)

No/unclear medical writing support – other (n = 89)

Complete compliance with CONSORT guidelines

Is there a difference?

RCT, randomized controlled trial
Most CONSORT items were at least partially described in almost all papers

- Most papers were industry sponsored

Poorly reported

Item 9. Concealment of random allocation

Item 10. Implementation of randomization

Item 14. Dates of recruitment and follow-up periods
Greater completion of CONSORT items with medical writing support

- Declared medical writing support was associated with completion of significantly more CONSORT items
  - difference between groups 0.75 items completed, 95% CI 0.07 to 1.43, P = 0.03

- Not statistically significant when half marks were counted if items were present but incompletely described
  - difference between groups 0.53 items completed, 95% CI –0.02 to 1.07, P = 0.06

<table>
<thead>
<tr>
<th></th>
<th>Medical writer support (n = 152)</th>
<th>Other papers (n = 89)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Number of CONSORT items completed</td>
<td>16.9</td>
<td>2.5</td>
</tr>
<tr>
<td>Items completed with half marks for incomplete item</td>
<td>18.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Declared medical writing support was associated with completion of significantly more CONSORT items—difference between groups 0.75 items completed, 95% CI 0.07 to 1.43, P = 0.03.

Not statistically significant when half marks were counted if items were present but incompletely described—difference between groups 0.53 items completed, 95% CI –0.02 to 1.07, P = 0.06.

Conclusions

- Publications that acknowledged assistance from professional medical writers were more likely to comply with the CONSORT guidelines than papers that did not.

- However, the difference, although statistically significant, was small, and the practical importance of the difference is unknown.


Lack of involvement of medical writers and the pharmaceutical industry in publications retracted for misconduct: a systematic, controlled, retrospective study

Karen L. Woolley
Chief Executive Officer, ProScribe Medical Communications; Professor, University of Queensland, Australia; A/Professor, University of the Sunshine Coast, Australia

Rebecca A. Lew
Senior Strategist

Abstract

Objectives: The primary objective of this study was to quantify how many publications retracted because of misconduct involved declared medical writers (i.e., not ghostwriters) or declared pharmaceutical industry support. The secondary objective was to investigate factors associated with misconduct retractions.
Systematic, controlled, retrospective study of retraction for misconduct

Publications retracted due to misconduct rarely had medical writing support

- Publications retracted because of misconduct rarely involved declared medical writers (3/213; 1.4%) or declared pharmaceutical industry support (8/213; 3.8%)

- No misconduct retractions involved both declared medical writers and the industry

Lower likelihood of retraction for misconduct with medical writing support

<table>
<thead>
<tr>
<th>Category</th>
<th>Odds Ratio (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MW support &amp; Pharma</td>
<td>0.16 (0.05–0.57)</td>
</tr>
<tr>
<td>MW support</td>
<td>0.25 (0.11–0.58)</td>
</tr>
<tr>
<td>Pharma</td>
<td>2.04 (1.01–4.12)</td>
</tr>
<tr>
<td>Single author</td>
<td>2.05 (1.35–3.11)</td>
</tr>
<tr>
<td>First author with ≥1 retraction</td>
<td>2.34 (1.18–4.63)</td>
</tr>
<tr>
<td>First author affiliated with a low/middle income country</td>
<td></td>
</tr>
</tbody>
</table>

*The odds ratio could not be calculated for the declared involvement of medical writers and the pharmaceutical industry as there were no misconduct retractions that involved both declared medical writer and industry involvement.

Conclusions

- Publications retracted because of misconduct rarely involved declared medical writers or declared pharmaceutical industry support.

- Results suggest that the risk to the integrity of the literature from non-commercial factors must be managed with as much vigour and rigour as the risk from commercial factors.


- Survey to understand current challenges and develop guidance related to authorship of industry-sponsored trials
- Examined respondents’ familiarity with authorship guidelines
  - Clinical investigators significantly less familiar and more often than other groups reported they were not aware of any guidelines (28%)
  - Publication professionals had the highest awareness of ICMJE and GPP2 guidelines

Survey respondents (n = 498)

- Clinical investigators (n = 145, 29%)
- Journal editors (n = 108, 22%)
- Publication professionals (n = 132, 26%)
- Medical writers (n = 113, 23%)

North America (44%)
Europe (39%)
Asia (13%)

- The Global Publication Survey
  - Large-scale international survey of publication professionals (n = 469)
  - Most respondents (78%) had worked on medical publications for ≥5 years and 62% had a PhD/MD

Over 90% of industry, agency and CRO respondents routinely refer to GPP2 and the ICMJE requirements

Most respondents (≥ 78%) received mandatory training on ethical publication practices

Over 90% of respondents’ companies had publication guidelines or policies and required medical writing support to be acknowledged in publications

5. Gattrell et al. BMJ Open 2016

BMJ Open
Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study

William T. Gattrell,1,2 Sally Hopewell,3 Kate Young,4 Paul Farrow,1 Richard White,1,2 Elizabeth Wager,5,6 Christopher C Winchester1,7

ABSTRACT
Objectives: Authors may choose to work with professional medical writers when writing up their research for publication. We examined the relationship between medical writing support and the quality and timeliness of reporting of the results of randomised controlled trials (RCTs).

Design: Cross-sectional study.

Study sample: Primary reports of RCTs published in BioMed Central journals from 2000 to 16 July 2014, subdivided into those with medical writing support (n=110) and those without medical writing support.

Strengths and limitations of this study

First study to examine the value that professional medical writing support brings to manuscript development across a broad range of journals.

Used robust methodology and objective measures to assess systematically the quality of reporting of randomised controlled trials in BioMed Central journals.

In this observational study, the characteristics of the two groups of articles differed in some respects, in addition to the involvement of


http://bmjopen.bmj.com/content/6/2/e010329.full
Cross-sectional study of medical writing support and quality of trial reporting

Medical writing support (n = 110)

BioMed Central articles describing RCTs

No medical writing support (n = 123)

Quality of reporting

Quality of written English

Speed of acceptance

Is there a difference?

Gattrell WT et al. BMJ Open 2016 21;6:e010329 http://bmjopen.bmj.com/content/6/2/e010329.full
Higher rate of reporting of CONSORT items with medical writing support

CONSORT item (number) | Relative risk (95% CI)
--- | ---
Pre-defined primary outcome (6a) | 1.77 (1.47–2.13)
How sample size was determined (7a) | 1.39 (1.10–1.75)
Method used to generate random allocation (8a) | 0.97 (0.72–1.32)
Type of randomization (8b) | 2.03 (1.17–3.53)
Mechanism to implement random allocation sequence (9) | 0.99 (0.60–1.63)
Who generated the allocation sequence (10) | 1.16 (0.72–1.88)
Who was blinded (11a) | 1.24 (0.84–1.84)
Description of similarity of interventions (11b) | 1.96 (1.48–2.61)
Participant flow diagram (13) | 2.04 (1.32–3.17)
Dates defining recruitment and follow-up (14a) | 1.64 (1.34–2.01)
Trial registration (23) | 7.83 (0.98–62.62)
Access to study protocol (24) |

Items were chosen that are often poorly reported
Medical writing support was associated with enhanced reporting of CONSORT checklist items (≥ 50%) versus no medical writing support.

Irrespective of industry funding.

NS, not significant
Improved quality of written English with medical writing support

- Medical writing support was associated with significantly better written English, as judged by peer reviewers
  - Acceptable
  - Needs some language corrections before being published
  - Not suitable for publication unless extensively revised

Proportion of articles with acceptable English (%)

- MW support: 81.1
- No MW support: 47.9

\( p < 0.05 \)
Slight reduction in speed of acceptance with medical writing support

- Median time from submission to acceptance was longer for articles with medical writing support than for those without
  - 23.9 versus 19.4 weeks ($p < 0.01$)
  - Attributable to increased time for peer review and responding to reviewers

Gattrell WT et al. BMJ Open 2016 21;6:e010329  http://bmjopen.bmj.com/content/6/2/e010329.full
Conclusions

• Declared medical writing support was associated with higher quality reporting of RCTs, compared with no writing support
  – Other differences between the study groups do not explain findings

Gattrell WT et al. BMJ Open 2016 21;6:e010329 http://bmjopen.bmj.com/content/6/2/e010329.full

Study of the role of medical writing support in timely dissemination and transparent reporting of data

New drugs approved by FDA in 2014 \( n=27 \)

Approval trials and trial characteristics established

PubMed search to establish trials for each drug published in Medline-indexed journal \( \leq 29 \text{ Feb 2016} \)

Primary publications \( n=379 \)

Secondary publications

Online search: classify post-hoc publications

Medical writer involved?

1°: Publication timing

2°: ↑ in # pubs of different complexity

2°: ↑ in % pubs in better IF journals

Primary publications with medical writing support published significantly faster

<table>
<thead>
<tr>
<th>Parameter</th>
<th>n</th>
<th>Mean (SD) time for publication, months</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publications with medical writer support</td>
<td>234</td>
<td>14.4 (13.41)</td>
<td>p &lt; 0.0001</td>
</tr>
<tr>
<td>Publications without medical writer support</td>
<td>145</td>
<td>36.7 (19.25)</td>
<td></td>
</tr>
</tbody>
</table>

Timely dissemination of research: primary publication within 18 months post-study completion

22.3 months faster (average)

Medical writing support associated with increased quality of evidence

Medical writer support had a significant impact in increasing the number of publications with different complexities (decreasing random error and selection bias).
Conclusions

• Medical writing support can:
  • Expedite data availability and aid timely dissemination of clinical data
  • Help dissemination of varied clinical data through publications of different complexities, increasing hierarchy of evidence available in public domain

• These data availability may indirectly help to manage costs, eliminate duplicative efforts and stimulate further research ideas

7. Gattrell et al. *ISMPP* 2017

- Built on the COMPare project
  - Evaluates outcome reporting of RCTs published in the top 5 medical journals
  - Data are publicly available

- Examined the relationship between outcome reporting, funding source and medical writing support
  - Industry-funded articles with medical writing support were less likely to include non-pre-specified outcomes than those without this support

**Figure 3.** Reporting of non-pre-specified outcomes by funding source and medical writer support.

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Medical Writer Support</th>
<th>Mean Number of Non-pre-specified Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry-funded</td>
<td>MW support (n=17)</td>
<td>2.2</td>
</tr>
<tr>
<td>Industry-funded</td>
<td>no MW support (n=17)</td>
<td>6.5</td>
</tr>
<tr>
<td>Non-Industry-funded</td>
<td>no MW support (n=32)</td>
<td>6.3</td>
</tr>
</tbody>
</table>

Publications with medical writer support reported the fewest non-pre-specified outcomes
A new phase of proactivity about transparency and value of medical writing

- Growing evidence base that supports the role of medical writers in the ethical, accurate and timely dissemination of medical research

- More research is needed
  - This should be published in peer-reviewed journals

- Get involved and collaborate
  - We can help to advance patient care

Contact

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