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

William Gattrell, Sally Hopewell, Kate Young, Paul Farrow, Richard White, Elizabeth Wager and Christopher Winchester

MedComms Networking Event 4 May 2016
Paul Farrow DPhil CMPP

- Communications Director at Oxford PharmaGenesis
  - More than 10 years of experience in medical communications
  - Contract Global Publications Lead for a top-10 pharma company
  - Head of the PharmaGenesis Publications Ethics, Planning and Research group
  - GPP3 reviewer
  - Guest lecturer on GPP at the University of Oxford, UK
Medical writing is misunderstood and sometimes gets bad press.
Our industry bodies say ...

“... medical writers can often improve the efficiency and effectiveness of manuscript preparation by working with the research team to develop clear and concise manuscripts in a timely fashion”

“... involving medical writers may therefore raise the standard of publications and accelerate the writing and publication process”

but is there any evidence to support these statements?

Available evidence

“When professional medical writers help authors prepare manuscripts, these manuscripts are less likely to be retracted for misconduct, are more compliant with best-practice reporting guidelines, and are accepted more quickly for publication.”

Woolley KL et al. Poor compliance with reporting research results – we know it’s a problem … how do we fix it? *Curr Med Res Opin* 2012;28:1857–60


Peer-reviewed evidence of the value of medical writing support

- Collaboration with experts in publications ethics and reporting standards
  - Liz Wager (author of GPP1 and GPP3, COPE)
  - Sally Hopewell (Oxford Clinical Trials Unit, CONSORT)
- Awarded best research prize at Annual and European meetings of ISMPP in 2015
- Published in BMJ Open in February 2016
  - Impact factor: 2.3

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

Medical writing support (n = 110)

BioMed Central articles describing RCTs

No medical writing support (n = 123)

Quality of reporting¹,²

Quality of written English

Speed of acceptance

Is there a difference?

RCT, randomized controlled trial

Higher rate of reporting of CONSORT items with medical writing support ...

**CONSORT item (number)**

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

**Items were chosen that are often poorly reported**
... irrespective of funding source

- Medical writing support was associated with enhanced reporting of CONSORT checklist items (≥ 50%) versus no medical writing support
- Irrespective of industry funding

<table>
<thead>
<tr>
<th>Industry-funded, MW support</th>
<th>Industry-funded, no MW support</th>
<th>Non-/part-industry-funded, no MW support</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>38.0</td>
<td>17.9</td>
</tr>
<tr>
<td>p = NS</td>
<td>p &lt; 0.05</td>
<td>p &lt; 0.05</td>
</tr>
</tbody>
</table>

NS, not significant
Improved quality of written English

- 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

- 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

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Peer review</th>
<th>Responding to reviewers</th>
<th>Editorial acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical writing support</td>
<td>87</td>
<td>60</td>
<td>49</td>
</tr>
<tr>
<td>No medical writing support</td>
<td>55</td>
<td>32</td>
<td>50</td>
</tr>
</tbody>
</table>
Accepted in higher impact journals …

- Also true for the subgroup of industry-sponsored articles with (n = 108) and without medical writing support (n = 39)
- Mean impact factor: 2.6 vs 1.8; p < 0.001
... and receive an increased number of citations in the first year

- For the subgroup of industry-sponsored articles with and without medical writing support, mean number of citations within the first year: 2.9 vs 1.9; \( p = 0.542 \)

Secondary analysis presented at ISMPP 2016
No significant differences in other measures of article impact

- **Article views per year (mean)**
  - MW support: 1946
  - No MW support: 2107
  - *p* = 0.84

- **Altmetric score (mean)**
  - MW support: 3.8
  - No MW support: 9.4
  - *p* = 0.21

- **Citation rate per year (mean)**
  - MW support: 5.2
  - No MW support: 4.6
  - *p* = 0.11

Secondary analysis presented at ISMPP 2016
Study conclusions

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

- Secondary analyses suggest that articles with medical writing support are accepted in higher impact journals
  - Articles with medical writing support were published more recently

- First study to demonstrate convincingly the value of medical writing support
- Further research is warranted
How did we make our voice heard?

- ISMPP posters
- News article
- Twitter direct messages to influential tweeters
- Twitter take-over
- Press release
- Author videos

With support from
- Peter Llewellyn (MedComms Networking)
- Ryan Woodrow (The Publication Plan)
The warm reaction

So far, Altmetric has seen 154 tweets from 88 users, with an upper bound of 86,957 followers.
Reach after 5 days

- Abstract views (journal browsing)
  - Lopez et al. BMJ Open 2016;6:e009288
    Published 23/02/2016
  - Mekonnen et al. BMJ Open 2016;6:e010003
    Published 23/02/2016
  - Gattrell et al. BMJ Open 2016;6:e010329
    Published 22/03/2016

- Full-text views (article reads)
  - Lopez et al. BMJ Open 2016;6:e009288
    Published 23/02/2016
  - Mekonnen et al. BMJ Open 2016;6:e010003
    Published 23/02/2016
  - Gattrell et al. BMJ Open 2016;6:e010329
    Published 22/03/2016

3497 full-text views so far

Correct at 29 April 2016
How can our evidence be used?

- 87% positive impact, ~75% had or would use this evidence

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19

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ISMPP: An Important Announcement about the CAST directive (31 March 2016).
We would like to thank our collaborators and co-authors

- Richard White and Chris Winchester from Oxford PharmaGenesis
- Sally Hopewell from the Consolidated Standards of Reporting Trials (CONSORT) group
- Liz Wager from Sideview
- Catherine Sheard from the Department of Zoology, Oxford University
- Will Gattrell, Kate Young, Stephen Lang and Lizzie Costigan

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Contact

Paul Farrow  DPhil CMPP
Communications Director
Oxford PharmaGenesis
Tubney Warren Barn
Oxford OX13 5QJ
UK

✉ paul.farrow@pharmagenesis.com
📞 +44 1865 390 144
💻 www.pharmagenesis.com

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http://bmjopen.bmj.com/content/6/2/e010329.full

http://www.eposters2u.com/654575/