Professional medical writers increase the quality and speed of clinical trial reporting

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Professional medical writing support and the quality, ethics and timeliness of clinical trial reporting: a systematic review

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**Competing interests**
- Obaro Evuarherhe, Richard White and Christopher Winchester are employees of Oxford PharmaGenesis, Oxford, UK
- William Gattrell is an employee of Ipsen Pharma, Milton Park, UK
- Christopher Winchester and Richard White are directors of, and own shares in, Oxford PharmaGenesis Holdings Ltd

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Introduction

• The timely and accurate reporting of clinical trial results is a scientific and ethical imperative

• Pharmaceutical companies are often criticized, and are facing increased scrutiny for a perceived lack of transparency in the disclosure of clinical trial results (Goldacre et al. 2018)
Professional medical writing support helps authors and sponsors to disclose their research in peer-reviewed journals and at scientific congresses in an ethical, accurate, and timely manner, with the ultimate aim of advancing patient care. Professional medical writers have extensive knowledge of ethical publication guidelines.

AMWA–EMWA–ISMPP Joint Position Statement on the Role of Professional Medical Writers
January 2017
We conducted a systematic review to identify and to analyse published studies that investigated the association between professional medical writing support and the **quality**, **ethics** and **timeliness** of clinical trial reporting

**Objectives**

- **Quality and ethics**
  - Examples of quality- and ethics-related outcomes include:
    - adherence to Consolidated Standards of Reporting Trials (CONSORT) or CONSORT for Abstracts (CONSORT-A)
    - quality of written English
    - reporting of non-pre-specified outcomes

- **Timeliness**
  - Examples of timeliness-related outcomes include:
    - time from study completion to primary manuscript publication
    - time from manuscript submission to manuscript publication

CONSORT, Consolidated Standards of Reporting Trials; CONSORT-A, CONSORT for Abstracts
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The systematic review process

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Search
- Define databases
- Predetermine search strings based on PICOS
- Combine search results and exclude duplicates

Screen
- Screen publications based on title and abstract
- Inclusion/exclusion according to eligibility criteria

Full-text review
- Review of full-text publications to confirm eligibility

Data extraction
- Complete predefined data extraction table

Synthesis and deliverables
- Report findings: tables (included studies and results), figures (PRISMA flow diagram, visual representation of findings), text (descriptive results sections)

PICOS, Population Intervention Comparator Outcome Study Design; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses
Systematic search

• Embase, MEDLINE and the Cochrane databases were searched on 8 March 2018
  – The search strategy comprised terms relating to medical writing, medical publication professional and medical communication, combined with terms for observational, cross-sectional or epidemiological studies
  – There were no limits on date, language or country in which the research was conducted

• Supplementary searches were conducted of the ISMPP congress proceedings and the journals *Medical Writing* and *The Write Stuff* using the terms ‘medical writ*’ and ‘medical publication professional’

• Supplementary searches were limited to 2014–2018
Study selection and data collection

• Identified studies were screened against inclusion and exclusion criteria in accordance with the 2009 PRISMA guidelines.

• Studies eligible for inclusion were in English and evaluated the quality, ethics or timeliness of articles reporting clinical trials, comparing those that had been developed with and those that had been developed without acknowledged professional medical writing support (PMWS).

PMWS, professional medical writing support; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses
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Of the eight included studies, three were full publications (two in peer-reviewed journals) and five were congress abstracts (four poster presentations and one oral presentation).
Identified studies

The eight included studies analysed 849 articles that had been developed with PMWS and 2073 articles that had been developed without PMWS.
### Results: adherence to CONSORT guidelines

<table>
<thead>
<tr>
<th>Effect of PMWS</th>
<th>Positive</th>
<th>Non-significant</th>
<th>Negative</th>
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</thead>
</table>
| The proportion of articles that completely reported at least 50% of the assessed CONSORT items | • With PMWS: 43/110 articles (39.1%; 95% CI 29.9–48.9) | • Without PMWS: 26/123 articles (21.1%; 95% CI 14.3–29.4, \( p < 0.05 \)) | |}
| CONSORT items were significantly more likely to be completed in papers with PMWS than in those without (OR 1.44; 95% CI 1.04–2.00; \( p = 0.03 \)) | | | |}
| 23/97 articles with PMWS (24%) had 80–100% CONSORT adherence, whereas 5/105 articles developed without PMWS (5%) had 80–100% CONSORT adherence (\( p < 0.0001 \)) | | | |}

CI, confidence interval; CONSORT, Consolidated Standards of Reporting Trials; OR, odds ratio; PMWS, professional medical writing support

# Results: adherence to CONSORT-A guidelines

<table>
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<th>Effect of PMWS</th>
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- **Positive**: The mean proportion of CONSORT-A items reported was similar with and without PMWS (64.3% vs 66.5%, respectively; \( p = 0.30 \))

- **Non-significant**: PMWS was associated with a lower level of compliance with reporting of study setting (RR 0.40; 95% CI 0.23–0.70) and a higher level of adherence to disclosure of harms or side effects (RR 2.04; 95% CI 1.37–3.03) and funding source (RR 1.75; 95% CI 1.18–2.60)

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*PMWS was associated with a lower level of compliance with reporting of study setting (RR 0.40; 95% CI 0.23–0.70) and a higher level of adherence to disclosure of harms or side effects (RR 2.04; 95% CI 1.37–3.03) and funding source (RR 1.75; 95% CI 1.18–2.60)*

CI, confidence interval; CONSORT-A, Consolidated Standards of Reporting Trials for Abstracts; PMWS, professional medical writing support; RR, relative risk

## Results: quality of written English

### Effect of PMWS

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<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Non-significant</th>
<th>Negative</th>
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<tbody>
<tr>
<td><strong>Proportion of articles rated by all reviewers during peer review as having an acceptable standard of written English</strong></td>
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<tr>
<td>With PMWS:</td>
<td>81.1% (43/53 articles; 95% CI 67.6–90.1)</td>
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<tr>
<td>Without PMWS:</td>
<td>47.9% (23/48 articles; 95% CI 33.5–62.7)</td>
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</table>

**Gattrell et al. 2016**

CI, confidence interval; PMWS, professional medical writing support

Gattrell WT *et al.* BMJ Open 2016;6:e010329
### Results: journal- or article-related outcomes

<table>
<thead>
<tr>
<th>Effect of PMWS</th>
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<tbody>
<tr>
<td>Likelihood of publication in a journal with an impact factor was significantly higher with PMWS ($p = 0.001$)</td>
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<td>Mean impact factor of publication journal was significantly higher with PMWS ($p &lt; 0.001$)</td>
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<tr>
<td>Mean number of citations per year was not significantly different with PMWS ($p = 0.11$)</td>
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<td>Mean number of article views per year was not significantly different with PMWS ($p = 0.84$)</td>
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<td>Altmetric score was not significantly different with PMWS ($p = 0.55$)</td>
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Results: reporting of non-pre-specified outcomes

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<tr>
<th></th>
<th>Positive</th>
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<th>Negative</th>
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<tbody>
<tr>
<td><strong>Effect of PMWS</strong></td>
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<tr>
<td><strong>Positive</strong></td>
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<tr>
<td>Non-pre-specified outcomes were reported significantly less often in articles developed with PMWS than in industry-funded or non-industry-funded articles developed without PMWS (2.2 vs 6.5 or 6.6, (p = 0.028, \ p &lt; 0.01))</td>
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Gattrell *et al.* 2017
### Results: time to publication

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<tr>
<td><strong>Positive</strong></td>
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<tr>
<td>Gattrell <em>et al.</em> 2016</td>
<td><img src="image1.png" alt="Image" /></td>
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<td>Time from manuscript submission to acceptance was increased with PMWS (167 days [IQR 114.5–231 days] vs 136 days [IQR 77–193 days], <em>p</em> &lt; 0.01); mean number of versions submitted was unchanged</td>
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<td><strong>Shah <em>et al.</em> 2016</strong></td>
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<td>Time to publication from last patient visit in clinical trials was reduced with PMWS (18.6 [SD 13.2] months vs 30.8 [SD 11.7] months)</td>
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<td><strong>Woolley <em>et al.</em> 2006</strong></td>
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<td>Time from manuscript submission to acceptance was reduced with PMWS (83.6 days vs 132.2 days), although this difference was not statistically significant (<em>p</em> = 0.053)</td>
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IQR, interquartile range; PMWS, professional medical writing support; SD, standard deviation

## Results: summary

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Effect of PMWS</th>
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<tr>
<td>Adherence to CONSORT</td>
<td>Positive</td>
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<tr>
<td>Adherence to CONSORT-A</td>
<td>Non-significant</td>
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<tr>
<td>Quality of written English</td>
<td>Negative</td>
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<tr>
<td>Impact factor-related outcomes</td>
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<td>Article impact-related outcomes</td>
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<tr>
<td>Reporting of non-pre-specified outcomes</td>
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<tr>
<td>Time to publication (end-of-trial to publication)</td>
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<tr>
<td>Time to publication (submission to acceptance)</td>
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</table>

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Strengths and limitations

• **Strengths**
  – Broad search strategy with no limits on date, country, language or type of observational study
  – To limit publication bias, conference proceedings were searched for relevant studies
  – Outcomes assessed were widely accepted measures of quality (e.g. adherence to CONSORT) or were assigned independently of the investigators involved in each of the articles analysed in each included study (e.g. standard of written English)

• **Limitations**
  – Most identified studies were presented at conferences or published in non-peer-reviewed journals; future studies on the impact of professional medical writers should be published in full in peer-reviewed journals
Implications

- The results of this study inspire confidence in the quality and transparency of articles reporting clinical trials that are written with professional medical writing support.
- PMWS was also associated with a reduced time from clinical trial completion to primary publication.
- Thus, PMWS adds value to clinical trial reporting.
Further research

• Further research is needed to assess the impact of professional medical writers on other types of studies published by the pharmaceutical industry
  – PMWS is associated with increased transparency relating to the source of funding, the author disclosures of financial interest and the acknowledgements of conflicts of interest (or lack thereof) in health economics and outcomes research publications (Desai et al. 2018)
Conclusions

• In our systematic review of eight studies assessing 849 articles developed with professional medical writing support and 2073 articles developed without professional medical writing support, professional medical writing support was associated with:

  - improved reporting quality
  - higher quality of written English
  - faster reporting of results