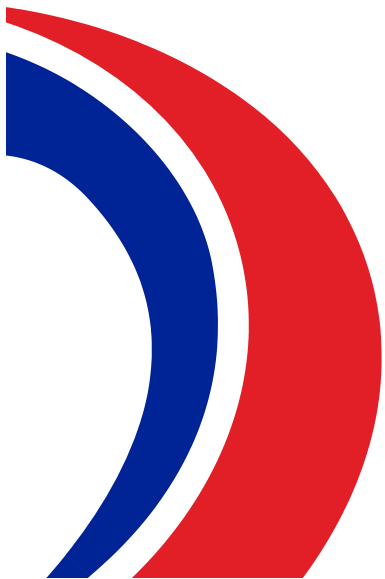


Professional medical writers increase the quality and speed of clinical trial reporting

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

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Research Integrity and
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REVIEW Open Access

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

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Abstract

Background: Many authors choose to work with professional medical writers when reporting the results of clinical trials. We conducted a systematic review to examine the relationship between professional medical writing support (PMWS) and the quality, ethics and timeliness of publications reporting clinical trials.

Methods: Using terms related to 'medical writer' and 'observational study', we searched MEDLINE and Embase (no date limits), as well as abstracts and posters from meetings of the International Society for Medical Publication Professionals (ISMP, 2014–2018). We also hand-searched the journals *Medical Writing* and *The Write Stuff* (2014–2018) and the bibliographies of studies identified in the electronic searches. We screened the results to identify studies that compared the quality, ethics and timeliness of clinical trial publications written with and without declared PMWS.

Results: Our searches identified 97 potentially relevant studies, of which 89 were excluded during screening and full paper review. The remaining eight studies compared 849 publications with PMWS with 2073 articles developed without such support. In these eight studies, PMWS was shown to be associated with increased adherence to Consolidated Standards of Reporting Trials (CONSORT) guidelines (in 3/3 studies in which this was assessed), publication in journals with an impact factor (one study), a higher quality of written English (one study), and a lower likelihood of reporting non-pre-specified outcomes (one study). PMWS was not associated with increased adherence to CONSORT for Abstracts guidelines (one study) or with the impact of published articles (mean number of citations per year, mean number of article views per year and Altmetric score; one study). In studies that assessed timeliness of publication, PMWS was associated with a reduced time from last patient visit in clinical trials to primary publication (one study), whereas time from submission to acceptance showed inconsistent results (two studies).

Conclusions: This systematic review of eight observational studies suggests that PMWS is positively associated with measures of overall quality of reporting of clinical trials and may improve the timeliness of publication.

Keywords: Medical writing, Medical writer, Clinical trials transparency, Reporting guidelines, Adherence

Background

Timely and complete reporting of the results of clinical trials is an ethical imperative [1]; it helps to efficiently disseminate research findings and eliminate duplicative effort thereby reducing waste in research funding [2], enables researchers to develop more up-to-date study hypotheses and allows clinicians and patients to judge the benefits or risks of different therapies. Although the pharmaceutical industry has made great strides to address criticism for a perceived lack of transparency in the disclosure of clinical trial results, the quality, ethics and timeliness of clinical trial reporting remain closely scrutinized for both industry-funded and academically funded trials [3–7].

Pharmaceutical companies often offer authors professional medical writing support (PMWS) to assist in the reporting of clinical trial results [8]. International guidelines endorse the acknowledgement of PMWS [9, 10], and the proportion of articles in the medical literature with such an acknowledgement is 5–18% [8, 11, 12]. We

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Disclosures and acknowledgements

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- This study was funded by Oxford PharmaGenesis

- **Competing interests**

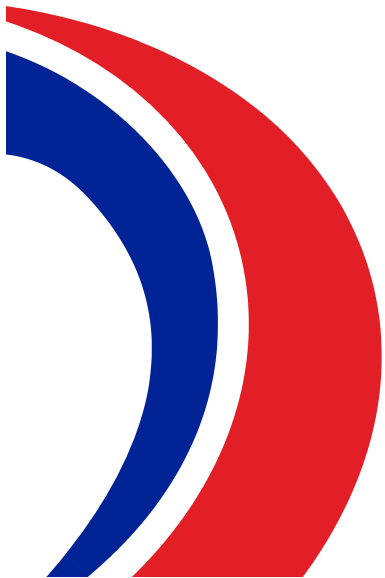
- Obaro Evuarherhe, Richard White and Christopher Winchester are employees of Oxford PharmaGenesis, Oxford, UK
- William Gattrell is an employee of Ipsen Pharma, Milton Park, UK
- Christopher Winchester and Richard White are directors of, and own shares in, Oxford PharmaGenesis Holdings Ltd

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- 2** | Methods
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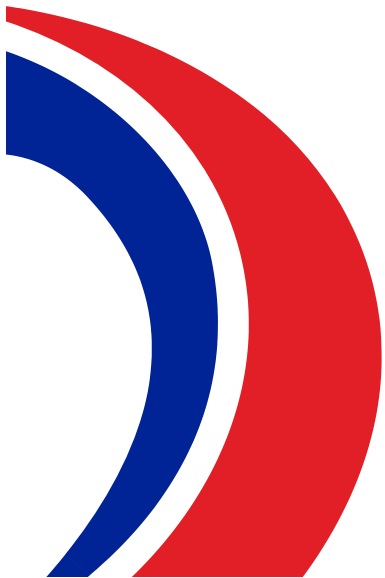


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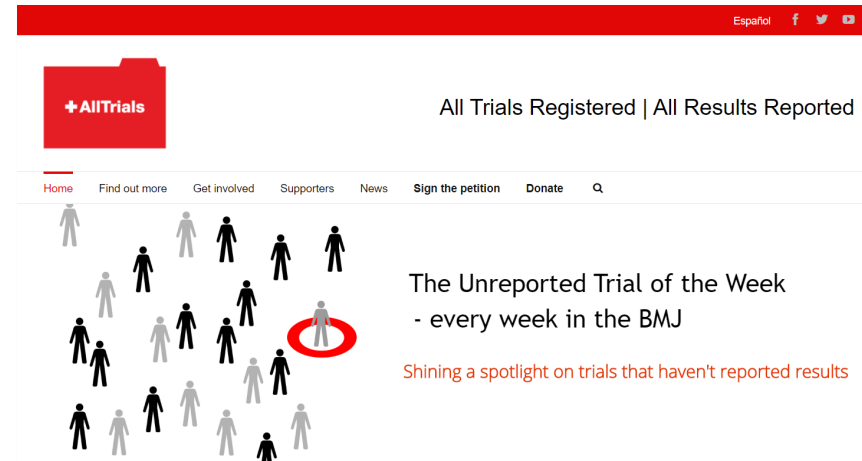


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Introduction

- 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)



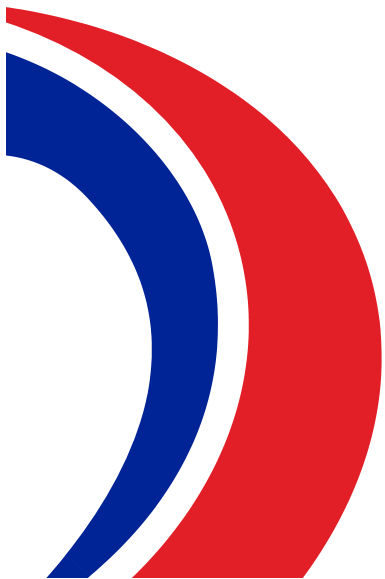
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Professional medical writing support helps authors and sponsors to disclose their research in peer-reviewed journals and at scientific congresses in an ethical, accurate, and timely manner, with the ultimate aim of advancing patient care. Professional medical writers have extensive knowledge of ethical publication guidelines.

”

AMWA–EMWA–ISMPP Joint Position Statement on the
Role of Professional Medical Writers
January 2017

AMWA, American Medical Writers Association; EMWA, European Medical Writers Association;
ISMPP, International Society for Medical Publication Professionals



Objectives

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

- **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

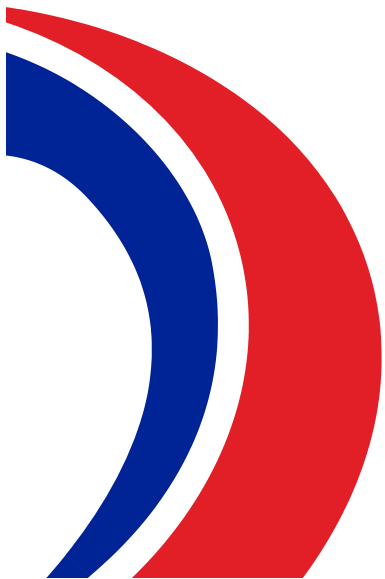


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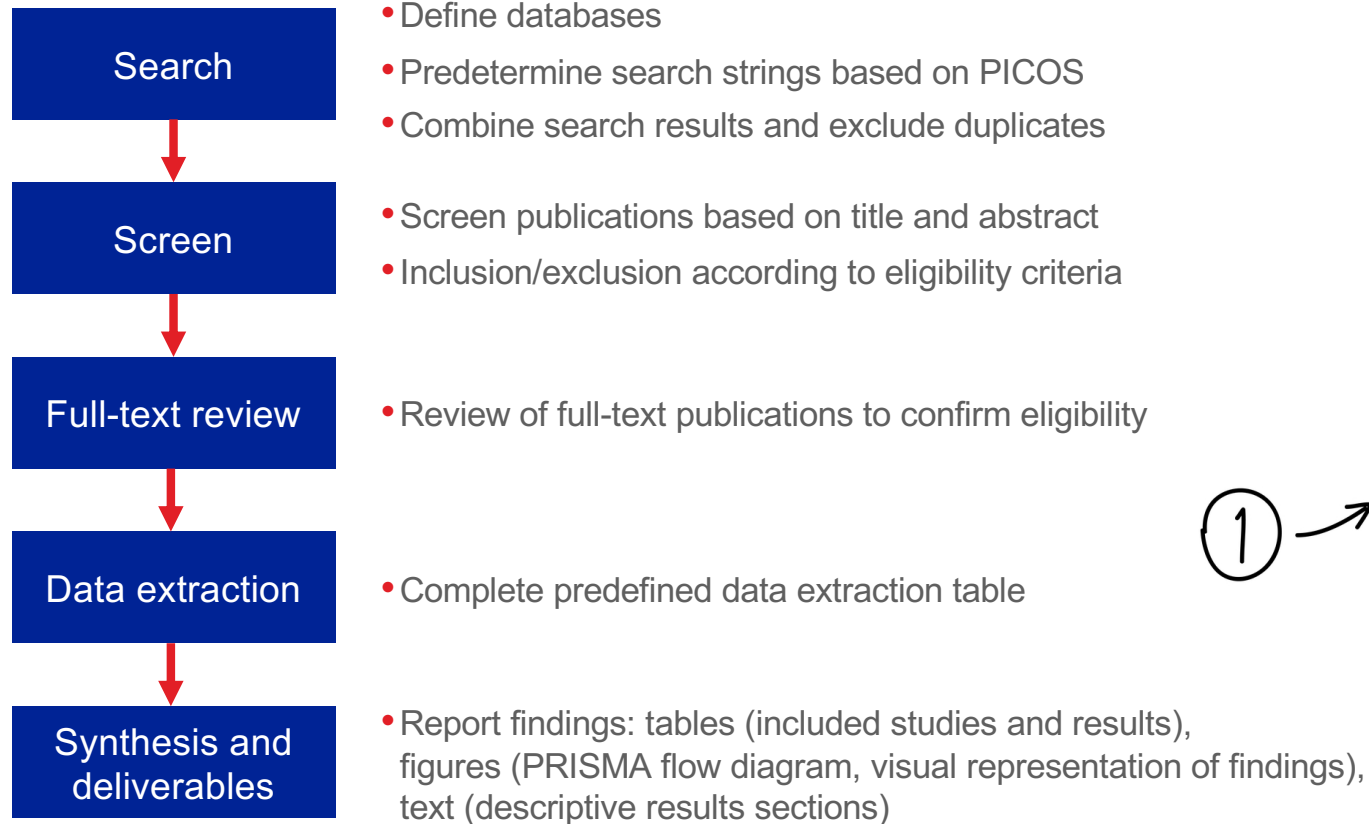
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The systematic review process



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

Searches

- 1 (medical writer* or medical writing or medical publication professional* or medical communication or medcomms).mp.
- 2 ((observational adj (study or studies)) or (cross sectional adj (study or studies)) or (epidemiologic\$ adj (study or studies))).mp. or exp study/ or exp trial/
- 3 and/1-2

- 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)

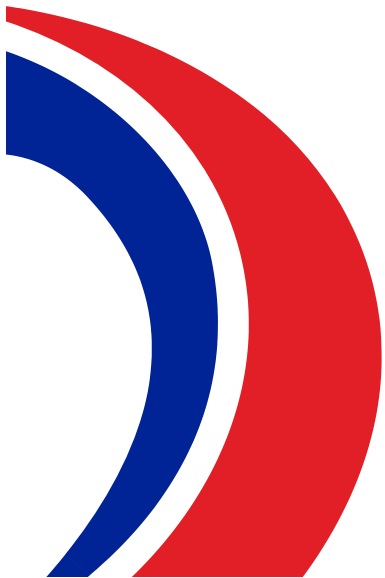


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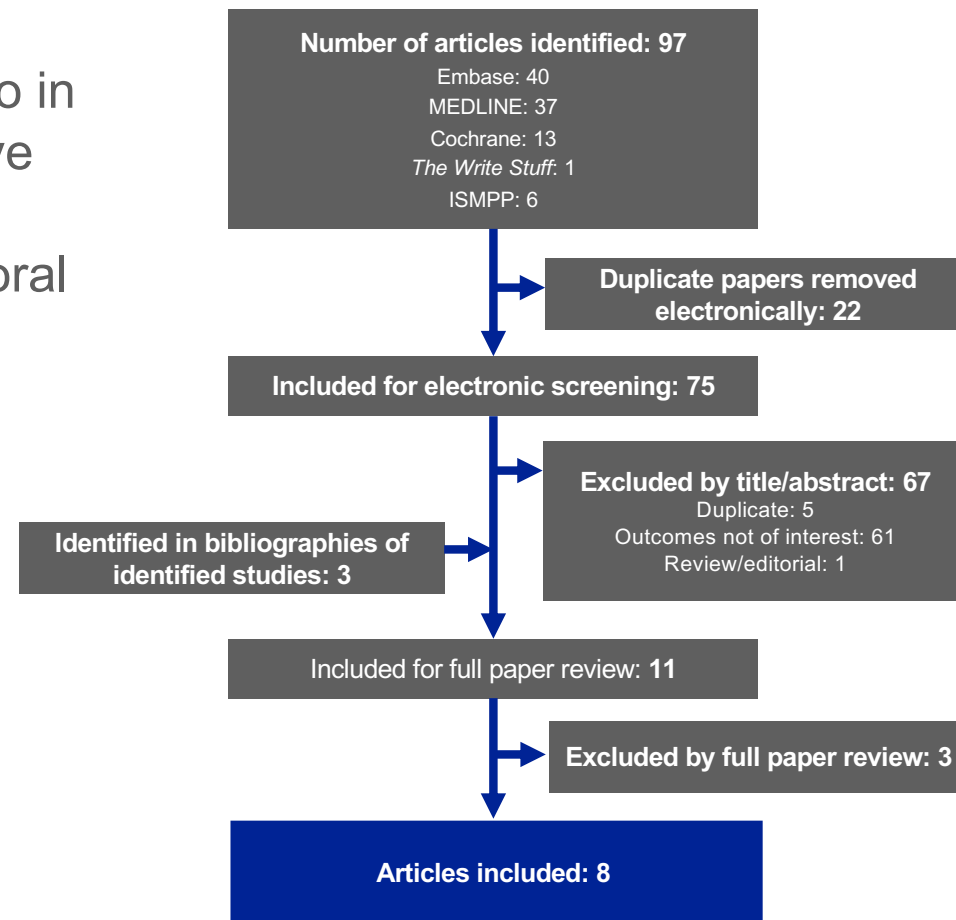


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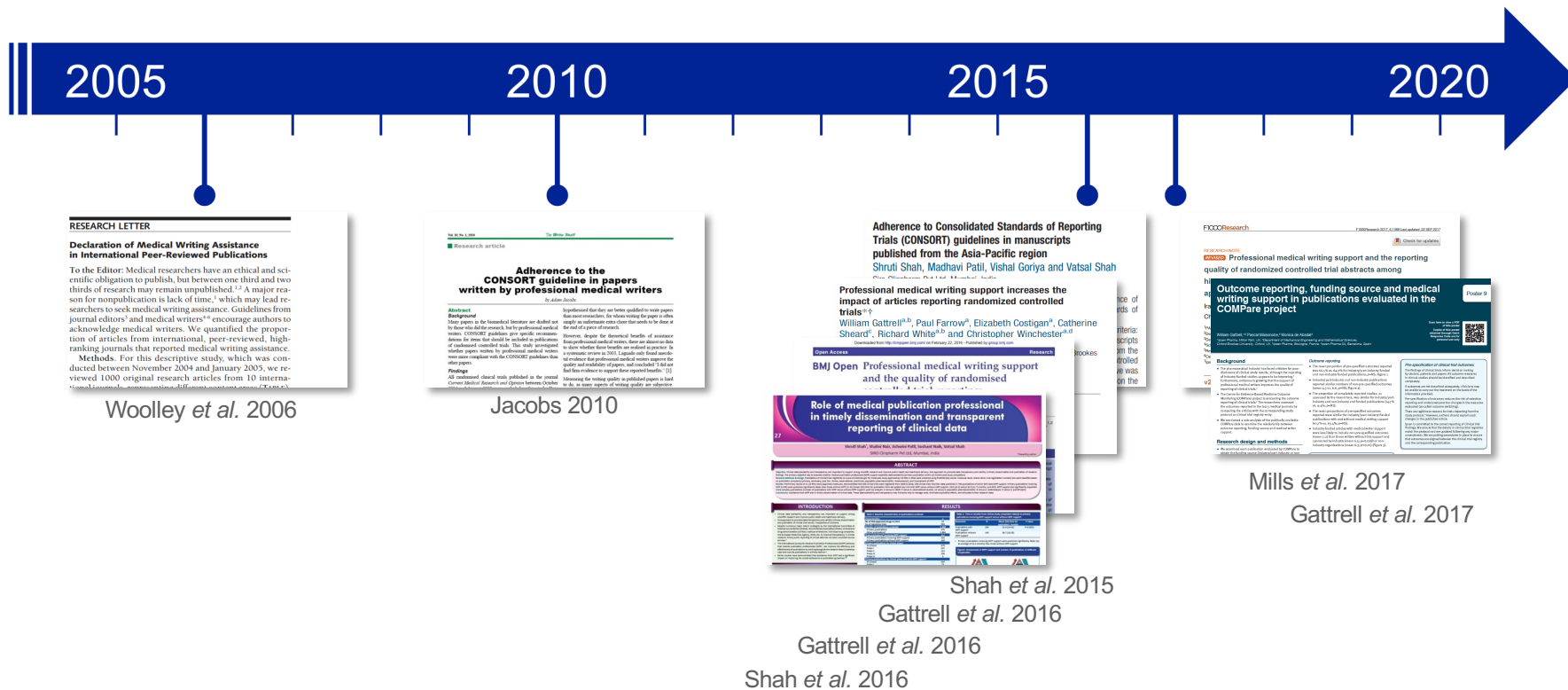
PRISMA flow diagram

- 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

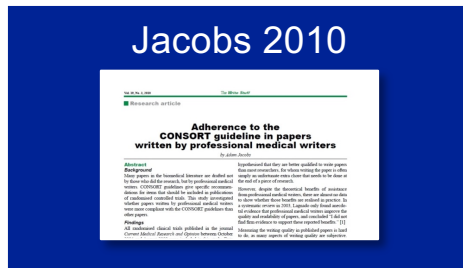
The eight included studies analysed 849 articles that had been developed with PMWS and 2073 articles that had been developed without PMWS



PMWS, professional medical writing support
 Gattrell W *et al. Curr Med Res Opin* 2016;32(Suppl 1):S17; Gattrell W *et al. Curr Med Res Opin* 2017;33 (Suppl 1):27; Gattrell WT *et al. BMJ Open* 2016;6:e010329; Jacobs A. *Write Stuff* 2010:196–200; Mills I *et al. F1000Res* 2017;6:1489; Moher D *et al. BMJ* 2009;339:b2535; Shah S *et al. Curr Med Res Opin* 2015;31(Suppl 1):S5; Woolley KL *et al. JAMA* 2006;296:932–4



Results: adherence to CONSORT guidelines



Effect of PMWS		
Positive	Non-significant	Negative
<p>The proportion of articles that completely reported at least 50% of the assessed CONSORT items</p> <ul style="list-style-type: none"> • 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, $p < 0.05$) 		
<p>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; $p = 0.03$)</p>		
<p>23/97 articles with PMWS (24%) had 80–100% CONSORT adherence, whereas 5/105 articles developed without PMWS (5%) had 80–100% CONSORT adherence ($p < 0.0001$)</p>		

CI, confidence interval; CONSORT, Consolidated Standards of Reporting Trials; OR, odds ratio; PMWS, professional medical writing support
 Gattrell WT *et al. BMJ Open* 2016;6:e010329; Jacobs A. *Write Stuff* 2010;196–99;
 Shah S *et al. Curr Med Res Opin* 2015;31(Suppl 1):S5



Results: adherence to CONSORT-A guidelines



Mills *et al.* 2017



Effect of PMWS		
Positive	Non-significant	Negative
	The mean proportion of CONSORT-A items reported was similar with and without PMWS (64.3% vs 66.5%, respectively; $p = 0.30$) ^a	

^aPMWS 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
 Mills I *et al.* *F1000Res* 2017;6:1489



Results: quality of written English



Effect of PMWS		
Positive	Non-significant	Negative
<p>Proportion of articles rated by all reviewers during peer review as having an acceptable standard of written English</p> <ul style="list-style-type: none"> • With PMWS: 81.1% (43/53 articles; 95% CI 67.6–90.1) • Without PMWS: 47.9% (23/48 articles; 95% CI 33.5–62.7) 		



Results: journal- or article-related outcomes



Gattrell *et al.* 2016

Professional medical writing support increases the impact of articles reporting randomized controlled trials¹
 William Gattrell^{1,2,3}, Paul Farrow⁴, Elizabeth Costigan⁵, Catherine Sheldrick⁶, Richard White^{7,8} and Christopher Winchester^{9,10}
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⁴School of Medicine, Pharmacy & Health, Durham University, UK
⁵Oral Presentation
⁶Received poster at the 12th Annual Meeting of ISMP
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Effect of PMWS		
Positive	Non-significant	Negative
Likelihood of publication in a journal with an impact factor was significantly higher with PMWS ($p = 0.001$)		
Mean impact factor of publication journal was significantly higher with PMWS ($p < 0.001$)		
	Mean number of citations per year was not significantly different with PMWS ($p = 0.11$)	
	Mean number of article views per year was not significantly different with PMWS ($p = 0.84$)	
	Altmetric score was not significantly different with PMWS ($p = 0.55$)	



Results: reporting of non-pre-specified outcomes



Effect of PMWS		
Positive	Non-significant	Negative
<p>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, $p = 0.028$, $p < 0.01$)</p>		



Results: time to publication



Gattrell *et al.* 2016

Shah *et al.* 2016

Woolley *et al.* 2006

Effect of PMWS		
Positive	Non-significant	Negative
		Time from manuscript submission to acceptance was increased with PMWS (167 days [IQR 114.5–231 days] vs 136 days [IQR 77–193 days], $p < 0.01$); mean number of versions submitted was unchanged
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)		
	Time from manuscript submission to acceptance was reduced with PMWS (83.6 days vs 132.2 days), although this difference was not statistically significant ($p = 0.053$)	

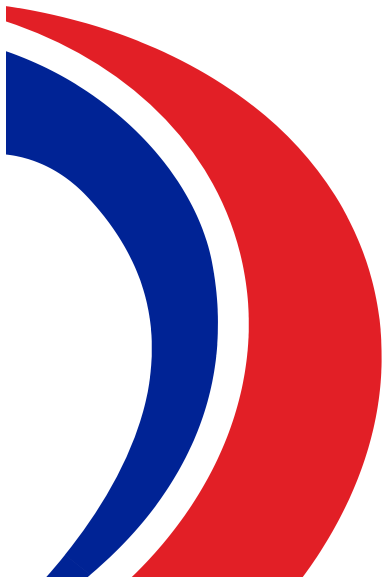


Results: summary

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



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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

