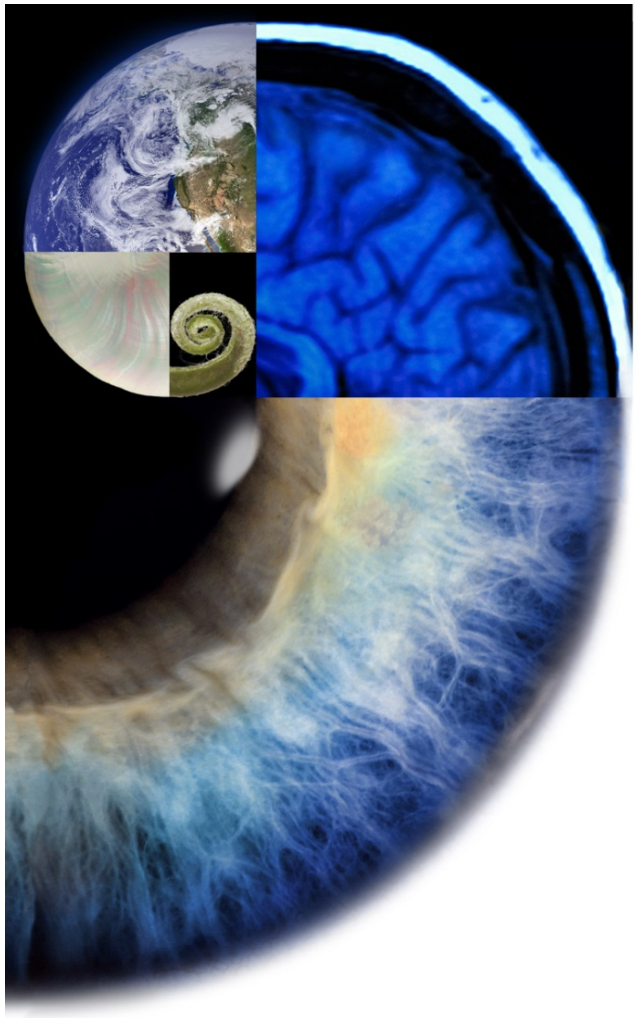


Unpacking the evidence behind the AMWA–EMWA–ISMPP Joint Position Statement

Paul Farrow DPhil CMPP

MedComms Networking Brunch Club

5 April 2017

Paul Farrow DPhil CMPP™

- 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,[14] accurate,[15,16] and timely[17] manner, with the ultimate aim of advancing patient care. Professional medical writers have extensive knowledge of ethical publication guidelines.[18,19]

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

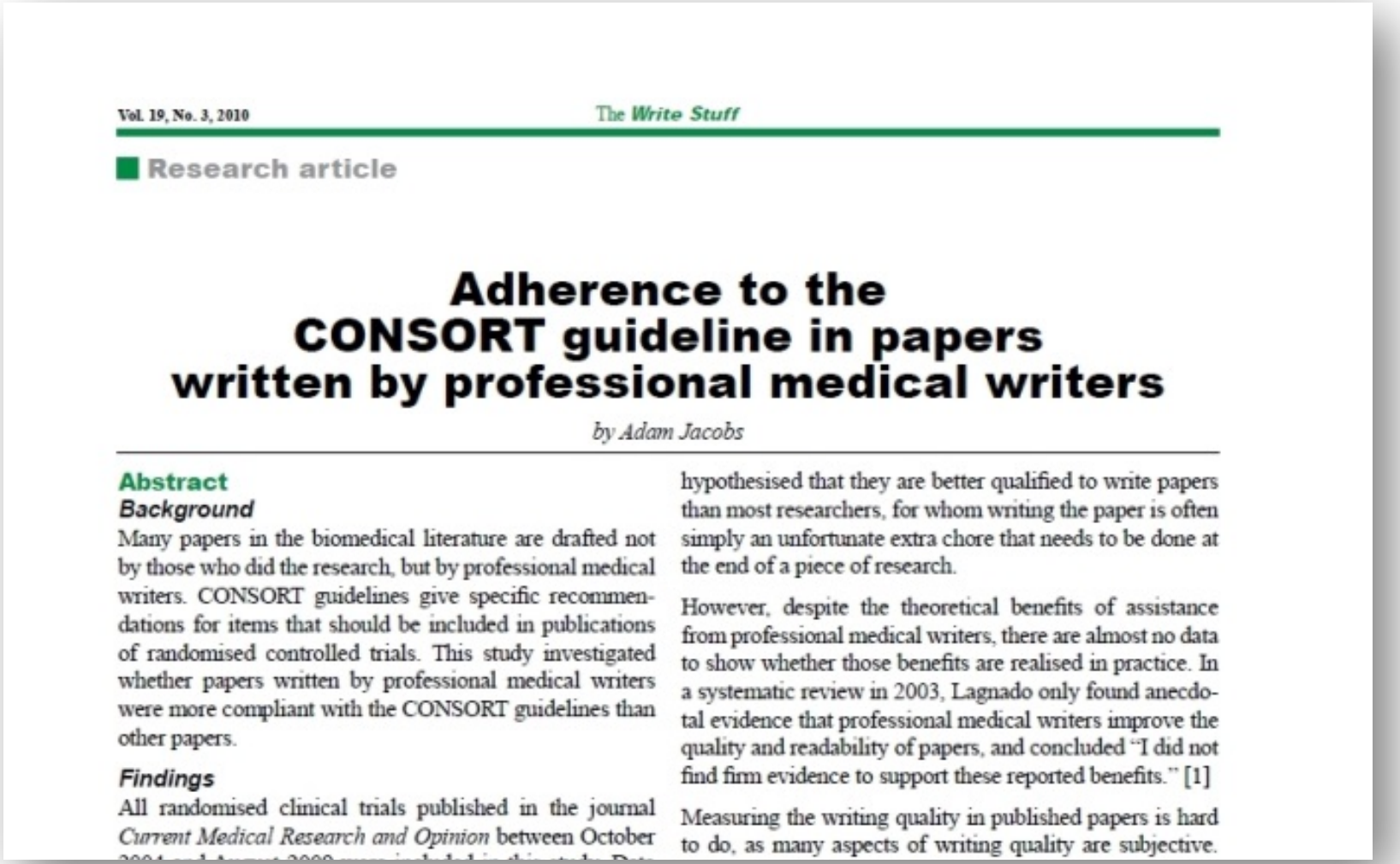
AMWA-EMWA-ISMPP Join Position Statement
http://tinyurl.com/lemlgqn (Accessed 3 April 2017)

Building an evidence base for the value of medical writing support

2010 2011 2012 2013 2014 2015 2016 2017

Jacobs A. *The Write Stuff* 2010; 19 (3):196–200; Woolley KL *et al*. *Curr Med Res Opin* 2011;27:1175–82; Marušić *et al. BMC Medicine 2014;*12:197–206. Wager E *et al. BMJ Open* 2014;4:e004780. Gattrell WT *et al*. *BMJ Open* 2016 21;6:e010329; Shah S *et al. Curr Med Res Opin* 2016;32(Suppl 1):S12; Gattrell W *et al.* Poster at the European meeting of ISMPP 2017.

1. Jacobs *et al. The Write Stuff* 2010



Vol. 19, No. 3, 2010 The *Write Stuff*

Research article

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

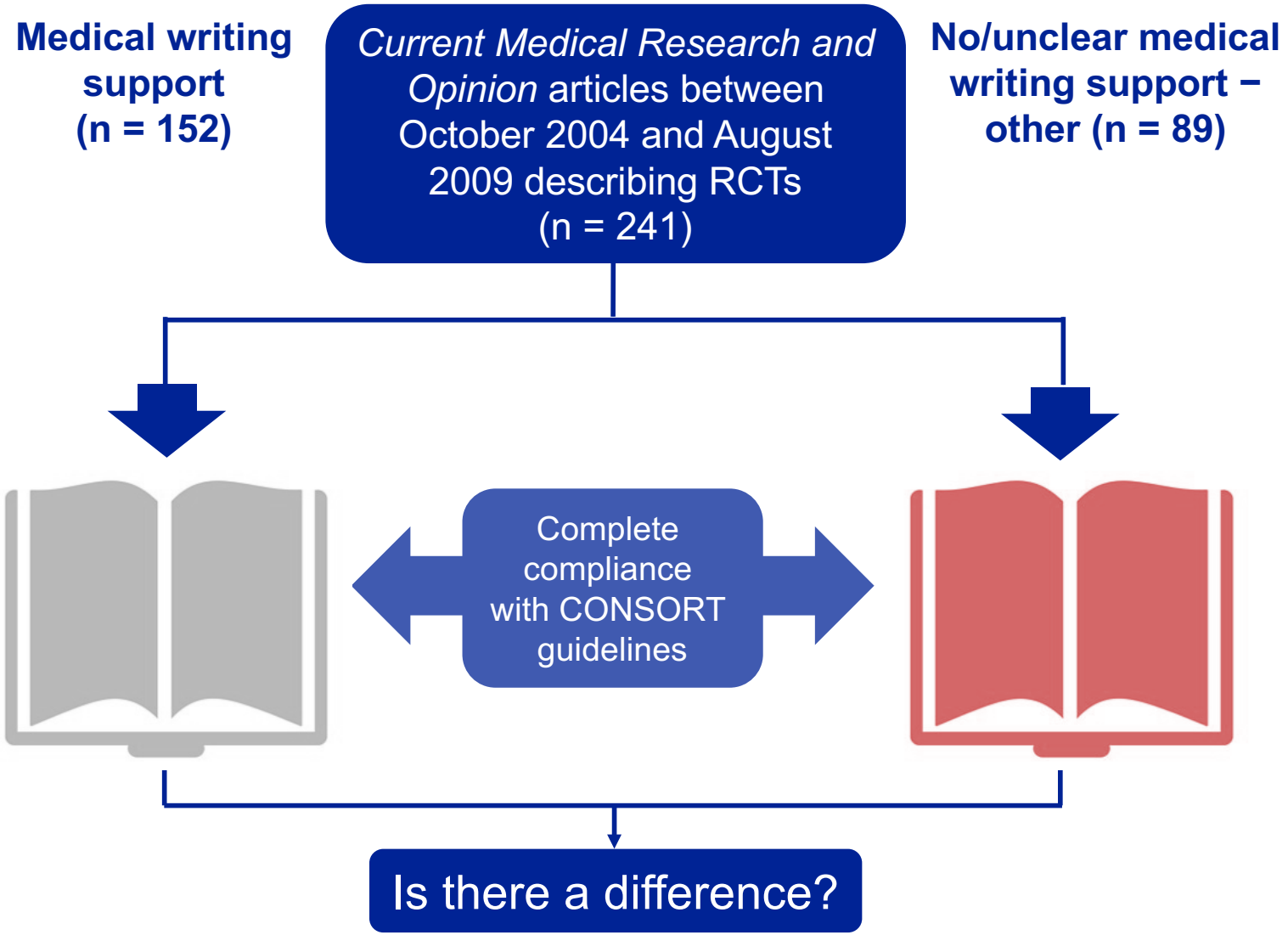
All randomised clinical trials published in the journal *Current Medical Research and Opinion* between October

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

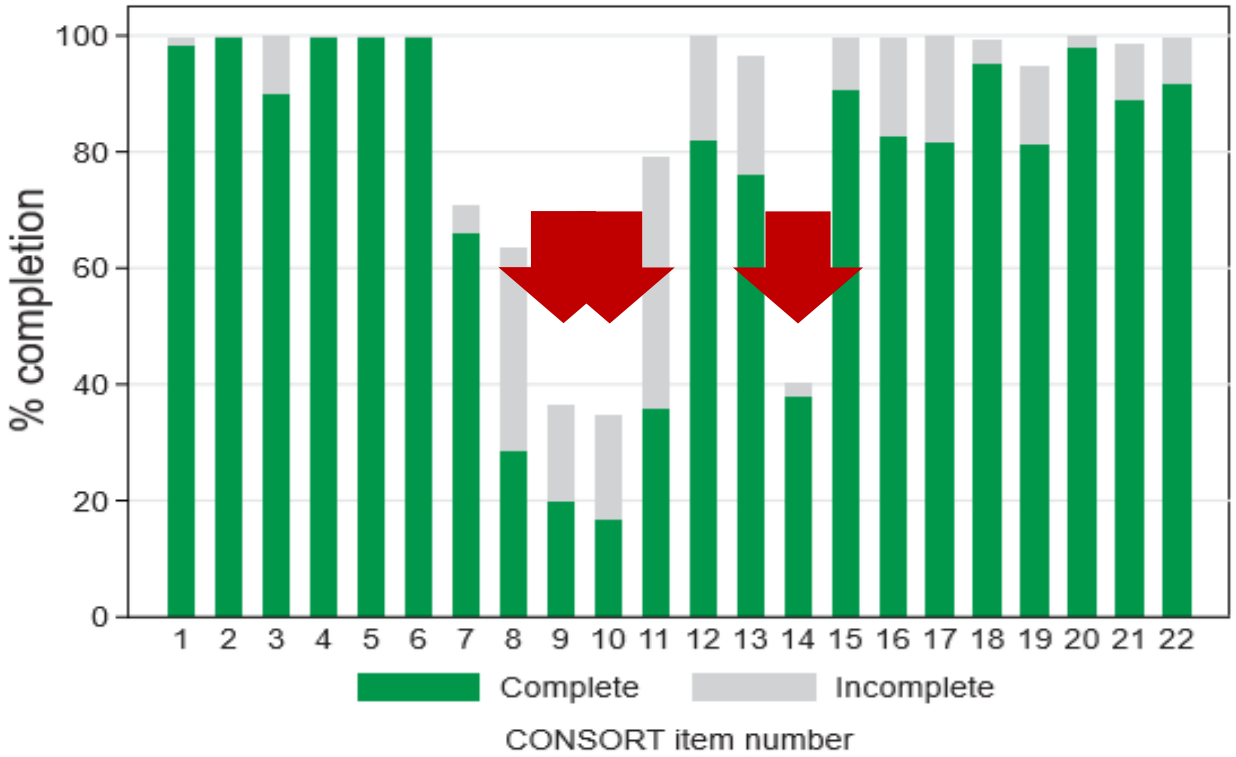


RCT, randomized controlled trial

Jacobs A. *The Write Stuff* 2010; 19 (3):196–200.

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

Jacobs A. *The Write Stuff* 2010; 19 (3):196–200.

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

	Medical writer support (n = 152)		Other papers (n = 89)	
	Mean	SD	Mean	SD
Number of CONSORT items completed	16.9	2.5	16.1	2.7
Items completed with half marks for incomplete item	18.0	2.0	17.5	2.1

Jacobs A. *The Write Stuff* 2010; 19 (3):196–200.

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

Jacobs A. *The Write Stuff* 2010; 19 (3):196–200.

2. Woolley *et al. Curr Med Res Opin* 2011

CMRO

Current Medical Research & Opinion Vol. 27, No. 6, 2011, 1175–1182

0300-7995
doi:10.1185/03007995.2011.573546

Article ST-0032.R1/573546

Original article

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

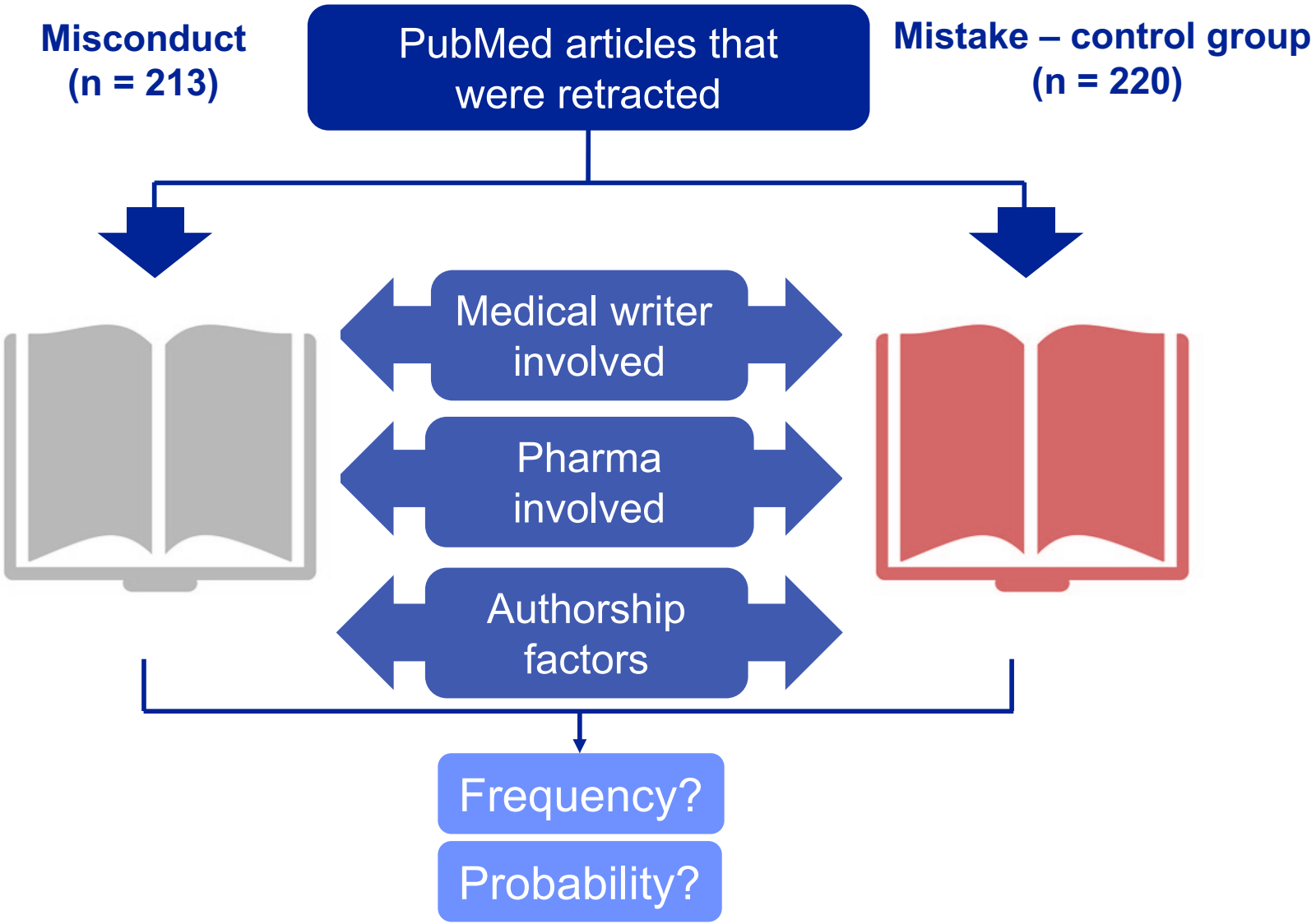
Rebecca A. Lew
Serina Stretton

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.

Woolley KL *et al*. *Curr Med Res Opin* 2011;27:1175–82.

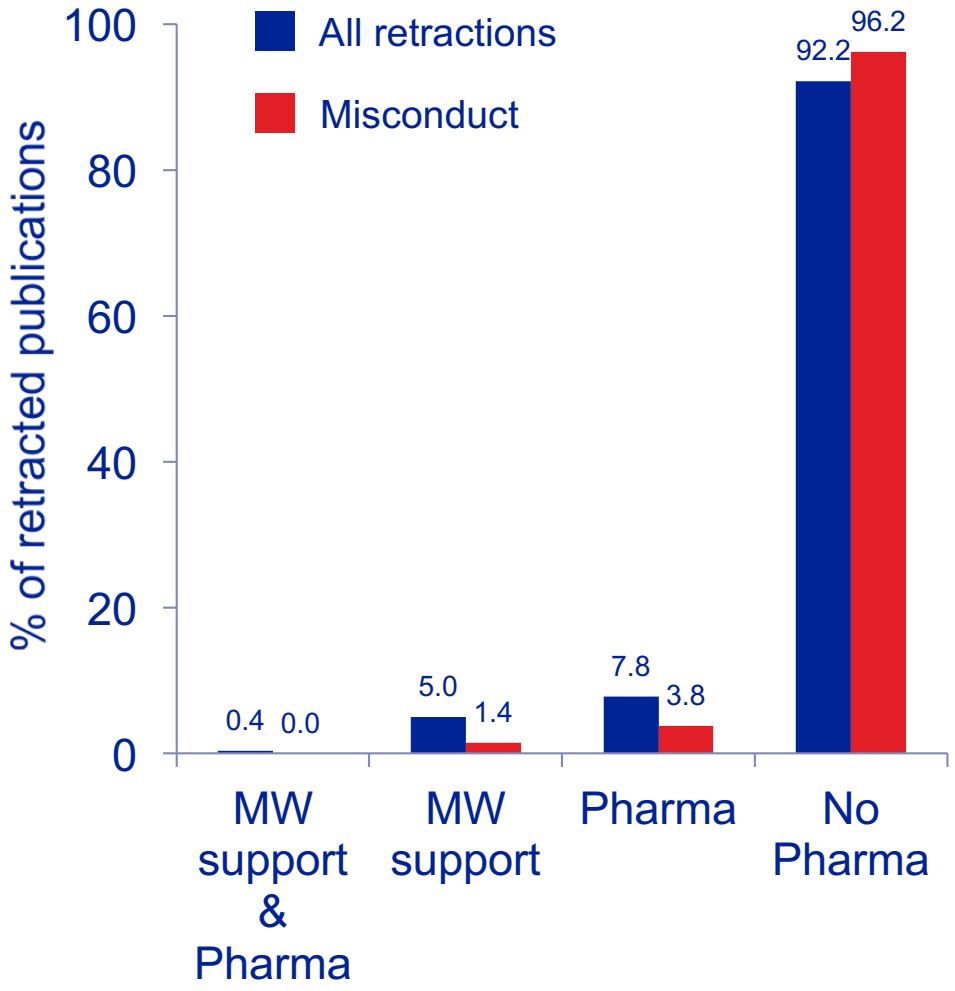
Systematic, controlled, retrospective study of retraction for misconduct



Woolley KL *et al*. *Curr Med Res Opin* 2011;27:1175–82.

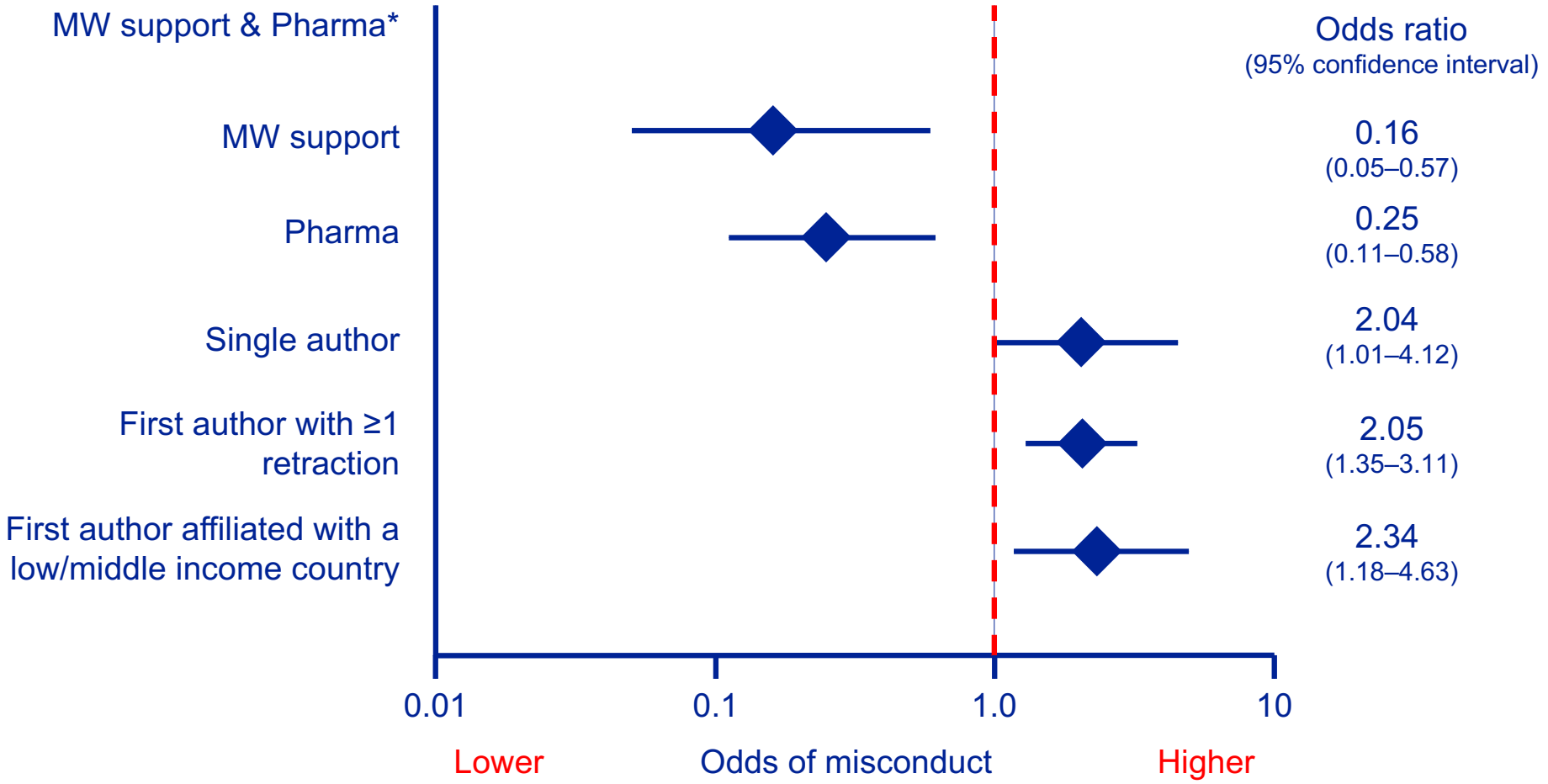
Publications retracted due to misconduct rarely had medical writing support

- 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



Woolley KL *et al*. *Curr Med Res Opin* 2011;27:1175–82.

Lower likelihood of retraction for misconduct with medical writing support



*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.

Woolley KL *et al. Curr Med Res Opin* 2011;27:1175–82.

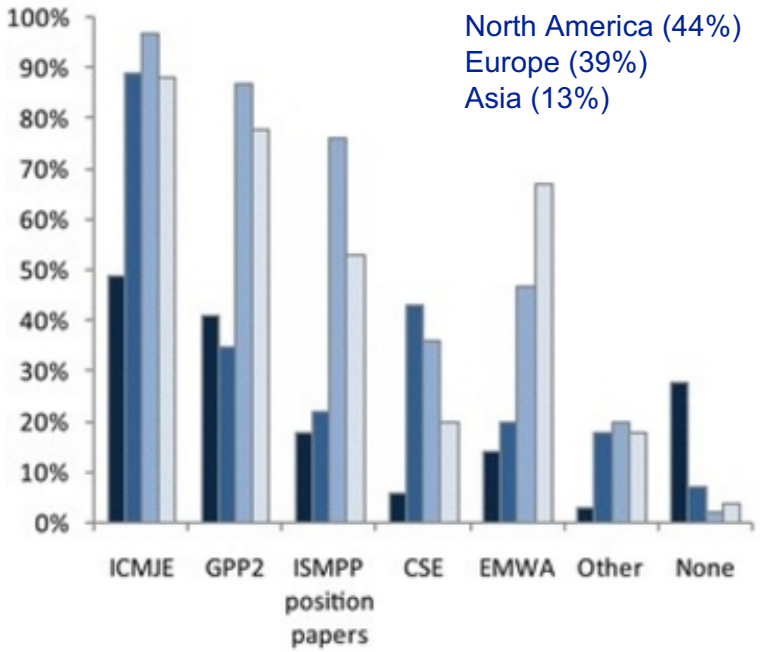
Conclusions

- 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

Woolley KL *et al*. *Curr Med Res Opin* 2011;27:1175–82.

3. Marušić *et al. BMC Medicine* 2014

- 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%)

CSE, Council of Science Editors; EMWA, European Medical Writers Association; GPP2, Good publication practice 2; ICMJE, International Committee of Medical Journal Editors; ISMPP, International Society of Medical Publication Professionals. Marušić *et al. BMC Medicine 2014;*12:197–206.

4. Wager *et al. BMJ Open* 2014

- 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

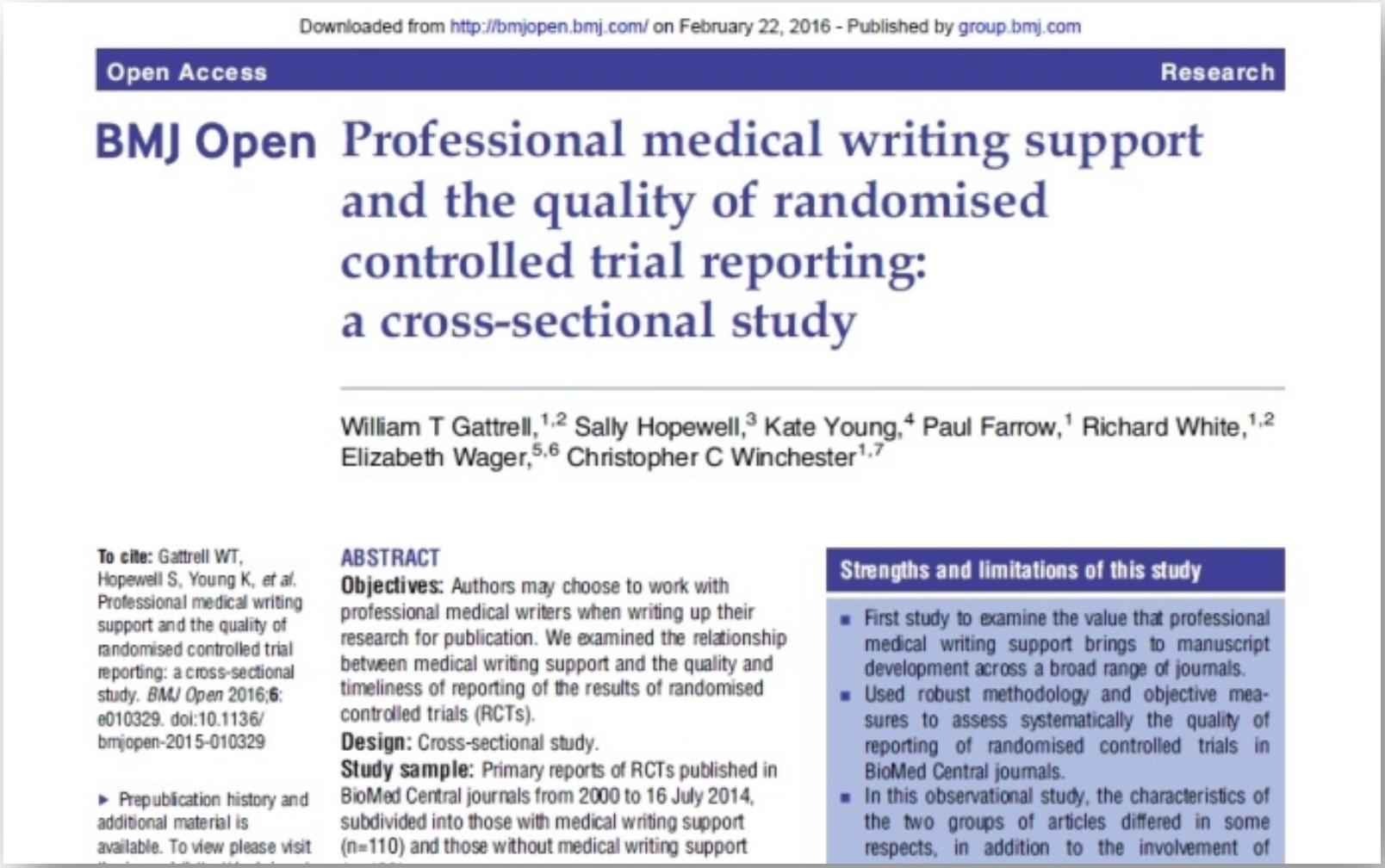
Over 90% of industry, agency and CRO respondents routinely refer to GPP2 and the ICMJE requirements

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

CRO, Contract research organization; GPP2, Good publication practice 2; ICMJE, International Committee of Medical Journal Editors. Wager E *et al. BMJ Open* 2014;4:e004780.

5. Gattrell *et al. BMJ Open* 2016



Open Access Research

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 Winchester[1,7]

To cite: Gattrell WT, Hopewell S, Young K, *et al*. Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study. *BMJ Open* 2016;**6**: e010329. doi:10.1136/bmjopen-2015-010329

► Prepublication history and additional material is available. To view please visit

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).

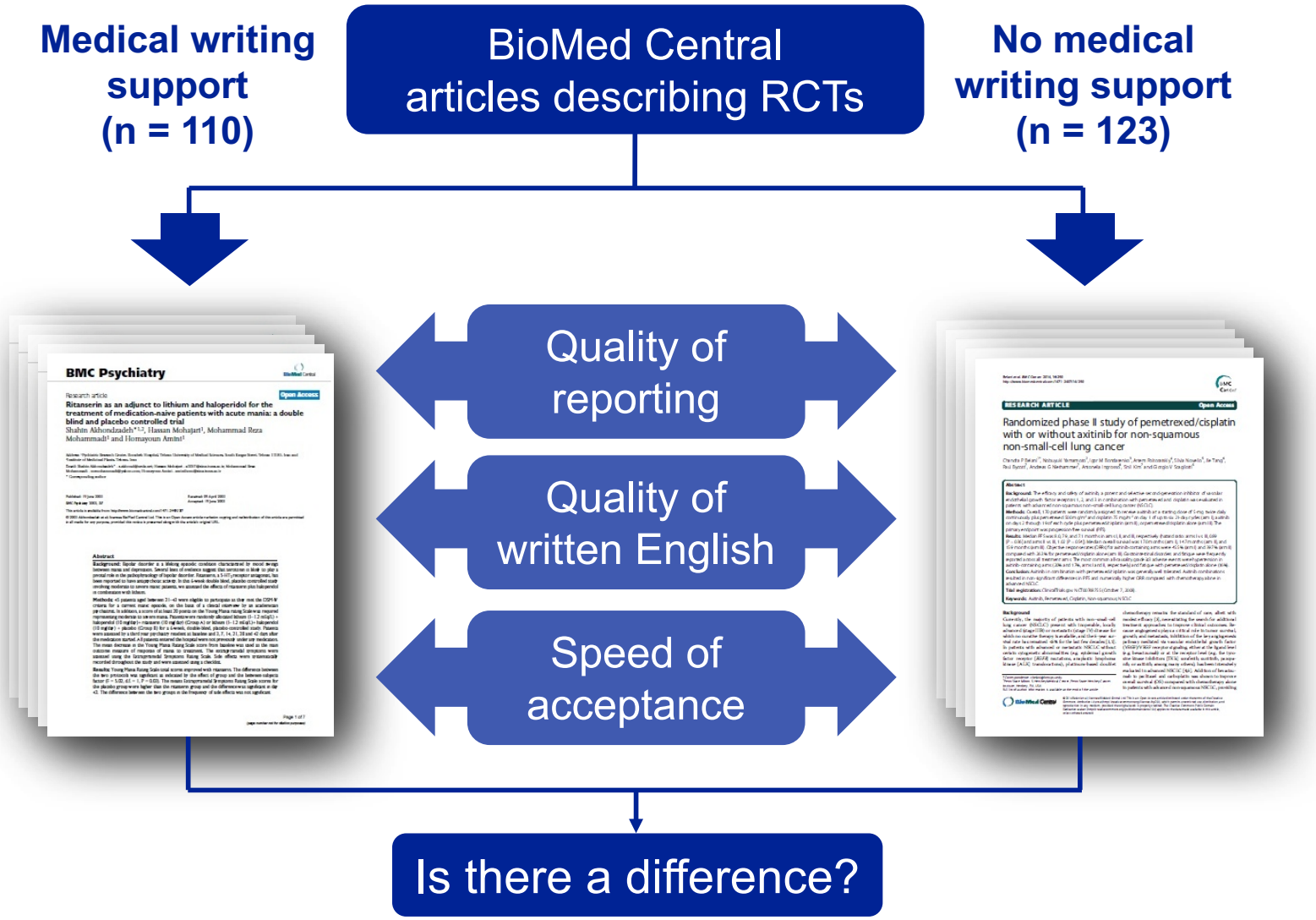
Design: Cross-sectional study.

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

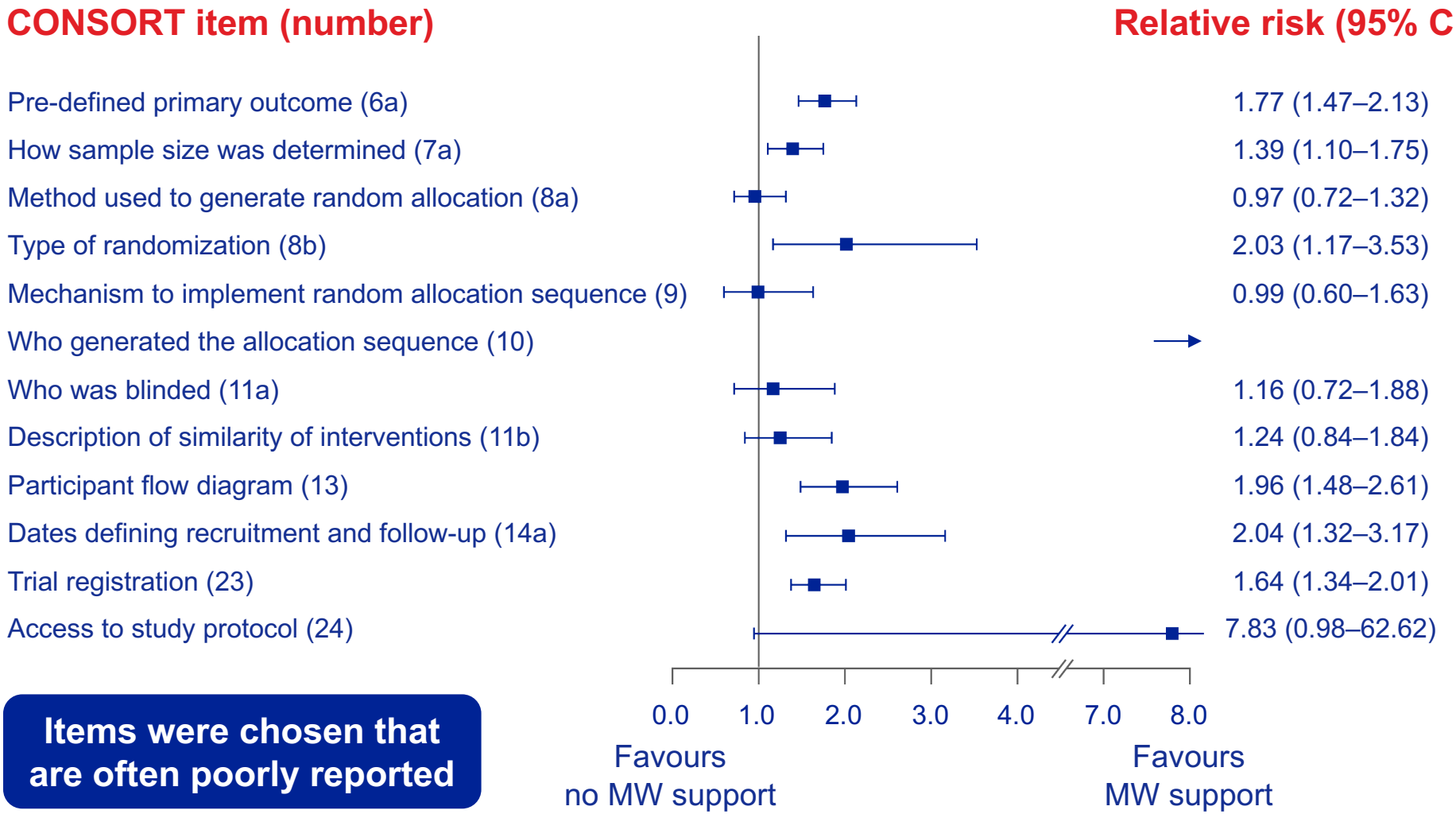
Strengths and limitations of this study

- 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

Cross-sectional study of medical writing support and quality of trial reporting



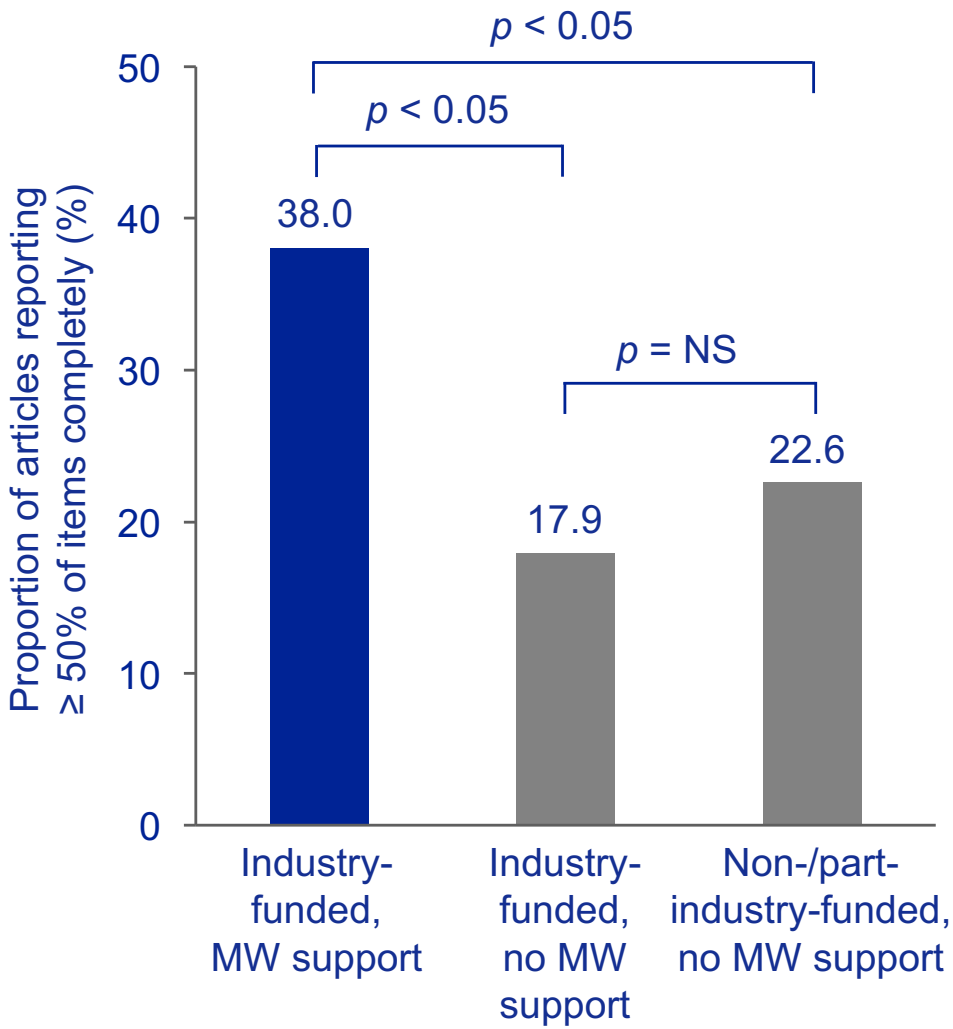
Higher rate of reporting of CONSORT items with medical writing support



Items were chosen that are often poorly reported

… irrespective of funding source

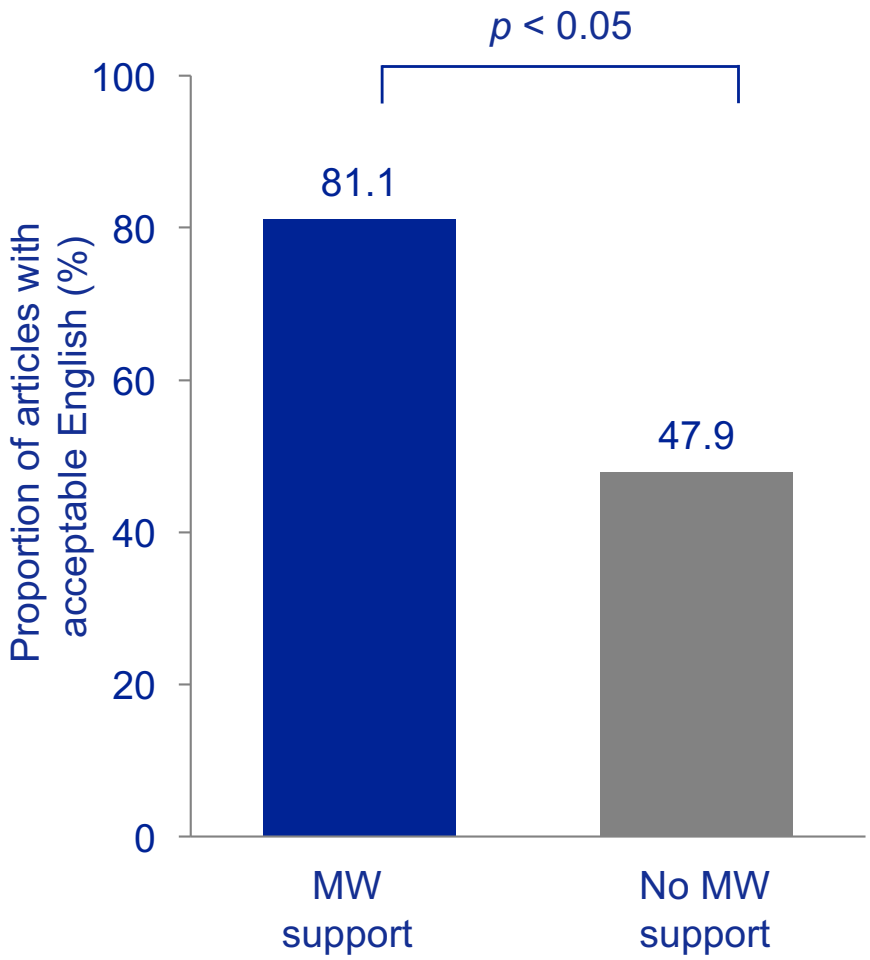
- Medical writing support was associated with enhanced reporting of CONSORT checklist items (≥ 50%) versus no medical writing support
- Irrespective of industry funding



NS, not significant

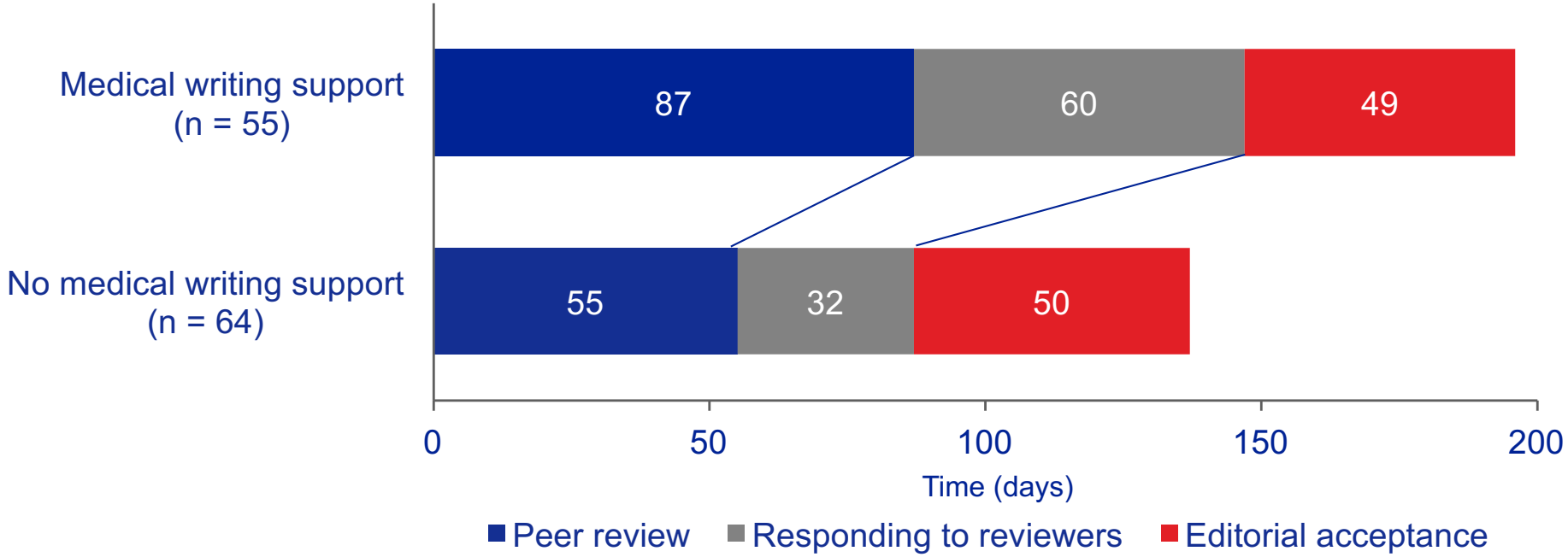
Improved quality of written English with medical writing support

- 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



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

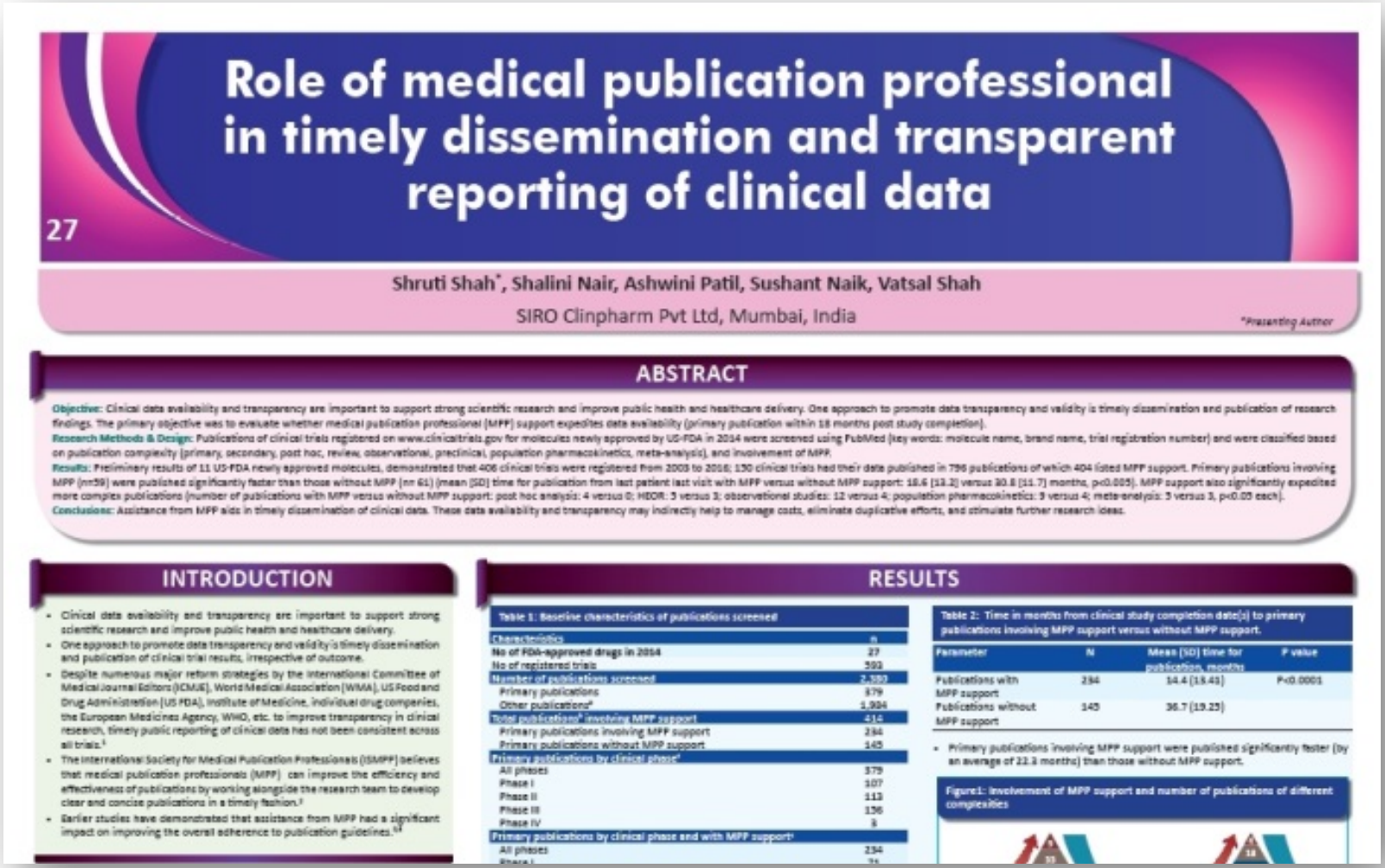


Gattrell WT *et al*. *BMJ Open* 2016 21;6:e010329 http://bmjopen.bmj.com/content/6/2/e010329.full

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

6. Shah *et al. ISMPP* 2016



Role of medical publication professional in timely dissemination and transparent reporting of clinical data

27

Shruti Shah*, Shalini Nair, Ashwini Patil, Sushant Naik, Vatsal Shah

SIRO Clinpharm Pvt Ltd, Mumbai, India

*Presenting Author

ABSTRACT

Objective: Clinical data availability and transparency are important to support strong scientific research and improve public health and healthcare delivery. One approach to promote data transparency and validity is timely dissemination and publication of research findings. The primary objective was to evaluate whether medical publication professional (MPP) support expedites data availability (primary publication within 18 months post study completion).

Research Methods & Design: Publications of clinical trials registered on www.clinicaltrials.gov for molecules newly approved by US-FDA in 2014 were screened using PubMed (key words: molecule name, brand name, trial registration number) and were classified based on publication complexity (primary, secondary, post hoc, review, observational, preclinical, population pharmacokinetics, meta-analysis), and involvement of MPP.

Results: Preliminary results of 11 US-FDA newly approved molecules, demonstrated that 406 clinical trials were registered from 2003 to 2016; 150 clinical trials had their data published in 796 publications of which 404 listed MPP support. Primary publications involving MPP (n=59) were published significantly faster than those without MPP (n= 61) (mean [SD] time for publication from last patient last visit with MPP versus without MPP support: 18.6 [13.2] versus 30.8 [11.7] months, p<0.005). MPP support also significantly expedited more complex publications (number of publications with MPP versus without MPP support: post hoc analysis: 4 versus 0; HEOR: 3 versus 3; observational studies: 12 versus 4; population pharmacokinetics: 3 versus 4; meta-analysis: 3 versus 3, p<0.05 each).

Conclusions: Assistance from MPP aids in timely dissemination of clinical data. These data availability and transparency may indirectly help to manage costs, eliminate duplicative efforts, and stimulate further research ideas.

INTRODUCTION

- Clinical data availability and transparency are important to support strong scientific research and improve public health and healthcare delivery.
- One approach to promote data transparency and validity is timely dissemination and publication of clinical trial results, irrespective of outcome.
- Despite numerous major reform strategies by the International Committee of Medical Journal Editors (ICMJE), World Medical Association (WMA), US Food and Drug Administration (US FDA), Institute of Medicine, individual drug companies, the European Medicines Agency, WHO, etc. to improve transparency in clinical research, timely public reporting of clinical data has not been consistent across all trials.[1]
- The International Society for Medical Publication Professionals (ISMPP) believes that medical publication professionals (MPP) can improve the efficiency and effectiveness of publications by working alongside the research team to develop clear and concise publications in a timely fashion.[2]
- Earlier studies have demonstrated that assistance from MPP had a significant impact on improving the overall adherence to publication guidelines.[3,4]

RESULTS

Table 1: Baseline characteristics of publications screened

Characteristics	n
No of FDA-approved drugs in 2014	27
No of registered trials	593
Number of publications screened	2,503
Primary publications	579
Other publications*	1,924
Total publications† involving MPP support	414
Primary publications involving MPP support	264
Primary publications without MPP support	145
Primary publications by clinical phase‡	
All phases	379
Phase I	107
Phase II	113
Phase III	156
Phase IV	3
Primary publications by clinical phase and with MPP support‡	
All phases	234

Table 2: Time in months from clinical study completion date(s) to primary publications involving MPP support versus without MPP support.

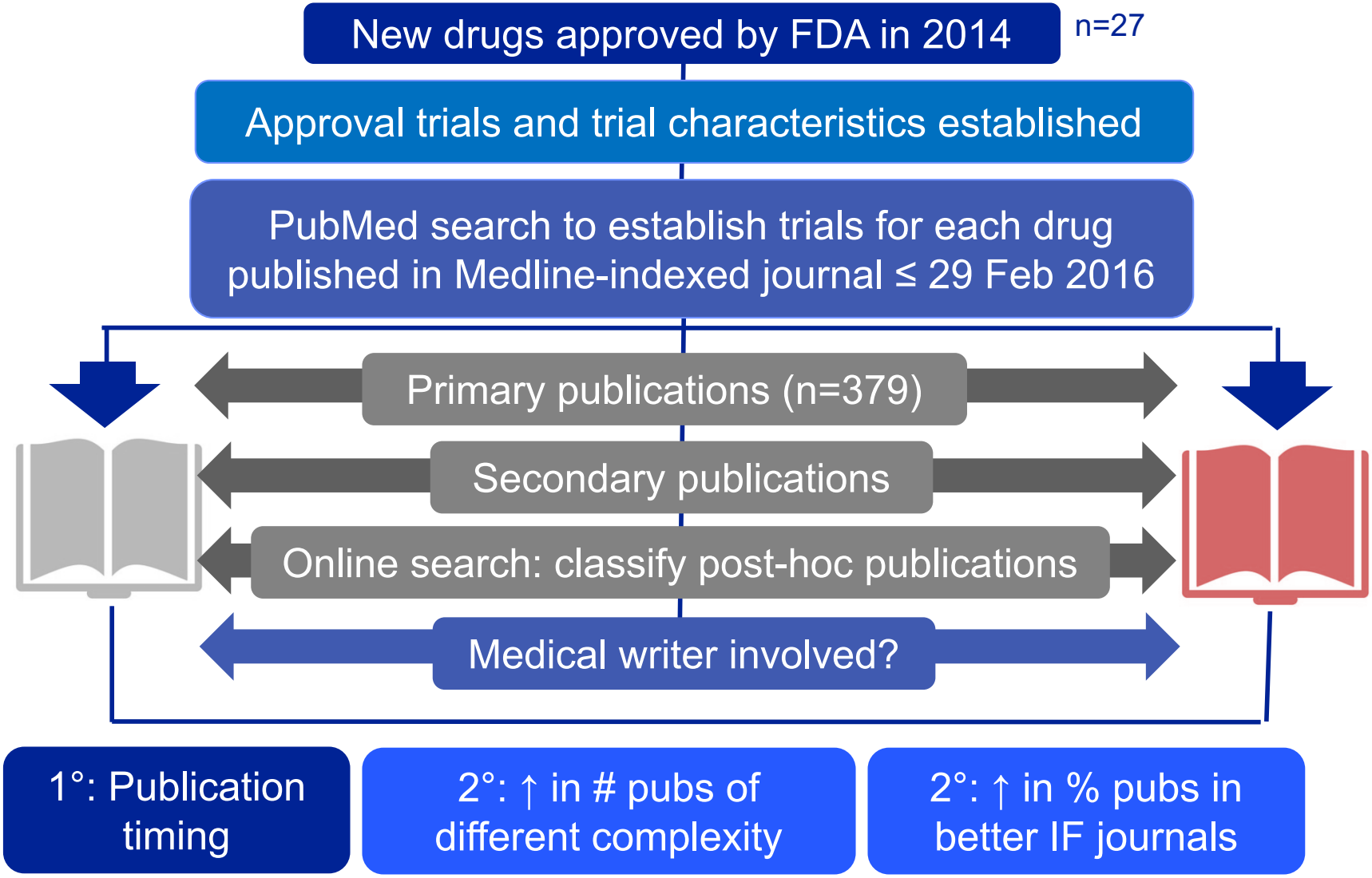
Parameter	N	Mean (SD) time for publication, months	P value
Publications with MPP support	234	14.4 (13.43)	P<0.0001
Publications without MPP support	145	36.7 (19.25)	

- Primary publications involving MPP support were published significantly faster (by an average of 22.3 months) than those without MPP support.

Figure1: Involvement of MPP support and number of publications of different complexities

Shah S *et al. Curr Med Res Opin* 2016;32(Suppl 1):S12. Poster presented at the 12th International Meeting of the International Society of Medical Publication Professionals, National Harbor USA, 11–13 April 2016.

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



Shah S *et al. Curr Med Res Opin* 2016;32(Suppl 1):S12. Poster presented at the 12th International Meeting of the International Society of Medical Publication Professionals, National Harbor USA, 11–13 April 2016.

Primary publications with medical writing support published significantly faster

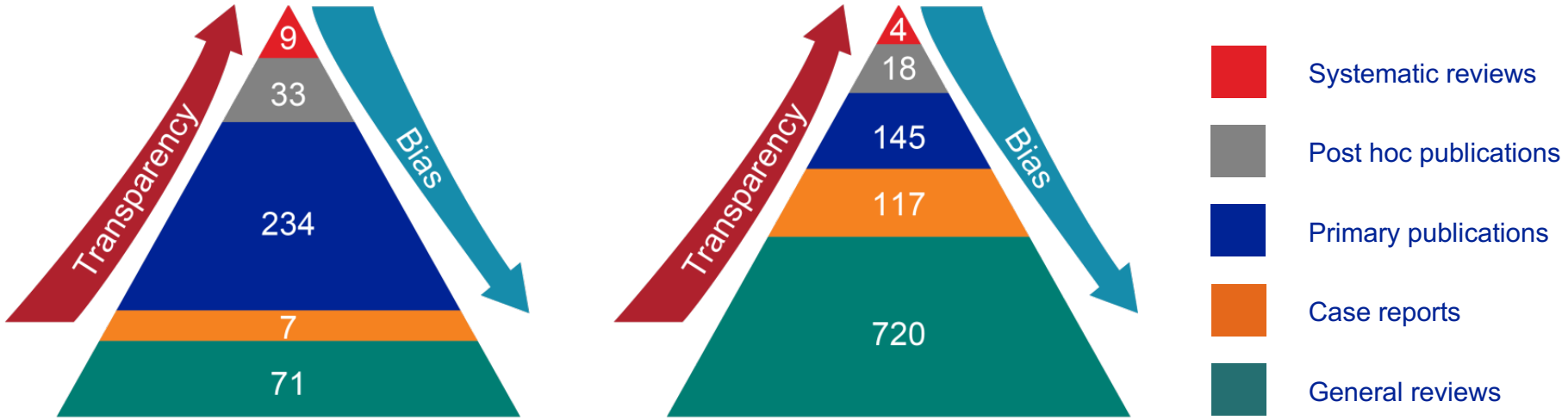
Parameter	n	Mean (SD) time for publication, months	*p* value
Publications with medical writer support	234	14.4 (13.41)	$p < 0.0001$
Publications without medical writer support	145	36.7 (19.25)	

22.3 months faster (average)

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

Shah S *et al. Curr Med Res Opin* 2016;32(Suppl 1):S12. Poster presented at the 12th International Meeting of the International Society of Medical Publication Professionals, National Harbor USA, 11–13 April 2016

Medical writing support associated with increased quality of evidence



Medical writer support

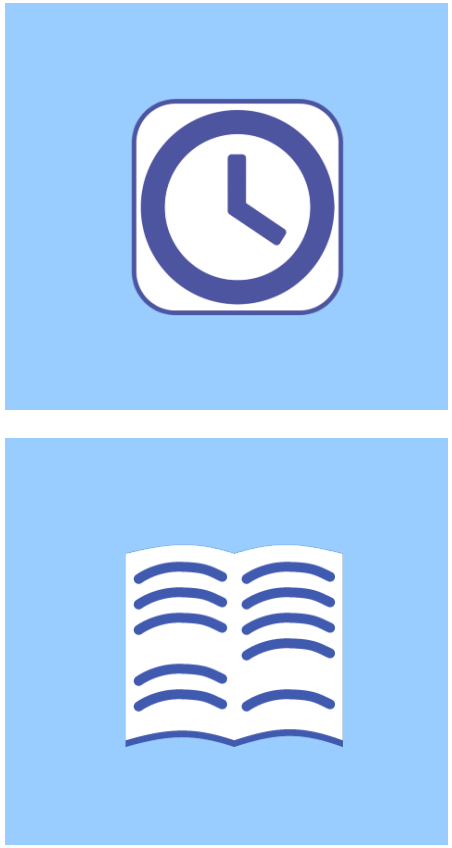
No medical writer support

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

Shah S *et al. Curr Med Res Opin* 2016;32(Suppl 1):S12. Poster presented at the 12th International Meeting of the International Society of Medical Publication Professionals, National Harbor USA, 11–13 April 2016

Conclusions

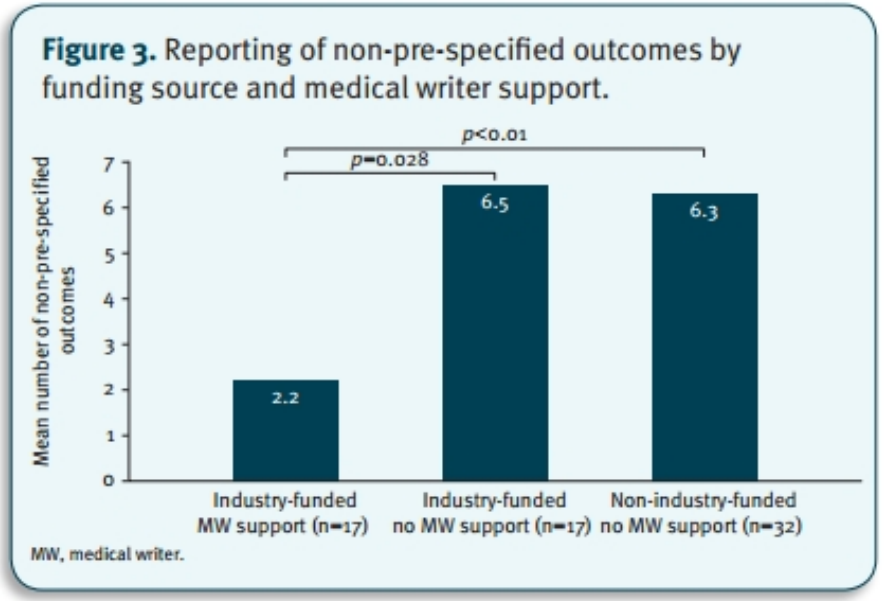
- Medical writing support can:
  - Expedite data availability and aid timely dissemination of clinical data
  - Help dissemination of varied clinical data through publications of different complexities, increasing hierarchy of evidence available in public domain
- These data availability may indirectly help to manage costs, eliminate duplicative efforts and stimulate further research ideas



Shah S *et al. Curr Med Res Opin* 2016;32(Suppl 1):S12. Poster presented at the 12th International Meeting of the International Society of Medical Publication Professionals, National Harbor USA, 11–13 April 2016

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 publically 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



Publications with medical writer support reported the fewest non-pre-specified outcomes

Gattrell W *et al.* Poster presented at the European Meeting of the International Society of Medical Publication Professionals, London, UK, 17–18 January 2017; Goldacre B *et al.* www.COMPare-trials.org (accessed 3 April 2017).

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


Articles

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

Cindy W. Hamilton, Pharm.D., E.L.S., Art Gertel, M.S., Adam Jacobs, Ph.D., Jackie Marchington, Ph.D., C.M.P.P., Shelley Weaver, Pharm.D. & Karen Woolley, Ph.D., C.M.P.P.

Pages 178-194 | Accepted author version posted online: 01 Sep 2015, Published online: 01 Sep 2015

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