

GAPP email 14 Feb 2012

Hello Ivan,

Good questions. Again, I hope these answers are helpful.

1. Can GAPP exert pressure on industry to make it a priority their data get published?
The people in industry that I work with prioritize publication – indeed, they are held accountable for having data published. GAPP members are working, voluntarily, with those in industry, academia, and journals (editors and publishers) to make it a priority for authors to publish their data – regardless of funding source. The people in industry that I work with are responsible for ensuring authors have sufficient resources (access to data, access to medical writing assistance) to submit high-quality manuscripts on time. They are responsible for ensuring authors, writers, and their industry colleagues are aware of and adhere to their company's publication policy.

A major push to get data published is coming from within the industry. Have you read the IFPMA Joint Position Statement on publishing? Almost all of the pharma clients we work with are members of IFPMA – it does have an international reach. Given your query about negative results, I have attached this document and appended one section below:

WHICH TRIALS:

All industry-sponsored³ clinical trials⁴ should be considered for publication in the scientific literature **irrespective of whether the results of the sponsors' medicine(s) are positive or negative.** At a minimum, results from all phase 3⁵ clinical trials and any clinical trial results of significant medical importance should be submitted for publication. This includes investigational clinical products whose development programs are discontinued.

In terms of your comment about clinical trial databases, did you also read the Prayle et al. BMJ 2012 paper? Industry is not perfect in terms of meeting clinical trial disclosure deadlines, but industry's performance was 4-fold better than the performance from non-industry. Industry has to do better....but it is a shame that few people seem concerned about the woeful disclosure rates in academia.

2. Lack of time as a major reason for not publishing?
Time is ONE of the MAJOR factors authors cite for not publishing. People seem to find this hard to believe...it does not make the news, but it is the reality. There are other reasons and some of these were cited in a meta-analysis presented at the Peer Review Congress back in 2009....unfortunately, these data have not been published! Song et al., published a paper that seemed to be related to this original research they presented....but these data were not included. I have appended the abstract below.

Reasons for Not Publishing Studies: A Meta-analysis of Data From Empirical Studies

Fujian Song,¹ Caroline Hing,² Sheetal Parekh,³ Lee Hooper,¹ Yoon Loke,¹ Jon Ryder,¹ Alex Sutton,⁴ and Ian Harvey¹

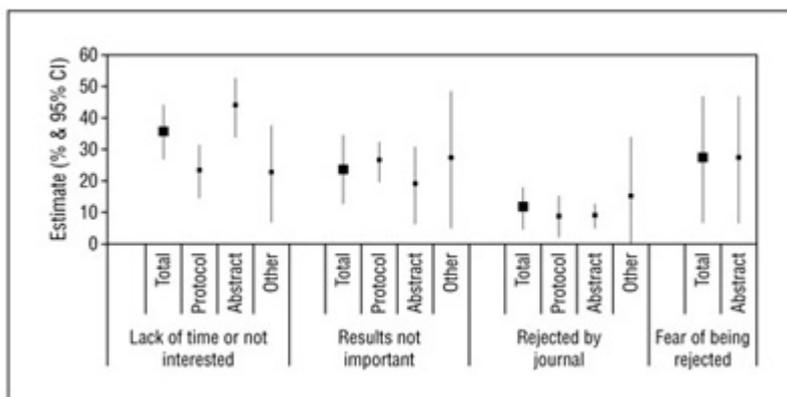
Objective To summarize data on reasons given by investigators for not publishing their studies.

Design As part of a comprehensive updated review of publication bias, we searched MEDLINE and the Cochrane Methodology Register Database (up to August 2008) to identify studies that provide data on reasons given by investigators for not publishing studies. References of retrieved articles were also checked for relevant studies. Percentages of specific

reasons from individual studies were transformed to log odds and pooled using random-effects model.

Results Twenty-one studies were included (published between 1992 and 2006) including 5 studies of investigators of protocol cohorts, 11 studies of authors of meeting abstracts, and 5 studies of other or miscellaneous authors. There was significant heterogeneity in results across studies. **The main reasons for nonpublication were lack of time or low priority** (34.5%; 95% confidence interval [CI], 27.4%-42.3%), results not important enough (19.6%; 95% CI, 12.0%-30.4%), and journal rejection (10.2%; 95% CI, 5.5%-18.2%) (**Figure 2**). Pooled percentages of specific reasons were similar across different types of empirical studies, except that the lack of time or low interest were significantly higher in studies of meeting abstracts (43.1%; 95% CI, 35.9%-50.6%) than in studies of protocol cohorts (23.8%; 95% CI, 15.9%-34.0%) or studies of other authors (20.7%; 95% CI, 7.7%-44.9%). In the 5 studies of meeting abstracts, fear of journal rejection was given as a reason for 23.7% (95% CI, 8.9%-49.6%) of unpublished studies.

Figure 2. Reasons for Not Publishing Studies: Pooled Results of Empirical Studies



Conclusions Main reasons given by investigators for not publishing studies include lack of time or low priority and results being considered not important. Some study results remained unpublished because of journal rejection or anticipated journal rejection.

¹School of Medicine, Health Policy and Practice, Faculty of Health, University of East Anglia, Norwich NR4 7TJ, UK, e-mail: fujian.song@uea.ac.uk; ²Watford General Hospital, Watford, Hertfordshire UK; ³School of Allied Health Professions, Faculty of Health, University of East Anglia, Norwich, UK; ⁴Department of Health Sciences, University of Leicester, Leicester, UK

Thank you for your interest in GAPP. We think the experiences and perspectives of professional medical writers should be part of the ongoing discussions about ensuring publication of data. We're not at the policy front, but we are at the front line.

With kind regards,

Karen Woolley, PhD, Certified Medical Publication Professional

Professor, University of Queensland; Professor, University of the Sunshine Coast; Honorary Fellow, American Medical Writers Association; ISMPP Director and Chair, Asia-Pacific Advisory Committee
CEO

ProScribe - Internationally recognised for excellence in medical communications

T: +61 7 5455 6330 **F:** +61 7 5455 6331 **E:** kw@proscribe.com.au **W:** www.proscribe.com.au

ProScribe's services include: manuscripts; clinical, regulatory, and marketing documents; training courses (medical writing and publication planning courses).



The information contained in or attached to this message is intended only for the people it is addressed to. If you are not the intended recipient, any use, disclosure or copying of this information is unauthorised and prohibited. This information may be confidential or subject to legal privilege. Please reply to the sender if you have received this message in error. Thank you.