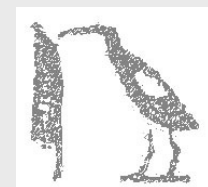


# Publication Planning Update

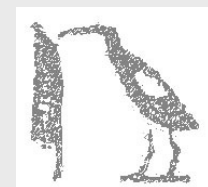
*Liz Wager*

[liz@sideview.demon.co.uk](mailto:liz@sideview.demon.co.uk)



# What's new?

- GPP2 (implementation)
- IFPMA / EFPIA / PhRMA joint position
- CONSORT 2010
- PRISMA (replaces QUOROM)
- ICMJE new CoI form
- Data sharing policies
- EudraCT
- Journal cascades
- More from Senator Grassley



## RESEARCH METHODS & REPORTING

### Good publication practice for communicating company sponsored medical research: the GPP2 guidelines

Chris Graf,<sup>1</sup> Wendy P Battisti,<sup>2</sup> Dan Bridges,<sup>3</sup> Victoria Bruce-Winkler,<sup>4</sup> Joanne M Conaty,<sup>5</sup> John M Ellison,<sup>6</sup> Elizabeth A Field,<sup>7</sup> James A Gurr,<sup>8</sup> Mary-Ellen Marx,<sup>9</sup> Mina Patel,<sup>10</sup> Carol Sanes-Miller,<sup>5</sup> Yvonne E Yarker,<sup>11</sup> for the International Society for Medical Publication Professionals

In response to changes in the environment in which authors, presenters, and other contributors work together to communicate medical research the **International Society for Medical Publication Professionals** has updated the good publication practice guidelines

<sup>1</sup>John Wiley & Sons, Wiley-Blackwell, Oxford OX4 2DQ

<sup>2</sup>Johnson & Johnson Pharmaceutical Research & Development, Raritan, NJ, USA

<sup>3</sup>Excerpta Medica, Elsevier, London

<sup>4</sup>Dunblane

<sup>5</sup>AstraZeneca Pharmaceuticals, Wilmington, DE, USA

<sup>6</sup>LifeScan, Milpitas, CA, USA

<sup>7</sup>Field Advantage Medical Communications, Chapel Hill, NC, USA

<sup>8</sup>Pfizer Collegeville, PA, USA

<sup>9</sup>Pharmacia, Princeton, NJ, USA

Authors and presenters are responsible for how medical research is interpreted and communicated. Often their work is the product of collaborations with other individuals (such as clinical investigators, biostatisticians, and professional medical writers) from around the world. Some or all of the people who contribute to this collaboration may be employees of research sponsors, contract research organisations, or medical communications agencies that may be funded by pharmaceutical, medical device, or biotechnology companies. The authors, collaborators, and organisations share responsibility for developing articles and presentations in a responsible and ethical manner.

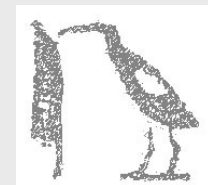
by companies. These guidelines were written in light of these developments.

#### Methods

The International Society for Medical Publication Professionals invited members with over 10 years of experience in biomedical publishing to develop these guidelines (figure). The 14 members named as contributors to this article responded to the invitation and formed the steering committee. The steering committee reviewed the original guidelines,<sup>6</sup> discussed items to be included in the revised guidelines (GPP2), and wrote the draft guidelines.

# GPP2 implementation

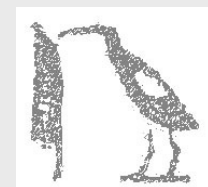
- Author agreements *(should make life easier in the long term, but need to be developed now)*
- No payment for authorship *(but payment by the hour for services eg stats or writing is OK)*
- Who determines authorship? *(wide range of company practices for this)*
- Who chooses journal?  
*(GPP2 says authors should do this)*



# IFPMA / EFPIA / PhRMA / JPMA Joint Position on the Publication of Clinical Trial Results (June 2010)

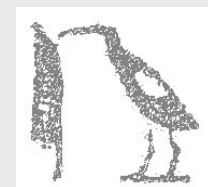


- [www.ifpma.org](http://www.ifpma.org)



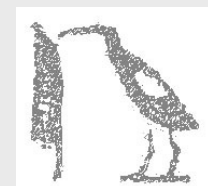
# What should be published?

- All trials ‘should be considered for publication’ but, at a minimum:
- All phase III trials
- Trials ‘of significant medical importance’
- Including discontinued products



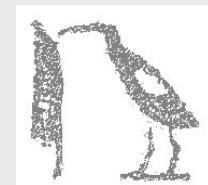
# Publication timing

- Should submit ‘wherever possible within 12 months’ and no later than 18 months of:
  - Trial completion (for marketed products)
  - Licensing / decision to discontinue



# Where should you publish?

- Peer-reviewed journals
- “Whenever possible, trial results should be submitted to journals indexed by online bibliographic databases (eg Medline)”



## RESEARCH METHODS & REPORTING

### CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz,<sup>1</sup> Douglas G Altman,<sup>2</sup> David Moher,<sup>3</sup> for the CONSORT Group

**EDITORIAL** by Antes  
**RESEARCH**, p 697

<sup>1</sup>Family Health International,  
Research Triangle Park, NC 27709,  
USA

<sup>2</sup>Centre for Statistics in Medicine,  
University of Oxford, Wolfson  
College, Oxford

<sup>3</sup>Ottawa Methods Centre, Clinical  
Epidemiology Program, Ottawa  
Hospital Research Institute,  
Department of Epidemiology and  
Community Medicine, University of  
Ottawa, Ottawa, Canada

Correspondence to: K F Schulz  
kschulz@fhi.org

Accepted: 9 December 2009

Cite this as: *BMJ* 2010;340:c332  
doi: 10.1136/bmj.c332

The CONSORT statement is used worldwide to improve the reporting of randomised controlled trials. **Kenneth Schulz and colleagues** describe the latest version, CONSORT 2010, which updates the reporting guideline based on new methodological evidence and accumulating experience

Randomised controlled trials, when appropriately designed, conducted, and reported, represent the gold standard in evaluating healthcare interventions. However, randomised trials can yield biased results if they lack methodological rigour.<sup>1</sup> To assess a trial accurately, readers of a published report need complete, clear, and transparent information on its methodology and findings. Unfortunately, attempted assessments frequently fail because authors of many trial reports neglect to provide lucid and complete descriptions of that critical information.<sup>2-4</sup>

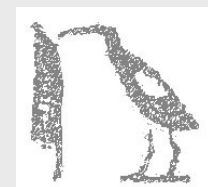
ence and additional experience has accumulated since the last revision in 2001. Consequently, we organised a CONSORT Group meeting to update the 2001 statement.<sup>6-8</sup> We introduce here the result of that process, CONSORT 2010.

#### Intent of CONSORT 2010

The CONSORT 2010 Statement is this paper including the 25 item checklist in the table and the flow diagram. It provides guidance for reporting all randomised controlled trials, but focuses on the most common design type—individually randomised, two group, parallel trials. Other trial designs, such as cluster randomised trials and non-inferiority trials, require varying amounts of additional information. CONSORT extensions for these designs,<sup>11 12</sup> and other CONSORT products, can be found through the CONSORT website ([www.consort-statement.org](http://www.consort-statement.org)). Along with the CONSORT statement, we have updated the explanation and elaboration article,<sup>13</sup> which explains the inclusion of each checklist item, provides methodological background, and gives published examples of transparent reporting.

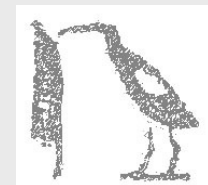
# CONSORT 2010

- Mostly minor changes *cf* previous version
- BUT some extra checklist items
- New 25-item checklist (*will need to be completed and submitted with paper for some journals*)



# CONSORT – new items:

- #23 – trial registration
- #24 – protocol availability
- #25 – funding details



# PRISMA

OPEN ACCESS Freely available online

PLOS MEDICINE

## Guidelines and Guidance

# Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

David Moher<sup>1,2\*</sup>, Alessandro Liberati<sup>3,4</sup>, Jennifer Tetzlaff<sup>1</sup>, Douglas G. Altman<sup>5</sup>, The PRISMA Group<sup>1</sup>

**1** Ottawa Methods Centre, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, **2** Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada, **3** Università di Modena e Reggio Emilia, Modena, Italy, **4** Centro Cochrane Italiano, Istituto Ricerche Farmacologiche Mario Negri, Milan, Italy, **5** Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom

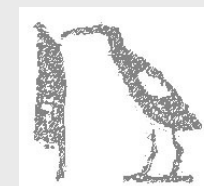
## Introduction

Systematic reviews and meta-analyses have become increasingly important in health care. Clinicians read them to keep up to date with their field [1,2], and they are often used as a starting point for developing clinical practice guidelines. Granting agencies may

clinicians, medical editors, and a consumer. The objective of the Ottawa meeting was to revise and expand the QUOROM checklist and flow diagram, as needed.

The executive committee completed the following tasks, prior to the meeting: a systematic review of studies examining the quality of reporting of systematic reviews, and a comprehensive literature

*PLoS Medicine* 2009;6(7):e1000097



# ICMJE Col form

- Launched Oct 09
- Required by ICMJE committee members (*Lancet, NEJM ..*)
- But *JAMA* still using its own form
- ?Final version due April 2010



## **ICMJE Uniform Disclosure Form for Potential Conflicts of Interest**

### **INSTRUCTIONS:**

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form has five parts.

#### **1. Identifying information.**

Each author should submit a separate form. Provide complete information and double-check the manuscript number. If you are NOT the corresponding author please insert his or her name.

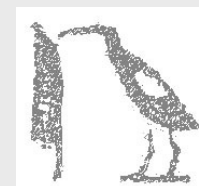
#### **2. The work under consideration for publication.**

Please provide information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself from the initial conception and planning to the present. The idea is to provide for the reader information about

# BMJ website (22 June 2010)

- For the next few months (from October 2009 **to April 2010**) the BMJ, along with other journals who are members of the International Committee of Medical Journal Editors, is trialling a new, unified disclosure form.
- The unified form is intended to make life easier for authors, in that the same form can be completed for several journals, saving authors the trouble of having to provide slightly different information for different journals. **Each journal, will, however, integrate the form into its processes in different ways.**

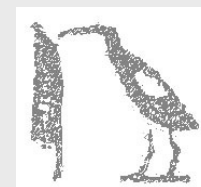
*Not quite as uniform as  
you might hope ...*



# *Annals of Internal Medicine*

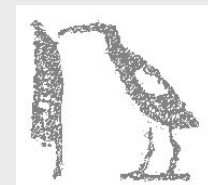
- At the time of manuscript submission, Annals of Internal Medicine requires corresponding authors to summarize all authors' conflict of interest disclosures. (We also require conflict of interest disclosures from members of panels that help formulate consensus or guideline recommendations, even if those contributors are not named authors on the consensus or guideline statement.) We provide the summary information collated by the corresponding author to editors and peer reviewers. **If editors later invite the authors to revise a manuscript after peer review, we ask each author, including the corresponding author, to complete his or her own International Committee of Medical Journal Editors (ICMJE) Conflict of Interest Disclosure Statement.** Information about this form, which all ICMJE member journals have adopted, is available at [www.ICMJE.org](http://www.ICMJE.org). At the time of manuscript acceptance, we ask authors to confirm and update, if necessary, their online disclosure statements.

2-stage process



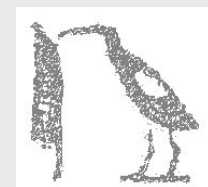
# ICMJE 'uniform' CoI form

- You still need to check individual journal requirements!



# Data sharing policies

- No journals actually requiring data sharing
- BUT
- *Annals* requires statement
- *“Annals does not require the sharing of these items but we do require authors to state their willingness to share, and any conditions for sharing. Access to these items may range from completely unrestricted (e.g., free availability of all the items via posting on an open-access Web site) to restricted (e.g., availability of certain portions of the items to approved individuals through written agreements with the author or research sponsor).”*



# BMJ takes similar line

## Managing research data for future use

The *BMJ* is now asking authors for data sharing statements

**Trish Groves** deputy editor, *BMJ*,  
London WC1H 9JR  
tgroves@bmj.com

**Competing interests:** None  
declared

**Provenance and peer review:**  
Commissioned; not externally  
peer reviewed.

Cite this as: *BMJ* 2009;338:b1252  
doi: 10.1136/bmj.b1252

For some time the *BMJ* has been watching other journals' efforts to encourage authors to make raw research data available. Now we are taking part too, by asking authors to include a data sharing statement at the end of each original research article. The statement will explain which additional data—if any—are available, to whom, and how. Those data could range from additional explanatory material to the complete dataset. People allowed access to the data might range from fellow researchers to everyone. And data might be available only on request, accessible online with a password, or openly accessible to all on the web with a link on [bmj.com](http://bmj.com).

We understand that many authors wish to guard data until they have published all their own papers, and we know that data sharing is hard to do. But we hope that

authors will, increasingly, set the data free, perhaps after a set period of personal use.

Data sharing means more than the open access publication of articles and the posting in online registries of

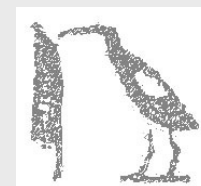
### Sharing medical research data: ethical and editorial barriers and proposed solutions<sup>1</sup>

Ethics committees: encourage researchers to include plans to publish data in trial information sheets and discuss the safeguards in place to protect the privacy of patients

Research funding agencies: give greater scrutiny to data sharing plans and monitor their enforcement

Journal editors and publishers: recommend that authors prepare data in line with an agreed standard (which requires further consideration). Encourage deposition of data in the journal or suitable third party repository as part of the submission process, potentially via an accession number system, as for trial registration

Trialists: obtain explicit consent for publication of suitably anonymised raw data as part of patient recruitment procedures



# Papers on data sharing

**Trials**



Editorial

**Open Access**

## **Towards agreement on best practice for publishing raw clinical trial data**

Iain Hrynaszkiewicz<sup>\*1</sup> and Douglas G Altman<sup>2</sup>

Address: <sup>1</sup>BioMed Central Ltd, 236 Gray's Inn Road, London, WC1X 8HL, UK and <sup>2</sup>Centre for Statistics in Medicine, University of Oxford, Wolfson College Annex, Linton Road, Oxford, OX2 6JD, UK

Email: Iain Hrynaszkiewicz<sup>\*</sup> - [iain.hrynaszkiewicz@biomedcentral.com](mailto:iain.hrynaszkiewicz@biomedcentral.com); Douglas G Altman - [doug.altman@cs.m.ox.ac.uk](mailto:doug.altman@cs.m.ox.ac.uk)

<sup>\*</sup> Corresponding author

Published: 18 March 2009

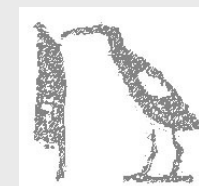
Received: 3 March 2009

Trials 2009, 10:17 doi:10.1186/1745-6215-10-17

Accepted: 18 March 2009

This article is available from: <http://www.trialsjournal.com/content/10/1/17>

*Trials* 2009;**10**:17



# RESEARCH METHODS & REPORTING

## Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers

Iain Hrynaszkiewicz,<sup>1</sup> Melissa L Norton,<sup>1</sup> Andrew J Vickers,<sup>2</sup> Douglas G Altman<sup>3</sup>

**Iain Hrynaszkiewicz and colleagues** propose a minimum standard for anonymising datasets to ensure patient privacy when sharing clinical research data

Many peer-reviewed journals' instructions for authors require that authors should be prepared to share their raw (that is, unprocessed) data with other scientists on request. Although data sharing is commonplace in some scientific disciplines and is a requirement of a number of major research funding agencies' policies, this culture has not yet been widely adopted by the clinical research com-

*form Requirements for Manuscripts Submitted to Biomedical Journals* require that patient privacy be protected, and maintaining confidentiality and privacy is ingrained in various legal statutes such as the UK Data Protection Act and the Health Insurance Portability and Accountability Act (HIPAA) in the US.<sup>6</sup>

In Europe, the Data Protection Directive (Directive 95/46/EC) provides some harmony in data protection legislation, but in the US there is no overarching data protection law. Therefore, in an increasingly global research and publishing industry, universally agreed definitions as to what constitutes anonymised patient information would benefit clinical researchers. The HIPAA provides a list of

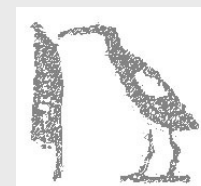
### EDITORIAL by Groves

<sup>1</sup>BioMed Central, 236 Gray's Inn Road, London WC1X 8HL

<sup>2</sup>Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, 1275 York Avenue, NY, NY 10021, USA

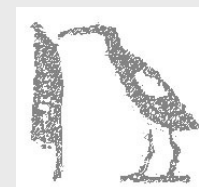
<sup>3</sup>Centre for Statistics in Medicine

*BMJ* 2010;**340**:c181



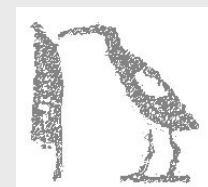
# EudraCT

- Consultation paper published 1<sup>st</sup> June 2010
- Comments by 30<sup>th</sup> Sept 2010
- Protocol-related info to be public Sept 2010
- Results to be submitted within 12m of study end (for adult trials) but 6m for paed trials
- Similar fields as [ClinicalTrials.gov](http://ClinicalTrials.gov)



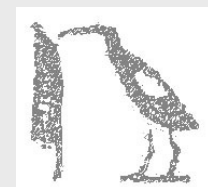
# Journal 'cascades' and consortia

- At last .. some good news!
- Publishers are increasingly willing to pass submissions between journals
- Eg *Lancet* to *Lancet Neurology*  
*PLoS* to *PLoS One*



# Benefits of cascades

- May save time on peer review
- 2<sup>nd</sup> journal uses 1<sup>st</sup> journal's review
- May reduce delays for reformatting
  
- BUT – you still have to decide if this is the right journal for your work
- It's an offer, not an ultimatum ...



# *More from our friend Chuck*

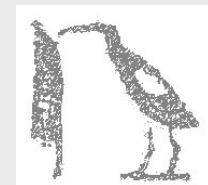


## **Ghostwriting in Medical Literature Minority Staff Report**

**111th Congress**

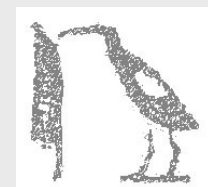
**United States Senate Committee on Finance  
Sen. Charles E. Grassley, Ranking Member**

**June 24, 2010**

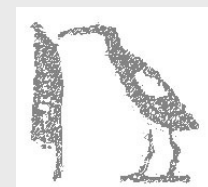


# Finance Committee contacted

- Medical schools:
  - Columbia, Duke, Harvard, Johns Hopkins, UCSF, Stanford, Penn, Washington, Yale
- Journals:
  - *Annals Int Med, Archives Int Med, JAMA, Nature Med, NEJM, PLoS, etc.*
- Reviewed Merck, Wyeth documents  
(DesignWrite, STI named)



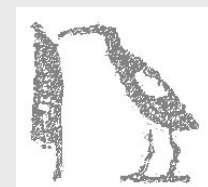
*“Medical ghostwriting is a practice where pharma or device companies hire medical education, marketing or communications companies to draft articles that are presented to prominent physicians and scientists to sign on as authors to increase the likelihood that the article will be published in an important medical journal. Ghostwritten articles include articles that are drafted by ... company employees who are not acknowledged in the final publication.”*



*“Senator Grassley is concerned about the lack of transparency that exists in medical ghostwriting. Not only are the articles typically initiated and paid for by a pharmaceutical or device company, but also more significantly, the final publications do not disclose the company’s role and financial support for the article.”*

*“The articles may be review articles, editorials or primary research papers”*

Report calls for more transparency from NIH



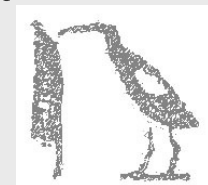
# The New York Times

## *Report Urges More Curbs on Medical Ghostwriting*

By NATASHA SINGER

Published: June 24, 2010

- *A new Congressional report calls on medical journals, medical schools, and even the NIH to take additional measures to ensure the integrity of the scientific articles many doctors rely on to make treatment decisions for their patients.*
- *The report, issued **24 June** by Senator Charles Grassley of Iowa, the ranking Republican on the Senate Finance Committee, focuses on medical ghostwriting.*



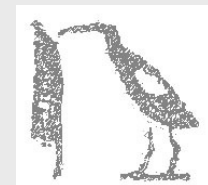
# Are things better or worse for publication planners?

## Headaches

- Authorship is still a sticky issue
- Need to implement GPP2 (develop author agreements)

## Improvements

- Author agreements will make life easier ...eventually!
- ?Uniform CoI form
- Journal cascades / consortia

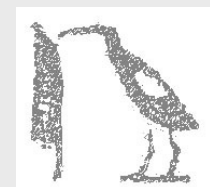


# Anticipating the future

- Data sharing policies
- More journals may adopt:
  - CONSORT 2010
  - CONSORT for Abstracts
  - PRISMA
- Physician Payments Sunshine Act (2012)
- EudraCT (European register)

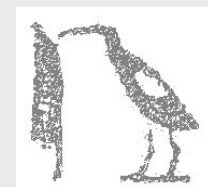


# Extra



# ISPOR Code (March 08)

- Members should endeavor to publicly disseminate their work, and to publish it in peer reviewed journals when possible.
- Members should discourage, where possible, listing of an author on any publication where the individual has not performed substantial work. As a point of reference, members should look to the checklists provided by major peer reviewed journals to assist them in deciding inclusion of authors.
- Members should seek to establish, in advance, a clear agreement on whether the results of a given piece of work could be published. This could include statements on whether the sponsor has a right to review or approve any manuscript prior to publication. Considerations could include revelations of safety issues.
- Members should respect contractual rights when they agree to perform work for hire and should refrain from disseminating information which they agreed in advance to keep proprietary.



# ISPOR Code (contd)

- Methods sections of papers should give thorough, transparent attention to all measures taken to minimize bias.
- Methods sections of papers should identify and justify all departures from the a priori analysis plan.
- Members should work with editors of journals and other publications to encourage the establishment and/or maintenance of an appropriate peer review process that examines the quality of the methodological rigor independently of the institution for which the individual works.
- Any contributor to a report or publication should disclose any current or past relationships with a company or competitor of any product discussed in the work.

