Overview of Good Publication Practice Guidelines, including GPP3: Why should medical writers care?

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San Antonio, TX• 2015 October 02

AMERICAN MEDICAL WRITERS ASSOCIATION
LEADING MEDICAL WRITING FOR 75 YEARS
75 YEARS
The Resource for Medical Communicators

ISMPP International Society for Medical Publication Professionals

Disclosure

- Terry Peña is an employee of Bristol-Myers Squibb and Board Chair of International Society for Medical Publication Professionals™ (ISMPP)

- Information presented reflects my personal knowledge and opinion as the presenter and does not necessarily represent the position of my current or past employers or the position of ISMPP unless otherwise stated

LEARNING OBJECTIVES

By the end of this session, attendees should be able to:

- Explain why GPP Guidelines are relevant to Medical Writers and all stakeholders involved with industry-sponsored presentations and publications
- Understand key guidelines considered industry best practice
- List the main elements of the newly-published GPP3 that are particularly important to Medical Writers
- Know how to access key Good Publication Practice Guidelines, including GPP3

Landmarks in Publications*

Publication organizations

1940
- American Medical Writers Association (AMWA)

1978
- Meeting of the "Vancouver group", later becomes International Committee of Medical Journal Editors (ICMJE)

1982
- European Association of Scientific Editors (EASE)

1989
- European Medical Writers' Association (EMWA)

1995
- World Association of Medical Editors (WAME)

2005
- International Society for Medical Publication Professionals (ISMPP)

2008
- Medical Publishing Insights and Practices (MPIP) initiative

Guidelines issued

1979
- Uniform requirements for manuscripts submitted to biomedical journals (ICMJE)

1997, 2003, 2010, 2013
- Major revisions of ICMJE's uniform guidance

2003
- First GPP guidelines published
- Recommendations for group authorship published by Council of Science Editors (CSE)

2005
- ICMJE's study registration requirements implemented
- EMWA guidelines on role of medical writers
- PhRMA principles and guidelines

2006
- Integrity in scientific journal publications white paper published by CSE

Continuing to improve publication practices

2001
- Task force - contribution of medical writers to scientific publications (AMWA)

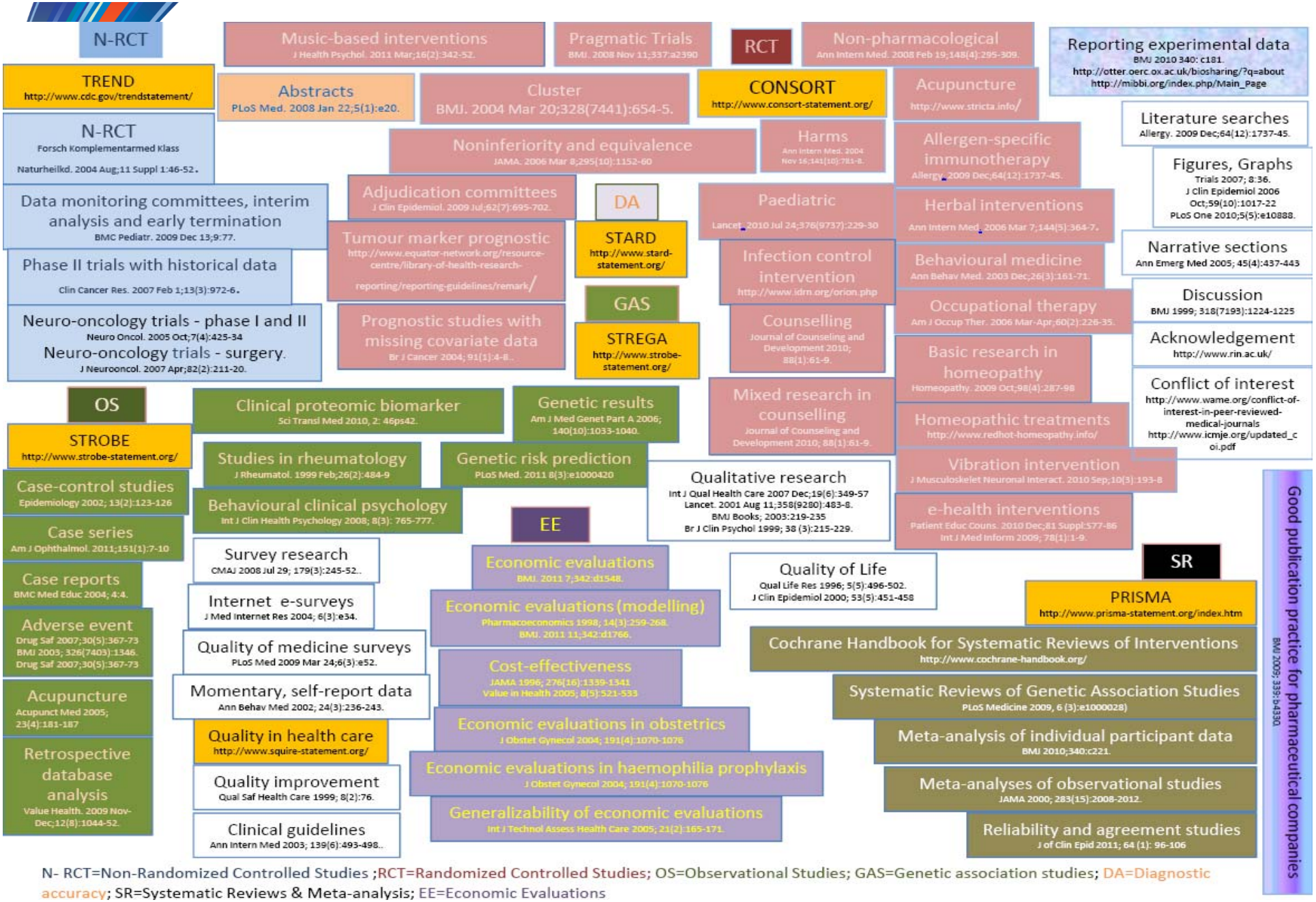
2007
- FDA Amendments Act signed into law
- ICMJE study registration requirements expanded
- International Publication Planning Association (TIPPA) established

2009
- GPP2 guidelines published
- ICMJE's disclosure form for potential conflicts of interest published
- Conflict of interest guidance added to AMWA policy
- PhRMA principles and guidelines updated
- CSE's white paper updated

2010
- Joint Position of Pharmaceutical Manufacturers Association published
- ISMPP Code of Ethics

2014
- Principles for Responsible Clinical Trial Data Reporting (PhRMA, efpia)
- EASE guidelines for scientific articles (and translations)

***Adapted from: Clark et al. (MPIP) Int J Clin Prac. 2010;64(8):1028–1023.**



A. Reeves, A. Rossi, Pamela Haendler: Good Writing Practice. The Write Stuff, 20 (3): 2011

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Why All the Guidelines?

- Peer-reviewed publications have the power to impact medical practice, drive treatment decisions and patient outcomes and the guidelines help reinforce the standards of excellence
- Guidelines help direct the ethical, accurate, complete, and transparent reporting of medical research
- Guidelines establish an unbiased framework and best practice standards for the development of ethical and transparent peer-reviewed journal articles and presentations at scientific congresses aimed at advancing the scientific and medical profession
- Lack of public trust in medical research and reporting of results

Misconduct in Medical Research

EARLY REPORT

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, M A Thomson, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic-resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associated by the parents, with measles, mumps, and rubella vaccination in eight of the 12 children, with measles infection in one child, and otitis media in another. All 12 children had intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Histology showed patchy chronic inflammation in 11 children and reactive ileal lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). There were no focal neurological abnormalities and MRI and EEG tests were normal. Abnormal laboratory results were significantly raised urinary methylmalonic acid compared with age-matched controls ($p=0·003$), low haemoglobin in four children, and low serum IgA in four children.

Interpretation We identified associated gastrointestinal disease and developmental regression in a group of previously normal children, which was generally associated in time with possible environmental triggers.

Lancet 1998; **351**: 637–41
See Commentary page

Inflammatory Bowel Disease Study Group, University Departments of Medicine and Histopathology (A J Wakefield FRCS, A Anthony MB, J Linnell PhD, A P Dhillon MRCPath, S E Davies MRCPath) **and the University Departments of Paediatric Gastroenterology** (S H Murch MB, D M Casson MRCP, M Malik MRCP, M A Thomson FRCP, J A Walker-Smith FRCP,), **Child and Adolescent Psychiatry** (M Berelowitz FRCPsych), **Neurology** (P Harvey FRCP), **and Radiology** (A Valentine FRCR), **Royal Free Hospital and School of Medicine, London NW3 2QG, UK**

Correspondence to: Dr A J Wakefield

Introduction

We saw several children who, after a period of apparent normality, lost acquired skills, including communication. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and vomiting and, in some cases, food intolerance. We describe the clinical findings, and gastrointestinal features of these children.

Patients and methods

12 children, consecutively referred to the department of paediatric gastroenterology with a history of a pervasive developmental disorder with loss of acquired skills and intestinal symptoms (mainly abdominal pain, bloating and food intolerance), were investigated. All children were admitted to the ward for a week, accompanied by their parents.

Clinical investigations

A full history, including details of immunisations and exposure to infectious diseases, and assessed the children. In 11 cases the history was obtained by the senior clinician (JW-S). Neurological and psychiatric assessments were done by consultant staff (PH, MB) with HMS-4 criteria.[1] Developmental history included a review of prospective developmental records from parents, health visitors, and general practitioners. Four children did not undergo psychiatric assessment in hospital; all had been assessed professionally elsewhere, so these assessments were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was performed by SHM or MAT under sedation with midazolam and pethidine. Paired frozen and formalin-fixed mucosal biopsy samples were taken from the terminal ileum; ascending, transverse, descending, and sigmoid colons, and from the rectum. The procedure was recorded by video or still images, and were compared with images of the previous seven consecutive paediatric colonoscopies (four normal colonoscopies and three on children with ulcerative colitis), in which the physician reported normal appearances in the terminal ileum. Barium follow-through radiography was possible in some cases.

Also under sedation, cerebral magnetic-resonance imaging (MRI), electroencephalography (EEG) including visual, brain stem auditory, and sensory evoked potentials (where compliance made these possible), and lumbar puncture were done.

Laboratory investigations

Thyroid function, serum long-chain fatty acids, and cerebrospinal-fluid lactate were measured to exclude known causes of childhood neurodegenerative disease. Urinary methylmalonic acid was measured in random urine samples from eight of the 12 children and 14 age-matched and sex-matched normal controls, by a modification of a technique described previously.[2] Chromatograms were scanned digitally on computer, to analyse the methylmalonic-acid zones from cases and controls. Urinary methylmalonic-acid concentrations in patients and controls were compared by a two-sample *t* test. Urinary creatinine was estimated by routine spectrophotometric assay.

Children were screened for antiendomyseal antibodies and boys were screened for fragile-X if this had not been done

JAMA The Journal of the American Medical Association

Research Misconduct Identified by the US Food and Drug Administration
Out of Sight, Out of Mind, Out of the Peer-Reviewed Literature
Charles Seife, MS
JAMA Internal Medicine April 2015 Volume 175, Number 4

Behind the Veil: Conflicts of Interest and Fraud in Medical Research

on February 17, 2015 by Chris Kresser

Chicago Tribune

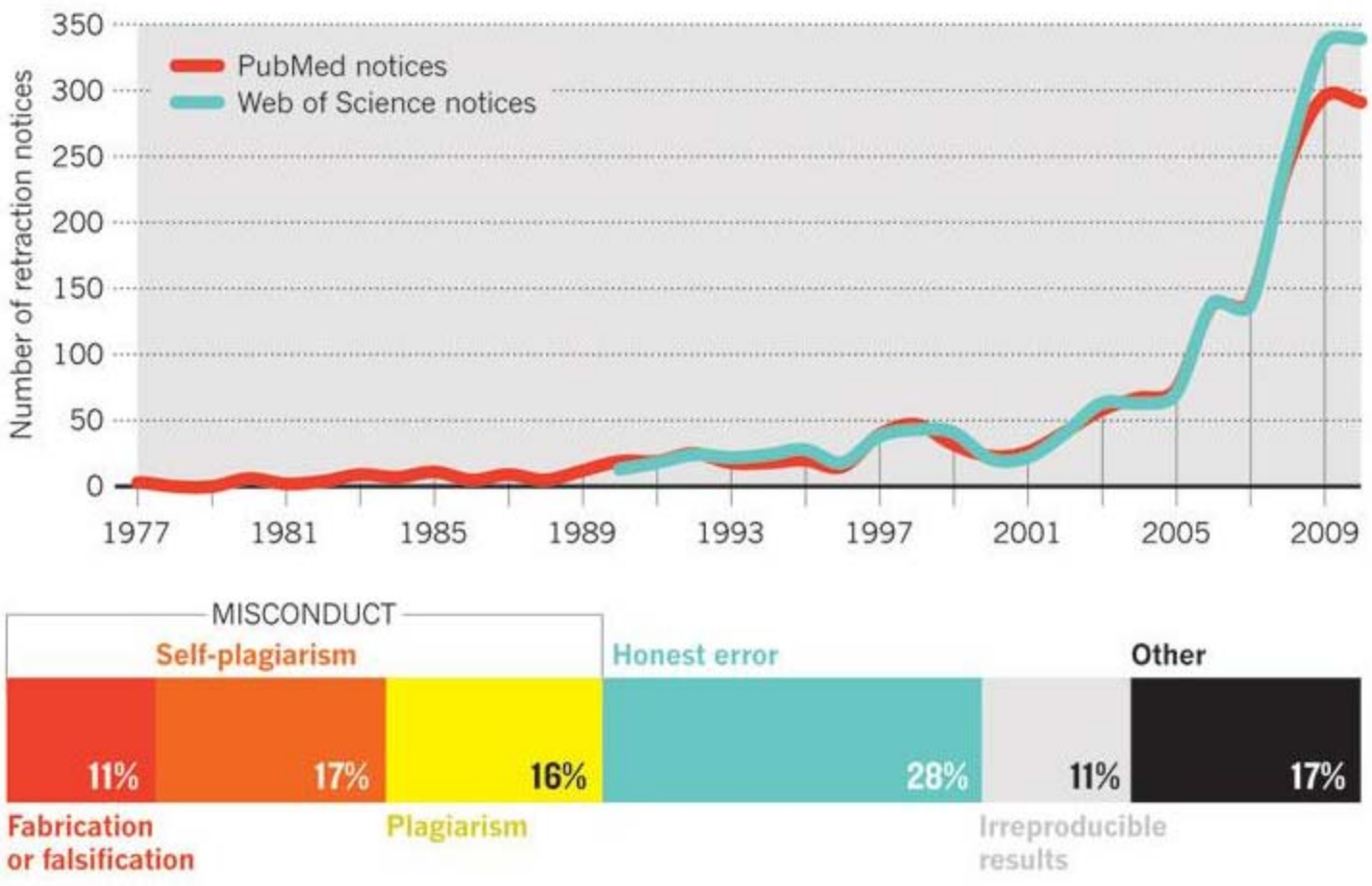
Commentary:
Should you put your trust in medical research?
Cory Franklin
June 8, 2015

Forbes

Mar 20, 2014 @ 11:53 AM **1,960 views**

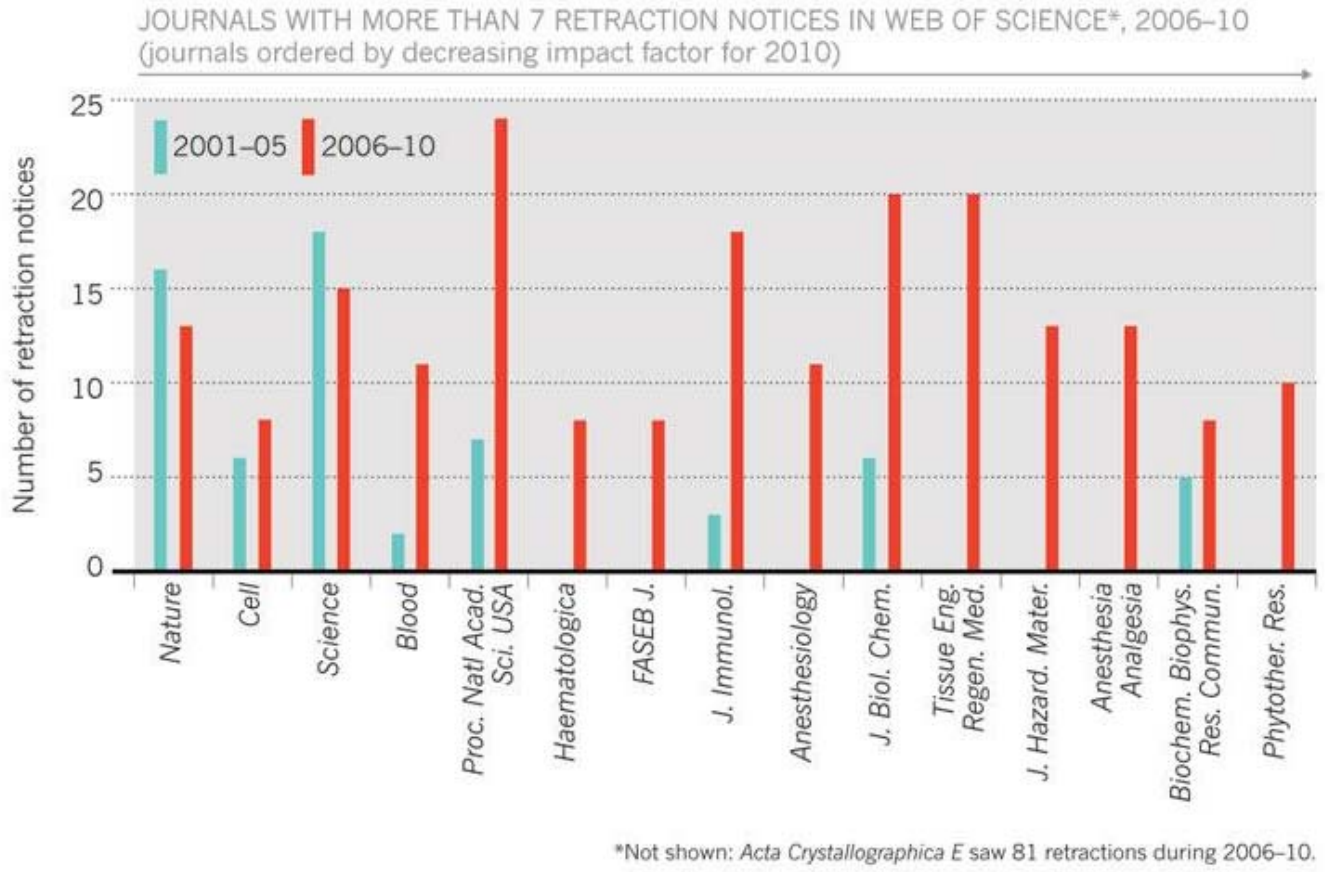
Medical Research Fraud And HHS's Office Of Research Integrity: Watching The Watchdog

Retraction Notices are on the Rise



Nature 478, 26-28 (2011) | doi:10.1038/478026a

Increase in Published Retractions in Higher Impact Journals



*Not shown: *Acta Crystallographica E* saw 81 retractions during 2006–10.

Nature 478, 26-28 (2011) | doi:10.1038/478026a

Medical Writers is Your Reputation Under Fire Too?

Guest Authorship and Ghostwriting in Publications Related to Rofecoxib

A Case Study of Industry Documents From Rofecoxib Litigation

The New York Times

Medical Papers by Ghostwriters Pushed Therapy

By NATASHA SINGER
Published: August 4, 2009

COMMENTARY

THE AMERICAN JOURNAL of MEDICINE®

Ghostwriting: Research Misconduct, Plagiarism, or Fool's Gold?

PLoS MEDICINE

Editorial

Ghostwriting: The Dirty Little Secret of Medical Publishing That Just Got Bigger

The *PLoS Medicine* Editors*

theguardian

Scientists credited on ghostwritten articles 'should be charged with fraud'

Ghostwritten medical articles called fraud

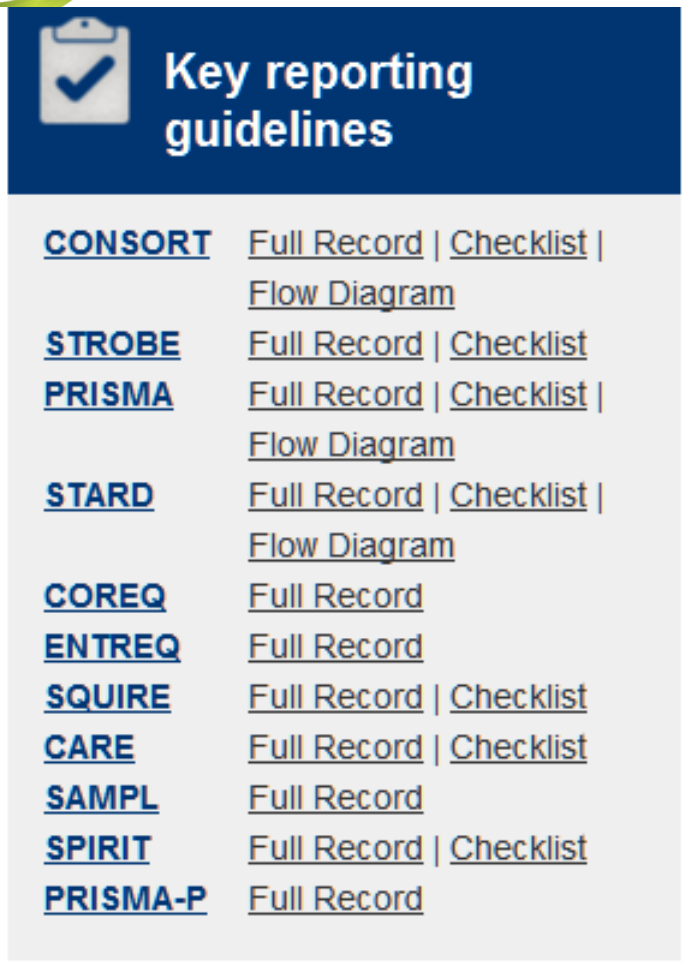
CBC News
Posted: Aug 02, 2011 6:18 PM ET

How to Navigate the Sea of Guidelines

- Know the guidelines (ICMJE, GPP3…)
- Know how to access the right guidelines
- Know and follow the local regulations and guidelines
- Follow reporting standards relevant to your dataset
- Review ethics statements standards issued from professional organizations regularly
- When navigating ‘Grey Zones’, let the following principles guide you:
  - Integrity
  - Completeness
  - Accuracy
  - Transparency
  - Accountability
  - Responsibility

Slide adapted from *GUIDELINES – WHAT YOU SHOULD KNOW*, ISMPP U
Wendy P. Battisti, PhD

Enhancing the Quality And Transparency Of Health Research



equator network

http://www.equator-network.org/

- CONSORT – randomized clinical trials
- STROBE – observational studies in epidemiology
- PRISMA – systematic reviews and meta-anlaysis (PRISMA- P – for related protocols)
- STARD – diagnostic accuracy
- SPIRIT – protocol standards
- CHEERS – health economic reporting
- STRICTA – acupuncture trials (extension of CONSORT)

International Council Of Medical Journal Editors

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

http://www.icmje.org/

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*

I. About the Recommendations
A. Purpose of the Recommendations

A. Preparing a Manuscript for Submission to
ical Journal

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Good Publication Practice Guidelines (GPP3)

GPP3 guideline full *Annals of Internal Medicine (AIM)* article can be accessed through ww.ismpp.org/GPP3

The GPP3 guidelines were sponsored by the International Society for Medical Publication Professionals (ISMPP)

Why is GPP3 Relevant to Medical Writers?

Annals of Internal Medicine RESEARCH AND REPORTING METHODS

Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3

Wendy P. Battisti, PhD; Elizabeth Wager, PhD; Lise Baltzer ; Dan Bridges, PhD; Angela Cairns ; Christopher I. Carswell, MSc; Leslie Citrome, MD, MPH; James A. Gurr, PhD; LaVerne A. Mooney, DrPH; B. Jane Moore, MS; Teresa Peña, PhD; Carol H. Sanes-Miller, MS; Keith Veitch, PhD; Karen L. Woolley, PhD; and Yvonne E. Yarker, PhD

This updated Good Publication Practice (GPP) guideline, known as GPP3, builds on earlier versions and provides recommendations for individuals and organizations that contribute to the publication of research results sponsored or supported by pharmaceutical, medical device, diagnostics, and biotechnology companies. The recommendations are designed to help individuals and organizations maintain ethical and transparent publication practices and comply with legal and regulatory requirements. These recommendations cover publications in peer-reviewed journals and presentations (oral or poster) at scientific congresses. The International Society for Medical Publication Professionals invited more than 3000 professionals worldwide to apply for a position on the steering committee, or as a reviewer, for this guideline. The GPP2 authors reviewed all applications (n = 241) and assembled an 18-member steering committee that represented 7 countries and a diversity of publication professions and institutions. From the 174 selected reviewers, 94 sent comments on the second draft, which steering committee members incorporated after discussion and consensus.

The resulting guideline includes new sections (Principles of Good Publication Practice for Company-Sponsored Medical Research, Data Sharing, Studies That Should Be Published, and Plagiarism), expands guidance on the International Committee of Medical Journal Editors' authorship criteria and common authorship issues, improves clarity on appropriate author payment and reimbursement, and expands information on the role of medical writers. By following good publication practices (including GPP3), individuals and organizations will show integrity, accountability, and responsibility for accurate, complete, and transparent reporting in their publications and presentations.

Ann Intern Med. doi:10.7326/M15-0288 **www.annals.org**

For author affiliations, see end of text.

This article was published online first at www.annals.org on 11 August 2015.

Why are GPP3 Guidelines Important?

- Provide guidance on how to responsibly and ethically develop and publish findings from clinical trials sponsored by pharmaceutical companies
- Demonstrate industry's commitment to integrity, accountability, and responsibility for accurate, complete and transparent reporting of company-sponsored publications
- Broadly applicable to non-industry sponsored research such as academic and government funded work

"*If these efforts do not soon bring about a necessary sea change in the way industry funded trials are performed, the BMJ may well decide to stop publishing them.* Whether an editor would survive such a decision is a question I may have to test."

Fiona Godlee, editor in chief BMJ
BMJ 2014;348:g171

Battisti WP, *et al. Ann Intern Med 2015.*
Smith R, et al. BMJ 2014;348:g171 doi: 10.1136/bmj.g171

What's new in GPP3?

New elements include:
1. Guidance on updated ICMJE 2014 authorship criteria
2. Guidance on common issues regarding authorship
3. Guidance and improved clarity on author payment and reimbursement
4. Additional clarity on what constitutes ghost or guest authorship
5. Expanded information on the role and benefit of professional medical writers
6. Guidance for appropriate data sharing
7. Overall simplification of language and format with a new guiding principles section and quick reference tables addressing guidance on authorship criteria and common authorship issues

GPP3 Section *2.4:*
Professional Medical Writers

UPDATE

2.4.2: Working With Authors

1. The authors will control and direct the content of the publication or presentation. The writer must receive direction from the authors at the earliest possible stage (for example, before the outline is prepared)
2. All authors have agreed to the writer's involvement.
3. All authors have a documented agreement with the sponsor that identifies their respective rights, roles, and responsibilities.
4. The authors will disclose, at a minimum, the writer's name, professional qualifications, affiliation, funding source, and any other information required by the journal or congress.
5. Good publication practices will be followed.

Battisti WP, *et al. Ann Intern Med 2015.*
*Mansi BA, *et al. Mayo Clin Proc. 2012.*

GPP3 Guidance on Authorship

UPDATE

GPP3 provides insights and examples to help clarify ICMJE authorship

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Annals of Internal Medicine RESEARCH AND REPORTING METHODS

Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3

1	Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work	**Defines what is substantial contribution and what it is not with examples**
2	Drafting the work or revising it critically for important intellectual content	**Provides clarity on what constitutes a critical revision**
3	Final approval of the version to be published	**Important for the author to read the entire manuscript**
4	Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved	**Each author is accountable for the work and should have confidence in the integrity of other authors' contributions**

Authors must meet all 4 criteria

Common Authorship Issues

Most common authorship issues addressed in GPP3 include:

1. Number of authors
2. Author Sequence
3. Addition or removal of authors
4. Death or incapacity of an author
5. Change of affiliation
6. Company or sponsor-employed authors
7. Professional writers as authors

Battisti WP, *et al. Ann Intern Med 2015.*

A Call to Action For Medical Writers

"If everyone is moving forward together, then success takes care of itself"

- Henry Ford

Leverage the GPP guidelines to promote and educate on the credibility of your profession

- Drive local education:
  - promote increased understanding and adoption of GPP3 Section *2.4: Professional Medical Writers* to help educate at investigator meetings, advisory board, publication meetings
- Communicate the data:
  - Share evidence referenced in GPP3 to promote understanding of ethics and integrity in medical publications and the role medical writers play
- Partner with like minded organizations such as ISMPP:
  - Elevate the quality and reputation of medical publications and researchers

Thank You!

GPP3 Resources

- GPP3 article 'key' resources include:
  - Summary of 'top ten' principles of good publication practice
  - Detailed appendices on GPP3 guideline and recommendations, and contributorship
  - Quick reference tables providing guidance on authorship criteria and common issues about authorship

- www.ismpp.org/GPP3 provides access to supporting GPP3 materials
  - GPP3 translation in Chinese and Japanese, Q4 2015
  - GPP3 presentation from ISMPP annual meeting
  - GPP historical archive – includes links to GPP and GPP2
  - **Coming soon!**
    - Frequently Asked Questions