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

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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

<table>
<thead>
<tr>
<th>Year</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1940</td>
<td>American Medical Writers Association (AMWA)</td>
</tr>
<tr>
<td>1978</td>
<td>Meeting of the “Vancouver group”, later becomes International Committee of Medical Journal Editors (ICMJE)</td>
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<tr>
<td>1982</td>
<td>European Association of Scientific Editors (EASE)</td>
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<tr>
<td>1989</td>
<td>European Medical Writers’ Association (EMWA)</td>
</tr>
<tr>
<td>1995</td>
<td>World Association of Medical Editors (WAME)</td>
</tr>
<tr>
<td>2005</td>
<td>International Society for Medical Publication Professionals (ISMPP)</td>
</tr>
<tr>
<td>2008</td>
<td>Medical Publishing Insights and Practices (MPIP) initiative</td>
</tr>
</tbody>
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## Guidelines issued

<table>
<thead>
<tr>
<th>Year</th>
<th>Guidelines</th>
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<tbody>
<tr>
<td>1979</td>
<td>Uniform requirements for manuscripts submitted to biomedical journals (ICMJE)</td>
</tr>
<tr>
<td>2003</td>
<td>First GPP guidelines published</td>
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<tr>
<td>2003</td>
<td>Recommendations for group authorship published by Council of Science Editors (CSE)</td>
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<tr>
<td>2005</td>
<td>ICMJE’s study registration requirements implemented</td>
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<tr>
<td>2005</td>
<td>EMWA guidelines on role of medical writers</td>
</tr>
<tr>
<td>2006</td>
<td>PhRMA principles and guidelines</td>
</tr>
<tr>
<td>2009</td>
<td>GPP2 guidelines published</td>
</tr>
<tr>
<td>2009</td>
<td>ICMJE’s disclosure form for potential conflicts of interest published</td>
</tr>
<tr>
<td>2009</td>
<td>Conflict of interest guidance added to AMWA policy</td>
</tr>
<tr>
<td>2009</td>
<td>PhRMA principles and guidelines updated</td>
</tr>
<tr>
<td>2009</td>
<td>CSE’s white paper updated</td>
</tr>
<tr>
<td>2010</td>
<td>Integrity in scientific journal publications white paper published by CSE</td>
</tr>
</tbody>
</table>

## Continuing to improve publication practices

<table>
<thead>
<tr>
<th>Year</th>
<th>Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>Task force - contribution of medical writers to scientific publications (AMWA)</td>
</tr>
<tr>
<td>2007</td>
<td>FDA Amendments Act signed into law</td>
</tr>
<tr>
<td>2007</td>
<td>ICMJE study registration requirements expanded</td>
</tr>
<tr>
<td>2007</td>
<td>International Publication Planning Association (TIPPA) established</td>
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<tr>
<td>2009</td>
<td>GPP2 guidelines published</td>
</tr>
<tr>
<td>2009</td>
<td>ICMJE’s disclosure form for potential conflicts of interest published</td>
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<td>2009</td>
<td>CSE’s white paper updated</td>
</tr>
<tr>
<td>2010</td>
<td>Joint Position of Pharmaceutical Manufacturers Association published</td>
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<tr>
<td>2010</td>
<td>ISMPP Code of Ethics</td>
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<tr>
<td>2014</td>
<td>Principles for Responsible Clinical Trial Data Reporting (PhRMA, efpia)</td>
</tr>
<tr>
<td>2014</td>
<td>EASE guidelines for scientific articles (and translations)</td>
</tr>
</tbody>
</table>

*Adapted from: Clark et al. (MPIP) Int J Clin Pract. 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

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

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

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

Nature 478, 26-28 (2011) | doi:10.1038/478026a
Guest Authorship and Ghostwriting in Publications Related to Rofecoxib
A Case Study of Industry Documents From Rofecoxib Litigation

COMMENTARY

The New York Times

Medical Papers by Ghostwriters Pushed Therapy
By NATASHA SINGER
Published: August 4, 2009

Guest Authorship and Ghostwriting in Publications Related to Rofecoxib
A Case Study of Industry Documents From Rofecoxib Litigation

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*

Ghostwritten medical articles called fraud

Scientists credited on ghostwritten articles 'should be charged with 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

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

http://www.equator-network.org/
International Council 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
   B. Who Should Use the Recommendations

A. Preparing a Manuscript for Submission to a Medical Journal
   I. General Principles

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 www.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
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

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

#### 2.4.2: Working With Authors

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>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)</td>
</tr>
<tr>
<td>2</td>
<td>All authors have agreed to the writer's involvement.</td>
</tr>
<tr>
<td>3</td>
<td>All authors have a documented agreement with the sponsor that identifies their respective rights, roles, and responsibilities.</td>
</tr>
<tr>
<td>4</td>
<td>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.</td>
</tr>
<tr>
<td>5</td>
<td>Good publication practices will be followed.</td>
</tr>
</tbody>
</table>
GPP3 Guidance on Authorship

GPP3 provides insights and examples to help clarify ICMJE authorship.

1. Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
2. Drafting the work or revising it critically for important intellectual content.
3. Final approval of the version to be published.
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.

Authors must meet all 4 criteria.

Definitions:
- Defines what is substantial contribution and what it is not with examples.
- Provides clarity on what constitutes a critical revision.
- Important for the author to read the entire manuscript.
- Each author is accountable for the work and should have confidence in the integrity of other authors’ contributions.

www.icmje.org
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

A Call to Action For Medical Writers

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

“If everyone is moving forward together, then success takes care of itself”
- Henry Ford
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