Charting a Course to Excellence: Discovering the Latest in Medical Publication Guidelines

Presented by the MAPS Medical Communications FAWG

Presenters

Speakers

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Educational Objectives

This session will provide a learning opportunity for our audience by:

- Ensuring awareness of the most recent guidance updates on publication of company-sponsored biomedical research
- Discussing the impact of these updates on publication planning and process
- Providing insights on application of principles from guidance updates for emerging topics

Overview

UPDATED GUIDELINES

- Good Publication Practice (GPP)

- International Committee of Medical Journal Editors (ICMJE) Recommendations

- World Association of Medical Editors: Statement on Artificial Intelligence (AI)

HOT TOPICS

- Part 1: Authorship, equity, inclusivity

- Part 2: Technology and communication channels

eCademy

Updated Guidelines

Good Publication Practice
International Committee of Medical Journal Editors
World Association of Medical Editors

What roles do guidelines play for Medical Affairs?

- Balance frameworks
  - Regulatory frameworks
  - Publications, medical education, other scientific exchange
- Balance stakeholder concerns
  - Regulators
  - Academic community
  - Patients and advocates
  - Payors
  - General public

What are some recent updates of interest?

GPP 2022

- Overall revision of format
- Useful for training and communication
- Expanded content
- Greater focus on communications
- Plain language summaries (PLS)
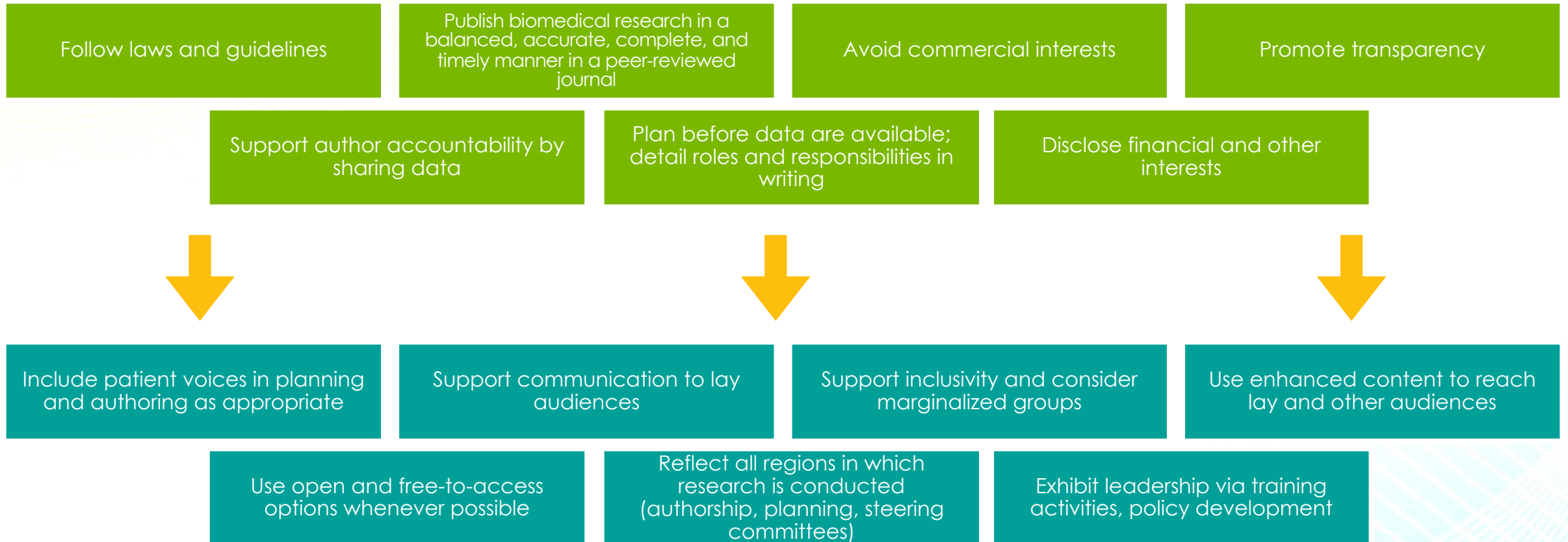- Enhanced content
- Patients

ICMJE

- Statements on AI
- Revision to authorship criterion #2

WAME

- Statement on AI

Major GPP principles

Follow laws and guidelines	Publish biomedical research in a balanced, accurate, complete, and timely manner in a peer-reviewed journal	Avoid commercial interests	Promote transparency
	Support author accountability by sharing data	Plan before data are available; detail roles and responsibilities in writing	Disclose financial and other interests

Include patient voices in planning and authoring as appropriate	Support communication to lay audiences	Support inclusivity and consider marginalized groups	Use enhanced content to reach lay and other audiences
	Use open and free-to-access options whenever possible	Reflect all regions in which research is conducted (authorship, planning, steering committees)	Exhibit leadership via training activities, policy development

GPP has been evolving since 2003

Current Medical Research and Opinion

- Initiated by industry professionals in 1998
- First guidelines describing standards for company-sponsored publications
- Limited consultation
- Main themes: publication bias and the relationship between industry and academia

Wager E, et al. *Curr Med Res Opin* 2003;19:149–154.

Annals of Internal Medicine

- Extensive consultation process
- Further updates reflecting the ever-evolving medical publications environment
- Restructured, with additional sections on principles of publication practice, data sharing, studies that should be published and plagiarism

Battisti WP, et al. *Ann Intern Med* 2015;163:461–464.

Original GPP: 2003	GPP2: 2009	GPP3: 2015	GPP update 2022

British Medical Journal

- More rigorous methodology
- Updated to reflect evolving standards in clinical trial conduct and communication
- Additional sections on reimbursement, publication planning, specific publication types and documentation

Graf C, et al. *BMJ* 2009;339:b4330.

Annals of Internal Medicine

- Extensive consultation process under the leadership of ISMPP
- Updated guidance on ethics and transparency, as well as new and emerging publication tools reflective of current environment
- Restructured to provide practical advice for teams working in publication planning

De Tora LM, et al. *Ann Intern Med* 2022;175:1298–1304. https://www.acpjournals.org/doi/full/10.7326/M22-1460

GPP, Good Publication Practice; ISMPP, International Society for Medical Publication Professionals.

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Original GPP: 2003

GPP update 2022

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GPP 2022 overview

Strengthens core values such as ethics, transparency, accountability and responsibility: adds inclusivity

Updated guidance on the types of studies that should be published (e.g., HEOR, RWE, translational and biomarker studies)

Information added on the role of patients as authors

More guidance on author agreements
Removed limit on author numbers

Guidance on working with alliance partners

Advice on the role of social media in publication planning

Guidance on enhanced content and PLSs for publications

Clarity of the timing of data sharing to improve transparency

A detailed supplement includes practical help on various topics

Publication types

Publication professional roles and professional development

Steering committees

Publication plans

Publication working groups

Authorship and contributorship determination

Publication process

Documentation

HEOR, health economics and outcomes research; PLS, plain language summary; RWE, real-world evidence.
Please note: Slide adapted from materials courtesy of Nucleus Global, An Inizio Company prepared for ISMPP U.

ICMJE Recommendations: May 2023 updates

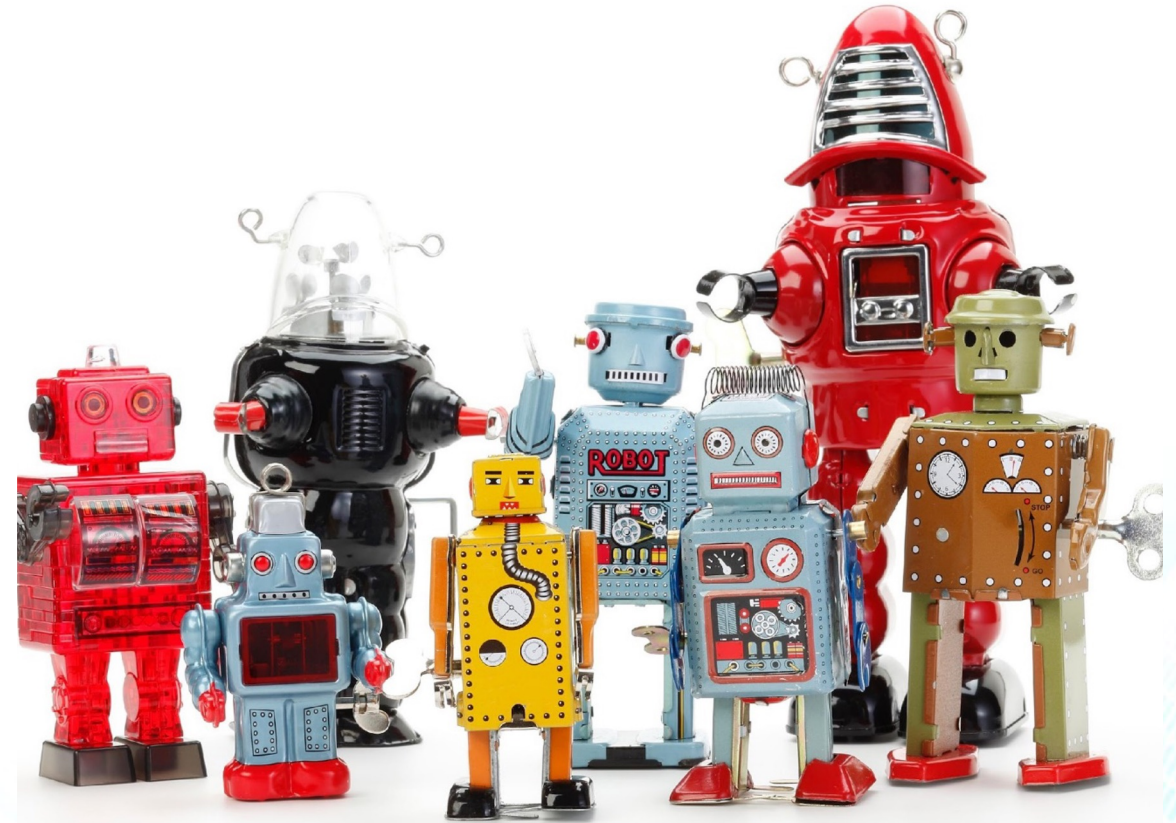Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Updated May ~~2022~~ ← 2023

- I. About the Recommendations
  - A. Purpose of the Recommendations
  - B. Who Should Use the Recommendations?
  - C. History of the Recommendations
- II. Roles and Responsibilities of Authors, Contributors, Reviewers, Editors, Publishers, and Owners
  - A. Defining the Role of Authors and Contributors
    1. Why Authorship Matters
    2. Who Is an Author?
    3. Non-Author Contributors
  - B. Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest
    1. Participants
       a. Authors
       b. Peer Reviewers
       c. Editors and Journal Staff

       4. Artificial Intelligence (AI)-Assisted Technology

- G. Supplements, Theme Issues, and Special Series
- H. Sponsorship and Partnerships
- I. Electronic Publishing
- J. Advertising
- K. Journals and the Media
- L. Clinical Trials
    1. Registration
    2. Data Sharing
- IV. Manuscript Preparation and Submission
  - A. Preparing a Manuscript for Submission to a Medical Journal
    1. General Principles
    2. Reporting Guidelines
    3. Manuscript Sections
       a. Title Page
       b. Abstract
       c. Introduction

- Authorship criteria (Section II.A)

- Responsibilities of peer reviewers (Section II.C.3)

- Duplicate publication (Section III.D.2)

- Reporting guidelines related to sex and gender (Section IV.A.2)

- Guidance on how work conducted with the assistance of artificial intelligence(AI) technology should be acknowledged (Sections II.A, II.C.3, IV.A.3.g)

- Other revisions to assure more inclusive language

- Annotated .pdf available at: https://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_may23.pdf

WAME Statement on AI

- AI is not a qualified author
- AI should be acknowledged as appropriate
  - How was the AI used?
- PDF available at: https://wame.org/pdf/Chatbots-Generative-AI-and-Scholarly-Manuscripts.pdf

Hot Topic 1: Authorship, equity, inclusivity

Quick note on ICMJE authorship criterion #2 update

2. Who Is an Author?

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

2. Drafting the work or reviewing it critically for important intellectual content; AND

3. Final approval of the version to be published; AND

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.

- Updated from "revising" to "reviewing"
- Captures the original intent for authors
  - Must review the manuscript critically for important intellectual content
  - Deserve the opportunity to make changes if warranted

Authorship [Supplement Section G]

Follow journal and conference guidelines

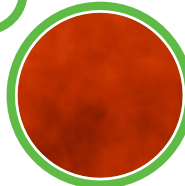Authors negotiate decisions about journal selection and author order

Think about accountability, author groups, study groups and investigator groups

Reasonable number

No limit on number of authors

Don't limit per function

Follow current ICMJE recommendations

DeTora et al. *Ann Intern Med*. 2023;176:eL220490.

"Byline" authors

Authors listed on the main part of the paper

For a large study team, a few members may serve as byline authors "for" the group

Different groups can be listed and will be indexed in PubMed

Author group

All meet all authorship criteria

Investigator group

All study investigators

May not meet all authorship criteria

Study group

Investigators and study contributors; others

May not meet all author criteria

DeTora et al. *Ann Intern Med*. 2023;176:eL220490.

Process to determine authorship: GPP

Communicate before authoring begins, if possible, at the investigator meeting

Use of group lists	Author requirements	Lead investigator	Steering committee
• Investigator group • Study group	• Target journal • How to serve • Author agreements	• If steering committee head	• How to serve • Selection process

During manuscript development

Include qualified authors per ICMJE authorship criterion #1	Authors decide main scientific messages	At submission	Re-evaluate after peer review
	• Medical writer should follow author directions • Authors review and make comments	• Consider new analyses and medical writer contributions	• Comment consolidation • New data requests

DeTora et al. *Ann Intern Med*. 2023;176:eL220490.

Diversity, equity, inclusion: GPP and ICMJE

- Demographic
  - Race, gender, ethnicity

- Geographic
  - Include authors from each region in which research performed

- Expertise/functions
  - Patients
  - Scientific specialties
  - Company and other authors

- Should consider research design as well as publication

- Medical Affairs professionals have an opportunity to exhibit leadership

Per International Committee of Medical Journal Editors (ICMJE), editors should

"seek to engage a broad and diverse array of authors, reviewers, editorial staff, editorial board members, and readers"

Hot Topics 2: Technology and communication channels

Artificial intelligence: potential uses in medical publications

Authors

- Writing
- Graphics/illustrations
- Journal selection

Editors/Reviewers/Publishers

- Article screening & quality control
- Alternate journal advice
- Peer review
- Copy editing & reference checking
- Metadata creation/enrichment

Readers/Publishers

- Summarization
- Collections
- Post-publication quality/ impact evaluation
- Accessibility

Artificial intelligence: risks

Lack of transparency

- Undisclosed use of generative AI by authors or reviewers
- IP and privacy infringement

Confidentiality

- Secure storage of uploaded data
- Access to content

Hallucinations

- Made up, but plausible sounding information

Bias

- Trained on biased data

Papermills

- Text generation
- Image fabrication

What do the guidelines say?

	ICMJE	WAME
Authorship	• Chatbots cannot be listed as authors	
Use when authoring	• Use of AI-assisted technologies should be disclosed to Editors • Authors are responsible for the submitted material	
	• AI-generated material cannot be referenced as a primary source	
Use when peer reviewing	• Reviewers must maintain confidentiality of the manuscripts they are reviewing • Use of AI-assisted technologies should be disclosed to Editors • Reviewers are responsible for the output of AI-assisted technologies	
Use during the editorial workflow		• Use of AI-assisted technologies should be disclosed to Authors • Editors are responsible for the output of AI-assisted technologies • Editors need and should have access to tools to detect AI use

What do journal policies say?

- No to authorship
- Use must be acknowledged
- Authors are responsible for the contents of articles

Artificial intelligence (AI). Text generated from AI, machine learning, or similar algorithmic tools cannot be used in papers published in *Science* journals, nor can the accompanying figures, images, or graphics be the products of such tools, without explicit permission from the editors. In addition, an AI program cannot be an author of a *Science* journal paper. A violation of this policy constitutes scientific misconduct.

Artificial intelligence (AI). Use of large language models and other generative AI tools is not allowed. The reviewer is responsible for writing their own review and should not solicit input from colleagues without first obtaining permission from the editor.

Science

Why *Nature* will not allow the use of generative AI in images and video

Source:
https://www.nature.com/articles/d41586-023-01546-4

Plain language summaries (PLS)

- Encouraged by GPP 2022
  - Recommends submission with any paper that follows the CONSORT Guideline (https://www.equator-network.org/reporting-guidelines/consort/) and any other publication of clinically relevant information about any currently marketed product
  - Encouraged for all research

- When possible
  - Publish in the same journal as the original publication
  - PLS should be peer reviewed, indexed and fully discoverable
  - Open access or free to access.

- A standalone PLS may present information from one or more existing publications

Social Media is not a Scientific Safe Harbor

Regulatory frameworks apply

- May vary by country or region
- Must avoid promotional or off-label claims
  - Investigational or marketed products

Avoid using personal accounts

- Be careful about "likes" and "shares

Respect employer policies

- Communication office
- Intellectual property
- Promotion

Remember

- Academic policies may differ

Q&A

Takeaways

Keeping up to date may require adjustments to SOPs and working relationships

Updated guidelines provide helpful information for day-to-day practice, but are limited by best understanding at the time of publication

Considering the rapid pace of change, communicate your experience and feedback within your professional organizations

Thank you for listening

Acknowledgements

- Some slides were developed for a presentation to JMCA by Lisa DeTora

- Additional slides were developed for a Medical Affairs Professional Society webinar delivered in March 2023 by Lisa DeTora, Fiona Plunkett, and Zoe Preston

- Information was derived from a presentation given by Blake Souchest, PhD at the Drug Information Association Medical Affairs and Scientific Communication meeting in April 2023.

- More material is from a "Frequently Asked Questions" document prepared for the International Society of Medical Publication Professionals in May 2023 by Lisa DeTora and the GPP Steering Committee.

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No financial support was received for participation in the "GPP 4" Steering Committee or contributing to GPP 2022

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