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

Chris Graf,[1] Wendy P Battisti,[2] Dan Bridges,[3] Victoria Bruce-Winkler,[4] Joanne M Conaty,[5] John M Ellison,[6] Elizabeth A Field,[7] James A Gurr,[8] Mary-Ellen Marx,[9] Mina Patel,[10] Carol Sanes-Miller,[5] Yvonne E Yarker,[11] 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 industry research the **International Society for Medical Publication Professionals** has updated the good publication practice guidelines

[1]John Wiley & Sons, Wiley-Blackwell, Oxford OX4 2DQ
[2]Johnson & Johnson Pharmaceutical Research & Development, Raritan, NJ, USA
[3]Excerpta Medica, Elsevier, London
[4]Dunblane
[5]AstraZeneca Pharmaceuticals, Wilmington, DE, USA
[6]LifeScan, Milpitas, CA, USA
[7]Field Advantage Medical Communications, Chapel Hill, NC, USA
[8]Pfizer Collegeville, PA, USA
[9]PharmaWrite, Princeton, NJ, USA
[10]Cephalon, Frazer, PA, USA
[11]Knowledgepoint 360 Group, Newtown, PA, USA
Correspondence to:
C Graf chris.graf@wiley.com
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Authors and presenters are responsible for how medical research is interpreted and communicated. Often their work is the product of collaborations with other individuals from around the world. Some or all of the people who contribute to this collaboration may be employees of commercial companies.

The conduct and communication of medical research, including that sponsored by companies, continues to be criticised.[1-5] Since 2003, when the original good publication practice guidelines were published,[6] the environment in which medical research is reported has evolved.[7-16] The updated good publication practice (GPP2) guidelines presented here were written in the light of these developments and make recommendations that will help individuals and organisations maintain ethical practices and comply with current requirements when they contribute to the communication of medical research sponsored by companies. These guidelines apply to peer reviewed journal articles and presentations at scientific congresses.

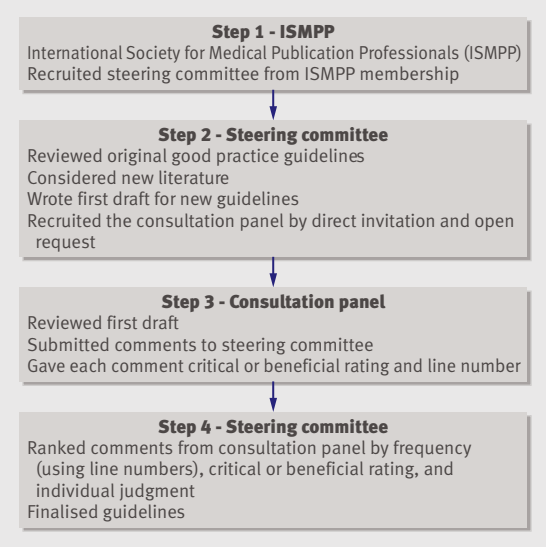
Methods

The figure summarises the methods used to develop the guidelines. Further details are available in the full version of this article on bmj.com.

WHAT'S NEW

GPP2 updates earlier good publication practice guidelines.[6]
New elements include:
- An extensive consultation process was used to write the guidelines
- Authorship guidance recommends assignment of a lead author and guarantor
- Contributorship guidance recommends describing the role of the sponsor
- Recommendations about reimbursement
- Recommendations for specific types of articles and presentations
- Recommendations for publication planning and documentation

Updated elements include:
- Guidance on defining the roles of authors, sponsors, and other contributors
- Guidance on establishing a publication steering committee
- Confirmation of the role of professional medical writers



Methods used to write GPP2

Guidelines and recommendations

Roles and responsibilities

Written agreement

We recommend that companies describe obligations for good publication practice in written publication agreements with authors of articles or presentations and with members of writing groups or publication steering committees. We recommend that the written agreement confirms the sponsors' responsibilities to:
- Grant authors full access to study data
- Confirm the authors' freedom to make public or publish the study results
- Provide authors with copies of the sponsor's publication policy.

We recommend that the written agreement confirms the authors' responsibilities to:
- Plan and produce articles or presentations that are accurate and complete in a timely manner
- Avoid premature publication or release of study information

- Avoid duplicate publication
- Make decisions about practical issues concerning presentation and publication (for example, choice of congress or journal)
- Disclose potential conflicts of interest in all articles and presentations
- Identify funding sources in all articles and presentations
- Ensure authorship is attributed appropriately
- Acknowledge in all articles and presentations all significant contributions made by individuals and organisations
- Provide the sponsor with copies of publication policies from the authors' institutions.

We recommend that the written agreement confirms the shared responsibilities of all contributors, including authors and sponsors, and that it:

- Confirms that sponsors will work with investigators, authors, and contributors to report and publish studies in a timely and responsible manner
- Defines the criteria that will be used to determine authorship for articles and presentations
- Confirms that the sponsor and the investigators will be informed about the publication process
- Provides protection to parties with intellectual property rights, and establishes a reasonable period before study results are made public for intellectual property rights to be protected
- Establishes the right of the sponsor to review, in a timely manner, articles and abstracts before they are submitted, and to share scientific comments with the authors
- Describes what, if any, support for the development of the article or presentation will be provided
- Establishes a process founded on honest scientific debate as the means to resolve scientific differences in interpretation of findings or study presentation
- Establishes that all articles and presentations will conform to good publication practice and other recognised standards (table 1 on bmj.com)

We recommend that written agreements for articles and presentations from research studies are made at the earliest opportunity. Written agreements must respect the institutional policies of authors, investigators, and other contributors, as well as those of the sponsor.

Access to data

Sponsors have a responsibility to share the data and the analyses with the investigators who participated in the study. Sponsors must provide authors and other contributors with full access to study data.

Reimbursement

It may be appropriate for companies to reimburse reasonable out of pocket expenses incurred by contributors or pay for specialised services. Details of this reimbursement must be disclosed. We recommend that no honorariums are paid for authorship of peer reviewed articles or presentations.

Publication steering committee

It may be useful to form a publication steering committee of authors and contributors to oversee and produce articles and presentations from a research study. This committee may include:

- Members of the study steering committee and the protocol development team
- Investigators and other individuals who have expertise in the area and who are willing to interpret the data and write or review articles and presentations
- Employees of, or contributors contracted by, the sponsor company who are involved in the study (for example, clinicians, statisticians, or professional medical writers).

Authors

We recommend using the criteria for authorship described in the International Committee of Medical Journal Editors (ICMJE) uniform requirements.[8] Guidance regarding authorship is also available from the World Association of Medical Editors[17] and the Council of Science Editors.[18] We recommend following individual journal and congress requirements when these differ from ICMJE criteria. ICMJE criteria allow assignment of authorship to individuals who have contributed to the analysis and interpretation of a study but who may not have contributed to its conception and design. In these instances, or if authors differ from initial plans, particular care should be taken to attribute authorship and to acknowledge contributions appropriately.

We recommend that authorship criteria are applied consistently. All authors listed on an article or presentation must fulfil authorship criteria, and all those who fulfil the criteria must be listed as authors. Before writing begins one author (a lead author who may also be guarantor) should take the lead for writing and managing each publication or presentation. One author (identified as guarantor) should take overall responsibility for the integrity of a study and its report.

Contributorship and acknowledgments

Contributorship and contributors

Using a contributorship model to describe who did what helps to remove ambiguity.[8 19 20] We recommend including clear, concise descriptions of the role of each contributor during preparation of the article or presentation.

Acknowledgments

We recommend that all articles and presentations include an acknowledgment to describe:

- Author contributions—for example: "A and B designed the study. C was the study statistician. A, B, and C critically reviewed the manuscript and approved the final version for submission"

- Contributions to the article or presentation from people who are not listed as authors, including name and affiliation or employer—for example: "The authors would like to thank D, YZ Pharmaceuticals, for overall management of the trial"
- The role of the sponsor in the study and its reporting. For example: "In collaboration with A and B, YZ Pharmaceuticals designed the study, analysed, and interpreted the data, and edited the report. All authors had full access to the data. The authors had final responsibility for the decision to submit for publication"
- Funding sources, if any, for the research and for the article or presentation.

Professional medical writers

Professional medical writers should ensure that authors control and direct writing and that disclosures of funding, potential conflicts of interest, and acknowledgment of contributions are made.[21] Professional medical writers are not ghostwriters. The Association of American Medical Colleges states "transparent writing collaboration with attribution between academic and industry investigators, medical writers and/or technical experts is not ghostwriting."[22] This is echoed by the US Institute of Medicine.[23] We recommend using a recently published checklist to discourage ghostwriting.[24]

We recommend that particular care is taken to ensure appropriate acknowledgment of the contributions made by medical writers and to describe their funding. Companies funding the work of medical writers should ensure that writers follow good publication practice.

Working with authors

Professional medical writers must be directed by the lead author from the earliest possible stage and all authors must be aware of the medical writer's involvement. The medical writer should remain in frequent contact with the authors throughout development of the article or presentation. The authors must critically review and comment on the outline and drafts, approve the final version of the article or presentation before it is submitted to the journal or congress, approve changes made during the peer review process, and approve the final version before it is published or accepted for presentation.

As authors

Professional medical writers, depending on the contributions they make, may qualify for authorship.

Conflicts of interest

We recommend that authors disclose financial and non-financial relationships that could inappropriately influence or seem to influence professional judgment. We recommend that these disclosures are made in all articles submitted for publication in peer reviewed journals, as well as in abstracts and posters submitted to congresses at the time of submission, if space requirements allow, and that they are included in oral presentations and posters at the time of presentation. Until discussions about how to address conflicts of interest are resolved,[23 25-27] we recommend authors favour greater, rather than lesser, disclosure.

Recommendations for specific types of articles and presentations

Primary and secondary publications

We recommend that all articles and presentations include statements to indicate whether they are the primary article or first presentation from a study. Authors preparing secondary articles and presentations must avoid duplicate publication. All post-hoc and exploratory analyses must be clearly identified as such.

Authorship of secondary articles and presentations may differ from that of primary articles and presentations from the same study. We recommend that one or more authors of the primary article from a study contribute to the secondary articles and presentations from the same study.

Duplicate publication

We recommend that the same study results are not published in more than one peer reviewed journal article unless:

- The results are substantially re-analysed, re-interpreted for a different audience, or translated into a different language; and
- The primary publication is clearly acknowledged and cited; and
- The article is clearly presented as an analysis derived from the previously published primary results or is a translation, is not presented as reporting the primary results, and respects copyright law.

Presentations

Congress guidelines should be followed for presentations that describe study results that have been presented at an earlier congress. With approval from the authors of the primary article, research submitted for presentation at national or local meetings may include authors who do not appear on the primary article.

Review articles

We recommend that review articles are comprehensive and that the methods for searching, selecting, and summarising information are clearly stated. We recommend that discussions in review articles founded principally on opinion are clearly identified as such. We also recommend that care is taken to ensure appropriate description of contributions from professional medical writers and other contributors. We refer readers to the *BMJ*'s "Who prompted this submission?" guidance.[20]

Table 1 | GPP2 checklist for articles and presentations

Characteristic	Check
Integrity	
Accurate, objective, balanced writing	
Full access to data for authors and contributors	
Absence of duplicative publications	
Honest attribution of authorship	
Completeness	
Clear description of research hypotheses	
Reporting the detail required to ensure unbiased presentation	
Complete and honest reference to related work	
Use of unique trial identifiers	
Discussion of limitations of study design and findings	
Making public or publishing results regardless of outcome	
Transparency	
Making clear sources of funding	
Disclosure of potential conflicts of interest	
Acknowledging individuals who have made significant contributions, including but not limited to those made by authors, and by description of these contributions	
Recognising the contributions of research sponsors	
Accountability	
Being accountable for the work and, in the case of authors and presenters, taking public responsibility for the work	
Assigning a guarantor	
Responsibility	
Making public or publishing results in a timely manner	
Respecting intellectual property	
Respecting the responsibilities of contributing individuals and organisations for good publication practice	

Table 2 | GPP2 checklist of basic requirements for written publication agreements

	Check
Does the agreement describe the roles and responsibilities of the sponsor, authors, and contributors?	
Confirmation of full access to data for authors and contributors	
Confirmation of authors' freedom to make public or publish the study results	
Confirmation of the intent to report or publish studies in a timely and responsible manner	
Definition of criteria that will be used to determine authorship	
Requirement that premature and duplicate publication are avoided	
Establishment of right of sponsor to review articles and presentations and responsibility to do so in a timely manner	
Establishment of process founded on honest scientific debate to resolve differences in study interpretation or presentation	
Requirement that intellectual property rights are respected	
Does the agreement confirm that all articles and presentations will conform to good publication practice and other recognised standards?	
Was the agreement established at the earliest opportunity (for example, when protocol was finalised)?	

Reporting standards

We recommend that authors follow established reporting standards.[16]

Planning, registering, posting, and documenting

Publication planning

Publication plans can help study sponsors ensure that clinical trial results are communicated in an effective and timely manner. They can also enable sponsors to identify the timelines and resources necessary to meet their obligations for reporting and publishing clinical trial results. Authors retain responsibility for decisions about articles and presentations from individual studies, which may be described in a publication plan.

Before publication

Research sponsors must register and post all applicable clinical trials according to the definitions and timelines required of them by relevant legislation and guidelines.[8-15] Authors should not submit their work for consideration by more than one peer reviewed journal at any one time. All parties should respect embargos set by journals, congresses, and other media.

Documentation

We recommend that companies, and the organisations or individuals working for them, document how publications are initiated and developed.

Checklists

Articles and presentations following good publication practice will show the characteristics described in table 1. Written agreements using good publication practice will cover, at a minimum, the items described in table 2.

International Society for Medical Publication Professionals initiated the development of these guidelines. The opinions expressed here do not necessarily represent those of the authors' employers. We thank the consultation panel for their comments. We thank Elizabeth Wager, Sideview, for her work on the original guidelines[6] that GPP2 updates (some of the earlier guidance remains in these new guidelines) and for her willingness for ISMPP to sponsor the authors to write GPP2. We thank Sheema Sheikh at Excerpta Medica, Elsevier for compiling comments from the consultation.

Contributors: Jane Moore, Medtronic, and John Draper, Peloton Advantage, were members of the steering committee and contributed to discussions about the recommendations made in this document (JD in particular on managed care, pharmacoeconomic, and health outcomes). CG wrote the first and final draft; WPB wrote the draft sections on publication planning, documentation, and conflict of interest; DB, EAF, CSM, and MP contributed to outline, intermediate drafts, and revisions; VBW wrote the draft sections on authors, contributorship, acknowledgments, and medical writers; JMC the draft duplicate publication section, JME the draft review articles section, JAG the draft publication steering committee section, and YEY the draft access to data section. MEM compiled steering committee comments after the consultation, and contributed to outline, intermediate drafts, and revisions. All the authors contributed to the literature analysis and review before writing these guidelines. All the authors contributed to the outline and to the first and subsequent drafts, to interpretation of the comments gathered during the consultation phase, and reviewed the final draft. All the authors approve this document and CG is the guarantor.

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