Conference abstracts: what do the guidelines tell us?

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Our focus for today

- GPP3 and congress requirements
- CONSORT for abstracts

Annals of Internal Medicine RESEARCH AND REPORTING METHODS

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

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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.

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For author affiliations, see end of text.

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Incomplete, inaccurate, misleading, or delayed reporting of medical research may result in poorly informed decision making and reduce the efficiency and quality of health care (1). Therefore, scientific and clinical research should be reported in a complete, accurate, balanced, and timely manner. Such research is often initiated by, or involves collaboration with, commercial organizations, such as pharmaceutical, biotechnology, medical device, and diagnostics companies. This updated Good Publication Practice guideline, known as GPP3, is designed primarily to help individuals and organizations maintain ethical practices when they contribute to the communication of this type of research. The principles of GPP3 apply to all research, however, so we expect that this guideline will be applicable to all medical and health care professionals involved in publications.

The GPP guideline, published in 2003 (2) and updated in 2009 (as GPP2) (3), has been widely adopted. In an international survey of almost 500 people involved in publishing industry-sponsored research, more than 90% of respondents said they routinely referred to GPP2, which is a similar proportion to those who reported using International Committee of Medical Journal Editors (ICMJE) guidelines (4). The GPP guidelines have also been endorsed by medical journals (5) and cited in their instructions to authors.

The latest revision, GPP3, reflects changes in the medical publications environment and aims to clarify and strengthen the principles and practices described in earlier versions. This guideline also reflects some important changes from GPP2 (Table).

Throughout the guideline, we use the term "publications" to include the full range of formats published in peer-reviewed journals (for example, original research articles, short reports, reviews, or letters to the editor) and "presentations" to include abstracts, posters, and slides for oral presentations at scientific congresses. "Sponsors" are organizations that provide primary support, which may include funding, for a study. "Publication professionals" are professional medical writers, publication planners, and publication managers, usually working either in or for companies. This guideline does not cover regulatory documents, medical education programs, or marketing or advertising materials, all of which are regulated or accredited by specific national or regional authorities.

METHODS

In August 2013, an e-mail invitation was sent to more than 3000 professionals from around the world, including International Society for Medical Publication Professionals (ISMPP) members ($n = 1630$); persons invited to review GPP2 ($n = 288$); and a distribution list from the Medical Publishing Insights and Practices initiative that included approximately 1400 investigators, researchers, and journal editors. Candidates were invited to volunteer as members of the GPP3 steering committee or reviewers (or both). Eight GPP2 authors screened the applications ($n = 241$). Of 118 steering committee applicants, 11 were chosen and joined 7 of the former GPP2 authors to provide a broad range of perspectives (from 7 countries, including employees of pharmaceutical, biotechnology, medical device, and

CONSORT for reporting randomised trials in journal and conference abstracts

In 2006, Arthur Amman, President of Global Strategies for HIV Prevention, made a disquieting remark: "I recently

Yet a study that examined 35 journals' instructions for authors found that only 4% of the text was devoted to the content or format of the abstract.[4] When key details about a trial are lacking, it is difficult to assess the validity of the results and their applicability.

In collaboration with members of the CONSORT Group, we have extended the current CONSORT Statement to develop a checklist of essential items which authors should include when reporting the main results of a randomised trial in a journal or conference abstract. We recognise that many journals have developed their own structure for reporting abstracts. Our intention is not to suggest changes to these formats, but to recommend what information should be reported within them when describing randomised trials.

In developing this checklist we generated a list of items from existing tools for quality assessment and

Item	Description
Title	Identification of the study as randomised
Authors*	Contact details for the corresponding author
Trial design	Description of the trial design (eg, parallel, cluster, non-inferiority)
Methods	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomisation	How participants were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment
Results	
Numbers randomised	Number of participants randomised to each group
Recruitment	Trial status
Numbers analysed	Number of participants analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side-effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding

* For conference abstracts.

Table: Items to include when reporting randomised trials in journal or conference abstracts*

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008 DOI:10.1016/S0140-6736(07)61835-2

GPP3 guidelines reminder

01 All clinical trials should be reported in a **complete**, **accurate**, **balanced**, **transparent**, and **timely manner**

02 Reporting and publication processes should follow **applicable laws** and **guidelines**

03 **Journal** and **congress requirements** should be followed, particularly to avoid duplicate publication

04 Publication planning and development should **be a collaboration**, reflecting the collaborative nature of research and the range of skills required to conduct, analyse, interpret, and report research findings

05 Rights, roles, requirements, and responsibilities of all contributors should be **confirmed in writing**, ideally at the start of the research and, in all cases, before publication preparation begins

06 All authors should have **access** to relevant aggregated **study data** and other information required to understand and report research findings

07 **Authors** should take **responsibility** for the way that research findings are published, be fully involved at all stages of publication development, and be willing to take public responsibility for all aspects of the work

08 **Author lists** and **contributorship statements** should accurately **reflect all substantial intellectual contributions** to the research, data analyses, and publication development. Relevant contributions from non-authors should also be disclosed

09 **Role of the sponsor** in the research should be **fully disclosed** in all publications. Involvement by persons or organisations with an interest in the findings should also be disclosed

10 All **authors** and **contributors** should **disclose** any **relationships** or potential **competing interests** relating to the research and its publication

Congress requirements

- **Congress requirements should be followed, especially ethical guidelines on originality and avoiding redundancy (that is, duplicate publication)**
  - *CROI requirements: If your study data or abstract information has been published, submitted for publication (anticipated publication on or before December 31, 2015), or presented at any other major national or international scientific or medical conference (i.e., 400 or more attendees), you will be asked to provide details on the previous presentation or publication*

Trial registration

- ***Clinical trial registration or identifier numbers*** **should be included in all presentations and publications, *including abstracts*, that present findings from a registered study or studies so that the source may be identified, *even if this is not required by the congress.***
- **Unregistered clinical trials should be declared and the reason for nonregistration should be provided**

Embargoes

- **Embargoes set by congresses must be respected**
  - For example, authors, sponsors, and institutions should not issue a press release about an article that has been accepted for presentation without consulting the congress
    - *Abstracts submitted to ASCO meetings are considered **final and confidential** from the time of submission*
    - *Prior to the abstract information being publicly released in conjunction with an ASCO Meeting, the author, coauthors, sponsor of the research, journalists, and others may not:*
      - *make the information public, or provide it to others who may make it public (such as news media),*
      - *publish or present the information or provide it to others who may publish or present it,*
      - *use the information for trading in the securities of any issuer, or provide it to others who may use it for securities trading purposes*

Encores

- **Re-presentation of data is allowable but check with congress guidelines**
  - Copyright requirements must be respected
- **Encore presentation allows information to be disseminated across geographic regions taking into account local language translation**

Authorship

- **Qualification**
  - Same criteria as for journal publications (e.g. ICMJE)
- **Number of authors**
  - High number questions whether all provided “substantial intellectual contribution”
  - Some congresses limit number, as does character count on abstracts
- **Author sequence**
  - Determine early and base on role in study and greatest contribution to abstract development
- **Addition or removal of authors**
  - Only with agreement of all authors
  - Addition for encore in local language should be clearly identified as “Presenting on behalf of…”

Presenting author responsibilities

- **Presenting the abstract for oral or poster presentation, if accepted**
  - Assuring that financial relationships with commercial entities have been disclosed for self, spouse, and institution
- **Assuring that if the presenting author is replaced with a new presenter, the new presenter will disclose:**
  - financial relationships with commercial entities for self, spouse, and institution
  - disclosure information for the author who will present
- **Providing complete and accurate contact and affiliation information for ALL coauthors; correct e-mail addresses are essential**
- **Assuring that ALL coauthors have reviewed and approved the abstract's content**
- **Providing an electronic version of a poster abstract**
  - Poster room credentials will not be issued until electronic versions of posters have been received

Contributorship and acknowledgement

- **All specific congress requirements for acknowledgment and disclosure should be followed**
- **Non author contributors listed in the acknowledgment section are not expected to approve the final presentation**
  - courtesy copy may be provided before submission

Disclosure

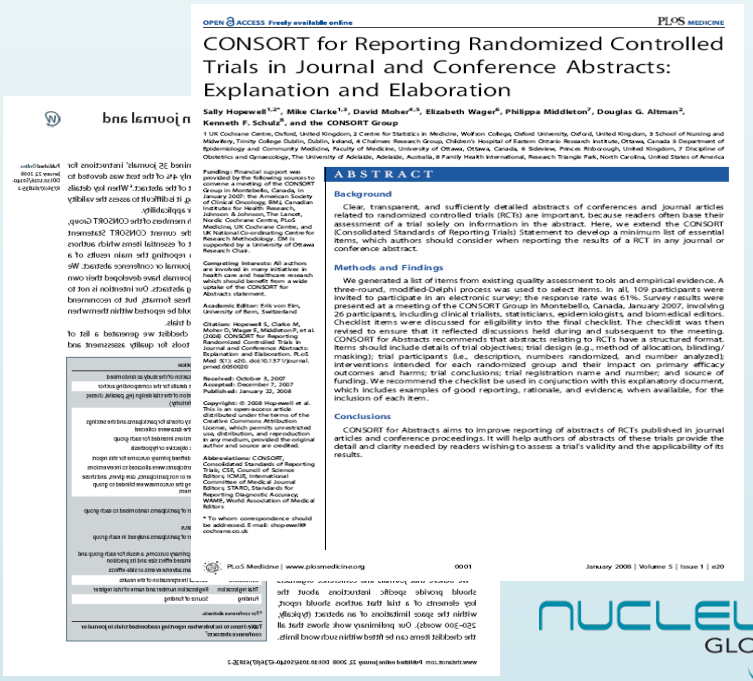
- **Disclosure statements should also be included in slides for oral presentations and on posters**
  - Authors should disclose prior presentations at other congresses (if the abstract submission system allows) and include the trial registration number
  - The role (if any) of the sponsor (e.g. funding of the study, its publication, or writing support) should always be clearly disclosed
    - When journals or congresses do not allow inclusion of this information within the presentation, recommended to include with the submission (e.g. in a cover letter or supplementary file)
    - As a minimum, this information should be documented in the project file

Typical reasons for rejection

- Subject matter is not appropriate for conference
- Information not new enough
- Abstract is duplicative of other submissions
- Format does not follow guidelines (e.g., section[s] missing, more than 1 graphic, table, or figure submitted)
- Submission is poorly written overall
- Background does not summarise the hypothesis
- Methodology is inadequate or insufficient to support conclusions
- Controls are absent or inadequate
- Statistical evaluation is inadequate or absent
- Summary of essential results is inadequate or absent
- Data are not included or offer inadequate/insufficient support for conclusions
- Submission reports clinical trial data from unplanned analysis or incomplete or ongoing studies

Which brings us to CONSORT

- ***CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration***
- **Authors:**
  - Sally Hopewell , Mike Clarke, David Moher, Elizabeth Wager, Philippa Middleton, Douglas G Altman, Kenneth F Schulz, and the CONSORT Group
- **PLOS Medicine**
- **Published: January 22, 2008**



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CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration

Sally Hopewell[1,2*], Mike Clarke[1,3], David Moher[4,5], Elizabeth Wager[6], Philippa Middleton[7], Douglas G. Altman[2], Kenneth F. Schulz[8], and the CONSORT Group

ABSTRACT

Background

Clear, transparent, and sufficiently detailed abstracts of conferences and journal articles related to randomized controlled trials (RCTs) are important, because readers often base their assessment of a trial solely on information in the abstract. Here, we extend the CONSORT (Consolidated Standards of Reporting Trials) Statement to develop a minimum list of essential items, which authors should consider when reporting the results of a RCT in any journal or conference abstract.

Methods and Findings

We generated a list of items from existing quality assessment tools and empirical evidence. A three-round, modified-Delphi process was used to select items. In all, 109 participants were invited to participate in an electronic survey; the response rate was 61%. Survey results were presented at a meeting of the CONSORT Group in Montebello, Canada, January 2007, involving 26 participants, including clinical trialists, statisticians, epidemiologists, and biomedical editors. Checklist items were discussed for eligibility into the final checklist. The checklist was then revised to ensure that it reflected discussions held during and subsequent to the meeting. CONSORT for Abstracts recommends that abstracts relating to RCTs have a structured format. Items should include details of trial objectives; trial design (e.g., method of allocation, blinding/masking); trial participants (i.e., description, numbers randomized, and number analyzed); interventions intended for each randomized group and their impact on primary efficacy outcomes and harms; trial conclusions; trial registration name and number; and source of funding. We recommend the checklist be used in conjunction with this explanatory document, which includes examples of good reporting, rationale, and evidence, when available, for the inclusion of each item.

Conclusions

CONSORT for Abstracts aims to improve reporting of abstracts of RCTs published in journal articles and conference proceedings. It will help authors of abstracts of these trials provide the detail and clarity needed by readers wishing to assess a trial's validity and the applicability of its results.

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Abbreviations: CONSORT, Consolidated Standards of Reporting Trials; CSE, Council of Science Editors; ICMJE, International Committee of Medical Journal Editors; STARD, Standards for Reporting Diagnostic Accuracy; WAME, World Association of Medical Editors

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Overview

- **CONSORT for Abstracts recommends that:**
  - abstracts relating to randomised controlled trials (RCTs) have a ***structured format***
- **Items should include:**
  - **details of trial objectives**
  - **trial design (e.g. method of allocation, blinding/masking)**
  - **trial participants (i.e. description, numbers randomized, and number analysed)**
  - **interventions intended for each randomised group and their impact on primary efficacy outcomes and harms**
  - **trial conclusions**
  - **trial registration name and number**
  - **source of funding**
- **CONSORT recommend their checklist be used when developing abstracts**

Authors

- ***Contact details for the corresponding author***
  - Adequate contact details for the corresponding author are particularly important for RCTs reported in conference proceedings because:
    - ***Abstracts may be the only lasting source of information for many trials***
      - Approximately half of RCTs reported in conference proceedings are subsequently published in full
      - Adequate contact information enable readers to contact trialists for additional information or clarifications regarding reported data

Randomisation

- ***How participants were allocated to interventions***
  - The method of allocation concealment is generally poorly reported in conference abstracts
    - In a review of 494 abstracts presented at an oncology conference in 1992 and 2002, only nine (2%) abstracts reported the method of allocation concealment. This information was missing from the remaining 485 conference abstracts, with no improvements seen over the ten-year period

Results

- ***For the primary outcome, a result for each group and the estimated effect size and its precision***
  - For the primary outcome, authors should report:
    - a summary of the outcome in each group (e.g., the number of participants with or without the event, or the mean and standard deviation of measurements)
    - the contrast between groups known as the effect size
  - ***Poor reporting of results is also a problem for trials presented in conference abstracts***
    - A study of 494 reports of RCTs in oncology found that only 26% of conference abstracts reported the size of the effect and significance of the result

Results: Harms

- ***Important adverse events or side effects***
  - In order to make rational and balanced decisions, readers need information about the relative benefits and harms of an intervention
  - Authors should describe any important adverse (or unexpected) effects of an intervention in the abstract. If no important adverse events have occurred, the authors should state this explicitly
  - ***Harms are also poorly reported in conference abstracts***
    - An examination of over 800 ophthalmology conference abstracts reporting trials found that the majority (71%) did not report harms related to the treatment intervention, and harms were reported as a primary outcome measure in only 6% of abstracts

Conclusions

- ***General interpretation of the results***
  - The conclusions of the trial, consistent with the results reported in the abstract, should be clearly stated along with their clinical application (avoiding over-generalisation)
  - Authors should balance the benefits and harms in their conclusions
  - Where applicable, authors should also note whether additional studies are required before the results are used in clinical setting

Summary

- **Follow conference guidelines when preparing abstracts and conference presentations**
  - Respect embargoes and copyright
  - Disclose prior presentation
  - Ensure author contact details are accurate
  - Respect acknowledgement and disclosure requirements particularly on oral slide presentations and posters
  - Obtain all permissions if there is a need to replace an author/presenter
- **Use CONSORT for abstracts checklist**
  - Pay attention to correct and accurate reporting of:
    - Allocation to treatment randomisation
    - Description of treatments and outcomes
    - Effect size and harms

20