Conference abstracts: what do the guidelines tell us?

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Our focus for today

- GPP3 and congress requirements
- CONSORT for abstracts
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**
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