Effect of active implementation of CONSORT guidelines on the reporting of abstracts in high impact medical journals: an interrupted time-series analysis

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Clear, transparent and sufficiently detailed abstracts of journal articles reporting randomized trials are important:

- Readers will often base their initial assessment of a trial on the content of the abstract.

In some cases, health practitioners will have access only to the abstract, and may, therefore, make healthcare decisions based solely on the information in that abstract.
CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration

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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 in 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.

In 2006, Arthur Amaran, President of Global Strategies for HIV Prevention, made a disquieting remark: “I recently met a physician from southern Africa, engaged in perinatal HIV prevention, whose primary access to information was abstracts posted on the Internet. Based on a single abstract, they had altered their perinatal HIV prevention program from an effective therapy to one with lesser efficacy. Had they read the full text article they would have undoubtedly realized that the study results were based on short-term follow-up, a small placebo group, incomplete data, and unlikely to be applicable to their country situation. Their decision to alter treatment based solely on the abstract’s conclusions may have resulted in increased perinatal HIV transmission.”

For clinical trials, clear, transparent, and sufficiently detailed abstracts of journal articles and conference abstracts are important because readers often base their assessment of a trial solely on information in a document. Some use an abstract to decide whether to seek more information about a trial. However, in some parts of the world, health professionals often have access to the abstracts only, so health-care decisions are based on abstracts of randomized trials. When a trial is reported at a conference, the abstract might provide the only permanent information accessible to most readers.

The CONSORT Statement, first published in 1996 and updated in 2001, provides recommendations for reporting randomized trials in health care journals and elsewhere. CONSORT has been endorsed by the World Association of Medical Editors, the International Committee of Medical Journal Editors (ICME), and the Council of Science Editors. Currently, the CONSORT Statement requires a minimum level of guidance for preparing abstracts and, while it encourages the use of a structured format, this is not a formal requirement. The ICME Uniform Requirements also provide minimum guidance on the format of abstracts for journal articles.

We believe that journals and conference organizers should provide specific instructions about the key elements of a trial that authors should report, within the space limitations of an abstract (typically, 250-300 words). Our preliminary work shows that all the checklist items can be fitted within such word limits.

CONSORT for reporting randomised trials in journal and conference abstracts

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“Articles on clinical trials should contain abstracts that include the items that the CONSORT group has identified as essential.”
CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

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| Table 1: CONSORT 2010 checklist of information to include when reporting a randomised trial* |
|-----------------------------------------------|-----------------------------------------------|
| **Section/Topic**                             | **Item No**                                   | **Checklist Item**                           |
| Title and abstract                            | 1a                                            | Identification as a randomised trial in the title |
|                                               | 1b                                            | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) |
| Introduction                                  | 2a                                            | Scientific background and explanation of rationale |
|                                               | 2b                                            | Specific objectives or hypotheses             |
| Background and objectives                     | 3a                                            | Description of trial design (such as parallel, factorial) including allocation ratio |
|                                               | 3b                                            | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |
| Methods                                       | 4a                                            | Eligibility criteria for participants         |
|                                               | 4b                                            | Settings and locations where the data were collected |
| Participants                                  | 5                                             | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |
| Interventions                                 | 6a                                            | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |
Objective

- To investigate the impact of the CONSORT for Abstracts guidelines, and different editorial policies used in five leading general medical journals to implement the guidelines, on the reporting quality of abstracts of randomized trials.
We randomly selected up to 60 primary reports of randomized trials per journal per year from *Annals of Internal Medicine, BMJ, Lancet, JAMA* and *NEJM* in 2006 to 2009, if indexed in PubMed with an electronic abstract.
Methods

- We classified journals in three categories:
  - journals not mentioning CONSORT for Abstracts guidelines in ‘Instructions to Authors’ (JAMA and NEJM).
  - journals referring to the CONSORT for Abstracts guidelines in their ‘Instructions to Authors’ but with no specific policy to implement guidelines (BMJ).
  - journals referring to the CONSORT for Abstracts guidelines in their ‘Instructions to Authors’ and with a policy to implement these guidelines (Annals of Internal Medicine and Lancet).
Outcome measures

- Mean number of items reported in <50% of the abstracts across the five journals in 2006 (0-9 scale).
- Mean number of items reported in <20% of abstracts across the five journals in 2006 (0-5 scale).
Items poorly reported in 2006

- Trial design (20%)
- Sequence generation (0%)
- Allocation concealment (0%)
- Who was blinded (6%)
- Number participants randomized in each group (43%)
- Number participants analysed in each group (19%)
- Result for each group + effect size (main outcome) (43%)
- Harms (35%)
- Funding source (0%)
Change in number of items reported (Jan 2006 to Dec 2009) before and after introduction of CONSORT for Abstracts – all journals

Items reported <50% of abstracts

Items reported <20% of abstracts
Change in number of items reported before and after introduction of CONSORT for Abstracts – guidelines included in journal’s instructions to authors, with active implementation policy (Annals of Internal Medicine, Lancet)

Items reported <50% of abstracts

Items reported <20% of abstracts
Change in number of items reported before and after introduction of CONSORT for Abstracts – guidelines included in journal’s instructions to authors only (BMJ)

Items reported <50% of abstracts

Items reported <20% of abstracts
Change in number of items reported before and after introduction of CONSORT for Abstracts – guidelines not mentioned in journal’s instructions to authors (JAMA, NEJM)

- Items reported <50% of abstracts
- Items reported <20% of abstracts
Limitations

- We only included randomized published in high impact journals
  - the resources and procedures available for these journals are not the same for all journals.
- The overall quality of reporting in these five journals might be higher than other journals.
- Our primary outcome focused on poorly reported items assuming each item equally important
  - this may not always be the case depending on the perspective of the reader.
  - however, by focusing only on items which were poorly reported we hoped to see the greatest impact of implementation of the guidelines.
Conclusion

- Our results show that CONSORT for Abstracts guidelines improved reporting only when implemented by a specific editorial policy, for example:
  - email sent to authors to revise the abstract according to CONSORT for Abstracts.
  - changes made by the assistant editors.

- Our results are consistent with systematic reviews (of clinical practice guidelines) showing that passive dissemination is generally ineffective,
  - specific strategies to implement research based recommendations are necessary to change practices.
We are grateful to those journal editors providing insight into their editorial processes.

For more information about our study see: BMJ. 2012 Jun 22;344:e4178.