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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Background

- 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 Abstracts: *PLoS Med* and *Lancet*, January 2008

OPEN ACCESS Freely available online PLoS MEDICINE

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

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Funding: Financial support was provided by the following sources to convene a meeting of the CONSORT Group in Montebello, Canada, in January 2007: the American Society of Clinical Oncology, BMJ, Canadian Institutes for Health Research, Johnson & Johnson, The Lancet, Nordic Cochrane Centre, PLoS Medicine, UK Cochrane Centre, and UK National Co-ordinating Centre for Research Methodology. DM is supported by a University of Ottawa Research Chair.

Competing Interests: All authors are involved in many initiatives in health care and healthcare research which should benefit from a wide uptake of the CONSORT for Abstracts statement.

Academic Editor: Erik von Elm, University of Bern, Switzerland

Citation: Hopewell S, Clarke M, Moher D, Wager E, Middleton P, et al. (2008) CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. PLoS Med 5(1): e20. doi:10.1371/journal.pmed.0050020

Received: October 3, 2007
Accepted: December 7, 2007
Published: January 22, 2008

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

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.

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 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 pivotal 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."[1]

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 on such information. 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 made on the basis of abstracts of randomised trials.[1] When a trial is reported at a conference, the abstract might provide the only permanent information accessible to most readers.[2]

The CONSORT Statement, first published in 1996[3] and updated in 2001,[4] provides recommendations for reporting randomised 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 (ICMJE), and the Council of Science Editors. Currently, the CONSORT Statement provides limited guidance about preparing abstracts and, while it encourages the use of a structured format, this is not a formal requirement. The ICMJE Uniform Requirements[5] also provide limited guidance on the format of abstracts for journal articles.

We believe that journals and conference organisers 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.

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.[6] 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*

www.thelancet.com Published online January 22, 2008 DOI:10.1016/S0140-6736(07)61835-2

International Committee of Medical Journal Editors

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication

Updated October 2008

"Articles on clinical trials should contain abstracts that include the items that the CONSORT group has identified as essential."

RESEARCH METHODS & REPORTING

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[45,65])
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	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
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	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.

Methods

- 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

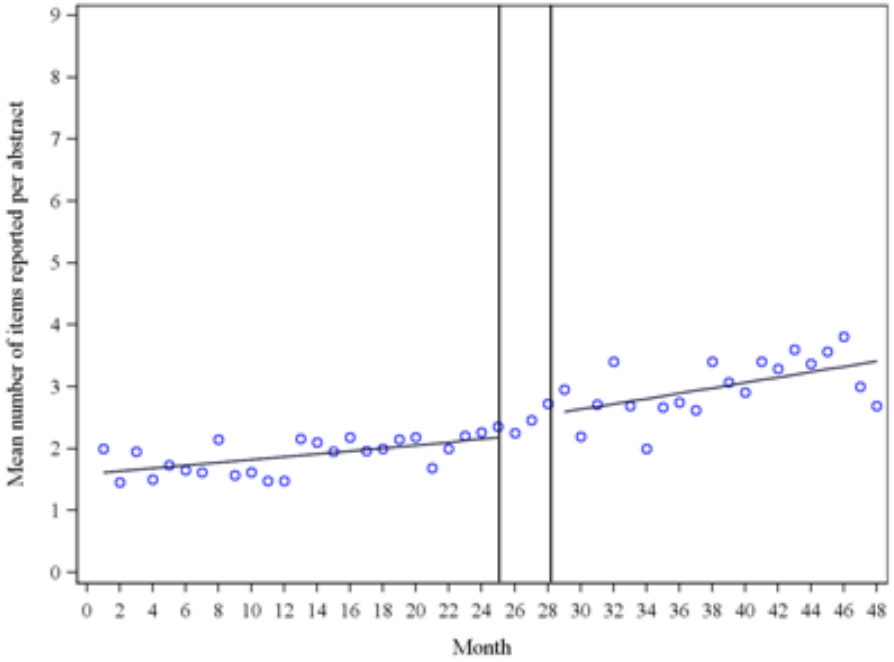
- Mean number of items reported in <50% of the abstracts across the five journals in 2006 (0-9 scale).
- Mean number of items reported in <20% of abstracts across the five journals in 2006 (0-5 scale).

Items poorly reported in 2006

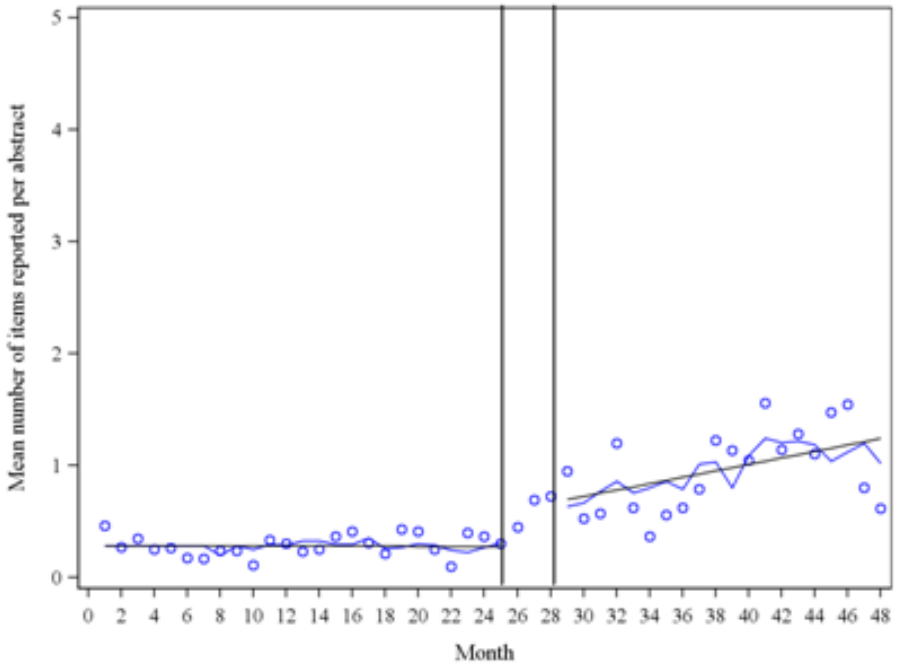
- Trial design (20%)
- Sequence generation (0%)
- Allocation concealment (0%)
- Who was blinded (6%)
- Number participants randomized in each group (43%)
- Number participants analysed in each group (19%)
- Result for each group + effect size (main outcome) (43%)
- Harms (35%)
- Funding source (0%)

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

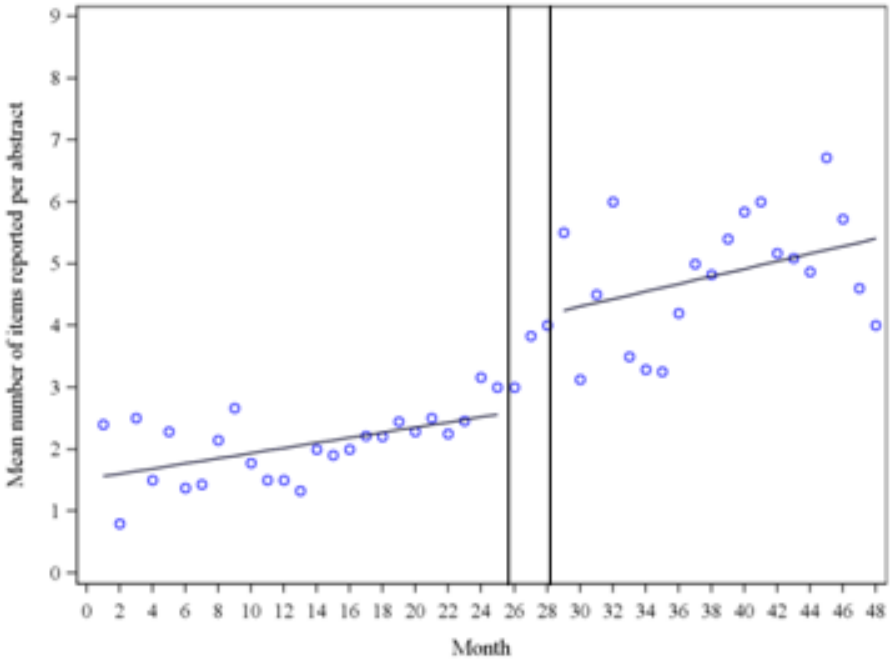


Items reported <20% of abstracts

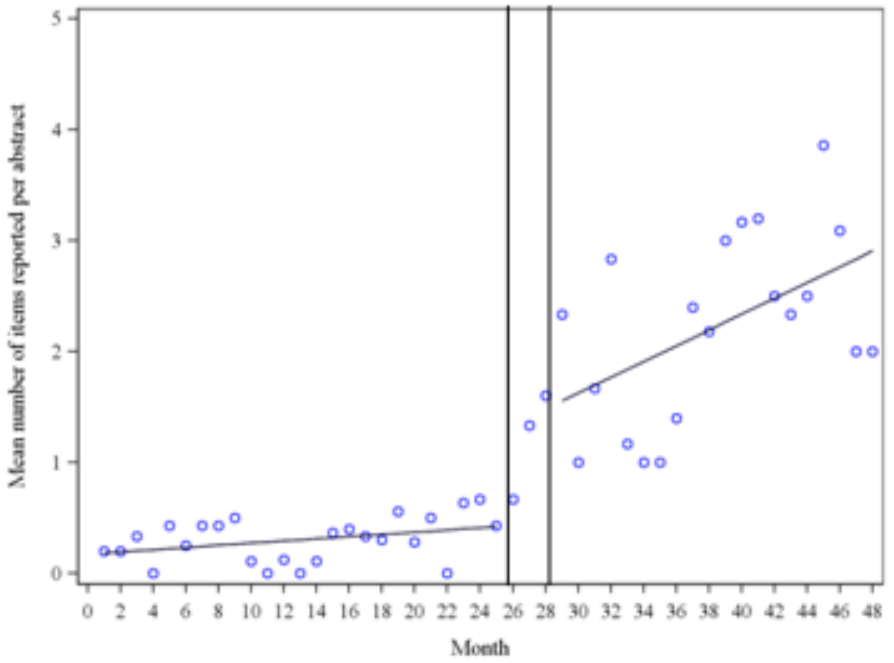


Change in number of items reported before and after introduction of CONSORT for Abstracts – guidelines included in journal's instructions to authors, with active implementation policy (Annals of Internal Medicine, Lancet)

Items reported <50% of abstracts

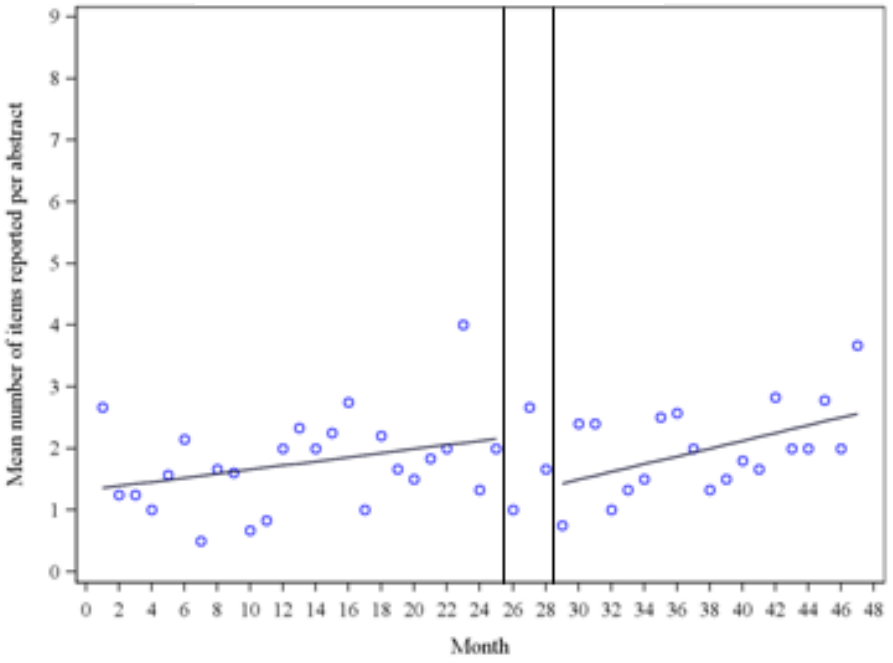


Items reported <20% of abstracts

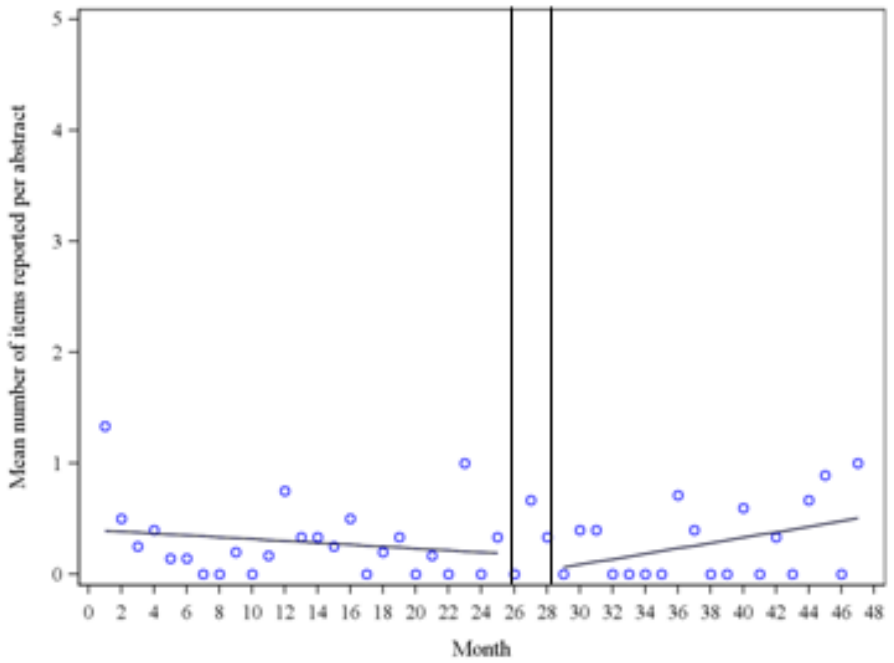


Change in number of items reported before and after introduction of CONSORT for Abstracts – guidelines included in journal's instructions to authors only (BMJ)

Items reported <50% of abstracts

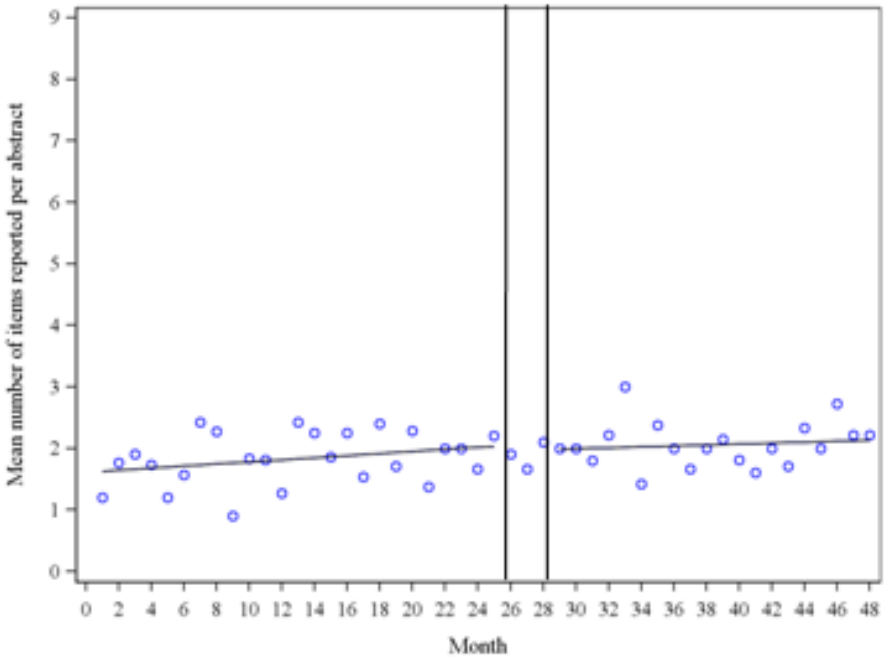


Items reported <20% of abstracts

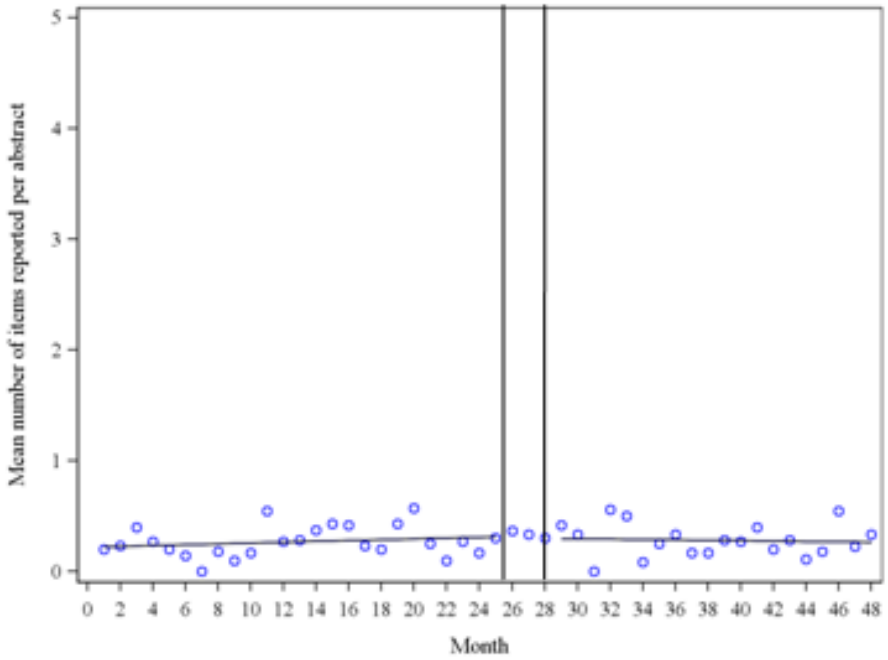


Change in number of items reported before and after introduction of CONSORT for Abstracts – guidelines not mentioned in journal's instructions to authors (JAMA, NEJM)

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.

Acknowledgements

- 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.