# Dissemination experiences from CONSORT and other reporting guidelines

**Doug Altman**

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<Thanks to David Moher>

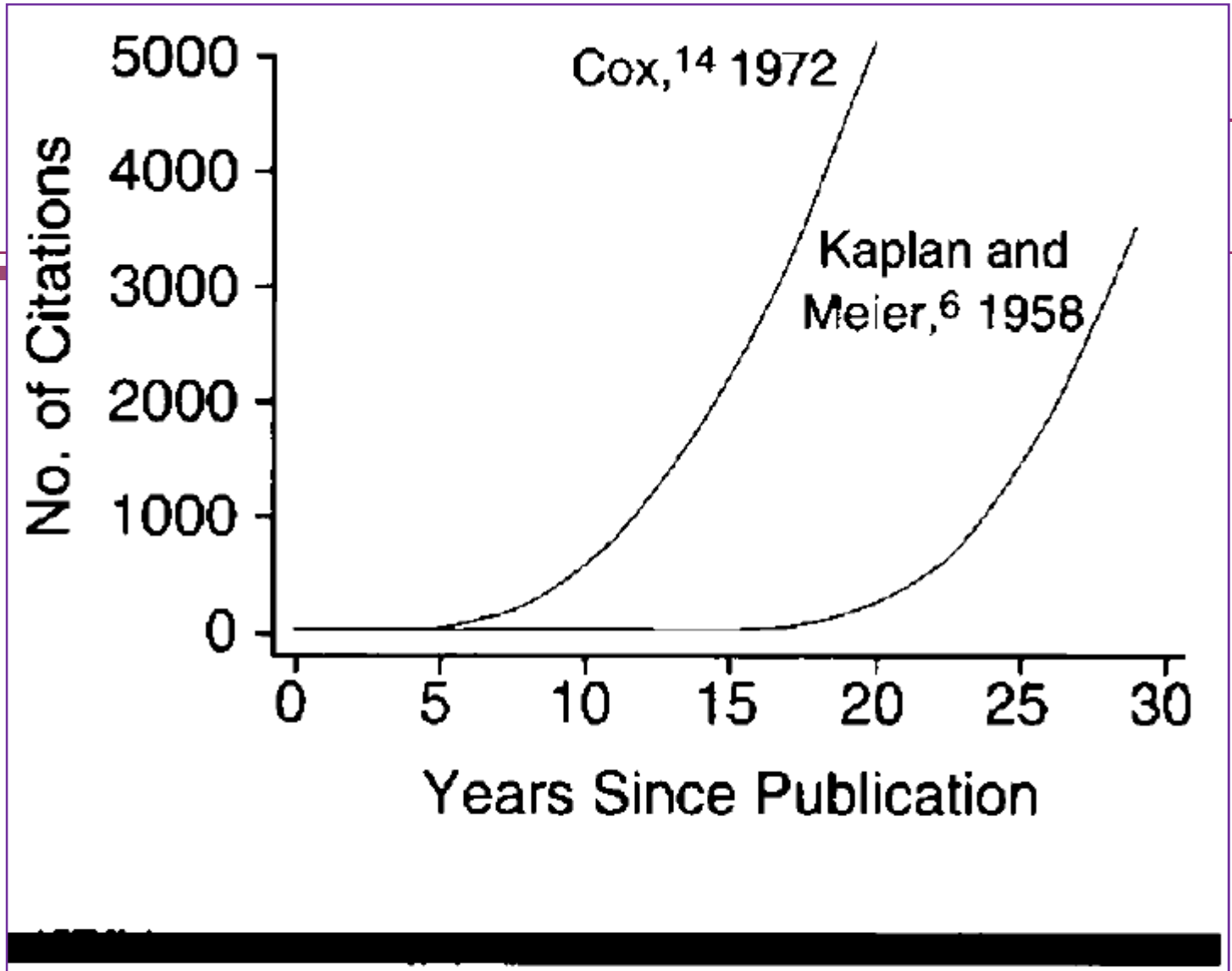



Fig 2.—Cumulative citations in medical journals for two heavily cited articles on survival analysis methods.

[Altman and Goodman, *JAMA* 1994]

*Getting research findings into practice* *BMJ* 1998;317:465–8

# Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings

Lisa A Bero, Roberto Grilli, Jeremy M Grimshaw, Emma Harvey, Andrew D Oxman, Mary Ann Thomson on behalf of the Cochrane Effective Practice and Organisation of Care Review Group

**"Passive dissemination of information is generally ineffective"**

**"It seems necessary to use specific strategies to encourage implementation of research based recommendations and to ensure changes in practice"**

behavioural change.[3 4] In this paper we examine systematic reviews of different strategies for the dissemination and implementation of research findings to identify evidence of the effectiveness of different strategies and to assess the quality of the systematic reviews.

recommendations and to ensure changes in practice

Further research on the relative effectiveness and efficiency of different strategies is required

# Dissemination

- **Passive dissemination is standard**
  - often it's all we do

- **Research findings**
- **Clinical practice guidelines**
- **Methodological advances**
- **Reporting guidelines**

[how might these differ?]

# Importance of transparent reporting of research

- **Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information and reach his or her own conclusions about the results**
  - Relevant?
  - Reliable?
  - Reproducible?

- **Especially important for randomised trials (RCTs)**

**"After reading the trial publication, the oncology care provider should be able to judge the credibility of the results and the risks and benefits and decide on whether to begin recommending the new treatment to patients within his or her practice."** [Dancey et al, *JNCI* 2010]

**"… editors could greatly improve the reporting of clinical trials by providing authors with a list of items that they expected to be strictly reported."**

[DerSimonian R et al, *NEJM* 1982]

# Why we need reporting guidelines

- **Study of 262 reports of randomized trials from most prominent oncology journals** [Duff et al, *JNCI* 2010]

- **10 essential elements about intervention**
  - e.g., drug name, dose, route....
- **Overall, only 11% of articles reported all 10 essential items**

- **Hundreds of other studies reporting similar findings**
  - Reports of research are frequently inadequate

# CONSORT Statement
# *JAMA* 1996

**Special Communication**

## Improving the Quality of Reporting of Randomized Controlled Trials

### The CONSORT Statement

Colin Begg, PhD; Mildred Cho, PhD; Susan Eastwood, ELS(D); Richard Horton, MB; David Moher, MSc; Ingram Olkin, PhD; Roy Pitkin, MD; Drummond Rennie, MD; Kenneth F. Schulz, PhD; David Simel, MD; Donna F. Stroup, PhD

OPEN ACCESS Freely available online

PLoS MEDICINE

Guidelines and Guidance

# CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials

Kenneth F. Schulz[1]*, Douglas G. Altman[2], David Moher[3], for the CONSORT Group[¶]

# RESEARCH METHODS & REPORTING

## CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

David Moher,[1] Sally Hopewell,[2] Kenneth F Schulz,[3] Victor Montori,[4] Peter C Gøtzsche,[5] P J Devereaux,[6] Diana Elbourne,[7] Matthias Egger,[8] Douglas G Altman[2]

**Table 1 | CONSORT 2010 checklist of information to include when reporting a randomised trial***

| Section/Topic | Item No | Checklist item | Reported or |
|---|---|---|---|
| **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 | |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | |
| Sample size | 7a | How sample size was determined | |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | |
| | 11b | If relevant, description of the similarity of interventions | |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | |
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | |

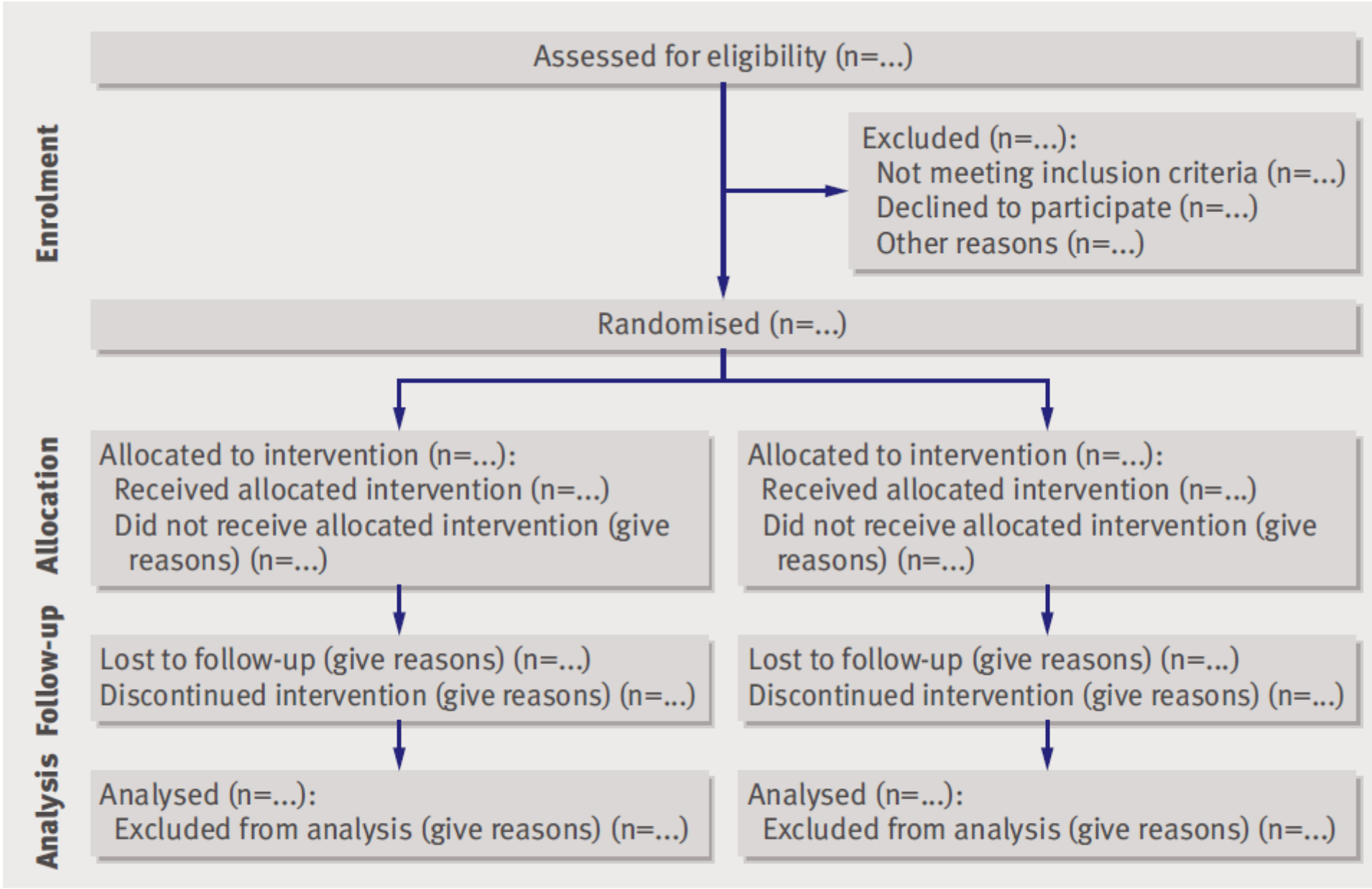



**Fig 1 |** Flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis)[52-54]

# CONSORT 1996

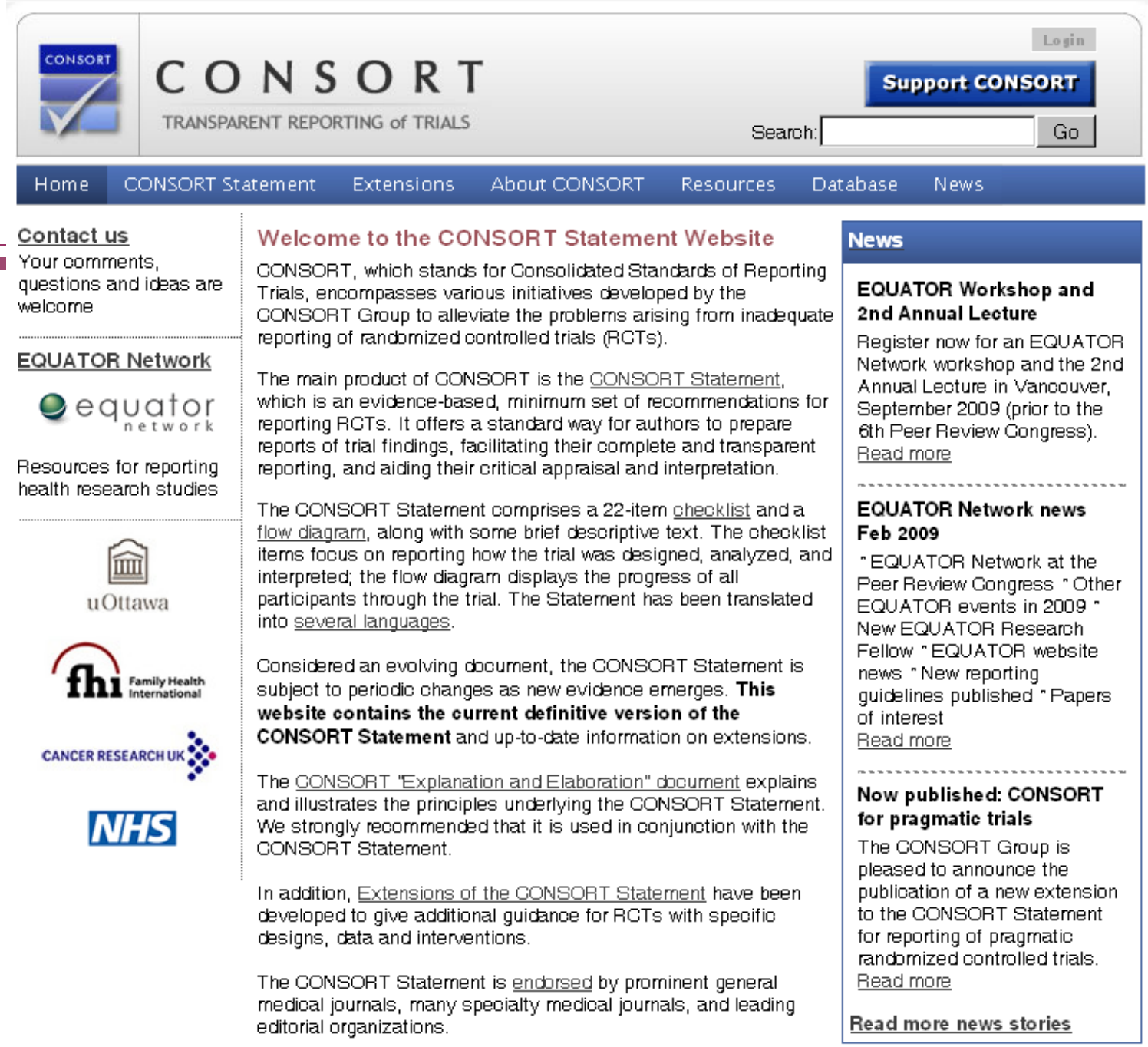
- **Published in a top journal (*JAMA*)**
- **Early support from several leading journals**
  - Some with editorials
- **What else could be done?**

# CONSORT: what else could we do?

- **Press release / talk to journalists**
- **Multiple (duplicate) publication**
- **Accompanying publications**
  - Explanation and elaboration
- **Website**
- **Conference presentations**
- **Commentaries**
  - By authors
  - By others
- **Review subsequence adherence**
- **…**

# CONSORT:
# evolution of publication strategy

| | |
|---|---|
| **1996** | **1 journal** |
| **2001** | **3 journals (+ 12 later, incl. other languages)**<br>**+ "Explanation and elaboration" (1 journal)** |
| **2010** | **9 journals (+2 later)**<br>**+ "Explanation and elaboration" (3 journals)**<br>**+ article in Lancet** |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Welcome to the CONSORT Statement Website
CONSORT, which stands for Consolidated Standards of Reporting Trials, encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs).
The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.
The CONSORT Statement comprises a 22-item checklist and a flow diagram, along with some brief descriptive text. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted; the flow diagram displays the progress of all participants through the trial. The Statement has been translated into several languages.
Considered an evolving document, the CONSORT Statement is subject to periodic changes as new evidence emerges. This website contains the current definitive version of the CONSORT Statement and up-to-date information on extensions.
The CONSORT "Explanation and Elaboration" document explains and illustrates the principles underlying the CONSORT Statement. We strongly recommended that it is used in conjunction with the CONSORT Statement.
In addition, Extensions of the CONSORT Statement have been developed to give additional guidance for RCTs with specific designs, data and interventions.
The CONSORT Statement is endorsed by prominent general medical journals, many specialty medical journals, and leading editorial organizations.
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Register now for an EQUATOR Network workshop and the 2nd Annual Lecture in Vancouver, September 2009 (prior to the 6th Peer Review Congress).
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Now published: CONSORT for pragmatic trials
The CONSORT Group is pleased to announce the publication of a new extension to the CONSORT Statement for reporting of pragmatic randomized controlled trials.
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Read more news stories
CONSORT is part of a broader effort, to improve the reporting of different types of health research, and

# Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement

John P.A. Ioannidis, MD; Stephen J.W. Evans, MSc; Peter C. Gøtzsche, MD, DrMedSci; Robert T. O'Neill, PhD; Douglas G. Altman, DSc; Kenneth Schulz, PhD; and David Moher, PhD, for the CONSORT Group*

**In response to overwhelming evidence and the consequences of poor-quality reporting of randomized, controlled trials (RCTs), many medical journals and editorial groups have now endorsed the CONSORT (*Con*solidated *S*tandards *o*f *R*eporting *T*rials) statement, a 22-item checklist and flow diagram. Because CONSORT primarily aimed at improving the quality of reporting of efficacy, only 1 checklist item specifically addressed the reporting of safety.**

**Considerable evidence suggests that reporting of harms-related data from RCTs also needs improvement. Members of the CONSORT Group, including journal editors and scientists, met in Montebello, Quebec, Canada, in May 2003 to address this problem. The result is the following document: the standard CONSORT checklist with 10 new recommendations about reporting harms-related issues, accompanying explanation, and examples to highlight specific aspects of proper reporting.**

**We hope that this document, in conjunction with other CONSORT-related materials (www.consort-statement.org), will help authors improve their reporting of harms-related data from RCTs. Better reporting will help readers critically appraise and interpret trial results. Journals can support this goal by revising Instructions to Authors so that they refer authors to this document.**

*Ann Intern Med.* 2004;141:781-788. www.annals.org

For author affiliations, see end of text.

For definitions of terms, see Glossary.

*For a list of members of the CONSORT Group, see Appendix 1, available at www.annals.org.

# Likely factors in success of CONSORT

- **Membership of group**
  - Methodologists / Trialists / Editors
- **Reporting rather than conduct**
- **Evidence-based**
- **Focus on main issues**
  - 'One side of paper'
- **No competitors**
- **High profile publications**
- **Endorsements and support**


*"My question is: Are we making an impact?"*

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# Support for CONSORT

- **Today > 600 journals endorse CONSORT**
- **Important editorial groups endorse CONSORT**
  - ICMJE, CSE, WAME

- **Reviews of journals' Instructions to authors:**
  - 167 journals in 2003 [Altman 2005]
    - 22% mentioned CONSORT
  - 165 journals in 2007 [Hopewell et al, 2008]
    - 38% mentioned CONSORT
      - 37% of these: "requirement"

**"Manuscripts that fail to comply with CONSORT guidelines will not be reviewed for publication."**
*[Gastroenterology]*

**"Please report these in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement."** *[BMJ]*

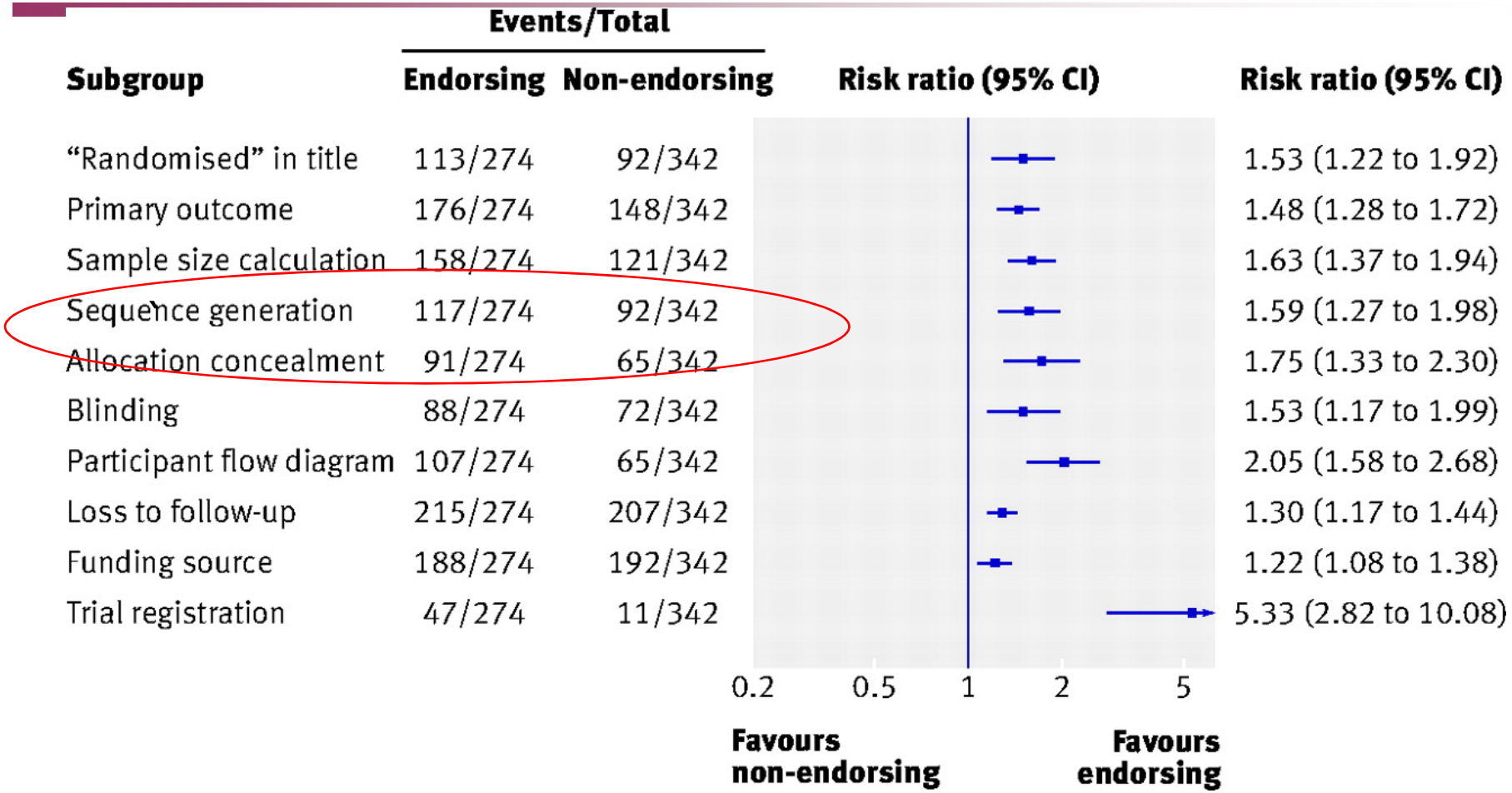
**"Investigators embarking on randomized controlled studies may wish to consider the CONSORT statement."** *[Br J Surgery]*

# Does CONSORT improve the quality of reporting of clinical trial reports?

- **CONSORT systematic review** [Plint et al, *Med J Aust* 2006]
  - Pre versus post CONSORT endorsement
  - Endorsers vs non-endorsers
  - 8 studies included
  - CONSORT endorsement was associated with improved reporting
    - Weak evidence

- **Review update**
  - Ongoing (2011)
  - 52 studies assessed CONSORT impact!

# Is CONSORT endorsement associated with improved reporting? (2006)




[Hopewell et al, *BMJ* 2010]

# Incentives?

- **Why should authors comply with CONSORT ?**

- **It's the right thing to do!**
  - Transparency maximises value to readers
- **Journals expect it (but largely don't enforce it)**

**But**

- **It's more work**
- **May provide more ammunition for peer reviewers and editors to reject the paper**

# Mandating authors

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## Editorial

### Improving the Quality of Research Reporting: *Headache* Steps Up to the Plate

Elizabeth W. Loder, MD, MPH; Donald B. Penzien, PhD

*Good reporting is not an optional extra: it is an essential component of good research . . . we all share this obligation and responsibility.*
Professor Douglas Altman, Centre for Statistics in Medicine, University of Oxford, United Kingdom.[1]

Have you ever read a research article and searched in vain for important details about how the work was conducted? Perhaps you wanted to know how the authors decided on the sample size, whether the subjects in the study were similar to patients you treat, or how many participants dropped out of the study over time. Have you ever searched Medline for the answer to a clinical question and been unable to glean even basic information from the abstracts returned by your search?

Research reports and abstracts should contain sufficient information to meet the needs of their many end users, but often they do not.[2] This has bad consequences for doctors, patients, and policymakers who rely on them to make treatment and funding decisions. Other researchers, too, rely on research reports to plan their own projects. And increasingly, previously published research evidence is summarized in systematic reviews and meta-analyses. All of these activities are dependent upon the quality of information in the original research report.

If you have submitted an article to *Headache* since the beginning of this year, you probably noticed that you were asked to upload a reporting checklist along with your work. In an attempt to improve the quality of research reports in the journal, *Headache* now requires a completed reporting checklist as a condition of article submission. The electronic manuscript submission system used by the journal has been updated so that the appropriate checklist appears automatically once a prospective author selects a submission category. This change brings our policies in line with those of the leading academic journals.[3,4]

The published report of a study is the only enduring evidence that the research has been carried out, and of exactly how it has been performed. Good reports should contain a clear explanation of the study methods, describe statistical techniques in enough detail to allow verification of the results from original data, report all results, and interpret and present findings in a balanced and forthright way. If important information is missing from the report, crucial data are

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*Conflict of Interest:* Dr Loder receives salary support from the British Medical Journal in exchange for services as a clinical editor. She is an associate editor of Headache and reports no other conflicts of interest. Dr Penzien reports no conflicts of interest.



**"If you have submitted an article to *Headache* since the beginning of this year, you probably noticed that you were asked to upload a reporting checklist along with your work.**

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  - This change brings our policies in line with those of the leading academic journals."



**Loder & Penzien, *Headache* 2009**

# Other reporting guidelines

- **Several other guidelines have followed the CONSORT model:**
  - QUOROM (now PRISMA), STROBE, STARD, REMARK, TREND etc
  - See EQUATOR Network website (>100)

- **A few studies of adherence in publications**
- **Some limited evidence from reviews journals' Instructions to Authors**
  - Much less support than CONSORT

# STARD (2003)

1999 vs 2004

- **There was no significant improvement in mean number of reported items for the articles published after the introduction of the STARD statement**

2001 vs 2004

- **"The quality of reporting of diagnostic accuracy studies has improved slightly over time, without a more pronounced effect in journals that adopted the STARD statement."**
  [Smidt et al, *Neurology* 2006]

2001, 2002, 2004, 2005

- **"… the frequency with which individual items on the STARD checklist were reported before and after STARD statement publication has remained relatively constant, with little difference between STARD and non-STARD journals."**
  [Wilczynski, *Radiology* 2008]

# Other reporting guidelines

- **Meerpohl et al 2010 (2008 data)**
  - 69 paediatric journals' Instructions to authors
    - 20%  mentioned CONSORT
    - 4% to 6% mentioned other reporting guidelines

# Generalizations across reporting guidelines

- Endorsement is limited
- Adherence is worse
- Reporting guidelines do not appear to be part of the peer review process
- Reporting guidelines appear to work, if only modestly
- Educational modules appear non-existent for authors, peer reviewers, and editors

# "KT Canada" project: objectives

[Knowledge translation (KT) = dissemination]

- **Identify barriers and facilitators to the adoption of reporting guidelines by health care journals by editors phone interviews and surveys**
- **Design a KT strategy to improve the uptake of reporting guidelines**
- **Undertake a controlled before and after feasibility study to determine the potential benefits of the strategy**

# Interviews with Editors

- **N=7 editors:**
  **6 CONSORT-endorsing journals, 1 non-endorser**
  - Surprisingly difficult to identify journals that did not, in some capacity, endorse CONSORT
- **Key findings:**
  - Journals open to trying new practices
  - Want evidence showing link between reporting quality and health care practice
  - Need to demonstrate flexibility of CONSORT implementation
  - Include educational component with KT strategy

# Survey of Editors

- **297 editors approached; 79 completed survey**
  - > 75% respondents were editors in chief

- **Are authors REQUIRED to submit a completed CONSORT checklist before the journal decides whether to send a manuscript for peer review?**
  - Yes: 38% (20); No: 62% (33)
- **Does your journal REQUIRE that peer reviewers complete their assessments following the CONSORT guidelines?**
  - Yes: 13.5% (7); No: 86.5% (45)
- **Do your editors and/or editorial staff use the CONSORT guidelines to help make a final publication decision?**
  - Always: 35% (18); Sometimes: 49% (25)

# Survey of Editors

- **Which of the following, if any, do you feel are disadvantages to using the CONSORT statement within the editorial process?**
  - Strict endorsement of CONSORT can lead to formulaic writing: 35%
  - Strict endorsement of CONSORT can diminish the importance of clinical content: 18%
  - I do not feel there are any drawbacks to using the CONSORT statement within the editorial process: 55%

# Survey of Editors

- **What would (further) facilitate the endorsement of CONSORT in your journal?**
  - Web-enabled applications (e.g., programs to connect CONSORT submission with other documents at peer-review): 81%
  - Links to educational tutorials about CONSORT items (e.g., webinars): 59%

# KT Strategy

- **2 CONSORT uptake strategies:**

**Endorsement strategy:**

- **Target CONSORT non-endorsing journals;**
  - Show evidence of reporting quality associated with CONSORT
  - Provide examples of how CONSORT is helping other journals

**Adherence strategy:**

- **Target CONSORT endorsers: publishers, editors, peer-reviewers, authors**
  - Educational resources
  - Web resource to complete CONSORT checklist

# Learning from CONSORT


# For SPIRIT: take implementation seriously

- **Need champions**
  - Ethics groups
  - Trial registers (Clinicaltrials.gov; WHO trials portal)
  - Funding agencies
  - Regulatory agencies
  - Journals
  - Trial groups
  - Educators
- **Promote evidence that use of reporting guidelines is associated with better reporting, including enhanced transparency**
  - Evaluate SPIRIT and encourage others to do likewise
- **Address when to use SPIRIT**
  - Develop educational tools to facilitate authors, peer reviewers and editors, particularly managing editors

# Closing comments

- **Awareness (knowledge) is necessary but not sufficient to change behaviour**
- **Dissemination activities speed up awareness**
  - Should translate into actions
  - Probably slowly
- **Lack of incentives**
- **Dissemination activities take time and resources**