Launching the Canadian EQUATOR Centre

past, present, and future

David Moher
Director, Canadian EQUATOR Centre

16th October 2014
“Complexity is the enemy of transparency”
NOTICE TO CUSTOMERS

Effective Sunday, December 23, 2012 Route 106 will be extended to and from downtown in the early morning on an hourly basis. These changes will provide 24/7 service and improved connections to the Children’s Hospital of Eastern Ontario and The Ottawa Hospital, General Campus on Smyth Road.

AVIS AUX USAGERS

Outline of talk

- **Past**
  - Developing CONSORT
  - Developing PRISMA

- **Present**
  - CONOSRT 2010
  - SPIRIT 2013
  - CONSORT extensions
  - Assessing whether CONSORT improves completeness of reporting

- **Future**
  - PRISMA-P
  - Helping guide the developing of reporting guidelines
    - CONSORT-C
  - Endorsement and implementation of reporting guidelines
    - Bring knowledge translation into the picture
  - Training editors, peer reviewers, and authors
Ottawa, Canada, October 7th and 8th 1993
<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
<th>Unable to Determine</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. State the unit of assignment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. State the method used to generate the intervention assignment schedule.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Describe the method used to conceal the intervention assignment schedule from participants and clinicians until recruitment was complete and irrevocable.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Describe the method(s) used to separate the generator and executor of the assignment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Describe an auditable process of executing the assignment method.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Identify and compare the distributions of important prognostic characteristics and demographics at baseline.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. State the method of masking.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. State how frequently care providers were aware of the intervention allocation, by intervention group.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. State how frequently participants were aware of the intervention allocation, by intervention group.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. State whether (and how) outcome assessors were aware of the intervention allocation, by intervention group.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. State whether the investigator was unaware of trends in the study at the time of participant assignment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. State whether masking was successfully achieved for the trial.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. State whether the data analyst was aware of intervention allocation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. State whether individual participant data were entered into the trial database without awareness of intervention allocation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. State whether the data analyst was masked to intervention allocation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Describe fully the numbers and flow of participants, by intervention group, throughout the trial.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. State clearly the average duration of the trial, by intervention group, and the start and closure dates for the trial.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Report the reason for dropout clearly, by intervention group.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Describe the actual timing of measurements, by intervention group.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. State the predefined primary outcome(s) and analyses clearly.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Describe clearly whether the primary analysis has used the intention-to-treat principle.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. State the intended sample size and its justification.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23. State and explain why the trial is being reported now.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. Describe and/or compare trial dropouts and completers.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. State or reference the reliability, validity, and standardization of the primary outcome.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. Define what constituted adverse events and how they were monitored by intervention group.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. State the appropriate analytical techniques applied to the primary outcome measure(s).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Present appropriate measures of variability (eg, confidence intervals for primary outcome measures).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. Present sufficient simple (unadjusted) summary data on primary outcome measures and important side effects so that the reader can reproduce the results.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. State the actual probability value and the nature of the significance test.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31. Present appropriate interpretations (eg, NS, no effect; P&lt;05, proof).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32. Present the appropriate emphasis in displaying and interpreting the statistical analysis, in particular controlling for unplanned comparisons.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Asilomar, USA, March 14th to 16th 1994

[Image of a wave crashing against rocks]

[Map showing locations of Asilomar, Monterey Bay, Pacific Grove, Pebble Beach, Carmel, and other nearby cities]

[Equator Network logo]
Table 1. Checklist of Information for Inclusion in Reports of Clinical Trials

In reports of clinical trials, the Methods section should detail the study design in terms of the final plan, which should be in written form and agreed upon by investigators before the study begins. An example of such a plan is a protocol submitted to obtain institutional, commercial, or governmental approval for the proposed human experimentation; for example, in the United States, a protocol submitted to an institutional review board (IRB). The Results section should include two parts: 1) details of the actual conduct of the study, and 2) the clinical findings. Clinical investigators and journal peer reviewers are encouraged to use the following checklist of general content as an aid in writing and reviewing reports of clinical trials:

Introduction, include:
A priori hypothesis, specific protocol objectives

Methods
Study as designed, include:
- Planned study population, including controls
- Inclusion and exclusion criteria
- Planned subgroup analyses
- Prognostic factors that may affect study results
- Outcome measures and minimum difference(s) to be considered clinically important
- Planned treatment interventions
- Method of assignment of subjects to treatments (for example, randomization method, blinding or masking procedure, matching criteria)
- Planned sample size, power calculations
- Rules for stopping the study
- Methods of statistical analysis in sufficient detail to permit replication

Results
Study as conducted, include:
- Inclusive dates of accrual of study population
- Sample size achieved
- How many subjects were excluded or withdrew and the reasons
- Demographics and clinical characteristics of the study population, including controls
- How the study as conducted deviated from the study as planned and the reasons (for example, compliance)

Study findings, include
- Estimates of treatment effects, stated as comparisons among treatment groups (for example, differences in risks, rates, or means of outcome measures, as well as exact P values, not just P < 0.05 or P > 0.05)
- Measures of precision for outcome measures and for estimates of treatment effects (confidence intervals, standard errors)
- Summary data and appropriate descriptive statistics
- Complications of treatment
- Repository where original data can be obtained (for example, principal investigator, or NAPS*)

Discussion, include:
- Interpretation of study findings
- Results considered in the context of results in other trials reported in the literature
“so the next step is for members of the two groups to get together and decide which parts of which proposal are worthwhile”
<table>
<thead>
<tr>
<th>Heading</th>
<th>Subheading</th>
<th>Description</th>
<th>Was It Reported?</th>
<th>On What Page No.?</th>
</tr>
</thead>
</table>
| **Title**       |                                | Identify the study as a randomized trial.  

**Abstract**  
Use a structured format.  

**Introduction**  
State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses.  

**Methods**  

**Protocol**  
Describe  

Planned study population, together with inclusion/exclusion criteria.  

Planned interventions and their timing.  

Primary and secondary outcome measure(s) and the minimum important difference(s), and indicate how the target sample size was powered.  

Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention-to-treat basis.  

Prospectively defined stopping rules (if warranted).  

**Assignment**  
Describe  

Unit of randomization (e.g., individual, cluster, geographic).  

Method used to generate the allocation schedule.  

Method of allocation concealment and timing of assignment.  

Method to separate the generator from the executor of assignment.  

**Masking (Blinding)**  
Describe mechanism (e.g., capsules, tablets): similarity of treatment characteristics (e.g., appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful blinding among participants, person doing intervention, outcome assessors, and data analysts.  

**Results**  

**Participant Flow and Follow-up**  
Provide a trial profile (Figure) summarizing participant flow, numbers and timing of randomization, assignment, interventions, and measurements for each randomized group.  

**Analysis**  
State estimated effect of intervention on primary and secondary outcome measures, including a point estimate and measure of precision (confidence interval).  

State results in absolute numbers when feasible (e.g., 10/20, not 50%).  

Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication.  

Describe prognostic variables by treatment group and any attempt to adjust for them.  

Describe protocol deviations from the study as planned, together with the reasons.  

State specific interpretation of study findings, including sources of bias and imprecision (internal validity) and discussion of external validity, including appropriate quantitative measures when possible.  

State general interpretation of the data in light of the totality of the available evidence.  

**Comment**  
Registered or Eligible Patients (n=…)

Not Randomized (n=…)

Reasons (n=…)

Received Intervention as Allocated (n=…)

Did Not Receive Standard Intervention as Allocated (n=…)

Received Intervention as Allocated (n=…)

Did Not Receive Intervention as Allocated (n=…)

Followed Up (n=…)

Timing of Primary and Secondary Outcomes

Withdrawn (n=…)

Intervention Ineffective (n=…)

Lost to Follow-up (n=…)

Other (n=…)

Followed Up (n=…)

Timing of Primary and Secondary Outcomes

Withdrawn (n=…)

Intervention Ineffective (n=…)

Lost to Follow-up (n=…)

Other (n=…)

Completed Trial (n=…)

Completed Trial (n=…)
The QUOROM Statement

<table>
<thead>
<tr>
<th>Heading</th>
<th>Subheading</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td></td>
<td>Identify the report as a systematic review of RCTs*</td>
</tr>
<tr>
<td>Abstract</td>
<td></td>
<td>Use a structured format*</td>
</tr>
<tr>
<td></td>
<td>Objectives</td>
<td>The clinical question explicitly</td>
</tr>
<tr>
<td></td>
<td>Data sources</td>
<td>The databases (e.g., Medline), and other information sources</td>
</tr>
<tr>
<td></td>
<td>Randomization</td>
<td>The randomization scheme (e.g., by blocks of 4 or by coin flip)</td>
</tr>
<tr>
<td></td>
<td>Blinding</td>
<td>The details of blinding (e.g., who was blinded and at what stages)</td>
</tr>
<tr>
<td></td>
<td>Analysis</td>
<td>Methods for assessing bias and heterogeneity</td>
</tr>
<tr>
<td></td>
<td>Results</td>
<td>Characteristics of the RCTs included and excluded; qualitative and quantitative findings (e.g., point estimates and confidence intervals, and subgroup analyses)</td>
</tr>
<tr>
<td></td>
<td>Conclusion</td>
<td>The limitations</td>
</tr>
</tbody>
</table>

**Introduction**

The explicit clinical question, biological rationale for the intervention, and rationale for review

**Methods**

The information sources, selection criteria, strategies, and the methods for identifying, screening, assessing the eligibility of studies, and data abstraction

Selection criteria

The criteria used to select the cases (e.g., age, sex) and how the study population was defined

Data abstraction

The criteria used to select the studies (e.g., age, sex) and how the study population was defined

**Quantitative data synthesis**

The principal measures of effect (e.g., relative risk, odds ratio) and the method of combining results (e.g., fixed-effects model; inverse variance method; random-effects model; Mantel-Haenszel method; fixed-effects model; random-effects model) |

**Discussion**

**Summary of findings:** Discuss clinical importance, overall evidence, and clinical utility; interpret the results in light of the variability of study results; and suggest further research needs

**RCTs identified and screened for retrieval (n=...)**

**RCTs excluded, with reasons (n=...)**

**RCTs retrieved for more detailed evaluation (n=...)**

**RCTs excluded, with reasons (n=...)**

**Potentially appropriate RCTs to be included in the meta-analysis (n=...)**

**RCTs excluded from meta-analysis, with reasons (n=...)**

**RCTs included in meta-analysis (n=...)**

**RCTs withdrawn, by outcome, with reasons (n=...)**

**RCTs with usable information, by outcome (n=...)**
### PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

**Section/Topic** | # of records identified through database searching | # of additional records identified through other sources  
--- | --- | ---  
**Title** | 1 Identify the report as a systematic review, meta-analysis, or both.  
**Abstract** | 2 Include a structured summary including all applicable background objectives, study aims, study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.  
**Introduction** | 3 Describe rationale for the review in the context of what is already known.  
**Objectives** | 4 Provide an explicit statement of questions being addressed with reference to participants, interventions, comparators, outcomes, and study design (PICOs).  
**Methods** | 5 Indicate if a review protocol exists, and if and where it can be accessed (e.g., Web address), and if available, provide registration information including registration number.  
**Eligibility criteria** | 6 Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.  
**Information sources** | 7 Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.  
**Search** | 8 Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.  
**Study selection** | 9 State the process for selecting studies (i.e., assessing eligibility, included in systematic review, and, if applicable, included in the meta-analysis).  
**Data collection process** | 10 Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.  
**Data items** | 11 List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.  
**Risk of bias in individual studies** | 12 Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.  
**Summary measures** | 13 State the principal summary measures (e.g., risk ratio, difference in means) for each meta-analysis.  
**Synthesis of results** | 14 Describe methods of handling data and combining results of studies. If done, include measures of consistency (e.g., I²) for each meta-analysis.  
**Risk of bias across studies** | 15 Specify any assessment of risk of bias that may affect validity of the results of individual studies (e.g., publication bias, selective reporting within studies).  
**Additional analyses** | 16 Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression) if done, indicating which were pre-specified.  
**Results** | 17 Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.  
**Study characteristics** | 18 For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.  
**Risk of bias within studies** | 19 Present data on risk of bias of each study and, if available, any summary level (see item 15).  
**Results of individual studies** | 20 For all outcomes considered (benefits or harms), present, for each study, its simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.  
**Synthesis of results** | 21 Present results of each meta-analysis done, including confidence intervals and measures of consistency.  
**Risk of bias across studies** | 22 Present results of any assessment of risk of bias across studies (see item 15).  
**Additional analysis** | 23 Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression (see item 16)).  
**Discussion** | 24 Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers).  
**Limitations** | 25 Discuss limitations at study and outcome level (e.g., risk of bias, inclusion criteria level (e.g., incomplete retrieval of identified research, reporting bias).  
**Conclusions** | 26 Provide a general interpretation of the results in the context of other evidence and implications for future research.  
**Funding** | 27 Describe sources of funding for the systematic review and other support (e.g., supply of data, role of funders for this systematic review).  

---

**Total # of duplicates removed**  
**Total # of articles assessed for eligibility**  
**Total # of studies included in qualitative synthesis of systematic review**  
**Total # of studies included in quantitative synthesis of systematic review**
How to develop reporting guidelines

Guidance and Guidance

Guidance for Developers of Health Research Reporting Guidelines

David Moher1,2, Kenneth F. Schulz3, Iveta Simera4, Douglas G. Altman4

1 Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, 2 Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada, 3 Family Health International, Research Triangle Park, North Carolina, United States of America, 4 Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom

Introduction

Publishing health research is a thriving, and increasing enterprise. On any given month about 65,000 new articles are indexed in PubMed, the United States National Library of Medicine’s public access portal for health-related publications. However, the quality of reporting in most health care journals remains inadequate. Glazious and colleagues [1] assessed descriptions of given treatments in 80 trials and systematic reviews for which summaries were published during one year (October 2005 to October 2006) in Evidence-Based Medicine, a journal that is aimed at physicians working in primary care and general medicine. Treatment descriptions were inadequate in 41 of the original published articles, which made their use in clinical practice difficult if not impossible to replicate. This is just one of numerous examples of a large and disturbing literature indicating the general failure in the quality of reporting health research [2-6]. Many publications lack clarity, transparency, and completeness in how the authors actually carried out their research.

Inadequate reporting is problematic for several reasons. If authors do not provide sufficient details concerning the conduct of their study, readers are left with an incomplete picture of what was done. As such, they are not able to judge the reliability of the results and interpret them. There are also ethical and moral reasons for reporting research adequately [7].

The EQUATOR (Enhancing the QUality and Transparency Of Health Research) Network is a new international initiative seeking to improve the quality of scientific publications by promoting transparent and accurate reporting [8]. The Network (http://www.equator-network.org) provides resources and training relating to the reporting of health research and assists in the development, dissemination, and implementation of reporting guidelines. As part of its initial resource development, the Network’s Web site contains a comprehensive and up-to-date database of reporting guidelines relevant to health research. A review. And research funders can benefit from introducing reporting guidelines into the research application system [11]. Ensuring clear and complete reporting of funded research through the use of reporting guidelines should facilitate more efficient use of the new findings and bring better returns on research investments. There are enormous potential benefits of good reporting. However, despite the impressive recent upsurge in the number and range of reporting guidelines, the literature on how individual guidelines were developed remains sparse [12,13] and there is no generic guidance on how to develop one.

In this paper we update and expand upon an earlier effort to outline a strategy for developing reporting guidelines that was published only in Spanish [14]. We recognize that there is no single best or correct approach. However, this paper benefits from our collective experiences of helping to develop more than ten reporting guidelines over the last 16 years, over which period these ideas have evolved considerably. If reporting guidelines are to be useful and more widely disseminated, they need to be developed using robust and widely accepted methodologies.

This strategy assumes the involvement of an executive group to facilitate the guideline development and the expectation of having a face-to-face meeting as part of the reporting guideline development. We propose 18 steps to occur in five phases, which are outlined in Table 1.

Published February 16, 2010

Copyright: © 2010 Moher et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Funding: No specific funding was received to write this piece. DGA is supported...
# CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item number</th>
<th>Checklist Item</th>
<th>Reported on Page number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1a</td>
<td>Identification of a randomized trial in the title</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts 11a, 11b)</td>
<td></td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and objectives</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
<td></td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial design</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial), including allocation ratio</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Setting and location where the data were collected</td>
<td></td>
</tr>
<tr>
<td>Interventions</td>
<td>5a</td>
<td>The intervention for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Completely defined protocol for treatment regimen, including how and when they were assigned</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Any change to trial outcomes after the trial commenced, with reasons</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>How sample size was determined</td>
<td></td>
</tr>
<tr>
<td>Randomization</td>
<td>7a</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
<td></td>
</tr>
<tr>
<td>Sequence generation</td>
<td>7b</td>
<td>Method used to generate the random allocation sequence</td>
<td></td>
</tr>
<tr>
<td>Allocation concealment mechanism</td>
<td>8a</td>
<td>Method used to implement the random allocation sequence (such as sequentially numbered envelopes), describing any steps taken to conceal the sequence until interventions were assigned</td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td>9a</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9b</td>
<td>If used, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how</td>
<td></td>
</tr>
<tr>
<td>Blinding</td>
<td>10a</td>
<td>If used, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10b</td>
<td>If relevant, description of the similarity of interventions</td>
<td></td>
</tr>
<tr>
<td>Statistical methods</td>
<td>11a</td>
<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11b</td>
<td>Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant flow (a diagram is strongly recommended)</td>
<td>12a</td>
<td>For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12b</td>
<td>For each group, losses and exclusions after randomization, together with reasons</td>
<td></td>
</tr>
<tr>
<td>Recruitment</td>
<td>13a</td>
<td>Data defining the periods of recruitment and follow-up</td>
<td></td>
</tr>
<tr>
<td>Randomization data</td>
<td>14a</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
<td></td>
</tr>
<tr>
<td>Number analyzed</td>
<td>15a</td>
<td>For each group, number of participants randomized, included in each analysis and who the analysis was by original assigned groups</td>
<td></td>
</tr>
<tr>
<td>Outcome and estimation</td>
<td>16a</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>16b</td>
<td>For binary outcomes, presentation of both absolute and relative effect size is recommended</td>
<td></td>
</tr>
<tr>
<td>Ancillary analysis</td>
<td>17a</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing primary from secondary investigations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>17b</td>
<td>All important harms or unanticipated effects in each group (specific guidance, see CONSORT for harms 21a)</td>
<td></td>
</tr>
<tr>
<td>Discussion</td>
<td>Limitations</td>
<td>20a</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and/or relevance, multiplicity of analyses</td>
</tr>
<tr>
<td>Generalizability</td>
<td>21a</td>
<td>Generalizability external validity, applicability of the trial findings</td>
<td></td>
</tr>
<tr>
<td>Interpretation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>22a</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
<td></td>
</tr>
<tr>
<td>Other information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration</td>
<td>23a</td>
<td>Registration number and name of trial registry</td>
<td></td>
</tr>
<tr>
<td>Protocol</td>
<td>24a</td>
<td>Where the full trial protocol can be accessed, if available</td>
<td></td>
</tr>
<tr>
<td>Funding</td>
<td>25a</td>
<td>Sources of funding and other support such as scope of other, role of funders</td>
<td></td>
</tr>
</tbody>
</table>
Welcome to the CONSORT Website

CONSORT stands for Consolidated Standards of Reporting Trials and encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials.

The CONSORT Statement

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting randomized trials. 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 25-item checklist and a flow diagram. 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 CONSORT "Explanation and Elaboration" document explains and
CONSORT extensions, published

- CONSORT PRO, 2013
- CONSORT for Cluster trials, updated 2013
- CONSORT for Equivalence and Non-Inferiority trials, updated 2013
- STRICTA (CONSORT for acupuncture)
- CONSORT for Herbal Medicine
- CONSORT for Moxibustion
- CONSORT NPT
- CONSORT for Harms
- CONSORT for Abstracts
- CONSORT for Pragmatic trials
- CONSORT e-Health
- CONSORT –e(quity)
- CENT
- IMPRINT, infertility treatment(s) trials

CONSORT extensions, in development

- CONSORT for crossover trials
- CONSORT for multi-arm trials
- CONSORT within person trials
- CONSORT-C(children)
Enhancing the QUALity and Transparency Of health Research

The resource centre for good reporting of health research studies

Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.

Key reporting guidelines

- CONSORT: Full Record, Checklist, Flow Diagram
- STROBE: Full Record, Checklist
- PRISMA: Full Record, Checklist, Flow Diagram
- STARD: Full Record, Checklist, Flow Diagram
- COREQ: Full Record
- ENTREQ: Full Record
- SQUIRE: Full Record, Checklist
- CARE: Full Record, Checklist
- SAMPL: Full Record
- SPIRIT: Full Record, Checklist
The Library for health research reporting provides an up-to-date collection of guidelines and policy documents related to health research reporting. These are aimed mainly at authors of research articles, journal editors, peer reviewers and reporting guideline developers.

- Search for reporting guidelines
- Reporting guidelines under development
- Translations of reporting guidelines
- Guidance on scientific writing
- Guidance developed by editorial groups
- Research funders' guidance on reporting requirements
- Industry sponsored research - additional guidance
- Research ethics, publication ethics and good practice guidelines
- Links
- About the Library
SPIRIT (http://www.spirit-statement.org/)

- To improve content and quality of clinical trial protocols through evidence-based guidance
Impact
<table>
<thead>
<tr>
<th>Decade</th>
<th>Milestones in Health Care Interventions and Delivery Strategies</th>
<th>Milestones in Research Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>1940s</td>
<td>Antibiotic agents (penicillin and streptomycin), kidney dialysis, general anesthesia, radiotherapy, first heart-pump machine, influenza vaccine, Papanicolaou (Pap) smear to detect cervical cancer, cortisone, intraocular lens implants for cataracts</td>
<td>First large-scale, randomized, controlled trial</td>
</tr>
<tr>
<td>1950s</td>
<td>Cardiopulmonary resuscitation, kidney transplantation, vaccination against poliomyelitis, chlorpromazine for schizophrenia, Zeiss fluorescence microscope, antitubercular therapy, cardiac pacemaker, artificial heart valve, successful open-heart bypass surgery</td>
<td>Case–control methodology, Kaplan–Meier survival estimator</td>
</tr>
<tr>
<td>1960s</td>
<td>Charnley’s hip replacement, coronary-artery bypass grafting surgery, heart transplantation, oral contraceptive pill, prenatal diagnosis of Down’s syndrome</td>
<td>Explanatory versus pragmatic trial concept, data and safety monitoring, growth of observational research methods committees</td>
</tr>
<tr>
<td>1970s</td>
<td>Cure for some childhood cancers; neonatal intensive care; computed tomography; coronary angiography; quality measures in health care; ambulatory surgery; vaccinations against smallpox, measles, mumps, rubella, and pneumonia</td>
<td>Cox proportional-hazards model; meta-analysis; ascendency of randomized, controlled trials; statistical stopping rules</td>
</tr>
<tr>
<td>1980s</td>
<td>Insulin therapies for diabetes mellitus, thrombolysis for heart attacks, antihypertensive drugs, magnetic resonance imaging, robotic surgery, permanent artificial-heart implant, deep-brain electrical stimulation system, first laser surgery on the human cornea, hepatitis B vaccine</td>
<td>Propensity score; large, simple trials; prognostic models (e.g., Framingham risk score), growth of decision and cost-effectiveness analyses</td>
</tr>
<tr>
<td>1990s</td>
<td>Coronary stents, triple therapy for the acquired immune deficiency syndrome, introduction of biologics, “physician extenders,” facial transplantation, vaccine against hepatitis A, first rotavirus vaccines</td>
<td>Evidence-based medicine, cumulative meta-analysis, reporting guidelines (CONSORT statement), ascendency of registries, electronic health records, Markov chain Monte Carlo sampling for Bayesian inference</td>
</tr>
<tr>
<td>2000s</td>
<td>Human Genome Project completed, drug-eluting coronary stents, FDA guidance on patient-reported outcomes, minimally invasive techniques for surgery, human papillomavirus vaccine to prevent cervical cancer</td>
<td>Trial registration (ClinicalTrials.gov), comparative-effectiveness research, implementation science, large-scale genomic research, reproducible research</td>
</tr>
<tr>
<td>2010s</td>
<td>Genomics, epigenomics, individualized medicine, health information technology, emergence of telehealth, meaningful-use initiatives, Affordable Care Act becomes law</td>
<td>Patient-centered outcomes research</td>
</tr>
</tbody>
</table>

* Information on health care interventions and delivery strategies are from Le Fanu.¹ CONSORT denotes Consolidated Standards of Reporting Trials, and FDA Food and Drug Administration.
• Total citations to all main CONSORT docs: 9783
• PloS Med: 2010 Statement
  – top 1% of content

• JCE: 2010 Statement & E&E
  – Top read articles overall
PRISMA Metrics

- **Citations:**
  - Statement: 4500
  - Elaboration and Explanation: 2202

- **Endorsing Journals:** 300+
  - Organizations: Cochrane, CADTH, AHRQ, WAME

- **Twitter:** @prismastatement
  - 776 followers
A different kind of metric: journal endorsement

- Typically statement in “Instructions to Authors”
- 600+ endorsers and likely more
  - Occurs passively, at will of editors
  - Difficult/impossible to track
- Two studies examined endorsement by high-impact journals
  - 22% endorsers (Altman *BMJ* 2005, based on 2001 IF)
  - 38% endorsers (Hopewell *Trials* 2008 based on 2006 IF)
Do reporting guidelines work?

Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals (Review)


Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review

Lucy Turner, Larissa Shamseer, Douglas G Altman, Kenneth F Schulz and David Moher

Abstract

Background: The Consolidated Standards of Reporting Trials (CONSORT) Statement is intended to facilitate better reporting of randomised clinical trials (RCTs). A systematic review recently published in the Cochrane Library assesses whether journal endorsement of CONSORT impacts the completeness of reporting of RCTs; those findings are summarised here.

Methods: Evaluations assessing the completeness of reporting of RCTs based on any of 27 outcomes formulated based on the 1996 or 2001 CONSORT checklists were included; two primary comparisons were evaluated. The 27 outcomes were the 22 items of the 2001 CONSORT checklist, four sub-items describing binding and a total summary score of aggregate items, as reported. Relative risks (RR) and 99% confidence intervals were calculated to determine effect estimates for each outcome across evaluations.

Results: Fifty-three reports describing 50 evaluations of 16,604 RCTs were assessed for adherence to at least one of 27 outcomes. Sixty-nine of 81 meta-analyses show relative benefit from CONSORT endorsement on completeness of reporting. Between endorsing and non-endorsing journals, 25 outcomes are improved with CONSORT endorsement, five of these significantly (a = 0.05). The number of evaluations per meta-analysis was often low with substantial heterogeneity; validity was assessed as low or unclear for many evaluations.

Conclusions: The results of this review suggest that journal endorsement of CONSORT may benefit the completeness of reporting of RCTs they publish. No evidence suggests that endorsement hinders the completeness of RCT reporting. However, despite relative improvements when CONSORT is endorsed by journals, the completeness of reporting of trials remains suboptimal. Journals are not sending a clear message about endorsement to authors submitting manuscripts for publication. As such, fidelity of endorsement as an "intervention" has been weak to date. Journals need to take further action regarding their endorsement and implementation of CONSORT to facilitate accurate, transparent and complete reporting of trials.

Keywords: CONSORT, Endorsement, Reporting guideline, Completeness of reporting
Sequence generation is approximately 56% better reported in the 673 trial reports in endorsing journals compared to the 1231 trials published in non-endorsing journals (RR = 1.56; 95% CI: 1.36, 1.80).
### CONSORT Checklist Item

<table>
<thead>
<tr>
<th>CONSORT Checklist Item</th>
<th># of Evaluations</th>
<th># of RCTs</th>
<th>RR</th>
<th>99% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and Abstract</td>
<td>7</td>
<td>1,233</td>
<td>1.13</td>
<td>(0.96, 1.33)</td>
</tr>
<tr>
<td>Introduction</td>
<td>5</td>
<td>513</td>
<td>1.07</td>
<td>(1.01, 1.14)</td>
</tr>
<tr>
<td>Participants</td>
<td>6</td>
<td>683</td>
<td>0.95</td>
<td>(0.87, 1.05)</td>
</tr>
<tr>
<td>Interventions</td>
<td>6</td>
<td>638</td>
<td>1.00</td>
<td>(0.95, 1.05)</td>
</tr>
<tr>
<td>Objectives</td>
<td>5</td>
<td>540</td>
<td>1.01</td>
<td>(0.96, 1.06)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>8</td>
<td>1,302</td>
<td>1.17</td>
<td>(0.95, 1.44)</td>
</tr>
<tr>
<td>Sample Size</td>
<td>11</td>
<td>1,843</td>
<td>1.61</td>
<td>(1.13, 2.29)</td>
</tr>
<tr>
<td>Sequence Generation</td>
<td>14</td>
<td>2,231</td>
<td>1.59</td>
<td>(1.38, 1.84)</td>
</tr>
<tr>
<td>Allocation Concealment</td>
<td>16</td>
<td>2,396</td>
<td>1.81</td>
<td>(1.25, 2.62)</td>
</tr>
<tr>
<td>Implementation</td>
<td>5</td>
<td>498</td>
<td>1.47</td>
<td>(0.65, 3.32)</td>
</tr>
<tr>
<td>Blinding of Participants</td>
<td>5</td>
<td>711</td>
<td>1.39</td>
<td>(0.87, 2.22)</td>
</tr>
<tr>
<td>Blinding of Intervention</td>
<td>5</td>
<td>710</td>
<td>1.25</td>
<td>(0.74, 2.12)</td>
</tr>
<tr>
<td>Blinding of Outcome Assessor</td>
<td>5</td>
<td>719</td>
<td>1.72</td>
<td>(0.69, 4.30)</td>
</tr>
<tr>
<td>Blinding of Data Analyst</td>
<td>3</td>
<td>497</td>
<td>3.56</td>
<td>(0.40, 31.8)</td>
</tr>
<tr>
<td>Blinding Any description</td>
<td>8</td>
<td>1,851</td>
<td>1.23</td>
<td>(0.93, 1.62)</td>
</tr>
<tr>
<td>Statistical Methods</td>
<td>5</td>
<td>894</td>
<td>1.03</td>
<td>(0.90, 1.18)</td>
</tr>
<tr>
<td>Participant Flow</td>
<td>8</td>
<td>2,461</td>
<td>1.16</td>
<td>(0.94, 1.44)</td>
</tr>
<tr>
<td>Recruitment</td>
<td>6</td>
<td>959</td>
<td>1.03</td>
<td>(0.75, 1.41)</td>
</tr>
<tr>
<td>Baseline Data</td>
<td>5</td>
<td>529</td>
<td>1.07</td>
<td>(0.94, 1.22)</td>
</tr>
<tr>
<td>Numbers Analysed</td>
<td>13</td>
<td>2,145</td>
<td>1.23</td>
<td>(0.98, 1.55)</td>
</tr>
<tr>
<td>Outcomes and Estimation</td>
<td>6</td>
<td>617</td>
<td>1.00</td>
<td>(0.95, 1.05)</td>
</tr>
<tr>
<td>Ancillary Analyses</td>
<td>4</td>
<td>378</td>
<td>1.31</td>
<td>(0.48, 3.58)</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>8</td>
<td>911</td>
<td>1.14</td>
<td>(0.86, 1.52)</td>
</tr>
<tr>
<td>Interpretation</td>
<td>5</td>
<td>540</td>
<td>1.01</td>
<td>(0.96, 1.06)</td>
</tr>
<tr>
<td>Generalisability</td>
<td>4</td>
<td>540</td>
<td>1.22</td>
<td>(0.88, 1.70)</td>
</tr>
<tr>
<td>Overall Evidence</td>
<td>4</td>
<td>317</td>
<td>1.03</td>
<td>(0.91, 1.17)</td>
</tr>
</tbody>
</table>

Pooled Risk ratios and 99% CI
Future
• Guidance for those preparing protocols of systematic reviews
• Three sections
• 18-item checklist
Knowledge translation and reporting guidelines

- Uptake of reporting guidelines
  - difficult to measure

- Measuring uptake:
  - Analyzing Citations
    - Provides little information about how reporting guideline is used
  - Tracking endorsement
    - Inefficient to track; occurs haphazardly, at journal’s will
Problems with endorsement

- Does not indicate what, if anything, journals are doing to ensure guideline adherence
- Onus to ensure/verify good reporting placed solely on journals – downstream in the research process
- Endorsement not considered an “intervention” that might improve reporting
Implementing reporting guidelines

- Actual use of reporting guidelines (implementation) in the publication process is haphazard and unguided
- Better knowledge translation of reporting guidelines needed
  - Often an afterthought of reporting guideline developers, if at all
  - Requires strategies to change behaviours (of authors, editors, peer reviewers, others)
Knowledge Translation (KT) Interventions

- **Choice of interventions should be based upon:**
  - ‘Diagnostic’ assessment of barriers
  - Understanding mechanism of action of interventions
  - Empirical evidence about effects of interventions
  - Available resources
  - Practicalities, logistics, etc.

- **Need to understand how behaviours change**
  - Make use of theory
Designing a KT intervention: use a systematic approach

1. Who needs to do what differently?

2. What are the factors (e.g. barriers and facilitators) influencing behaviour?

3. Which intervention components can overcome modifiable barriers/enhance facilitators?

4. How will behaviour change be measured?

e.g., French *Implementation Science* 2012
Who?
• Identify those involved in the development, reporting, accessibility, and assessment of SR protocols (i.e. stakeholders)

What?
• Using a theoretical framework, interview stakeholders to identify barriers and facilitators to reporting (frequency and completeness) SR protocols (e.g. “do you create protocols before doing a systematic review?”)

How?
• Select interventions and tailored to specific stakeholders; multiple approaches likely needed. E.g. provide knowledge about existing tools (e.g. PRISMA-P, PROSPERO), facilitate social network, persuasion, feedback and monitoring, reward good behaviour (funding)

Did it work?
• Evaluate the effectiveness of strategy, e.g. measure availability of protocols by frequency of protocol registration and publication, assess completeness of reporting
IT and reporting guidelines

- Populate checklist
  - Ideally completely automated
  - Realistically, semi-automated
- Include as a submission file
- Publish as a supplemental file
Training editors, peer reviewers, and authors

- In synch with other training initiatives from other EQUATOR centres
Results

- Journal Editing – No studies found
- Peer Review – 5 studies
  - 2 RCTs & 2 CBAs examined mean review quality score
    - All found no difference between groups
  - 1 Pre-post study found that knowledge of the publishing process improved for 36 undergraduate students
    - No statistical analysis was performed

Galipeau J. et al. A systematic review highlights a knowledge gap regarding the effectiveness of health-related training programs in journalology. Forthcoming, Journal of Clinical Epidemiology
In synch with other training initiatives from UK EQUATOR centre

Core competencies

Publications officers
Help develop reporting guidelines, particularly from those initiated in Canada

- PRISMA-NMA
- CONSORT-C
- CONSORT-e
- SPIRIT-C
- STREGA

Train editors and peer reviewers
With thanks to our funders

- AHRQ, US
- Centre for Journalology, OHRI
- CIHR
- Cochrane Collaboration
- MRC, UK
- NIHR, UK
- PAHO
With thanks to ….

- Doug Altman
- Brian Hutton
- Bill Cameron
- Craig Campbell
- An-Wen Chan
- Dean Fergusson
- John Fletcher
- James Galipeau
- Ian Graham
- Jeremy Grimshaw
- Paul Hebert
- Paul Hendry
- Julian Little
- Jessie McGowan
- Don Miller
- Martin Offringa
- Anita Palepu
- Jason Roberts
- Ken Schulz
- Larissa Shamseer
- Becky Skidmore
- Iveta Simera
- Adrienne Stevens
- Jennifer Tetzlaff
- Peter Tugwell
- Lucy Turner
- Vivian Welch
- Liz Wager

- To all my students who’ve made me think more deeply about the issues
Guidelines for Reporting Health Research: A User’s Manual

Edited by David Moher, Douglas Altman, Kenneth Schulz, Iveta Simera, Elizabeth Wager

• How to choose and correctly apply the appropriate guidelines
• Covers CONSORT, STROBE, PRISMA, STARD, and more
• Written by the authors of health research reporting guidelines, in association with the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network

2014 | 9780470670446| £29.99 | €34.90 | $49.95
www.wiley.com/buy/9780470670446

Available digitally for download onto your computer, laptop, or mobile device. Explore the possibilities on Wiley.com or visit your preferred eBook retailer.