Reporting guidelines: past, present and future

Acknowledge:
Doug Altman, Isabelle Boutron, John Hoey, Sally Hopewell, Philippe Ravaud, Drummond Rennie, Ken Schulz, and Iveta Simera
Health research reporting guidelines: past, present and future
• ICMJE (1979)
  – Focused on format rather than scientific details
• BMJ (1983)
  – Did not differentiate between conduct and report
• BJOG (1989)
  – Reporting of trials, screening and diagnostic tests, and observational studies
• CMAJ (1990)
  – Series of recommendations for different types of study designs
• Prior to the mid 1990s
  – Few efforts specifically devoted to developing reporting guidelines for health research studies
  – Very limited endorsement and implementation of reporting guidelines within healthcare journals
What is a reporting guideline?

• A minimum set of items allowing assessment of study findings and, if necessary, the reproduction of the study
  – A checklist of items that should be addressed when reporting a study

• Some reporting guidelines might also include a flow diagram so that authors can report the process of participants (or study reports) throughout the study’s conduct
Ottawa, Canada, October 1993
Standards Of Reporting Trials, 1994

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

Registered or Eligible Patients (n=...)
Not Randomized (n=...)
Randomized (n=...)
Received Intervention as Allocated (n=...)
Did Not Receive Intervention as Allocated (n=...)
Followed Up (n=...)
Timing of Outcome Measures
Withdrawn (n=...)
Intervention Ineffective (n=...)
Unavailable for Follow-up (n=...)
Other (n=...)
Completed Trial (n=...)
Asilomar beach, USA, March 1994
“so the next step is for members of the two groups to get together and decide which parts of which proposal are worthwhile”
Hilton hotel, Chicago’s O’hare airport, September 1995
### CONSORT, 1996

<table>
<thead>
<tr>
<th>Heading</th>
<th>Subheading</th>
<th>Description</th>
<th>Was It Reported?</th>
<th>On What Page No.?</th>
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</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Abstract</td>
<td>Identify the study as a randomized trial</td>
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<tr>
<td><strong>Methods</strong></td>
<td>Introduction</td>
<td>Use a structured format</td>
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<td>Primary and secondary outcomes measured, and the minimum important difference(s)</td>
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<td>and indicate how the largest sample size was projected</td>
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<td>Allocation schedule control, blinding of codes during trial and when broken</td>
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<td>Evidence for successful blinding among participants, person doing intervention, outcome assessors, and data analysts</td>
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<tr>
<td><strong>Results</strong></td>
<td>Participant Flow and Follow-up</td>
<td>Provide a trial profile figure, summarizing participant flow, numbers and timing of randomization assignment, interventions, and measurements for each randomized group</td>
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<td>Analysis</td>
<td>State estimated effect of intervention on primary and secondary outcome measures</td>
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<td>Including a point estimate and measures of precision (confidence interval)</td>
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<td>State results in absolute numbers when feasible (eg, 10/20, not 52%)</td>
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<td>Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication</td>
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<td>Describe prognostic variables by treatment group and any attempt to adjust for them</td>
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<td>Describe protocol deviations from the study as planned, together with the reasons</td>
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<td>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</td>
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<td>State general interpretation of the data in light of the totality of the available evidence</td>
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health research reporting
guidelines: past, present and future
Current focus for using reporting guidelines in the knowledge generation cycle

gap in guidance

Research → Publication → Knowledge translation

open access!

Scientific writing guidance
Journals’ I to A
Editorial process & peer review

Reporting guidelines
• 80 reporting guidelines
• Covers a broad spectrum of health research
• Some areas are well covered while others are not
• www.equator-network.org
Little guidance on how to develop reporting guidelines


• In development
  – “Considerations when developing guidelines for reporting health research: a structured approach” (Moher, Schulz, Altman)
Phase I: pre-meeting activities
1. Rationale for developing a reporting guideline†
2. Review the literature to identify‡:
   - previous relevant guidance
   - relevant evidence on the quality of reporting in published research articles
   - key information related to the potential sources of bias in such studies
3. Identify stakeholders
4. Seek and obtain funding
5. Decide size and duration of meeting
6. Book the meeting venue†
7. Develop list of participants to be invited†
8. Produce a review of existing literature
9. Conduct a Delphi exercise
10. Develop program for meeting†
    - invite presentations on relevant background topics, including summary of evidence
    - present results of Delphi exercise, if done
    - Discuss potential checklist items
    - invite session chairs
11. Develop meeting logistics
12. Prepare materials to be sent to participants prior to meeting
13. Record the meeting

Phase II: the meeting
1. Clarify meeting objectives
2. Present and discuss pre-meeting activities†
   - present and discuss relevant evidence
   - develop specific guidelines by structured discussion
   - discuss strategy for producing documents; identify who will be involved in which activities; discuss authorship
   - discuss dissemination strategy

Phase III: post meeting activities leading to publication
1. Drafting guidance†
2. Incorporating draft feedback†
3. Piloting checklist and diagram
4. Developing an explanatory document†
5. Publication strategy
6. Website development

Phase IV: post publication strategies
1. Journal endorsement†
2. Evaluation of guidance†
3. Handling of criticism
4. Updating the reporting guideline
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Health research reporting guidelines: past, present and future
Continue to develop and refine methodology to appropriately develop reporting guidelines

– Delphi process
– Piloting checklist and diagram
Development must include an evaluative component of their impact on the quality of reporting

- Currently done by 17% (n=5) of developers
- How best to achieve this goal
  - CONSORT systematic review
    - Design issues
- Need to introduce more qualitative approaches
  - To more broadly engage readers as part of this process


Reporting guidelines need to be kept up-to-date

- Currently 83% (n=25) think guideline will need updating
- ‘When’ and ‘how’ to update
- Funding to update guideline


Moher D, Tsertsvadze A, Tricco A, Eccles M, Grimshaw J, Sampson M, Barrowman N. Systematic review identified few methods and strategies describing when and how to update systematic reviews. Journal of Clinical Epidemiology 2007; 60:1095-1104
Better dissemination of uptake - implementation strategies to:

- Authors  
  - currently 43%
- Journals  
  - currently 40%
- Need to more actively engage knowledge translation/implementation experts as part of the development process

Better endorsement by journals

• Need stronger language for authors

• 2003, 22% (36/166) high impact factor journals provided any mention of CONSORT

• 2008, 38% (62/165) high impact factor journals
  – 73% relative improvement

• Same (121) journals in both years
  – 26% in 2003 and 39% in 2008


Better adherence by journals

- Need stronger approaches by journals
  - CONSORT was a requirement
    - ‘Instructions to authors’, 23 journals
    - Authors must conform to the CONSORT Statement
  - Remaining journals were less clear in the recommendations
    - Authors “should consult the CONSORT guidelines”
    - “we encourage authors to follow the CONSORT Statement”
  - Very few journals provided any mention of CONSORT extension papers
    - Cluster (n=5)
    - Harms (n=3)
    - Herbals (n=2)
    - Non-inferiority and equivalence (n=1)

The Effectiveness Of A Home Care Program For Supporting Caregivers Of Persons With Dementia In Developing Countries: A randomised controlled trial from Goa, India

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<th>Subheading</th>
<th>Descriptor</th>
<th>Was it reported? Yes or No</th>
<th>If &quot;Yes&quot;, what section?</th>
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<tr>
<td>Title</td>
<td>1. Identify the study as a randomised trial</td>
<td>YES title</td>
<td></td>
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<td>Methods</td>
<td>Protocol Describe</td>
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<td>4. Planned study population, together with inclusion/ exclusion criteria</td>
<td>YES Method</td>
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<td>5. Planned interventions and their timing</td>
<td>YES Method, Intervention</td>
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<td>6. Primary and secondary outcome measure(s) and the minimum important difference(s), ...and how the target sample size was projected.</td>
<td>YES Outcome Results</td>
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<td>7. Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention-to-treat basis</td>
<td>YES Analysis</td>
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<td>8. Prospectively defined stopping rules (if warranted).</td>
<td>None</td>
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<td>Assignment</td>
<td>Describe</td>
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<td>9. Unit of randomisation (eg individual, cluster, geographic).</td>
<td>YES Method, Randomisation</td>
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<td>10. Method used to generate the allocation schedule.</td>
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<td>YES (No Placebo involved in this study. Evaluators were masked to intervention status)</td>
<td></td>
<td>Outcome/ Analysis</td>
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Need to develop a robust scheme to grade reporting guidelines

- Not all reporting guidelines are created equal
- The ‘Intel’ inside label of approval
Leverage reporting guidelines early on in the knowledge generation cycle to improve design and conduct of health research.
What are reporting guidelines?
Reporting guidelines are statements that provide methods and findings. They focus on encouraging transparent reporting of the facts relating to the research.

Most widely recognized guidelines reflect consensus in particular field, including research methodologists and editors.

Reporting guidelines complement advice on scientific basic writing principles and styles of research reports.

What are the basic requirements for research?
Most biomedical journals require authors to comply Manuscripts Submitted to Biomedical Journals prepared by Editors of Medical Journal Editors (ICMJE). This document standardizes conduct and reporting of research and provides recommendations on writing and editing.

The Grey Literature International Steering Committee
The need for national and international funding
Funders, researchers, authors, peer reviewers, editors, journals publishers, and consumers must work together to improve the design, conduct, and reporting of health research.

we all share this obligation and responsibility.