Reporting Guidelines of the EQUATOR Network

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India Editor, BMJ
Session Outline

• Background

• Frequently used reporting guidelines

• EQUATOR Network

• Impact on quality of reporting research

• Barriers to their use

• What may we do as journal editors
Problems in reporting

- Of 616 published reports of randomized trials, % of studies that reported:
  - A primary outcome: 53%
  - Sample size calculation: 45%
  - Random sequence generation: 34%
  - Allocation concealment: 25%
  - Blinding: 56%
  - Participant flow diagram: 28%
Of 80 published studies of treatment important for clinical practice, less than half reported elements of the intervention necessary for replication.

http://www.equator-network.org/resource-centre/library-of-health-research-reporting/presentations/
Key aspects of reporting guidelines

• Minimum set of items critical to ensure reliability and reproducibility of the research

• Guidance to authors to ensure completeness of reporting and for editors and reviewers to evaluate

• Not an indicator of methodological quality of the study
Reporting Guidelines

• **CONSORT**: RCTs
• **PRISMA**: Meta-analysis of RCTs
• **STROBE**: Observational studies
• **MOOSE**: Meta-analysis of observational studies
• **STARD**: Diagnostic accuracy studies
• **CHEERS**: Economic evaluation
• .....
<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
<td></td>
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<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
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<tr>
<td>Introduction</td>
<td></td>
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<tr>
<td>Background and objectives</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
<td></td>
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<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
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<tr>
<td>Methods</td>
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<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>
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<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
<td></td>
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<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
<td></td>
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<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were actually assessed</td>
<td></td>
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<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
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<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
<td></td>
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<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
<td></td>
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<tr>
<td>Randomisation:</td>
<td></td>
<td></td>
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<tr>
<td>Sequence generation</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
<td></td>
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<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
<td></td>
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<tr>
<td>Allocation</td>
<td>9</td>
<td>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</td>
<td></td>
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<tr>
<td>concealment mechanism</td>
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<tr>
<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td></td>
</tr>
<tr>
<td>Blinding</td>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those who assessed outcomes, those who analysed the data)</td>
<td></td>
</tr>
</tbody>
</table>
CONSORT Statement 2010 Flow Diagram

Assessed for eligibility (n=)

Excluded (n=)
• Not meeting inclusion criteria (n=)
• Declined to participate (n=)
• Other reasons (n=)

Randomized (n=)

Allocated to intervention (n=)
• Received allocated intervention (n=)
• Did not receive allocated intervention (give reasons) (n=)

Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)

Analyzed (n=)
• Excluded from analysis (give reasons) (n=)

Allocated to intervention (n=)
• Received allocated intervention (n=)
• Did not receive allocated intervention (give reasons) (n=)

Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)

Analyzed (n=)
• Excluded from analysis (give reasons) (n=)

http://www.consort-statement.org/consort-statement/
Enhancing the QUAlity & Transparency Of health Research

http://www.equator-network.org/
Library for health research reporting

The EQUATOR Network library currently contains:

- An introduction to reporting guidelines
- Comprehensive lists of the available reporting guidelines, listed by study type:
  - Experimental studies
  - Observational studies
  - Diagnostic accuracy studies
  - Biospecimen reporting
  - Reliability and agreement studies
  - Systematic reviews
  - Qualitative research
  - Mixed methods studies
  - Economic evaluations
  - Quality improvement studies
  - Other reporting guidelines

Quick links to reporting guidelines:

- CONSORT checklist and flow diagram
- CONSORT extensions
- TREND checklist
- STARD checklist & flow diagram
Impact of reporting guidelines

*Improvement in the quality and completeness of reporting; but still sub-optimal*

86% of systematic reviews report sub-optimal adherence to reporting guidelines [CONSORT, PRISMA, QUORUM, STROBE] and inadequate reporting quality

Japan: Adherence to CONSORT

Of 98 published reports of RCTs:

- Sample size determination: 23%
- Random sequence generation: 39%
- Allocation concealment: 17%
- Blinding: 29%
- Numbers analyzed: 53%
- Flow diagram: 6%
- Funding sources: 20%

Raise your hand if:

- You are or have been an editor of a medical journal
- ‘Instructions to authors’ of your journal indicates the reporting guidelines/checklists to be complied with
- You do not accept a paper unless the appropriate checklist has been completed and submitted
Barriers Identified

• Poor adherence to guidelines by authors
• Lack of endorsement by journals
• Unclear communication to authors about reporting expectations of the journal
What journal editors can do

• Select appropriate guidelines to endorse

• Make explicit the endorsement:
  – Instructions to authors
  – Guidance for peer reviewers
  – Manuscript submission system

• Spread the word and stay updated
BMJ: Instructions to Authors

As supplemental files

- the original protocol for a clinical trial or, if the protocol has been published in an open access online journal, its reference and url. We appreciate that studies sometimes deviate from protocols, but please explain any important deviations in the manuscript, particularly those about choice of outcomes and analyses or change in sample size.

- the original protocol for an observational study or systematic review, if available. We recommend that protocols for randomised trials are written using the SPIRIT checklist.

- for a randomised controlled trial, the appropriate completed CONSORT checklist showing on which page of your manuscript each checklist item appears, the CONSORT-style structured abstract, and the CONSORT flowchart (CONSORT has several extension statements, eg for cluster RCTs, pragmatic trials).

- PRISMA checklist and flowchart for a systematic review or meta-analysis of randomised trials and other evaluation studies.

- MOOSE checklist for a meta-analysis of observational studies.

- STARD checklist and flowchart for a study of diagnostic accuracy.

- STROBE checklist for an observational study.

- GRIPS for genetic risk prediction studies.

- CHEERS for an economic evaluation.

http://www.bmj.com/about-bmj/resources-authors/article-types/research
Please report statistical aspects of the study in line with the "Statistical Analyses and Methods in the Published Literature (SAMPL) Guidelines." We also ask you to ensure that the manuscript includes all the information recommended in the relevant reporting statement, for example CONSORT. To find research reporting guidelines and statements such as CONSORT you may find it easiest to go to the website of the EQUATOR network, where they are all available in one place. We do not use reporting guidelines as critical appraisal tools to evaluate study quality or filter out articles. We're simply aiming to make research articles so clear that peer reviewers, editors, clinicians, educators, ethicists, policy makers, systematic reviewers, guideline writers, journalists, patients, and the general public can tell what really happened during a study.
BMJ: Guidance to Peer Reviewers

Scientific reliability

- Research question — clearly defined and appropriately answered?
- Overall design of study — appropriate and adequate to answer the research question?
- Participants — adequately described, their conditions defined, inclusion and exclusion criteria described? How representative were they of patients whom this evidence might affect?
- Methods — adequately described? Main outcome measure clear? Is the study fully reported in line with the appropriate reporting statement or checklist (these are all collected and regularly updated at http://www.equator-network.org/)? Was the study ethical (this may go beyond simply whether the study was approved by an ethics committee or IRB)?
- Results — answer the research question? Credible? Well presented?
- Interpretation and conclusions — warranted by and sufficiently derived from/focused on the data? Discussed in the light of previous evidence? Message clear?
- References — up to date and relevant? Any glaring omissions?
- Abstract/summary/key messages/what this paper adds — reflect accurately what the paper says?
- Documents in the supplemental files eg checklists for reporting statements eg CONSORT, PRISMA, and STROBE (see http://www.equator-network.org for other examples and for extensions to existing statements); and the protocol for an RCT. Do these properly match what is in the manuscript? Do they contain information that should be better reported in the manuscript, or raise questions about the work?
Administrative changes

STEP 1 – Select study type

Please download, complete and save the CONSORT checklist. You MUST upload this checklist with your manuscript as a separate file from the main manuscript file (File Type: Checklist) to enable submission.

STEP 2 – Depending on the Study Type selection in Step 1, the system will provide a link to the form in Word format that must be downloaded, completed and uploaded as a Checklist file. In this example, RCT (Pharmacotherapy) was selected. The system provided a link to the CONSORT checklist.
A Committed Movement

“Good reporting is not an optional extra: it is an essential component of doing good research”

- Doug Altman
THANK YOU