Making sense of reporting guidelines

Iveta Simera

EASE conference, Split, June 2014
* STUFF TO BUY

- Printer Ink
- Kid's Tylenol (grape)
- Jumbo Loo Roll
- Q-tips
- Fish Tank Filter
- 5x7 Picture Frames
- Windex
- Light Bulbs
- Wrapping Paper
- A Car

http://www.theanimatedwoman.com/2011/03/shopping-list.html
• ‘Reminders’ of scientific content

  – Methodology

  – Clinical / Research related focus
Reporting guidelines (RGs)

• Focus on scientific content of the article

• Definition:
  – Specify a **minimum set** of items required for a clear and transparent account of what was done and what was found in a research study, reflecting in particular issues that might introduce bias into the research

  – Form: structured advice, often as a checklist (perhaps also a flow diagram)

• Most internationally accepted RGs
  – Based on evidence
  – Consensus of relevant stakeholders (multidisciplinary group)
Typical research (designs) published by journals

- Randomised trials
- Cohort studies
- Cross-sectional studies
- Case-control studies
- Case reports
- Qualitative research
- Research synthesis (systematic reviews)
Typical research (designs) published by journals

- Randomised trials → CONSORT
- Cohort studies → STROBE
- Cross-sectional studies
- Case-control studies
- Case reports → CARE
- Qualitative research → COREQ
- Research synthesis (systematic reviews) → PRISMA
- ENTREQ

Study reporting framework
<table>
<thead>
<tr>
<th>Section / topic</th>
<th>#</th>
<th>Checklist item</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE &amp; ABSTRACT</td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for</td>
</tr>
<tr>
<td></td>
<td></td>
<td>specific guidance see CONSORT for abstracts)</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
</tr>
<tr>
<td>objectives</td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
</tr>
<tr>
<td>METHODS</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</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ratio</td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>criteria), with reasons</td>
</tr>
<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
</tr>
<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>including how and when they were actually administered</td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>including how and when they were assessed</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
</tr>
<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
</tr>
<tr>
<td>Randomisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequence generation</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
</tr>
<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block</td>
</tr>
<tr>
<td></td>
<td></td>
<td>size)</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>9</td>
<td>Mechanism used to implement the random allocation sequence (such as sequentially</td>
</tr>
<tr>
<td></td>
<td></td>
<td>numbered containers), describing any steps taken to conceal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>allocation</td>
</tr>
</tbody>
</table>
Reporting RCTs - CONSORT

- Revised checklist
- Short paper
  (published in 9 journals)
- Revised (and expanded) explanatory paper (E&E)
Types of studies by research questions / focus

- Treatment evaluations - RCTs
- Disease aetiology, harms, .. - Observational studies
- Prognostic studies
- Diagnostic studies
- Experiences, views, .. – Qualitative studies
- Quality improvement studies
- Economic evaluations
- Patients’ involvement in research
Generic guideline for each of these types of studies:

- Treatment evaluations – RCTs
  - CONSORT
- Disease aetiology, harms, .. - Observational studies
  - STROBE
- Prognostic studies
  - [TRIPOD]
- Diagnostic studies
  - STARD
- Experiences, .. – Qualitative studies
  - COREQ
- Quality improvement studies
  - SQUIRE
- Economic evaluations
  - CHEERS
- Patients’ involvement in research
  - GRIPP
More specific guidelines

**Protocol**
- SPIRIT

**RCT - Study report**
- CONSORT

**Abstracts**
- CONSORT for abstracts

**Harms**
- CONSORT for harms

**Specific trial design**
- CONSORT Clusters

### Content specific (medical area)

- Trials in Asthma
- Trials in AML
Best place to find reporting guidelines

Enhancing the QUALity and Transparency Of health Research

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.

- Search for reporting guidelines
- Visit the library for more resources

Key reporting guidelines

- CONSORT
- STROBE
- PRISMA
- STARD
- COREQ
- ENTREQ
- SQUARE
- CARE
- SAMPL
- SPIRIT

- Full Record
- Checklist
- Flow Diagram

EQUATOR highlights

- 23/05/2014 - AllTrials video – make clinical trials count
  AllTrials.net have produced a new video highlighting the issue of non-publication of clinical trial results. Read More

- 16/04/2014 - The STROBE Statement webinar recording now available
  The recording of the EQUATOR – FAHO March 2014 webinar on the STROBE Statement Read More

- 17/03/2014 - Scientific meeting and the EQUATOR Annual Lecture 2014, 16 May 2014, Paris, France
  The INSERM Centre Paris City Epidemiology and Statistics Research

News

- EQUATOR is recruiting
  2/06/2014

- Journals must adopt high methodological standards
  28/05/2014

- Scientific meeting and EQUATOR Annual Lecture 2014
  22/05/2014

- researchwaste.net
  9/05/2014

- EQUATOR Network Newsletter April 2014
EQUATOR Network

Enhancing the Quality and Transparency of health Research

- Launched in June 2008

- EQUATOR Network is an international initiative set up to improve reliability and value of medical research literature by promoting good research reporting:
  - Accurate
  - Clear
  - Transparent
  - Complete
EQUATOR focus

- Provision of resources
- Education and training
- Research, evaluation, development
- Collaboration, global expansion

- Builds on and advances the work of CONSORT and other guidelines groups
  - Programme focus is more on RG implementation (rather than their development) to support better publication of research
Library for health research reporting

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

Key reporting guidelines

- CONSORT
  - Full Record
  - Checklist
  - Flow Diagram
- STROBE
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  - Checklist
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Translations

Some reporting guidelines are also available in languages other than English. Find out more in our Translations section.

About the Library

For information about Library scope and content, identification of reporting guidelines and inclusion/exclusion criteria please visit About the Library.

Visit our Help page for information about searching for reporting guidelines and for general information about using our website.

Our full catalogue of reporting guidelines is
Editors of research publications

The following resources will help you to produce high quality research publications:

- Developing journal's policies on research reporting
- Guidance for peer reviewers
- Do you want to write an editorial about EQUATOR?
- What can I do to support the EQUATOR Network's effort

Developing journal's policies on research reporting

To help editors with selecting appropriate reporting guidelines to improve the accuracy and completeness of the research they publish, the EQUATOR Network has prepared a brief outline of the steps and issues editors might consider when introducing these guidelines into their journals:

- How to implement reporting guidelines in your journal: guidance from EQUATOR

The following guidance from our Library will be useful for developing or updating journals' policies and instructions on research reporting:

- Guidelines developed by influential editorial groups (WAME, ICMJE, COPE, etc.)
- Research ethics, publication ethics and good practice guidelines
- Publishers' policies on publication ethics
- Reporting guidelines

Other useful resources:

- Case studies: How journals implement reporting guidelines
5.6: Reporting guidelines: a tool to increase completeness, transparency, and value of health research published in your journal

Iveta Simera
EQUATOR Network, Centre for Statistics in Medicine, Oxford, UK

Guidelines for reporting health research: How to promote their use in your journal

Written by the EQUATOR Network Group; updated August 2013

Key points:

- Reporting guidelines help to improve the accuracy, transparency and completeness of health research publications and increase the value of published research.

EQUATOR provides free online resources in English at www.equator-network.org and in Spanish at www.espanol.equator-network.org including a comprehensive collection of reporting guidelines for health research studies.

EQUATOR recommends that editors explore the available reporting guidelines; select well developed guidelines appropriate for the reporting of research studies published by their journal; ask authors to adhere to these guidelines and ask peer reviewers to use them when assessing manuscripts.

In this document you will find information on:

- How your journal can support better reporting of health research
  - How to introduce reporting guidelines into your journal
  - How to select reporting guidelines for your journal
  - How and where to use reporting guidelines in a journal
- How to refer to the EQUATOR Network and reporting guidelines in your instructions to Authors and Instructions for Peer Reviewers
- How to describe the EQUATOR Network text that might be inserted into your Instructions to Authors; examples of how some journals encourage the use of reporting guidelines and refer to EQUATOR

Introduction

Although the ultimate responsibility for the design, conduct and accurate publication of research studies lies with the researchers, editors "should take all reasonable steps to ensure the quality of the material they publish."[1]. Guidelines for reporting health research are important tools to facilitate this task. They specify a minimum set of items needed for a complete and clear account of study methods and subsequent findings. Adherence to reporting guidelines improves the accuracy and transparency of publications (2-5). Examples of the most frequently used reporting guidelines include:

- CONSORT Statement for reporting randomised controlled trials (RCTs) (6)
- PRISMA Statement for reporting systematic reviews and meta-analyses evaluating healthcare interventions (7)
- STROBE Statement for reporting observational studies (8)
- MOOSE Statement for reporting meta-analyses of observational studies (9)
- TUGG Statement for reporting trials of diagnostic and screening tests (10)
- CHECKLIST Statement for reporting reviews of diagnostic and screening tests (11)

Background

Substantial evidence continues to accumulate demonstrating serious deficiencies in the reporting of research studies. The health research literature has become the most scrutinised area due to the rapid expansion in the development of systematic reviews and the direct impact the results of such reviews can have on patients’ care. However, other fields, for example the veterinary sciences, are quickly catching up, indicating that reporting deficiencies may be a problem across the sciences. Box 1 highlights the key

Box 1: Reporting guidelines

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Details</th>
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<tr>
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Effect of electronic medical guidelines on the reporting of abstracts of randomised controlled trials in four medical journals: systematic review and longitudinal study. 

Sally Hopewell and Isabelle Boutron. 

BMJ 2012;344:e4178 doi:

Fig 2 Change in outcomes from January 2006 to December 2009, before and after introduction of the CONSORT for Abstracts guidelines implemented in January 2008 for each journal category. Circles=actual values; straight lines=regression lines traced out by the structural predicted values; vertical lines=transition phase (February to April 2008)
Questions?

www.equator-network.org