Reporting guidelines: lessons for journal editors from the EQUATOR Network

Doug Altman

The EQUATOR Network
Centre for Statistics in Medicine, Oxford, UK

EASE, Split, June 2014
Conduct vs reporting

“By itself, accurate, transparent reporting doesn’t make good science. Knowing that editors expect a high standard of accuracy and transparency in reports of finished research can, however, encourage researchers do a better job in planning and carrying out the research in the first place.

[Davidoff F. Ann Intern Med 2000;133:229-31.]
“By itself, accurate, transparent reporting doesn’t make good science. Knowing that editors expect a high standard of accuracy and transparency in reports of finished research can, however, encourage researchers do a better job in planning and carrying out the research in the first place. Accurate, transparent reporting is like turning the light on before you clean up a room: It doesn’t clean it for you, but does tell you where the problems are.”

“Poorly conducted trials are a waste of time, effort, and money. The most dangerous risk associated with poor-quality reporting is an overestimate of the advantages of a given treatment … Whatever the outcome of a study, it is really hard for the average reader to interpret and verify the reliability of a poorly reported RCT. In turn, this problem could result in changes in clinical practice that are based on false evidence and that may harm patients.

Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information and reach his or her own conclusions about results

- to assess reliability and relevance

Readers need a clear understanding of exactly what was done

- Clinicians, Researchers, Systematic reviewers, Policy makers, ...

Research article
Transparency and value

Clinical practice and public health policy decisions depend on high-quality information about research findings

- **Research only has value if**
  - Study methods have validity
  - Research findings are published in a usable form

- **The goal should be transparency**
  - Should not mislead
  - Should allow replication (in principle)
  - Can be included in systematic review and meta-analysis

- **We need good reporting to be able to assess strength of methods**
  - This is often not what we get
Concern about methodology and reporting

- Concerns about quality of methods in health research go back to 1920s

- Concerns over reporting quality surfaced in 1980s with the growth of systematic reviews

- Huge number of studies of the quality of publications of health research
Taxonomy of poor reporting

- **Non-publication**
  Failure to publish a report of a completed study (even if was presented at a conference)
Taxonomy of poor reporting

- **Non-publication**
  Failure to publish a report of a completed study (even if was presented at a conference)

- **Selective reporting**
  Biased reporting of data within published report
Studies of outcome reporting bias in reports of randomised trials

- Several studies have found clear evidence of selective reporting of outcomes
  - Non-significant findings are less likely to be published

- 4 empirical studies found that statistically significant outcomes were more likely to be completely reported than nonsignificant outcomes (range of odds ratios: 2.2 to 4.7)
Taxonomy of poor reporting

- **Non-publication**
  Failure to publish a report of a completed study (even if was presented at a conference)

- **Selective reporting**
  Biased reporting of data within published report

- **Incomplete reporting**
  Key information is missing
Incomplete reporting of research is very common

- Hundreds of published reviews show that key elements of trial methods and findings are commonly missing from journal reports
  - Methods
  - Results
- We often cannot tell exactly how the research was done
- These problems are generic
  - not specific to randomised trials
  - not specific to studies of medicines
  - not specific to research by pharmaceutical companies

| Setting and locations where the data were collected | 69% |
| Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 86% |
| Method used to generate the random allocation sequence | 25% |
| Type of randomization; details of any restriction | 19% |
| Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned | 14% |
| Statistical methods used to compare groups for primary and secondary outcomes | 51% |
| For each primary and secondary outcome, results for each group, and the estimated effect size and its precision | 46% |
76 studies of diagnostic accuracy for DR screening published during 1995–2006

- The mean score was 20 out of a maximum of 50
- Only 9 (12%) manuscripts completely reported at least 50% of the STARD items.
Taxonomy of poor reporting

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- **Selective reporting**
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- **Incomplete reporting**
  Key information is missing

- **Misleading presentation**
  e.g. misrepresenting how study was done;
  post hoc change of focus (spin)
“Spin”

- Review of breast cancer trials
  “... spin was used frequently to influence, positively, the interpretation of negative trials, by emphasizing the apparent benefit of a secondary end point. We found bias in reporting efficacy and toxicity in 32.9% and 67.1% of trials, respectively, with spin and bias used to suggest efficacy in 59% of the trials that had no significant difference in their primary endpoint.”
  [Vera-Badillo et al, Ann Oncol 2013]
Taxonomy of poor reporting

- **Non-publication**
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- **Selective reporting**
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- **Incomplete reporting**
  Key information is missing

- **Misleading presentation**
  e.g. claiming study is an RCT when it isn’t; post hoc change of focus (spin)

- **Inconsistencies between sources**
  e.g. publication conflicts with protocol
Inconsistencies between sources are very common

- Several studies have made comparison of publications and protocols or registry entries

- For RCTs, discrepancies are common between the primary outcomes in different sources
Review of 227 drug trials

[Redmond et al, *J Clin Epidemiol* 2013]

227 trial protocols and amendments were compared with 333 matching articles published during 1990-2008

- 870 of 2,966 (29%) unique outcomes were reported discrepantly
- 7% of protocol-defined primary outcomes were not reported
- 10% of reported outcomes were not defined in protocol
- Corresponding percentages for secondary outcomes: 19% & 14%
153 test accuracy studies registered before completion

- **32%** showed discrepancies between registry and publication
- **12%** inclusion criteria had changed (+7% unclear)
- **6%** discrepancies in index test or threshold (+15%)
- **24%** showed discrepancies in primary outcome (+14%)
Taxonomy of poor reporting

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  e.g., claiming study is an RCT when it isn’t; post-hoc change of focus (spin)

- **Inconsistencies between sources**
  e.g., publication conflicts with protocol

*All of these practices are very common!*
Consequences of inadequate reporting

- Assessing the reliability of published articles is seriously impeded by inadequate reporting
  - Clinicians cannot judge whether to use a treatment
  - Data cannot be included in a systematic review

- Serious consequences for clinical practice, research, policy making, and ultimately for patients
Poor reporting is a serious problem for systematic reviews and clinical guidelines

“Risk of bias assessment was hampered by poor reporting of trial methods.”

“Poor reporting of interventions impeded replication”

“Poor reporting of duration of follow-up was a problem, making it hard to calculate numbers needed to treat to benefit.”
[Casas et al. Commentary on Inglis et al. Telemonitoring for chronic heart failure. *CDSR* 2010]

“Poor reporting of data meant that individual effect size could not be calculated for any of these studies.”
Bleakley et al. Some conservative strategies are effective when added to controlled mobilisation with external support after acute ankle sprain: a systematic review. *Aust J Physiother* 2008.
Reporting guidelines

- A minimum set of items required for a clear and transparent account of what was done and what was found in a research study
  - Reflect in particular issues that might introduce bias into the research
  - Evidence-based & reflect consensus opinion

- Benefits of using reporting guidelines
  - Improved accuracy and transparency of publications
  - Easier appraisal of reports for research quality and relevance
The CONSORT Statement for Reporting RCTs

[First version 1996; Latest version: Schulz et al, BMJ 2010]

- 25 items which should be reported in the paper
  - Based on empirical evidence where possible
- Also a flow diagram describing patient progress through the trial, which should be included in the trial report
- Most leading general medical journals and many specialist journals have already adopted the CONSORT recommendations
  - Authors should not be able to hide study inadequacies by omitting important information – transparency
CONSORT – reporting RCTs

- Structured advice, checklist and flow diagram
- Based on evidence, consensus of relevant stakeholders
- Explanation and elaboration paper

CONSORT 2010 checklist of information to include when reporting a randomised trial

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<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No.</th>
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<td>Identification as a randomised trial in the title</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>2a</td>
<td>Scientific background and explanation of rationale</td>
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<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
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<tr>
<td>Methods</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>
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<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
<td></td>
</tr>
<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 assessed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
<td></td>
</tr>
<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
<td></td>
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</table>

CONSORT 2010 Flow Diagram
CONSORT

- First and best known reporting guideline
- Model for many subsequent reporting guidelines
Many extensions to CONSORT

- Nonpharmacological treatments
- Harms
- Abstracts
- Cluster trials
- Non-inferiority and equivalence trials
- Acupuncture
- Patient reported outcomes
- ...

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Other reporting guidelines

- Other study types – CONSORT as a model
  - PRISMA (Systematic reviews of RCTs)
  - STARD (diagnostic accuracy studies)
  - STROBE (observational studies)
  - REMARK (tumour marker prognostic studies)
  - ARRIVE (animal research)
  - GRIPS (genetic risk prediction studies)
  - TRIPOD (risk prediction models) ...

- Most guidelines are not yet widely supported by medical journals or adhered to by researchers
  - Their potential impact is blunted
Factors in success of CONSORT

- Membership of group
  - Methodologists, Trialists, Editors
- Reporting rather than conduct
- Focus on main issues
  - ‘One side of paper’
- No competitors
- High profile publications
- Supported by major editorial groups, >600 journals, some funding agencies
- But adherence remains problematic
Guidance for Developers of Health Research Reporting Guidelines

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

¹Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, ²Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada, ³Family Health International, Research Triangle Park, North Carolina, United States of America, ⁴Centre 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 63,000 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. Glasziou 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 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
Review of 53 reports describing 50 evaluations of 16,604 RCTs

Endorsement of CONSORT by journals is associated with better reporting for many items of CONSORT

The completeness of reporting of trials remains sub-optimal
Has STROBE improved reporting?

- **We don’t know yet**
  - More evidence available for RCTs
  - Difficult to identify specific impact of a guideline

- **Empirical studies keep identifying deficiencies in reporting**

- **Any effect depends on endorsement / enforcement by journals**
456 cohort, case-control, and cross-sectional studies published between 2004 and 2010 in four dermatological journals

Time series of six-monthly mean STROBE scores and values predicted from the segmented and simple linear regression models.
EQUATOR Network

• Enhancing the QUALity and Transparency of health Research

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

• Launched in June 2008
EQUATOR focus

• Increase awareness of problems resulting from inadequate reporting and promote rigorous research reporting
  – Accurate, complete, transparent, timely

• 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
EQUATOR works with

- Health research professionals, clinicians
- Journals, editors, peer reviewers; publishers
- Medical librarians
- Research organisations (universities)
- Research funders
- Professional organisations and societies
New EQUATOR website

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.

Search for reporting guidelines

Visit the library for more resources

Key reporting guidelines

- CONSORT
  - Full Record
  - Checklist
  - Flow Diagram
- STARD
  - Full Record
  - Checklist
- STROBE
  - Full Record
  - Checklist
- PRISMA
  - Full Record
  - Checklist
  - Flow Diagram
- COREQ
  - Full Record
- ENTREQ
  - Full Record
- SQUIRE
  - Full Record
  - Checklist
- CHEERS
  - Full Record

Toolkits

The EQUATOR Network works to improve the reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

EQUATOR highlights

9/08/2013 - EQUATOR Network at the Peer Review Congress 2013 in Chicago

EQUATOR will be present at the Seventh International Congress on Peer Review and Biomedical Publication, 8-10 September 2013. We are organising the EQUATOR workshop for editors on reporting of research.

News

The New ICMJE Recommendations
29/08/2013

Better Reporting of Scientific Studies: Why It Matters
29/08/2013
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

Key reporting guidelines

- CONSORT
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- ENTREQ
  - Full Record
- SQUIRE
  - Full Record
  - Checklist
- CHEERS
  - Full Record

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...
Toolkits
This section of our website will help you to use guidance listed in our Library to promote, teach and practice accurate, complete and ethical publication of health research.

In addition we also provide practical resources for groups developing reporting guidelines to ensure the highest standards and usefulness of these guidelines.

Authors
Information and resources for authors

Editors
Information and resources for editors and peer reviewers

Developers
Information and resources for guideline developers

Librarians
Information and resources for librarians

Teachers
Information and resources for teachers

Key reporting guidelines
- CONSORT
- STARD
- STROBE
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- CHEERS

Library index
- 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
State of play

- Research reports are seriously inadequate
- Improvement over time is very slow
- Reporting guidelines exist
  - Adherence is generally poor
  - ... even in journals that endorse them
“It is the responsibility of everyone involved to ensure that the published record is an unbiased, accurate representation of research.”

[PLoS Medicine Editors, 2009]
How to shift the ‘reporting culture’

- **Collaboration of all parties involved in research publishing needed**
  - Scientists, research organisations, funders and regulators
  - Journals (editors, peer reviewers, publishers)
  - Other organisations (higher education, REC, ...)

- **Working towards ...**
  - Accurate, complete and transparent reporting of research studies is considered the norm

- **How to achieve this?**
  - Clearly defined policies, requirements and expectations
  - Provision of tools and other resources
  - Education and training
  - Motivation and incentives
  - Application of safeguards and checks
What should editors do?

- Be aware of the needs of readers

- Be aware of, and require authors to follow, major reporting guidelines

- Train peer reviewers

- Support registration of studies and publication of protocols
  - Ask to see protocol
Only 41/116 journals (35%) provided online instructions.
- All 41 guided reviewers about the logistics

39/41 (95%) gave instructions about evaluating manuscript
- Great variation in explicit instruction for reviewers about how to evaluate manuscript content.

19/41 (46%) mentioned reporting guidelines
- usually as general statements suggesting they may be useful
- All 19 named CONSORT but little mention of others
“AJOT has now joined 28 other major rehabilitation and disability journals in a collaborative initiative to enhance clinical research reporting standards through adoption of the EQUATOR Network reporting guidelines, described below. Authors will now be required to use these guidelines in the preparation of manuscripts that will be submitted to AJOT. Reviewers will also use these guidelines to evaluate the quality and rigor of all AJOT submissions. By adopting these standards we hope to further enhance the quality and clinical applicability of articles to our readers.”
P-values in baseline tables of randomised controlled trials are inappropriate but still common in high impact journals

MJ Knol, RHH Groenwold and DE Grobbee

<table>
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<th>Journal</th>
<th>Total N</th>
<th>p-value in baseline table N (%)</th>
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<td>JAMA</td>
<td>149</td>
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<td>NEJM</td>
<td>321</td>
<td>169 (54.3%)</td>
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<td>59 (47.2%)</td>
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<td>European Heart Journal</td>
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<td>BMJ</td>
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<td>11 (7.7%)</td>
</tr>
<tr>
<td>Lancet</td>
<td>254</td>
<td>5 (2.0%)</td>
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<tr>
<td>Total</td>
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<td>388 (34.8%)</td>
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Results of a longitudinal study of rigorous manuscript submission guidelines designed to improve the quality of clinical research reporting in a peer-reviewed surgical journal

Kathryn E. Wynne, B. Joyce Simpson, Loren Berman, Shawn J. Rangel, Jay L. Grosfeld, R. Lawrence Moss

The *Journal of Pediatric Surgery* instituted specific reporting guidelines for authors in June 2006. 73 articles before implementation and 147 articles after implementation were independently assessed by 2 reviewers (observational studies). Mean global composite scores increased from 72.2 to 80.1 post-Guidelines (P<0.0001).
Active assessment of randomized clinical trial reporting during the editorial process (n=23; 7 were published)

All published trials in 2011-2013, reported 33 of 37 CONSORT (sub) items.
Can the lessons learned from health be extended to other disciplines?

Definitely!

- The principles of good reporting apply to all scientific research
  - Reproducibility implies transparent reporting
## Citations of CONSORT 2001 (n=5312)

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• Biomedical (laboratory) research – *omics* disciplines
  – MIBBI portal

• Veterinary sciences

• Animal research
  – ARRIVE guideline (animal laboratory research)
  – REFLECT statement (RCT in livestock)

• Forensic sciences

• Software engineering

... growing interest in reporting quality and RG development
Survey of the Quality of Experimental Design, Statistical Analysis and Reporting of Research Using Animals

Carol Kilkenny¹*, Nick Parsons², Ed Kadyszewski³, Michael F. W. Festing⁴, Innes C. Cuthill⁵, Derek Fry⁶, Jane Hutton⁷, Douglas G. Altman⁸

Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research

Carol Kilkenny¹*, William J. Browne², Innes C. Cuthill³, Michael Emerson⁴, Douglas G. Altman⁵
10.1 Introduction

In the transaction of science and humanities, inaccurate acting in the field of archaeo-
logical interpretation of geophysical data causes hardly reparable damages to mutual trust, an indispen-
sable precondition in interdisciplinary research. A proper interpretation of data not only requires being
native in one’s own special field, in this case in the field of applied geophysics, but it also challenges qual-
ities of a versed translator. Since geophysical works in archaeology may be related to manifold kind of
archaeological sites starting
PsychDisclosure.org: Grassroots Support for Reforming Reporting Standards in Psychology

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Importance of good research reporting

Research reports should present sufficient information to allow a full evaluation of the presented data and further use of these findings

Good reporting is an essential part of doing good research

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