Reporting guidelines and EQUATOR resources

Iveta Simera

The EQUATOR Network workshop
7 September, Chicago, USA
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)
“Hierarchy” of reporting guidelines

Recommendations

RGs

Broad

GENERIC

Narrow

SPECIFIC
“Hierarchy” of reporting guidelines

**Recommendations**
- Broad
- Narrow

**RGs**
- GENERIC
- SPECIFIC

**Frequency of RGs**
- Few RGs
- Many RGs
Different focus of RG (1)

- **STUDY DESIGN / METHODOLOGY**

- Generally applicable, key methodology features, no details specific to diseases, etc.

- Generic framework for reporting key aspects of:
  - Main study designs / types (generic guidelines)
  - More specialised designs
  - Specific methods, evaluations, analyses

Core RG ("Must")
Examples: main study design

Guidelines and Guidance

CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials

Kenneth F. Schulz1*, Douglas G. Altman2, David Moher3, for the CONSORT Group

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

Introduction

Randomised controlled trials, when appropriately designed, conducted, and reported, represent the gold standard in evaluating healthcare interventions. However, randomised trials can yield biased results if they lack methodological rigour [1]. To assess a trial accurately, readers of a published report need complete, clear, and transparent information on its methodology and findings. Unfortunately, attempted assessments frequently fail because authors of many trial reports neglect to provide lucid and complete descriptions of that critical information [2,3,4].

That lack of adequate reporting fuelled the development of the original CONSORT (Consolidated Standards of Reporting Trials) statement in 1996 [5] and its revision five years later [6,7,8]. While those statements improved the reporting quality for some randomised controlled trials [9,10], many trial reports still remain inadequate [2]. Furthermore, new methodological evidence and additional experience has accumulated since the last revision in 2001. Consequently, we organised a CONSORT Group meeting to update the 2001 statement [6,7,8]. We introduce here the result of that process, CONSORT 2010.

Intent of CONSORT 2010

The CONSORT 2010 Statement is this paper including the 25 indirect goal of our work. Moreover, CONSORT can help researchers in designing their trial.

Background to CONSORT

Efforts to improve the reporting of randomised controlled trials accelerated in the mid-1990s, spurred partly by methodological research. Researchers had shown for many years that authors reported such trials poorly, and empirical evidence began to accumulate that some poorly conducted or poorly reported aspects of trials were associated with bias [14]. Two initiatives aimed at developing reporting guidelines culminated in one of us (DM) and Drummond Rennie organising the first CONSORT statement in


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Examples: specialised design

RESEARCH METHODS & REPORTING

Consort 2010 statement: extension to cluster randomised trials

The Consolidated Standards of Reporting Trials (CONSORT) statement was developed to improve the reporting of randomised controlled trials. It was initially published in 1996 and focused on the reporting of parallel group randomised controlled trials. The statement was revised in 2001, with a further update in 2010. A separate CONSORT statement for the reporting of abstracts was published in 2008. In earlier papers we considered the implications of the 2001 version of the CONSORT statement for the reporting of cluster randomised trials. In this paper we provide updated and extended guidance, based on the 2010 version of the CONSORT statement and the 2008 CONSORT statement for the reporting of abstracts.

Marion K Campbell director¹, Gilda Piaggio honorary professor², Diana R Elbourne professor of healthcare evaluation², Douglas G Altman director³, for the CONSORT Group

¹Health Services Research Unit, University of Aberdeen, Aberdeen AB25 2ZD, UK; ²Department of Medical Statistics, London School of Hygiene and Tropical Medicine, London, UK; ³Centre for Statistics in Medicine, University of Oxford, Oxford, UK

Many journals now require that reports of trials conform to the guidelines in the Consolidated Standards of Reporting Trials (CONSORT) statement, first published in 1996, which in the terms “community” or “group” randomised trials are included.
Examples: methods

Basic Statistical Reporting for Articles Published in Biomedical Journals: The “Statistical Analyses and Methods in the Published Literature” or The SAMPL Guidelines

Thomas A. Lang\textsuperscript{a} and Douglas G. Altman\textsuperscript{b}
\textsuperscript{a}Principal, Tom Lang Communications and Training International
\textsuperscript{b}Director, Centre for Statistics in Medicine, Oxford University

\textit{Have they reflected that the sciences founded on observation can only be promoted by statistics? . . . If medicine had not neglected this instrument, this means of progress, it would possess a greater number of positive truths, and stand less liable to the accusation of being a science of unfixed principles, vague and conjectural.}

Jean-Etienne Dominique Esquirol, an early French psychiatrist, quoted in The Lancet, 1838 [1]

\textbf{Introduction}

The first major study of the quality of statistical reporting in the biomedical literature was published in 1966 [2]. Since then, dozens of similar studies have been published, every one of which has found that large proportions of articles contain errors in the application, analysis, interpretation, or reporting of statistics or in the design or conduct of research. (See, for example, references 3 through 19.) Further, large proportions of these errors are in basic, not advanced, statistical methods [23]. Perhaps advanced methods are suggested by consulting statisticians, who then competently perform the analyses, but it is also true that authors are far more likely to use only elementary statistical methods, if they use any at all [23-26]. Still, articles with even major errors continue to pass editorial and peer review and to be published in leading journals.
Different focus of RG (2)

- SPECIFIC DISCIPLINE / CLINICAL AREA
- Different ‘degree’ of specificity
- May or may not address general methodology items
- May focus on a complete research study / paper or only on a part

Should be used with relevant generic methodology guidelines as they often focus only on content specifics
Examples

Preliminary Core Set of Domains and Reporting Requirements for Longitudinal Observational Studies in Rheumatology

FREDERICK WOLFE, MARISSA LASSE, DÉSIRÉE van der HEIJDE, GEROLD STUCKI, MARIA SUAREZ-ALMAZOR, THEODORE PINCUS, KERSTIN EBERHARDT, TORE K. KVIEN, DEBORAH SYMMONS, ALAN SILMAN, PIET van RIEL, PETER TUGWELL, and MAARTEN BOERS

ABSTRACT. Observational and longitudinal observational studies (LOS) provide essential information about the course and outcome of rheumatic disorders that cannot be provided by randomized controlled trials, and they constitute the major clinical scientific communication in rheumatology. There has been no consensus as to the full and appropriate content of LOS. This report defines a core set of domains and reporting requirements for LOS. At the 1998 OMERACT IV Conference a consensus process evaluated the literature of rheumatology in light of the constructs, variables, and outcomes of rheumatology by using introductory lectures, nominal groups, and plenary sessions. The result of this process was to identify 5 “core” domains that should be included in every LOS: Health Status, Disease Process, Damage, Mortality, and Toxicity/Adverse Reactions. Two additional domains, Work Disability and Costs, were recognized as important, but need not be used in all LOS. Eleven subdomains were identified that divided the domains into convenient clinical and conceptual units. A set of reporting requirements was also determined. The core recommendations, which follow on the WHO ICD-9 outline, are not disease-specific: the substitution of different “disease process” and “damage” measures make them suitable for many rheumatic disorders. The core set is intended to serve as a core for LOS in almost all rheumatic conditions. (J Rheumatol 1999;26:484-9)

Key Indexing Terms:
OMERACT  RHEUMATIC DISEASES  LONGITUDINAL AND OBSERVATIONAL STUDIES

Longitudinal and observational studies (LOS) provide essential information about the course and outcome of Included in the information that may be provided by these studies are effects of treatment, sociodemographic factors.
Revised Recommendations of the International Working Group for Diagnosis, Standardization of Response Criteria, Treatment Outcomes, and Reporting Standards for Therapeutic Trials in Acute Myeloid Leukemia


Abstract: An International Working Group met to revise the diagnostic and response criteria for acute myelogenous leukemia originally published in 1990, as well as to provide definitions of outcomes and reporting standards to improve interpretability of data and comparisons among trials. Since the original publication, there have been major advances in our understanding of the biology and molecular genetics of acute leukemia that are clinically relevant and warrant incorporation into response definitions. Differences from the 1990 recommendations included a category of leukemia-free state, new criteria for complete remission, including cytogenetic and molecular remissions and remission duration. Storage of viable blasts for correlative studies is important for future progress in the therapy of these disorders.


In 1988, a group of investigators interested in the design and conduct of clinical trials in acute myeloid leukemia (AML) met at the National Cancer Institute (United States) and developed a set of recommendations for response assessment. The subsequent publication was widely adopted as a standardized means of designing and reporting trials, although various study directors have identified deficiencies that revisions of these guidelines were needed. In addition, new therapeutic agents with different mechanisms of action and toxicities had become available. As a result, an international group of investigators met in Madrid, Spain, March 23–25, 2001, to develop a revised set of recommendations that incorporated new concepts of biology and therapy (Table 1).

The following guidelines were developed with the intent of...
Large number of RGs

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
  - Biopsychometric reporting
  - Reliability and agreement studies
  - Systematic reviews
  - Qualitative research
  - Mixed methods studies
  - Economic evaluations
  - Quality improvement studies
  - Other reporting guidelines
  - Reporting data
  - Statistical methods and analyses
  - Sections of research reports
  - Specific conditions or procedures.

- Reporting guidelines under development
- Reporting guidelines in other research fields
- Guidance on scientific writing
- Guidance developed by editorial groups
- Industry sponsored research – additional guidance
- Research ethics, publication ethics and good practice guidelines
- Development and maintenance of reporting guidelines
- Editorials introducing RGs
- Examples of guidelines for peer reviewers
- Case studies: RG implementation
- Examples of good research reporting
- Useful and interesting presentations
- EQUATOR ‘pick’ – comments, discussion and other thought provoking articles and

EQUATOR Library currently over 200 RG (2013)

EQUATOR selection criteria:

- Deliberately broad (comprehensive collection)
- No assessment of development methods, usability, etc.

Available RG vary in:

- Scope
- Development methods
- Presentation of recommendations

Need to understand this to use available guidelines effectively
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, Flow Diagram
- 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
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

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

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...
Displaying 216 reporting guidelines found.

Most recently added records are displayed first.

1. Neuroimaging standards for research into small vessel disease and its contribution to ageing and neurodegeneration


3. Systematic Reviews: CRD’s guidance for undertaking reviews in health care


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Our full catalogue of reporting guidelines is available to download as a PDF: Reporting Guideline Catalogue August 2013.
Editors toolkit

Editors toolkit

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
Questions ?

www.equator-network.org