Reporting guidelines and EQUATOR resources

Iveta Simera

The EQUATOR Network workshop
7 September, Chicago, USA

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C S M

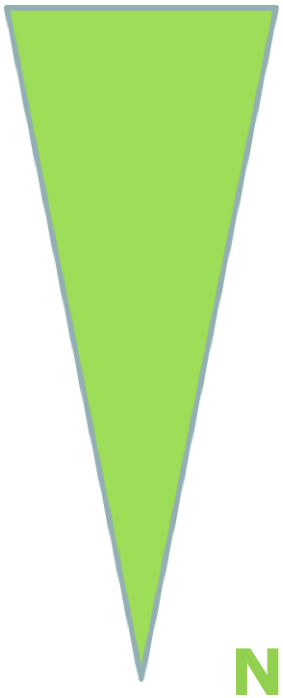
Reporting guidelines (RGs)

- 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

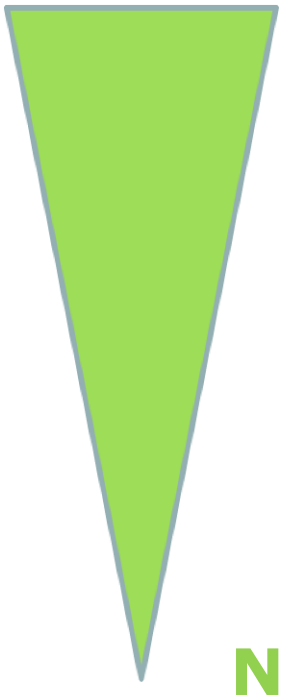
GENERIC

Narrow

SPECIFIC

"Hierarchy" of reporting guidelines

Recommendations | RGs | Frequency of RGs



Broad — **GENERIC** — **Few RGs**

Narrow — **SPECIFIC** — **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

OPEN ACCESS Freely available online

PLoS MEDICINE

Guidelines and Guidance

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

Kenneth F. Schulz[1]*, Douglas G. Altman[2], David Moher[3], 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

Citation: Schulz KF, Altman DG, Moher D, CONSORT Group (2010) CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials. PLoS Med 7(3): e1000251. doi:10.1371/journal.pmed.1000251

Published March 24, 2010

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Examples: specialised design

BMJ 2012;345:e5661 doi: 10.1136/bmj.e5661 (Published 4 September 2012)

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 trial. 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 *director*[1], Gilda Piaggio *honorary professor*[2], Diana R Elbourne *professor of healthcare evaluation*[2], Douglas G Altman *director*[3], for the CONSORT Group

[1]Health Services Research Unit, University of Aberdeen, Aberdeen AB25 2ZD, UK; [2]Department of Medical Statistics, London School of Hygiene and Tropical Medicine, London, UK; [3]Centre 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 and revised 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[a] and **Douglas G. Altman**[b]
[a] Principal, Tom Lang Communications and Training International
[b] Director, Centre for Statistics in Medicine, Oxford University

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]

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

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.

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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 LASSERE, 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 ICIDH-2 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

Examples

SPECIAL ARTICLE

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

By Bruce D. Cheson, John M. Bennett, Kenneth J. Kopecky, Thomas Büchner, Cheryl L. Willman, Elihu H. Estey, Charles A. Schiffer, Hartmut Doehner, Martin S. Tallman, T. Andrew Lister, Francesco Lo-Coco, Roel Willemze, Andrea Biondi, Wolfgang Hiddemann, Richard A. Larson, Bob Löwenberg, Miguel A. Sanz, David R. Head, Ryuzo Ohno, and Clara D. Bloomfield

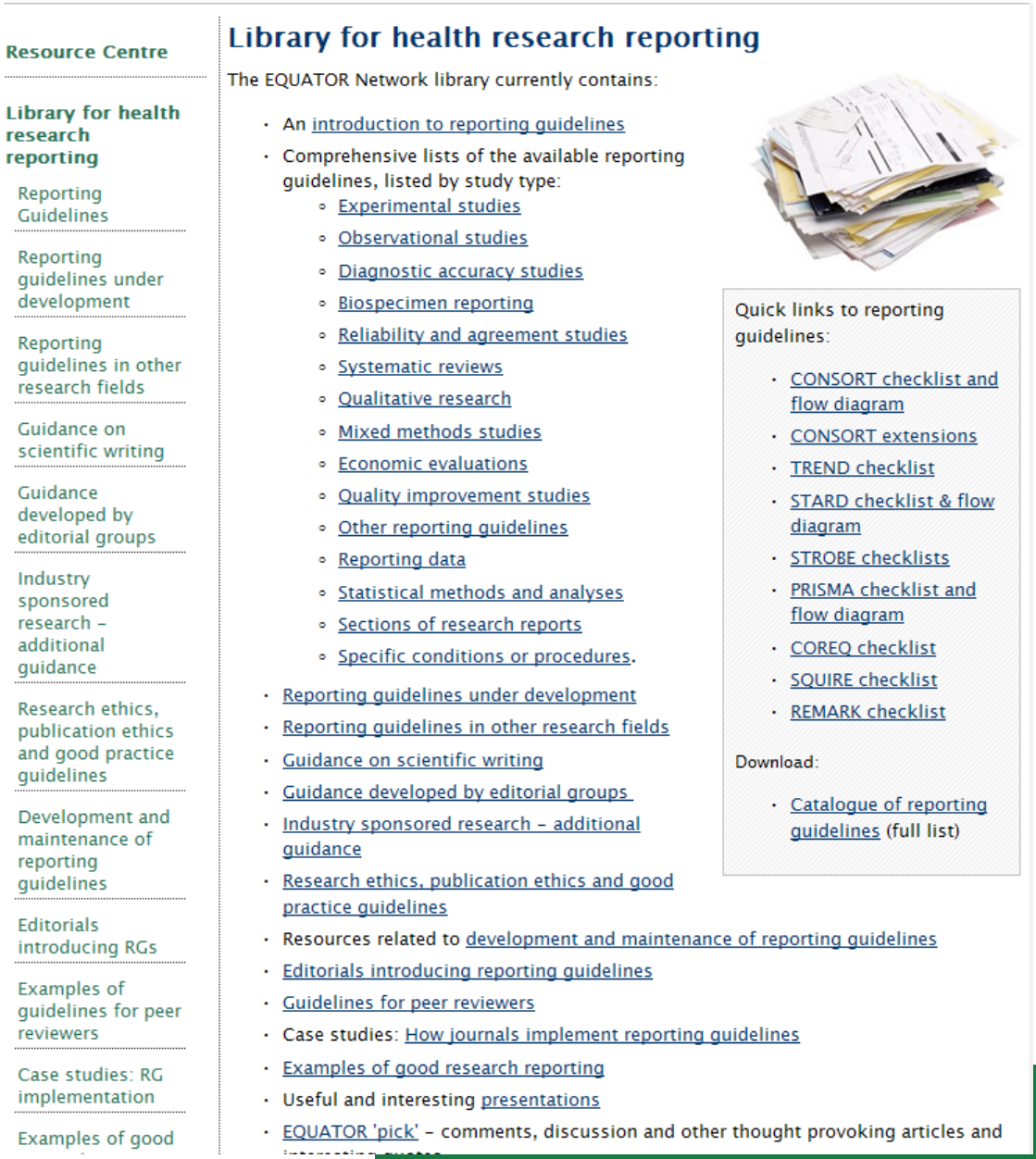
Abstract: **An International Working Group met to revise the diagnostic and response criteria for acute myelogenous leukemia originally published in 1990, as well as to provide definitions of outcomes and reporting standards to improve interpretability of data and comparisons among trials. Since the 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.**
J Clin Oncol 21:4642-4649.

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.[1] The subsequent publication was widely adopted as a standardized means of designing and reporting trials,[1] although various study

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



Resource Centre

Library for health research reporting

- Reporting Guidelines
- 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

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
  - 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
- Resources related to development and maintenance of reporting guidelines
- Editorials introducing reporting guidelines
- Guidelines for peer reviewers
- Case studies: How journals implement reporting guidelines
- Examples of good research reporting
- Useful and interesting presentations
- EQUATOR 'pick' – comments, discussion and other thought provoking articles and

Quick links to reporting guidelines:

- CONSORT checklist and flow diagram
- CONSORT extensions
- TREND checklist
- STARD checklist & flow diagram
- STROBE checklists
- PRISMA checklist and flow diagram
- COREQ checklist
- SQUIRE checklist
- REMARK checklist

Download:

- Catalogue of reporting guidelines (full list)

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

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Enhancing the QUAlity and Transparency Of health Research

Visit the EQUATOR Spanish Website

Home | Library | Toolkits | Courses & events | News | Blog | About us | Contact

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

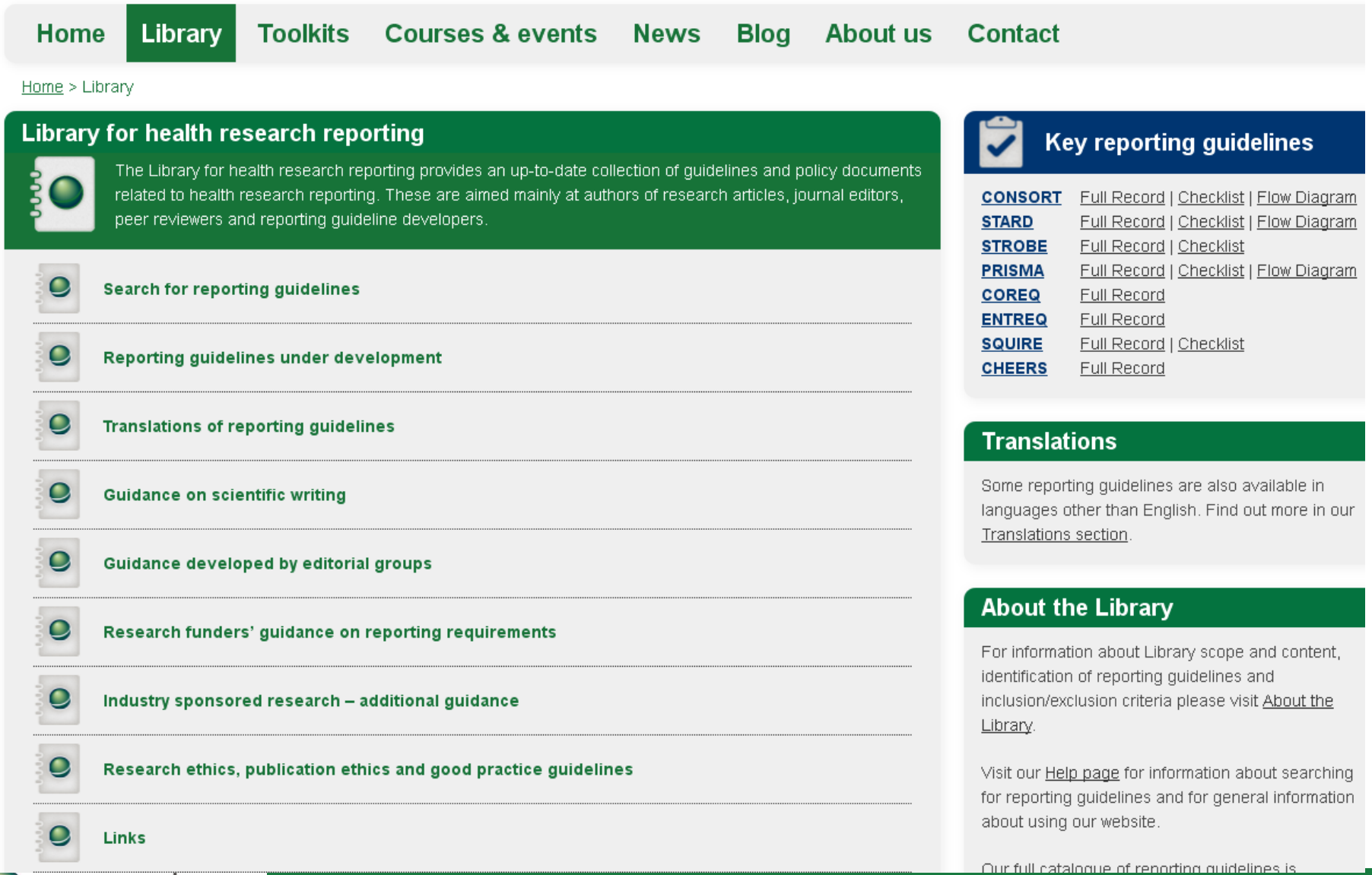
EQUATOR will be present at the Seventh International Congress on Peer Review and Biomedical Publication, 8-10 September 2013. We are organising the EQUATOR workshop for editors on reporting of research

News

The New ICMJE Recommendations
29/08/2013

Better Reporting of Scientific Studies: Why It Matters
28/08/2013

Library for health research reporting



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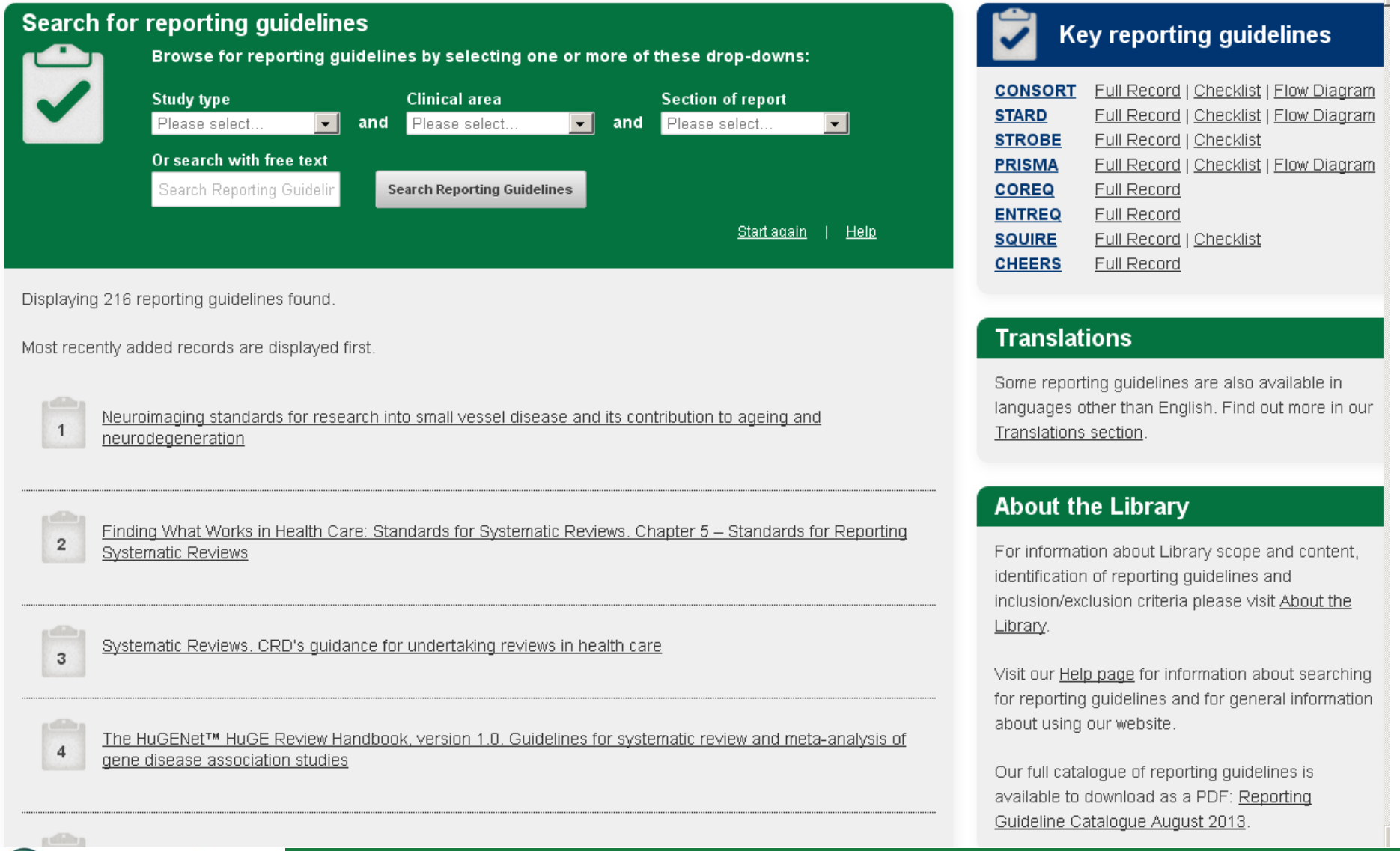
Reporting guidelines database



Editors toolkit

Home | Library | **Toolkits** | Courses & events | News | Blog | About us

Home > Toolkits

Toolkits

This section of our website will help you to use guidance listed in our
complete and ethical publication of health research.

In addition we also provide practical resources for groups developing
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

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
- Simera I.: Reporting guidelines: a tool to increase completeness,transparency, and value of health research published in your journal. Chapter 5.6 (in proof) in Smart P., Maisonneuve H. and Polderman A. (eds) Science Editors' Handbook European Association of Science Editors. www.ease.org.uk.

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

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Questions ?

www.equator-network.org