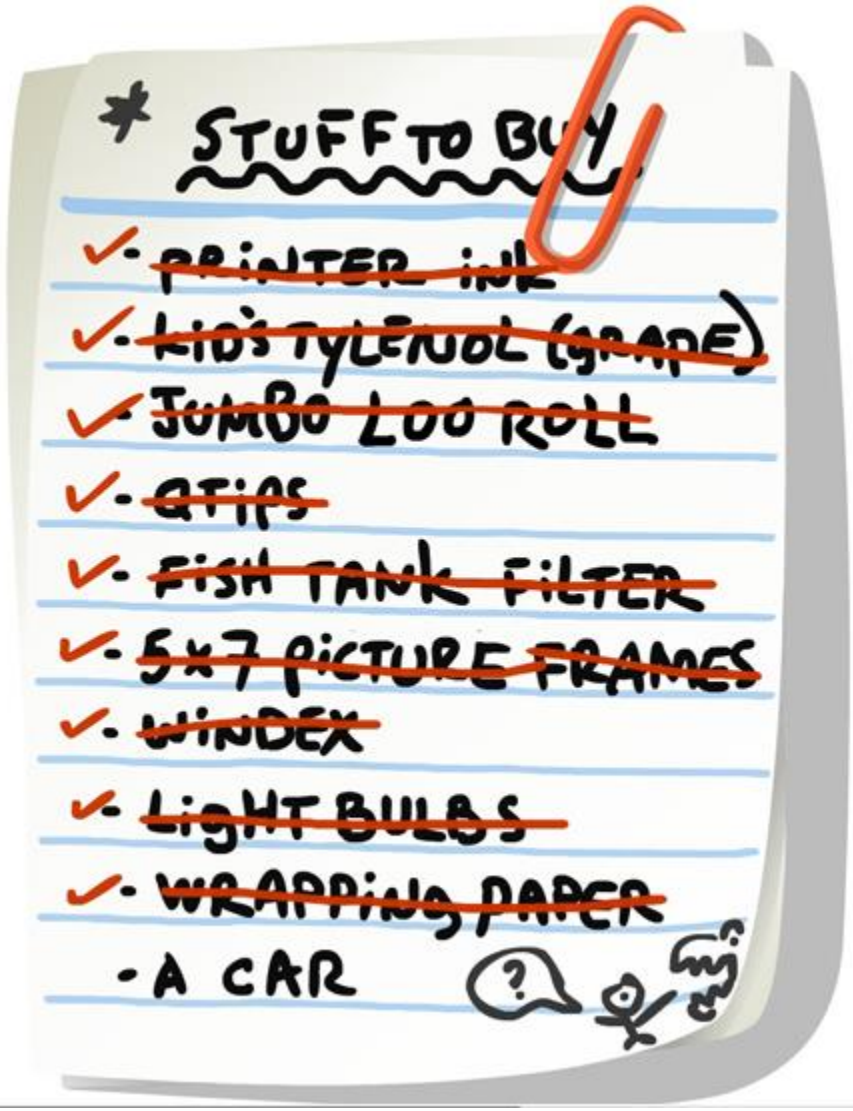
Making sense of reporting guidelines

Iveta Simera

EASE conference, Split, June 2014


* STUFF TO BUY
- PRINTER INK
- KID'S TYLENOL (GRAPE)
- JUMBO LOO ROLL
- QTIPS
- FISH TANK FILTER
- 5x7 PICTURE FRAMES
- WINDEX
- LIGHT BULBS
- WRAPPING PAPER
- A CAR

Reporting guidelines

- '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

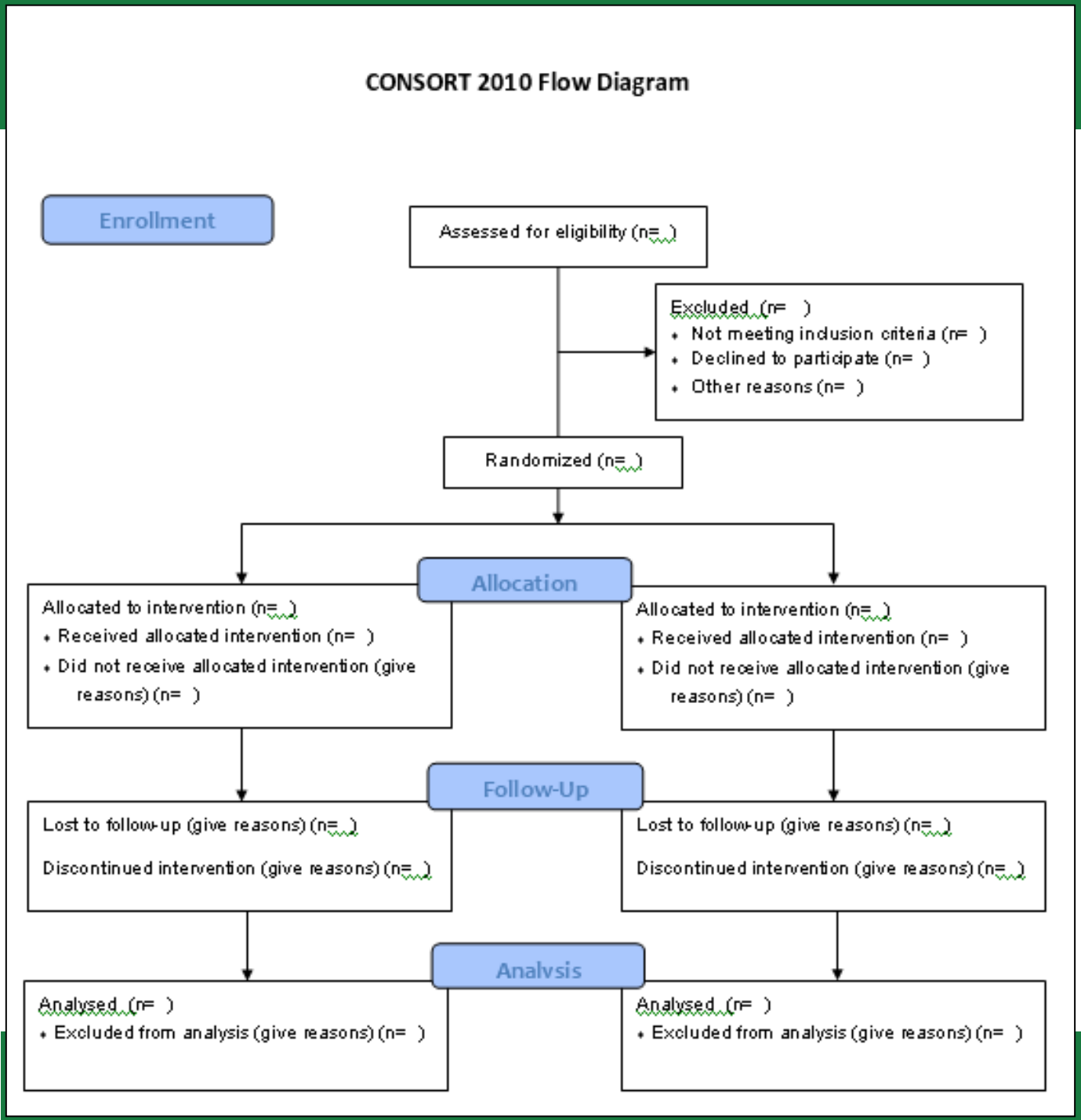
- Randomised trials → **CONSORT**
- Cohort studies
- Cross-sectional studies
- Case-control studies → **STROBE**
- Case reports → **CARE**
- Qualitative research → **COREQ**
- Research synthesis (systematic reviews) → **PRISMA** **ENTREQ**

Study reporting framework

Reporting RCTs - CONSORT

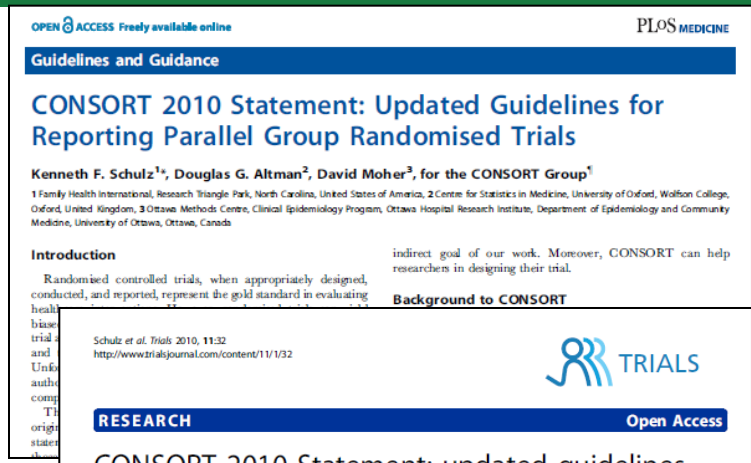
CONSORT 2010 Checklist **www.consort-statement**

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


CONSORT 2010 Flow Diagram
Enrollment
Assessed for eligibility (n=)
Excluded (n=)
Not meeting inclusion criteria (n=)
Declined to participate (n=)
Other reasons (n=)
Randomized (n=)
Allocation
Allocated to intervention (n=)
Received allocated intervention (n=)
Did not receive allocated intervention (give reasons) (n=)
Allocated to intervention (n=)
Received allocated intervention (n=)
Did not receive allocated intervention (give reasons) (n=)
Follow-Up
Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)
Lost to follow-up (give reasons) (n=)
Discontinued intervention (give reasons) (n=)
Analysis
Analysed (n=)
Excluded from analysis (give reasons) (n=)
Analysed (n=)
Excluded from analysis (give reasons) (n=)

Reporting RCTs - CONSORT

- Revised checklist
- Short paper
  (published in 9 journals)
- Revised (and expanded)
  explanatory paper (E&E)



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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

indirect goal of our work. Moreover, CONSORT can help researchers in designing their trial.

Background to CONSORT

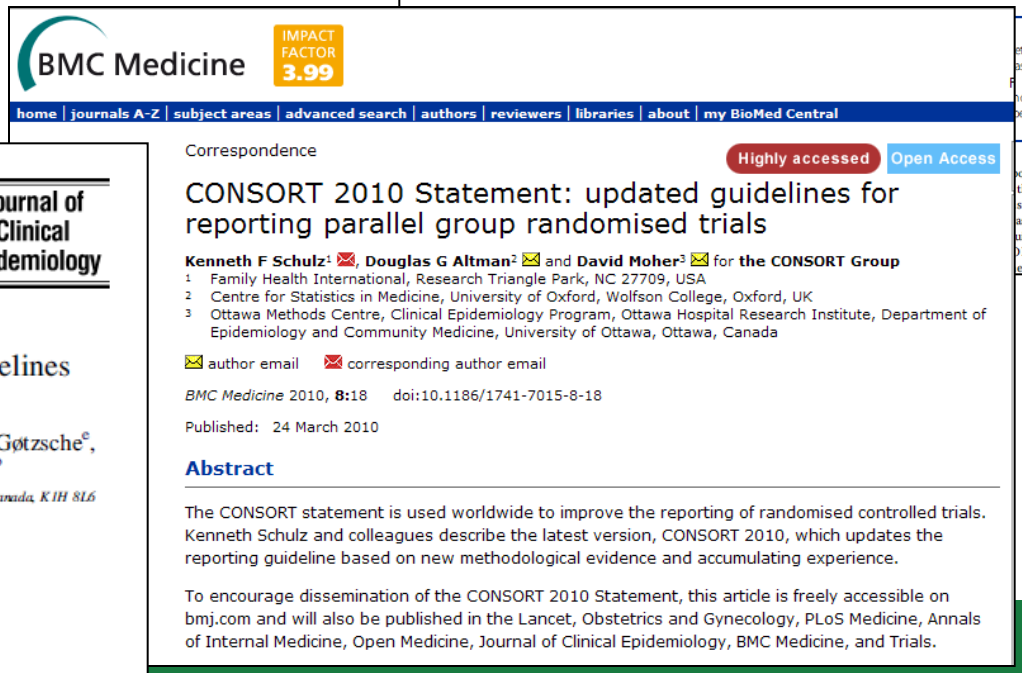
Schulz et al. Trials 2010, 11:32
http://www.trialsjournal.com/content/11/1/32

TRIALS

RESEARCH Open Access

CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz[1*], Douglas G Altman[2], David Moher[3], the CONSORT Group



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CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz[1] ✉, **Douglas G Altman**[2] ✉ and **David Moher**[3] ✉ for **the CONSORT Group**

1 Family Health International, Research Triangle Park, NC 27709, USA
2 Centre for Statistics in Medicine, University of Oxford, Wolfson College, Oxford, UK
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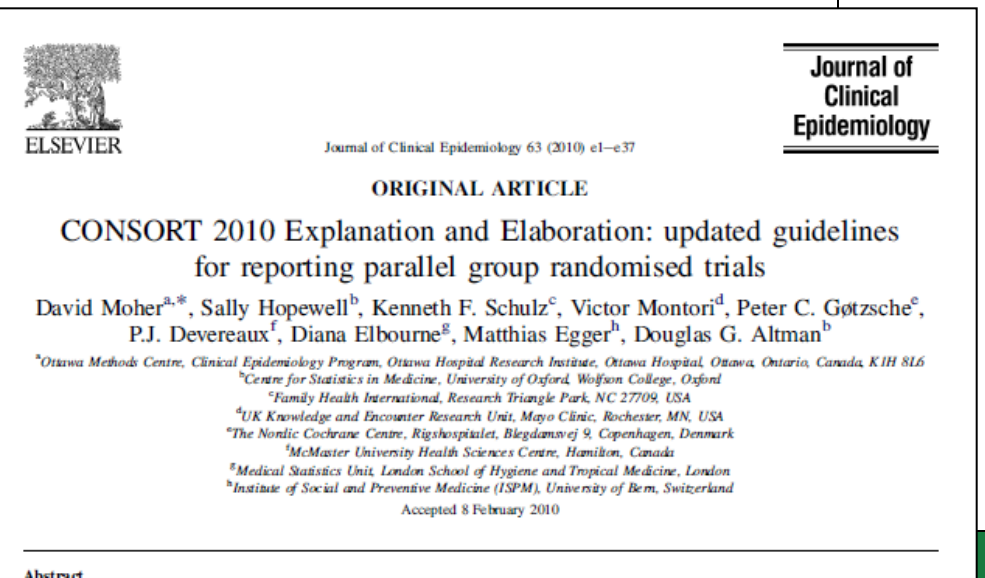
BMC Medicine 2010, **8**:18 doi:10.1186/1741-7015-8-18

Published: 24 March 2010

Abstract

The CONSORT statement is used worldwide to improve the reporting of randomised controlled trials. Kenneth Schulz and colleagues describe the latest version, CONSORT 2010, which updates the reporting guideline based on new methodological evidence and accumulating experience.

To encourage dissemination of the CONSORT 2010 Statement, this article is freely accessible on bmj.com and will also be published in the Lancet, Obstetrics and Gynecology, PLoS Medicine, Annals of Internal Medicine, Open Medicine, Journal of Clinical Epidemiology, BMC Medicine, and Trials.



ELSEVIER

Journal of Clinical Epidemiology

Journal of Clinical Epidemiology 63 (2010) e1–e37

ORIGINAL ARTICLE

CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

David Moher[a,*], Sally Hopewell[b], Kenneth F. Schulz[c], Victor Montori[d], Peter C. Gøtzsche[e], P.J. Devereaux[f], Diana Elbourne[g], Matthias Egger[h], Douglas G. Altman[b]

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[h]*Institute of Social and Preventive Medicine (ISPM), University of Bern, Switzerland*

Accepted 8 February 2010

Abstract

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

Types of studies by research questions / focus

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

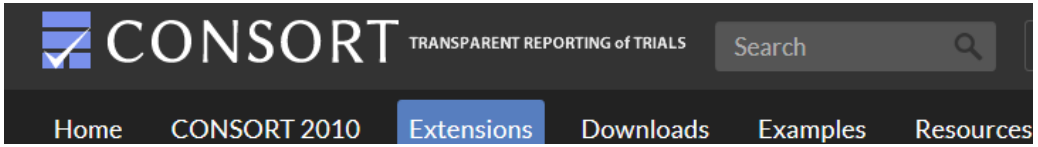
Protocol
SPIRIT

RCT - Study report
CONSORT

Abstracts
CONSORT for abstracts

Harms
CONSORT for harms

Specific trial design
CONSORT Clusters



Designs	Interventions	Data
Cluster Trials	Herbal Medicinal Interventions	CONSORT-Pro
Non-Inferiority and Equivalence Trials	Non-Pharmacologic Treatment Interventions	Harms
Pragmatic Trials	Acupuncture Interventions	Abstracts

Content specific (medical area)

Trials in Asthma
Trials in AML

Best place to find reporting guidelines

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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
STROBE	Full Record | Checklist
PRISMA	Full Record | Checklist | Flow Diagram
STARD	Full Record | Checklist | Flow Diagram
COREQ	Full Record
ENTREQ	Full Record
SQUIRE	Full Record | Checklist
CARE	Full Record | Checklist
SAMPL	Full Record
SPIRIT	Full Record | Checklist

Toolkits

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

Our Toolkits support different user groups, including:

Authors

Information and resources for authors

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 – PAHO 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

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 **QUA**lity and **T**ransparency **O**f health **R**esearch

- 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**

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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

EQUATOR Library

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
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SQUIRE	Full Record | Checklist
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SAMPL	Full Record
SPIRIT	Full Record | Checklist

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

EQUATOR toolkits

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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Smart P., Maisonneuve H. and Polderman A. (eds) Science Editors' Handbook
European Association of Science Editors. www.ease.org.uk

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, U

"Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication."
Declaration of Helsinki - Ethical principles for medical research (www.wma.net/en/30publications/10policies/b3/index.html)

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

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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 health care

Effect of e
guidelines
medical jo

Sally Hopewell *ser*
Isabelle Boutron *a*

BMJ 2012;344:e4178 doi:

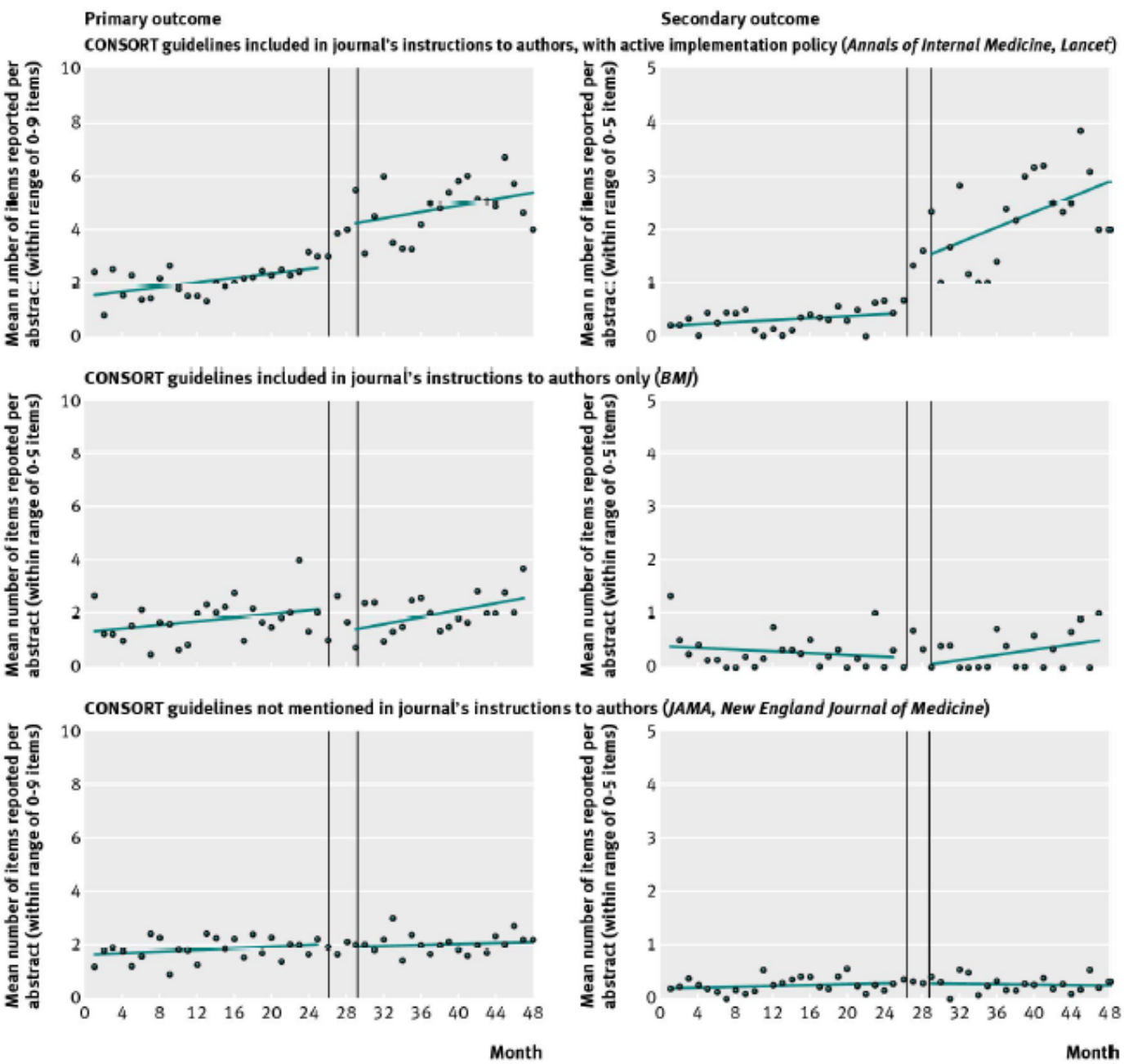

Fig 2 Change in outcomes from January 2006 to December 2009, before and after introduction of the CONSORT for Abstracts guidelines implemented in January 2008 for each journal category. Circles=actual values; straight lines=regression lines traced out by the structural predicted values; vertical lines=transition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

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Questions ?

www.equator-network.org