The EQUATOR Network:

Guidance to encourage accurate and transparent reporting in health research publications

Iveta Simera & Eleana Villanueva

The EQUATOR Network workshop
22 October 2012, CRICS, Washington

Who we are

Iveta Simera

Head of Programme Development

EQUATOR Network; Oxford

Experience:

Laboratory research, systematic reviews, research reporting and reporting guidelines

Writing, reviewing, training

Eleana C Villanueva

Advisor, Research Promotion and Development, PAHO, Washington

Experience:

Technical publishing, social marketing, communications, audience research, dissemination

What we plan to do today

Time	Title	Facilitator	Session description
18.00	Introduction, workshop agenda, learning objectives	IS	
18.05	Clarity, completeness, accuracy: three essential elements of good research reporting	IS	*Introductory talk followed by questions*
18.25	EQUATOR Network: helping editors, peer reviewers and authors to publish well reported research studies	IS	*Talk followed by questions*
18.30	Introducing key reporting guidelines	IS	*Talk followed by questions*
18.45	Questions ***(optional short break)***		
18.55	EQUATOR – PAHO collaboration to raise standards in research reporting	EV	*Talk followed by questions*
19.10	How to increase awareness and implementation of principles of good research reporting and available resources: seeking collaborators	IS / EV	*Group discussion*
19.30	Workshop ends	IS	

What we hope to achieve today

1. Understand the importance of transparency, accuracy, and completeness in reporting health research and be familiar with common deficiencies in the reporting of research studies

2. Understand the key concepts of reporting guidelines and their efficient use

3. Learn about the main elements of selected reporting guidelines: CONSORT (reporting RCTs); PRISMA (reporting systematic reviews and meta-analyses) and STROBE (reporting epidemiological studies)

4. Understand and efficiently use the EQUATOR Network online resources available in English and Spanish (www.equator-network.org; www.espanol.equator-network.org)

5. Discuss the practical implementation of reporting guidelines within health research journals and organisations

Clarity, completeness, accuracy:

three essential elements of good research reporting

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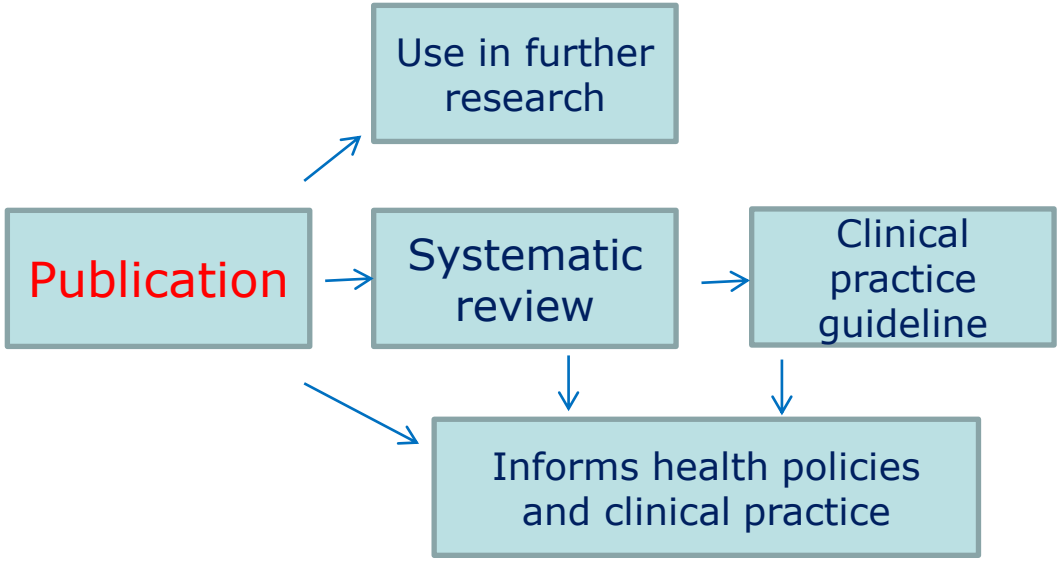
Research article: "fit for purpose"

- Published research article is a permanent record
- Will be used by different users for different purposes which means different needs for reporting
  - From brief scanning for information
  - To rigorous scrutiny of methodology and findings for possible comparison across studies in systematic reviews
- Published article should be fit for these multiple purposes
- New ways of publishing (e.g. online suppl) can aid readability without excluding crucial information

Research article

- Research article is 'end product' of one process …

- …and 'raw material' of other processes



Much evidence of poor reporting

- Hundreds of reviews of assessing published research articles
  - Highlighting severe deficiencies in reporting (biased or unusable research reports)
  - These deficiencies limit or prevent use of many of the published findings further in research or clinical practice

OPEN ACCESS Freely available online — PLoS one

Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias

Kerry Dwan[1]*, Douglas G. Altman[2], Juan A. Arnaiz[3], Jill Bloom[4], An-Wen Chan[5], Eugenia Cronin[6], Evelyne Decullier[7], Philippa J. Easterbrook[8], Erik Von Elm[9,10], Carrol Gamble[1], Davina Ghersi[11], John P. A. Ioannidis[12,13], John Simes[14], Paula R. Williamson[1]

1 Centre for Medical Statistics and Health Evaluation, University of Liverpool, Liverpool, United Kingdom, 2 Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom, 3 Clinical Pharmacology Unit, IAISP Hospital Clinic, Barcelona, Spain, 4 Moorfields Eye Hospital, London, United Kingdom, 5 Randomized Controlled Trials Unit, Canadian Institutes of Health Research, Ottawa, Canada, 6 Healthier Communities/Public Health, Greenwich Council, London, England, 7 Clinical Epidemiology Unit, DIM-Hospices Civils de Lyon, Lyon, France, 8 Department of HIV/GUM, King's College London, London, United Kingdom, 9 Institute of Social and Preventive Medicine, University of Bern, Bern, Switzerland, 10 German Cochrane Centre, Department of Medical Biometry and Medical Informatics, University Medical Centre Freiburg, Freiburg, Germany, 11 NHMRC Clinical Trials Centre, Camperdown, Australia, 12 Department of Hygiene and Epidemiology, University of Ioannina School of Medicine, Ioannina, Greece, 13 Institute for Clinical Research and Health Policy Studies, Dep… Massachusetts, United States of America, 14 National Health and Medical R…

Abstract

Background: The increased use of meta-analysis in sys… types of bias that can arise during the completion … recognised as a potential threat to the validity of meta… decision making. Until recently, outcome reporting bia…

Methodology/Principal Findings: We review and sur… assessed study publication bias and outcome reporting … which only two followed the cohort all the way throu… outcomes. Eleven of the studies investigated study pu… studies have found that statistically significant outcor… significant outcomes (range of odds ratios: 2.2 to 4.7). In… studies had at least one primary outcome that was cha… analysis due to the differences between studies.

Conclusions: Recent work provides direct empirical e… reporting bias. There is strong evidence of an associat… positive or significant results are more likely to be publi… of being fully reported. Publications have been found t… of the problems of both types of bias and efforts shou…

Citation: Dwan K, Altman DG, Arnaiz JA, Bloom J, Chan A-W, et al. (2008… Reporting Bias. PLoS ONE 3(8): e3081. doi:10.1371/journal.pone.0003081

Editor: Nandi Siegfried, Medical Research Council South Africa, South A…

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Copyright: © 2008 Dwan et al. This is an open-access article distrib… unrestricted use, distribution, and reproduction in any medium, provide…

Funding: This work forms part of the first author's PhD, funded by the … Cancer Research UK. Funders were not involved in the work.

Compe…

* E-mail…

Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials

Comparison of Protocols to Published Articles

An-Wen Chan, MD, DPhil; Asbjørn Hróbjartsson, MD, PhD; Mette T. Haahr, BSc; Peter C. Gøtzsche, MD, DrMedSci; Douglas G. Altman, DSc

Context Selective reporting of outcomes within published studies based on the nature or direction of their results has been widely suspected, but direct evidence of such bias is currently limited to case reports.

Objective To study empirically the extent and nature of outcome reporting bias in a cohort of randomized trials.

Design Cohort study using protocols and published reports of randomized trials approved by the Scientific-Ethical Committees for Copenhagen and Frederiksberg, Denmark, in 1994-1996. The number and characteristics of reported and unreported trial outcomes were recorded from protocols, journal articles, and a survey of trialists. An outcome was considered incompletely reported if insufficient data were presented in the published articles for meta-analysis. Odds ratios relating the completeness of outcome reporting to statistical significance were calculated for each trial and then pooled to provide an overall estimate of bias. Protocols and published articles were also compared to identify discrepancies in primary outcomes.

Main Outcome Measures Completeness of reporting of efficacy and harm outcomes and of statistically significant vs nonsignificant outcomes; consistency between primary outcomes defined in the most recent protocols and those defined in published articles.

Results One hundred two trials with 122 published journal articles and 3736 outcomes were identified. Overall, 50% of efficacy and 65% of harm outcomes per trial were incompletely reported. Statistically significant outcomes had a higher odds of being fully reported compared with nonsignificant outcomes for both efficacy (pooled odds ratio, 2.4; 95% confidence interval [CI], 1.4-4.0) and harm (pooled odds ratio, 4.7; 95% CI, 1.8-12.0) data. In comparing published articles with protocols, 62% of trials had at least 1 primary outcome that was changed, introduced, or omitted. Eighty-six percent of survey responders (42/49) denied the existence of unreported outcomes despite clear evidence to the contrary.

Conclusions The reporting of trial outcomes is not only frequently incomplete but

SELECTIVE PUBLICATION OF STUDIES with statistically significant results has received widespread recognition.[1] In contrast, selective reporting of favorable outcomes within published studies has not undergone comparable empirical investigation. The existence of outcome reporting bias has been widely suspected for years,[2-12] but direct evidence is limited to case reports that have low generalizability[13-15] and may themselves be subject to publication bias.

Our study had 3 goals: (1) to determine the prevalence of incomplete outcome reporting in published reports of randomized trials; (2) to assess the association between outcome reporting and statistical significance; and (3) to evaluate the consistency between primary outcomes specified in trial pro-

ANALYSIS

Downloaded from bmj.com on 8 July 2009

What is missing from descriptions of treatment in trials and reviews?

Replicating non-pharmacological treatments in practice depends on how well they have been described in research studies, say **Paul Glasziou** and **colleagues**

Have you ever read a trial or review and wondered exactly how to carry out treatments such as a "behavioural intervention," "salt reduction," or "exercise programme"? Although CONSORT and related initiatives have focused on the assessment of validity and presentation of results,[1 2] less attention has been given to the adequacy of the description of the treatment used. For pharmacological treatments the description would need to include the dose, titration, route, timing, duration, and any monitoring used. For complex treatments the problems are even greater.

Why are full descriptions of treatment important?

The uptake of positive findings from trials is often slow and sometimes negligible.[3] Rea-

receiving numerous requests for additional details from doctors and patients, the author of a randomised trial on graded exercise for chronic fatigue syndrome[5] subsequently published a supplementary article with a more detailed "prescription."[6] Similarly, it is not possible to set up a stroke unit, offer low fat diets, or give smoking cessation advice without sufficient details on the components that were planned and delivered.[4]

Extent of the problem

To assess the extent of problems with descriptions of treatment we prospectively assessed 80 consecutive studies selected for abstraction in the journal *Evidence-Based Medicine* from October 2005 to October 2006. The journal is aimed specifically at doctors working in primary care and general medicine.

Fig 2 | Percentage of studies with sufficient description of treatment initially (based only on the published paper) and after supplementary information was obtained

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Serious deficiencies identified in health research literature

- Non-reporting (or delayed reporting) of whole studies
  - Often studies with 'disappointing' results
- Incomplete reporting
  - Omission of crucial aspects of research methods (study participants, interventions, randomisation in trials, etc.)
  - Incomplete results: data cannot be included in meta-analysis
  - Inadequate reporting of harms
- Selective reporting
  - Patient outcomes
  - Analyses, e.g. subgroups, alternative analyses
- Misleading reporting
  - Misinterpretation of study findings "spin" (e.g. presenting study in more positive way; discrepancies between abstract and whole text, etc.)
  - Misrepresentation of study design (e.g. study claiming is an RCT when is not)
- Unacknowledged discrepancies between sources
  - e.g. publication conflicts with study protocol or information in the register

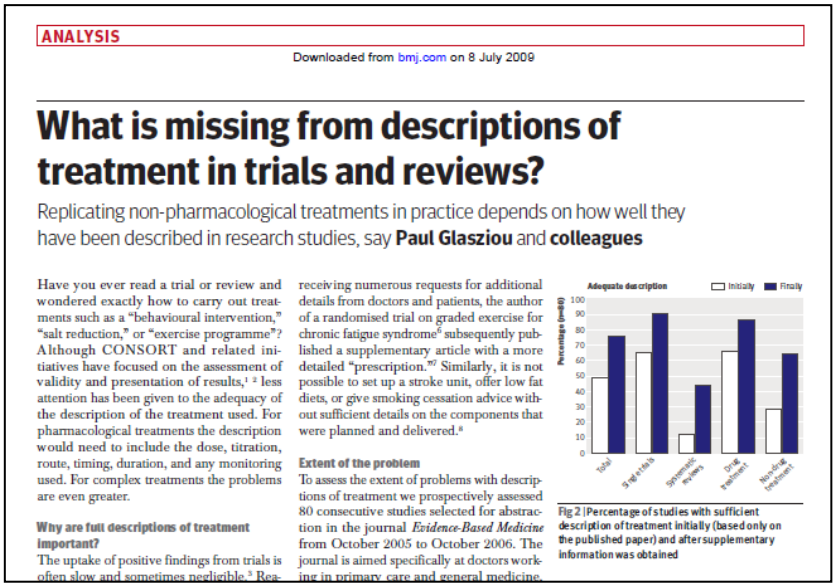
Poor description of intervention

- Glasziou *et al.*

  (BMJ 2008, 336: 1472 – 1474)

  - assessed descriptions of treatments in 80 articles (55 randomised trials & 25 systematic reviews) published in EBM journal aimed at practitioners

  - crucial elements of the interventions were missing in 41 of those studies (of 25 SR only 3 provided intervention description sufficient for implementation)



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Inadequate reporting of harms

- **Only 16/49 trials reported all adverse events (AEs)**
- **67% reported only some AEs**
  - e.g. the most frequent, if P<0.05, or 'selected' AEs

"These facts obstruct our ability to choose HAART based on currently published data."

[Chowers et al. JAC 2009]

The *Journal of Antimicrobial Chemotherapy* recently published a systematic review investigating the quality of reporting of adverse events in randomized trials assessing highly-active antiretroviral therapy (HAART) for treatment-naive HIV-infected patients.[6] Life-long HAART requires near-perfect drug adherence, which is possible only with drugs that minimally disrupt patients' lives. Monitoring and carefully documenting adverse events in clinical trials is crucial for further successful use of tested drugs. The review authors found great variability and lack of standardization in the reporting of adverse events: reporting was mostly selective and selection criteria were highly variable based on severity grade or an occurrence threshold. The observed variability in reporting made the comparison of adverse events between trials impossible and seriously obstructed the ability to choose appropriate treatment.

Consequences of poor reporting

- Poor reporting is a serious problem for SR and CPG, and ultimately for patients' care
  - Prevents inclusions of all eligible studies and comparison across studies
  - "The biggest problem was the quality of reporting, which did not allow us to judge the important methodological items ..."
  - "Data reporting was poor. 15 trials met the inclusion criteria for this review but only 4 could be included as data were impossible to use in the other 11."
  - "If the CONSORT recommendations were followed in the reporting of future studies, the effects of Morita therapy would be clearer. Much important data within the included studies were so poorly reported that clinicians, funders and recipients of care might have reason to feel let down by the research community."

(Cochrane Library, accessed on 18 Sept 10)

Poor reporting of systematic reviews

Curr Atheroscler Rep (2011) 13:447–452
DOI 10.1007/s11883-011-0203-2

NUTRITION (WILLIAM S. HARRIS, SECTION EDITOR)

Chocolate and Coronary Heart Disease: A Systematic Review

Owais Khawaja · J. Michael Gaziano · Luc Djoussé

- No where in the paper any mention of the review methodology!

Example of good reporting

Ried *et al. BMC Medicine* 2010, **8**:39
http://www.biomedcentral.com/1741-7015/8/39

BMC Medicine

RESEARCH ARTICLE Open Access

Does chocolate reduce blood pressure? A meta-analysis

Karin Ried[1*], Thomas Sullivan[2], Peter Fakler[1], Oliver R Frank[1], Nigel P Stocks[1]

Abstract

Background: Dark chocolate and flavanol-rich cocoa products have attracted interest as an alternative treatment option for hypertension, a known risk factor for cardiovascular disease. Previous meta-analyses concluded that cocoa-rich foods may reduce blood pressure. Recently, several additional trials have been conducted with conflicting results. Our study summarises current evidence on the effect of flavanol-rich cocoa products on blood pressure in hypertensive and normotensive individuals.

Methods: We searched Medline, Cochrane and international trial registries between 1955 and 2009 for randomised controlled trials investigating the effect of cocoa as food or drink compared with placebo on systolic and diastolic blood pressure (SBP/DBP) for a minimum duration of 2 weeks. We conducted random effects meta-analysis of all studies fitting the inclusion criteria, as well as subgroup analysis by baseline blood pressure (hypertensive/normotensive). Meta-regression analysis explored the association between type of treatment, dosage, duration or baseline blood pressure and blood pressure outcome. Statistical significance was set at $P < 0.05$.

Results: Fifteen trial arms of 13 assessed studies met the inclusion criteria. Pooled meta-analysis of all trials revealed a significant blood pressure-reducing effect of cocoa-chocolate compared with control (mean BP change ± SE: SBP: -3.2 ± 1.9 mmHg, $P = 0.001$; DBP: -2.0 ± 1.3 mmHg, $P = 0.003$). However, subgroup meta-analysis was significant only for the hypertensive or prehypertensive subgroups (SBP: -5.0 ± 3.0 mmHg; $P = 0.0009$; DBP: -2.7 ± 2.2 mm Hg, $P = 0.01$), while BP was not significantly reduced in the normotensive subgroups (SBP: -1.6 ± 2.3 mmHg, $P = 0.17$; DBP: -1.3 ± 1.6 mmHg, $P = 0.12$). Nine trials used chocolate containing 50% to 70% cocoa compared with white chocolate or other cocoa-free controls, while six trials compared high- with low-flavanol cocoa products. Daily flavanol dosages ranged from 30 mg to 1000 mg in the active treatment groups, and interventions ran for 2 to 18 weeks. Meta-regression analysis found study design and type of control to be borderline significant but possibly indirect predictors for blood pressure outcome.

Conclusion: Our meta-analysis suggests that dark chocolate is superior to placebo in reducing systolic hypertension or diastolic prehypertension. Flavanol-rich chocolate did not significantly reduce mean blood pressure below 140 mmHg systolic or 80 mmHg diastolic.

line blood pressure, dosage, duration, type of control, study design, age, body mass index and trial quality on blood pressure outcome.

Methods

Search strategy

We searched the Medline and Cochrane databases for randomised controlled trials of chocolate or cocoa on blood pressure published between 1955 and 2009 using the following search terms: chocolate OR cocoa AND blood pressure. We also searched reference lists of published studies and checked international trial registries http://www.clinicaltrials.gov; http://www.trialregister.nl; http://www.anzctr.org.au; http://www.controlled-trials.com for unpublished but completed studies investigating chocolate/cocoa for blood pressure.

Selection of trials

Trials were included in the meta-analysis if the control group received a placebo or a low dose of flavanol-containing cocoa product (drink, bar or tablet), the trial duration was ≥ 14 days, and the clinical mean or median systolic or diastolic blood pressure (SBP/DBP) and standard deviation (SD) were available. We contacted authors of studies which did not report numerical mean SBP/DBP or SD and received datasets from two studies [18,22], which we included in the meta-analysis. Three eligible completed but unpublished studies were excluded because data were not available at the time of this study [25-27].

Data extraction and quality assessment

Data were abstracted and quality was assessed independently by two investigators (KR, PF) using guidelines published by the Cochrane Collaboration [28] (Tables 1,2,3). Any disagreement was resolved by discussion between the authors (KR, PF) in consultation with the statistician (TS). Characteristics of trials included in the meta-regression analysis are shown in Table 1. We assessed quality on the basis of randomisation, blinding, whether blood pressure was a primary outcome measure, loss to follow-up, funding source and whether compliance and dietary chocolate intake had been assessed, as these could have influenced findings (Table 3). No trial was excluded in the meta-analysis on grounds of quality; however, higher-quality trials (score ≥ 3.5 of 5 points) were compared with lower-quality trials by meta-regression analysis.

Analysis

Meta-analysis was conducted using the Cochrane Program Review Manager version 5 [29]. Owing to high

line mean blood pressure, similar to our recent meta-analysis of the effect of garlic on blood pressure [30]. For systolic blood pressure, trials were divided into a hypertensive subgroup (SBP ≥ 140 mmHg) and a normotensive subgroup (SBP < 140 mmHg) at the start of treatment. For diastolic blood pressure, a division into a higher BP subgroup (DBP ≥ 80 mmHg) and lower BP subgroup (DBP < 80 mmHg) at the start of treatment allowed an even distribution of trials between subgroups and reduction in heterogeneity.

Meta-regression analyses were conducted using Stata version 10 [31] to explore reasons for high heterogeneity in the pooled meta-analysis of all studies. The following variables were tested, as their associations with blood pressure outcomes are physiologically plausible: Dosage of polyphenols in the active treatment group (continuous variable), type of control (categorical variable: low-flavanol control as drink, tablet or bar/flavanol-free control as white chocolate, milk, or placebo capsules), duration (continuous and categorical > 2 weeks yes/no), study design (parallel versus crossover), starting SBP (continuous and categorical > 140 mmHg yes/no), starting DBP (continuous and categorical >80 mmHg yes/no), quality score (≥ 3.5 yes/no), average body mass index (BMI) (continuous and categorical > 25 or > 30 yes/no) and average age (continuous).

If meta-regression results indicated a variable to contribute significantly to heterogeneity between studies, subgroup analysis by this variable was conducted, testing whether there was an effect of treatment on blood pressure outcomes within each subgroup. If heterogeneity was reduced, the subgroup analysis provided a more reliable estimate of pooled effect size between the treatment groups. Additionally, sensitivity analysis excluding selected trials explored the robustness of results. Publication bias or small study effect was assessed by Begg's funnel plots and Egger's regression tests [32,33].

Results

Summary of included studies

A total of 18 publications including 21 trial arms were assessed in detail for inclusion [10-13,15-24,34-38] (Figure 1). Fifteen trial arms reported in 13 publications met the inclusion criteria [10-13,15-18,20-24] (Figure 1, Table 1). Six trial arms were excluded because 1) the same population and protocol were used in [19] compared with [13]; 2) the comparison group received other vasoactive substances rather than placebos as a) chocolate ± plant sterols [34,35], b) tomato extract in phase 2 of trial [23], or c) half dose of chocolate [38]; 3) mean SBP/DBP and SD were not reported and could not be obtained from the authors [36]; and 4) the trial was of

Reporting guidelines (RG)

- Focus on scientific content of the article
- Provide structured advice on what to include in a research report
- 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: often as a checklist (flow diagram)

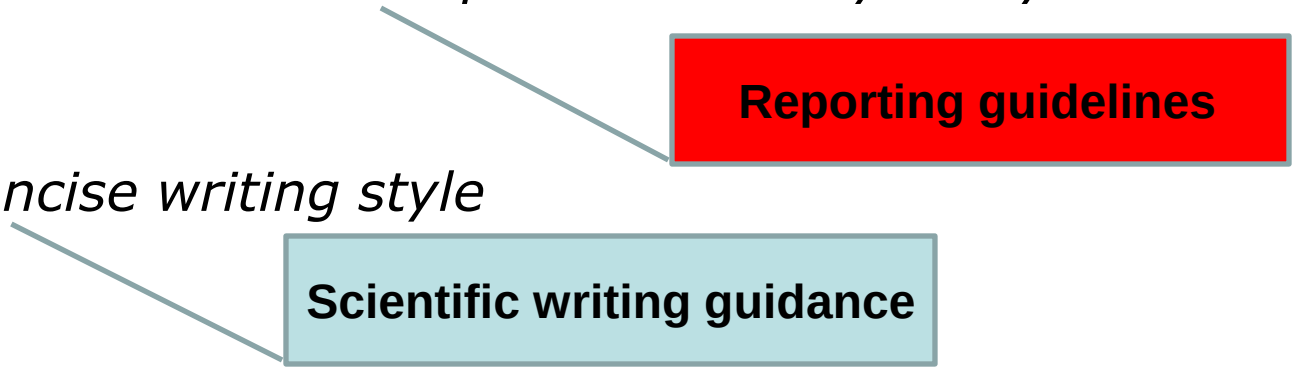
CONSORT 2010 Checklist www.consort-statement

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 mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Where can RG help?

- Good research paper is based on carefully designed and well conducted study

- Combines:
  - *Good logical structure*
  - *Complete and accurate description of the key study elements*
  - *Clear and concise writing style*



Reporting guidelines

- Available RG vary greatly in
  - Scope
  - Development methods
  - Presentation of recommendations

- Scope – two major RG types
  - Study design / methodology
  - Specific discipline / clinical area

RG: Study design / methodology

- Generic framework for reporting key methodology aspects of:
  - Main study designs (generic guidelines)
  - More specialised designs
  - Specific methods, evaluations, analyses
- No details relating to specific diseases
- Examples:
  - CONSORT (randomised controlled trials)
  - STROBE (observational studies in epidemiology)
  - STARD (diagnostic accuracy studies)
  - PRISMA (systematic reviews of RCTs)
  - COREQ (qualitative research)
- These are internationally accepted RG
  - Based on evidence
  - Consensus of relevant stakeholders (multidisciplinary group)
  - Endorsed by number of journals

RG: Specific discipline / clinical area

- Key focus is on discipline / clinical area specific issues

  Disease / Type of **investigation** / **Procedure / Combination of the above**

- May or may not address general methodology items

- Examples:
  - TREND (non-randomised studies of behavioural and public health interventions)
  - REMARK (tumour marker prognostic studies)
  - STARE-HI (evaluation studies in health informatics)
  - STRICTA (CONSORT extension for acupuncture trials)
  - Economic evaluations in obstetrics
  - Quality of life assessment in cancer trials

Reporting guidelines

- Benefits of using RG:
  - Improved accuracy and transparency of publications
  - Easier appraisal of reports for research quality and relevance
  - Better further use of presented findings
  - Improved efficiency of literature searching

- Large number of RG exist but they are still not being widely known and used
  - Many reasons

….. To promote RG and support their implementation we set up the EQUATOR Network (launched in June 2008)

Questions ?

EQUATOR: helping editors, peer reviewers, and authors to publish well reported studies

Enhancing the QUAlity and Transparency of health Research

equator network

EQUATOR Network

- EQUATOR Network is an international initiative set up to improve reliability and value of medical research literature

- EQUATOR promotes

  transparent

  accurate

  complete

  and timely

  reporting of health research studies

EQUATOR online resources – "one stop shop"

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:

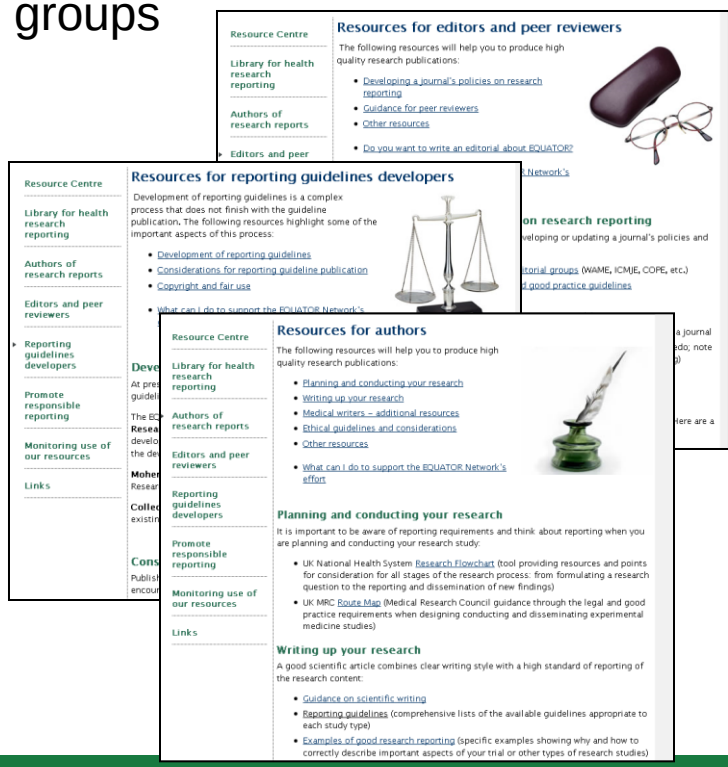
- CONSORT checklist and flow diagram
- CONSORT extensions
- TREND checklist
- STARD checklist & flow diagram
- STROBE checklists
- PRISMA checklist and flow diagram
- COREQ checklist
- SQUIRE checklist
- REMARK checklist

Download:

- Catalogue of reporting guidelines (full list)

All collated resources are available in our Library

Some of the resources are grouped according to relevance to our main user groups



EQUATOR Library – resources (1)

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
  - Medical writers – additional resources
  - 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

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

Download:

- Catalogue of reporting guidelines (full list)

- **Reporting guidelines**
  - Key (box on right side)
- Reporting guidelines under development
- Sections of research reports (figures, graphs, COI, etc.)
- Statistical methods & analyses
- Guidance on scientific writing
- Guidance on research & publication ethics, good practice, etc.

EQUATOR Library – resources (2)

Resource Centre

- Library for health research reporting
- Reporting Guidelines
- Reporting guidelines under development
- Reporting guidelines in other research fields
- Guidance on scientific writing
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- Development and maintenance of reporting guidelines
- Editorials introducing RGs
- Examples of guidelines for peer reviewers
- Case studies: RG implementation
- Examples of good research reporting

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
  - 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
- Medical writers – additional resources
- 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 interesting quotes

Quick links to reporting guidelines:

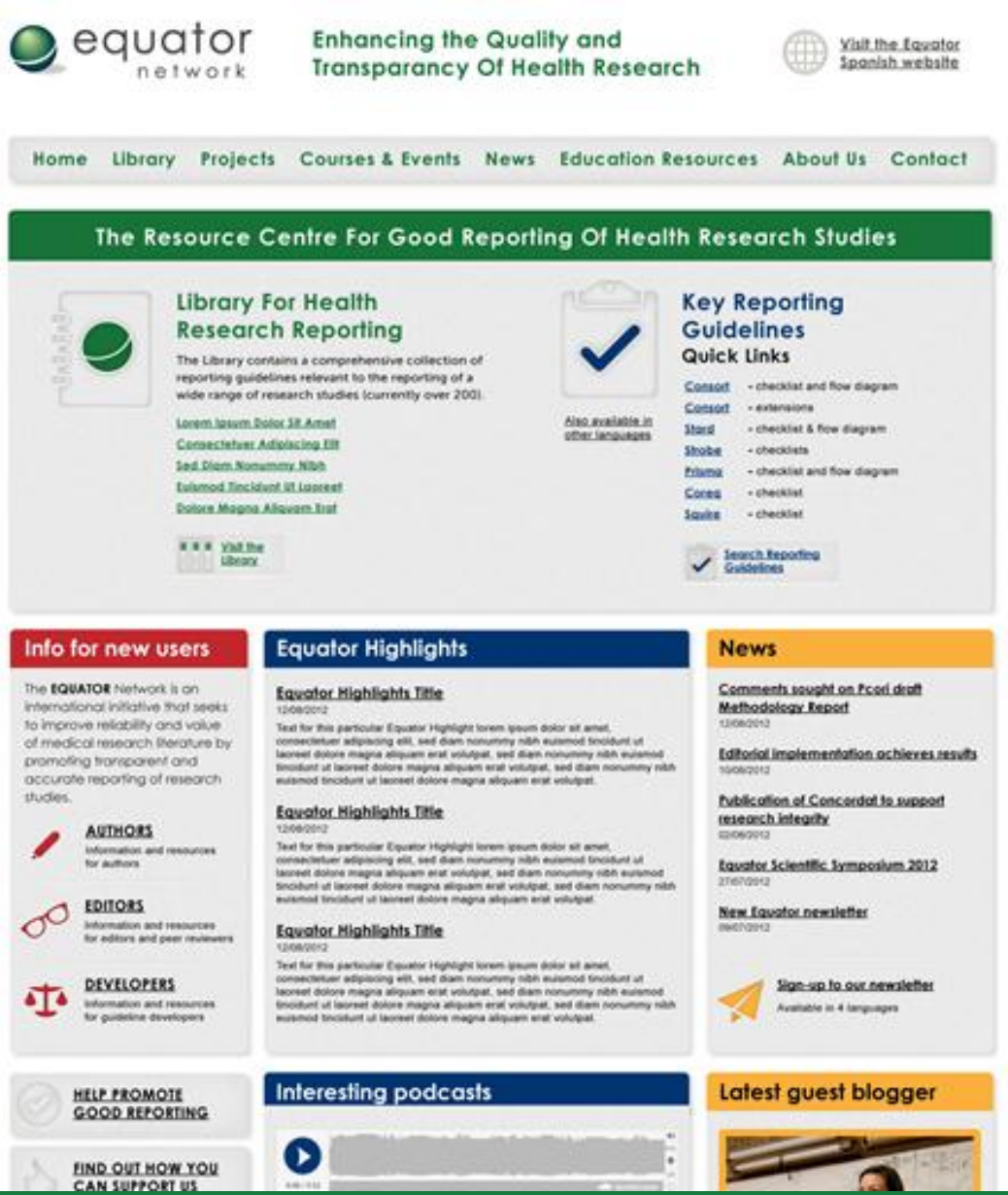
- CONSORT checklist and flow diagram
- CONSORT extensions
- TREND checklist
- STARD checklist & flow diagram
- STROBE checklists
- PRISMA checklist and flow diagram
- COREQ checklist
- SQUIRE checklist
- REMARK checklist

Download:

- Catalogue of reporting guidelines (full list)

- Guidance for specific user groups:
  - Industry sponsored research (medical writers)
  - Guidance developed by editorial groups
- Editors
  - Editorials introducing RG
  - Guidelines for peer reviewers
  - Examples from journals
  - How to select suitable RG
- Authors
  - Guidance on scientific writing
  - Links to resources on research design, conduct, etc.
- Peer reviewers
- RG developers

EQUATOR website re-design



Questions ?

Introducing key reporting guidelines

equator network

Core methodology RG

- CONSORT (randomised trials) – Sp / Port / Fr
- STROBE (observational studies) – Sp / Port
- PRISMA (systematic reviews) - Sp
- STARD (diagnostic accuracy studies)
- COREQ (qualitative research) - Sp
- SQUIRE (quality improvement studies) – Sp

Find it on:

www.equator-network.org

www.consort-statement.org

www.strobe-statement.org

www.prisma-statement.org

Reporting randomised trials

- CONSORT: the "oldest" and most influential RG

  [CONsolidated Standards Of Reporting Trials]

- CONSORT Statement first published in 1996, revised 2001, 2010

  History:

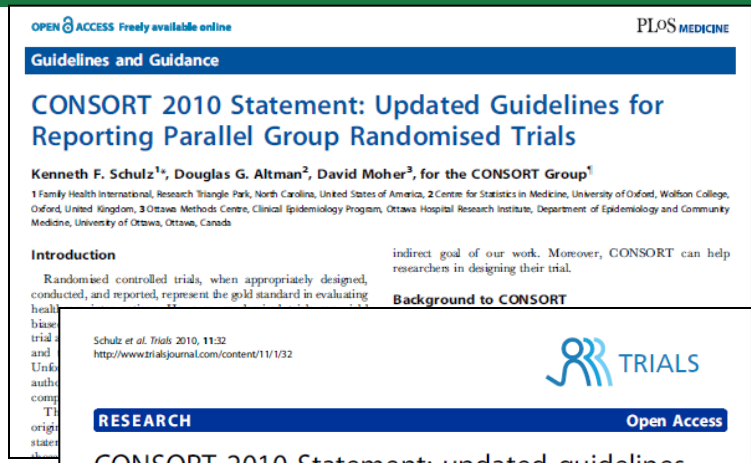
  - Two sets of recommendations for reporting RCTs published in 1994 (SORT Group, Asilomar Group)
  - CONSORT meeting in Chicago, 1995

- CONSORT Statement is an evidence-based, minimum set of recommendations for reporting RCTs

  It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

2010 Revision of CONSORT

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



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

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

Background to CONSORT

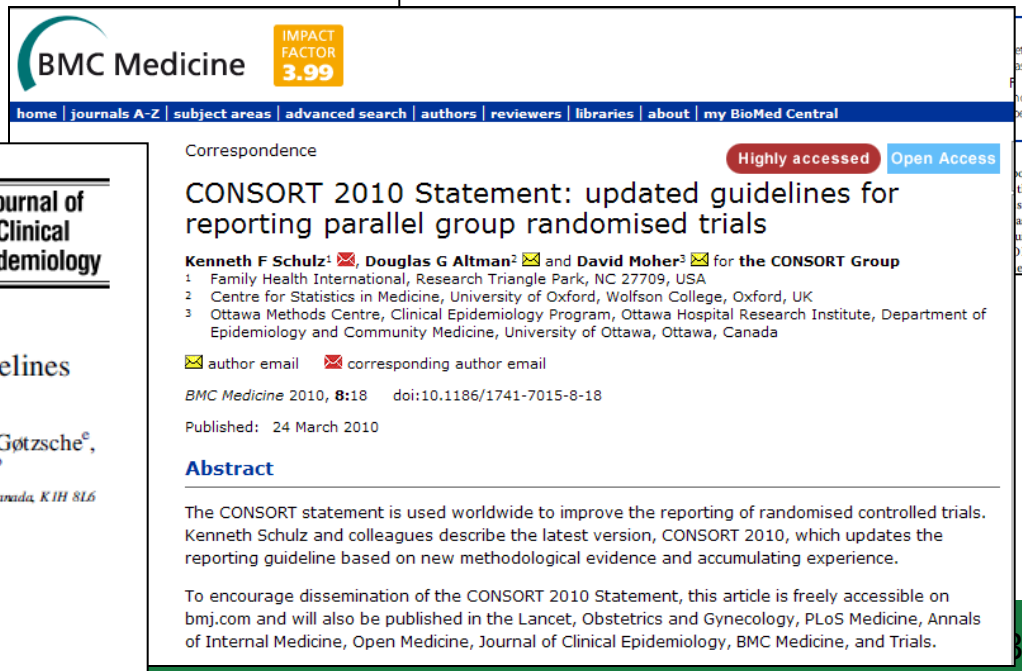
Schulz et al. Trials 2010, 11:32
http://www.trialsjournal.com/content/11/1/32

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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Correspondence

Highly accessed Open Access

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
3 Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Canada

✉ author email ✉ corresponding author email

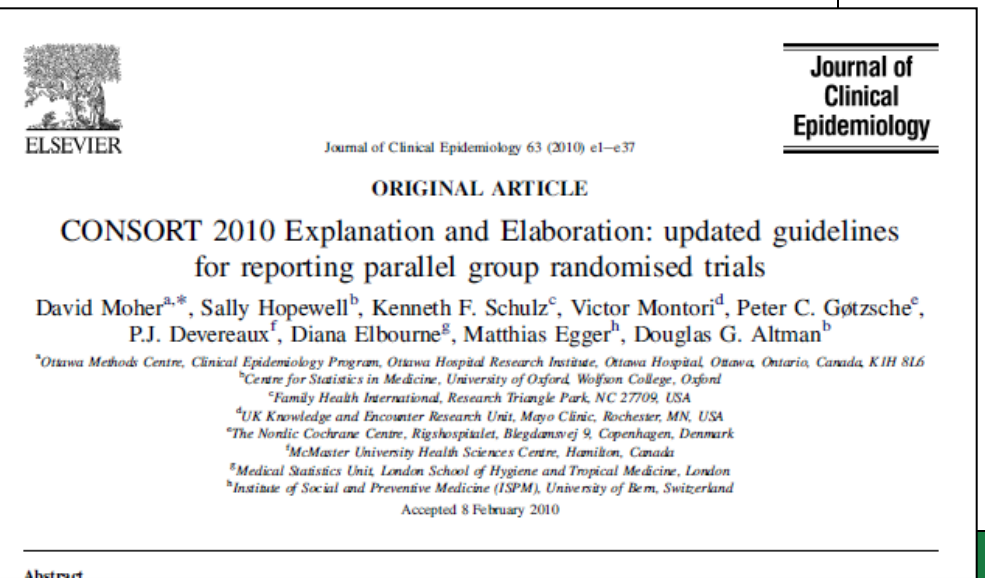
BMC Medicine 2010, **8**:18 doi:10.1186/1741-7015-8-18

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]

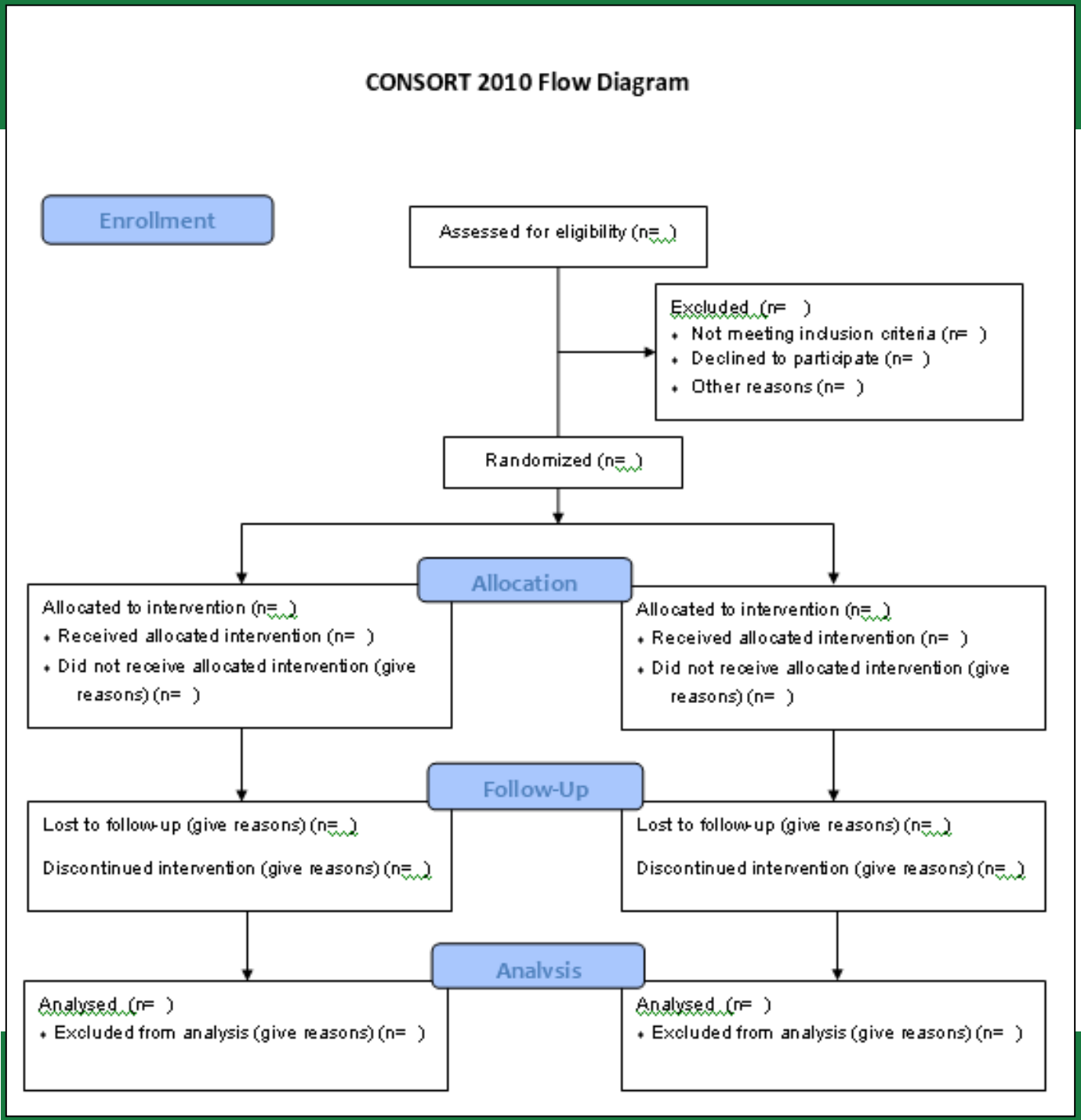
[a]Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa Hospital, Ottawa, Ontario, Canada, K1H 8L6
[b]Centre for Statistics in Medicine, University of Oxford, Wolfson College, Oxford
[c]Family Health International, Research Triangle Park, NC 27709, USA
[d]UK Knowledge and Encounter Research Unit, Mayo Clinic, Rochester, MN, USA
[e]The Nordic Cochrane Centre, Rigshospitalet, Blegdamsvej 9, Copenhagen, Denmark
[f]McMaster University Health Sciences Centre, Hamilton, Canada
[g]Medical Statistics Unit, London School of Hygiene and Tropical Medicine, London
[h]Institute of Social and Preventive Medicine (ISPM), University of Bern, Switzerland

Accepted 8 February 2010

Abstract

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 mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned


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=)

Example: good (clear) reporting

Sequence generation:

- "Independent pharmacists dispensed either active or placebo inhalers according to a computer generated randomization list."

  [Bolliger et al, *BMJ* 2000]

- "... The randomization code was developed using a computer random number generator to select random permuted blocks. The block lengths were 4, 8, and 10 varied randomly ..."

  [Coutinho et al, *Obstet Gynecol* 2008]

Example: Clear reporting but poor methodology

"Randomization was alternated every 10 patients, such that the first 10 patients were assigned to early atropine and the next 10 to the regular protocol, etc. To avoid possible bias, the last 10 were also assigned to early atropine."

[Lessick et al, *Eur J Echocardiography* 2000;1:257-62]

Current CONSORT extensions

DESIGNS	**Cluster**	**Non-inferiority/ equivalence**	**Pragmatic**
INTERVENTIONS	**Herbal**	**Non-pharmacological**	**Acupuncture (STRICTA)**
DATA	**Harms**	**Abstracts**	

Full details (pdfs and checklists) on CONSORT website:

http://www.consort-statement.org/

Example: CONSORT for Abstract

Item	Description
Title	Identification of the study as randomized
Authors *	Contact details for the corresponding author
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)
Methods	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomization	How participants were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment
Results	
Numbers randomized	Number of participants randomized to each group
Recruitment	Trial status
Numbers analysed	Number of participants analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding

Example: a typical abstract

Courtesy of Sally Hopewell
Senior Research Fellow, CONSORT Group
Centre for Statistics in Medicine, Oxford

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

BMJ 2006;333(7580):1193.

BEFORE

Objectives **To compare the effectiveness of an early switch to oral antibiotics with the standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.**
Design **Multicentre randomised controlled trial.**
Setting **Five teaching hospitals and 2 university medical centres in the Netherlands.**
Participants **302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.**
Intervention **Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics.**
Main outcome measures **Clinical cure and length of hospital stay.**
Results **302 patients were randomised** **(mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 patients for intention to treat analysis. Mortality at day 28 was 4% in the intervention group and 6% in the control group (mean difference 2%, 95% confidence interval 3% to 8%). Clinical cure was 83% in the intervention group and 85% in the control group (2%, 7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) *v* 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) *v* 11.5 (4.9) days; 0.6 to 3.2), respectively.**
Conclusions **Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.**
Trial registration Clinical Trials NCT00273676.

Item	Reported
Title	√
Trial design	
Methods	
Participants	√
Intervention	√
Objective	√
Outcomes	√
Randomization	
Blinding	
Results	
Number randomized	
Recruitment	
Number analysed	
Outcome	√
Harms	
Conclusions	√
Trial registration	√
Funding	

Word count: 248

Effectiveness of early switch from intravenous to oral antibiotics in severe community acquired pneumonia: multicentre randomised trial

BMJ 2006;333(7580):1193.

AFTER

Objectives **Effectiveness of early switch to oral antibiotics compared with standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.**

Design **Multicentre parallel randomised controlled open label trial. A central randomisation centre used computer generated tables to allocate treatments.**

Setting **Five teaching hospitals and 2 university medical centres in the Netherlands.**

Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.

Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics. Follow-up 28 days.

Main outcome measures Clinical cure and length of hospital stay.

Results **302 patients (early switch=152; standard care=150) were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 (n=132; n=133) patients for intention to treat analysis. Clinical cure was 83% in the intervention group and 85% in the control group (2%, 7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) *v* 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) *v* 11.5 (4.9) days; 0.6 to 3.2), respectively.**

Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days. Mobility and other side effects were comparable across groups.

Trial registration Clinical Trials NCT00273676.

Funding: Dutch Health Insurance Council, OG 99-64.

Item	Reported
Title	√
Trial design	√
Methods	
Participants	√
Intervention	√
Objective	√
Outcomes	√
Randomization	√
Blinding	√
Results	
Number randomized	√
Recruitment	√
Number analysed	√
Outcome	√
Harms	√
Conclusions	√
Trial registration	√
Funding	√

Word count: 260

COMPARISON

Objectives Effectiveness of early switching to oral antibiotics compared with the standard 7 day course of intravenous antibiotics in severe community acquired pneumonia.

Design Multicentre parallel randomised controlled, open label, trial. A central randomisation centre used computer generated tables to allocate treatments. **Setting** Five teaching hospitals and 2 university medical centres in the Netherlands.

Participants 302 patients in non-intensive care wards with severe community acquired pneumonia. 265 patients fulfilled the study requirements.

Intervention Three days of treatment with intravenous antibiotics followed, when clinically stable, by oral antibiotics or by 7 days of intravenous antibiotics. Follow-up 28 days.

Main outcome measures Clinical cure and length of hospital stay.

Results 302 patients (early switch n=152: standard care n=150) were randomised (mean age 69.5 (standard deviation 14.0), mean pneumonia severity score 112.7 (26.0)). 37 patients were excluded from analysis because of early dropout before day 3, leaving 265 patients (n=132; n=133) for intention to treat analysis. Clinical cure was 83% in the intervention group and 85% in the control group (2%, 7% to 10%). Duration of intravenous treatment and length of hospital stay were reduced in the intervention group, with mean differences of 3.4 days (3.6 (1.5) v 7.0 (2.0) days; 2.8 to 3.9) and 1.9 days (9.6 (5.0) v11.5 (4.9) days; 0.6 to 3.2), respectively. Adverse events were comparable across groups.

Conclusions Early switch from intravenous to oral antibiotics in patients with severe community acquired pneumonia is safe and decreases length of hospital stay by 2 days.

Trial registration Clinical Trials NCT00273676.

Funding: Dutch Health Insurance Council, OG 99-64.

Deleted: To compare the effectiveness

Deleted: an

Deleted: switch

Deleted: Mortality at day 28 was 4% in the intervention group and 6% in the control group (mean difference 2%, 95% confidence interval 3% to 8%).

Reporting systematic reviews

- Systematic review (SR) is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarise the findings of similar but separate studies.

- It may include a quantitative synthesis (meta-analysis), depending on the available data

[Eden et al. Finding what works in health care: Standards for systematic reviews, Institute of Medicine, 2011]

Key characteristics of SR

- Focused well defined research question
- Clearly stated title and objectives
- Comprehensive strategy for identification of all relevant studies (published & unpublished)
- Explicit (and justified) predefined inclusion & exclusion criteria
- Critical appraisal of studies
- Clear analysis of the results of eligible studies
  - Quantitative (meta-analysis)
  - Qualitative
- Structured report

Poor reporting of systematic reviews

- Good reporting of primary studies is crucial for SR development

  BUT

- Reviews are not immune to the problems of poor reporting
  - Moher et al. assessed epidemiological and reporting characteristics and bias-related aspects of 300 systematic reviews (of which 125 were Cochrane reviews). The overall quality of reporting of key aspects of methodology was very inconsistent with particularly discouraging findings for non-Cochrane reviews.

    [Moher; PLoS Medicine 2007]

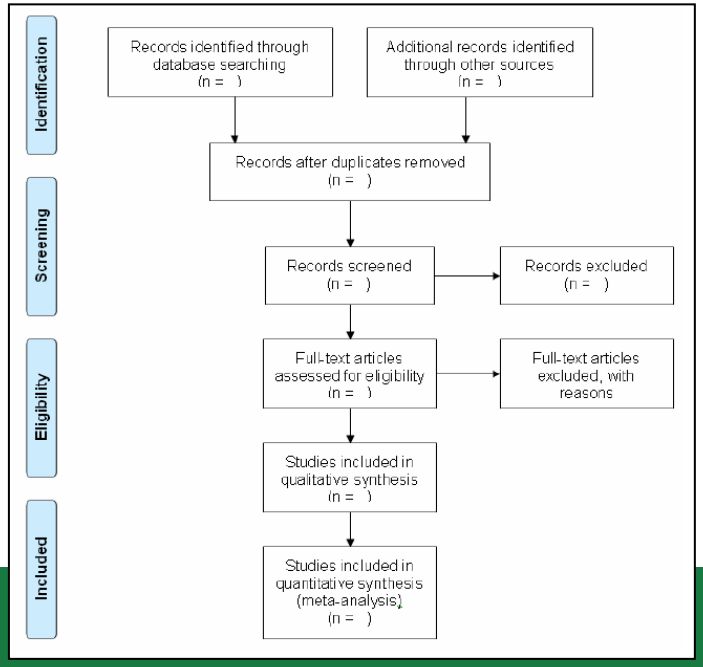
PRISMA 2009 Checklist

PRISMA 2009 Checklist www.prisma-statement.org

Section / topic	#	Checklist item
TITLE		
Title	1	Identify the report as a systematic review, meta-analysis, or both.
ABSTRACT		
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.
INTRODUCTION		
Rationale	3	Describe the rationale for the review in the context of what is already known.
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).
METHODS		
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).

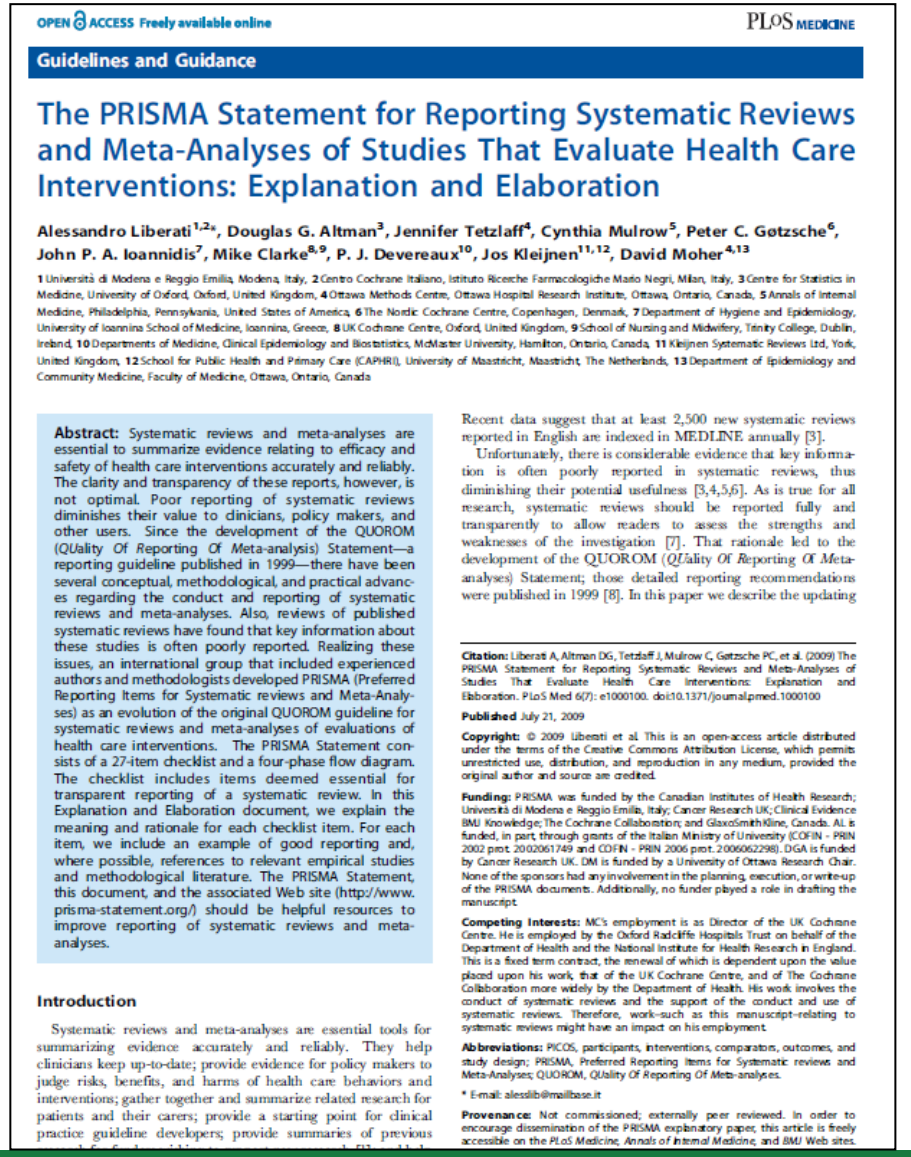
Preferred Reporting Items for Systematic Reviews and Meta-Analyses (2009)

27-item checklist, flow diagram



In your folders

- PRISMA explanation & elaboration paper
  - Explanation and rationale for reporting of suggested information (items)
  - Examples of good reporting
  - Relevant data about how this information is reported presently



OPEN ACCESS Freely available online

PLoS MEDICINE

Guidelines and Guidance

The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration

Alessandro Liberati[1,2*], Douglas G. Altman[3], Jennifer Tetzlaff[4], Cynthia Mulrow[5], Peter C. Gøtzsche[6], John P. A. Ioannidis[7], Mike Clarke[8,9], P. J. Devereaux[10], Jos Kleijnen[11,12], David Moher[4,13]

1 Università di Modena e Reggio Emilia, Modena, Italy, 2 Centro Cochrane Italiano, Istituto Ricerche Farmacologiche Mario Negri, Milan, Italy, 3 Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom, 4 Ottawa Methods Centre, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada, 5 Annals of Internal Medicine, Philadelphia, Pennsylvania, United States of America, 6 The Nordic Cochrane Centre, Copenhagen, Denmark, 7 Department of Hygiene and Epidemiology, University of Ioannina School of Medicine, Ioannina, Greece, 8 UK Cochrane Centre, Oxford, United Kingdom, 9 School of Nursing and Midwifery, Trinity College, Dublin, Ireland, 10 Departments of Medicine, Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada, 11 Kleijnen Systematic Reviews Ltd, York, United Kingdom, 12 School for Public Health and Primary Care (CAPHRI), University of Maastricht, Maastricht, The Netherlands, 13 Department of Epidemiology and Community Medicine, Faculty of Medicine, Ottawa, Ontario, Canada

Abstract: Systematic reviews and meta-analyses are essential to summarize evidence relating to efficacy and safety of health care interventions accurately and reliably. The clarity and transparency of these reports, however, is not optimal. Poor reporting of systematic reviews diminishes their value to clinicians, policy makers, and other users. Since the development of the QUOROM (*QU*ality *O*f *R*eporting *O*f *M*eta-analysis) Statement—a reporting guideline published in 1999—there have been several conceptual, methodological, and practical advances regarding the conduct and reporting of systematic reviews and meta-analyses. Also, reviews of published systematic reviews have found that key information about these studies is often poorly reported. Realizing these issues, an international group that included experienced authors and methodologists developed PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) as an evolution of the original QUOROM guideline for systematic reviews and meta-analyses of evaluations of health care interventions. The PRISMA Statement consists of a 27-item checklist and a four-phase flow diagram. The checklist includes items deemed essential for transparent reporting of a systematic review. In this Explanation and Elaboration document, we explain the meaning and rationale for each checklist item. For each item, we include an example of good reporting and, where possible, references to relevant empirical studies and methodological literature. The PRISMA Statement, this document, and the associated Web site (http://www.prisma-statement.org/) should be helpful resources to improve reporting of systematic reviews and meta-analyses.

Introduction

Systematic reviews and meta-analyses are essential tools for summarizing evidence accurately and reliably. They help clinicians keep up-to-date; provide evidence for policy makers to judge risks, benefits, and harms of health care behaviors and interventions; gather together and summarize related research for patients and their carers; provide a starting point for clinical practice guideline developers; provide summaries of previous

Recent data suggest that at least 2,500 new systematic reviews reported in English are indexed in MEDLINE annually [3].

Unfortunately, there is considerable evidence that key information is often poorly reported in systematic reviews, thus diminishing their potential usefulness [3,4,5,6]. As is true for all research, systematic reviews should be reported fully and transparently to allow readers to assess the strengths and weaknesses of the investigation [7]. That rationale led to the development of the QUOROM (*QU*ality *O*f *R*eporting *O*f *M*eta-analyses) Statement; those detailed reporting recommendations were published in 1999 [8]. In this paper we describe the updating

Citation: Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, et al. (2009) The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration. PLoS Med 6(7): e1000100. doi:10.1371/journal.pmed.1000100

Published July 21, 2009

Funding: PRISMA was funded by the Canadian Institutes of Health Research; Università di Modena e Reggio Emilia, Italy; Cancer Research UK; Clinical Evidence BMJ Knowledge; The Cochrane Collaboration; and GlaxoSmithKline, Canada. AL is funded, in part, through grants of the Italian Ministry of University (COFIN - PRIN 2002 prot. 2002061749 and COFIN - PRIN 2006 prot. 2006062298). DGA is funded by Cancer Research UK. DM is funded by a University of Ottawa Research Chair. None of the sponsors had any involvement in the planning, execution, or write-up of the PRISMA documents. Additionally, no funder played a role in drafting the manuscript.

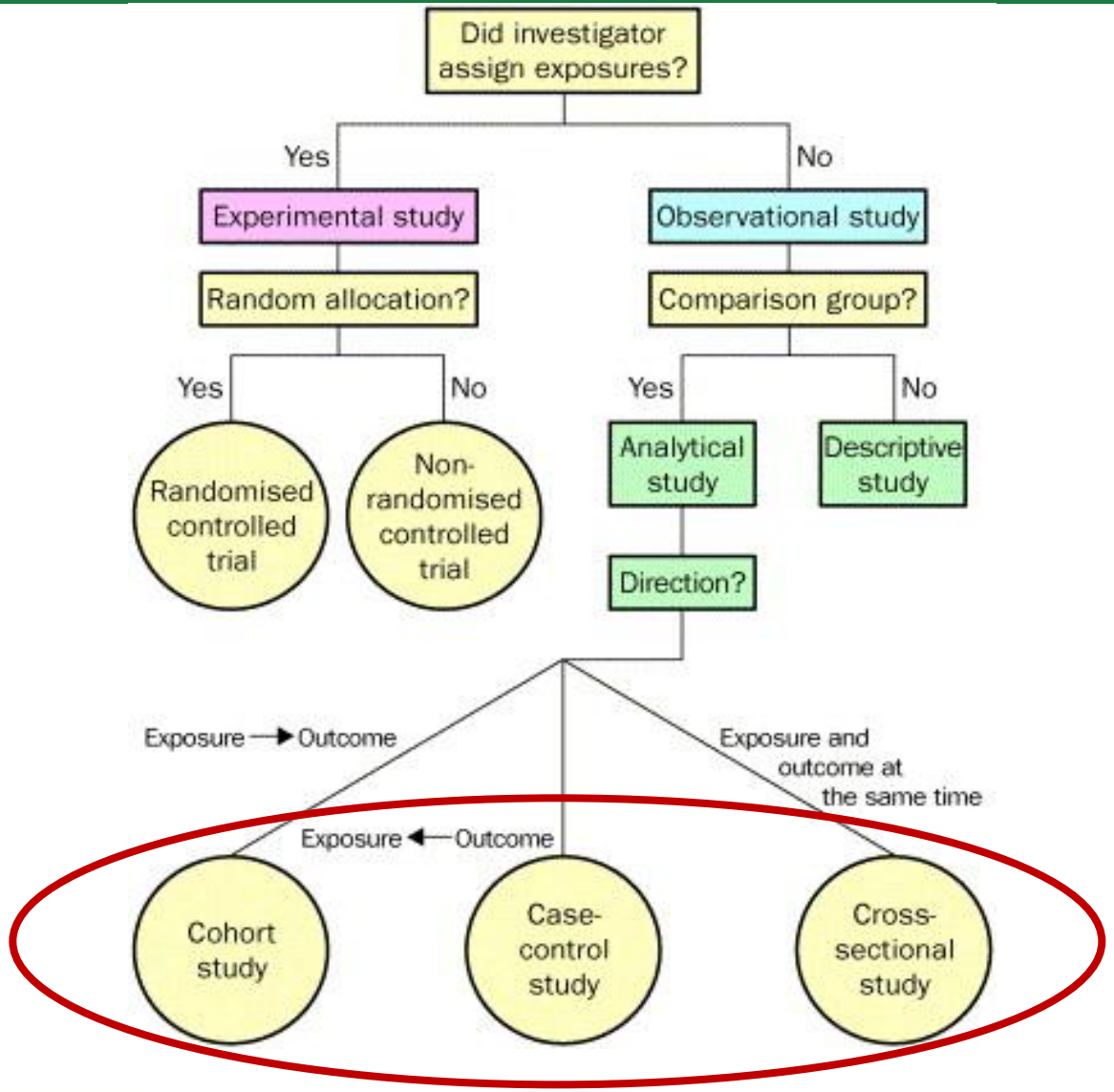
Competing Interests: MC's employment is as Director of the UK Cochrane Centre. He is employed by the Oxford Radcliffe Hospitals Trust on behalf of the Department of Health and the National Institute for Health Research in England. This is a fixed term contract, the renewal of which is dependent upon the value placed upon his work, that of the UK Cochrane Centre, and of The Cochrane Collaboration more widely by the Department of Health. His work involves the conduct of systematic reviews and the support of the conduct and use of systematic reviews. Therefore, work-such as this manuscript-relating to systematic reviews might have an impact on his employment.

Abbreviations: PICOS, participants, interventions, comparators, outcomes, and study design; PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses; QUOROM, *QU*ality *O*f *R*eporting *O*f *M*eta-analyses.

* E-mail: alesslib@mailbase.it

Provenance: Not commissioned; externally peer reviewed. In order to encourage dissemination of the PRISMA explanatory paper, this article is freely accessible on the *PLoS Medicine*, *Annals of Internal Medicine*, and *BMJ* Web sites.

Reporting observational studies

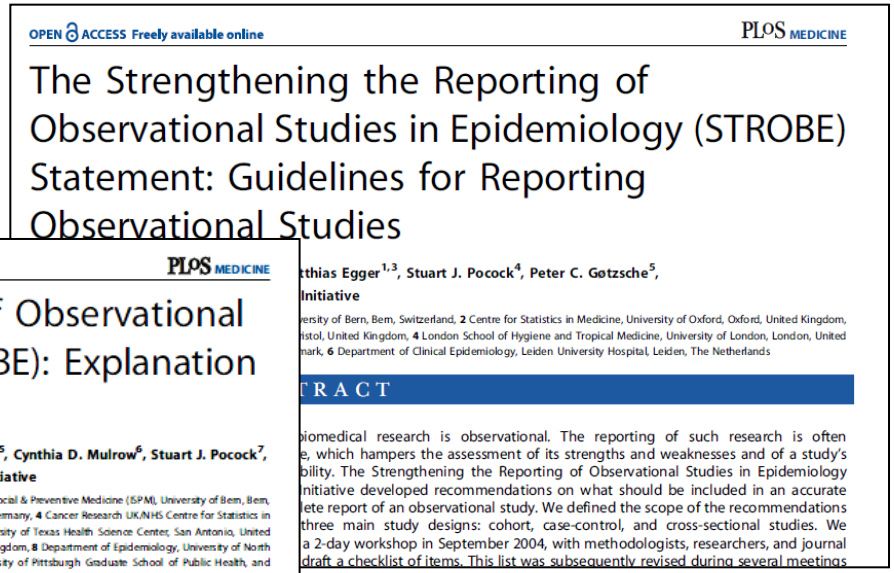


STROBE

Grimes, DA, Schulz KF. An overview of clinical research: the lay of the land. *Lancet* 2002; 359**;** 57-61.

STROBE Statement

- Guidance on how to report observational studies well (which is rare!)
  - Focus on 3 main study designs: cohort, case-control, cross-sectional studies
- Published in Oct 2007: short paper and E&E
- Adopted by many journals



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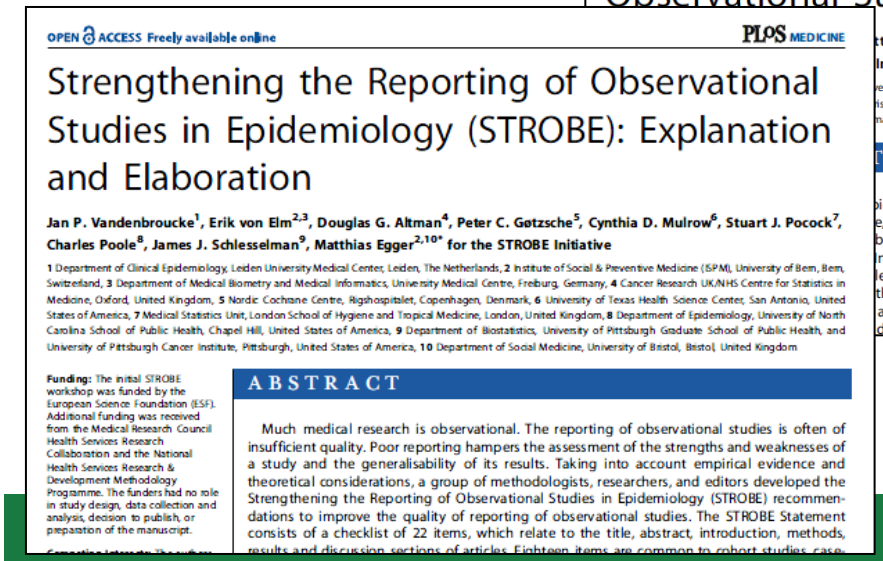
The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies



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Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration

Jan P. Vandenbroucke[1], Erik von Elm[2,3], Douglas G. Altman[4], Peter C. Gøtzsche[5], Cynthia D. Mulrow[6], Stuart J. Pocock[7], Charles Poole[8], James J. Schlesselman[9], Matthias Egger[2,10*] for the STROBE Initiative

ABSTRACT

Much medical research is observational. The reporting of observational studies is often of insufficient quality. Poor reporting hampers the assessment of the strengths and weaknesses of a study and the generalisability of its results. Taking into account empirical evidence and theoretical considerations, a group of methodologists, researchers, and editors developed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations to improve the quality of reporting of observational studies. The STROBE Statement consists of a checklist of 22 items, which relate to the title, abstract, introduction, methods, results and discussion sections of articles. Eighteen items are common to cohort studies, case-

STROBE Statement

- **Checklist with 22 items**
  - Heading (where in paper), item No
  - Recommendation, divided into:
    cohort, case-control, cross-sectional study - where different

STROBE 2007 Checklist **www.strobe-statement.org**

Section / topic	#	Recommendation	R o #
TITLE & ABSTRACT			
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	
INTRODUCTION			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
METHODS			
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	

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Three STROBE extensions (1)

- STREGA (2009)
  - reporting of genetic association studies

Table 1. STREGA Reporting Recommendations, Extended from STROBE Statement

Item	Item Number	STROBE Guideline	Extension for Genetic Association Studies (STREGA)
Title and Abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract.	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found.	
Introduction			
Background rationale	2	Explain the scientific background and rationale for the investigation being reported.	
Objectives	3	State specific objectives, including any pre-specified hypotheses.	***State if the study is the first report of a genetic association, a replication effort, or both.***
Methods			
Study design	4	Present key elements of study design early in the paper.	
Setting	5	Describe the setting, locations and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	
Participants	6	(a) **Cohort study** – Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. **Case-control study** – Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. **Cross-sectional study** – Give the eligibility criteria, and the sources and methods of selection of participants.	***Give information on the criteria and methods for selection of subsets of participants from a larger study, when relevant.***
		(b) **Cohort study** – For matched studies, give matching criteria and number of exposed and unexposed. **Case-control study** – For matched studies, give matching criteria and the number of controls per case.	
Variables	7	(a) Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	***(b) Clearly define genetic exposures (genetic variants) using a widely-used nomenclature system. Identify variables likely to be associated with population stratification (confounding by ethnic origin).***

Three STROBE extensions (2)

- STROBE – ME (Oct 2011)
  - Reporting molecular epidemiology (biomarker studies)

Table 1. The Strengthening the Reporting Observational studies in Epidemiology – Molecular Epidemiology (STROBE-ME) Reporting Recommendations: Extended from STROBE statement.

Item	Item number	STROBE Guidelines	Extension for Molecular Epidemiology Studies (STROBE-ME)
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	**ME-1** State the use of specific biomarker(s) in the title and/or in the abstract if they contribute substantially to the findings
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	**ME-2** Explain in the scientific background of the study how/why the specific biomarker(s) have been chosen, potentially among many others (e.g., others are studied but reported elsewhere, or not studied at all)
Objectives	3	State specific objectives, including any pre-specified hypotheses	**ME-3** *A priori* hypothesis: if one or more biomarkers are used as proxy measures, state the *a priori* hypothesis on the expected values of the biomarker(s)
Methods			
Study design	4	Present key elements of study design early in the paper	**ME-4** Describe the special study designs for molecular epidemiology (in particular nested case/control and case/cohort) and how they were implemented
Biological sample collection			**ME-4.1** Report on the setting of the biological sample collection; amount of sample; nature of collecting procedures; participant conditions; time between sample collection and relevant clinical or physiological endpoints.

Three STROBE extensions (3)

- STROBE abstract

  - Reporting observational studies in conference abstracts (online draft)

Item	Recommendation
Title	Indicate the study's design with a commonly used term in the title (e.g cohort, case-control, cross sectional)
Authors	Contact details for the corresponding author
Study design	Description of the study design (e.g cohort, case-control, cross sectional)
Objective	Specific objectives or hypothesis
Methods	
Setting	Description of setting, follow-up dates or dates at which the outcome events occurred or at which the outcomes were present, as well as any points or ranges on other time scales for the outcomes (e.g., prevalence at age 18, 1998-2007).
Participants	*Cohort study*—Give the most important eligibility criteria, and the most important sources and methods of selection of participants. Describe briefly the methods of follow-up *Case-control study*—Give the major eligibility criteria, and the major sources and methods of case ascertainment and control selection *Cross-sectional study*—Give the eligibility criteria, and the major sources and methods of selection of participants
	Cohort study—For matched studies, give matching and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	Clearly define primary outcome for this report.
Statistical methods	Describe statistical methods, including those used to control for confounding
Results	
Participants	Report Number of participants at the beginning and end of the study
Main results	Report estimates of associations. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Report appropriate measures of variability and uncertainty (e.g., odds ratios with confidence intervals
Conclusions	General interpretation of study results

Explanation & elaboration papers

- CONSORT 'invention', now followed by a number of guidelines

- Papers provide
  - Explanation and rationale for reporting of suggested information (items)
  - Examples of good reporting
  - Relevant data about how this information is reported presently

Long but recommend to read!

Fantastic educational value

Other RG of interest to CRICS

INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS 78 (2009) 1–9

ELSEVIER

journal homepage: www.intl.elsevierhealth.com/journals/ijmi

STARE-HI—Statement on reporting of evaluation studies in Health Informatics

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ABSTRACT

Objective: Development of guidelines for publication of evaluation studies of Health Informatics applications.
Methods: An initial list of issues to be addressed in reports on evaluation studies was drafted based on experiences as editors and reviewers of journals in Health Informatics and as

Original Articles © Schattauer 1999

Systematic Prioritization of the STARE-HI Reporting Items

An Application to Short Conference Papers on Health Informatics Evaluation

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Keywords
Publication, standards, guidelines as topic, evaluation studies, congresses

Summary
Background: We previously devised and published a guideline for reporting health informatics evaluation studies named STARE-HI, which is formally endorsed by IMIA and EFMI.
Objective: To develop a prioritization framework of ranked reporting items to assist authors when reporting health informatics

items by two reviewers. From these ratings a priority adjusted completeness score was computed for each paper.
Results: We identified 104 reporting items from the STARE-HI guideline. The response rate for the survey was 59% (66 out of 111). The most important reporting items (mean score ≥9) were "Interpret the data and give an answer to the study question – (in Discussion)", "Whether it is a laboratory, simulation or field study – (in Methods-study design)" and "Description of the outcome measure/evaluation criteria – (in Methods-dy design)". Per reporting area the statis-ally more significant important reporting ms were distinguished from less important es. Four reporting items had a mean score . The mean priority adjusted completeness evaluation papers of recent health in-

1. Introduction

Modern healthcare tends increasingly to depend on health informatics applications such as electronic patient records, order entry and image processing systems. Within the last two decades, the principle that interventions in healthcare should be evidence-based has become the accepted norm. In this context, it is imperative to ensure that health informatics innovations are evaluated and that new implementations are based on the resultant scientific evidence base [1, 2]. Until now this has seldom been the case, and in those cases where health informatics applications have been assessed the reports on these evaluations are often of limited value because essential information is not properly com-

JMIR The leading eHealth journal

Journal of Medical Internet Research
The leading peer-reviewed eHealth journal
Current Issue Submit Membership Editorial Board

J Med Internet Res. 2011 Oct-Dec; 13(4): e126.

Published online 2011 December 31. doi: 10.2196/jmir.1923

PMCID: PMC3278112

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions

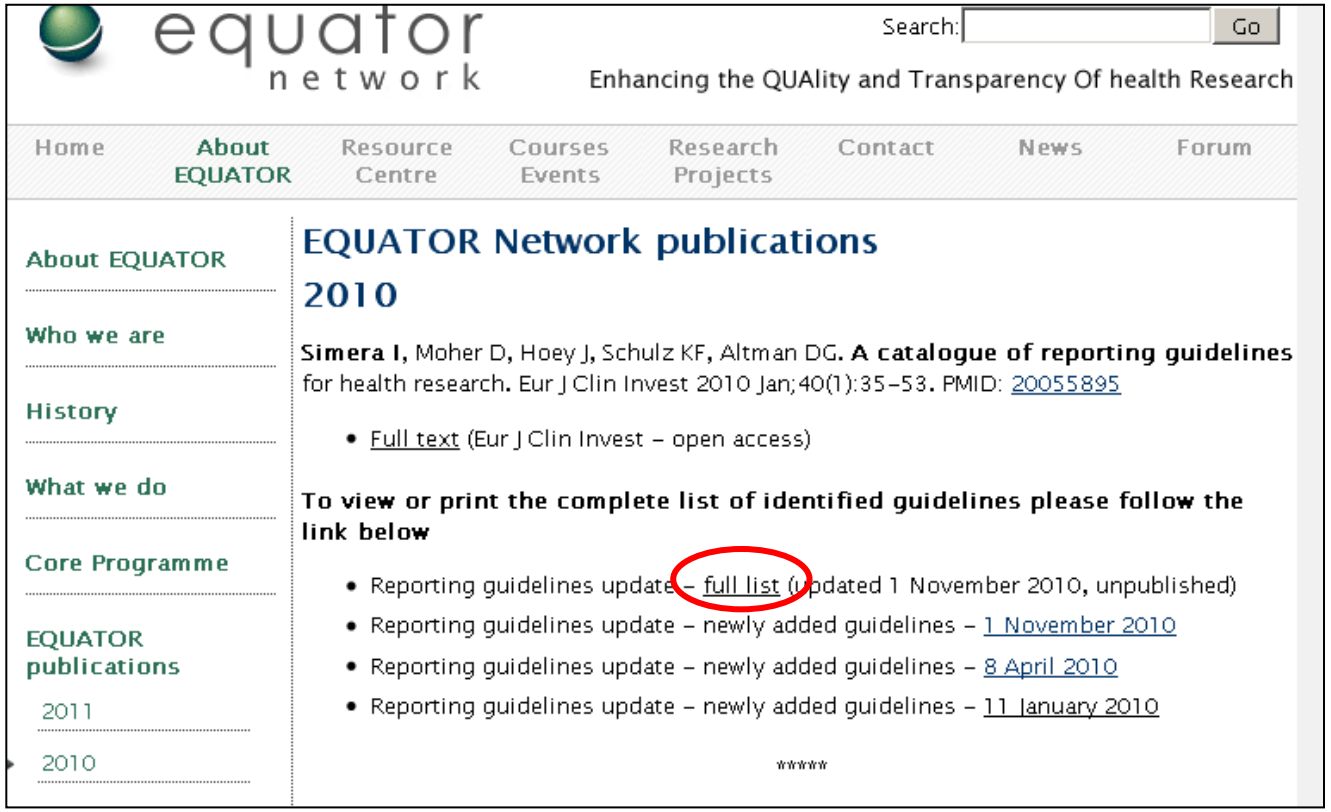
Gunther Eysenbach, MD, MPH, FACMI[1,2,3,4] and CONSORT-EHEALTH Group[4]

Examples of RG and where they can help (sheet in your folders)

Structure of a medical research paper: key content elements, writing tips and examples of reporting guidelines from the EQUATOR website

Section	Key content *	Reporting guidelines that provide recommendations on reporting information relating to:			
		Study design / methodology • Generic framework for reporting key methodology aspects of: - Main study designs (generic guidelines) - More specialised designs - Specific methods, evaluations, analyses • No details relating to specific to diseases		**Specific discipline / clinical area** • Key focus is on discipline / clinical area specific issues • May or may not address general methodology items	
		Framework for a complete research study / research paper **Examples include:**	Framework for only a part of the research study / research paper **Examples include:**	Framework for a complete research study / paper **Examples include:**	Framework for only a part of the research study / paper **Examples include:**
Title	Indicate the focus of the paper and include important relevant 'keywords' to allow identification of the study through electronic searches. Be concise, precise, and informative.	<u>**Main study designs**</u> (generic guidelines): CONSORT: parallel randomised trials		TREND: non-randomised studies of behavioural and public health interventions	
Abstract	Most journals require a structured abstract, typically including key information on the following: - Objectives - Methods (setting, participants, intervention, main outcome measures) - Results - Conclusions	STROBE: observational studies in epidemiology STARD: diagnostic accuracy studies	CONSORT for abstracts STROBE for abstracts	REMARK: tumour marker prognostic studies STARE-HI: evaluation studies in health informatics	STARE-HI for abstracts of studies in health informatics
Introduction	Provide the scientific background and clearly explain what questions you were trying to answer. Be brief and relevant to the study: start from a broad context of what is already known, proceed to the specific unknown problems, and finish with clearly stated study objectives	COREQ: qualitative research SQUIRE: quality improvement studies		Longitudinal studies in rheumatology Adverse events reports in traditional Chinese medicine	
Methods	Describe in a logical sequence how the study was designed, carried out, and analysed. A typical methods section provides key information on the following: - Setting, location - Participants (or objects) - Study design including planned sample size - Interventions (or exposures) - Outcomes (variables) - All statistical methods - Ethical issues (e.g. consent) Information should be clear, accurate, and complete (provide enough details to repeat, assess, and compare with other studies) Content should correspond with the Result section	COGS: clinical practice guidelines PRISMA: systematic reviews MOOSE: systematic reviews of observational studies in epidemiology Case reports <u>**More specialised designs**</u> (often extending the generic guidance): CONSORT for cluster trials CONSORT non-inferiority trials CONSORT for pragmatic trials	<u>Statistical guidelines:</u> Bayesian analysis in clinical trials Subgroup analyses in trials <u>Economic evaluations:</u> Cost-effectiveness analysis Economic evaluations in trials Quality of life assessment in trials STARLITE: literature searches	Case series of colon tumours	<u>Intervention:</u> STRICTA (CONSORT extension for acupuncture trials) Cancer pain educational interventions <u>Procedures:</u> Cardiovascular magnetic resonance examinations <u>Statistical guidelines:</u> Multivariate logistic regression in transplantation research <u>Economic evaluations:</u> Economic evaluations in obstetrics Quality of life assessment in cancer trials

- And many other guidelines and other resources … see the current list of all guidelines on the EQUATOR website:



Questions ?

EQUATOR – PAHO collaboration

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Memorandum of understanding

- 2010: to raise standards in health research reporting in the American regions

- First project carried under the memorandum
  - Translation of the EQUATOR website and main reporting guidelines into Spanish
  - Promotion of reporting guidelines in SA and Caribbean

- Second project (in preparation)
  - Further develop the Spanish website (needs 'local touch'!)
  - Prepare a series of webinars on research reporting and reporting guidelines

EQUATOR Spanish website – launched July 2010

Signed collaboration agreement with PAHO to raise standards of research reporting in South America and Caribbean

We are looking for **collaborators** to establish local centres of activities supporting better reporting of research studies

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Examples of resources in Spanish

In English | Iniciar sesión

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Buscar: | Ir

Enhancing the QUAlity and Transparency Of health Research

Mejoramos la calidad y la claridad de la investigación sanitaria

Home | Acerca de EQUATOR | Centro de recursos | Cursos y eventos | Proyectos | Contacto | Noticias

Centro de recursos

- **Biblioteca, presentación informes sanitarios**
- Directrices para la presentación de informes
- Directrices: informes en preparación
- Directrices para la presentación de informes en otros campos de investigación
- Orientación sobre redacción científica
- Orientación elaborada por grupos editoriales
- Escritores médicos/Recursos adicionales
- Ética en la investigación,ética en la publicación
- Desarrollo y

Biblioteca para la presentación de informes de investigación sanitaria

Actualmente, la biblioteca de EQUATOR Network contiene:

- Introducción a las directrices para la presentación de informes
- Listas completas de las directrices disponibles para la presentación de informes, enumeradas por tipo de estudio:
  - Estudios experimentales
  - Estudios observacionales
  - Estudios de precisión diagnóstica
  - Estudios sobre confiabilidad y acuerdo
  - Revisiones sistemáticas
  - Investigaciones cualitativas
  - Estudios de métodos mixtos
  - Evaluaciones económicas
  - Estudios de mejora de la calidad
  - Otras directrices para la presentación de informes
  - Presentación de datos
  - Secciones de informes de investigación
  - Afecciones o procedimientos específicos
- Directrices para la presentación de informes en proceso de desarrollo
- Directrices para la presentación de informes en otros campos de investigación
- Orientación sobre redacción científica
- Orientación elaborada por grupos editoriales
- Escritores médicos/Recursos adicionales

Directrices disponibles en español

- Declaración CONSORT
- Declaración TREND
- Declaración STROBE
- Declaración PRISMA
- Guía SQUIRE

Descarguar:

- Un catálogo de las directrices

Examples of resources in Spanish

- Estudios Experimentales
- Estudios Observacionales
- Estudios de precisión diagnóstica
- Estudios sobre confiabilidad y acuerdo
- Revisiones de sistemáticas y metanálisis
- Investigación cualitativa
- Estudios de métodos mixtos
- Evaluaciones económicas
- Estudios de mejora de la calidad
- Otras directrices, presentación informes
- Presentación de datos
- Métodos y análisis estadísticos
- Secciones de informes de

- Estudios de intervención para el control de infecciones
- Investigación básica en homeopatía

Directriz de presentación de informes para:	Nombre del sitio web de la directriz (si está disponible)	Referencias y número de PMID
Ensayos controlados aleatorizados	Declaración CONSORT	Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Ann Int Med 2010;152 (11):726-32. PMID: 20335313 BMC Medicine 2010, 8:18. PMID: 20334633 BMJ 2010;340:c332. PMID: 20332509 J Clin Epi 2010; 63(8): 834-40 PMID: 20346629 Lancet 2010; 375(9721):1136 supplementary webappendix Obstet Gynecol 2010;115(5):1063-70. PMID: 20410783 Open Med 2010;4(1):60-68. PLoS Med 2010;7(3): e1000251. PMID: 20352064 Trials 2010, 11:32. PMID: 20334632 Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG, for the CONSORT Group. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trial. BMJ 2010;340:c869. PMID: 20332511 J Clin Epi 2010; 63(8): e1-e37 PMID: 20346624 **Traducción al español** (Med Clin (Barc). 2011 Jan 14. doi:10.1016/j.medcli.2010.09.034) **La Declaración CONSORT 2010 reemplaza a la directriz CONSORT 2001** (PMID: 11323066; PMID: 11304107)

Examples of resources in Spanish

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Buscar: Ir

Enhancing the QUAlity and Transparency Of health Research

Mejoramos la calidad y la claridad de la investigación sanitaria

Home | Acerca de EQUATOR | Centro de recursos | Cursos y eventos | Proyectos | Contacto | Noticias

- Centro de recursos
- Biblioteca, presentación informes sanitarios
- Autores de informes de investigación
- Editores y revisores externos
- Recursos para formuladores de directrices para presentación de informes
- Enlaces

Recursos para editores y revisores externos

Los siguientes recursos lo ayudarán a elaborar publicaciones de investigación de alta calidad:

- Desarrollo de las políticas para la presentación de informes de investigación de una publicación
- Orientación para revisores externos
- Otros recursos
- ¿Desea escribir un editorial sobre EQUATOR?
- Cómo puedo apoyar el esfuerzo de EQUATOR Network

Desarrollo de las políticas para la presentación de informes de investigación de una publicación

Los siguientes recursos servirán para desarrollar o actualizar las políticas e instrucciones para la presentación de informes de investigación de una publicación:

Recursos en español

Comité de Ética para Publicaciones (COPE)
Asociación Europea de Editores Científicos (EASE)

- Orientación elaborada por grupos editoriales (WAME, ICMJE, COPE etc.)
- Ética en la investigación, ética en la publicación y directrices de prácticas adecuadas
- Directrices para la presentación de informes
- Editoriales que presentan políticas nuevas y directrices para la presentación de informes en una publicación
- Instrucciones para autores (recopilado por la Biblioteca Mulford de la Universidad de Toledo; tenga en cuenta que no todas las instrucciones enumeradas proporcionan una buena orientación sobre presentación de informes de investigación)

How to increase awareness and implementation of principles of good research reporting?

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Discussion – what can we do?

- Role of journals, editors, peer reviewers
- Role of scientists
- Role of medical librarians / information specialists
- Role of research organisations
- Role of research funders
- Role of professional organisations and societies

Take home tasks

- Has this workshop inspired you to do anything to contribute to improvement of health research literature?

- Can you identify one thing you would like to do?

Closing thoughts

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Closing thoughts

- Reporting guidelines are helpful tools when used correctly and at right time
- Read Explanation and Elaboration papers of the main generic reporting guidelines – good learning source about general principles!
- Carefully select which reporting guidelines you should use for your research
- Even if your target journal does not require compliance with any reporting guidelines - select and follow those suitable for your study, following them improve the quality of your manuscript
- Have a browse through the EQUATOR website to see what is available

For suggestions of more specific actions see 'Steps to consider' in Simera *et al*. *BMC Medicine* 2010,8:24

Every well conducted and well reported research study, regardless of where in the world it is published, counts towards the global body of evidence and extends our knowledge further.

"Avoidable waste in the production and reporting of research evidence"

- Paper by Chalmers & Glasziou (Lancet 2009)
- "Without accessible and usable reports, research cannot help patients and their clinicians."

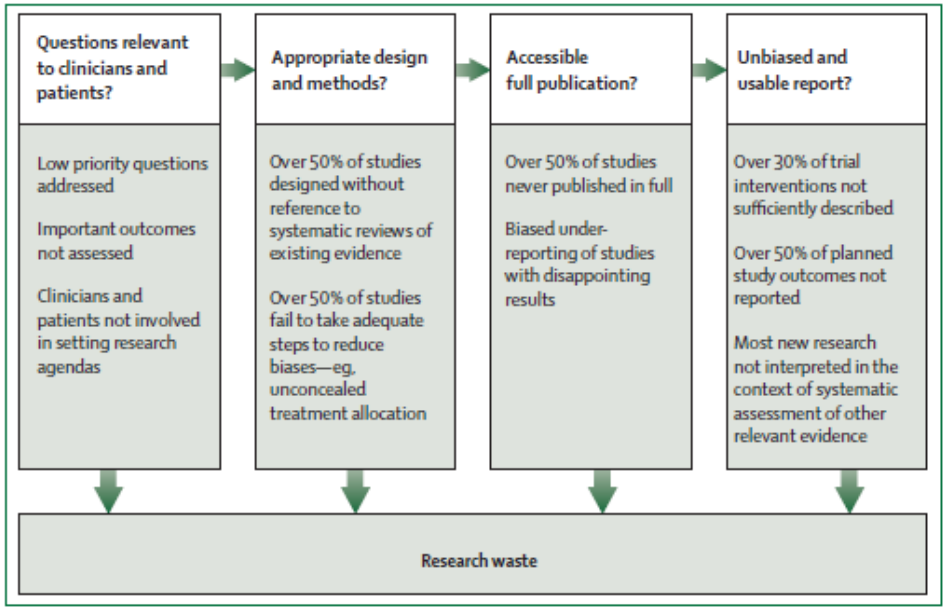

Figure: Stages of waste in the production and reporting of research evidence relevant to clinicians and patients

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Questions ?

www.equator-network.org
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