

# Impactful biomedical research: reporting guidelines can help you to maximise the value and impact of your systematic review



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EQUATOR Network, Centre for Statistics in Medicine,  
NDORMS, University of Oxford, UK**



# Presentation Outline

- \* **Importance of accurate and transparent research reports**
- \* **Impact of poor reporting on systematic reviews**
- \* **Highlight reporting guidelines and the EQUATOR Network**
- \* **Discuss the implementation of reporting guidelines within your research and their potential impact**

The EQUATOR Network is funded by:



# Systematic review: purpose

**“Systematic reviews aim to identify, evaluate and summarise the findings of all relevant individual studies, thereby making the available evidence more accessible to decision-makers...Systematic reviews adhere to a strict scientific design based on **explicit, pre-specified** and **reproducible** methods. Because of this, when carried out well, they provide **reliable** estimates about the effects of interventions so that conclusions are **defensible**”**

Systematic Reviews. CRD's Guidance for undertaking reviews in health care. Centre for Reviews and Dissemination, University of York. 2008.

# Systematic review: key steps

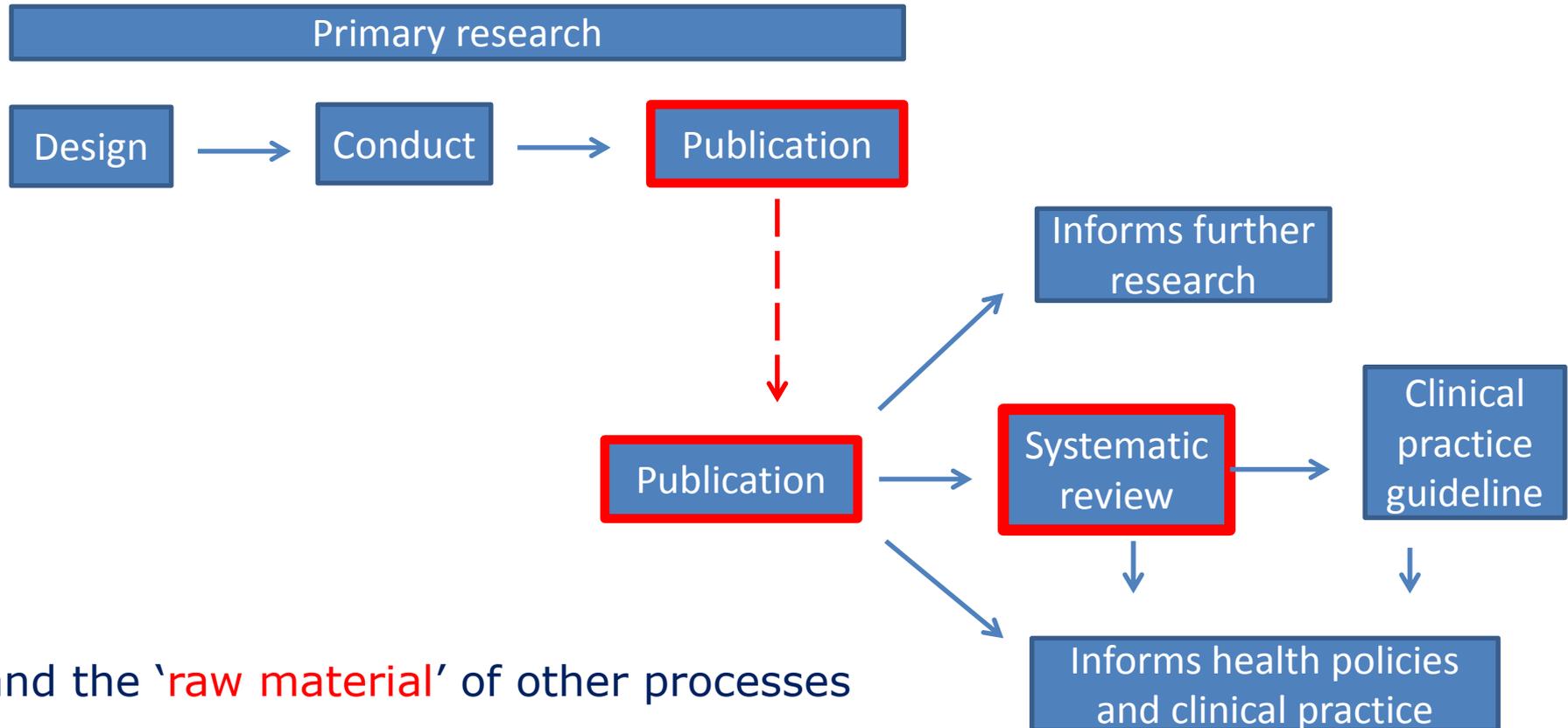


- \* Formulation of a clear question
- \* Eligibility criteria for studies
- \* Search for potentially relevant studies
- \* Selection of studies into the review
- \* Extraction of data
- \* Assessment of methodological quality of included studies (risk of bias)
- \* Synthesis of findings (possibly using meta-analysis)
- \* Presentation of data and results
- \* Interpretation and drawing conclusions

Each step is important in ensuring that the results are reliable and reproducible

# Systematic review: key component

A research article is the 'end product' of one process...



...and the 'raw material' of other processes

# Systematic review: reliability

Systematic reviews rely on the robustness of the methods and results of primary research and on how primary studies are reported



PubMed.gov  
US National Library of Medicine  
National Institutes of Health

PubMed [dropdown] [input] [Advanced]

Abstract [dropdown] [Send to: dropdown]

J Trop Pediatr. 2006 Feb;52(1):34-8. Epub 2005 Jul 13.

**Features of whey protein concentrate supplementation in children with rapidly progressive HIV infection.**  
Moreno YF<sup>1</sup>, Sgarbieri VC, da Silva MN, Toro AA, Vilela MM.

Author information

**Abstract**  
HIV infection is associated with subnormal GSH levels. An increase in glutathione levels has been observed in HIV-infected adults under oral whey protein supplementation. We studied the features associated with a whey protein concentrate supplementation in children with rapidly progressive AIDS. A prospective double-blind clinical trial was carried out for 4 months with 18 vertically HIV-infected children (1.98-6.37 years), under antiretroviral therapy, who had received whey protein, maltodextrin (placebo) or none. Erythrocyte glutathione concentration, T lymphocyte counts (CD4+ and CD8+) and occurrence of associated co-infections were evaluated. Wilcoxon's and Fischer's Exact tests were used to assess differences between whey protein-supplemented and control (placebo and non-supplemented) groups. A significant median increase of 16.14 mg/dl (p = 0.018) in erythrocyte glutathione levels was observed in the whey protein-supplemented group; the TCD4/CD8 lymphocyte ratio showed a non significant increase and lower occurrence of associated co-infections was also observed. In conclusion, whey protein concentrate supplementation can stimulate glutathione synthesis and, possibly, decrease the occurrence of associated co-infections.

PMID: 16014759 [PubMed - indexed for MEDLINE]

**Guidelines for an integrated approach to nutritional care of HIV-infected children (6 month-14 years)**  
Preliminary version for country introduction

Authors:  
World Health Organization

**Handbook**  
Preliminary version for country introduction

**Publication details**  
Number of pages: 79 (Handbook), 15 (Guide for local adaptation), 32 (Chart booklet)  
Publication date: 2009  
Languages: English  
ISBN: 978 92 4 159752 4

**Downloads**  
- Handbook pdf, 793kb  
- [Guide for local adaptation](#)

Cochrane Library  
Trusted evidence. Informed decisions. Better health.

Search title, abstract, keyword [input] [Browse] [Advanced Search]

Cochrane Reviews [dropdown] Trials [dropdown] More Resources [dropdown] About [dropdown] Help [dropdown]

Go to old article view

Cochrane Database of Systematic Reviews

**Nutritional interventions for reducing morbidity and mortality in people with HIV**

Review [checkbox] Intervention [checkbox]

Liesl Grobler, Nandi Siegfried, Marianne E Visser, Sarah SN Mahlangu, Jimmy Volmink

# Systematic review: risk of bias

A crucial part of preparing a systematic review involves an assessment of the risk of bias for included studies

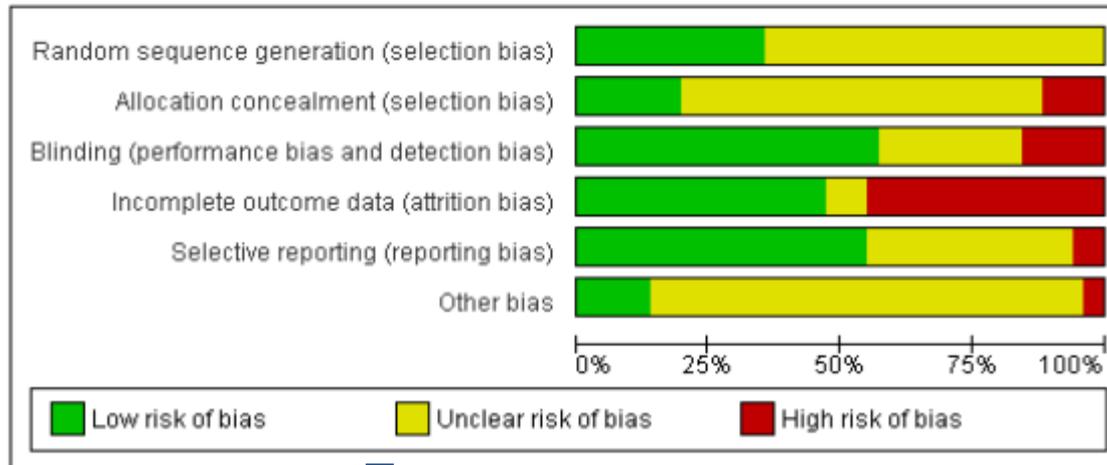
- \* Risk of bias results from suboptimal methods
- \* Methods must be reported well to allow risk of bias assessment

## **METHODS – each aspect of the methods**

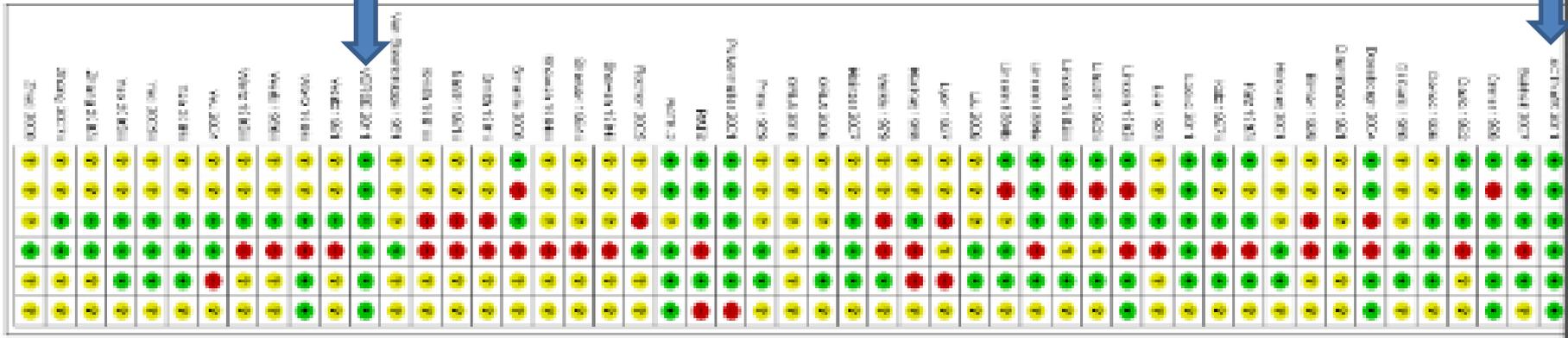
|   | <b>Done well</b> | <b>Done poorly</b> | <b>Not done</b> |
|---|------------------|--------------------|-----------------|
| <b>Fully reported<br/>(=reproducible)</b>       |                  |                    |                 |
| <b>Ambiguously or<br/>incompletely reported</b> |                  |                    |                 |
| <b>Not reported</b>                             |                  |                    |                 |

# Cochrane risk of bias tool

Figure 5. 'Risk of bias' graph: review authors' judgements about each 'Risk of bias' item presented as percentages across all included studies.

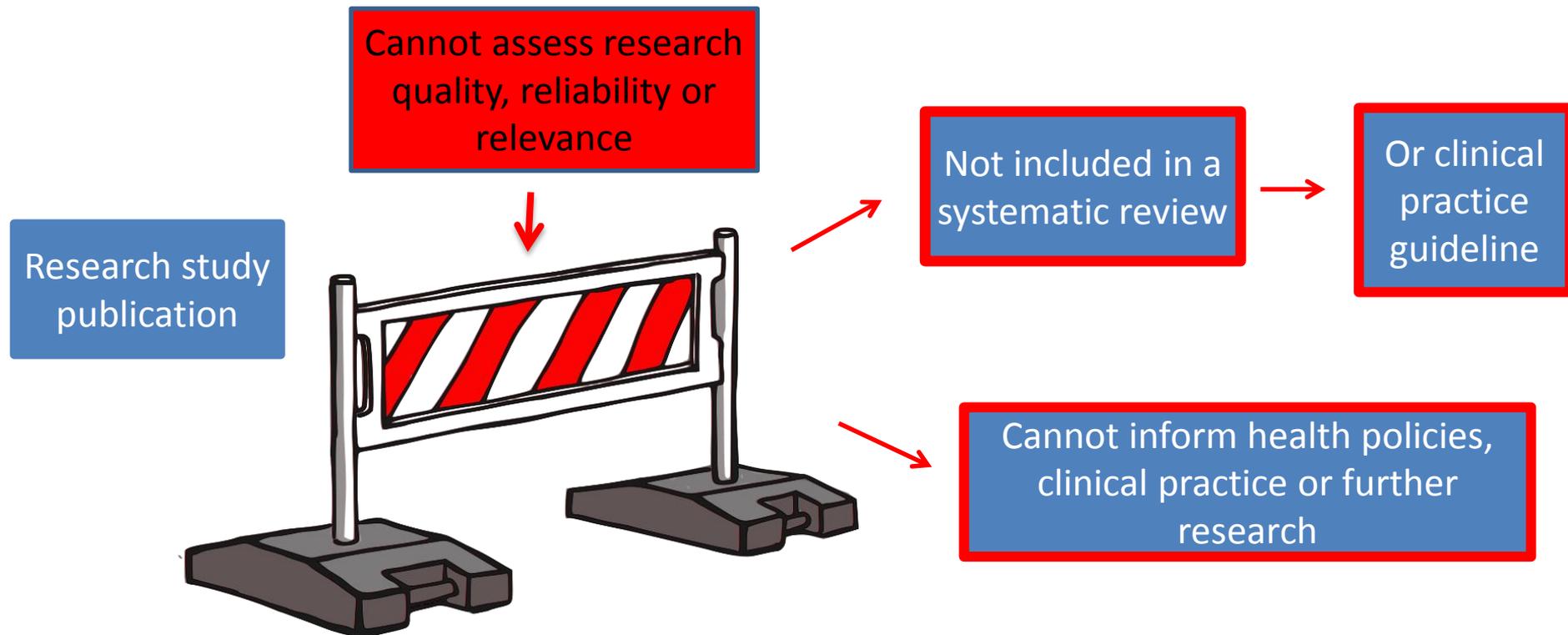


**Yellow is a problem** – we simply do not know as not enough details are provided in the study report



# Importance of accurate and transparent research reports

Failure to provide a detailed and clear description of what was done and what was found by a research study prevents its full utilisation



# Consequences of poor reporting

**Poor reporting is a serious problem particularly for systematic reviews and clinical guideline development. It prevents the inclusion of all eligible studies and comparison across studies:**

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”

“...the trial did not report many data in a form that we could analyse in this review”

“The biggest problem was the quality of reporting, which did not allow us to judge the important methodological items ...”

“...in one trial it was not clear whether data were appropriately reported”

“Reporting quality in the studies was generally poor by current standards”

“randomised clinical trials...are warranted...Such trials ought to be conducted with low risk of systematic error (bias) and low risk of random error (play of chance), and should follow the SPIRIT and CONSORT guidelines”

“...this systematic review included only three trials of poor methodological quality... Additionally, the data are incomplete, and some important clinical outcomes were not reported”

*Cochrane Library, accessed on 4 May 2016)*

# Deficiencies in health research reporting

**A research article is often the only available record that a research study was conducted**

**Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information**

**Readers need a clear understanding of exactly what was done and found**

**5 main areas where deficiencies have been identified in the health research literature:**

- **Non-reporting (or delayed reporting) of studies**
- **Incomplete reporting of studies**
- **Selective reporting**
- **Misleading reporting**
- **Unacknowledged discrepancies between sources**

**Recently there has been an explosion in the publication of studies highlighting poor reporting practices.**

Impact of document type on reporting quality of clinical drug trials: a comparison of registry reports, clinical study reports, and journal publications

## 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"?

receiving numerous requests for additional details from doctors and patients, the author of a randomised trial on graded exercise for



### ARTICLE

## Adequacy of Published Oncology Randomized Controlled Trials to Provide Therapeutic Details Needed for Clinical Application

Jennifer M. Duff, Helen Leather, Edmund O. Walden, Kourtnay D. LaPlant, Thomas J. George Jr

Manuscript received July 9, 2009; revised March 15, 2010; accepted March 16, 2010.

Correspondence to: Thomas J. George Jr, MD, FACP, Division of Hematology Oncology, Department of Medicine, University of Florida, PO Box 100278, Gainesville, FL 32610-0278 (e-mail: thom.george@medicine.ufl.edu).

**Background** Randomized-controlled trials (RCTs) improve clinical care through evidence-based medicine, but specific details of therapeutic administration and trial design are often missing. We assess the reporting methodology in RCTs published in the medical literature.

**Methods** Ten essential elements of RCT reporting were identified and included a maximum number of cycles, premedication, growth factor support, patient adjustments for hematologic and organ-specific toxicity. All therapy-based RCTs published in the *New England Journal of Medicine (NEJM)*, *Journal of Clinical Oncology (JCO)*, *Journal of*

Clin Chem Lab Med 2012;50(3):411-413 © 2012 by Walter de Gruyter • Berlin • Boston, DOI 10.1515/cclm-2011-0904

## An appeal to medical journal editors: the need for a full description of laboratory methods and specimen handling in clinical study reports

elements.

27 from Cancer, 18% of complete data for toxicity (5/27; 18%), did not substantiate the results necessary for

## Exercise prescription: a case for standardised reporting

Susan Carolyn Slade, Jennifer Lyn Keating

### ABSTRACT

**Background** Structured, regularly recommended to improve health takes many forms and varies in its frequency. The authors use exercise for chronic health conditions as an example to describe how exercise programmes are described in reviews.

Two independent reviewers of exercise reporting practices for exercise effects for material. Inclusion criteria characterised the effects of exercise with chronic health conditions. Views of studies of children and adolescent

## Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials: Comparison of Protocols to Published Articles

An-Wen Chan, MD, DPhil  
Ashjorn Hróbjartsson, MD, PhD  
Mette T. Haahr, BS  
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 1994-1995. The number and characteristics of reported and unreported trial outcomes were recorded from protocols, journal articles, and a survey of trials. 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. Odds ratios of the extent and nature of outcome reporting bias were used to enhance strength, endurance, flexibility, function.

SELECTIVE PUBLICATION OF STUDIES with statistically significant results has received widespread recognition.<sup>1</sup> In contrast, selective reporting of favorable

enhance strength, endurance, flexibility, function.

These abbreviations. use of session. burden cardio-2 diagnosis, by physical 57.

html#Resolutions). The four main goals are promo-

## Reporting of adverse events in randomized controlled trials of highly active antiretroviral therapy: systematic review

Michal Y. Chowers<sup>1,2\*</sup>, Bat Sheva Gottesman<sup>1,2</sup>, Leonard Leibovici<sup>1,3</sup>, Ulrike Pielmeier<sup>4</sup>, Steen Andreassen<sup>4</sup> and Mijal Paul<sup>1,3</sup>

<sup>1</sup>Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; <sup>2</sup>Meir M Rabin Medical Center, Beilinson Campus, Petah-Tiqva, Israel; <sup>3</sup>Center for Support, Aalborg University, Aalborg, Denmark

### RESEARCH ARTICLE

Open Access

## Reporting and Interpretation of Randomized Controlled Trials With Statistically Nonsignificant Results for Primary Outcomes

Isabelle Boutron, MD, PhD  
Susan Dutton, MSc  
Philippe Ravaud, MD, PhD  
Douglas G. Altman, DSc

**Context** Previous studies indicate that the interpretation of trial results can be distorted by authors of published reports.

**Objective** To identify the nature and frequency of distorted presentation or "spin" (ie, specific reporting strategies, whatever their motive, to highlight that the experimental treatment is beneficial, despite a statistically nonsignificant difference for the primary outcome, or to distract the reader from statistically nonsignificant results) in published reports of randomized controlled trials (RCTs) with statistically nonsignificant results for primary outcomes.

**Data Sources** March 2007 search of MEDLINE via PubMed using the Cochrane Highly Sensitive Search Strategy to identify reports of RCTs published in December 2006.

## Electronic search strategies to identify reports of cluster randomized trials in MEDLINE: low precision will improve with adherence to reporting standards

Monica Taljaard<sup>1,2\*</sup>, Jessie McGowan<sup>1,3,4,5</sup>, Jeremy M Grimshaw<sup>1,6</sup>, Jamie C Brebaut<sup>1,2</sup>, Andrew McRae<sup>7</sup>, Martin P Eccles<sup>8</sup>, Allan Donner<sup>7,9</sup>

OPEN ACCESS Freely available online

## Publication Bias in Antipsychotic Trials: A Efficacy Comparing the Published Literature and the Food and Drug Administration Database

Lee Shapley<sup>5</sup>

Gregory, United States of America. <sup>2</sup>Department of Health Care, Oregon Health & Science University Medical Center, Portland, Oregon, United States

of evidence-based medicine, yet a drug regulatory agencies, e.g., the US which data in journal articles can be ch extent to which it inflates apparent

ACCURATE PRESENTATION of the results of a randomized controlled trial (RCT) is the cornerstone of the disse-

# Quality of reporting in systematic reviews

Volume 31 , Issue 2  
March/April 2016  
Pages 338–351

## Quality Assessment of Systematic Reviews on Oral Implants

Momen A. Atieh, BDS, MSc, DClinDent, PhD/Warwick J. Duncan, BDS, MDS,

Applicable or non-applicable: investigations of clinical heterogeneity in systematic reviews

Laura E. Chess and Joel J. Gagnier ✉

*BMC Medical Research Methodology* BMC series – open, inclusive and trusted 2016 16:19  
DOI: 10.1186/s12874-016-0121-7 | © Chess and Gagnier. 2016

## Compliance of Systematic Reviews in Plastic Surgery With the PRISMA Statement

Seon-Young Lee, BMedSc<sup>1</sup>; Harkiran Sagoo, BSc(Hons)<sup>2</sup>; Katharine Whitehurst, B  
Georgina Wellstead, BSc(Hons)<sup>4</sup>; Alexander J. Fowler, BSc(Hons), MBBS<sup>5</sup>; Riaz A  
(Oxf), MRCSEng, FHEA, FRSPH<sup>6</sup>; Dennis Orgill, MD, PhD<sup>7</sup>

*J Clin Epidemiol.* 2016 Jan 13. pii: S0895-4356(16)00039-1. doi: 10.1016/j.jclinepi.2016.01.008. [Epub a

## Strong heterogeneity of outcome reporting in systematic reviews.

Sautenet B<sup>1</sup>, Contentin L<sup>2</sup>, Bigot A<sup>3</sup>, Giraudeau B<sup>4</sup>.

## Systematic reviews experience major limitations in reporting absolute effects

Pablo Alonso-Coello✉✉, Alonso Carrasco-Labra, Romina Brignardello-Pete  
A. Akl, Robin W.M. Vernooij, Brad C. Johnston, Xin Sun, Matthias Briel, Jason  
Carlos E. Granados, Alfonso Iorio, Affan Irfan, Laura Martínez García, Reem  
Morera, Anna Selva, Ivan Solà, Andrea Juliana Sanabria, Kari A.O. Tikkinen,  
Zazueta, Yuqing Zhang, Qi Zhou, Holger Schünemann, Gordon H. Guyatt

## Risk of Bias in Systematic Reviews of Non-Randomized Studies of Adverse Cardiovascular Effects of Thiazolidinediones and Cyclooxygenase-2 Inhibitors: Application of a New Cochrane Risk of Bias Tool

Anja Bilandzic, Tiffany Fitzpatrick, Laura Rosella, David Henry ✉

Published: April 5, 2016 • <http://dx.doi.org/10.1371/journal.pmed.1001987>

## A third of systematic reviews changed or did not specify the primary outcome: A PROSPERO register study

Andrea C. Tricco<sup>a, b, c</sup>, ✉, Elise Cogo<sup>a</sup>, Matthew J. Page<sup>c</sup>, Julie Polisen<sup>d, e</sup>, Alison Booth<sup>f</sup>, Kerry  
Dwan<sup>g</sup>, Heather MacDonald<sup>a</sup>, Tammy J. Clifford<sup>d</sup>, Lesley A. Stewart<sup>f</sup>, Sharon E. Straus<sup>a, h</sup>, David Moher<sup>i</sup>

# About the EQUATOR Network



**Enhancing the QUALity and  
Transparency Of health Research**

International initiative to improve the reliability and value of medical research literature by promoting transparent and accurate reporting.

Our main focus:

- \* Raising awareness
- \* Provision of resources
- \* Education and training
- \* Research

Established due to growing evidence of serious deficiencies in research literature and its effect on the reliability and usability of research results.

Many reporting guidelines available but awareness and adherence still low.

# EQUATOR website: [www.equator-network.org](http://www.equator-network.org)



Enhancing the QUALITY and Transparency Of health Research



Enhancing the QUALITY and Transparency Of health Research

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Essential resources for writing and publishing health research

[Home](#) > [About us](#) > Canadian EQUATOR Centre

## 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
- Not sure which reporting guideline to use?
- Reporting guidelines under development
- Visit the library for more resources

## Reporting guidelines for main study types

- |   |                         |                            |                       |
|---|-------------------------|----------------------------|-----------------------|
| <a href="#">Randomised trials</a>               | <a href="#">CONSORT</a> | <a href="#">Extensions</a> | <a href="#">Other</a> |
| <a href="#">Observational studies</a>           | <a href="#">STROBE</a>  | <a href="#">Extensions</a> | <a href="#">Other</a> |
| <a href="#">Systematic reviews</a>              | <a href="#">PRISMA</a>  | <a href="#">Extensions</a> | <a href="#">Other</a> |
| <a href="#">Case reports</a>                    | <a href="#">CARE</a>    |                            | <a href="#">Other</a> |
| <a href="#">Qualitative research</a>            | <a href="#">SRQR</a>    | <a href="#">COREQ</a>      | <a href="#">Other</a> |
| <a href="#">Diagnostic / prognostic studies</a> | <a href="#">STARD</a>   | <a href="#">TRIPOD</a>     | <a href="#">Other</a> |
| <a href="#">Quality improvement studies</a>     | <a href="#">SQUIRE</a>  |                            | <a href="#">Other</a> |
| <a href="#">Economic evaluations</a>            | <a href="#">CHEERS</a>  |                            | <a href="#">Other</a> |
| <a href="#">Animal pre-clinical studies</a>     | <a href="#">ARRIVE</a>  |                            | <a href="#">Other</a> |
| <a href="#">Study protocols</a>                 | <a href="#">SPIRIT</a>  | <a href="#">PRISMA-P</a>   | <a href="#">Other</a> |

[See all 316 reporting guidelines](#)

## Canadian EQUATOR Centre

In addition to helping to carry out the strategic vision of the EQUATOR Network in Canada, the focus of the Canadian EQUATOR centre is on initiatives that have relevant down stream consequences for the conduct and reporting of biomedical research. Our current programs include:

- A broad research program on predatory journals
- Developing core competencies for journal editors
- Instituting, piloting, and evaluating a publications officer
- Teaching a course on journalology (academic graduate level)

**EQUATOR Wizard tool**  
[www.peneloperesearch.com/equator-wizard](http://www.peneloperesearch.com/equator-wizard)

Have you remembered everything?

Forgetting important details can delay publication and stop your work being cited or replicated. Checklists, made by experts and tailored to different study designs, can help.

This tool will help you find the right checklist for your work from the EQUATOR library.

[start](#) press ENTER

## 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

**Editors**

## EQUATOR highlights

**30/03/2016 - EQUATOR and RAHO develop practical action plan for universities to support their scientists in responsible reporting**



On 15 March 2016, Dr Iveta Silmers, Deputy Director of the UK EQUATOR Centre gave the presentation: Research papers that make a difference: how to increase research value, reputation, and impact at the 4th University Internationalization Seminar held in Washington ... [Read More](#)

**23/03/2016 - Two great EQUATOR events in Oxford this summer**

EQUATOR will be at Evidence

## News

**Rose Miro**  
7/04/16

**The EQUATOR**  
24/03/16

**Two great EQUATOR**  
23/03/16

**RAHO Portuguese**  
reporting  
22/02/2016

**New Australasian EQUATOR Centre opening in**  
March

# EQUATOR database of reporting guidelines

## Search for reporting guidelines



Browse for reporting guidelines by selecting one or more of these drop-downs:

Study type

Please select...

Clinical area

Please select...

Section of report

Please select...

Or search with free text

Search Reporting Guide

Search Reporting Guidelines

[Start again](#) | [Help](#)

Displaying 318 reporting guidelines found.

Most recently added records are displayed first.

1 [The Single-Case Reporting Guideline In Behavioural Interventions \(SCRIBE\) 2016 Statement](#)

2 [Consensus on Recording Deep Endometriosis Surgery: the CORDES statement](#)

3 [Developing the Clarity and Openness in Reporting: E3-based \(CORE\) reference user manual for creation of clinical study reports in the era of clinical trial transparency](#)

4 [SCCT guidelines for the interpretation and reporting of coronary CT angiography: a report of the Society of Cardiovascular Computed Tomography Guidelines Committee](#)

## Search for reporting guidelines

Use your browser's Back button to return to your search results



### The Single-Case Reporting Guideline In Behavioural Interventions (SCRIBE) 2016 Statement

Reporting guideline provided for?  
(I.e. exactly what the authors state in the paper)

Reporting single-case research.

Full bibliographic reference

Tate, R. L., M. Perdices, U. Rosenkoetter, W. Shadish, S. Vohra, D. H. Barlow, R. Homer, A. Kazdin, T. Kratochwill, S. McDonald, M. Sampson, L. Shamsseer, L. Togher, R. Albin, C. Beckman, J. Douglas, J. J. Evans, D. Gest, R. Manolov, G. Mitchell, L. Nickels, J. Nikles, T. Ownsworth, M. Rose, C. H. Schmid and B. Wilson. The Single-Case Reporting Guideline in BEhavioural Interventions (SCRIBE) 2016 Statement.

Arch Sci Psychol. 4(1): 1-9. doi:10.1037/arc0000028

Language

English

Explanation and elaboration papers

Tate, R. L., M. Perdices, U. Rosenkoetter, S. McDonald, L. Togher, W. Shadish, R. Homer, T. Kratochwill, D. H. Barlow, A. Kazdin, M. Sampson, L. Shamsseer and S. Vohra, for the SCRIBE Group (2016). The Single-Case Reporting Guideline in BEhavioural Interventions (SCRIBE) 2016: Explanation and elaboration. Arch Sci Psychol. 4(1): 10-31. doi:10.1037/arc0000027

Reporting guideline website URL

<http://sydney.edu.au/medicine/research/scribe/>

Reporting guideline acronym

SCRIBE

Study design

Experimental studies, Observational studies, Other

Clinical area

Behavioural medicine

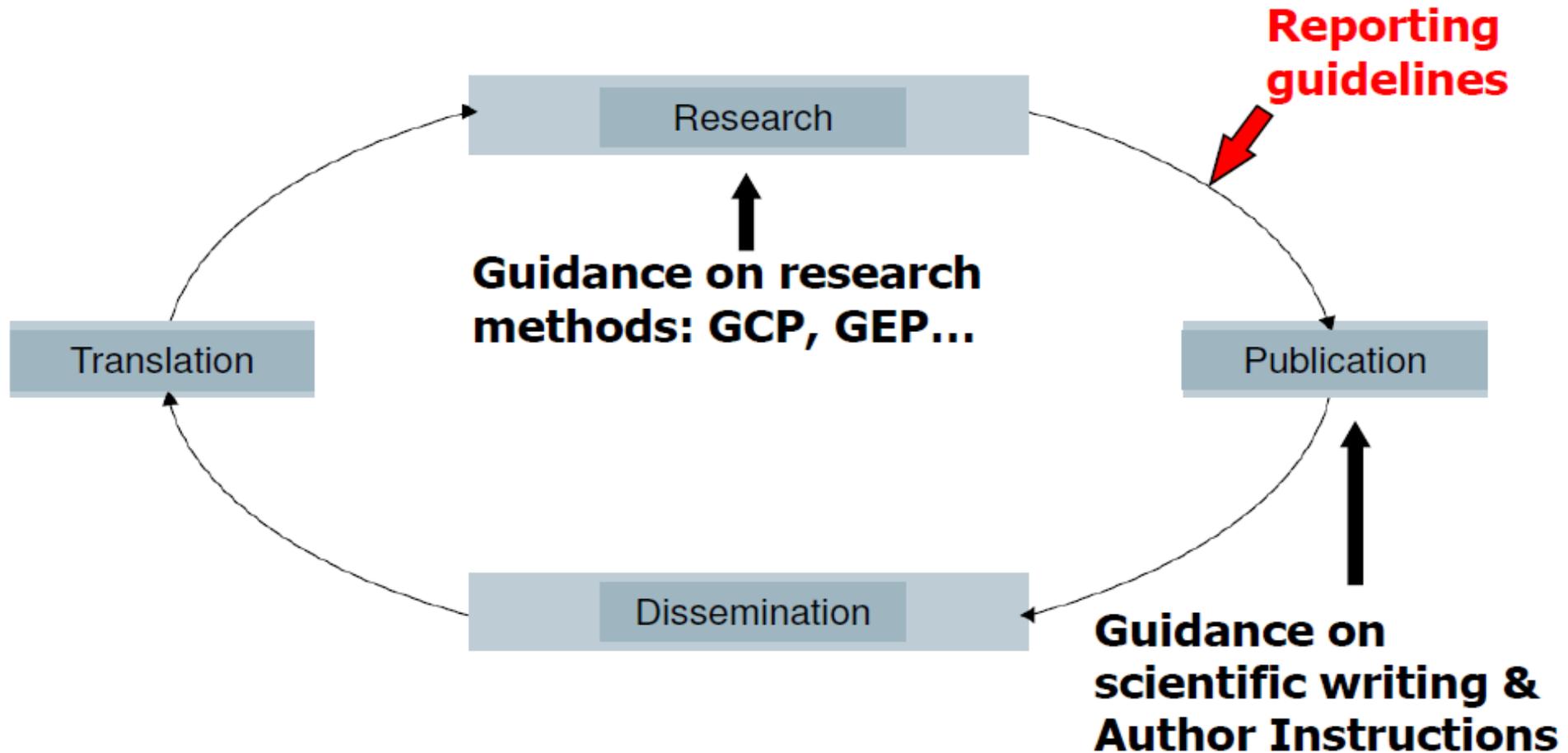
Applies to the whole report or to individual sections of the report?

Whole report

Additional information

Read the [SCRIBE project abstract](#) which was prepared to outline development of this reporting guideline.

# How to improve reporting



# What are reporting guidelines?

- \* Statements that provide advice on how to report research methods and findings
- \* 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
- \* Typically take the form of a checklist, flow diagram or piece of explicit text
- \* Based on available evidence and reflect the consensus opinion of experts in a particular field
- \* Complement advice on scientific writing and journals' instructions to authors

- \* Some examples include:



# PRISMA Statement



**PRISMA**

TRANSPARENT REPORTING OF SYSTEMATIC REVIEWS AND META-ANALYSES

[www.prisma-statement.org/](http://www.prisma-statement.org/)

## Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

David Moher , Alessandro Liberati, Jennifer Tetzlaff, Douglas G. Altman, The PRISMA Group 

Published: July 21, 2009 • <http://dx.doi.org/10.1371/journal.pmed.1000097>

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

Alessandro Liberati , Douglas G. Altman, Jennifer Tetzlaff, Cynthia Mulrow, Peter C. Gøtzsche, John P. A. Ioannidis, Mike Clarke, P. J. Devereaux, Jos Kleijnen, David Moher

Published: July 21, 2009 • <http://dx.doi.org/10.1371/journal.pmed.1000100>

# PRISMA checklist and flow diagram

## PRISMA Statement 2009 – Reporting guideline for systematic reviews and meta-analyses

PRISMA stands for Preferred Reporting Items for Systematic reviews and Meta-Analyses. It is an evidence-based minimum set of standards for reporting systematic reviews and meta-analyses. It consists of a 27-item checklist and a flow diagram which depicts the flow of information through the different phases of a systematic review.

This guideline replaces the existing QUOROM Statement; journals and other organisations are encouraged to update their instructions and resources and refer authors to the new PRISMA guidance.

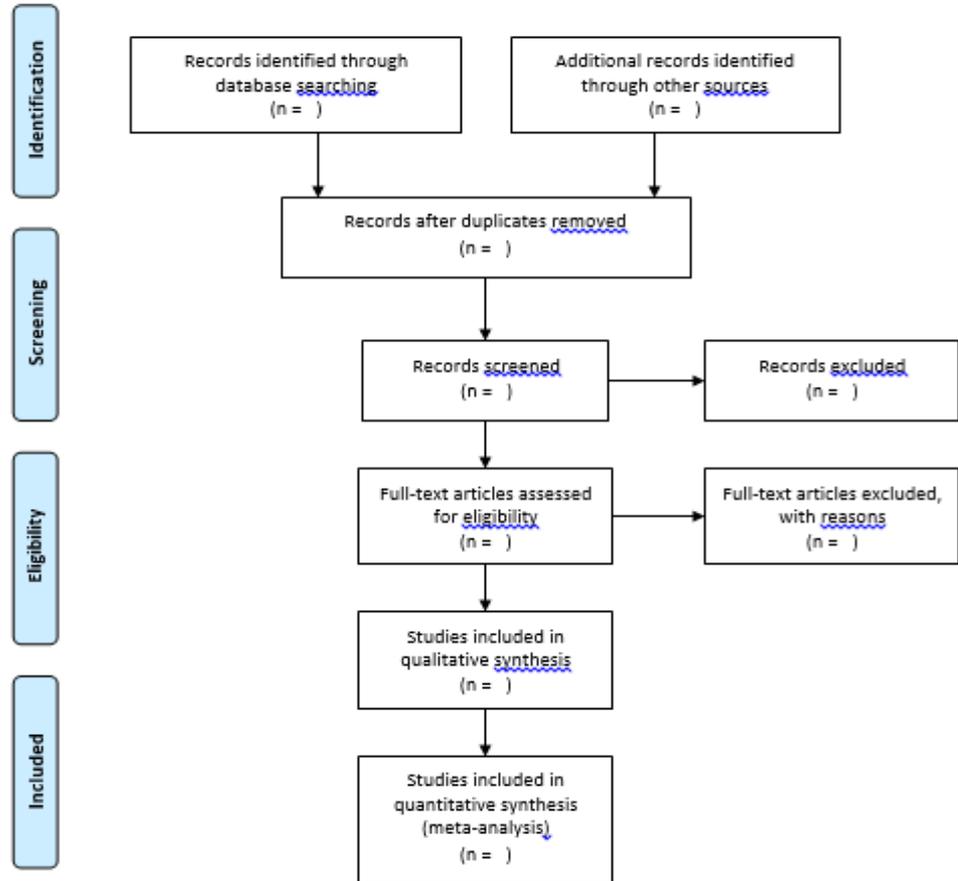
### PRISMA 2009 Checklist

[www.prisma-statement.org](http://www.prisma-statement.org)

| Section / topic                    | #  | Checklist item  | Reported on page # |
|------------------------------------|----|---|--------------------|
| <b>TITLE</b>                       |    |   |                    |
| Title                              | 1  | Identify the report as a systematic review, meta-analysis, or both.   |                    |
| <b>ABSTRACT</b>                    |    |   |                    |
| 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. |                    |
| <b>INTRODUCTION</b>                |    |   |                    |
| 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).  |                    |
| <b>METHODS</b>                     |    |   |                    |
| 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.  |                    |



## PRISMA 2009 Flow Diagram



# PRISMA extensions

[PRISMA harms checklist: improving harms reporting in systematic reviews](#)

[The PRISMA Extension Statement for Reporting of Systematic Reviews Incorporating Network Meta-analyses of Health Care Interventions: Checklist and Explanations](#)

[Preferred Reporting Items for Systematic Review and Meta-Analyses of individual participant data: the PRISMA-IPD Statement](#)

[Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols \(PRISMA-P\) 2015 statement](#)

[PRISMA-Equity 2012 Extension: Reporting Guidelines for Systematic Reviews with a Focus on Health Equity](#)

[PRISMA for Abstracts: Reporting Systematic Reviews in Journal and Conference Abstracts](#)

# PRISMA-P

## PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol\*

| Section and topic                 | Item No | Checklist item  |
|-----------------------------------|---------|---|
| <b>ADMINISTRATIVE INFORMATION</b> |         |   |
| Title:                            |         |   |
| Identification                    | 1a      | Identify the protocol   |
| Update                            | 1b      | If the protocol is updated, describe the changes  |
| Registration                      | 2       | If registered, provide the registration number and name of the registry   |
| Authors:                          |         |   |
| Contact                           | 3a      | Provide name and contact information for the corresponding author   |
| Contributions                     | 3b      | Describe contributions of protocol authors and identify the guarantor of the review   |
| Amendments                        | 4       | If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments |
| Support:                          |         |   |
| Sources                           | 5a      | Indicate sources of financial or other support for the review   |
| Sponsor                           | 5b      | Provide name for the review funder and/or sponsor   |
| Role of sponsor or funder         | 5c      | Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol  |
| <b>INTRODUCTION</b>               |         |   |
| Rationale                         | 6       | Describe the rationale for the review in the context of what is already known   |
| Objectives                        | 7       | Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparisons, outcomes, and study design                                 |
| <b>METHODS</b>                    |         |   |
| Eligibility criteria              | 8       | Specify search and screening criteria   |
| Information sources               | 9       | Identify all information sources searched   |

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement

David Moher , Larissa Shamseer, Mike Clarke, Davina Ghera, Alessandro Liberati, Mark Petticrew, Paul Shekelle, Lesley A Stewart and PRISMA-P Group

*Systematic Reviews* 2015 4:1 | DOI: 10.1186/2046-4053-4-1 | © Moher et al.; licensee BioMed Central. 2015

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation

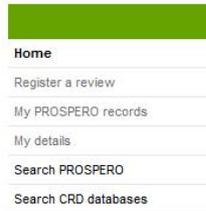
*BMJ* 2015 ; 349 doi: <http://dx.doi.org/10.1136/bmj.g7647> (Published 02 January 2015)

Cite this as: *BMJ* 2015;349:g7647

# PROSPERO

UNIVERSITY of York  
Centre for Reviews and Dissemination

NHS  
National Institute for  
Health Research



[www.crd.york.ac.uk/PROSPERO/](http://www.crd.york.ac.uk/PROSPERO/)

- \* **International database of prospectively registered systematic reviews in health and social care**
- \* **Important features from the protocol are recorded and maintained as a permanent record**
- \* **Helps to avoid unplanned duplication and to enable comparison of reported review methods with what was planned in the protocol**

Disorganized Systematic Reviews and Meta-analyses: Time to Systematize the Conduct and Publication of These Study Overviews?

Irbaz Bin Riaz, MD, Muhammad Shahzeb Khan, MBBS, Haris Riaz, MD, Robert J. Goldberg, PhD

"...there was an abundance of redundant and disorganized meta-analyses, creating confusion...The registration of systematic reviews should be mandatory in prospective registries, such as PROSPERO, and the PRISMA checklist should be updated..."

# Published reporting guidelines for systematic reviews

## Search for reporting guidelines



Browse for reporting guidelines by selecting one or more of these drop-downs:

Study type

Systematic reviews/Met

and

Clinical area

Please select...

and

Section of report

Please select...

Or search with free text

Search Reporting Guidelines

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Displaying 24 reporting guidelines found.

18

[Collaborative Approach to Meta Analysis and Review of Animal Data from Experimental Studies \(CAMARADES\)](#)

19

[Bayesian methods in health technology assessment: a review](#)

20

[RAMESES publication standards: meta-narrative reviews](#)

21

[RAMESES publication standards: realist syntheses](#)

22

[Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology \(MOOSE\) group](#)

23

[Meta-analysis of individual participant data: rationale, conduct, and reporting](#)

24

[Reporting and presenting information retrieval processes: the need for optimizing common practice in health technology assessment](#)

# Examples of journal requirements

## Standards of reporting



BioMed Central advocates complete and transparent reporting of biomedical and biological research. Please refer to the [Minimum standards of reporting checklist](#) when reporting your research (published in *BMC Biology*). Exact requirements may vary depending on the journal; please refer to the journal's instructions for authors. We also strongly recommend that authors refer to the minimum reporting guidelines for health research hosted by the [EQUATOR Network](#) when preparing their manuscript, and the [BioSharing Portal](#) for reporting checklists for biological and biomedical research, where applicable. Authors should adhere to these guidelines when drafting their manuscript, and peer reviewers will be asked to refer to these checklists when evaluating such studies.

Checklists are available for a number of study designs, including:

- Randomized controlled trials (CONSORT) and protocols (SPIRIT)
- Systematic reviews and meta-analyses\* (PRISMA) and protocols (PRISMA-P)
- Observational studies (STROBE)
- Case reports (CARE)
- Qualitative research (COREQ)
- Diagnostic/prognostic studies (STARD and TRIPOD)
- Economic evaluations (CHEERS)
- Pre-clinical animal studies (ARRIVE)



Research ▾ Education ▾ News & Views ▾ Campaigns ▾

### As supplemental files

- The original protocol for a clinical trial or, if the protocol has been published in an open access online journal, its reference and URL. We appreciate that studies sometimes deviate from protocols, but please explain any important deviations in the manuscript, particularly those about choice of outcomes and analyses or change in sample size.
  - The original protocol for an observational study or systematic review, if available. We recommend that protocols for randomised trials are written using the [SPIRIT checklist](#).
  - For a randomised controlled trial, the appropriate completed [CONSORT](#) checklist showing on which page of your manuscript each checklist item appears, the CONSORT-style structured abstract, and the CONSORT flowchart (CONSORT has several extension statements - for example, for cluster RCTs, pragmatic trials).
  - For a randomised controlled trial, a completed [TIDieR checklist](#) - this helps to ensure that trial interventions are fully described in ways that are reproducible, usable by other clinicians, and clear enough for systematic reviewers and guideline writers.
  - [PRISMA](#) checklist and flowchart for a systematic review or meta-analysis of randomised trials and other evaluation studies.
  - [STARD](#) checklist and flowchart for a study of diagnostic accuracy.
  - [STROBE](#) checklist for an observational study.
- Please use the STROBE extensions, where appropriate:

- [RECORD: The REporting of studies Conducted using Observational R Statement](#)
- [RDS: Strengthening the Reporting of Observational Studies in Epidemiology](#)
- [MF: Strengthening of Reporting of Observational Studies: STROBE-RL](#)

## THE LANCET

- Reports of trials must conform to [CONSORT 2010 guidelines](#), and should be submitted with their protocol and flowchart.
- All reports of randomised trials should include a section entitled Randomisation and masking, within the text of the main text.
- Cluster-randomised trials must be reported according to [CONSORT extended guidelines](#)
- Randomised trials that report harms must be described according to [extended CONSORT guidelines](#)
- Studies of diagnostic accuracy must be reported according to [STARD guidelines](#)
- Observational studies (cohort, case-control, or cross-sectional designs) must be reported according to their protocols
- We encourage the registration of all observational studies on a WHO-compliant registry (see [Lancet 2013](#))
- Genetic association studies must be reported according to [STREGA guidelines](#)
- Systematic reviews and meta-analyses must be reported according to [PRISMA guidelines](#)
- To find reporting guidelines see <http://www.equator-network.org>

## Annals of Internal Medicine

ESTABLISHED IN 1927 BY THE AMERICAN COLLEGE OF PHYSICIANS

|                      |   |
|----------------------|---|
| Reporting guidelines | Follow relevant reporting recommendations. The <a href="#">EQUATOR</a> includes the following: <ul style="list-style-type: none"> <li>• <a href="#">PRISMA</a> reporting guideline for systematic reviews and meta-analysis</li> <li>• <a href="#">MOOSE</a> reporting guidelines for meta-analysis of observational studies</li> <li>• <a href="#">ENTREQ</a> reporting guideline for synthesis of qualitative research</li> </ul> |
|----------------------|---|



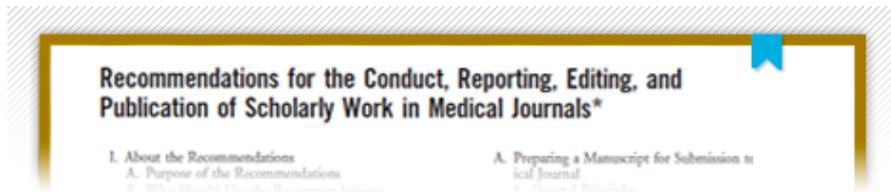


Recommendations

Conflicts of Interest

Journals  
Following the ICMJE Recommendations

## Recommendations



Read the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals.

[www.icmje.org/icmje-recommendations.pdf](http://www.icmje.org/icmje-recommendations.pdf)

ted and sent for peer review simultaneously with the primary manuscript.

## 2. Reporting Guidelines

Reporting guidelines have been developed for different study designs; examples include CONSORT ([www.consort-statement.org](http://www.consort-statement.org)) for randomized trials, STROBE for observational studies (<http://strobe-statement.org/>), PRISMA for systematic reviews and meta-analyses (<http://prisma-statement.org/>), and STARD for studies of diagnostic accuracy ([www.stard-statement.org/](http://www.stard-statement.org/)). Journals are encouraged to ask authors to follow these guidelines because they help authors describe the study in enough detail for it to be evaluated by editors, reviewers, readers, and other researchers evaluating the medical literature. Authors of review manuscripts are encouraged to describe the methods used for locating, selecting, extracting, and synthesizing data; this is mandatory for systematic reviews. Good sources for reporting guidelines are the EQUATOR Network ([www.equator-network.org/home/](http://www.equator-network.org/home/)) and the NLM's Research Reporting Guidelines and Initiatives ([www.nlm.nih.gov/services/research\\_report\\_guide.html](http://www.nlm.nih.gov/services/research_report_guide.html)).

## 3. Manuscript Sections

The following are general requirements for reporting within sections of all study designs and manuscript for-

## Confl

Use the I  
a disclos

# Why use reporting guidelines for systematic reviews?

**Reporting guidelines are simply an aide memoire - a list of items deemed essential for a clear and transparent account of what was done and what was found in a research study**

They help you to:

- \* improve the accuracy, completeness and reproducibility of your review
- \* comply with journal submission requirements
- \* ensure that your research study provides a more reliable basis for making clinical decisions or for inclusion in further research
- \* ensure the results of your review can be transferred into practice more quickly
- \* improve the quality of the research output of your department / institution / organisation

***You can improve not only the quality and subsequent usability of published health research but also help advance the global body of health knowledge ultimately leading to improved patient care!***

# Impact (1)

## European Heart Journal - Cardiovascular Imaging

Reporting standards in cardiac MRI, CT, and SPECT diagnostic accuracy studies: analysis of the impact of STARD criteria 

Edd N. Maclean, Ian S. Stone, Felix Ceelen, Xabier Garcia-Albeniz, Wieland H. Sommer, Steffen E. Petersen

DOI: <http://dx.doi.org/10.1093/ehjci/et277> 691-700 First published online: 23 January 2014

“The reporting standards of diagnostic accuracy studies in the field of non-invasive cardiac imaging are satisfactory at best and have **improved since the introduction of STARD**. Those journals that **advise authors to refer to STARD have significantly higher impact factors**, and authors should be encouraged that **journals of relatively high impact factors publish diagnostic accuracy studies of higher reporting quality.**”

## INTERNATIONAL JOURNAL OF SURGERY

Impact of the mandatory implementation of reporting guidelines on reporting quality in a surgical journal: A before and after study

Riaz Ahmed Agha, Alexander J. Fowler  , Chris Limb, Katie Whitehurst, Robert Coe, Harkiran Sagoo, Daniyal Jafree, Charmilie Chandrakumar, Buket Gundogan

“...**STROBE compliance** following implementation of the policy, **increased by a statistically significant 12%** (68% to 77%,  $p=0.00018$ )...**CONSORT compliance increased (50% to 70%)** as did **PRISMA compliance (48% to 76%)**...”

## Calls for development of additional reporting guidelines for reviews:

A scoping review on the conduct and reporting of scoping reviews

Andrea C. Tricco , Erin Lillie, Wasifa Zarin, Kelly O'Brien, Heather Colquhoun, Monika Kastner, Danielle Levac, Carmen Ng, Jane Pearson Sharpe, Katherine Wilson, Meghan Kenny, Rachel Warren, Charlotte Wilson, Henry T. Stelfox and Sharon E. Straus

*BMC Medical Research Methodology* BMC series – open, inclusive and trusted 2016 16:15 |

DOI: 10.1186/s12874-016-0116-4 | © Tricco et al. 2016

Conclusion: “...improvements in reporting and conduct are imperative. Further research on scoping review methodology is warranted, and in particular, **there is need for a guideline to standardize reporting.**”

# Impact (2): UK Academy of Medical Sciences

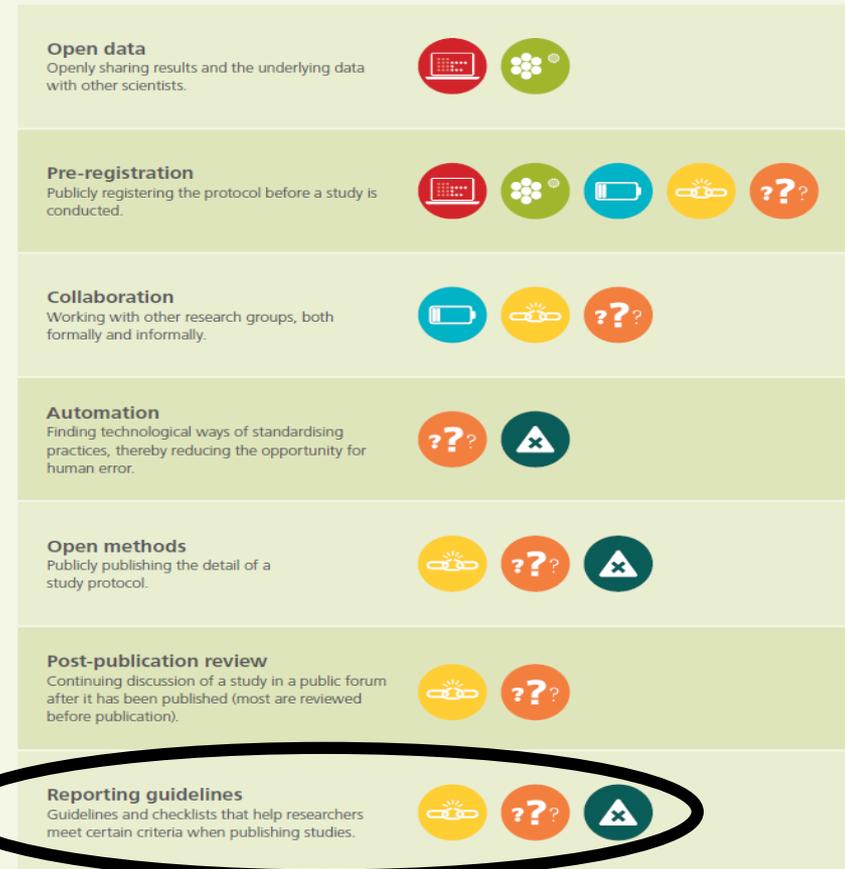
## Reproducibility and the conduct of research



Improving reproducibility will ensure that research is as efficient and productive as possible. This figure summarises aspects of the conduct of research that can cause irreproducible results, and potential strategies for counteracting poor practice in these areas. Overarching factors can further contribute to the causes of irreproducibility, but can also drive the implementation of specific measures to address these causes. The culture and environment in which research takes place is an important 'top-down' overarching factor. From a 'bottom-up' perspective, continuing education and training for researchers can raise awareness and disseminate good practice.

Figure taken from the report of the symposium, 'Reproducibility and reliability of biomedical research', organised by the Academy of Medical Sciences, BBSRC, MRC and Wellcome Trust in April 2015. The full report is available from <http://www.acmedsci.ac.uk/researchreproducibility>.

## Possible strategies



# Impact (3): HEFCE



RESEARCH POLICY | November 10th 2015

## Research impact: learning lessons from the REF

**Lesson 5: Researchers who deliver high-quality academic research also deliver high-quality impact**

# Impact (4)

RESEARCH ARTICLE

## Is Quality and Completeness of Reporting of Systematic Reviews and Meta-Analyses Published in High Impact Radiology Journals Associated with Citation Rates?

Christian B. van der Pol<sup>1</sup>, Matthew D. F. McInnes<sup>1,2\*</sup>, William Petrcich<sup>2</sup>, Adam S. Tunis<sup>1</sup>, Ramez Hanna<sup>1</sup>

<sup>1</sup> Department of Radiology, University of Ottawa, Ottawa, Ontario, Canada, <sup>2</sup> Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada

\* [mmcinn@toh.on.ca](mailto:mmcinn@toh.on.ca)



### Conclusion

There is a positive correlation between the quality and the completeness of a reported SR or MA with citation rate which persists when adjusted for journal IF and journal 5-year IF.

 OPEN ACCESS

Citation: van der Pol CB, McInnes MDF, Petrcich W, Tunis AS, Hanna R (2015) Is Quality and Completeness of Reporting of Systematic Reviews

# Final thoughts...

Research reporting is just one aspect of a much wider problem within biomedical research today involving industry, publishers, governments, funders, regulators, researchers and academic institutions which is attracting increasing debate and examination.

**"Perhaps all of us engaged in the enterprise we call “science” need to pause and reflect on the present state of what we do...How should the entire scientific enterprise change to produce reliable and accessible evidence that addresses the challenges faced by society and the individuals who make up those societies?"**

Kleinert S, Horton R. How should medical science change? Lancet. 2014 Jan 18;383(9913):197-8.

# Research waste & REWARD campaign

## REWARD

Priorities | Design conduct analysis | Regulation & management | Accessibility | C



The Lancet REWARD (REduce research Waste And Reward Diligence) Campaign invites everyone involved in biomedical research to critically examine the way they work to reduce waste and maximise efficiency. Read the REWARD statement and join the campaign



## The Reward Alliance

Home About The REWARD statement Events Document

# Research

## Increasing value, reducing waste

It has been estimated that 85% of research is wasted, usually because it asks the wrong questions, is badly designed, not published or poorly reported. This diminishes the value of research and also represents a significant financial loss. However, many causes of this waste are simple problems that could easily be fixed, such as appropriate randomisation or blinding of a clinical trial. A first step towards increasing the value of research and reducing waste is to monitor the problems and develop solutions that aim to fix them.

<http://researchwaste.net/>

## Research: increasing value, reducing waste

Published: January 8, 2014

### Executive Summary

The Lancet presents a Series of five papers about research. In the first report Iain Chalmers *et al* discuss how decisions about which research to fund should be based on issues relevant to users of research. Next, John Ioannidis *et al* consider improvements in the appropriateness of research design, methods, and analysis. Rustam Al-Shahi Salman *et al* then turn to issues of efficient research regulation and management. Next, An-Wen Chan *et al* examine the role of fully accessible research information. Finally, Paul Glasziou *et al* discuss the importance of unbiased and usable research reports. These papers set out some of the most pressing issues, recommend how to increase value and reduce waste in biomedical research, and propose metrics for stakeholders to monitor the implementation of these recommendations.

### Comments

#### How should medical science change?

Sabine Kleinert, Richard Horton

Summary | Full-Text HTML | PDF

#### Biomedical research: increasing value, reducing waste

Malcolm R Macleod, Susan Michie, Ian Roberts, Ulrich Dirnagl, Iain Chalmers, John P A Ioannidis, Rustam Al-Shahi Salman, An-Wen Chan, Paul Glasziou

Summary | Full-Text HTML | PDF

### Series Papers

#### How to increase value and reduce waste when research priorities are set

Iain Chalmers, Michael B Bracken, Ben Djulibegovic, Silvio Garattini, Jonathan Grant, A Metin Gülmezoglu, David W Howells, John P A Ioannidis, Sandy Oliver

Summary | Full-Text HTML | PDF

#### Increasing value and reducing waste in research design, conduct, and analysis

John P A Ioannidis, Sander Greenland, Mark A Hlatky, Muin J Khoury, Malcolm R Macleod, David Moher, Kenneth F Schulz, Robert Tibshirani

Summary | Full-Text HTML | PDF

#### Increasing value and reducing waste in biomedical research regulation and management

Rustam Al-Shahi Salman, Elaine Beller, Jonathan Kagan, Elina Hemminki, Robert S Phillips, Julian Savulescu, Malcolm Macleod, Janet Wisely, Iain Chalmers

Summary | Full-Text HTML | PDF

#### Increasing value and reducing waste: addressing inaccessible research

An-Wen Chan, Fujian Song, Andrew Vickers, Tom Jefferson, Kay Dickersin, Peter C Gøtzsche, Harlan M Krumholz, Davina Ghersi, H Bart van der Worp

Summary | Full-Text HTML | PDF

#### Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager

Summary | Full-Text HTML | PDF

### Updates

#### REWARD Alliance Update April 2016, by Professor Paul Glasziou

The 2015 REWARD/EQUATOR conference in Edinburgh abstracts are downloadable at <http://rewardalliance.net/research-waste-equator-conference/>. The first video in a series from the conference is an 8-minute video providing a great overview of the main issues of research waste: <https://youtu.be/W0Wyc5w6bQE>. Several other short videos from the conference on different themes are in preparation and will be available in the next few weeks. Please watch, enjoy and tweet.

More...

### Related Content

#### COMMENT

Increasing value and reducing waste in biomedical research: librarians are listening and are part of the answer

Shona Kirtley

The Lancet, Vol. 387, No. 10028, p1601

Published in issue: April 16, 2016

Summary | Full-Text HTML | PDF

#### EDITORIAL

Maximising the value of research for brain health

The Lancet Neurology

The Lancet Neurology, Vol. 14, No. 11, p1065

Published in issue: November, 2015

Summary | Full-Text HTML | PDF

#### COMMENT

How should medical science change?

Sabine Kleinert, Richard Horton

The Lancet, Vol. 383, No. 9913, p197-198

Published online: January 8, 2014

Summary | Full-Text HTML | PDF

#### COMMENT

Biomedical research: increasing value, reducing waste

Malcolm R Macleod, Susan Michie, Ian Roberts, Ulrich Dirnagl, Iain Chalmers,

John P A Ioannidis, Rustam Al-Shahi Salman, An-Wen Chan, Paul Glasziou

The Lancet Vol. 383, No. 9912, p101-104

# EQUATOR Network

## Steering group



## UK EQUATOR Centre



## French EQUATOR Centre Since 2014:



## Canadian EQUATOR Centre



## Acknowledgements

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# Thank you!

[www.equator-network.org](http://www.equator-network.org)



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