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

Shona Kirtley, Senior Research Information Specialist, EQUATOR Network, Centre for Statistics in Medicine, NDORMS, University of Oxford, UK
* 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
“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 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
A research article is the ‘end product’ of one process...

...and the ‘raw material’ of other processes
Systematic reviews rely on the robustness of the methods and results of primary research and on how primary studies are reported.
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**

<table>
<thead>
<tr>
<th></th>
<th>Done well</th>
<th>Done poorly</th>
<th>Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully reported (=reproducible)</td>
<td></td>
<td></td>
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<tr>
<td>Ambiguously or incompletely reported</td>
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<tr>
<td>Not reported</td>
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</table>
Cochrane risk of bias tool

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.

- Cannot assess research quality, reliability or relevance
- Not included in a systematic review
- Or clinical practice guideline
- Cannot inform health policies, clinical practice or further research
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 trials.

"Reporting quality in the studies was generally poor by current standards"

"...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"

"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.

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

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
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.”

The authors received numerous requests for additional details from doctors and patients, the author of a randomised trial on graded exercise for exercise prescription: a case for standardised reporting

Susan Carolyn Slade, Jennifer Lyn Keating

ABSTRACT

Exercise prescription for chronic heart condition exercise programs are described reviews. Two independent reviewers performed exercise effects for severe. Inclusion criteria biased the effects of exercise prescription for chronic heart condition exercise programs are described.

Background Structured, regular exercise prescription for chronic heart condition exercise programs are described.

The authors used exercise for chronic heart condition exercise programs are described.

Methods Ten independent reviewers performed exercise effects for severe. Inclusion criteria biased the effects of exercise prescription for chronic heart condition exercise programs are described.

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


Open Access Freely available online

Publication Bias in Antipsychotic Trials: A Network Meta-Analysis Comparing the Published Literature with the Published Literature Database

Lee Skapley

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

Monica Taljaard,1,2,3 Jessie McGowan,3,4 Jeremy M Grimsaw,5,6 Jamie C Brehaut,7 Andrew McBae,8 Martin P Eccles,9 Alpın Dönmez10

Research Article

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

Research

Adequacy of Published Oncology Randomized Controlled Trials (RCTs) to Provide Therapeutic Details Needed for Clinical Application


Background — Randomized-controlled trials (RCTs) improve clinical care through evidence-based RCT reports, but specific details of the therapeutic administration are often missing in the reporting of RCTs published in oncology journals.

Methods — Ten independent reviewers performed exercise effects for severe. Inclusion criteria biased the effects of exercise prescription for chronic heart condition exercise programs are described.

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

Ae-Won Chon, MD, PhD

Adriana Hedgcock, MD, PhD

Meire T. Haagsma, PhD

Peter C. Gotzsche, MD, DrMedSci

Douglas C. Altman, PhD

Selective reporting of outcomes is an important ethical issue in clinical trials. The authors wanted to know whether the results of published randomized trials were consistent with the outcomes included in the published protocols.

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

Michelle Y. Chow1,2,3, Bat Sheva Gottesman2,3, Leonard Leibovici2,3, Ulrike Piemeier2,3, Steen Andreassen4 and Micael Paul5

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

Michal Y. Chow2,1, Bat Sheva Gottesman2,1, Leonid Leibovici2,3, Ulrike Piemeier2,3, Steen Andreassen4 and Micael Paul5

Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; 2Mieir Medical Center, Beilinson Campus, Petah-Tiqwa, Israel; 3Center for Support, Aalborg University, Aalborg, Denmark

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


OPEN ACCESS Freely available online

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Monica Taljaard, Jessie McGowan, Jeremy M Grimsaw, Jamie C Brehaut, Andrew McBae, Martin P Eccles, Alpın Dönmez
About the EQUATOR Network

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.
How to improve reporting

Guidance on research methods: GCP, GEP...

Translation

Research

Dissemination

Publication

Guidance on scientific writing & Author Instructions

Reporting guidelines
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:

![CONSORT](https://example.com/consort)

![PRISMA](https://example.com/prisma)

![STROBE Statement](https://example.com/strobe)

![Equator Network](https://example.com/equator)
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**

<table>
<thead>
<tr>
<th>Section / topic</th>
<th>#</th>
<th>Checklist item</th>
<th>Reported in checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
<td></td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>2</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
<td></td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
<td></td>
</tr>
<tr>
<td>METHODS</td>
<td>5</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td></td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td></td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td></td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
<td></td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

**PRISMA 2009 Flow Diagram**

1. **Records identified through database searching**
   
2. **Records after duplicates removed**
   
3. **Records screened**
   
4. **Records excluded**
   
5. **Full-text articles assessed for eligibility**
   
6. **Studies included in qualitative synthesis**

7. **Studies included in quantitative synthesis (meta-analysis)**

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

<table>
<thead>
<tr>
<th>Section and topic</th>
<th>Item No</th>
<th>Checklist item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADMINISTRATIVE INFORMATION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title:</td>
<td>1a</td>
<td>Identify the systematic review or for each protocol being registered, provide a title and a brief description.</td>
</tr>
<tr>
<td>Update</td>
<td>1b</td>
<td>If the protocol is an update of a previous protocol, identify the protocol that is being updated.</td>
</tr>
<tr>
<td>Registration</td>
<td>2</td>
<td>If registered, provide registration number.</td>
</tr>
<tr>
<td>Authors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact</td>
<td>3a</td>
<td>Provide name and contact details of person responsible for completing the protocol.</td>
</tr>
<tr>
<td>Contributions</td>
<td>3b</td>
<td>Describe contributions of protocol authors and identify the guarantor of the review.</td>
</tr>
<tr>
<td>Amendments</td>
<td>4</td>
<td>If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes made; otherwise, state plan for documenting important protocol amendments</td>
</tr>
<tr>
<td>Support:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sources</td>
<td>5a</td>
<td>Indicate sources of financial or other support for the review.</td>
</tr>
<tr>
<td>Sponsor</td>
<td>5b</td>
<td>Provide name for the review funder and/or sponsor.</td>
</tr>
<tr>
<td>Role of sponsor or funder</td>
<td>5c</td>
<td>Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>6</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
</tr>
<tr>
<td>Objectives</td>
<td>7</td>
<td>Provide an explicit statement of the question(s) the review will address with reference to participants, interventions,</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
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<tr>
<td>Eligibility criteria</td>
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<td></td>
</tr>
<tr>
<td>Information sources</td>
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<td></td>
</tr>
</tbody>
</table>

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
* 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

"...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

Displaying 24 reporting guidelines found.

18. Collaborative Approach to Meta Analysis and Review of Animal Data from Experimental Studies (CAMARADES)


20. RAMESES publication standards: meta-narrative reviews

21. RAMESES publication standards: realist syntheses


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
ICMJE

Recommendations

Use the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

www.icmje.org/icmje-recommendations.pdf
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!
“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.”

"...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:

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."
Reproducibility and the conduct of research

Issues

- Data dredging: Also known as p-hacking, this involves repeatedly searching a dataset or trying alternative analyses until a “significant” result is found.
- Omitting null results: When scientists or journals decide not to publish studies unless results are statistically significant.
- Underpowered study: Statistical power is the ability of an analysis to detect an effect, if the effect exists – an underpowered study is too small to reliably indicate whether or not an effect exists.
- Errors: Technical errors may exist within a study, such as misidentified reagents or computational errors.
- Underspecified methods: A study may be very robust, but its methods not shared with other scientists in enough detail, so others cannot precisely replicate it.
- Weak experimental design: A study may have one or more methodological flaws that mean it is unlikely to produce reliable or valid results.

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.

Possible strategies

- Open data: Openly sharing results and the underlying data with other scientists.
- Pre-registration: Publicly registering the protocol before a study is conducted.
- Collaboration: Working with other research groups, both formally and informally.
- Automation: Finding technological ways of standardising practices, thereby reducing the opportunity for human error.
- Open methods: Publicly publishing the detail of a study protocol.
- Post-publication review: Continuing discussion of a study in a public forum after it has been published (most are reviewed before publication).

Reporting guidelines: Guidelines and checklists that help researchers meet certain criteria when publishing studies.

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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/research/reproducibility](http://www.acmedsci.ac.uk/research/reproducibility).
Lesson 5: Researchers who deliver high-quality academic research also deliver high-quality impact
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 Pol¹, Matthew D. F. McInnes¹,²*, William Petrich², Adam S. Tunis¹, Ramez Hanna¹

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

* mmcInnes@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.
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?"

Research waste & REWARD campaign

The Reward Alliance

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/
Acknowledgements
Many thanks to both Professor Doug Altman and Dr Iveta Simera for permission to reproduce some of their slides and for helpful comments on this presentation.
Thank you!

www.equator-network.org

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