
Can we trust the medical research literature: poor reporting and its consequences

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Reliable evidence

- **Clinical practice and public health policy decisions depend on high-quality information about research findings**
- **We need reliable evidence from research**
 - Good quality research
 - Good reporting of that research
- **Not always what we get**



Importance of good research reporting

- **Without accessible and usable reports, research cannot help patients and their clinicians**

[Chalmers and Glasziou 2009]

- **Complete, accurate and transparent reporting is an integral part of responsible research conduct**

... All scientists have a responsibility to ensure that they conduct their work with honesty and integrity; to ensure that methods and results are reported in an accurate, orderly, timely and open fashion. ...

International Council for Science. Freedom, Responsibility and Universality of Science. 2008



Research article

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

Primary research

Design

Conduct

Publication



Research article

- Research article is '**end product**' of one process ...

Primary research

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- ...and '**raw material**' of other processes

Publication

Informs further research

Systematic review

Clinical practice guideline

Informs health policies and clinical practice

Research article

- **Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information and reach his or her own conclusions about results**
 - to assess reliability and relevance
- **Readers need a clear understanding of exactly what was done**
 - Clinicians, Researchers, Systematic reviewers, Policy makers, ...
- **The goal should be transparency**
 - Should not mislead
 - Should allow replication (in principle)
 - Can be included in systematic review and meta-analysis



Taxonomy of poor reporting

- **Non-reporting (or delayed reporting) of whole studies**
(even when some results have been presented in public)
- **Misrepresentation of study design**
 - e.g. study claiming is an RCT when is not
- **Selective reporting**
 - patient outcomes
 - analyses, e.g. subgroups, alternative analyses
- **Incomplete publication**
 - Omission of crucial aspects of research methods, e.g. interventions
 - Incomplete results: data cannot be included in meta-analysis
- **Misleading interpretation (spin)**
 - e.g. post hoc change of focus,
- **Inconsistencies between sources**
 - e.g. publication conflicts with protocol



In simple terms...

- **Non-reporting**
- **Selective reporting**
- **Poor reporting**
- **All are very common**



Consequences of inadequate reporting

- **Assessing the reliability of published articles is seriously impeded by inadequate reporting**
 - Clinicians cannot judge whether to use a treatment
 - Data cannot be included in a systematic review
- **Serious consequences for clinical practice, research, policy making, and ultimately for patients**



Incomplete reporting of research is very common

- **Hundreds of published reviews show that key elements of trial methods and findings are commonly missing from journal reports**
- **We often cannot tell exactly how the research was done**
- **These problems are generic**
 - not specific to randomised trials
 - not specific to studies of medicines
 - not specific to commercially sponsored research



Incomplete reporting of research is very common



■ INSTRUCTIONAL REVIEW: GENERAL ORTHOPAEDICS
A systematic survey of the quality of research reporting in general orthopaedic journals

“In 37% of papers patient numbers were inadequately reported;

20% of papers introduced new statistical methods in the ‘results’ section not previously reported in the ‘methods’ section, and

23% of papers reported no measurement of error with the main outcome measure.”

[Parsons et al, *J Bone Joint Surg Br* 2011]



Case-control studies

Bias in psychiatric case-control studies: literature survey. [Lee et al, *Br J Psychiatry* 2007]

- **RESULTS**

“The reporting of methods in the 408 identified papers was generally poor, with basic information about recruitment of participants often absent ...”

- **CONCLUSIONS**

“Poor reporting of recruitment strategies threatens the validity of reported results and reduces the generalisability of studies.”



“Spin”

- **Review of breast cancer trials**

“... spin was used frequently to influence, positively, the interpretation of negative trials, by emphasizing the apparent benefit of a secondary end point. We found bias in reporting efficacy and toxicity in 32.9% and 67.1% of trials, respectively, with spin and bias used to suggest efficacy in 59% of the trials that had no significant difference in their primary endpoint.”

[Vera-Badillo et al, *Ann Oncol* 2013]



Poor Reporting of Quality of Life Outcomes in Dermatology Randomized Controlled Clinical Trials

Le Cleach et al, *Dermatology* 2008

Among 67 studies:

- 87% did not adequately describe the questionnaires
- 75% did not address handling of missing data
- 95% did not disclose before-and-after results as means of overall scores and each dimension



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- The quality of reporting of RCTs is generally poor in public health dentistry journals. Overall, the quality of reporting has not substantially improved since the publication of CONSORT guidelines.
 - The reporting of RCTs of vaccines is incomplete, with important methodological details missing from most reports.



Poor reporting is a serious problem for systematic reviews and clinical guidelines

“Risk of bias assessment was hampered by poor reporting of trial methods.”

[Meuffels et al. Computer assisted surgery for knee ligament reconstruction, *CDSR* 2011]

“Poor reporting of interventions impeded replication”

[Gordon and Findlay. Educational interventions to improve handover in health care: a systematic review. *Med Educ* 2011]

“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.”

[Nolte et al. Amphetamines for schizophrenia. *CDSR* 2004]

“Poor reporting of data meant that individual effect size could not be calculated for any of these studies.”

Bleakley et al. Some conservative strategies are effective when added to controlled mobilisation with external support after acute ankle sprain: a systematic review. *Aust J Physiother* 2008.

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Maximising the value of research

- **Research is done to generate new knowledge**
- **A research article is for communicating that new knowledge**
- **Published research articles should be fit for multiple readerships with multiple purposes**
- **There are ethical, moral, scientific and financial reasons for maximising the value of research**



What is needed?

- **Authors should be aware of ethical/moral responsibility to publish their findings**
 - Honestly and transparently
- **Authors, editors and peer reviewers should be aware of the needs of readers**
 - Principle of reproducibility
 - Should be includable in a future systematic review
- **Be aware of, and follow, major reporting guidelines**

