
Transparency and accuracy in reporting health research

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Transparency and value

- **Research only has value if**
 - Study methods have validity
 - Research findings are published in a usable form

Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou

Lancet 2009; 374: 86–89
Published Online

Without accessible and usable reports, research cannot help patients and their clinicians. In a published

research involving patients have been disincentives for those who might otherwise



Research article

- **A published research article is often the only permanent record of a research study**
 - Some readers might be satisfied with scanning an article, or a brief summary
 - Others will study it in detail for possible inclusion in a systematic review or to influence a clinical practice guideline
- **Only an adequately reported research study can be fully appraised and used appropriately**
 - to assess reliability and relevance



Research article

- **Readers need a clear understanding of exactly what was done and what was found**
 - Clinicians, Researchers, Systematic reviewers, Policy makers, ...
- **The goals should be transparency and accuracy**
 - Should allow replication (in principle)
 - Can be included in systematic review and meta-analysis
 - Should not mislead



What do we mean by poor reporting?

- **Key information is missing, incomplete or ambiguous**
 - methods and findings
- **Misrepresentation of the study**
- **Misleading interpretation**

Of particular concern

- **Non-publication of whole studies**
- **Selective reporting of methods or findings**



Taxonomy of poor reporting

- **Non-reporting**
Failure to publish a report of a completed study
(even if was presented at a conference)
- **Selective reporting**
Biased reporting of data within a published report
- **Incomplete reporting**
Key information is missing
- **Misleading presentation**
e.g. claiming study is an RCT when it isn't;
post hoc change of focus (spin)
- **Inconsistencies between sources**
e.g. publication conflicts with protocol

All are very common



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]



Adherence of Randomized Trials Within Children's Surgical Specialties Published During 2000 to 2009 to Standard Reporting Guidelines

Martin L Blakely, MD, MS, FACS, Lillian S Kao, MD, MS, FACS, Kuojen Tsao, MD, FACS, Eunice Y Huang, MD, MS, FACS, Anthony Tsai, MD, Stacy Tanaka, MD, FACS, Shiraz Younas, MD, Zengqi Lu, MS, Kevin P Lally, MD, MS, FACS, and the Pediatric Surgery Research Collaborative

5/228 trials (2%) met all 7 CONSORT criteria reviewed.

52% specified a primary outcome

43% reported attrition (loss to follow up)

36% reported information about blinding

28% described randomization scheme

27% described allocation concealment

22% described an adequate power calculation



Ecological studies

The quality of modern cross-sectional ecologic studies: a bibliometric review [Dufault & Klar, *Am J Epidemiol* 2011]

N=125

- “Most investigators who adjusted their outcomes for age or sex did so improperly (64%)
- Statistical validity was a potential issue for 20% of regression models
- Many authors omitted important information when discussing the ecologic nature of their study (31%), the choice of study design (58%), and the susceptibility of their research to the ecological fallacy (49%).”



“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]



Inconsistency between sources

Comparison of content of RCT reports in surgical journals and trial registry entries (n=51)

	Primary	Secondary
No discrepancy	55%	33%
Complete omission	8%	31%
New introduction	8%	39%
Change in definition	10%	6%
Downgrading from primary to secondary	22%	
Upgrading from secondary to primary	14%	

[Rosenthal & Dwan, *Ann Surg* 2013]



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**



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.

We need research we can rely on

“Assessment of reliability of published articles is a necessary condition for the scientific process”

[Ziman. *Reliable Knowledge*, 1978]

“... clinical research involving human participants can only be justified ethically when such experiments are done to produce generalizable knowledge.”

[Korn & Ehringhaus. *PLoS Clin Trials* 2006]

- **Authors (and journals) have an obligation to ensure that research is reported adequately**



Reporting research is not new concern, but it is a relatively neglected one

“... incompleteness of evidence is not merely a failure to satisfy a few highly critical readers. It not infrequently makes the data that are presented of little or no value.”

[Mainland. *The treatment of clinical and laboratory data*, 1938]



TRANSPARENCY DECLARATION

The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

*The manuscript's guarantor.

[Altman and Moher, *BMJ* 2013]



