Improving the quality and value of research publications: How can we speed up progress?

Doug Altman

The EQUATOR Network

Centre for Statistics in Medicine, Oxford, UK
Research article

- A published research article is a permanent record that will be used by users for many different purposes
- 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
- Published research articles should be fit for multiple purposes
  - New ways of publishing (e.g., with online supplements with methodological information) can help to meet these varying needs
• Research article is ‘end product’ of one process ...
Research article

• Research article is ‘end product’ of one process ...

• ...and ‘raw material’ of other processes
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 failure to publish

- Non-publication of research findings always leads to a reduced evidence-base.

- Main concern is that inadequate publication *distorts* the evidence-base – if choices are driven by results.

- Even if there is no bias the evidence-base is diminished and thus there is extra (and avoidable) imprecision and clinical uncertainty.
Evidence of poor reporting

- There is considerable evidence that many published articles omit vital information
  - Hundreds of reviews of published research articles

- 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 research by pharmaceutical companies
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

- **262 reports of randomized trials from prominent oncology journals** [Duff et al, *JNCI* 2010]

- Only 11% of articles reported all 10 essential details of the intervention
  - e.g. drug name, dose, route, ...
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

Le Cleach et al, *Dermatology* 2008
Poor reporting is a serious problem for systematic reviews and clinical guidelines

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

“Poor reporting of interventions impeded replication”

“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 duration of follow-up was a problem, making it hard to calculate numbers needed to treat to benefit.”

“… one of the largest trials of the effects of cardiac rehabilitation, which found no beneficial effect, is yet to be published in a peer-reviewed journal over a decade after its completion.”
[Casas et al. Commentary on Inglis et al. Telemonitoring for chronic heart failure. CDSR 2010]
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
Reporting guidelines

- A minimum set of items required for a clear and transparent account of what was done and what was found in a research study
  - Reflect in particular issues that might introduce bias into the research
  - Evidence-based & reflect consensus opinion

- Benefits of using reporting guidelines
  - Improved accuracy and transparency of publications
  - Easier appraisal of reports for research quality and relevance
  - Improved efficiency of literature searching
CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz¹, Douglas G Altman², David Moher³, the CONSORT Group

CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials

David Moher,¹ Sally Hopewell,² Kenneth F Schulz,³ Victor Montori,⁴ Peter C Gøtzsche,⁵ P J Devereaux,⁶ Diana Elbourne,⁷ Matthias Egger,⁸ Douglas G Altman²
Other reporting guidelines

- Other study types – CONSORT as a model
  - PRISMA (Systematic reviews of RCTs)
  - STARD (diagnostic accuracy studies)
  - STROBE (observational studies)
  - REMARK (tumour marker prognostic studies)
  - ARRIVE (animal research)
  - GRIPS (genetic risk prediction studies)
  - ...

  See EQUATOR website

- Most guidelines are not yet widely supported by medical journals or adhered to by researchers
  - Their potential impact is blunted
Responsible research publication: international standards for authors

A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010

Elizabeth Wager & Sabine Kleinert
State of play

- Not all research is published
- Research reports are seriously inadequate
- Improvement over time is very slow
- Reporting guidelines exist for most research types
- Also several statements on responsible research conduct and reporting
- It’s much easier to continue to document the problems than to change behaviour
How can we speed up progress?

- No easy answers to behaviour change
- All parties should play a role:
  - authors
  - peer reviewers
  - editors
  - research funders
  - medical educators
  - ethics committees
  - ...

- It’s time to end the persistent widespread failure of major bodies to recognise the waste and harm associated with bad reporting of research
What should authors do?

- Be aware of ethical/moral responsibility to publish their findings
  - Honestly and transparently

- 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
What should editors do?

- Be aware of the needs of readers
- Be aware of, and make authors follow, major reporting guidelines
- Train peer reviewers
- Support registration of studies and publication of protocols
  - Ask to see protocol
What should others do?

- **Research funders should have explicit policies**
  - Failure to comply would compromise further funding

- **Ethics committees should monitor publications**
  - Clarify what they expect from researchers

- **Responsible reporting of research should be taught as an essential component of research training**

- **More research is needed into how to improve the value of research articles (knowledge translation)**
"Additional reviews based on reporting guidelines improve manuscript quality, although the observed effect was smaller than hypothesised and not definitively demonstrated."
Results of a longitudinal study of rigorous manuscript submission guidelines designed to improve the quality of clinical research reporting in a peer-reviewed surgical journal

Kathryn E. Wynne, B. Joyce Simpson, Loren Berman, Shawn J. Rangel, Jay L. Grosfeld, R. Lawrence Moss

The *Journal of Pediatric Surgery* instituted specific reporting guidelines for authors in June 2006. 73 articles before implementation and 147 articles after implementation were independently assessed by 2 reviewers (observational studies). Mean global composite scores increased from 72.2 to 80.1 post-Guidelines (P<0.0001).
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
An Unbiased Scientific Record Should Be Everyone’s Agenda

The PLoS Medicine Editors

Editorials

Reporting research results: a moral obligation for all researchers

David Moher PhD

Epidemiology:
May 2000 - Volume 11 - Issue 3 - pp 361-363
Epidemiology and Society

Failure to Publish Results of Epidemiologic Studies Is Unethical

Savitz, David A.
ACT now: Accuracy, Completeness, and Transparency in health research
ACT now