Enhancing the quality and transparency of health research through the use of reporting guidelines

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Research and publication

Medical research should advance scientific knowledge and – directly or indirectly – lead to improvements in treatment or prevention of disease

If research is not published it might as well not have been done

- [Implications for *access* to research]

A research report is the only tangible evidence that the study was done

The purpose of a research article

Articles are written for multiple readerships

- Clinicians
- Researchers
- Policy makers
- Patients
- Media

Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information and reach his or her own conclusions about results

- Assess reliability and relevance

The purpose of a research article

Clinicians might read it to learn how to treat their patients better

- "Editors, reviewers and authors are often tempted to pander to this group, by sexing up the results with unjustified clinical messages – sometimes augmented by an even more unbalanced press release."

  [Buckley *Emerg Med Australas* 2005]

Researchers might read it to help plan a similar study or as part of a systematic review

- Need a clear understanding of exactly what was done

Importance of transparent reporting of research

Scientific manuscripts should present sufficient data so that the reader can fully evaluate the information and reach his or her own conclusions about results

- Reliability and relevance

Assessment of reliability of published articles is seriously impeded by inadequate reporting

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]

- It is seriously impeded by inadequate reporting

Good reporting is an essential part of good research

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

- i.e. transparently and completely

Biased reporting is scientific misconduct

"In return for the altruism and trust that make clinical research possible, the research enterprise has an obligation to conduct research ethically and to report it honestly."

[International Committee of Medical Journal Editors, 2004]

"Failure to publish an adequate account of a well-designed clinical trial is a form of scientific misconduct which can lead to those caring for patients to make inappropriate treatment decisions." [Chalmers, 1990]

Evidence of poor reporting

There is considerable evidence that many published articles omit vital information

- Many reviews of published research articles

We cannot tell exactly how much research was done

519 Randomised trials published in December 2000

Failure to report key aspects of trial conduct:

73% Sample size calculation
55% Defined primary outcome(s)
60% Whether blinded
79% Method of random sequence generation
82% Method of allocation concealment

[Chan & Altman *Lancet* 2005]

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

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

"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." *(Cochrane Library, accessed on 18 Sept 07)*

Systematic reviews

"Despite quality guidelines, the average quality of published [systematic reviews] of antidepressants is barely acceptable. A need exists for adherence to standardized reporting and quality guidelines."

[Hemels et al. *Curr Med Res Opin* 2004. Systematic reviews of pharmaco-therapy in major depressive disorder]

"Reliability and relevance of current systematic reviews of diagnostic tests is compromised by poor reporting and review methods."

[Mallett et al. *BMJ* 2006. Systematic reviews of diagnostic tests in cancer: review of methods and reporting]

Case-control studies

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

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

[Lee et al. *Br J Psychiatry* 2007]

Selective reporting

In addition, there is accumulating evidence of two major threats to the medical literature

Study publication bias – studies with less interesting findings are less likely to be published

Outcome reporting bias – results included within published reports are selected to favour those with statistically significant results

Impact of poor reporting

Cumulative published evidence is misleading

Adverse effects on

- Other researchers
- Clinicians
- Patients

"Failures in the system of reporting clinical trials findings can result in harm to patients" [Glass 1994]

Whose fault is poor reporting?

Poor reporting indicates a collective failure of authors, peer reviewers, and editors

... on a massive scale

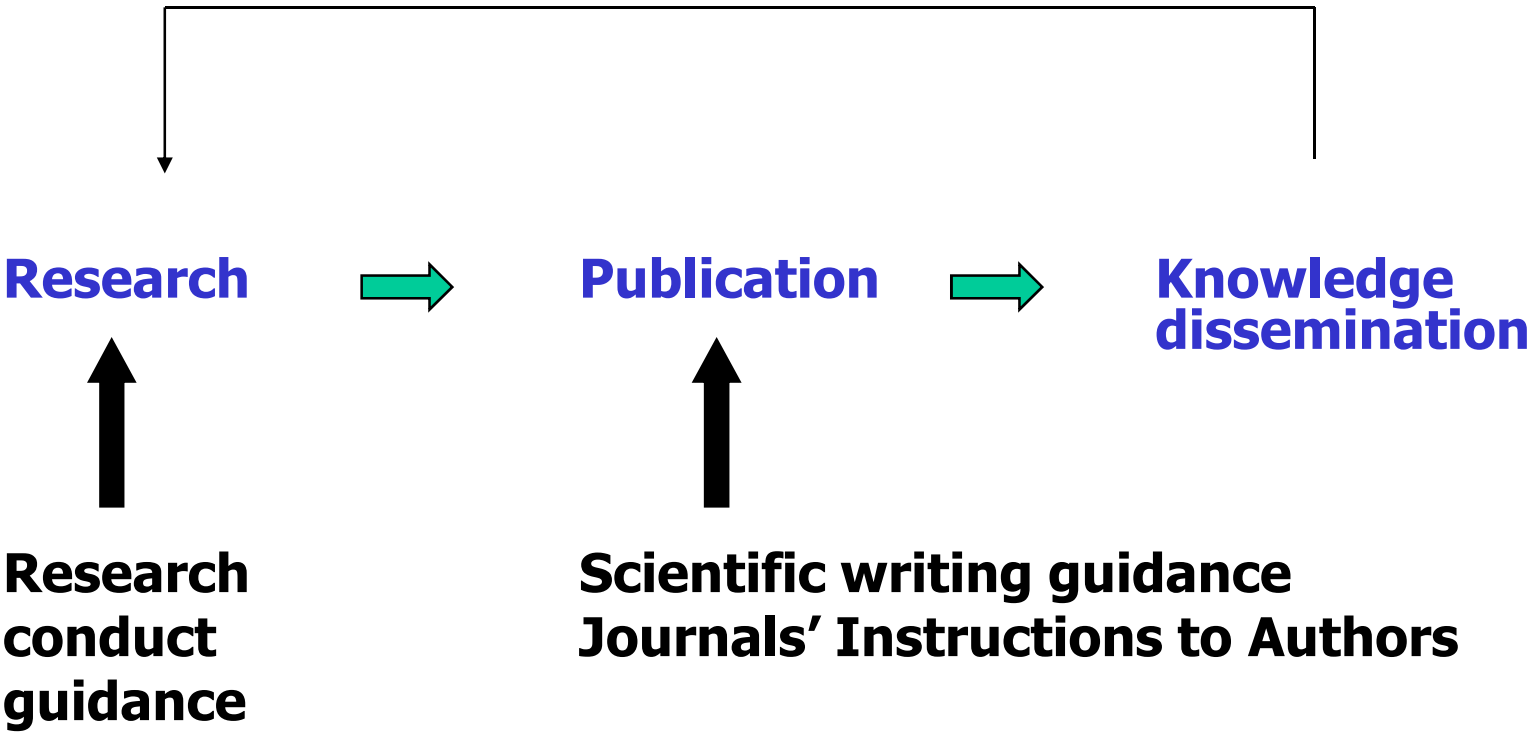
Researchers (authors) may not know what information to include in a report of research

Editors may not know what information should be included

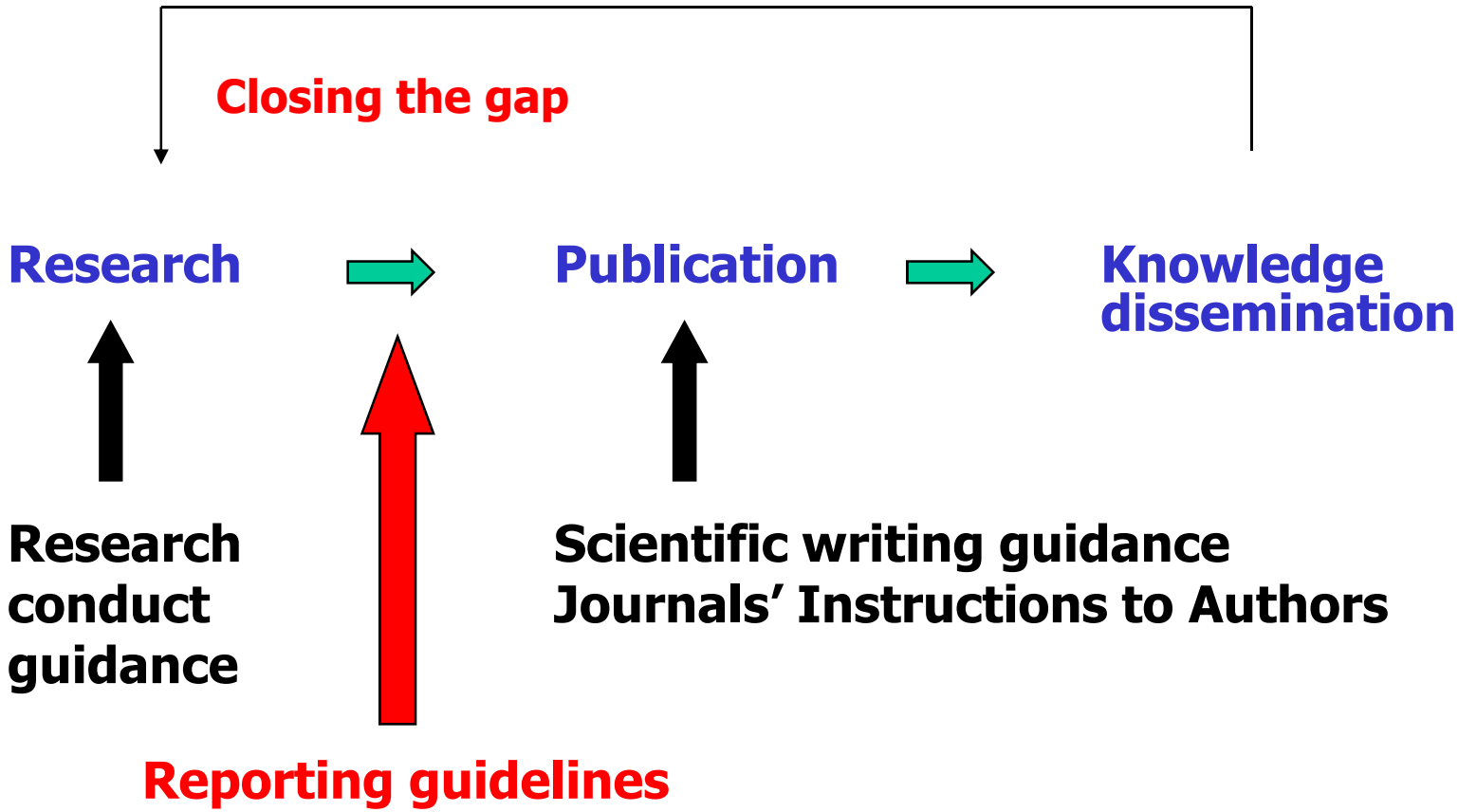
What help can be given to authors?

What can be done to improve research reports?

What can be done to improve research reports?



What can be done to improve research reports?



Transparency and reproducibility

All key aspects of how the study was done

- Allow repetition (in principle) if desired

"Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results."

[International Committee of Medical Journal Editors]

Same principle should extend to all study aspects

- Only 49% of 80 consecutive reports accepted for publication in *Evidence-Based Medicine* (2005-06) gave sufficient details of treatment studied to allow clinicians to reproduce it [Glasziou et al 2007]

An early call for guidance on reporting clinical trials (1950)

"This leads one to consider if it is possible, in planning a trial, in reporting the results, or in assessing the published reports of trials, to apply criteria which must be satisfied if the analysis is to be entirely acceptable….

"A basic principle can be set up that … it is at least as important to describe the techniques employed and the conditions in which the experiment was conducted, as to give the detailed statistical analysis of results."

[Daniels M. Scientific appraisement of new drugs in tuberculosis. *Am Rev Tuberc* 1950;61:751-6.]

The CONSORT Statement for reporting RCTs

[Moher *et al, JAMA/Annals/Lancet* 2001]

Minimum set of essential items necessary to evaluate the study

22 items that should be reported in a paper

- Based on empirical evidence where possible

Also a flow diagram describing patient progress through the trial

Long explanatory paper (E&E)

www.consort-statement.org

Goals of CONSORT

Main objective

To facilitate critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials

Secondary objective

To encourage and provide incentives for researchers to conduct high-quality, unbiased randomized trials

Impact of CONSORT

The 2001 CONSORT Statement has been downloaded >47,000 times from journal websites [January 2007]

All leading general medical journals and hundreds of specialist journals support CONSORT

- Not necessarily enforced

Adoption of CONSORT by journals is associated with improved reporting [Plint et al, *Med J Aust* 2006]

Official extensions

- e.g. Cluster trials, non-inferiority and equivalence trials, harms

Unofficial extensions

- e.g. Acupuncture (STRICTA), Nonrandomised public health interventions (TREND)

Factors in the success of CONSORT

Collaborative, open, ongoing process

Membership of group

- Methodologists
- Trialists
- Editors

Focus on reporting rather than conduct

Evidence-based

High profile publications

Other guidelines

Other study types – CONSORT as a model

- QUOROM (meta-analyses of RCTs)
- STARD (diagnostic studies)
- STROBE (observational studies)
- REMARK (tumour marker prognostic studies)
- …

Such guidelines are still not widely supported by medical journals or adhered to by researchers

- Their potential impact is blunted

Key aspects of reporting guidelines

Guidance not requirements

- Journals may enforce adherence

For authors, editors, and readers

Not methodological quality

"Accurate and transparent reporting is like turning the light on before you clean up a room: It doesn't clean it for you but does tell you where the problems are."

[Frank Davidoff, *Ann Intern Med* 2000]

Adherence does not guarantee a high quality study!

EQUATOR: Enhancing the QUAlity and Transparency Of health Research

EQUATOR grew out of the work of CONSORT and other guidelines groups

Guidelines are available but not widely used

Recognised the need to actively promote guidelines

EQUATOR Network

- Editors of general and specialty journals, researchers, guideline developers, medical writers

The goal:
Better reporting, better reviewing, better editing

Survey of developers of reporting guidelines

Survey of 37 guidelines developers (81% response)

Lack of sufficient funding and time constraints were identified as the most pressing issues

- 1/3 of guidelines developed without any dedicated funding

Desirable to harmonise methods used in the development of reporting guidelines

Need to give more attention to active promotion and implementation

www.equator-network.org

equator network

Enhancing the QUAlity and Transparency Of health Research

Home | Resource Centre | Training Courses | Research Projects | Links | About Equator | Contact | News and Events

Welcome to the EQUATOR Network website

Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is a new initiative that seeks to improve the quality of health care by promoting transparent and accurate reporting of health research.

Find out how that goal will be achieved.

If you share this goal, why not join our Network?

On this site:

Resource centre

Find up-to-date information about the reporting of health research.

Training Courses

We are also developing educational materials and training modules for editors, peer reviewers and researchers.

Support for reporting guidelines developers

Find out how to join the EQUATOR Network.

Progress in health research reporting

Find out how we are monitoring progress in the improvement of health research reporting.

reporting guidelines

Go straight to the reporting guidelines

editors

Read editorials on reporting guidelines

supporters

NHS

Funded by: National Knowledge Service and National Institute for Health Research

EQUATOR Core Programme: Objectives

1. **Provide resources enabling the improvement of health research reporting**
   - Website
   - Courses

2. **Monitor progress in the improvement of health research reporting**

Achieving funding for such work is a major headache!

Good reporting is not an optional extra: it is an essential component of doing good research

www.consort-statement.org

www.strobe-statement.org

www.equator-network.org