
The importance of good reporting of medical research

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- **Why reporting matters**
 - **CONSORT and other reporting guidelines**
 - **EQUATOR Network**
 - **Other things**



The impact of a 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
 - ...



Importance of good research reporting

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

[Chalmers and Glasziou, *Lancet* 2009]

“... 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]



What do we mean by poor reporting?

Mainly:

- **Key information is missing, incomplete or ambiguous**
 - Methods
 - Findings
- **Interpretation is misleading**



Reporting vs conduct: study methods

METHODS – each aspect of the methods

	Done well	Done poorly	Not done
Fully reported (=reproducible)			
Ambiguously or incompletely reported			
Not reported			

Types of missing information

- **Non-publication of research findings always leads to a reduced evidence-base**
- **Main concern is non-publication (or misleading publication) driven by study findings that distorts the evidence-base**
 - Non-reporting (or delayed reporting) of entire studies
 - Selective reporting of only some outcomes
 - Inconsistencies between sources, e.g. publication vs protocol
 - Incomplete reporting: data cannot be included in meta-analysis
 - Omission of crucial aspects of research methods
 - Misinterpretation of study (spin), e.g. post hoc change of focus
 - Misleading abstract



Bad reporting of health research

- **Empirical evidence that all these are very common**
 - 100s of reviews of published studies
- **Serious consequences for clinical practice, research, policy making, and ultimately for patients**



Reporting of adverse events in RCTs of HAART: systematic review.

[Chowers et al. *J Antimicrob Chemother* 2009]

- **Only 16/49 trials reported all adverse events (AEs)**
- **67% reported only some AEs**
 - e.g. the most frequent, if $P < 0.05$, or 'selected' AEs
- **“These facts obstruct our ability to choose HAART based on currently published data.”**



Reporting of Studies on New Medicines — in Major Medical Journals: A Case Study in Breast Cancer

AI Vitry¹

“A comparison of the results of pivotal trials on three new medicines for advanced breast cancer published in medical journals with those presented in the US Food and Drug Administration (FDA) reviews showed that analyses reported in journals were of lower quality and were given a favorable interpretation by minimizing toxicity and ignoring methodological shortcomings.”

[Vitry. *Clin Pharmacol Ther* 2010]



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]

“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. Telemonitoring for chronic heart failure. *CDSR* 2010]



What should be reported?

“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]

- **A similar principle should extend to all study aspects**
 - Selection of participants, Interventions, Outcomes etc
- **The goal should be transparency**
 - Should not mislead
 - Should allow replication (in principle)



Reports of RCTs indexed on PubMed

519 Randomised trials published in Dec 2000
Failure to report key aspects of trial conduct:

	Dec 2000 (N=519)	Dec 2006 (N=616)
Defined primary outcome(s)	45%	53%
Sample size calculation	27%	45%
Method of random sequence generation	21%	34%
Method of allocation concealment	18%	25%
Whether blinded	40%	41%

[Chan & Altman, *Lancet* 2005; Hopewell et al, *BMJ* 2010]

Modest improvement between 2000 and 2006



Whose fault is poor reporting?

- **Poor reporting indicates a collective failure of authors, peer reviewers, and editors**
 - ... on a massive scale
 - What about funders, medical educators, ethics committees, ...??
- **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?

Reporting guidelines for RCTs: History of CONSORT

- **Two sets of recommendations published in 1994**
 - SORT Group, Asilomar Group
- **CONSORT meeting in Chicago, 1995**
[CONsolidated Standards Of Reporting Trials]
- **CONSORT Statement published in 1996**
- **CONSORT revision published in 2001**
 - With a long “explanatory” paper



Goals of CONSORT

- **“The objective of CONSORT is to facilitate critical appraisal and interpretation of RCTs by providing guidance to authors about how to improve the reporting of their trials.”**
- **“To encourage and provide incentives for researchers to conduct high-quality, unbiased randomized trials”**



2010 Revision of CONSORT

- **Revised checklist**
- **Short paper (published in 9 journals)**
- **Revised (and expanded) explanatory paper (E&E)**

RESEARCH METHODS & REPORTING

CONSORT 2010 Statement: updated guidelines for reporting
parallel group randomised trials

Kenneth F Schulz,¹ Douglas G Altman,² David Moher,³ for the CONSORT Group



Endorsement vs adherence

- **>600 journals endorse CONSORT**
- **Adherence remains inadequate even for key issues**



Other guidelines

- **CONSORT is a model**
- **The same principles are being applied to other types of research**
 - QUOROM (meta-analyses or RCTs) (→ PRISMA)
 - STARD (diagnostic studies)
 - STROBE (observational studies)
 - REMARK (tumour marker prognostic studies)
 - etc
- **Developed by researchers and editors**
- **Standardized advice across many journals**



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 supported by medical journals or adhered to by researchers**
 - Their potential impact is blunted
 - They need to be actively promoted
- **EQUATOR Network**
 - Editors of general and specialty journals, researchers, guideline developers, medical writers

“Better reporting, better reviewing, better editing”



Welcome to the EQUATOR Network website – the resource centre for good reporting of health research studies



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

The EQUATOR Network is an international initiative that seeks to improve reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.

Highlights

EQUATOR Spanish website

New site launched on 16 July 2010 in collaboration with the Pan American Health Organization (PAHO). Find out [more](#) and visit the [site](#)

Promote good reporting

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We are seeking a Research Information Specialist / Website Assistant to support the development and promotion of our online resources and other activities.

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Reporting guidelines



[Library for Health Research Reporting](#)

Authors



[Information for authors of research reports](#)

Editors



[Resources for journal editors and peer reviewers](#)

Developers



[Resources for developers of reporting guidelines](#)

Closing Comments on Checklists

- **They help AUTHORS ensure that they have addressed important issues in the report of their study**
- **They help PEER REVIEWERS and EDITORS by reminding them what issues should be addressed**
- **“Necessary but not sufficient!”**



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





www.consort-statement.org



www.equator-network.org