

Responsible reporting of health research studies: transparent, complete, accurate and timely

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Complete, accurate and transparent reporting is an integral part of responsible research conduct. However, many studies have shown that health research publications frequently lack crucial information. Reporting guidelines like the CONSORT Statement help to improve the quality of research reports. Unfortunately, their uptake by journals and authors is still limited and does not maximize their potential. The EQUATOR Network, a new international initiative, leads the effort to promote transparent reporting of research and the use of reporting guidelines. It provides online resources and training relating to the reporting of health research, and assists in the development, dissemination and implementation of reporting guidelines (www.equator-network.org). Poor reporting practices can be decreased only through close collaboration of all parties involved in research and its publication; EQUATOR can facilitate the process.

Keywords: EQUATOR Network, reporting guidelines, research reporting

Introduction

'Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports.'

(Declaration of Helsinki; Basic principles for all medical research)

Research publications are the most fundamental vehicle for disseminating new scientific knowledge. To fulfil that role efficiently, they need to include a complete, accurate and balanced account of what was done and what was found during a research study. Authors should present sufficient information to allow the reader to critically evaluate the reliability and relevance of the new research information. All research studies, both with positive as well as negative findings, need to be published without unnecessary delay and without any data-driven 'improvements' of the original research protocols.

A growing number of evaluative studies, however, have highlighted serious shortcomings in reporting across the health research literature, including: withholding or delaying publication of whole studies with negative findings;¹ preferential selective reporting of positive outcomes or otherwise changing outcomes specified in research protocols;² omission of crucial information in methods and treatment descriptions;^{3,4} omissions from or misinterpretations of results in abstracts;⁵ and inadequate and misleading reporting of adverse effects.⁶ Such deficiencies have

serious consequences for clinical practice, research, policy making and, ultimately, for patients.

The *Journal of Antimicrobial Chemotherapy* recently published a systematic review investigating the quality of reporting of adverse events in randomized trials assessing highly-active anti-retroviral therapy (HAART) for treatment-naive HIV-infected patients.⁶ Life-long HAART requires near-perfect drug adherence, which is possible only with drugs that minimally disrupt patients' lives. Monitoring and carefully documenting adverse events in clinical trials is crucial for further successful use of tested drugs. The review authors found great variability and lack of standardization in the reporting of adverse events: reporting was mostly selective and selection criteria were highly variable based on severity grade or an occurrence threshold. The observed variability in reporting made the comparison of adverse events between trials impossible and seriously obstructed the ability to choose appropriate treatment.

Reporting guidelines

These problems could have been prevented if the authors of assessed clinical trials had adhered to the CONSORT Statement⁷ and its extension for reporting harms.⁸ The CONSORT Statement is one of many reporting guidelines developed to facilitate reporting of health research studies, in this case the reporting of randomized trials. Reporting guidelines specify a minimum set of information items required for a clear and transparent description of research methods and findings, focusing mostly on issues that might introduce bias into the research. The most widely recognized

guidelines are based on the available evidence and reflect consensus opinion of experts in a particular field, including research methodologists and journal editors. Reporting guidelines complement advice on scientific writing, which concentrates on the basic writing principles and styles of research publications, and journals' instructions to authors. Over the last 15 years, many reporting guidelines have been developed. They vary greatly in their scope: some provide generic recommendations for reporting a particular study design (e.g. STROBE for observational studies in epidemiology⁹ or PRISMA for systematic reviews¹⁰); some give more narrow guidance relating to specific medical conditions (for example reporting trials in acute myeloid leukaemia).¹¹ More than 90 reporting guidelines are currently included in the EQUATOR Network's online resources.¹² Journal support for reporting guidelines is associated with improved quality of reporting.¹³⁻¹⁵ Many journals now refer authors and peer reviewers to some of those guidelines, but in order to reach their full potential, reporting guidelines need to be used much more widely by authors, editors and peer reviewers.

The EQUATOR Network

The EQUATOR Network was launched in June 2008 to enhance the reliability of the health research literature by promoting transparent and accurate reporting of research studies. EQUATOR (Enhancing the QUALity and Transparency Of health Research) is an international initiative that brings together all parties involved in research publishing: researchers, journals, publishers, scientists developing reporting guidelines, educators and research funders. The programme is very practically oriented. The freely available online 'Library for Health Research Reporting' brings together resources for researchers writing up their studies (for example guidance on reporting, scientific writing, ethical research and publication conduct); for editors who wish to develop and implement policies to aid accurate and transparent research reporting in their journals; and for scientists wishing to develop, disseminate and update high-quality reporting guidelines.

The EQUATOR Network team is developing educational activities to disseminate knowledge of the principles of good research reporting and encourage the use of reporting guidelines. These initiatives address the specific needs of the main user groups (e.g. research students, young professionals, editors and peer reviewers). The EQUATOR website (www.equator-network.org) provides details of ongoing activities, and gives users an opportunity to provide comments and suggestions to steer the programme towards the most needed and useful activities.

Poor research reporting wastes valuable resources

In a recent article, Iain Chalmers and Paul Glasziou¹⁶ discuss the outrageous, yet avoidable, waste in the production and reporting of health research evidence: most deficiencies can be identified at the stage of choosing the research question, when designing a research study and choosing research methods, and at the stage of research publication. Questionable publication and reporting practices greatly contribute to the waste of resources invested in health research and seriously undermine the reliability and usability of research findings. Chalmers and Glasziou provide simple

recommendations that can lead to improvements. At the stage of producing unbiased and usable research reports these recommendations include increased author and journal awareness of available reporting guidelines, supported by training in their efficient use.¹⁶

Complete, accurate and transparent reporting should be regarded as an integral part of responsible research conduct. Researchers who fail to document their research study according to accepted standards should be held responsible for wasting money invested in their research project. In addition, researchers have a moral and ethical responsibility to research participants, funders and society at large. Peer reviewers and editors should also realize their responsibility in ensuring the high standards of research reporting. Readers of scientific journals consider peer and editorial review as a guarantee of high quality. It is important that reviewers and editors understand the principles of good research reporting and use the available robust tools to ensure that publications that have passed through their hands adhere to these standards. Open access to research publications, now required by many funders, supports wider dissemination and use of new research information. High-quality research reporting is even more important in easily accessible papers, as these might have more influence on future practice.

Conclusions

Reporting guidelines are important tools for achieving high standards in reporting health research. Adherence to reporting guidelines by authors decreases honest reporting errors, helps to uncover bad research practice, and improves the reliability and usefulness of publications. Their use in the editorial and peer review process can also help to prevent omission of key information. Reporting guidelines complement other safeguards, such as clinical trial registration and the public availability of research protocols. Wider awareness and routine use of EQUATOR resources can substantially contribute to the prevention of poor reporting practices. Journals, research funders and educational bodies should alert researchers to existing guidelines, and request complete and transparent reporting of research.

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Transparency declarations

None to declare.

References

- 1 Hopewell S, Loudon K, Clarke MJ *et al*. Publication bias in clinical trials due to statistical significance or direction of trial results. *Cochrane Database Syst Rev* 2009; **issue 1**: MR000006.
- 2 Dwan K, Altman DG, Arnaiz JA *et al*. Systematic review of the empirical evidence of study publication bias and outcome reporting bias. *PLoS One* 2008; **3**: e3081.

- 3** Glasziou P, Meats E, Heneghan C *et al.* What is missing from descriptions of treatment in trials and reviews? *BMJ* 2008; **336**: 1472–4.
- 4** Chan AW, Altman DG. Epidemiology and reporting of randomised trials published in PubMed journals. *Lancet* 2005; **365**: 1159–62.
- 5** Hopewell S, Clarke M, Moher D *et al.* CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 2008; **5**: e20.
- 6** Chowers MY, Gottesman BS, Leibovici L *et al.* Reporting of adverse events in randomized controlled trials of highly active antiretroviral therapy: systematic review. *J Antimicrob Chemother* 2009; **64**: 239–50.
- 7** Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001; **357**: 1191–4.
- 8** Ioannidis JPA, Evans SJW, Gotzsche PC *et al.* better reporting of harms in randomized trials: an extension of the CONSORT Statement. *Ann Intern Med* 2004; **141**: 781–8.
- 9** von Elm E, Altman DG, Egger M *et al.* The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. *PLoS Med* 2007; **4**: e296.
- 10** Moher D, Liberati A, Tetzlaff J *et al.* Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 2009; **6**: e1000097.
- 11** Cheson BD, Bennett JM, Kopecky KJ *et al.* Revised recommendations of the International Working Group for Diagnosis, Standardization of Response Criteria, Treatment Outcomes, and Reporting Standards for Therapeutic Trials in Acute Myeloid Leukemia. *J Clin Oncol* 2003; **21**: 4642–9.
- 12** EQUATOR Network online Library for Health Research Reporting. <http://www.equator-network.org/> (14 October 2009, date last accessed).
- 13** Plint AC, Moher D, Morrison A *et al.* Does the CONSORT checklist improve the quality of reports of randomized controlled trials? A systematic review. *Med J Austr* 2006; **185**: 263–7.
- 14** Smidt N, Rutjes AW, van der Windt DA *et al.* The quality of diagnostic accuracy studies since the STARD statement: has it improved? *Neurology* 2006; **67**: 792–7.
- 15** Prady SL, Richmond SJ, Morton VM *et al.* A systematic evaluation of the impact of STRICTA and CONSORT recommendations on quality of reporting for acupuncture trials. *PLoS One* 2008; **3**: e1577.
- 16** Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. *Lancet* 2009; **374**: 86–9.