Declaration of transparency for each research article

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"It is the responsibility of everyone involved to ensure that the published record is an unbiased, accurate representation of research"[1].

The research record is often manipulated for short term gain but at the risk of harm to patients. The medical research community needs to implement changes to ensure that readers obtain the truth about all research, especially reports of randomised trials, which hold a special place in answering what works best for patients.

Failure to publish the findings of all studies, especially randomised trials, seriously distorts the evidence base for clinical decision making. A recent systematic review of reboxetine for treating depression found that almost three quarters of included patients were in unpublished trials [2]. Of 904 completed trials of interventions for acute ischaemic stroke (1955–2008), a fifth were not properly published, “several of which may be large enough to influence clinical practice and the findings of systematic reviews and meta-analyses” [3].

Bad as non-publication is, incomplete or misleading publications cause greater problems. Results of clinical trials published in peer-reviewed publications may differ from what was previously submitted to regulatory agencies [4–6], with the published data being more positive. The primary outcome often differs from what the researchers had stated in the trial protocol [7, 8] or clinical trial registry [9, 10]. Selective non-publication favours statistically significant findings, biasing the literature [11, 12]. Furthermore, authors often distort the presentation and interpretation of their findings. One study found that such “spin” was common in 72 reports of randomised controlled trials with statistically non-significant primary outcomes [13]. Similar findings have been reported recently for studies of the accuracy of diagnostic tests [14].

Peer review is failing to ensure that journal articles contain the key clinical and methodological details that readers need. Reviews of published reports of randomised trials have found common deficiencies in the details of the interventions being evaluated [15, 16], participant eligibility criteria [17], and outcomes [18, 19]. Details of study methods are also often inadequate, especially in relation to allocation. A 2006 study found that only a third of trial reports described how the randomisation sequence was generated and only a quarter described an adequate method of allocation concealment [20]. A review of 357 phase III oncology trials concluded that “numerous items remained unreported for many trials” [21]. Harms, too, are poorly reported [22, 23].

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The problems associated with publishing and reporting other types of research may be worse than for randomised trials. Although less intensively studied, similar concerns have been expressed in relation to epidemiology [24, 25], pharmacoepidemiology [26], diagnosis research [27], prognosis research [28], and preclinical research [29, 30]. Of course, good reporting is not the same as high-quality research, but a full and clear report allows readers to judge a study’s reliability and relevance. There are concerns that commercially-sponsored research may be more likely to remain unpublished [2–31], but when published, these trials are reported more fully [32].

So what is needed? Published research articles should provide a clear and transparent description of how researchers conducted their study and what they found. Omission of important details of methods or study conduct should be deemed unacceptable, and journals should not publish them. Although detection of some deficiencies requires external information (for example, from a trials register or protocol), most deficiencies are inherent in a submitted manuscript and should be detected. Despite the availability of reporting guidelines such as CONSORT [33], improvements are slow to materialise [34].

By not making results of their research easily accessible, researchers are withholding knowledge, in contravention of the Declaration of Helsinki. Not only are current practices questionable on moral and scientific grounds, failure to publish all research findings is a massive waste of scarce resources and diminishes the social value of the research [35]. Researchers and funding organisations also fail the public when research findings are published in a misleading or inadequate way. Scientifically, this harms systematic reviewers who want to aggregate all of the evidence. Reviewing a partial picture provides biased and less precise estimates of effectiveness and safety than when the full information is used, and it may compromise the identification of what works best for patients.

We have a proposal that can be acted on almost immediately. We suggest that authors should sign a publication transparency declaration (box) as part of every journal submission. The same declaration could be appropriate for submissions in other contexts – for example, to regulatory agencies.

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.

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Editors and editorial groups can support this initiative by updating their instructions to authors so that a completed publication transparency pledge is required as part of the submission process. We see this action as a necessary scientific analogue of the currently widespread practice of asking authors about conflicts of interest. Subsequent revelation of withheld or incorrect information would be evidence of scientific misconduct, for which various actions could be taken. We hope that this step will encourage authors to reflect more carefully on how they write their article and encourage them to check that they have adhered to relevant reporting guidelines. The BMJ, for which one of us (DGA) is the senior statistics editor, and BMJ Open are leading the way by implementing this policy immediately. We invite other journals to do likewise and support the transparency declaration on the EQUATOR website (www.equator-network.org).

The scientific community and the public at large deserve an accurate and complete record of research; we need to make changes to ensure that we will get one. Widespread endorsement and implementation of a publication transparency declaration is one way to help get the maximum value from medical research. It will, however, have no influence on the non-publication of studies, which is a continuing disgrace.

References


