

CHAPTER 1

Importance of Transparent Reporting of Health Research

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“Reporting research is as important a part of a study as its design or analysis.” [1]

“Poorly conducted trials are a waste of time, effort, and money. The most dangerous risk associated with poor-quality reporting is an overestimate of the advantages of a given treatment ... Whatever the outcome of a study, it is really hard for the average reader to interpret and verify the reliability of a poorly reported RCT. In turn, this problem could result in changes in clinical practice that are based on false evidence and that may harm patients. The only way to avoid this risk and to be sure that the final message of a RCT can be correctly interpreted is to fulfill the items listed in the CONSORT statement.” [2]

Introduction

Research related to the health of humans should have the potential to advance scientific understanding or improve the treatment or prevention of disease. The expectation is that an account of the research will be published, communicating the results of the research to other interested parties. Publication is generally in the form of articles in scientific journals, which should describe what was done and what was found. Reports of clinical research are important to many groups, especially other researchers, clinicians, systematic reviewers, and patients.

What do readers need to know? While there are multiple aspects to that question, and the specifics vary according to the nature of both the research and the reader, certain broad principles should be unarguable. Obviously, research reports should be truthful and should not intentionally mislead.

Guidelines for Reporting Health Research: A User's Manual, First Edition. Edited by David Moher, Douglas G. Altman, Kenneth F. Schulz, Iveta Simera and Elizabeth Wager.
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As noted by the International Committee of Medical Journal Editors, "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" [3]. In addition, research reports must be useful to readers – articles should include all the information about methods and results that is essential to judge the validity and relevance of a study and, if desired, use its findings [4]. Journal articles that fail to provide a clear account of methods are not fit for their intended purpose [4].

A vast literature over several decades has documented persistent failings of the health research literature to adhere to those principles. Systematic reviews are a prime source of evidence of these failings (Box 1.1). In addition, hundreds of reviews of published articles, especially those relating to randomized controlled trials (RCTs), have consistently shown that key information is missing from trial reports [5, 6]. Similar evidence is accumulating for other types of research [7–11]. Without a clear understanding of how a study was done, readers are unable to judge whether the findings are reliable. Inadequate reporting means that readers have to either reject an article or take on trust that the study was done well in order to accept the findings.

Box 1.1: Examples of poor reporting highlighted in systematic reviews

"Risk of bias assessment was hampered by poor reporting of trial methods [64]."

"Poor reporting of interventions impeded replication [65]."

"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 [66]."

"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 [67]."

"Four studies compared two different methods of applying simultaneous compression and cryotherapy, but few conclusions could be reached. Poor reporting of data meant that individual effect size could not be calculated for any of these studies. Furthermore, two studies did not provide adequate information on the mode of cryotherapy, and all failed to specify the duration and frequency of the ice application [68]."

"With more complete reporting, the whole process of evaluating the quality of research should be easier. In my work as a systematic reviewer, it is such a joy to come across a clearly reported trial when abstracting data [69]."

This situation is unacceptable. It is also surprising, given the strong emphasis on the importance of peer review of research articles. Peer review is used by journals as a filter to help them decide, often after revision, which articles are good enough and important enough to be published. Peer review is widely believed to be essential and, in principle, it is valuable. However, as currently practised peer review clearly fails to

prevent inadequate reporting of research, and it fails on a major scale. This is clear from the fact that the thousands of studies included in the literature reviews already mentioned had all passed peer review. And articles published in the most prestigious (and highest impact) journals are not immune from errors as many of those literature reviews focussed entirely on those journals [12–14]. Peer review (and other quality checks such as technical editing) clearly could be much more effective in preventing poor quality reporting of research [15].

The abundant evidence from reviews of publications shows that ensuring that reports are useful to others does not currently feature highly in the actions, and likely the thinking, of many of those who write research articles. Authors should know by now that it is not reasonable to expect readers to take on trust that their study was beyond reproach. In any case, the issue is not just to detect poor methods but, more fundamentally, simply to learn exactly what was done. It is staggering that reviews of published journal articles persistently show that a substantial proportion of them lack key information. How can it be that none of the authors, peer reviewers, or editors noticed that these articles were substandard and, indeed, often unfit for purpose?

In this chapter, we explore the notion of transparent reporting and consider how to achieve it.

What do we mean by inadequate reporting of research?

Reporting problems affect journal articles in two main ways. First, the study methods are frequently not described in adequate detail. Second, the study findings are presented ambiguously, incompletely, or selectively. The cumulative effect of these problems is to render many reports of research unusable or even harmful; at the very least, such papers certainly represent a waste of resources [16].

Systematic assessments of published articles highlight frequent, serious shortcomings. These include but are not limited to

- omissions of crucial aspects of study methods, such as inclusion and exclusion criteria, precise details of interventions [17], measurement of outcomes [18, 19], statistical methods [20, 21],
- statistical errors [22, 23],
- selective reporting of results for only some of the assessed outcomes [24–26],
- selective reporting of statistical analyses (e.g. subgroup analyses) [27],
- inadequate reporting of harms [28],
- confusing or misleading presentation of data and graphs [29],

- incomplete numerical presentation of data precluding inclusion in a later meta-analysis [30]
- selective presentation of results in abstracts or inconsistency with the main text [31, 32]
- selective or inappropriate citation of other studies [33, 34]
- misinterpretation of study findings in the main article and abstract (“spin”) [35, 36].

A further concern is the clear evidence of frequent inconsistencies between details reported in a publication and those given in the study protocol or on a register [25, 37, 38]. Clear evidence of such discrepancies exists only for randomized trials, but the same concern applies to all research [39]. When researchers change details in the version written for a journal, we should suspect manipulation to enhance “publishability” [40].

All these deficiencies of the published research evidence are compounded by the fact that for many studies no results are ever published [41], a phenomenon often called publication bias although it results from selective *non*-publication, our preferred term. Failure to publish the results of completed research is surprisingly common [24, 42]. Furthermore, there is clear evidence that when results are published, studies with statistically significant results are published much more rapidly than those without [41].

Consequences of nonpublication and inadequate reporting

Nonpublication of the findings of some research studies, either through suppression of complete studies or selective reporting within publications, always diminishes the evidence base. Whether this diminution is due to carelessness, ignorance, or deliberately incomplete or ambiguous reporting, it creates avoidable imprecision and may mislead. The main concern is that the choices about whether and what to publish are driven by the results, specifically favoring the publication of statistically significant or otherwise favoured findings at the expense of so-called “negative” results [43]. Therefore, in the worst case, bad publication practices lead to both a biased and overly imprecise answer. This behavior has a harmful impact on patient care [44, 45].

Inadequate reporting of methodology can also seriously impede assessment of the reliability of published articles. For example, systematic reviewers and other readers should avoid making assumptions about the conduct of trials based on simple phrases about the trial methodology, such as “intention to treat” or “double blind,” rather than a full description of the methods actually used [46] as there is evidence that such phrases may be misleading. Indeed, even experts are confused by so-called “standard

terminology,” and authors can facilitate the understanding of research reports by avoiding the use of jargon and being more explicit [47]. Knowing how a study was conducted really matters – there is clear evidence that poor conduct of research is associated with biased findings [48, 49]. Thus, poor reporting may have serious consequences for clinical practice, future research, policy making, and ultimately for patients, if readers cannot judge whether to use a treatment or data cannot be included in a systematic review.

Poor reporting practices seriously distort the available body of research evidence and compromise its usefulness and reliability [16]. Such practices are unacceptable whether deliberate or resulting from lack of knowledge of what to report. Failure to publish may be seen as a form of scientific misconduct [50, 51]. It is also a moral hazard. A similar view may apply to inadequate reporting that renders a study’s findings unusable; the term “poor reporting” is thus rather kind. Overall, therefore, not only is there considerable waste of research that has been funded and performed [16], with both financial and scientific consequences, bad reporting of research breaches moral and ethical standards [52–54].

Principles of reporting research

From the preceding discussion on common deficiencies of research publications, several principles of good research reporting become evident. Box 1.2 shows one set of key principles of responsible research reporting. An

Box 1.2: Key principles of responsible research reporting

The research being reported should have been conducted in an ethical and responsible manner and should comply with all relevant legislation.

Researchers should present their results clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation.

Researchers should strive to describe their methods clearly and unambiguously so that their findings can be confirmed by others.

Researchers should follow applicable reporting guidelines. Publications should provide sufficient detail to permit experiments to be repeated by other researchers.*

The decision to publish should not be based on whether the results were “positive” or “negative.”*

Researchers should adhere to publication requirements that submitted work is original, is not plagiarized, and has not been published elsewhere.

Authors should take collective responsibility for submitted and published work.

The authorship of research publications should accurately reflect individuals’ contributions to the work and its reporting.

Funding sources and relevant conflicts of interest should be disclosed.

*Reproduced from the International standards for authors of scholarly publications [70] augmented by two items marked.

important additional point is that the numerical results should be presented in a form suitable for inclusion in meta-analyses.

The over-arching principle behind these specific ideas is that research reports should maximize the value derived from the cost and effort of conducting a trial. Currently, however, there is a massive amount of waste because of nonpublication and inadequate reporting [16, 55].

What can be done to improve the quality of reporting of research?

The widespread deficiencies of published articles indicate a major system failure. In particular, the fixation on positive findings is a serious blight on the health research literature. The importance of good reporting is seemingly not adequately appreciated by key stakeholders of the research community, including researchers, peer reviewers, editors, and funders of research. It is hard to discern whether the cause is a lack of awareness of the importance of good reporting, a lack of awareness of what information should be included in research reports, an overriding concern of authors to achieve publication at the expense of the (whole) truth [40], an overriding preference of peer reviewers or editors for novel or exciting results, or other reasons. Almost certainly it is a combination of many such factors. Few editors and peer reviewers have received relevant formal training. Similarly, few researchers are trained in a broad range of issues related to scientific writing and publishing, such as publication ethics (<http://publicationethics.org/>). Indeed, without training, and perhaps quality assurance in the form of certification, it is hard to imagine how the system can improve.

The medical literature is substandard; how can we fix it? [56] Changing behavior or attitude is always a major challenge, rarely amenable to simple solutions. Some aspects offer more hope, both to facilitate good reporting and, preferably, ensure it. Greater quality and value of health research publications could arise from actions by many different stakeholders. Improvements require, as a minimum, wide recognition of the importance of transparent and complete reporting (Box 1.2) and awareness of appropriate guidance to help ensure good reports of research. Numerous reporting guidelines now exist, relating to both broad research types, such as randomized trials or epidemiological studies, and very specific methodological or clinical contexts. The EQUATOR Network website (www.equator-network.org) listed over 200 such guidelines as of February 2014 (see Chapter 9).

Reporting guidelines provide structured advice on the minimum information to be included in an article reporting a particular type of health

research. They focus on the scientific content of an article and thus complement journals' instructions to authors, which mostly deal with formatting submitted manuscripts [57]. Some are generic for defined study designs (e.g., RCTs) and should always be observed when reporting this type of study. Most published guidelines are more specific, however, providing guidance relevant to a particular medical specialty or a particular aspect of research (e.g., reporting adverse events or economic evaluations). The content of each of these guidelines was carefully considered by multidisciplinary groups of relevant experts, and there is a strong rationale for each requested information item.

Following internationally accepted generic reporting guidelines helps to ensure that published articles contain all the information that readers need to assess a study's relevance, methodology, validity of its findings and its generalizability. Many medical journals encourage adherence to certain reporting guidelines (see Chapter 4). Later chapters give details of the most widely used reporting guidelines.

Journals have a key role in helping to improve the literature by requiring the full and transparent reporting of research [15]. Much progress has been made in recent years regarding guidelines about what to report in a journal article. Journals have the authority to require authors to comply with these. The power of journals has been illustrated well by the considerable success of the policy of making trial registration a requirement for publication [58], even if adherence is not ideal [59]. It is clear, however, that for journals simply to mention reporting guidelines in their "Instructions to Authors" is insufficient to ensure good reporting [57]. More active enforcement can work, as has been seen for abstracts [60], and some journals have moved in that direction [61]. Journals can also enable and encourage the publication of research protocols [62].

Other groups should also work to ensure that research is reported well. Simera *et al.* presented recommended actions for various groups to improve reporting of research – journals, editorial organizations, research funding organizations, academic and other research institutions, reporting guidelines developers, and (not least) authors of research articles [55]. Young researchers should find reporting guidelines useful when planning their research [63]. Universities and other centers of research activity should play a more active role in promoting complete and transparent reporting of research, particularly the research emanating from their centers. This can take many forms, including teaching courses about issues relating to scientific writing and publishing. There is also a need to consider more seriously how technology can be used to help improve the quality of reporting. Web-enabled reporting guidelines are one possibility as are machine-readable language software to help populate checklists automatically.

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