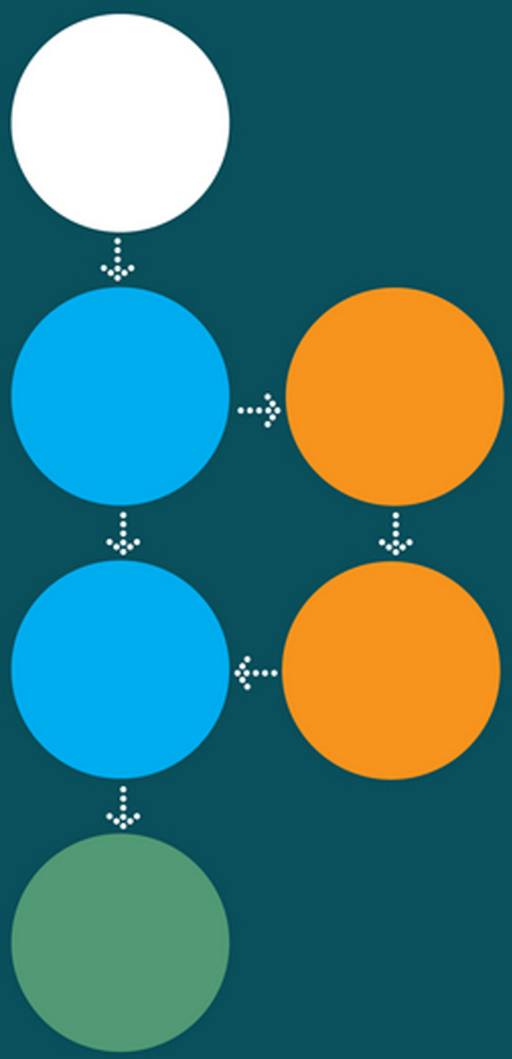
Guidelines for Reporting Health Research

A USER'S MANUAL

Edited by David Moher, Douglas G. Altman,
Kenneth F. Schulz, Iveta Simera and Elizabeth Wager



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Foreword

Guides to guidelines

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Introduction

Good patient care must be based on treatments that have been shown by good research to be effective. An intrinsic part of good research is a published paper that closely reflects the work done and the conclusions drawn. This book is about preventing, even curing, a widespread endemic disease: biased and inadequate reporting. This bias and poor reporting threatens to overwhelm the credibility of research and to ensure that our treatments are based on fiction, not fact.

Over the past two decades, there has been a spate of published guidelines on reporting, ostensibly to help authors improve the quality of their manuscripts. Following the guidelines, manuscripts will include all the information necessary for an informed reader to be fully persuaded by the paper. At the same time, the articles will be well organized, easy to read, well argued, and self-critical. From the design phase of the research, when they may serve as an intervention to remind investigators, editors, and reviewers who find it easy to get the facts, and to note what facts are missing, all the way through to the reader of the published article who finds it easy to access the facts, all of them in context.

To which, given the ignorance, ineptitude, inattention, and bias of so many investigators, reviewers, and journal editors, I would add a decisive "Maybe!"

How did it start? How did we get here?

In 1966, 47 years ago, Dr Stanley Schor, a biostatistician in the Department of Biostatistics at the American Medical Association, in Chicago, and Irving Karten, then a medical student, published in *JAMA* the results of a careful examination of a random sample of published reports taken from the

10 most prominent medical journals. Schor and Karten focused their attention on half of the reports that they considered to be "analytical studies," 149 in number, as opposed to reports of cases. They identified 12 types of statistical errors, and they found that the conclusions were invalid in 73%. "None of the ten journals had more than 40% of its analytical studies considered acceptable; two of the ten had no acceptable reports." Schor and Karten speculated on the implications for medical practice, given that these defects occurred in the most widely read and respected journals, and they ended presciently: "since, with the introduction of computers, much work is being done to make the results of studies appearing in medical journals more accessible to physicians, a considerable amount of misinformation could be disseminated rapidly." Boy, did they get that one right!

Better yet, this extraordinary paper also included the results of an experiment: 514 manuscripts submitted to one journal were reviewed by a statistician. Only 26% were "acceptable" statistically. However, the intervention of a statistical review raised the "acceptable" rate to 74%. Schor and Karten's recommendation was that a statistician be made part of the investigator's team and of the editors' team as well [1]. Their findings were confirmed by many others, for example, Gardner and Bond [2].

I got my first taste of editing in 1977 at the *New England Journal of Medicine*, and first there and then at *JAMA* the *Journal of the American Medical Association*, my daily job has been to try to select the best reports of the most innovative, important, and relevant research submitted to a large-circulation general medical journal. Although the best papers were exciting and solid, they seemed like islands floating in a swamp of paper rubbish. So from the start, the Schor/Karten paper was a beacon. Not only did the authors identify a major problem in the literature, and did so using scientific methods, but they tested a solution and then made recommendations based on good evidence.

This became a major motivation for establishing the Peer Review Congresses. Exasperatedly, in 1986, I wrote:

> One trouble is that despite this system (of peer review), anyone who reads journals widely and critically is forced to realize that there are scarcely any bars to eventual publication [3].

Was the broad literature so bad despite peer review or because of it? What sort of product, clinical research reports, was the public funding and we journals disseminating? Only research could find out, and so from the start the Congresses were limited strictly to reports of research.

At the same time, Iain Chalmers and his group in Oxford were struggling to make sense of the entire literature on interventions in health care, using and refining the science of meta-analysis to apply it to clinical reports.

This meant that, with Chalmers' inspired creation of the Cochrane Collaboration, a great many bright individuals such as Altman, Moher, Dickersin, Chalmers, Schulz, Gøtzsche, and others were bringing intense skepticism and systematic scrutiny to assess the completeness and quality of reporting of clinical research and to identify those essential items, the inadequate reporting of which was associated with bias. The actual extent of biases, say, because of financial conflicts or failure to publish, could be measured, and from that came changes in the practices of journals, research institutions, and individual researchers. Eventually, there even came changes in the law (e.g., requirements to register clinical trials and then to post their results). Much of this research was presented at the Congresses [4–6]. The evidence was overwhelming that poor reporting biased conclusions – usually about recommended therapies [7]. The principles of randomized controlled trials, the bedrock of evidence about therapies, had been established 40 years before and none of it was rocket science. But time and again investigators had been shown to be making numerous simple but crucial mistakes in the reporting of such trials.

What to do about it?

In the early 1990s, two groups came up with recommendations for reporting randomized trials [8, 9]. These were published but produced no discernible effect. In discussions with David Moher, he suggested to me that *JAMA* should publish a clinical trial according to the SORT recommendation, which we did [10], calling for comments – which we got in large numbers. It was obvious that one of the reasons that the SORT recommendations never caught on was that while they were the product of a great deal of effort by distinguished experts, no one had actually tried them out in practice. When this was done, the resultant paper was unreadable, as the guidelines allowed no editorial flexibility and broke up the logic and flow of the article.

David and I realized that editors were crucial in this process. Put bluntly, if editors demanded it at a time when the authors were likely to be in a compliant frame of mind – when acceptance of their manuscript depended on their following orders, then editorial policy would become the standard for the profession.

Owing to the genius, persistence, and diplomacy of David Moher, the two groups got their representatives together, and from this CONSORT was born in 1996 [10–13]. Criticism was drowned in a flood of approval. This was because the evidence for inclusion of items on the checklist was presented, and the community was encouraged to comment. The backing of journal editors forced investigators to accept the standards, and the

cooperation of editors was made easier when they were reassured, on Doug Altman's suggestion, that different journals were allowed flexibility in where they asked authors to include particular items. The guidelines were provisional, they were to be studied, and that there was a process for revision as new evidence accumulated.

The acceptance of CONSORT was soon followed by the creation and publication of reporting guidelines in many other clinical areas. The founding of the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) [14] Network in 2008 was not only a recognition of the success of such guidelines but also the need to get authors to write articles fit for purpose and provide much needed resources for all those involved with medical journals. As such, it represents a huge step in improving the transparency and quality of reporting research.

Are we there yet?

Forty-seven years later, Lang and Altman, referring to the Schor/Karten article that I mentioned at the beginning, write about the changes that seem to have occurred.

> Articles with even major errors continue to pass editorial and peer review and to be published in leading journals. The truth is that the problem of poor statistical reporting is long-standing, widespread, potentially serious, concerns mostly basic statistics, and yet is largely unsuspected by most readers of the biomedical literature [15].

Lang and Altman refer to the statistical design and analysis of studies, but a study where these elements are faulty cannot be trusted. The report IS the research, and my bet is that other parts of a considerable proportion of clinical reports are likely to be just as faulty. That was my complaint in 1986, and it is depressing that it is still our beef after all these efforts. I suspect there is more bad research reported simply because every year there are more research reports, but whether things are improving or getting worse is unclear. What it does mean is that we have work to do. This book is an excellent place to start the prevention and cure of a vastly prevalent malady.

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Preface

Medical research is intended to lead to improvements in the knowledge underpinning the prevention and treatment of illnesses. The value of research publications is, however, nullified if the published reports of that research are inadequate. Recent decades have seen the accumulation of a vast amount of evidence that reports of research are often seriously deficient, across all specialties and all types of research. The good news is that many of these problems are correctable. Reporting guidelines offer one solution to the problem by helping to increase the completeness of reports of medical research. At their core the vast majority of reporting guidelines consist of a checklist which can be thought of as reminder list for authors as to what information should be included when reporting their research. When endorsed and implemented properly by journals, reporting guidelines can become powerful tools.

Since the original CONSORT Statement, published in 1996, the development of reporting guidelines has been quite prolific. By early 2014 there were more than 200 reporting guidelines listed in the EQUATOR Network's library with several more in development. This book brings together many of the most commonly used reporting guidelines along with chapters on the development of the field itself. We encourage authors and peer reviewers to use reporting guidelines, and editors to endorse and implement them. Together this will help reduce waste and increase value. Using reporting guidelines will help to produce research papers that are able to pass future scrutiny and contribute usefully to systematic reviews, clinical practice guidelines, policy decision making and generally advance our scientific knowledge to improve patients' care and life of every one of us.

The reporting guidelines field is evolving quickly, which makes it a challenge to keep an 'old' technology – a hard copy book – up-to-date. In this regard readers should consult the EQUATOR web site (www.equator-network.org) for the most recent reporting guideline developments.

David Moher
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10th March 2014

PART I
General Issues

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.

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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