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REVIEW ARTICLES

Publication guidelines need widespread adoption

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Abstract

Objective: During the past two decades teams of researchers and editors have developed a variety of publishing guidelines to improve the quality of published research reports. Journals and editorial groups have adopted many of these guidelines. Whereas some guidelines are widely used, others have yet to be generally applied, thwarting attainment of consistent reporting among published research reports. The aim of this study is to describe the development and adoption of general publication guidelines for various study designs, provide examples of guidelines adapted for specific topics, and recommend next steps.

Study Design and Setting: We reviewed generic guidelines for reporting research results and surveyed their use in PubMed and Science Citation Index.

Results: Existing guidelines cover a broad spectrum of research designs, but there are still gaps in topics and use. Appropriate next steps include increasing use of available guidelines and their adoption among journals, educating peer reviewers on their use, and incorporating guideline use into the curriculum of medical, nursing, and public health schools.

Conclusion: Wider adoption of existing guidelines should result in research that is increasingly reported in a standardized, consistent manner.

Keywords: Clinical trials; Guidelines; Study design; Publication guidelines; Qualitative research; Surveys

1. Introduction

Well-designed clinical trials and observational studies are essential to provide appropriate information needed by clinicians to adapt or change treatments. The primary mode of communication among scientists is peer-reviewed publication. Hence, it is important that the quality of such publications be maximized. Even if clinicians prefer not to modify a practice with which they are familiar, the pressure to assure evidence-based practice and minimize health care costs will necessitate that even unpopular results, if rigorously documented and confirmed, be incorporated into treatment decisions. This will require that results of clinical research be increasingly scrutinized.

The limitations of any study should be carefully summarized in research publication. Variability in the format and presentation of research studies, however, can make it difficult to discern whether the limitations of the study are inherent in the design or whether the presentation of the results in their final published form are simply not providing sufficient clarity or specificity. For example, there is considerable variation in published descriptions of recruiting participants, training data collectors, calculating sample size, monitoring the integrity of an intervention, and assessing outcome measures. Even for a concept as basic as ‘‘blinding,’’ differences in interpretation have been noted [1]. In one survey of randomized clinical trials, 18 different combinations of groups were blinded, despite the fact that each study reported ‘‘double blinding’’ [2], and in a survey of 73 trials only 19% of ‘‘double blind’’ trials clearly described the blinding of participants [3].

To improve the clarity and consistency of research reports, efforts beginning in the 1990s were initiated by researchers, editors, and methodologists to develop and recommend specific standards for the publication of research [4,5]. The initial guidelines focused on randomized clinical trials, but since 1999 there has been a burgeoning of statements and checklists. The aim of this study is to describe the development and adoption of general publication guidelines for

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What is new?

Multiple guidelines have been developed for publishing a variety of types of studies; this study summarizes and compares such guidelines for major study designs.

Appropriate next steps would be to increase use of available guidelines and incorporating their use into curricula for health care professionals.

various study designs, provide examples of guidelines adapted for specific topics, and recommend next steps.

2. Review methodology

For this review, we defined ''general'' guidelines as those developed to serve as generic guides to the publication of studies using specific study designs. These include guidelines for studies using intervention, observational, and qualitative designs; systematic reviews and meta-analyses; and Internet surveys. To assess the extent to which guidelines are being used and cited, we searched PubMed for the years after the first publication of each guideline through December 2010 for references to the guideline. In PubMed we used the ''All Fields'' option in the Advanced Search mode linked with the title and acronym of each guideline. To determine the number of published articles that had cited specific guidelines we used the bibliographic and citation search features of the Science Citation Index (Thomson Reuters). This approach enabled us to search for articles that had cited a published version of the guideline in support of the authors' methods. The following sections and Table 1 summarize the generic guidelines for the publication of studies using various study designs, provide examples of guidelines which have been adapted for specific topics, and conclude with recommendations for next steps.

3. Generic guidelines by study design

3.1. Guidelines for intervention studies (CONSORT, TREND, SQUIRE)

The first statement designed to improve reporting of research was the Consolidated Standards of Reporting Trials (CONSORT). Motivated by evidence of inadequate and inconsistent reporting of randomized clinical trials work to develop this statement began in 1993 with 30 experts, including editors, authors, publishers, and scholars in the field, who met in Canada. Their first statement was published in 1994 [4,5]. A second group convened in California simultaneously developed and published a similar statement recommending standards for publishing results of clinical trials [5]. These two groups subsequently met in Chicago and produced the CONSORT document, published in 1996 [6]. The most recent update was published in 2010 [7] and includes 25 items in six categories: title and abstract, introduction, methods, results, discussion, and other (funding and registration). CONSORT has served as a template for the development of subsequent guidelines which extend the recommendations beyond randomized clinical trials and is the most frequently adopted statement to date; >500 publications listed in PubMed have cited CONSORT, and >150 journals had endorsed the statement. A Web site is maintained to provide up-to-date information about the guideline (http://www.consort-statement.org/home/).

The Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement was originated by The HIV/AIDS Prevention Research Synthesis (PRS) group at the Centers for Disease Control and Prevention (CDC) to improve the reporting of nonrandomized intervention trials [8]. These guidelines are endorsed by several dozen journals and have been used by investigators, although they have been cited with much less frequency than has CONSORT been [9].

In 1999, guidelines for Quality Improvement Reports (QIR) were initially published [10]. They were designed to be pragmatic, and there was no formal approach (e.g., workshop, Delphi technique, systematic literature review, and expert consensus) used in their development. QIR standards were adopted by several journals and used by a number of investigators as a template [11]. The Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines published in 2008 set standards for robust reporting of quality improvement projects using input from experts and public comment in a formalized vetting process. The checklist includes 19 items and has been endorsed by about a dozen journals [11–13].

Although these three guidelines—CONSORT, TREND, and SQUIRE—vary in the specific study designs for which they are intended, each includes criteria for intervention studies. Table 2 compares these three guidelines with regard to their recommendations for six components of a published report.

3.2. Guidelines for nonintervention, observational studies (MOOSE, STROBE)

The Meta-analysis Of Observational Studies in Epidemiology (MOOSE) guideline was developed out of a workshop funded by the (CDC) in 1997. A steering committee selected 27 expert participants, a systematic literature review was conducted, and 32 meta-analyses were examined. A checklist was developed and modified by experts. The resultant 35-item list including six domains for presenting results of observational studies—background, search strategy, methods, results, discussion, and conclusion—was