

Importance and use of guidelines to report main types of studies in medical research

Importancia y uso de guías para reportar los principales tipos de estudio en investigación médica

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Abstract

Medical care must be supported by research that meets reliable, valid, ethical, and reproducible principles. However, an essential fraction of research carried out in the medical field is inadequately reported due to omitting relevant information when it is published. This reduces their impact and the possibility that other researchers can realize critical appraisal, thereby compromising their application within medical practice. Because of this, guidelines have been developed to reduce this problem; their purpose is to increase research reports' methodological quality, transparency, validity, and reliability. Despite their importance, incorporating these guidelines in various journals and the knowledge and use by a significant part of the medical community is limited. In this context, this article aims to synthesize the main guidelines for reporting research in medicine.

Keywords: Guidelines. Medical writing. Research quality. Journal article. Medical education.

Resumen

La atención médica debe estar sustentada en investigaciones que cumplan principios confiables, válidos, éticos y reproducibles; sin embargo, una parte importante de las investigaciones realizadas en el campo médico son reportadas de manera inadecuada debido a que omiten información de trascendencia cuando son publicadas, lo cual disminuye su impacto y la posibilidad de que otros investigadores puedan evaluarlas de manera crítica y objetiva, comprometiendo con ello su aplicación dentro de la práctica médica. En un esfuerzo por atenuar este problema se han desarrollado guías cuya finalidad es incrementar la calidad metodológica, la transparencia, la validez y la fiabilidad de los reportes de investigación. No obstante su importancia, la incorporación de estas guías en diversas revistas, así como su conocimiento y utilización por una parte importante de la comunidad médica, son limitados. Dado este contexto, el objetivo del presente artículo es sintetizar las principales guías que existen para reportar investigaciones en medicina.

Palabras clave: Guías. Redacción médica. Calidad de la investigación. Artículo de revista. Educación médica.

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Introduction

Quality health care should be based on knowledge obtained through high-quality research, and as such, research should adhere to ethical, reliable, valid, transparent, and reproducible principles¹⁻⁴.

For years, it has been accepted that health care can be compromised due to avoidable methodological flaws in various types of studies, thus leading to “research waste”⁵. Similarly, the lack of academic training in medical research and its dissemination^{6,7}, the lack of research questions framed within the FINER criteria (Feasibility, Interest, Novelty, Ethics, and Relevance)⁸, issues with limited or inadequate statistical analyses, and the presence of biases limit the impact of research in this field of knowledge^{1,9}. Therefore, initiatives like The Lancet REWARD (REduce research Waste and Reward Diligence) declaration have been developed to prioritize appropriate research by promoting robust and accessible study designs, and thorough and useful reporting¹⁰.

In this context, inadequate reporting of medical research, weakness identification in the routine clinical practice and their impact on patient care led to the development of evidence-based medicine¹¹, which uses the scientific method to organize and apply the best evidence currently available. Evidence is often stratified into 6 levels based on the type of study, with meta-analyses of multiple randomized controlled trials having the highest level of evidence (IA), followed by randomized controlled trials with adequate internal (methodological error-free trials) and external (generalizable and applicable to patients) validity (IB), non-randomized clinical trials (IIA), cohort and case-control studies (IIB), cross-sectional studies (III), and expert opinions (IV)¹².

Despite the efforts made to systematize the level of evidence in the medical field and make stronger recommendations through the GRADE system (Grading of Recommendations, Assessment, Development, and Evaluation)¹³⁻¹⁵, many published articles related to different types of studies lack critical methodological information, bias control, systematic information synthesis, or the proper structure. They may also omit or overstate the results. This can result in a significant waste of time, money, and resources for centers and individuals alike involved in research, and hinder the application of new findings in medical practice^{5,16-18}. To address these issues, initiatives like the Equator Network (Enhancing the Quality and Transparency of Health Research) have emerged. This international

initiative lists guidelines that give recommendations to improve the design, transparency, validity, and reliability in generating and disseminating publications on medical research¹⁹. In parallel, the International Committee of Medical Journal Editors (ICMJE) has established a series of recommendations to improve ethical standards and practices in conducting and presenting research. These recommendations include adherence to and compliance with reporting guidelines, which allow for adequate evaluation of research by editors, reviewers, readers, and researchers²⁰.

Despite the decades-long existence of some guidelines to report studies, there is still a significant number of medical journals that do not emphasize the application and utility of adhering to these guidelines to their audience and potential authors²¹. Studies aimed at determining awareness of these guidelines have reported that < 50% of the authors are aware of their existence^{22,23}. Hence, there is this pressing need to promote and strengthen awareness around these guidelines. Given the aforementioned points, the objective of this article is to summarize the main guidelines available for reporting research results in the medical field and their characteristics.

Guidelines for reporting systematic reviews and meta-analyses

Systematic reviews and meta-analyses are important in health care; they can lead to the development of clinical practice guidelines and help make informed decisions on diagnostic criteria, treatments, prognostic criteria, and more. Additionally, they have the highest level of recommendation based on the hierarchy of scientific evidence for their application in the routine medical practice²⁴. Despite their importance, a substantial number of systematic reviews and meta-analyses are conducted without adhering to scientific criteria that would allow identifying strengths and weaknesses in their development. This has led to the proposal of using guidelines for reporting this type of research²⁵.

PRISMA guideline (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)

The origins of the PRISMA guideline can be traced back to 1996 through the QUORUM initiative (Quality of Reports of Meta-analyses), and in 2005, it acquired

its current name. Its aim is to improve the quality of systematic reviews and meta-analysis reporting. Since its inception, this guideline has undergone various changes, being the current version PRISMA 2020, so it is recommended that previous versions no longer be used for reporting such studies²⁴.

The PRISMA 2020 guideline consists of 27 items focused on establishing key aspects of systematic reviews and meta-analyses across different sections (abstract, introduction, methods, results, and discussion). These items include objectives, selection criteria, sources and search strategies, study selection, bias control, certainty of evidence, limitations, funding sources, and potential conflicts of interest, among others. This guideline also emphasizes the need to use a flowchart illustrating the various phases involved in the systematic review or meta-analysis. One of the new additions to this guideline is the use of a checklist for structured abstracts and an extended checklist including recommendations for reporting each item²⁴.

MOOSE Guideline (Meta-analyses Of Observational Studies in Epidemiology)

While randomized controlled trials have the highest level of scientific evidence, implementing and conducting such trials is not feasible for a significant part of the medical community. It has been noted that nearly 70% of systematic reviews are based on observational studies, as these study designs are the most common in the medical field²⁶. Given this scenario, the MOOSE guideline was published in 2000 to improve the quality of reporting meta-analyses of observational studies in epidemiology. However, it has been reported that < 5% of meta-analyses of observational trials conducted from 2017 through 2019 abide by this guideline, which stresses the importance of promoting and increasing its awareness in the medical field²⁶.

The MOOSE guideline consists of 35 items organized into different sections: background (6 items), search strategies (10 items), methods (8 items), results (4 items), discussion (3 items), and conclusions (4 items). Each one of these sections with their respective items must be certified through a checklist^{26,27}.

Guidelines for reporting randomized controlled trials

Randomized controlled trials are an important tool for making clinical decisions and are considered the gold standard for evaluating interventions due to their

ability to minimize or avoid biases. However, for such trials to be truly useful, they need to meet certain requirements associated with trial limitations, potential sources of bias, methodological weaknesses, and external validity^{28,29}.

CONSORT Guideline (Consolidated Standards of Reporting Trials)

The CONSORT guideline is aimed at reporting randomized controlled trials and was created back in 1996. It is constantly updated (the last update was in 2010). It consists of 25 items and a flowchart designed to inform on how to strengthen the reporting of such trials to assess their degree of internal and external validity²⁹.

The 25 items relate to the design, conducting, analysis, and interpretation of the randomized clinical trial across the following sections: title and abstract, introduction, methods, results, discussion, and other relevant information, such as trial registration and approval, and funding. The flowchart illustrates the addition based on participant selection criteria, allocation of intervention groups, participant follow-up, and analysis of the results obtained³⁰.

SPIRIT Guideline (Standard Protocol Items: Recommendations for Interventional Trials)

The protocols of clinical trials will define the approach with which the trials will be implemented, executed, and reported. However, there is heterogeneity regarding the study design, scope, dissemination plans, and damage control, among others. This can have negative consequences for participants, such as adverse events. Additionally, the lack of structure and appropriate guidelines covering the scope of the trials can be an obstacle when it comes to properly conducting the trials³¹.

The SPIRIT guideline, published in 2013, aims to improve the integrity and transparency of clinical trial protocols. It contains 33 items, including administrative information (title, registration, protocol version, funding, roles, and responsibilities), introduction, methods (participants, interventions, and outcomes, allocation of interventions, data mining, data management and analysis), ethical responsibilities, investigator and sponsor plans for result reporting, and appendices. Additionally, it recommends creating a diagram representing a general timeline, establishing recruitment, intervention schedules, and evaluations^{31,32}.

Guidelines for reporting observational trials

Most articles in the medical field correspond to observational research, making it essential to have guidelines to guide the reporting of such articles, and standardize result presentation³³.

STROBE Guideline (Strengthening the Reporting of Observational Studies in Epidemiology)

The STROBE guideline, published in 2007, provides recommendations for reporting observational studies. It is oriented towards reporting cross-sectional, case-control, and cohort studies and facilitating the reporting of the study endpoints, methods, results, and conclusions³³⁻³⁵.

It consists of a 22-item checklist, being 18 items common across study designs, and 4 providing specific information for each study design (items #6 and #12 related to methodology while items #14 and #15 related to results). The items are organized into sections such as title and abstract, introduction, methodology, results, and discussion. The STROBE guidelines aim to present a structured and appropriate report that allows for a comprehensive and critical analysis of the study^{33,34}.

Guidelines for reporting case reports

Case reports provide evidence that can be useful for clinical research, clinical practice guidelines, and medical training. Case reports can be more consistent and complete when written following certain reporting and presentation guidelines, and authors commit themselves to following them.³⁶

CARE 2013 Guideline (CAse REport)

The use of the CARE guideline improves the accuracy, transparency, utility, and quality of case reports³⁶⁻³⁸. This guideline, first published in 2013, contains 13 items covering sections such as title, keywords, abstract, introduction, patient information, clinical findings, chronology, diagnostic evaluation, therapeutic intervention, follow-up and results, discussion, patient perspective, and informed consent³⁶.

A flowchart has also been developed to allow systematic reporting of information related to the patient initial assessment, therapeutic intervention, follow-up, and outcome evaluation³⁷.

Guidelines for reporting qualitative research

Qualitative research is essential when trying to analyze and understand experiences, phenomena, and contexts that affect individuals directly, and can have a significant impact on their health^{39,40}.

Qualitative research examines how individuals build reality within their natural context and provides in-depth insight and understanding of the issues affecting them⁴¹.

SRQR Guideline (Standard for Reporting Qualitative Research)

The SRQR guideline, published in 2014, contains a total of 21 items considered essential for improving the content and transparency of qualitative research reporting. The items cover various sections, including title and abstract, introduction (problem formulation and research purpose or question), methods (qualitative approach and research paradigm, investigator characteristics, context, sampling strategy, ethical considerations, data mining methods and tools, units of analysis, data processing and analysis, and techniques to enhance reliability), results/findings (synthesis and interpretation and links to empirical data), discussion (integration, implications, transferability and contributions to the field, limitations), and other information (conflicts of interest and funding)⁴².

Data mining in qualitative research

In qualitative research, 2 of the most common data mining methods are interviews and focus group discussions. However, due to the variability on how these research types are reported, common elements are required to guide their development to obtain relevant information that can be critically and objectively evaluated⁴³.

The COREQ Guideline (Consolidated Criteria for Reporting Qualitative Research)

The COREQ guideline includes a checklist for in-depth interviews and focus groups to promote complete and transparent reporting, and enhance rigor, comprehensiveness, and credibility of these 2 data mining methods. The checklist includes 32 items, each with a description of the criterion, and is

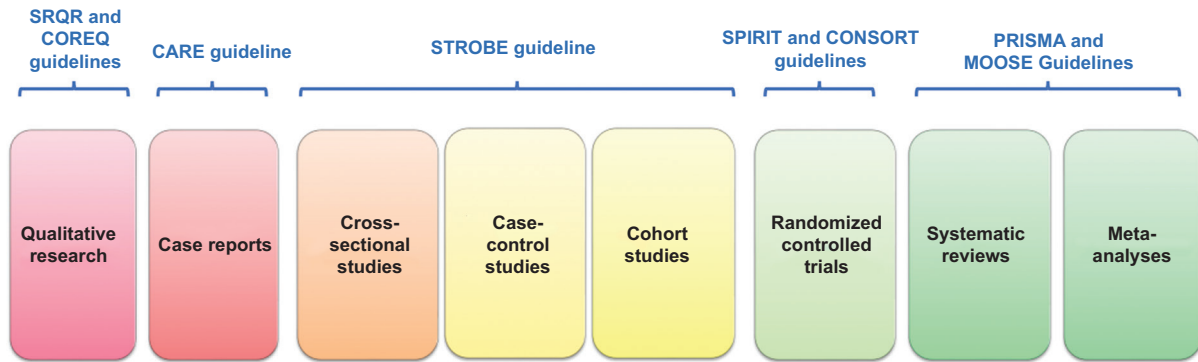


Figure 1. Use of guidelines for reporting the main types of clinical trials in medical research.

arranged into 3 different domains: research team and reflexivity, study design, and analysis and findings⁴⁴.

The research team and reflexivity domain includes the personal characteristics and relationships with participants. The study design domain covers the theoretical framework, participant selection, setting, and data mining, while the analysis and findings domain includes data study, participant roles, and theme analysis⁴⁴.

The use of the COREQ guideline is exclusive to interviews and focus groups, which is why it does not apply to other quality designs (case series, ethnography, or narrative research), whereas the SRQR guideline has a more flexible approach and can be used in any quality study design, including focus groups and interviews⁴⁵.

Fig. 1 shows a summary of the different types of work and guidelines for their proper reporting.

Discussion

It has been suggested that academic and curriculum pressures to publish encourage the development of research with serious flaws due to inappropriate use of scientific methodology and dissemination. This leads to the reporting of deficient or useless studies², false findings¹⁶, reproducibility crises⁴⁶, and lack of reliability in the results being published⁴⁷. Although these issues were recognized decades ago, they are still alive today⁴⁸. Additionally, research conducted in the medical field is often inadequately reported, omitting crucial information when being reported, which diminishes the ability to critically evaluate and replicate the results obtained and add findings to medical practice^{4,49-51}. To address these challenges, various international initiatives have emerged to enhance transparency in research, such as disclosing clinical

trials through ClinicalTrials.Gov⁵², transparency declarations promoted by the British Medical Journal⁵³, and the World Health Organization statement on the public disclosure of clinical trial results⁵⁴. The Cochrane Collaboration also provides guidance for systematic reviews of interventions to minimize biases and promote evidence-based decision-making⁵⁵. Therefore, sticking to the guidelines discussed above is relevant due to the potential biases that can arise from inadequate reporting⁵⁶.

In addition to the utility of sticking to the aforementioned guidelines, there are currently various initiatives and organizations dedicated to improving the reproducibility and transparency of research such as the REWARD declaration (REduce research Waste and Reward Diligence) and the Center for Open Science (COS), and the Declaration of San Francisco on research assessment. Some of them like AllTrials, Equator, and TranspariMed focused on bias reporting, and improving statistical and methodological processes through Open Science Framework and the EV-BRES consortium (EVIDence-Based RESearch)⁵⁷.

On the other hand, we should mention that medical research training, much like clinical medicine, relies significantly on a learning model⁵⁷. Therefore, it has been suggested that universities should emphasize, within their curriculum, the importance of research training rather than solely focusing on the clinical aspect. Failing to do so can result in addressing clinical problems with deficient or absent evidence-based knowledge, thus leading to significant deficiencies in its interpretation⁵⁸. Therefore, addressing this issue and understanding various aspects involved in the research process, such as being savvy on the guidelines described above, should be a central focus of medical training.

Conclusions

The quality of reporting different types of trials in medical research remains inadequate despite the availability of guidelines for proper reporting. Unless research is adequately reported, the time and resources invested in it will be fruitless. Therefore, it is essential that more medical journals use these guidelines in their author instructions so readers and authors alike can become familiar with these guidelines and, therefore, use them when reporting their investigations. Additionally, promoting knowledge of these guidelines from medical school curricula is essential to foster a better understanding of how different types of studies in the medical field should be reported and analyzed from a critical and structured perspective.

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Conflicts of interest

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Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article.

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