

Editorial

Prezado autor: quais os critérios de qualidade para publicação de um protocolo de prática clínica?

Dear author: what are the quality criteria for publishing a clinical practice protocol?

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The importance of the clinical practice protocols, guides and guidelines

In the last decades, clinical practice protocols, guides and guidelines became an essential component of health care. Clinical guidelines are positions or recommendations systematically developed to guide health professionals and patients about appropriate health care, in specific clinical circumstances.¹⁻⁴ Similarly, guides are evidence-based recommendations for the care of patients with specific conditions or diseases.⁵ If developed and implemented in accordance with the international standards, these documents have the potential to reduce unwarranted practice variation and to improve health care quality and safety.⁶

Clinical protocols are recommendations systematically developed with the objective of providing appropriate health care in relation to parts of the process and at a given health care point. Thus, protocols are specific documents, more focused on promotion, prevention, cure/care, rehabilitation or palliative actions, in which processes are defined with greater precision and less variability.⁷

A number of studies conducted around the world show that the procedures performed in healthcare institutions vary widely across health professionals, specialties and geographic regions. In this context, clinical practice protocols and guidelines are a common reference point for prospective and retrospective assessments of the practices performed by health professionals and institutions, providing criteria to implement and evaluate the best care practices. Guidelines that promote interventions of proven benefit improve care consistency and have the potential to reduce morbidity and mortality, improving people's quality of life.⁸

Both clinical guidelines and protocols can be used as a source of recommendations for the development of performance standards both for professionals and for health organizations. They offer, for example, objective instructions on which diagnostic or screening tests to order, the correct indication of consultations and surgical procedures, and the patients' length of stay in a hospital.⁸ Additionally, they assist in training health professionals and in informed decision-making⁹ by the patients. Thus, the main objective of these guidelines or protocols is to offer precise and concise instructions on how to provide health services, in order to obtain the best possible results for the patient, the professional and the institution involved.⁹

The potential benefits of the clinical guidelines, guides and protocols are directly proportional to the methodological quality of these documents. As quality can be extremely variable, it becomes necessary to adopt tools that assess the methodological rigor and transparency with which these documents are developed.¹⁰⁻¹¹ Is it possible that every protocol or clinical practice guideline has the potential to be transformed into a scientific article? To help answer this question, this editorial will discuss the quality criteria required for the proper elaboration and dissemination of clinical guidelines and protocols. In addition to that, essential aspects for restructuring a scientific publication will be presented, based on these documents.

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How to disclose clinical guidelines, guides and protocols following the quality criteria?

As already highlighted, guidelines, guides and protocols are important tools that assist teams in decision-making, especially in specific situations. Thus, it is fundamental that, in the stages of evaluation of the topic's quality, development and dissemination, the authors are aware of the methodological requirements necessary for conducting and elaborating precise and high-quality recommendations.

In the scope definition phase, the first step is to identify the real need for developing or updating the guideline, guide or protocol. Potential justifications would involve: changes in evidence, major changes in the results, new technologies or changes in the resources available for health care.¹² Subsequently, the title of the document to be elaborated must be defined, based on the scope, as well as its objective(s), team to be involved, target population, approaches to be included, and the questions that will be used as a guide for the process of searching and identifying scientific evidence. To prepare a good question, it is recommended that the authors use the PICO (Patient, Intervention, Comparator and Outcomes) acronym or its derivations.¹³ Thinking about the dissemination stage, it is important that the authors also define the indicators that will be used to monitor the implementation and the expected results, as well as the methods to search for scientific evidence that will be used.

In the development phase, the authors should: a) select the evidence based on previously defined search strategies; b) extract the main characteristics and results of the selected evidence; c) critically analyze the findings by evaluating the quality of the evidence for each question contained in the scope of the guideline; d) develop the recommendations based on the interpretation of the evidence and of other decision criteria; and e) structure a document summarizing the duly substantiated recommendations in a clear and objective manner.¹⁴

To assess the quality of the selected evidence, the scientific literature recommends various tools, depending on the type of study selected. Systematic review or meta-analysis studies, for example, can be assessed using the AMSTAR (A Measurement Tool to Assess systematic Reviews) instrument.¹⁵ The use of these instruments will qualify the assessment, reduce subjectivity and increase transparency in the process, minimizing the risks of bias. In addition to assessing the quality of the evidence, it is also recommended to analyze its strength. From this perspective, the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) system¹⁶ has been the most recommended method to assess the quality (high, moderate, low and very low) of the evidence set for each outcome, as well as the direction (favorable or unfavorable) and strength (strong or weak) of the evidence.

In the stage of discussion and elaboration of recommendations, contextual factors must be considered, in addition to assessing the quality of the evidence.¹⁴ These aspects may interfere to a greater or lesser extent in the process of implementing guidelines, guides or protocols, or even in the expected results. To such end, the use of formal consensus methods is recommended in order to assist in the decision-making process. The nominal group technique, the Delphi method and semi-structured interviews are among the most indicated methods in the literature for reaching a consensus of experts' opinion.¹⁷

Once the recommendations are defined, the text of the guidelines should contain the following: an introduction that includes the scope, justification and purpose of the document; methodological detailing for the elaboration of the recommendations; the results obtained and the recommendations; discussion; and references. In order to enhance the guidelines' transparency and validity, it is recommended that the material is subjected to an external review process.¹⁴

Table 1. Some items for decision-making regarding the publication of protocols, guidelines or guides.

Information	Institution or entity that developed the guideline ¹	Communication of regional or national scope ²	Scientific journal
Publication of the protocol, guideline or guide			
Author(s)	Institution and a group of local specialists.	Institution or entity of regional or national relevance and a group of specialists in the area with regional or national representation, with a process following all the quality processes.	Institution or entity of regional or national relevance and a group of specialists in the area with regional or national representation, with a process following all the quality processes.
Publication of secondary studies associated with the application of the protocol, guideline or guide ^{3,4}			
Study for the evaluation of health services			
Verification of the quality of the service	Yes	Yes	Yes
User satisfaction			
Structure, process and results indicators			
Observational studies assessing the following:			
Prevalence or incidence of a given outcome or situation defined	Yes	Yes	Yes
Adherence to the elements that constitute the work process			
Cost-effectiveness or economic studies	Yes	Yes	Yes

¹Broad disclosure of the protocols or guidelines is recommended to all those involved and through different communication means. ²Printed or electronic publication in communication means, according to the application context of the protocol or guideline. ³In studies with evaluation before and after implementation of the protocol, guideline or guide or with another methodological approach for impact analysis such as randomized clinical trials. ⁴It is recommended to read MS (2015)²⁵ ⁴Each of these study types has their own writing quality guides, we recommend that you look for them.²⁵



In the disclosure phase (dissemination and implementation) of the guidelines, guides and protocols, it is recommended that the authors follow some important steps. Recommendations will only be properly implemented in the clinical practice if conditions for their deployment are guaranteed, if information dissemination strategies are adopted for all the actors involved, and if knowledge dissemination mechanisms are established that enable the development of competences (knowledge, skills and attitudes) for the incorporation of evidence-based practice. The production of educational material, qualifications and training, opinion leadership, audits, alerts and customized or multifaceted interventions are among the most recommended strategies for carrying out this phase.¹⁴ To monitor the implementation, several instruments can be used, such as before-and-after knowledge questionnaires, evaluation surveys, analysis of data from medical records or prescriptions, audits and analysis of indicators, among others.

The methodological rigor in developing a guideline, guide or protocol can be assessed using the AGREE II (Appraisal of Guidelines for REsearch & Evaluation) instrument³, designed to address variability in the quality of the guidelines, or RIGHT (Reporting Items for practice Guidelines in HealThcare).¹⁸ AGREE II is a tool consisting of 23 items that are covered in six quality domains, namely: scope and purpose, stakeholder involvement, development rigor, presentation clarity, applicability and editorial independence.³ RIGHT is an instrument that includes 22 items distributed in seven domains: basic information, scope (background), evidence, recommendations, review and quality assurance, funding and conflict of interest declaration, and other information.¹⁸ It is to be noted, however, that, although having similar items, the instruments present differences, and the authors can choose to use only one or both, in a complementary manner.¹⁹

The use of adequate methodologies for the elaboration and disclosure of guidelines, guides and protocols is fundamental for the development of recommendations and for the implementation of appropriate health practices based on reliable and up-to-date scientific evidence. The methodological strategies employed and the results of the process can become an interesting information source for other professionals, managers and users. However, it is necessary to understand when and how a guideline, guide or protocol can turn into a scientific production.

How to turn a protocol, guideline or guide into a scientific production?

'When and what to publish?' is the routine question that researchers ask themselves. Despite the certainty that such paper deserves to be published, many times, at the end of the day, there is still a question about 'how to do it'. Reflecting on the best study format and on the best information to be presented is fundamental to reduce the number of refusals and increase the success rate in the publication of any type of scientific work. Dear author, first of all, we reassure you that this topic does not contain a 'cake recipe', which is often useless or whose application is not feasible. Its objective is to present some successful cases in the publication of articles related to the development of protocols, guidelines or guides that may help you to define the best writing choice for the results you have in your health service.

Countless editorials, books and even articles have been and will still be published on the topic of 'how to publish successfully' and, often, with a 'cake recipe' intended to make simplify the complex work of scientific writing. To write this editorial, this same search was made and simple answers, while not helping the authors, were the following: "Do you have a story to tell? Editors and reviewers are looking for original and innovative research studies that add to their field of study, shed new light on previous findings or bridge the gap between different areas or contexts." Or, "Is there an audience for your story? If your research contributes to knowledge in your area, your colleagues and researchers from other areas will probably be interested in your paper." Finally, "How can you tell your story? Academic articles come in a variety of shapes and sizes, each designed to fit research studies published at different stages, in different fields, and to share different aspects of the work".²⁰⁻²³

The uncertainty of publishing a scientific research study can be even greater when it is associated with a protocol, guide or guideline, which often, in their original design, aimed at solving, preventing or improving some process or activity in the 'world of work', that is, in their initial design stages, those involved did not intend to publish a scientific article. Thus, the question: 'Is it relevant to publish a protocol developed by a hospital, pharmacy, family health unit or other service?' Undoubtedly! However, this answer is complemented with another question: "Where to publish?" In addition to the quality of the aforementioned protocol or guideline, the answer will depend on who drafted it and on its scope.

It is recommended that the protocols or guidelines be widely and periodically disclosed to all those involved and by different communication means in the institution or entity that developed them since, over time, there is a trend for decreased adherence to protocols, guidelines or guides by the professionals.²⁴ However, the results associated with the development, validation or application of a protocol, guideline or guide do not always represent an innovation or have sufficient rigor to be published as an article in a scientific journal. Table 1 shows some points that can assist you in making a decision about spending time in the elaboration of a scientific article or not.

Revista Brasileira de Farmácia Hospitalar e Serviços de Saúde supports studies originating from health services and which can inspire other health professionals and services to improve their work processes and the care provided in health. In this sense, it selects articles associated with the development, validation and application of clinical practice protocols, guidelines and guides that can inspire improvement in the state-of-the-art in health care. See in our issues several articles published in the journal that can support you in disclosing your results. Only in the last two issues, five articles were published.²⁷⁻³¹ Enjoy!

Conflict of interests statement.

The authors declare that there is no conflict of interests in this article.



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