

Assessment of the methodological quality of a medication administration protocol using the AGREE II instrument

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Submitted: 13-09-2025 Resubmitted: 20-02-2026 Accepted: 21-02-2026

Double blind peer review

Abstract

Objective: To evaluate the methodological quality of the protocol entitled 'Recommendations for Inhalation Technique with Pressurized Metered-Dose Inhalers in Invasive Mechanical Ventilation' **Methods:** This is a descriptive study evaluating methodological quality using the international instrument Appraisal of Guidelines for Research and Evaluation II (AGREE II). Six domains of the protocol were assessed: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. These domains are organized into 23 items and rated on a 7-point Likert scale. Eligible members for the evaluation panel included PhD-level professors in the fields of medicine, pharmacy, nursing and physiotherapy with prior experience in intensive care, health technology assessment, epidemiology, or teaching and research. The quality score (QS), intraclass correlation coefficient (ICC) and Pearson's coefficient of variation (PCV) were calculated for each domain, as well as the overall quality score of the protocol. **Results:** Three PhD-level professors from the fields of medicine, pharmacy, and physiotherapy evaluated the protocol. Five domains achieved quality scores above 90%. The "stakeholder involvement" domain scored 68.52%, prompting revisions to the protocol to better align it with quality standards. The overall quality score was 100%. All evaluators recommended the protocol for clinical practice. **Conclusion:** After undergoing an extensive evaluation process, the protocol for the administration of inhaled medication during mechanical ventilation was published, achieving satisfactory scores in terms of its methodological quality. Although the AGREE II instrument is less commonly used to assess protocols and guidelines focused on medication use, it was applied in this study, demonstrating its feasibility for evaluating documents within this scope.

Keywords: health evaluation, practice guideline, clinical protocols, aerosol therapy, critical care.

Avaliação da qualidade metodológica de um protocolo de administração de medicamento por meio do instrumento AGREE II

Resumo

Objetivo: Avaliar a qualidade metodológica do protocolo intitulado "Recomendações para técnica inalatória com spray dosimetrado em ventilação mecânica invasiva". **Métodos:** Trata-se de um estudo descritivo sobre a avaliação da qualidade metodológica utilizando o instrumento internacional *Appraisal of Guidelines for Research and Evaluation II* (AGREE II). Seis domínios foram avaliados no protocolo sendo: escopo e finalidade, envolvimento das partes interessadas, rigor do desenvolvimento, clareza de apresentação, aplicabilidade e independência editorial, organizados em um total de 23 itens e pontuados de acordo com uma escala de 7 pontos, do tipo Likert. Para compor o painel de avaliadores foram considerados elegíveis: professores doutores nas áreas de medicina, farmácia, enfermagem e fisioterapia com experiência prévia em terapia intensiva, avaliação de tecnologias em saúde, epidemiologia ou ensino e pesquisa. A pontuação de qualidade (PQ), o coeficiente de correção intraclasse (CCI) e o coeficiente de variação de Pearson (CVP) foram calculados para cada domínio, além da pontuação de qualidade global do protocolo. **Resultados:** Três professores doutores, das áreas de medicina, farmácia e fisioterapia avaliaram o protocolo. Cinco domínios alcançaram pontuação de qualidade acima de 90%. O domínio "envolvimento das partes interessadas" obteve pontuação de 68,52%, o que levou a modificações no protocolo para alinhá-lo aos padrões de qualidade. A pontuação de qualidade global foi de 100%. Todos os avaliadores recomendaram o uso do protocolo para a prática clínica. **Conclusão:** Após passar por um extenso processo de avaliação, o protocolo de administração de medicamento inalatório durante VM foi publicado, atingindo escores satisfatórios quanto à sua avaliação metodológica. O instrumento AGREE II, embora menos utilizado para avaliação de protocolos e diretrizes com foco na utilização de medicamentos foi aplicado neste estudo, o que demonstra sua viabilidade para avaliação de documentos com este escopo.

Palavras-chave: avaliação em saúde, guia de prática clínica, protocolos clínicos, terapia com aerossóis, cuidados críticos.



Introduction

Bronchodilators, anti-inflammatory agents, and antibiotics are among the medications that may be prescribed for inhalation in patients undergoing mechanical ventilation (MV). Patients on MV who exhibit increased airway resistance may benefit from the inhalation of bronchodilators, as this can significantly reduce pulmonary resistance and improve respiratory mechanics¹.

The administration of bronchodilators via pressurized metered-dose inhalers (pMDIs) is a routine practice in intensive care units. The pMDI is preferred over other methods (such as nebulization) due to its greater ease of use and portability. Aerosol therapy, however, is influenced by a variety of factors that directly affect the deposition of the drug in the lower airways. Proper inhalation technique can significantly enhance pulmonary drug deposition^{2,3}.

In Brazil, there are no protocols, guidelines, or recommendations issued by the Ministry of Health regarding the administration of bronchodilator medications delivered via pMDI to mechanically ventilated patients. Official documents from medical societies also lack detailed information on aerosol therapy in this context, providing only limited recommendations on how to administer the medication, without delving into important technical aspects of the procedure^{4,5}.

In the international context, there are recommendations on the administration of aerosols during MV using different inhalation methods. These publications are generally consensus statements or expert opinions^{6,7} and may present gaps when applied to the Brazilian context, considering the differences in health systems, the structure of intensive care units, and the availability of specific devices for inhalation during MV.

Considering the lack of information on the topic and the potential of using guidelines and protocols for accurate professional guidance, a medication administration protocol was developed focusing exclusively on inhalation technique with pMDIs for adult patients undergoing mechanical ventilation⁸. The protocol is multidisciplinary in nature and provides recommendations on best practices for aerosol therapy, and it can be applied in Brazilian intensive care units.

According to the Institute of Medicine, clinical practice guidelines are statements developed with the aim of assisting professionals and patients in decisions about appropriate healthcare in specific clinical circumstances⁹. These guidelines should be built upon a rigorous methodological approach, with literature review, transparent practices in report development, and recommendations based on the best scientific evidence¹⁰.

The AGREE Collaboration is an international team of developers and researchers responsible for creating a series of tools to assist in the development, reporting, and evaluation of clinical guidelines (<https://www.agreetrust.org/>). One of the instruments created by the group, the AGREE II (*Appraisal of Guidelines for Research & Evaluation II*), is designed for assessing the methodological quality and transparency with which guidelines are developed¹¹. The use of the AGREE instrument is widely employed in the evaluation of various guidelines, whether they are newly developed or already published by official bodies and professional societies^{12,13,14}.

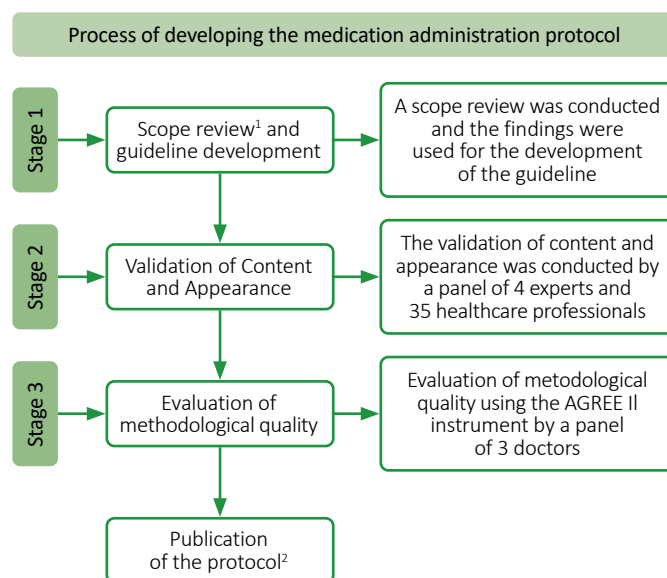
Although the developed protocol does not fully qualify as a clinical practice guideline, a critical appraisal of the document is highly relevant, as a satisfactory level of quality is necessary for its application in clinical practice. Therefore, the present study aimed to describe the process of evaluating the methodological quality of the developed protocol.

Methods

Descriptive study on the evaluation of the methodological quality of the medication administration protocol titled *Recommendations for Metered-Dose Inhaler Technique in Invasive Mechanical Ventilation* (International Standard Book Number 978-65-00-92743-6)⁸.

The guideline was structured in three stages: development, content and appearance validation, and assessment of methodological quality (Figure 1).

Figure 1. Flowchart of the protocol construction process.



¹ Asturian K, Balhego-Rocha M, Pilger D. Bronchodilator administration by pressurized inhaler during invasive mechanical ventilation in adults: A scoping review. Farm Hosp. 2024 May 27:S1130-6343(24)00048-5. DOI: 10.1016/j.farma.2024.03.012.

² Asturian K, Pilger D. Recomendações para técnica inalatória com spray dosimetrado em ventilação mecânica invasiva: Protocolo de Administração de Medicamento. 2024. Available in: <https://lume.ufrgs.br/bitstream/handle/10183/274448/001200484.pdf?sequence=1&isAllowed=y>. Source: Authors

Development and Validation of the Protocol

For the first stage, a literature review was conducted on the main concepts related to the administration of inhaled medications during mechanical ventilation, based on a scoping review¹⁵. The results of this review served as the foundation for the recommendations included in the protocol.

For the development of the document, three professionals were involved: two pharmacists (one professor and one clinical pharmacist) and a visual designer with experience in producing illustrations for health education. In this phase, the AGREE II instrument was used in its entirety for the construction of the protocol, as it provides a methodological framework for guideline development and specifies which information should be reported and how.

In the second stage, content and appearance validation was conducted using specific instruments by a panel of four intensive care specialists and 35 healthcare professionals (physicians,

nurses, physiotherapists, clinical pharmacists, and nursing technicians with experience in intensive care). The main objective of this phase was to evaluate the protocol by both experts and the target audience.

The third stage involved the assessment of the methodological quality of the protocol, and the present study addresses the methods and results of this final stage.

Critical Appraisal Using the AGREE II Instrument

For the evaluation of the protocol, the international instrument AGREE II was used. The AGREE II consists of 23 items, organized into six domains, which assess different dimensions of quality, including: Scope and Purpose; Stakeholder Involvement; Rigor of Development; Clarity of Presentation; Applicability; and Editorial Independence. Each domain includes space for comments and suggestions. At the end of the instrument, there are two items for the overall assessment of the protocol.

The AGREE II recommends that a guideline be assessed by two to four reviewers. Therefore, reviewers were invited based on a non-probabilistic convenience sampling method¹⁶, according to the eligibility criteria: doctoral professors affiliated with federal universities, specializing in medicine, pharmacy, physiotherapy, or nursing, with previous experience or expertise in intensive care, health technology assessment, epidemiology, and/or teaching and research.

For the application of the instrument, the evaluators received via email the protocol to be assessed, the technical research report with a detailed description of all study stages, the AGREE II user manual, the online training tool for evaluator calibration, and the research questionnaire.

The questionnaire was structured using Microsoft Forms® and divided into seven sections (corresponding to the six domains and the overall assessment). At the beginning of each section, instructions were provided on how each item should be scored (using a scale from 1 to 7). All AGREE II items were applied in full, without any adaptations. For each questionnaire item, there was a link directing the evaluator to the specific part of the AGREE II manual containing a detailed description of the item, guidance on where to find the information, and how to score it. At the end of each item, space was provided for comments and suggestions.

Statistical analysis

Quality scores were calculated for each domain, as proposed by the AGREE consortium. The obtained score is determined by the sum of the values of each item. The minimum score is given by 1 (strongly disagree) x number of items in the domain x number of assessors. The maximum score is given by 7 (strongly agree) x number of items in the domain x number of assessors, with the calculation defined by the formula:

$$\text{Quality score} = \frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100$$

The AGREE consortium does not establish minimum scores or scoring standards for interpreting the results obtained. Therefore, it was determined that domains with a score equal to or greater than 80% would be considered of high quality.

Descriptive statistical measures were used to summarize the data, including mean, median, and standard deviation. The median, interquartile range (IQR), and minimum and maximum scores were reported for each item.

As an additional analysis, the intraclass correlation coefficient (ICC) was calculated to assess the agreement among the raters, and the Pearson's coefficient of variation (PCV) was used to evaluate the variability of the domains relative to the mean. For the ICC, the following interpretative scale was adopted: <0.4 – poor correlation; 0.4 to 0.6 – fair; 0.6 to 0.75 – good; and 0.75 to 1.0 – excellent. For PCV, the lower the value of PCV, the more homogeneous the scores of the assessors. It was considered that in the occurrence of PCV > 25% and/or quality score < 80%, modifications regarding the domain would be made. The SPSS 27 software was used to perform the statistical analysis.

The entire evaluation process was conducted virtually and the evaluators who agreed to participate declared their Term Free and Informed Consent. The research took place between December 2023 and January 2024, with a total response time of 20 days. Each reviewer completed the instrument only once, anonymously and independently. The research was approved by the Research Ethics Committee of the Federal University of Rio Grande do Sul (CEP – UFRGS), CAAE 66187622.5.0000.5347.

Results

Three reviewers (E1, E2, E3) participated in the research, including one professor of medicine, one of pharmacy, and one of physiotherapy, with years of experience ranging from 28 to 30 years (Table 1). Evaluator E1 has extensive experience in the development, implementation, and evaluation of clinical guidelines using the AGREE II instrument. Evaluator E2 has experience in epidemiology, health literacy and the assessment of health technologies. Evaluator E3 has experience in continuing education and professional development in health. The evaluators did not participate in any previous stages of the study and were not part of the research group.

Table 1. Characteristics of evaluators.

Evaluator	Academic Background	Academic degree	Area of expertise
E1	Medicine	Doctorate in Medicine (Medical Sciences)	Development of clinical protocols
E2	Pharmacy	Doctorate in Medicine (Epidemiology)	Health Technology Assessment
E3	Physiotherapy	Doctorate in Education	Health Education

Domain 1 (Scope and Purpose) refers to the overall objective of the guideline, the specific health questions, and the target population. The predominant score in this domain was the maximum (score 7), reaching a quality score of 96.30% (Table 2). No comments or changes were suggested.

Domain 2 (Stakeholder Involvement) focuses on the extent to which the guideline was developed by appropriate stakeholders and represents the views of the intended users. One reviewer assigned the minimum score for items 4 and 5.

Table 2. Assessment of medication administration protocol. Domains: Scope and Purpose, Stakeholder Involvement, Rigor of Development.

Assessment items of the AGREE II	Median [IQR; Min-Max]	TS	QS	ICC
<i>Domain 1: Scope and Purpose</i>				
1. The overall objective(s) of the guideline is (are) specifically described.	7 [0; 7]	21		
2. The health question(s) covered by the guideline is (are) specifically described.	7 [0.5; 6 – 7]	20	96.30%	0
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	7 [0.5; 6-7]	20		
<i>Domain 2: Stakeholder Involvement</i>				
4. The guideline development group includes individuals from all relevant professional groups.	6 [2.5; 1 – 6]	13		
5. The views and preferences of the target population (patients, public, etc.) have been sought.	5 [3; 1 – 7]	13	68.52%	0.234
6. The target users of the guideline are clearly defined.	7 [0.5; 6 – 7]	20		
<i>Domain 3: Rigour of Development</i>				
7. Systematic methods were used to search for evidence.	7 [0; 7]	21		
8. The criteria for selecting the evidence are clearly described.	7 [0.5; 6 – 7]	20		
9. The strengths and limitations of the body of evidence are clearly described.	7 [0.5; 6 – 7]	20		
10. The methods for formulating the recommendations are clearly described.	7 [1.5; 4 – 7]	18	90.97%	-0.45
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	7 [1.5; 4 – 7]	18		
12. There is an explicit link between the recommendations and the supporting evidence.	7 [1.5; 4 – 7]	18		
13. The guideline has been externally reviewed by experts prior to its publication	7 [0; 7]	21		
14. A procedure for updating the guideline is provided.	6 [0.5; 6 – 7]	19		

Notes: *Appraisal of Guidelines for Research & Evaluation II* (AGREE II); Interquartile range (IQR); Minimum item score (min); Maximum item score (max); Total item score (TS); Quality score (QS); Intraclass correlation coefficient (ICC)

The reviewer commented that the information regarding these items was not fully included in the protocol but only in the research technical report, which justified the rating of “strongly disagree.” Furthermore, for item 5, the scores assigned were 1, 5, and 7 points, demonstrating differing opinions among the reviewers. The quality score obtained in the second domain was 68.52%.

Domain 3 (Rigor of Development) pertains to the process used to collect and synthesize evidence, the methods for formulating recommendations, and their updates. One reviewer assigned a score of 4 for items 10, 11, and 12, which was the lowest rating in the domain. No comments or changes were suggested, and the domain achieved a quality score of 90.97%.

Domain 4 (Clarity of Presentation) pertains to the language, structure, and format of the guideline. It obtained the highest quality score across the entire instrument, reaching 98.15%, as shown in Table 3. The maximum score was assigned to the majority of items, with only one rating of 6.

Domain 5 (Applicability) pertains to the likely facilitators and barriers to implementation, strategies to improve application, as well as the involvement of resources related to guideline use. The quality score achieved in this domain was 93.06%. Item 20 received different scores from each reviewer, with scores of 4, 6, and 7.

Finally, Domain 6 (Editorial Independence) pertains to the formulation of recommendations in a manner that is free from bias arising from conflicts of interest. The lowest score assigned was 6, and the quality score achieved was 97.22%. There were no comments or suggestions for domains 3, 4, 5, and 6.

The ICC ranged from -0.45 to 0.429, indicating low agreement between raters. Negative values or values close to zero suggest low reliability. Only domain 5 (ICC = 0.429) approached the threshold of reasonable reliability, while all others demonstrated low measurement consistency.

Table 4 specifies the mean, standard deviation, and calculated PCV for each domain. The PCV was below 25% in five domains, indicating homogeneity in the scores assigned by the reviewers. The “stakeholder involvement” domain showed the highest degree of dispersion (26.35%), resulting from two minimum scores (strongly disagree) assigned by one of the reviewers.

All reviewers assigned the maximum score in the overall assessment of the protocol (7 points). Therefore, the protocol was classified regarding its quality as the highest possible, resulting in an overall quality assessment of 100%. Regarding its use in clinical practice, all reviewers recommended the utilization of the protocol without any modifications needed.

Discussion

Few studies have evaluated the quality of guidelines focusing on medication use using the AGREE instrument. Girardis *et al.*¹⁷ evaluated guidelines for analgosedation in critically ill patients, Kelley-Quon *et al.*¹⁸ used the AGREE instrument to develop guidelines on opioid prescribing in children and adolescents, and a Brazilian study evaluated the overall quality of guidelines for therapeutic drug monitoring of medications for Chagas disease¹⁹.

Table 3. Assessment of medication administration protocol. Domains: Clarity of Presentation, Applicability, Editorial Independence.

Assessment items of the AGREE II	Median [IQR; Min-Max]	TS	QS	ICC
<i>Domain 4: Clarity of Presentation</i>				
15. The recommendations are specific and unambiguous.	7 [0; 7]	21		
16. The different options for management of the condition or health issue are clearly presented.	7 [0.5; 6 – 7]	20	98.15%	0
17. Key recommendations are easily identifiable.	7 [0; 7]	21		
<i>Domain 5: Applicability</i>				
18. The guideline describes facilitators and barriers to its application.	7 [0; 7]	21		
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	7 [0; 7]	21		
20. The potential resource implications of applying the recommendations have been considered.	6 [1.5; 4 – 7]	17	93.06%	0.429
21. The guideline presents monitoring and/or auditing criteria.	7 [0.5; 6 – 7]	20		
<i>Domain 6: Editorial Independence</i>				
22. The views of the funding body have not influenced the content of the guideline	7 [0; 7]	21		
23. Competing interests of guideline development group members have been recorded and addressed.	7 [0.5; 6-7]	20	97.22%	0

Notes: *Appraisal of Guidelines for Research & Evaluation II* (AGREE II); Interquartile range (IQR); Minimum item score (min); Maximum item score (max); Total item score (TS); Quality score (QS), Intraclass correlation coefficient (ICC).

Table 4. Mean values, standard deviation, and Pearson’s Coefficient of Variation (PCV) per domain.

Domain	Mean	Standard deviation	PVC (%)
Scope and Purpose	20.33	0.57	2.83
Stakeholder Involvement	15.33	4.04	26.35
Rigour of Development	19.38	1.30	6.72
Clarity of Presentation	20.66	0.57	2.79
Applicability	19.75	1.89	9.58
Editorial Independence	20.50	0.70	3.44

Notes: The average refers to the sum of the total score for each item, divided by the number of items in the domain.

The studies by Girardis *et al.*¹⁷ and Oliveira *et al.*¹⁹ evaluated clinical guidelines already published by professional societies or governmental agencies. The study by Girardis *et al.*¹⁷ reported that most guidelines on analgesia achieved high-quality scores, although the recommendations supporting the protocols were based on low-level evidence. In contrast, the study by Oliveira *et al.*¹⁹ indicated that the quality of guidelines for therapeutic drug monitoring in Chagas disease ranged from moderate to low.

To date, the present study is the first to use the AGREE II instrument both in the development phases of a protocol focused on medication use and in its critical appraisal by reviewers external to the research group. Furthermore, this is the first Brazilian protocol aimed at aerosol therapy during mechanical ventilation, which underscores the originality and relevance of the study for clinical practice.

The AGREE consortium stipulates that the individual assessment of domains and the scoring standards for interpreting results should be a decision made by the authors and guided by the context in which AGREE II is being used. Therefore, a review was conducted to identify the main cut-off points used in the assessment of guidelines. Scores ranging between 60 – 80% were found^{13, 19, 20, 21, 22}.

In nursing research, scoring standards typically range from 70 – 75%. Souza *et al.*²⁰ evaluated a protocol for detecting precursor lesions of cervical cancer and used a minimum scoring standard of 75%. Brasil *et al.*¹³ assessed a clinical protocol for family planning care for people living with HIV/AIDS and employed a scoring standard of 70%.

Researchers from a study conducted in Spain assessed the quality of clinical guidelines for Alzheimer’s and other dementias using the AGREE instrument and proposed the following classification: scores below 25% (very low quality); between 25 – 50% (low quality); between 50 – 75% (high quality); above 75% (very high quality)²³.

Considering that percentages between 70 – 80% were the most commonly used in studies identified in the literature, it was established for the medication administration protocol that domains with a score of $\geq 80\%$ were considered to have high quality.

Three domains achieved scores above 95% (Scope and Purpose, Clarity of Presentation, and Editorial Independence), indicating a high level of agreement among the reviewers. The clear presentation of the protocol, including the objectives, the addressed clinical condition, and the target audience, as well as the way the recommendations were described, contributed to the high scores in these domains and reflect well-structured guidance.

Two domains achieved scores between 90% and 95% (Rigor of Development and Applicability). These scores can be explained by the strong methodological rigor adopted in the development of the recommendations and the validation of the protocol.

Regarding the included studies, it should be noted that all were clinical trials that did not test the inhalation technique as an intervention¹⁵. This explains why the level of evidence for the recommendations was not classified and may account for the lower scores received for items 10, 11, and 12 in the Rigor of Development domain. Conversely, the strengths of the recommendations, the limitations of the evidence base, and the facilitators and barriers for protocol implementation were clearly described, which justifies the higher scores received in these domains.

Domain 2 (Stakeholder Involvement) received a quality score below 80%. The low score can be explained by the fact that the protocol development group shares the same professional background, indicating limited multidisciplinary participation. To mitigate this, the protocol was evaluated by external reviewers (Domain 3, Item 13). Information regarding the evaluation by external reviewers was added to the protocol in the “Development” section. This was the only modification made to the document after applying AGREE. Patient opinions and preferences were not considered, as the protocol is not aimed at patient and/or caregiver education but rather at specialized technical care.

In light of the identified gaps, it is estimated that the methods could be improved in future updates of the protocol. For a new version, the development group could be expanded to include authors from different professional backgrounds. The number of evaluators involved in the expert and target-audience assessment could also be increased, thereby broadening the perspectives on the content and appearance of the document.

Similarly, the number of reviewers in the third stage could be increased to enhance the robustness and generalizability of the results. Low ICC values can be partially explained by the small number of raters, since reliability estimates in small samples tend to be unstable and more sensitive to individual variations. Negative values (as occurred in domain 3) also suggest a systematic disagreement among raters (for this domain the lowest score was 4 and the highest 7).

Finally, the strengths of this study should be highlighted. The development of protocols aimed at the systematic and rigorous application of medications is of utmost importance, as these documents promote safer use of medications and/or health interventions in practice, support decision-making by healthcare professionals, and enhance patient safety. Systematic evaluation, periodic updates, and monitoring of protocol adherence are important practices that ensure quality.

For the continuation of this research, future perspectives include the application of the Appraisal of Guidelines Research and Evaluation–Recommendations Excellence (AGREE-REX) instrument, an extension of AGREE II. This instrument is capable of evaluating dimensions such as clinical applicability, values and preferences, and protocol implementability.

Conclusion

The medication administration protocol was evaluated for its methodological quality, obtaining an overall assessment score of 100%. Five domains scored above 90%, and the “stakeholder involvement” domain scored 68.52%, reflecting the need to expand the group developing the protocol.

All reviewers assigned the maximum rating for the overall evaluation of the protocol, achieving a total quality score of 100%. Regarding the question: “Would I recommend the use of this protocol?”, all assessors responded “Yes, without modifications.”

According to the presented results, and considering that the developed document achieved high quality, the guideline was published. Although AGREE II is less commonly used for the evaluation of guidelines focusing on medication use, this study demonstrated its feasibility for assessing the quality of such documents.

Funding sources

This research received no funding for its execution

Collaborators

Asturian K was responsible for the project design, data analysis, data interpretation, and drafting of the manuscript. Pilger D contributed to the project design, data interpretation, and critical revision of the intellectual content. Both authors approved the final version of the study and take full responsibility for the information contained in the manuscript, ensuring the accuracy and integrity of all its parts.

Acknowledgments

We thank the reviewers who participated in this research.

Conflict of interests statement

The authors declare that there are no conflicts of interest regarding this article.

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