

Development of an inhaled medication administration protocol for intensive care practice: an experience report

Desenvolvimento de um protocolo de administração de medicamento inalatório destinado à terapia intensiva: um relato de experiência

Kathleen Asturian¹; Diogo Pilger¹

¹Programa de Pós-graduação em Assistência Farmacêutica, Universidade Federal do Rio Grande do Sul, Porto Alegre/RS, Brasil.

Correspondent Author:

Kathleen Asturian. Anexo I da Faculdade de Farmácia, R. São Luís, 150 – Santana, Porto Alegre – RS, CEP 90620-170.
E-mail: asturiank@gmail.com

How to cite:

Asturian, K; Pilger, D. Desenvolvimento de um protocolo de administração de medicamento inalatório destinado à terapia intensiva: um relato de experiência. JAFF [Internet];11(1). Disponível em: <https://ojs.jaff.org.br/>

Received in: 12/18/2024

Accepted for publication on: 12/02/2025

ABSTRACT

Objectives: To describe the process of developing a protocol for administering bronchodilator therapy via metered-dose inhaler to patients undergoing mechanical ventilation (MV). **Methods:** This is a qualitative, descriptive study in the form of an experience report. The development process occurred in five stages: 1) literature review; 2) construct elaboration; 3) content and face validation; 4) methodological quality assessment; and 5) protocol publication. **Results:** In the first stage, 23 studies were selected. Data extracted from the review served as the basis for the protocol recommendations. In stage 2, four documents were used as methodological references for guideline and protocol development. Based on these documents, the main elements frequently cited were identified, and the first version of the protocol was drafted. The third stage consisted of two rounds of validation: the first involved assessment by four experts, and the second by healthcare professionals (n = 35). In both rounds, the validity index exceeded 0.95 (excellent). In stage 4, the protocol's methodological quality was evaluated by three PhD professors using the Appraisal of Guidelines for Research & Evaluation II instrument. Six quality domains were assessed. Five domains achieved scores above 90%, and one domain scored 68.52%. In the final stage, the protocol was formatted and published. **Conclusions:** The developed protocol is expected to provide support and recommendations enabling healthcare professionals to correctly administer inhaled medications during MV. **Key-words:** Interdisciplinary Communication; Practice Guideline; Teaching Materials; Medication Therapy Management; Critical Care; Respiration, Artificial.

RESUMO

Objetivo: descrever o processo de desenvolvimento de um protocolo de administração de broncodilatador em *spray* dosimetrado a pacientes em ventilação mecânica (VM). **Métodos:** Trata-se de um estudo qualitativo, descritivo, do tipo relato de experiência. O processo de desenvolvimento ocorreu em cinco etapas, sendo: 1) revisão de literatura, 2) elaboração do constructo, 3) validação de conteúdo e aparência, 4) validação da qualidade metodológica e 5) publicação do protocolo. **Resultados:** Para a primeira fase, 23 estudos foram selecionados. Os dados extraídos da revisão serviram como embasamento para as recomendações do protocolo. Na etapa 2, quatro documentos foram utilizados como referencial-metodológico sobre elaboração de diretrizes e protocolos. A partir desses documentos identificou-se os elementos-chaves comumente citados e a primeira versão do protocolo foi construída. A terceira etapa foi realizada em duas rodadas de validação, sendo a primeira, a avaliação por quatro especialistas e a segunda, a avaliação por profissionais de saúde (n=35). Em ambas rodadas o índice de validade foi acima de 0,95 (excelente). Na etapa 4, o protocolo foi avaliado quanto à sua qualidade metodológica por três professores doutores a partir do instrumento *Appraisal of Guidelines for Research & Evaluation II*. Seis domínios de qualidade foram avaliados. Cinco domínios atingiram pontuação acima de 90% e um domínio 68,52%. Como fase final, o protocolo foi diagramado e publicado. **Conclusões:** Estima-se que o protocolo desenvolvido seja capaz de fornecer subsídios e recomendações para que profissionais de saúde realizem a correta administração de fármacos inalatórios durante VM. **Palavras-chave:** Comunicação Interdisciplinar; Guia de Prática Clínica; Materiais de Ensino; Administração de Terapia Medicamentosa; Cuidados Críticos; Respiração Artificial.

Introduction

Intensive care is a multidisciplinary specialty that involves the comprehensive treatment of patients with, or at risk of developing, acute and life-threatening organ dysfunctions. Intensive Care Units (ICUs) are organized systems capable of providing specific care to critically ill patients. ICUs encompass a range of technologies that offer advanced support to vital organ systems during periods of organ or system failure.¹

Oxygen therapy is a treatment aimed at delivering oxygen to the lungs of patients with respiratory difficulties, and it can be provided in different ways depending on the degree of respiratory effort.² In pulmonary failure, mechanical ventilation (MV) is one of the oxygen delivery technologies most frequently used in patients with acute or acute-on-chronic respiratory failure.^{3,4} It is a form of ventilatory support that totally or partially replaces spontaneous ventilation, contributing to the improvement of gas exchange and the reduction of respiratory workload.⁵

Mechanical ventilation (MV) can be applied in a noninvasive manner, through an external interface such as a face mask, or in an invasive manner, through an orotracheal tube or tracheostomy cannula that directly accesses the airway.⁵ Patients undergoing MV may present increased airway resistance and obstruction to expiratory flow. In such cases, the inhalation of bronchodilator drugs can significantly reduce resistance, improving respiratory mechanics and synchrony between the patient and the ventilator.⁶

Different devices can be used for medication inhalation, including nebulizers, dry powder devices, and pressurized inhalers.^{7,8} In general, aerosol therapy with pressurized metered dose inhalers (pMDI), also known as metered sprays, is preferred because it is considered more cost-effective, better adapted to care routines, and associated with a lower likelihood of aerosolization of contaminated particles into the environment.^{9,10}

Aerosol therapy during MV is considered complex, since several factors influence the delivery of drug particles to the lungs, and these factors are related to the patient's clinical condition, the ventilator, and the aerosol-generating device itself.

Therefore, therapeutic effectiveness depends on drug administration using an appropriate inhalation technique, thus ensuring lower dose loss within the circuit and greater deposition of the drug in the lower airways.¹¹

At the national level, there are no protocols, guidelines, or directives exclusively focused on inhalation techniques during MV. The document *Practical Guidelines in Mechanical Ventilation* was jointly developed by medical societies and includes a brief section with recommendations regarding inhalation therapy using pMDI.¹² However, this document does not address important aspects of the therapy in depth, such as the devices used, methods of connection to the circuit, clinical particularities, among others, which reveals a significant gap.

At the international level, there are recommendations based on consensus statements and or expert opinions regarding inhalation techniques during MV, considering different aerosol-generating devices.^{13,14} However, these publications may present applicability gaps when considered within the Brazilian context, taking into account that some devices (such as spacers for MV) are not available in most Brazilian hospitals.

Thus, in view of the complexity of the topic, the gaps present in the literature, and the need for a theoretical and practical foundation for correct inhalation technique, a protocol was developed focusing on the administration of bronchodilators delivered via pMDI in adult patients undergoing MV.

In Brazil, although guidelines and protocols of greater impact are developed by the Ministério da Saúde (MS), this activity is not exclusive to the institution. In the absence of current guidelines, documents may be developed by health professional societies or other systems and services, provided that the document is based on scientific evidence.¹⁵ Especially in the hospital setting, whether public or private, the adoption of institutional protocols is a growing practice that serves to support clinical practice, decision-making, patient care, and service organization.¹⁶

Within the field of nursing, the term "care protocol" is widely used, and such documents can be found

with different focuses, such as pressure injury prevention,¹⁷ nursing care,¹⁸ educational actions for patients and families,¹⁹ safety protocols,²⁰ among others.

With regard to protocols focused on medication use, few studies were found in the literature, especially concerning how to construct this type of document. Smeulers et al.²¹ conducted a systematic review to evaluate quality indicators in the preparation and safe administration of medications. The study reported that the adoption of protocols for medication administration under specific regimens (such as high-alert medications, chemotherapeutic agents, antimicrobials, and thromboprophylactic drugs) represents a type of process-related quality indicator.

The objective of this study was to describe the process of developing a medication administration protocol aimed at intensive clinical practice and to discuss the strategies used to elaborate the construct.

Methods

This is a descriptive and qualitative study, focusing on an experience report regarding the development of an inhaled medication administration protocol aimed at clinical practice in intensive care. The study was conducted over a 12-month period (from March 2023 to March 2024).

Five development stages were carried out for the construction of the protocol, namely: 1) literature review; 2) elaboration of the construct; 3) content and face validation; 4) validation of methodological quality; and 5) layout and publication of the protocol.

Ethical principles for the conduct of the study were followed, with approval granted by the Comitê de Ética em Pesquisa (CEP/UFRGS), CAAE 66187622.5.0000.5347. All stages were conducted virtually, and participants who agreed to take part in the study (stages 3 and 4) declared their consent and signed the Informed Consent Form through an electronic document.

Stage 1: Literature review

To provide the theoretical foundation for the main concepts related to the administration of bron-

chodilators delivered via pMDI in mechanically ventilated patients, a comprehensive bibliographic survey was conducted through a scoping review. The results of this review²² served as the theoretical basis for developing the protocol recommendations.

The research question addressed by the review was: “How should the pressurized inhaler be connected to the circuit and what are the recommendations for the administration of bronchodilators in adult patients undergoing invasive mechanical ventilation?”.

The review was conducted between March and August 2023. The search strategy was carried out in the first week of August 2023 through consultation of the PubMed, Embase Elsevier, Cochrane Library, and Lilacs databases, with no language restrictions up to the cutoff date of July 31, 2023. The application of eligibility criteria and data extraction were performed independently by two researchers, and disagreements were resolved by a third reviewer.

The following data were extracted: patient preparation prior to the inhalation technique, the device used to connect the pMDI, positioning of the pMDI within the circuit, distance between the pMDI and the orotracheal tube (OTT), preparation of the MV circuit, care related to the medication, and the presence of figures or images related to the connection of the medication to the circuit.

Stage 2: Elaboration of the construct

After the bibliographic survey, the stage of elaborating the construct was initiated. As the protocol architecture, a digital document was designed so that its topics could be consulted in a practical and straightforward manner, resembling consultation of a manual.

A review was conducted to select documents that could serve as methodological references for the development of the construct. A search for guides, consensus statements, and national guiding documents on protocol development was carried out on the websites of the Ministério da Saúde, universities, and professional societies. A complementary search was performed on the Equator Network platform (an international initiative that provides guidelines for the conduct of various types of studies).

The elaboration of the construct took place between September and November 2023 and involved three professionals: a professor with a doctoral degree in Pharmaceutical Care and experience in Clinical Pharmacy, a clinical pharmacist with experience in intensive care, and a visual design student with experience in producing illustrations for health education. The constructive process was carried out entirely remotely through weekly virtual meetings lasting two hours.

Stage 3: Content and face validation

The evaluation of health guidelines by individuals external to the development group, a stage referred to as validation, is important to ensure that the perspectives of different audiences and or users of technical documents are considered.^{24,26} Thus, after the elaboration of the construct, the protocol (first version) was evaluated regarding its content and appearance.

For this stage, a methodological validation study was conducted between November and December 2023. Specific and previously validated instruments were used to assess content and appearance, namely the *Instrument for Validation of Educational Health Content (IVCES)* and the *Instrument for Validation of the Appearance of Educational Health Technologies (IVATES)*.^{27,28}

Validation at this stage was conducted in two mandatory rounds and involved the participation of experts (first round) and health professionals (second round). The first round aimed to provide a technical analysis of the protocol and included the participation of specialists in intensive care. In this round, suggestions and comments were provided, which led to the development of the second version of the protocol. The second version was evaluated by the target audience (second round), and based on this process, the third version of the protocol was achieved.

A non-probabilistic snowball sampling technique was used to select the evaluators in both rounds. This technique consists of referral chains in which key informants assist researchers in identifying individuals with the profile and qualifications required for the study.

The inclusion criteria for the experts were: physicians, nurses, clinical pharmacists, or physiotherapists working in adult ICUs and holding at least a specialist degree. For the target audience, the inclusion criteria were: physicians, nurses, clinical pharmacists, physiotherapists, or nursing technicians working in ICUs or in Urgent and Emergency Care settings, from public or private hospitals, with any level of specialization and length of professional experience, from all regions of the country.

For both rounds, the proportion of agreement among evaluators was the method used to analyze the responses. The Content Validity Index (CVI) was calculated for each questionnaire item and for the total score of each instrument. Scores with a $CVI \geq 0.78$ were considered satisfactory, according to the following scale: ≥ 0.78 , excellent (validated protocol); between 0.60 and 0.77, good (a new round would be required); and < 0.59 , poor (protocol not validated).

Stage 4: Validation of methodological quality

The assessment of methodological quality was the final validation stage. A methodological study was conducted between December 2023 and January 2024 using the international instrument *Appraisal of Guidelines for Research and Evaluation II (AGREE II)*.²⁹ The AGREE II has its own implementation guide, and all recommended instructions were followed during this stage of the study.

AGREE II, composed of 23 items, assessed six quality domains: scope and purpose; stakeholder involvement; rigor of development; clarity of presentation; applicability; and editorial independence. A scoring scale ranging from one to seven was used to evaluate the items, with a score of 1 (strongly disagree) assigned when no relevant information was present and a score of 7 (strongly agree) assigned when the quality of the information was excellent.

The quality score (QS, a metric proposed by AGREE II) was calculated for each domain. Domains with $QS \geq 80\%$ were considered to be of high quality. In cases where $QS < 80\%$, modifications would be made according to the evaluator's sugges-

tions. At the end of the instrument, evaluators were required to rate the protocol according to the following scale: 1 (lowest possible quality) to 7 (highest possible quality). Evaluators were also required to indicate whether they would recommend the protocol for clinical use.

The AGREE instrument recommends that a guideline be evaluated by up to four appraisers. Accordingly, the reviewers were selected based on the following eligibility criteria: faculty members holding doctoral degrees affiliated with federal universities, with academic backgrounds in Medicine, Nursing, Pharmacy, or Physiotherapy, and with prior experience or specialization in intensive care, health technology assessment, epidemiology, or teaching and research.

Stage 5: Protocol publication

After completion of the stages of construct elaboration and validation, the protocol proceeded to publication. This stage took place between January and March 2024.

Results

A total of 510 publications were identified in the databases (Stage 1). Eighty-one articles were excluded due to duplication, and 429 had their titles and abstracts screened for initial assessment. Sixty-seven publications were selected for full analysis, and 21 met the inclusion criteria. Two additional studies were identified from the reference lists of the previously included publications, resulting in a final sample of 23 studies.

All studies were experimental, including 19 (nineteen) randomized clinical trials and 4 (four) non-randomized intervention studies. Based on the data extracted from these studies, the protocol began to be developed (Stage 2), using the available evidence to support the recommendations. The document was designed to be divided into four sections, namely: introduction, recommendations on the inhalation technique, protocol development process, and application.

For the elaboration of the construct, three national documents^{23,24,25} and one international

document²⁶ were selected. None of them provided specific recommendations for the development of protocols intended for medication administration. However, analysis of these documents made it possible to identify key elements commonly cited for the composition of guidelines and protocols, such as clear definition of the construct's objectives, methods used for evidence searching, information on applicability, and a periodic update plan.

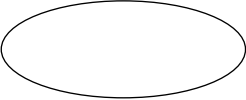
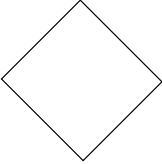

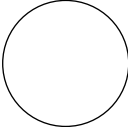
For the elaboration, textual resources, a flowchart, and illustrations were used. The flowchart aimed to organize the actions of health professionals and facilitate understanding of the procedures, and for its construction, standard symbols and definitions for algorithms proposed by Werneck et al.²⁵ were adopted. Table 1 shows how each symbol was applied in the protocol.

The illustrations aimed to demonstrate the inhalation technique and were added throughout the text and organized in a logical sequence (as a step-by-step process). Two types of illustrations were used: static illustrations, which showed the components required to assemble the MV circuit and the devices for connecting the pMDI to the circuit (Figure 1); and illustrations with representation of movement, which demonstrated the action to be performed (Figure 2).

After the construction of the protocol, the study proceeded to the stage of content and face validation (Stage 3). The evaluation instruments were combined to form an online assessment questionnaire containing 30 items. The first version of the protocol was evaluated by four experts, a physician, a nurse, a clinical pharmacist, and a physiotherapist, all holding specialist qualifications and with at least two years of experience in ICUs.

In this round, the CVI for content was 0.9861 and for appearance was 1.0 (excellent). The evaluators made suggestions to complement the protocol, including the inclusion of information on the most appropriate device for pMDI administration, discussion regarding the permanence of the device in the circuit, addition of captions to the figures, and inclusion of a new illustration. All suggestions were accepted, and the protocol was revised, resulting in the second version of the document.

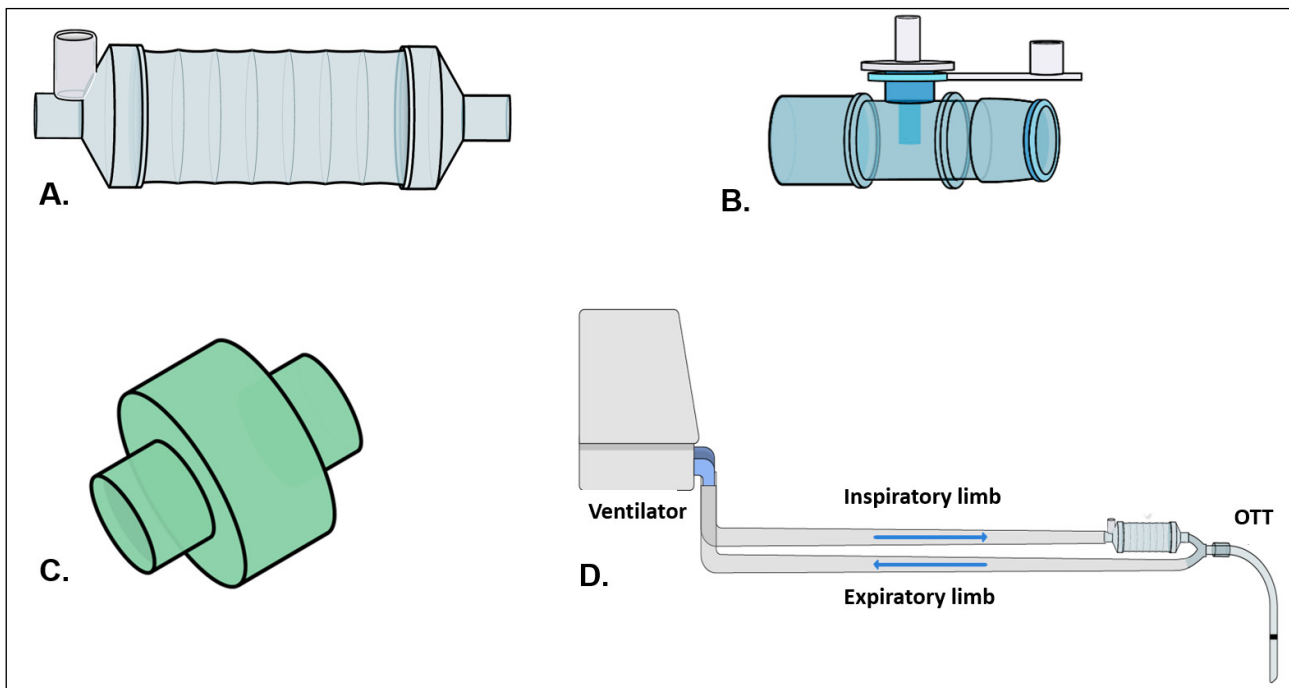
Table 1. Application of standard symbols for flowchart composition

Symbols	Definitions and application in the protocol
	<p>Beginning of the flowchart - represented the patient population covered by the protocol. From this symbol, an arrow extended to the next element.</p>
	<p>Decision point - represented the need for decision-making by the professional. Two outcomes were possible: yes or no. This is a moment in which the professional determines the next steps to be followed. From this symbol, two arrows originated, each representing one outcome.</p>
	<p>Intervention - represented the action that the professional should perform at that moment, that is, administration of the medication according to the protocol recommendations was indicated. From this symbol, an arrow extended to the final element.</p>
	<p>Final point - represented the last action to be taken by the professional. No arrows originated from this element.</p>

Notes: Symbol terminology (from top to bottom), oval, diamond, rectangle, circle.

Source: Prepared by the authors, adapted from Werneck et al.²⁵

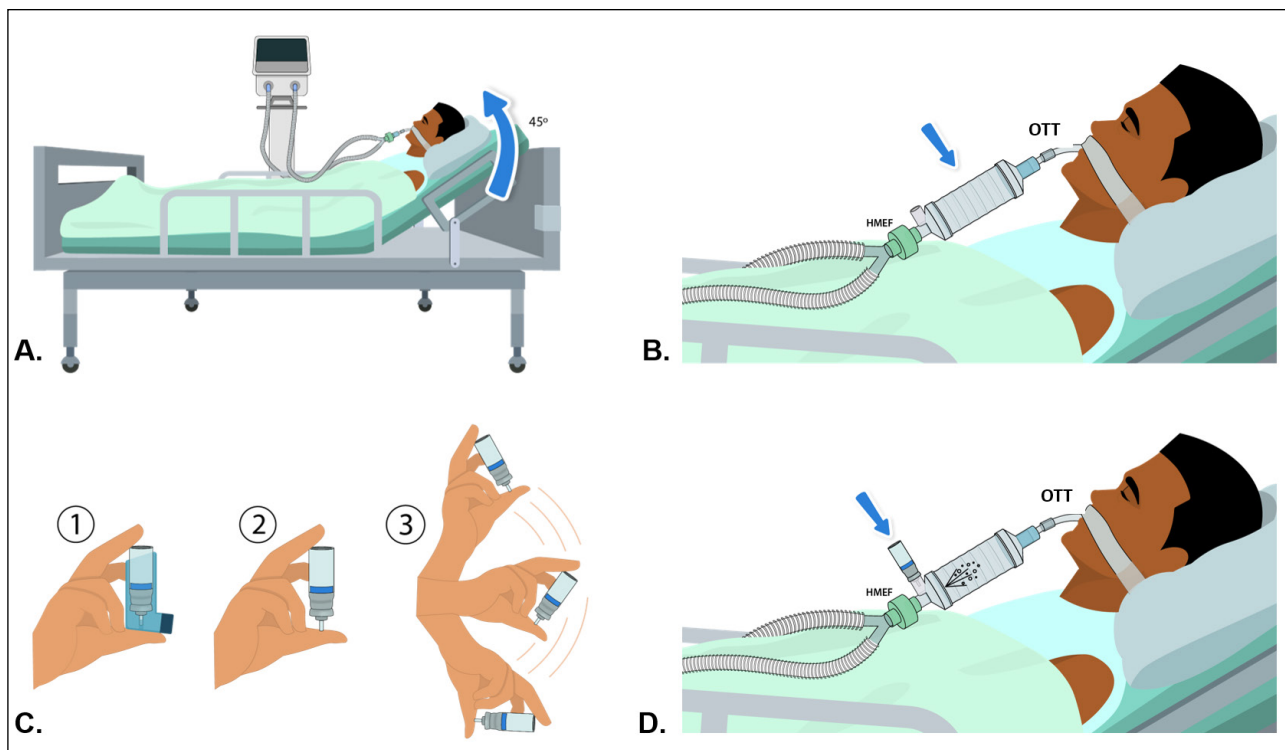
Figure 1: Static illustrations used in the protocol: A. Spacer for invasive mechanical ventilation; B. pMDI adapter; C. HMEF filter; D. Mechanical ventilation circuit.



Notes: Pressurized Metered Dose Inhaler (pMDI); Heat and moisture exchanger filter (HMEF); Orotracheal tube (TOT).

Source: Prepared by the authors.

Figure 2: Illustrations with representation of movement: A. Indicates patient positioning in the bed. B. Indicates the positioning site of the spacer in the circuit. C. Indicates vigorous shaking of the pMDI. D. Indicates medication administration



Notes: Pressurized Metered Dose Inhaler (pMDI); Heat and moisture exchanger filter (HMEF); Orotracheal tube (TOT).
Source: Prepared by the authors..

The second version was evaluated by a panel of 35 health professionals, with seven evaluators from each field (Medicine, Nursing, Physiotherapy, Pharmacy, and Nursing Technician). Most participants had between 0 and 4 years of professional experience ($n = 18$), held specialization in the residency modality ($n = 19$), and were from the Southern region of Brazil ($n = 20$), followed by the Southeastern region ($n = 10$).

The CVI for content was 0.9809 and for appearance was 0.9761 (excellent). In this round, the evaluators also provided comments and suggestions, such as the addition of new figures to better describe the technique, inclusion of a list of abbreviations, discussion of the influence of the HMEF (Heat and moisture exchanger filter), and clarification on how administration should be performed in patients with a closed suction system. The content was revised, resulting in the third version of the protocol.

Within this experience report, some opinions expressed by the evaluators are highlighted. All opinions regarding the relevance of the protocol were positive. Different professionals emphasized the lack of knowledge on the subject as well as the importance of the topic in light of the most recent COVID-19 pandemic, considering the significant increase in patients requiring MV.

The protocol undoubtedly stimulates professional interest and clarifies the main doubts related to the process of administering inhalation devices in patients undergoing mechanical ventilation. (Pharmacist working in a public university-affiliated hospital, length of experience between 2.1 and 4 years, Rio Grande do Sul/BR)

The protocol is of utmost importance, as the use of inhaled medications in patients undergoing MV requires an effective response, which often does not occur due to a lack of knowledge among the multiprofessional team. (Nurse working in a public hospital, with 8.1 to 10

years of professional experience, Rio Grande do Sul/BR, 2023).

The recommendations are highly relevant, as in our region there are still professionals who have doubts about how to administer spray medications in patients undergoing MV. (Nursing Technician working in a public university-affiliated hospital, with 0 to 2 years of professional experience, Tocantins/BR, 2023).

An extremely important topic, considering the most recent pandemic and the number of patients who required intubation and needed medications administered via the inhalation route. (Nurse working in a private hospital, with 0 to 2 years of professional experience, São Paulo/BR, 2023).

Extremely relevant. Many professionals do not know how to administer these medications. (Nurse working in a public university-affiliated hospital, with 6.1 to 8 years of professional experience, Rio Grande do Sul/BR, 2023).

The work is extremely relevant; there is still a global knowledge gap on this topic, and it is essential to discuss it more frequently in order to provide information to the majority of professionals working in ICUs. (Pharmacist working in a private hospital, with 8.1 to 10 years of professional experience, São Paulo/BR, 2023).

The opinions also expressed satisfaction with the illustrations; however, one opinion indicated disagreement that illustrations alone could modify professional behavior.

The illustrations are clear and correspond to the “equipment” and “materials” available at the institution where I currently work. (Nurse working in a private hospital, with 0 to 2 years of professional experience, São Paulo/BR, 2023).

The illustrations are clear and are able to convey the intended information. (Physiotherapist working in public and private hospitals, with 8.1 to 10 years of professional experience, São Paulo/BR, 2023).

The illustrations alone do not have the power to change behaviors. (Physiotherapist working in private and public university-affiliated hospitals, with more than 10 years of professional experience, Bahia/BR, 2023).

I liked the appearance. It helps to improve understanding. (Nursing Technician working in a public hospital, with 0 to 2 years of professional experience, Rio Grande do Sul/BR, 2023).

As the final validation stage, the third version of the protocol was evaluated for its methodological quality. Three faculty members holding doctoral degrees in the fields of Medicine, Pharmacy, and Physiotherapy, with professional experience ranging from 28 to 30 years, served as reviewers.

The quality scores obtained for each domain were as follows: 96.3% for scope and purpose, 68.52% for stakeholder involvement, 90.97% for rigor of development, 98.15% for clarity of presentation, 96.06% for applicability, and 97.22% for editorial independence.

Regarding the overall assessment of the protocol, all reviewers assigned the maximum score (7, highest possible quality). Concerning its use in clinical practice, all reviewers recommended the use of the protocol without the need for modifications.

Considering that the “stakeholder involvement” domain presented a QS < 80%, the authors made a modification to the “Development” section of the protocol, more clearly describing the document evaluation process and the working group involved. Thus, the protocol reached its final version.

After completion of all stages, the protocol proceeded to layout and publication (Stage 5). At this phase, no changes were made to the content or appearance; only layout formatting and the legal procedures for publication and registration were carried out. The organization of the final version of the protocol is shown in Table 2.

The protocol entitled “Recommendations for inhalation technique with metered-dose inhaler in invasive mechanical ventilation” was registered under the ISBN (International Standard Book Number) 978-65-00-92743-6 and published in electronic format in a digital repository.³⁰

The document is freely distributed, and total or partial reproduction of its content is permitted, provided that credit is given to the authors and that it is not used for commercial purposes. Although the protocol was developed and formatted for digital use, certain precautions were taken in case readers need to print it, namely: a white background, black as the primary font color, and the CMYK color standard (Cyan, Magenta, Yellow, and Black).

Table 2: Structure and organization of the final version of the protocol

Section	Items	Description
Introduction to the topic	Presentation	The purpose of the protocol, the reasons that justified its creation, and the general objectives were described.
	Introduction	The clinical situation and the problem of inadequate aerosol therapy during MV were addressed.
	Scope <i>Objective</i> <i>Setting</i> <i>Target audience</i> <i>Clinical condition involved</i>	It clearly described the specific objectives; the setting in which and the professionals by whom the document could be used; and the clinical characteristics of the patients covered by the protocol.
Recommendations	Flowchart	The evidence synthesized from the literature review was organized in this section.
	Important guidance <i>Types of devices</i> <i>Particularities</i> <i>Forms of connection to the circuit</i>	
	Inhalation technique	
Development	Methods for searching evidence in the literature	The databases used, eligibility criteria, the main search strategy, and the research question were specified.
	Included evidence	The characteristics of the included studies and the information collected for evidence synthesis were described.
	Development <i>Working group</i> <i>Conflicts of interest</i> <i>Funding</i> <i>Development stages</i>	The authors and their academic qualifications were described, as well as conflicts of interest and funding. The development stages were briefly described.
Application	Implementation Applicability Recommendations for practice Facilitators and barriers Monitoring Updating	Criteria for protocol applicability, recommendations for implementation, limitations, and plans for monitoring and periodic updating were described.

Source: Prepared by the authors.

Discussion

This study presented the rigorous process of developing a technical document intended for application in intensive care. As an initial step, a scoping review was conducted. Although this type of review is less commonly used for guideline development, it was employed because systematic reviews may present limitations when the objective is to address less precise or relatively new issues.³¹

The scoping review made it possible to map key concepts in the field of research, identify the available evidence, and synthesize the recommendations that provided the foundation for the protocol, considering the scarcity of publications on this topic.³²

In Brazil, Clinical Protocols and Therapeutic Guidelines (PCDTs) are documents developed by

the Ministério da Saúde and are characterized by a high level of technical rigor. The process begins with the search, selection, synthesis, and appraisal of evidence using systematic methods. For the formulation of evidence-based guidelines that support recommendations, the Ministério da Saúde employs different techniques, such as the Delphi method (for expert consensus), GRADE (Grades of Recommendation, Assessment, Development and Evaluation, for assessing the quality of studies), and external validation (through review or public consultation).³³

Care protocols not linked to the Ministério da Saúde show heterogeneity in their development processes. Vieira et al.³⁴ evaluated national and international protocols regarding evidence search methods and recommendation formulation. The study showed that several types of reviews were employed (narra-

tive, systematic, integrative, and scoping), and that the predominant validation method was the Delphi technique or expert validation. As assessment instruments, the study found that most protocols used author-developed and non-validated tools.

In this sense, the use of non-validated instruments can directly interfere with the quality of a guideline. In the present study, three previously validated instruments were used. IVATES and IVCES (Stage 3) were specifically developed to assess content and appearance dimensions for use in the health field and were applied in full, without any modification.

AGREE II is an international tool with three objectives: to assess quality, to provide a methodological framework for guideline development, and to inform what information should be reported and how it should be reported in guidelines. The application of this instrument implies minimum quality criteria for the publication of clinical protocols and guidelines.²⁹

In this study, AGREE II was used both as a methodological reference for the development of the construct (Stage 2) and as an instrument in Stage 4, thereby reinforcing the methodological rigor required for guideline development, as well as transparency regarding the processes of guideline development and publication.

Regarding the visual resources employed, it was considered that the information to be conveyed in the protocol was too complex to be fully understood through text alone. Visual elements are recognized as facilitators of the comprehension process, and in the health field, design can be used alongside other nonverbal communication elements as an important complement to written verbal communication.³⁵

Regarding the applicability of the protocol, it is recommended that health services conduct internal validation among the involved professionals in order to ensure proper understanding of the information and correct use of the document.²⁴ If this process is not feasible, it is recommended that training and educational activities be carried out, taking into account institutional particularities and workflow processes, in addition to monitoring adherence to the newly introduced recommendations.³³

As strengths of this study, it is highlighted that, to date, this is the first protocol developed with

specific recommendations on inhalation technique during MV. In addition, the application of multiple systematic stages in the development process reinforces the relevance, transparency, quality, and rigor of the protocol. As limitations, it is noted that although the protocol was validated by professionals from different fields, the primary authorship is composed of professionals with the same academic background, which may reflect similar approaches to a multiprofessional topic.

Conclusions

The present study described the rigorous process of developing a protocol focused on medication administration. It is estimated that the protocol resulting from this research is capable of providing the minimum necessary support and information for the correct administration of inhaled medications during MV. It is also expected that the construct may be used as an auxiliary element in multiprofessional training, considering the importance of educational resources as essential materials in the teaching–learning process within the field of health education.

As future perspectives for the continuation of this research, studies are proposed on the implementation of the protocol, evaluation of health professionals' adherence to the presented recommendations, and the establishment of a periodic update plan.

Author contributions

KA and DP: Study conception, manuscript writing, and approval of the final version; KA: Methodology; DP: Supervision.

Conflicts of interest

The authors declare no conflicts of interest.

Funding

Fundação Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPS) .

Data availability statement

The contents will be available at the time of article publication.

Responsible Editor

Lindemberg Assunção Costa

Referências

1. Marshall JC, Bosco L, Adhikari NK, Connolly B, Diaz JV, Dorman T *et al.* What is an intensive care unit? A report of the task force of the World Federation of Societies of Intensive and Critical Care Medicine. *J Crit Care.* 2017. 37:270-276. DOI: 10.1016/j.jcrc.2016.07.015.
2. Bellani G, Laffey JG, Pham T, Fan E, Brochard L, Esteban A, *et al.* Epidemiology, Patterns of Care, and Mortality for Patients With Acute Respiratory Distress Syndrome in Intensive Care Units in 50 Countries. *JAMA.* 2016. 23;315(8):788-800. DOI: 10.1001/jama.2016.0291.
3. Peñuelas O, Muriel A, Abaira V, Frutos-Vivar F, Mancebo J, Raymondos K, *et al.* Inter-country variability over time in the mortality of mechanically ventilated patients. *Intensive Care Med.* 2020. 46(3):444-453. DOI: 10.1007/s00134-019-05867-9.
4. Ferreira JC, Vianna AOA, Pinheiro BV, Maia IS, Baldisserotto SV *et al.* Joint statement on evidence-based practices in mechanical ventilation: suggestions from two Brazilian medical societies. *J Bras Pneumol.* 2025;51(1):e20240255: 1-15. DOI: 10.36416/1806-3756/e20240255.
5. Sociedade Brasileira de Pneumologia e Tisiologia, Associação de Medicina Intensiva Brasileira. *Direrizes Brasileiras de Ventilação Mecânica 2013.* Brasil, 2013. Available from: https://www.jornaldepneumologia.com.br/Content/imagebank/pdf/Cap_Suple_91_01.pdf
6. Maccari JG, Teixeira C, Gazzana MB, Savi A, Dexheimer-Neto FL, Knorst MM. Inhalation therapy in mechanical ventilation. *J Bras Pneumol.* 2015. 41(5):467-472. DOI: 10.1590/S1806-37132015000000035.
7. Fuller HD, Dolovich MB, Turpie FH, Newhouse MT. Efficiency of bronchodilator aerosol delivery to the lungs from the metered dose inhaler in mechanically ventilated patients. A study comparing four different actuator devices. *Chest.* 1994. 105(1):214-218. DOI: 10.1378/chest.105.1.214.
8. Marik P, Hogan J, Krikorian J. A comparison of bronchodilator therapy delivered by nebulization and metered-dose inhaler in mechanically ventilated patients. *Chest.* 1999. 115(6):1653-1657. DOI: 10.1378/chest.115.6.1653.
9. Kallet RH. Adjunct therapies during mechanical ventilation: airway clearance techniques, therapeutic aerosols, and gases. *Respir Care.* 2013. 58(6):1053-1073. DOI: 10.4187/respcare.02217.
10. Whittle JS, Pavlov I, Sacchetti AD, Atwood C, Rosenberg MS. Respiratory support for adult patients with COVID-19. *J Am Coll Emerg Physicians Open.* 2020. 13;1(2):95-101. DOI: 10.1002/emp2.12071.
11. Dhand R. How Should Aerosols Be Delivered During Invasive Mechanical Ventilation? *Respir Care.* 2017. 62(10):1343-1367. DOI: 10.4187/respcare.05803.
12. Associação de Medicina Intensiva Brasileira, Sociedade Brasileira de Pneumologia e Tisiologia. *Orientações Práticas em Ventilação Mecânica AMIB e SBPT.* Brasil, 2024. Available from: <https://d1xe7tfg0uwul9.cloudfront.net/amib-portal/wp-content/uploads/2024/09/18120131/Orientacoes-Praticas-de-Ventilacao-Mecanica-Interativo-SET-17.pdf>
13. Li J, Liu K, Lyu S, Jing G, Dai B, Dhand R, *et al.* Aerosol therapy in adult critically ill patients: a consensus statement regarding aerosol administration strategies during various modes of respiratory support. *Ann Intensive Care.* 2023. 13(1):63: 1-25. DOI: 10.1186/s13613-023-01147-4.
14. Laube BL, Janssens HM, de Jongh FH, Devadason SG, Dhand R, Diot P, *et al.* What the pulmonary specialist should know about the new inhalation therapies. *Eur Respir J.* 2011. 37(6):1308-1331. DOI: 10.1183/09031936.00166410.
15. Brasil. Ministério da saúde. Secretaria de Ciência, Tecnologia, Inovação e Complexo da Saúde. Departamento de Gestão e Incorporação de Tecnologias em Saúde. *Diretrizes metodológicas: elaboração de diretrizes clínicas.* Brasília, DF, 2023. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/diretrizes_metodologicas_elaboracao_metodologicas_led.pdf

16. Ministério da Saúde. Portaria no 529, de 1º de Abril de 2023. Institui o Programa Nacional de Segurança do Paciente (PNSP). BRASIL. Available from: https://bvsmms.saude.gov.br/bvs/sau-delegis/gm/2013/prt0529_01_04_2013.html
17. Vasconcelos JMB, Caliri MHL. Ações de enfermagem antes e após um protocolo de prevenção de lesões por pressão em terapia intensiva. *Esc Anna Nery - Rev Enferm.* 2017. 21(1):1-9. DOI: 10.5935/1414-8145.20170001.
18. Figueiredo TWB, Mercês NNA, Lacerda MR, Hermann AP. Construção de um protocolo de cuidados de enfermagem: relato de experiência. *Rev Bras Enferm.* 2018. 71(suppl 6):3004-3009. DOI:10.1590/0034-7167-2017-0846.
19. Santos NO, Predebon ML, Bierhals CCBK, Day CB, Machado DO, Paskulin LMG. Construção e validação de protocolo assistencial de enfermagem com intervenções educativas para cuidadores familiares de idosos após Acidente Vascular Cerebral. *Rev Bras Enferm.* 2020. 73(Suppl 3):1-9. DOI: 10.1590/0034-7167-2018-0894.
20. Paixão DPSS, Maziero ECS, Alpendre FT, Amaya MR, Cruz EDA. Adesão aos protocolos de segurança do paciente em unidades de pronto atendimento. *Rev Bras Enferm.* 2017. 71(Suppl 1):622-629. DOI: 10.1590/0034-7167-2017-0504.
21. Smeulders M, Verweij L, Maaskant JM, De Boer M, Krediet CTP, Nieveen Van Dijkum EJM, *et al.* Quality Indicators for safe medication preparation and administration: A systematic review. *PLoS One.* 2015. 10(4):1-14. DOI: 10.1371/journal.pone.0122695.
22. Asturian K, Balhego-Rocha M, Pilger D. Bronchodilator administration by pressurized inhaler during invasive mechanical ventilation in adults: A scoping review. *Farm Hosp.* 2025. 49(1):53-58. DOI: 10.1016/j.farma.2024.03.012.
23. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Gestão e Incorporação de Tecnologias em Saúde. Guia de elaboração de protocolos clínicos e diretrizes terapêuticas: delimitação do escopo. Brasília, DF. 2019. 2. ed. Available from: http://bvsmms.saude.gov.br/bvs/publicacoes/guia_elaboracao_protocolos_delimitacao_escopo_2ed.pdf
24. Pimenta CAM, Pastana I, Sichieri K, Solha R, Souza W. Guia para Construção de protocolos assistenciais de enfermagem. Conselho Regional de Enfermagem. COREN-SP; 2017. Available from: <https://portal.coren-sp.gov.br/sites/default/files/Protocolo-web.pdf>
25. Werneck MAF, Faria HP, Campos KFC. Protocolos de cuidado à saúde e de organização do serviço. Belo Horizonte: Nescon/UFMG, Coopmed, 2009. Available from: <https://www.nescon.medicina.ufmg.br/biblioteca/imagem/1750.pdf>
26. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, *et al.* AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *CMAJ.* 2010. 14;182(18):E. 839-842. DOI: 10.1503/cmaj.090449.
27. Leite SS, Áfio ACE, Carvalho LV, Silva JM, Almeida PC, Pagliuca LMF. Construction and validation of an Educational Content Validation Instrument in Health. *Rev Bras Enferm.* 2018. 71(suppl 4):1732-1738. DOI: 10.1590/0034-7167-2017-0648.
28. Souza ACC, Moreira TMM, Borges JWP. Development of an appearance validity instrument for educational technology in health. *Rev Bras Enferm.* 2020. 73(suppl 6):1-7. DOI: 10.1590/0034-7167-2019-0559.
29. AGREE Next Steps Consortium (2017). The AGREE II Instrument [Electronic version]. 2017. 1-52 p. Available from: <https://www.agreetrust.org/>
30. Asturian K, Pilger D. Recomendações para técnica inalatória com spray dosimetrado em ventilação mecânica invasiva: protocolo de administração de medicamento. Porto Alegre, Brasil. 2024.
31. Pollock DK, Khalil H, Evans C, Godfrey C, Pieper D, Alexander L, *et al.* The role of scoping reviews in guideline development. *J Clin Epidemiol.* 2024.169:111301: 1-7. DOI: 10.1016/j.jclinepi.2024.111301.
32. Peters MDJ, Godfrey C, Mcinerney P, Munn Z, Tricco AC, Khalil, H. Chapter 11: Scoping Reviews (2020 version). Aromataris E, Munn Z, editors. JBI Manual for Evidence Synthesis. JBI; 2020. Available from: <https://synthesismanual.jbi.global>

33. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia, Inovação e Complexo da Saúde. Departamento de Gestão e Incorporação de Tecnologias em Saúde Diretrizes metodológicas: elaboração de diretrizes clínicas. Brasília, DF. 2023. 138 p. Disponível em: https://www.gov.br/conitec/pt-br/midias/artigos_publicacoes/diretrizes/diretrizes-metodologicas-elaboracao-de-diretrizes-clinicas-2020.pdf
34. Vieira TW, Sakamoto VTM, Moraes LC, Blatt CR, Caregnato RCA. Validation methods of nursing protocols: an integrative review. *Rev Bras Enferm.* 2020. 73(suppl 5):1-10. DOI: 10.1590/0034-7167-2020-0050
35. Spinillo CG, Trotta T (org.). Design da Informação em Saúde: estudos e reflexões. Curitiba: Brioi, 2019. Available from: https://sbdi.org.br/sbdi/wp-content/uploads/2023/11/Livro_DI_Saude_Digital.pdf

