

Elaboration and validation of the content of an assistance protocol for nursing care with materials used in ventilatory support of a suspected patient or with confirmed COVID-19

Elaboração y validação de conteúdo de um protocolo de assistência para cuidados de enfermagem com materiais utilizados em suporte ventilatório de paciente suspeito ou com COVID-19 confirmado

Elaboração e validação de conteúdo de um protocolo assistencial para cuidados de enfermagem com materiais utilizados em suporte ventilatório de paciente suspeito ou com COVID-19 confirmada

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Abstract

The aim was to develop and validate a Standard Operating Protocol for the processing of inhalation material used in suspected patients or with confirmed COVID-19. This is a methodological research carried out in two stages: process of building the Standard Operating Protocol through best recommended practices and appreciation of it by experts. The analysis was performed by calculating the Content Validity Index. The Content Validity Index was obtained for each item and the Content Validity Index for the general scale (0.97). The item "Material – cleaning and disinfection" had the lowest individual score (0.85). The team must be trained and be aware of institutional protocols for disinfection, dressing and undressing. The use of N95 masks is recommended due to the risk of contagion by aerosols when cleaning the material. Thermal disinfection is the method of choice for processing materials used in ventilatory support during the pandemic. The protocol initially developed was improved following the experts' suggestions. A care protocol that was valid in terms of content was obtained, capable of being used by nurses in their care practice.

Descriptors: Materials Management, Hospital; Coronavirus infections; Disinfection; Nursing Care; Validation Study.

Resumen

El objetivo fue desarrollar y validar un Protocolo Operativo Estándar para el procesamiento de material de inhalación utilizado en pacientes sospechosos o con COVID-19 confirmado. Se trata de una investigación metodológica realizada en dos etapas: proceso de construcción del Protocolo Operativo Estándar a través de las mejores prácticas recomendadas y apreciación del mismo por expertos. El análisis se realizó mediante el cálculo del Índice de Validez de Contenido. Se obtuvo el Índice de Validez de Contenido para cada ítem y el Índice de Validez de Contenido para la escala general (0,97). El ítem "Material – limpieza y desinfección" obtuvo la puntuación individual más baja (0,85). El equipo debe estar capacitado y conocer los protocolos institucionales de desinfección, vestirse y desvestirse. Se recomienda el uso de mascarillas N95 por el riesgo de contagio por aerosoles al limpiar el material. La desinfección térmica es el método de elección para el procesamiento de materiales utilizados en el soporte ventilatorio durante la pandemia. El protocolo desarrollado inicialmente fue mejorado siguiendo las sugerencias de los expertos. Se obtuvo un protocolo de atención válido en su contenido, apto para ser utilizado por los enfermeros en su práctica asistencial.

Descriptores: Administración de Materiales de Hospital; Infecciones por Coronavirus; Desinfección; Atención de Enfermería; Estudio de Validación.

Resumo

Objetivou-se elaborar e validar um Protocolo Operacional Padrão para processamento de material inalatório utilizado em pacientes suspeitos ou com COVID-19 confirmado. Trata-se de uma pesquisa metodológica realizada em duas etapas: processo de construção do Protocolo Operacional Padrão através das boas práticas recomendadas e apreciação dele por especialistas. A análise foi realizada por meio do cálculo do Índice de Validade de Conteúdo. Obteve-se o Índice de Validade de Conteúdo para cada item e o Índice de Validade de Conteúdo para a escala geral (0,97). O item "Material – limpeza e desinfeção" apresentou o menor score (0,85) individual. A equipe deve ser treinada e ter ciência dos protocolos institucionais de desinfeção, paramentação e desparamentação. Orienta-se a utilização de máscaras N95 em virtude do risco de contágio por aerossóis durante a limpeza do material. A termodesinfeção constitui-se método de escolha para o processamento de materiais utilizados em suporte ventilatório durante a pandemia. O protocolo desenvolvido inicialmente foi aprimorado seguindo as sugestões dos especialistas. Obteve-se um protocolo assistencial válido em seu conteúdo, apto a ser utilizado por enfermeiros em sua prática assistencial.

Descritores: Administração de Materiais no Hospital; Infecções por Coronavírus; Desinfeção; Cuidados de Enfermagem; Estudo de Validação.



Gonçalves RCS, Sé ACS, Cardoso RB, Silva CPG, Vianna ECC, Figueiredo NMA, Tonini T team, for the processing of PPS used in ventilatory support of a suspected patient or with confirmed COVID-19?

Introduction

The first cases of COVID-19 emerged in December 2019, in Wuhan, Hubei Province, China. Those infected worked or lived near the local seafood market, where live animals were also sold^{1,2}.

Caused by the new coronavirus, COVID-19 results in considerably higher morbidities and mortality than other viruses belonging to the same family. In its early stages, severe symptoms of acute respiratory infection occur, with rapid development of acute respiratory distress syndrome, acute respiratory failure, and other serious complications^{2,3}.

The most serious forms of COVID-19 develop in a small portion of the population, but represent an expressive absolute number, capable of leading to the global collapse of health systems⁴⁻⁶.

Worldwide, the lack of intensive care beds and mainly mechanical ventilators, places ventilatory support at the center of the problem, added to the restriction of the use of non-invasive ventilation and high-flow nasal cannula due to the risk of aerosol dispersion and contagion of the multiprofessional team or other patients⁴⁻⁶.

With the COVID-19 pandemic, the Material and Sterilization Center (CME) was impacted by changing its routines. If, on the one hand, the cancellation of elective surgeries reduced the demand for surgical material, on the other hand, there was a significant increase in the processing of ventilatory assistance materials.

Health products (PPS) used in ventilatory support are classified as semi-critical and before being used in another patient, they must be submitted to at least an intermediate level of cleaning and disinfection. The physical process of thermosdisinfection is also recommended as another option⁷.

In pandemic situations, the Center for Disease Control (CDC) recommends that these PPS undergo high-level disinfection as a first choice. Safe disinfection methods include heat (physical method) for equipment resistant to high temperatures (e.g. 80°C) and immersion in disinfectant solution (chemical method) for the time recommended by the manufacturer^{8,9}.

In view of the above, the following question arises: what are the procedures to be adopted by the CME nursing

Thus, this study aims to develop and validate a Standard Operating Protocol (SOP) for the processing of health products (PPS) used in ventilatory support for a suspected patient or with confirmed COVID-19.

Methodology

This is a methodological research, of content validation, carried out in two stages.

First Step

It comprised the construction of the care protocol, through the best practices recommended¹⁰ by the Brazilian Association of Surgical Center Nurses, Anesthetic Recovery and Material and Sterilization Center (SOBECC), Technical Note¹¹ from the Advisory, Training and Specialization Center focused on the Material and Sterilization Center (NasceCME) and Technical Note GVIMS/GGTES/ANVISA No. 04/2020¹².

The use of these references was due to the scarcity of articles that addressed the theme from December 2019 to December 2021. The period is justified by the emergence of the COVID-19 pandemic in December 2019.

The research question was: What does the literature recommend as management of PPS used in ventilatory support of suspected or confirmed COVID-19 patients?

After reading the manuals and the recommendations of the specialist societies, a care protocol was developed.

Second Step

Developed after the project was approved by the Research Ethics Committee (CEP) of Cardoso Fontes Federal Hospital (HFCE), it aimed at the appreciation and evaluation of the SOP generated from the results of the previous stage by specialist nurses.

The sample consisted of nurses who met the definition of specialist described in Chart 1. In this definition, the nurse's four-year clinical practice is one of the mandatory requirements¹⁴.

Chart 1. Definition of specialist. Rio de Janeiro, RJ, Brazil, 2021

Expert definition criteria	Points
Clinical experience of at least four years in CME (mandatory)	4,0
For each year of clinical experience over four years, an extra point was added per year	1 point per year
Experience of at least one year in clinical teaching in the CME area	1,0
For each year of teaching experience over one year, an extra point was added per year	1 point per year
Research experience with published articles on CME	1,0
Participation of at least two years in a research group in the CME area	1,0
Doctorate in Nursing	2,0



Master's in Nursing	1,0
Lato sensu specialization in MSC and/or specialist title by SOBECC (Brazilian Association of Surgical Center Nurses, Anesthetic Recovery and Material and Sterilization Center)	1,0

The nurse's inclusion criterion in the study was a minimum total score of five points. As an exclusion criterion, nurses who had less than four years of experience in MSC were adopted.

An extra point was added for each year of clinical experience or teaching experience¹⁴. Thus, the experts ranked themselves according to the score:

- Junior Specialist: minimum score of five points, at least four years of clinical experience in the specific area of study.
- Master Specialist: score between six and 20 points.
- Senior Specialist: score greater than 20 points; knows as much as a junior or a master specialist, but has years of experience, which gives him senior status.

A committee of experts was formed in the areas of validation, processing of PPS and CME, chosen through analysis of the Lattes Curriculum, through a simple search, by subject, using the keywords: "Sterilization AND COVID-19" and by indication of participants, through the "Snowball" strategy.

The collection took place upon availability of the instrument through a link via the Internet. Participants answered a questionnaire through Google Drive.

The instrument consisted of a Likert scale with a score of 1 to 4, where: 1- I totally disagree; 2- I partially disagree; 3- I partially agree and 4- I totally agree¹³.

The values were used in the evaluation of the following criteria:

- Clarity: content that is easy to understand, explicit, transparent and that expresses only one idea without a doubt.

- Objectivity: practical; direct; objectively expresses the analyzed content.

The experts were asked about suggestions for other items not included in the instrument or identified during its

analysis. Suggestions should be added in the blank boxes intended for this purpose.

The collected data were categorized and stored in an Excel® spreadsheet. The professional profile of the sample was described by absolute and relative frequencies of categorical variables.

After the experts' evaluation, the committee agreement rate was calculated, obtained by calculating the percentage of each item or Content Validity Index for each item (I-IVC), through the sum of agreements of items 3 or 4 by specialist nurses¹⁵.

To perform this calculation, the formula was used: I-IVC = number of responses 3 or 4 / total number of responses. A CVI for general scale (S-IVC) greater than or equal to 0.90 was considered acceptable¹⁵⁻¹⁷.

The ethical precepts established by Resolution No. 466/2012 of the National Health Council and Circular Letter No. 1/2021 of CONEP/SECNS/MS were observed and developed after being approved by the Certificate of Presentation and Ethical Assessment (CAAE) : 49938421.0.0000.8066.

Results and Discussion

A feedback was obtained from 18 nurses. Of these, four who did not have four years of clinical experience were excluded, making 14 specialist nurses eligible.

The specialists who participated in the study are between 33 and 40 years old (n=6, 42.86%), are female (n=12, 85.71%), from the Southeast region (n=5, 35.72 %). They have worked for 10 years or more in MSC (n=8, 57.14%), have teaching experience (n=10, 71.43%) and do not have published scientific articles (n=9, 64.29%). but they have lato sensu specialization (n=8, 57.14%) and half of them attend some study group, related to the topic of interest (n=7, 50%), as described in Tables 1 and 2.

Table 1. Sociodemographic characteristics of the specialists. Rio de Janeiro, RJ, Brazil, 2021 (n=14)

Age	n	%
[33,40[06	42,86
[40,47[02	14,29
[47,54[02	14,29
[54,61[02	14,29
[61,68[02	14,29
Total	14	100,00
Sex	n	%
Feminine	12	85,71
Masculine	02	14,29
Total	14	100,00
Regions / State	n	%
North		
Pará	02	14,29
North East		
Maranhão	02	14,29
Ceará	01	7,14
Midwest		
	n	%



Goiás	01	7,14
Distrito Federal	01	7,14
Southeast	n	%
Rio de Janeiro	03	21,43
São Paulo	02	14,29
South	n	%
Rio Grande do Sul	02	14,29
Total	14	100,00

Table 2. Expert characteristics. Rio de Janeiro, RJ, Brazil, 2021 (n=14)

CME experience	n	%
4 to 6 years	03	21,43
7 to 9 years	03	21,43
10 years or more	08	57,14
Total	14	100,00
Clinical teaching in CME	n	%
1 to 3 years	03	21,43
4 to 6 years	03	21,43
7 to 9 years	01	7,14
10 years or more	03	21,43
Does not have	04	28,57
Total	14	100,00
Published articles	n	%
Yes	05	35,71
No	09	64,29
Total	14	100,00
CME research group	n	%
Yes	07	50,00
No	07	50,00
Total	14	100,00
Specialization	n	%
Yes	08	57,14
No	06	42,86
Total	14	100,00
Master's degree	n	%
Yes	01	7,14
No	13	92,86
Total	14	100,00
Doctorate degree	n	%
Yes	0	0
No	14	100,00
Total	14	100,00
Specialist rating	n	%
Junior	01	7,14
Master	11	78,57
Senior	02	14,29
TOTAL	14	100,00

With scores between six and 20 points, nurses were predominantly characterized as master specialists (n=11, 78.57%), as shown in Table 2.

The CVI was obtained for each item (I-IVC) and the CVI for the general scale (S-IVC), where the item "Material – cleaning and disinfection" had the lowest score (0.85) per

item among all the analyzed items, as can be seen in Table 3. An acceptable content validity index must be at least 0.78 for I-IVC. Regarding the S-IVC, the acceptable is 0.80 and preferably, its value must be greater than 0.90¹⁷. After the suggestions provided by the experts, the care protocol described in Chart 2 was developed.

Table 3. I-IVC and S-IVC of the analyzed items. Rio de Janeiro, RJ, Brazil, 2021

Analyzed item	I-IVC	
	Clearly	Objectivity
Protocol identification	1	1
Material - Personal protective equipment	1	1
Material - Registration	1	0,92
Material - Cleaning and disinfection	0,85	0,85

Paramentation	1	1
Reception and conference of material	1	1
Chemical disinfection – cleaning	1	1
Chemical disinfection – preparation	0,92	0,92
Undressing	1	1
S-IVC	0,97	0,97

Chart 2. Assistance protocol. Rio de Janeiro, RJ, Brazil, 2021

Assistance protocol for nursing care with materials used in ventilatory support of a suspected patient or with confirmed COVID-19
<p>Protocol identification</p> <ul style="list-style-type: none"> Objective: To describe the routine of care with respiratory material used in a patient suspected or confirmed for COVID-19. Scope: CME nursing team. Definition: Routine for receiving, cleaning and disinfecting respiratory material used in a patient suspected or confirmed for COVID-19.
<p>Material – PPE</p> <ul style="list-style-type: none"> Waterproof apron. Bonnet/ hat. Protective goggles. Face shield. Mask N95/ PFF2. Rubberized gloves for cleaning long barrels. Closed waterproof shoe. Private linen.
<p>Material – Registration</p> <ul style="list-style-type: none"> Traceability system – recommended. Ballpoint pen. Protocol book or form specific to the material forwarding institution.
<p>Material - Cleaning and disinfection (Chemical disinfection room)</p> <ul style="list-style-type: none"> Specific detergent for cleaning PPS. Thermo-disinfector (preferably). Container for diluting the detergent solution (when necessary). Cleaning brushes. Solution for chemical disinfection. Container for preparing the chemical disinfection solution. Reagent strip to control the chemical disinfection solution.
<p>Descrição das atividades – Paramentation</p> <ul style="list-style-type: none"> Dress up as recommended by the regulations: RDC 15/2012; Technical Standard 04/2020 of the Ministry of Health (revised on 02/25/2021) and NR 32/2005: <ol style="list-style-type: none"> Hygienize your hands. Put on the apron. Put on the N95/PFF2 mask. Put on the hat. Put on the glasses. Put on the face shield. Hygienize your hands. Put on procedure gloves.
<p>Reception and conference of the material - (Step carried out with the professional attire)</p> <ul style="list-style-type: none"> Sanitize your hands. Open the equipment door. Materials that have come into contact with the airways or that present a risk of contamination by COVID-19 must be forwarded to the CME, distributed in rigid, hermetically sealed packaging in order to ensure the safe transport of potentially contaminated material. The rigid packaging must be cleaned at the CME and sent to the sector of origin, according to the institution's routine. Put on procedure gloves. Immediately accommodate the respiratory material in the thermo-disinfector, respecting the capacity of the equipment and good reprocessing practices. Carefully check the material received, preferably during accommodation in the thermosinfector or in the disinfection solution, according to the institution's routine. Identify damaged materials and act according to the institution's routine. Remove gloves. Hygienize your hands. Close the thermosinfector door. Protocol the material received, according to the institution's routine. Start the cycle.
<p>Chemical disinfection - Cleaning and disinfection (Chemical disinfection room)</p> <ul style="list-style-type: none"> Dress up as recommended. Follow the dilution and exposure time recommendations for the detergent solution and disinfectant solution.



<ul style="list-style-type: none"> • Clean the material with a detergent solution to remove organic matter. • Totally immerse the material in the detergent solution, filling the inside of the pipes. • Let it act for the time suggested by the manufacturer. • Rinse and dry the material. • Dry the inside of the tubes using compressed air, taking care to accommodate a compress at the exit of the tubes, in order to avoid the dispersion of aerosols. • Immerse completely in disinfectant solution. • Fill the inside of the pipes with disinfectant solution. • Wait for the time stipulated by the manufacturer for disinfection. • Wash thoroughly with purified water after chemical disinfection (be careful not to leave disinfectant residues). • Dry with sterile compresses and/or trachea dryer.
<p>Chemical disinfection – Preparation</p> <ul style="list-style-type: none"> • Check the material, identifying possible damaged parts. • Packaging (use recommended packaging to accommodate the disinfected material). • Identify according to the institution's routine. • Store the material.
<p>Undressing</p> <ul style="list-style-type: none"> • Follow the step-by-step process of undressing recommended by the Ministry of Health (NT GVIMS/GGTES/ANVISA No. 04/2020 - updated on 02/25/2021): <ol style="list-style-type: none"> 1. Remove gloves. 2. Remove the apron. 3. Sanitize your hands. 4. Remove the face shield. 5. Remove the glasses. 6. Remove the cap. 7. Hygienize your hands. 8. Remove the N95/PFF2 mask without touching the external face. 9. Hygienize your hands. 10. Discard PPE as needed. • The professional must pay attention to the sequence of correct removal of the PPE and hand hygiene, since there is a risk of self-contamination. • Sanitize glasses and face shield before using it and after each use. • Hygienize hands with 70% alcohol whenever contamination is suspected and with soap and water when there is visible dirt. • Maintain the PPE recommended by RDC 15/2012 and GVIMS/GGTES/ANVISA No. 04/2020 throughout the working day, carrying out the necessary changes. • Waterproof shoes (boot type) must be sent for cleaning and disinfection with hypochlorite at the end of the day, according to the institution's routine.

Regarding PPE, Brazilian regulations recommend the use of private clothing, a hat and closed waterproof footwear by the employee in all technical and restricted areas of the CME. For the cleaning and chemical disinfection area, it is necessary to use protective goggles, mask, rubber gloves with long pipes, long-sleeved waterproof apron and waterproof and non-slip closed shoes⁷.

It is important that the team is trained and is aware of institutional protocols for dressing and undressing, in order to mitigate fear and insecurity at this time of a pandemic. As well as the adoption of good practices for the safety of workers.

Regarding the handling of dryers and thermo-disinfectors, the mandatory use of waterproof and thermal protection gloves is recommended. When not specified in the resolution, it is advised that the PPE must be "compatible with the risk inherent in the activity"⁷.

Transmission-based precautions prevent the spread of specific diseases and can be combined with standard precautions. During the COVID-19 pandemic period, employees are advised to use N95 masks due to the risk of contagion by aerosol formation during cleaning of contaminated material¹⁸. Aerosol generating processes should be avoided, the use of vaporizers or steamers is inadvisable^{11,18}.

Goggles, face shields (face shield) and waterproof shoes (boot type) should be cleaned with soap and/or

detergent water and subjected to disinfection with sodium hypochlorite or another product defined by the health institution and recommended by the manufacturer¹¹.

Records pertaining to material input and output are convenient for material traceability performance. It is recommended that it be done in a computerized way through a traceability system¹⁰. It is important that the CME carry out the control and monitoring of the steps carried out, with a view to infection control¹⁹.

Chemical cleaning and disinfection must be carried out in a specific room for this purpose, as established in Brazilian regulations⁷. It should be noted that a Brazilian study identified flaws in the practices of the CME Nursing team related to the chemical disinfection process. The authors pointed out the low adherence of the team in the correct execution of the PPS processing by chemical disinfection, causing the quality of the final product to be compromised, which puts patient safety at risk.²⁰

In the midst of the pandemic, thermidisinfection is the method of choice for processing materials used in ventilatory support⁸⁻⁹. Sterilization of these materials in low-temperature autoclaves, following the processing steps (cleaning, drying, inspection, packaging, labeling, sterilization and aeration) is not contraindicated¹⁰, but represents an additional cost to health facilities.



As limitations of the study, the reduced number of participating specialist nurses and the absence of available studies to compose the integrative review are pointed out.

Conclusion

The protocol initially developed was improved following the suggestions of specialist nurses. Finalizing the adjustments, a valid care protocol was obtained in its content, able to be used by nurses in their care practice in MSC, with an S-CVI of 0.97.

This protocol is believed to be useful in the standardization of nursing actions in care indirectly, contributing to safer care based on scientific principles.

Future studies are recommended with the objective of improving the protocol and adapting it to the reality of each health institution. Its practical application and consequent clinical validation is suggested in order to verify the feasibility by the nursing team.

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