

Validation of standard operating procedure for oral hygienization of intubated and tracheostomized patients

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ABSTRACT

Introduction: In Intensive Care Units, oral hygiene is a care action directly related to the safety and well-being of the patient, being one of the main ways of preventing Pneumonia Associated with Mechanical Ventilation. Although relevant, the recommendations and standardization on oral hygiene among critically ill patients are diffuse. **Objective:** To construct and validate a standard operating procedure (SOP) for oral hygiene performed by the nursing team for intubated and tracheostomized patients in an Intensive Care Unit (ICU). **Methods:** Methodological study developed in five stages: technical-scientific support; construction of SOP; recruitment and selection of experts; validation and presentation of the final version. The SOP was subjected to validation by judges with academic and/or clinical expertise (n=13) from all regions of Brazil, who assessed the validity criteria for each SOP item: Scope, Clarity, Coherence, Criticism, Objectivity, Scientific writing; Relevance, Sequence, and Uniqueness. The Content Validity Indices (CVI) of each validity criterion, SOP item, and the general CVI were calculated. **Results:** The experts were nurses (38.5%), dentists (38.5%), doctors (15.4%) and physiotherapists (7.7%). None of the SOP items had a CVI lower than 0.80. The general CVI was 0.95 and the experts' suggestions were mostly accepted (78.6%). The final version is available as an infographic, which illustrates the stages of the oral hygiene process of the intubated and tracheostomized patient. **Conclusion:** The constructed SOP has a satisfactory face and content validity, making a final total of 43 items to be used for oral hygiene of intubated and tracheostomy patients.

Keywords: oral hygiene; Pneumonia, Ventilator-Associated; patient safety; Intensive Care Units; Clinical Protocols.

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INTRODUCTION

Plaques that remain in the mouth for more than three days can create hundreds of bacteria, including Gram-negative, which cause localized infections in teeth, periodontal region, and oral mucosa, besides systemic disorders¹. This reality reinforces the need for systematic oral hygiene (OH), especially in critical moments, such as hospitalization².

In Intensive Care Units (ICU), the lowering of the level of consciousness; sleepiness/sedation; an inability for self-care; poor oral control; dehydration of the mucous membranes; lack of natural cleaning by chewing, and speech of the critically ill patient favors local microbial growth and colonization of the oral cavity by environmental pathogens³, in addition to the fact that Gram-negative bacteria may triple in 3-6 hours on the dental surfaces⁴. Thus, in these sectors, oral hygiene is a care action directly related to the patient's safety and quality of care, being one of the main ways to prevent Mechanical Ventilator-Associated Pneumonia (VAP)^{2,5}.

VAP is defined as a pulmonary infection that appears 48 to 72 hours after endotracheal intubation and institution of invasive mechanical ventilation, as well as up to 48 hours after extubation³. It has an incidence of 5 to 40% among patients mechanically ventilated for more than 2 days in the ICU⁶ and ranks first among the reasons for deaths caused by nosocomial infections, and about 33% to 50% of patients with VAP die as a direct result of this infection¹. Most of these infections are caused by microorganisms present in the mouth of the critically ill patient, therefore, aspiration of pathogenic bacteria from the oral cavity and pharynx is the main pathophysiological mechanism⁷, even though clinical conditions such as comorbidities, patient severity, and length of mechanical ventilation (MV) are well-accepted risk factors⁶.

Among MV patients, a study⁸ that compiled an analysis of 13 systematic reviews pointed out that the use of chlorhexidine (CHX) mouthwash (gel or mouth rinse), when used in concentrations ranging from 0.12 to 2.0%, reduced the risk of VAP incidence by about 40%, evidencing the efficacy of CHX used in ventilated patients when compared to the control group⁸.

Three systematic reviews reported on the good cost-effectiveness of CHX as an oral care intervention⁹⁻¹¹. CHX reduced the incidence of VAP by 43% and the comparative cost of CHX supply was less than 10% of the cost associated with creating a single case of VAP⁹, this is because the cost of CHX therapy for 14 patients was suggested to be less than 10% of the cost of antibiotic therapy for a single case of VAP⁹.

On the other hand, the technical-scientific material is not unanimous when pointing out which practices are more effective in the quality of oral hygiene for the prevention of VAP, such as example, the brushing technique; the presence/absence of mechanical brushing; tongue scraping; product used in chemical

disinfection; and frequency of OH^{1,2,8-14}. Moreover, a study shows that the OH practices performed in ICUs in the five regions of Brazil vary greatly¹⁵. This leads to the need for new studies that enable standardized means of performing OH, appropriate to clinical practice based on evidence, with its efficacy and effectiveness subsequently tested.

The construction and validation of a standard operating procedure (SOP) meet evidence-based practice and, in the context of ICU care, it is clear the need for review the means to leverage patient safety, both because of the high and persistent incidence of VAP⁶, and the criticality of the patient. The SOP must have a specific format so that it can be easily identified and, above all, describe each step of the task/process; be periodically revised, and the executing team is trained for its use¹⁶.

Even in face of the deficiency and/or greater elucidation regarding standardized practices on OH in ICU, it is common that these practices are operated by the nursing team^{2,4}, although the role of the hospital dental surgeon in these spaces is exponential and a clear necessity¹⁵. Considering the need to continuously increase strategies and instruments that enable safe care, including care in the ICU, the problem of this study arose.

Thus, the objective was to construct and validate a standard operating procedure (SOP) for oral hygiene performed by the nursing team for intubated and tracheostomized patients in an Intensive Care Unit (ICU).

METHODS

A methodological study of the development research type focused on the construction and validation of a standard operating procedure (SOP), carried out in five stages. The first stage consisted of a bibliographic survey in the databases Medical Literature Analysis and Retrieval System Online (Medline), via PubMed; Latin American and Caribbean Literature on Health Sciences (Lilacs); Scientific Electronic Library Online (SciELO); and Cochrane Library, to support the construction of the SOP. Systematic review with meta-analysis and randomized clinical trials were selected^{1,2,8-11,17-19}, for having higher levels of scientific evidence²⁰.

The second step consisted of the construction of the SOP, based on the survey of scientific literature as well as on the clinical experience of the professional/researcher - hospital dental surgeon, active in the ICU for more than five years, Master's degree student, oriented by a nurse, Ph.D., a researcher in the area of quality management. It is noteworthy that the construction of the SOP was based on the specific reality in which the researcher/professional was inserted and was also guided by the human, environmental, physical, and material resources available in this reality. Thus, the scenario was the adult ICU of a public university hospital in the Midwest of Brazil

The inclusion criteria for the academic judges were: a minimum degree of Doctorate and a scientific production of at least two articles published in the last three years in the ICU area, patient safety and/or infection control, verified on the Lattes Platform of the Brazilian National Council for Scientific and Technological Development (CNPq). As for the clinical specialists, they should have a minimum specialization degree and a proven experience in the ICU for at least two years. As exclusion criteria, for both cases, was defined the absence of response to data collection for three attempts.

The purposive sampling sought to ensure the validation of the SOP content by experts on the topic about it, to ensure the adoption of OH practices based on the best and most recent scientific evidence. Regarding professional categories, the following were defined for the composition of the sample of judges: dental surgeons, nurses, physicians, and physical therapists, because they are those who intervene more in the process of prevention and treatment of VAP, as well as in the oral care of patients in the ICU. Also, to achieve the greatest representativeness in the proposed validation, it was defined the need for participation of at least one judge in each region of Brazil, regardless of their professional category. It is noteworthy that to ensure applicability to the reality to which the SOP was built, 6 judges were from the Midwest region, and of these, 3 worked in the hospital where the study was developed, which ensured expertise and knowledge of the local reality.

For the recruitment and selection of the experts/judges, intentional sampling was used, as well as the snowball technique²¹. Data collection was carried out between August and September 2020 via e-mail, containing: an invitation letter with justification and objective of the study; a digital Informed Consent Form (ICF); a validation instrument with instructions and digital filling by the Google Forms platform[®]; the SOP of oral hygiene for intubated and tracheostomized patients built; and, a form for sociodemographic and professional characterization of the judges containing the variables: gender; age; profession; time of training; degree; region of Brazil; area of professional practice; time of professional practice; and, current job attachment.

In the fourth stage, the face and content validation of the SOP was performed. For this, the SOP content was submitted to evaluation using a Likert scale with scores from one to five, being: (five) agree, (four) agree, (three) neither agree nor disagree, (two) disagree, (one) disagree. Each item of the SOP was submitted to the evaluation of nine validity criteria, separately, namely: comprehensiveness; clarity; coherence; criticality; objectivity; scientific writing; relevance; sequence, and uniqueness.

Sixty-two professionals were invited, and of these, 49 did not respond to the invitation after three attempts. The survey included 13 judges, an odd number of participants, which prevents a tie in the consensus and is considered sufficient for the expected validation²²⁻²⁴.

The data were analyzed using descriptive statistics in Microsoft Office Excel[®], calculating the Content Validity Index (CVI) of each validity criterion and each item of the SOP, as well as the overall Content Validity Index (CVI). We considered the minimum percentage of 80% agreement between the experts²².

In data analysis, the judges' characterization variables were submitted to descriptive statistics, using measures of central tendency (mean) and dispersion (standard deviation) for quantitative variables, and measures of absolute and relative frequency (%), and 95% confidence interval for categorical variables. The judges' suggestions were analyzed against the recommendations in the literature that supported the construction of the SOP and compliance with them was also analyzed by descriptive statistics.

After the validation procedure, a training session on the SOP was planned for the intensivists professionals of the State of Mato Grosso using the digital platform Telessaúde-MT. The final validated version was made available as an illustrative infographic to be used to raise awareness of the ICU nursing teams of the hospital where the study was developed. Having said this, it is emphasized that the SOP is directed for use by this professional category and locality, however, multidisciplinary and diffusion to its practical deployment are encouraged. The construction and external validation of the SOP aimed to ensure that the best scientific evidence is applied to the reality studied. Its dissemination is based on the importance of subsidizing the construction of new care processes, besides supporting teaching in technical and undergraduate courses, and training in clinical practice.

All ethical precepts governing research involving human beings were respected. The study is duly registered under CAAE: 17599019.9.0000.5541 and institutionalized ethical opinion no. 3,603,809/2019.

RESULTS

Most experts were women (84.6%), nurses or dentists (38.5%), living in the central-western region of Brazil (46.2%) and working exclusively in the healthcare field (53.9%). The complete characterization of the sample of judges is presented in Table 1.

The SOP was composed of 43 items, and all items scored CVI above 0.80. Of these, 37 items scored CVI 0.90 or higher, and only 6 items scored CVI less than 0.90. Of these, 37 items scored CVI of 0.90 or higher, and only 6 items scored CVI lower than 0.90. Overall, the SOP obtained an overall CVI of 0.95. The total validation results are illustrated in Table 2.

Together, the judges made a total of 42 suggestions about the contents of the SOP. Some items received no suggestions and others received more than one. Among the suggestions, 29 (69.05%) were fully answered, 4 (9.52%) were partially answered, and 9 (21.43%) were not answered. The suggestions came from nurses (92.86%) and dentists (7.14%). Table 3 shows the experts'

suggestions about the validated SOP, partial or total approval, rejections, and justifications.

Based on the construction, validation, and critical appropriation of the judges' suggestions, the final validated version of the SOP was presented as an infographic, available in an electronic address of unrestricted access, culminating in social feedback about it²⁵.

DISCUSSION

Interprofessional collaboration is a fundamental requirement for the provision of safe and effective care in intensive care settings²⁶. The group of judges in the SOP validation was representatives of four professional categories: five dentists; five nurses; two

physicians and one physiotherapist. Among the experts, 9 (69.3%) worked in ICU or the academic area and also in a hospital ICU, which, in addition to interprofessionalism, enabled a possible good integration of the care area with the academic area, and the approximation of the actors responsible for direct care in the formulation of new means and instruments linked to work, based on scientific evidence.

All items of the SOP obtained CVI above 0.80 and the overall CVI was 0.95, making a second round of evaluations unnecessary. The experts' suggestions subsidized the revision of many items, even with satisfactory CVI, which also corroborates the experts' collaborative work and commitment to the proposed validation. However, suggestions emanated only from nurses and dental surgeons, probably related to the fact that these are the categories that are closely involved in the operation of the patients' HB in ICU^{2,15}, even if physicians and physiotherapists are closely linked to other direct actions of prevention and control of VAP⁵.

A systematic review with meta-analysis found that in routine HB, CHX may prevent nosocomial pneumonia in patients undergoing cardiac surgery, but may not decrease the risk of MV-associated pneumonia in patients undergoing other surgeries²⁷. Another study shows the possibility that CHX is associated with increased mortality²⁸.

Although CHX is one of the products most recommended by the Brazilian association for intensive care medicine (AMIB - *Associação de Medicina Intensiva Brasileira*)¹² for its proven efficacy in reducing VAP, it is worth noting that the studies on its use described above, besides having been developed more than 5 years ago, did not select only randomized clinical trials evaluating daily OH with CHX in any preparation, as well as did not pay attention to the different OH protocols used in the chosen studies, which suggests the need for studies with a high level of scientific evidence to verify the clinical results of its application.

An integrative literature review selected 17 articles published between 2010 and 2016 showed that cleaning with a soft-bristle or pediatric toothbrush was indicated as the best practice for mechanical control and CHX 0.12% for chemical control of plaque in the oral cavity. Thus, the study considered that the combined mechanical and chemical interventions were more effective in preventing respiratory infections², an aspect that was considered in the construction of the validated SOP, and that, despite the foundation of apparently promising evidence, deserves recurrent testing.

Cumulative evidence from a study that included systematic reviews and meta-analyses showed that there is strong evidence that the use of CHX in ventilated patients reduces the risk of VAP and that manual brushing decreased the risk of pneumonia in the frail elderly by 67%⁸. In this scope, the items "Dental brushing" and "Chemical decontamination of oral cavity" obtained CVI of 0.92 and 0.85, respectively, which shows that the judges agree with the practice of mechanical and chemical cleaning in the ICU OH care setting.

Table 1: Demographic, educational, and work characteristics of the judges participating in the validation of the standard operating procedure for oral hygiene of intubated and tracheostomized patients (n=13).

Variables	n (%)	Mean±Standard Deviation	95% Confidence Interval
Sex			
Female	11 (84.6)		[54.5–98.0]
Male	2 (15.4)		[1.9–45.4]
Age		38.46±10.96	
Profession (Education)			
Nurse	5 (38.5)		[13.8–68.4]
Dental Surgeon	5 (38.5)		[13.8–68.4]
Doctor	2 (15.4)		[1.9–45.4]
Physiotherapist	1 (7.7)		[0.1–36.0]
Education Time (Years)		15.11±9.17	
Titration			
Specialization	5 (38.4)		[13.8–68.4]
Master's Degree	4 (30.8)		[9.0–61.4]
PhD	4 (30.8)		[9.0–61.4]
Region of Brazil			
Midwest	6 (46.2)		[19.2–74.8]
Southeast	3 (23.1)		[5.0–53.8]
South	2 (15.3)		[1.9–45.4]
Northeast	1 (7.7)		[0.1–36.0]
North	1 (7.7)		[0.1–36.0]
Area of Professional Practice			
Intensive Care Unit	6 (46.1)		[19.2–74.8]
Academy ad Intensive Care Unit	3 (23.1)		[5.0–53.8]
Academy	2 (15.4)		[1.9–45.4]
Other*	2 (15.4)		[1.9–45.4]
Professional Experience		11.89±10.07	
Current Job Title			
Assistance	7 (53.9)		[25.1–80.7]
Teaching and Assistential	4 (30.7)		[9.0–61.4]
Teaching	1 (7.7)		[0.1–36.0]
No institutional affiliation	1 (7.7)		[0.1–36.0]

*Includes Gym and Oncological Area; and Dialysis Sector.

Table 2: Content Validity Indices (CVI) per criterion validity and item of the standard operating procedure (SOP) for oral hygiene of intubated and tracheostomized patients.

SOP Item	Criterion Validity											
	Scope	Clarity	Coherence	Criticality	Objectivity	Redaction	Relevance	Sequence	Uniqueness	General		
	IVC	IVC	IVC	IVC	IVC	IVC	IVC	IVC	IVC	IVC		
1. Checking the patient's restrictions	1,00	0,92	1,00	1,00	0,85	1,00	1,00	1,00	0,85	0,96		
2. Initial hand hygiene	1,00	0,92	1,00	1,00	0,92	1,00	1,00	1,00	0,85	0,96		
3. Gathering the materials needed for the procedure	0,92	0,92	1,00	1,00	0,92	1,00	1,00	1,00	1,00	0,97		
4. Paramentation with PPE	1,00	0,85	1,00	1,00	1,00	0,92	1,00	1,00	0,92	0,96		
5. Disposition of materials in sterile field	0,92	0,85	0,92	0,77	1,00	0,92	0,85	1,00	0,85	0,90		
6. Positioning the patient	0,85	0,92	1,00	1,00	1,00	1,00	1,00	1,00	0,92	0,96		
7. Layout of the towel or compress	0,85	0,85	1,00	0,85	0,92	0,92	0,92	1,00	0,92	0,91		
8. Connecting probe no. 12 or 14 to the vacuum or compressed air network and adjusting the valve	1,00	0,92	1,00	1,00	0,92	0,92	0,92	1,00	0,92	0,96		
9. Lowering of the bed side grid	0,92	0,92	1,00	0,92	0,92	0,92	0,92	0,92	0,92	0,93		
10. Checking cuff pressure	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00		
11. Air exhaust check	1,00	0,92	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99		
12. Changing the glove pair	0,92	1,00	1,00	0,92	0,85	0,92	1,00	1,00	1,00	0,96		
13. Checking the reference mark on the orotracheal tube	0,92	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99		
14. Aspiration of secretion contained over the cuff in case of the orotracheal tube or tracheostomy tube with a dorsal lumen for subglottic suction	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00		
15. Positioning of the plastic film over the patient's face and the professional's hands if the patient has aerosol precautions	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00		
16. Delimitation of the amount of probe to be introduced into the patient's nostrils	0,92	0,92	0,92	0,85	0,85	0,92	0,85	0,92	0,85	0,89		
17. Probe lubrication	1,00	0,92	1,00	1,00	0,92	0,92	1,00	1,00	0,92	0,96		
18. Upper airway aspiration	0,85	0,77	0,85	0,85	0,77	0,77	0,85	0,85	0,77	0,81		
19. Removal of secretions from the external part of the tube	0,85	0,77	0,85	0,85	0,77	0,77	0,85	0,85	0,85	0,82		
20. Cleaning and lubrication or hydration of parched lips and oral mucous membranes	0,85	0,85	0,85	0,85	0,92	0,92	0,85	0,92	0,92	0,89		
21. Opening the mouth and parting the lips	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00		

Continue...

Table 2: Continuation.

SOP Item	Criterion Validity													
	Scope	Clarity	Coherence	Criticality	Objectivity	Redaction	Relevance	Sequence	Uniqueness	General				
	IVC	IVC	IVC	IVC	IVC	IVC	IVC	IVC	IVC	IVC				
22. Removal of the oropharyngeal cannula	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
23. Adaptation of the probe to the kelly clamp	0,77	0,77	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,84
24. Initial aspiration of the oral cavity	0,92	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99
25. Detection and removal of orthoses/prostheses in the oral cavity	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,91
26. Connection of the brush with suction in the suction circuit	0,92	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99
27. Toothbrushing	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92
28. Reconnection of the probe fitted to the kelly clamp into the suction circuit	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,96
29. Removal of bacterial plaque and crusts from the external surface of the orotracheal tube	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92
30. Removal of bacterial plaque and crusts from the mucous membranes of the oral cavity	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,98
31. Tongue scraping	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
32. Chemical decontamination of oral cavity	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85	0,85
33. Final aspiration of the oral cavity	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
34. Drying and lubrication or moisturizing lips	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99
35. Replacement of orotracheal tube cuff/attachment, if necessary	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
36. Positioning of gases in places prone to pressure or friction of the lace/attachment	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,92	0,90
37. Lifting the bedside grid	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99
38. Hygiene of the dental orthosis/ prosthesis or obturator	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,98
39. Toothbrush processing	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
40. Disposal of PPE and disposable materials	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99
41. Final hand hygiene	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
42. Checking the prescription and writing the report in the medical record	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99
43. Registration and communication of intercurrent	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	0,99

Table 3: Experts' suggestions about the items of the standard operating procedure (SOP) for oral hygiene of intubated and tracheostomized patients.

SOP item*	Suggestion	Attendance and/or nonattendance with justifications
1) Checking the patient's restrictions	a) Change the description of the item. Where it reads: Verify the patient's restrictions, among others: spinal injury, flexion, extension, or polytrauma. Read: Verify the patient's physical and motor restrictions related to the head, neck, and cervical spine (polytrauma, cervical and spinal cord injuries).	a) Attended.
2) Initial hand hygiene	a) Change the description of the item. Where it reads: Perform with water and antiseptic chlorhexidine degerming 2% or alcoholic solution. Read: Carry out with soap and water or alcoholic solution.	a) Partially Attended. According to ANVISA, the use of antiseptics is intended for antiseptic hand hygiene and skin degerming. Antiseptic hand hygiene should be performed in cases of contact precautions recommended for patients with multidrug-resistant microorganisms, in cases of outbreaks, and when persistent antimicrobial activity is desired.
3) Gathering the materials needed for the procedure	a) The field need not be sterile; it can be a field or towel that generates the protection. b) Make a checklist with the material needed for the procedure.	a) Not Attended. The sterile field will be lined over the surface of the Mayo Table; bedside table or shower cart. The sterile Oral Hygiene Kit, gas pads, urethral tube, and other necessary materials will be placed on the field. b) Attended.
4) Paramentation with PPE	a) Use of double gloves is unnecessary.	a) Not Attended. There is no information about wearing double gloves in the item. The two pairs of gloves will be worn at different times. The first pair of gloves will be worn until item 11 and the second pair of gloves will be worn from item 12 to 40.
5) Disposition of materials in the sterile field	a) If it is impossible to use a sterile field to line the surface, use the Oral Hygiene Kit envelope itself. b) A clean surface (having disinfected the surface, and having it with a clean individual tissue to support the materials is ideal because the use of sterile material generates more costs to the service.	a) Attended. b) Not Attended. The surfaces of the Mayo Table, shower cart, and bedside table may be contaminated with hospital microorganisms even after cleaning. Furthermore, one will not always be certain that such surfaces have been decontaminated and/or have received effective decontamination. The sterile field provides safety from the high risk of cross-contamination in the ICU environment.
8) Connecting the urethral probe to the vacuum or compressed air network and adjusting the valve	a) Specify the probe to be used, not just the numbering. Some probes can be long, short, very, or not very pliable. Improve the product description.	a) Attended.
9) Lowering of the bedside grid	a) When orienting: "lower the bed rail" reinforce the need to evaluate if devices will be pulled, thus avoiding accidents, such as accidental removal of venous access, and extubation (when pulling the trachea of the mechanical ventilation circuit). b) This is a task inherent to any procedure and its omission from the protocol could be considered.	a) Attended. b) Not Attended. Due to the impossibility of performing oral hygiene adequately with the bedside rails up and due to the logical sequence of procedures to prevent cross-contamination, item 9 was preserved.
10) Checking cuff pressure	a) Emphasize that checking cuff pressure should occur before actually starting the oral hygiene procedure.	a) Attended.
12) Changing the glove pair	a) Include in the wording: "change pair of gloves after manipulating the vacuum or compressed air network, bed rails, and cuff meter". In the Justification, I suggest the following wording: "Avoid cross-infection".	a) Attended
13) Checking the reference mark on the orotracheal tube	a) Include in the wording: The information about the reference mark, in centimeters, that the fixation must be kept at the level of the labial commissure and must also be registered in the patient's chart after intubation and X-ray that confirms the correct positioning of the tube. b) Describe the attitude of the professional upon changing the positioning of the tube level after verification.	a) Attended. b) Attended.
14) Aspiration of secretion contained over the cuff in case of the orotracheal tube or tracheostomy tube with a dorsal lumen for subglottic suction	a) In patients with aerosol precautions, the compressed air network should not be used because it generates aerosols.	a) Attended.

Continue...

Table 3: Continuation.

SOP item*	Suggestion	Attendance and/or nonattendance with justifications
15) Positioning of the plastic film over the patient's face and the professional's hands if the patient has aerosol precautions	a) Remember that, in this specific situation, the professional should be wearing an N-95 mask.	a) Attended. It will be remembered that in this specific situation the professional should be dressed in a disposable waterproof apron; respirator-type mask (N95 or PFF2); disposable cap; goggles with side protection; and transparent face shield.
16- Delimitation of the amount of probe to be introduced into the patient's nostrils	a) Check if the is the most adequate material for aspiration. The urethral probe, even though it is efficient in aspiration, is not meant for such a purpose. There are specific materials that must be used.	a) Not attended. There is no specific probe for upper airway suction. The tracheal probe, used for lower airway aspiration, is larger (50 cm) and has a higher price. The urethral probe besides having a lower price is large enough (40 cm) for upper airway aspiration.
17) Probe lubrication	a) Where it reads: Lubricate part of the urethral tube to be introduced in one of the nasal cavities with water-soluble gel; do the same before introducing the tube in the other nasal cavity. Read: Lubricate part of the urethral tube to be introduced in one nostril with water-soluble gel, do the same before introducing the tube into the other nostril. b) To think: would the best term be "lucid patients" or "conscious patients"?	a) Attended. b) Attended. Upon reflection, the following changes were made: Where it reads: SOP items 17, 18, and 19 should not be performed on lucid patients. Read: SOP items 17, 18, and 19 should be avoided in conscious patients. Where it reads: SOP items 17, 18, and 19 should not be performed in lucid patients as introducing the urethral probe into the nasal cavities can cause a lot of discomfort and pain. Read: SOP items 17, 18, and 19 should be avoided in conscious patients as introducing the urethral probe into the nostrils can cause much discomfort and pain.
18) Upper airway aspiration	a) Where it reads: Introduce the clamped urethral probe into one of the nasal cavities and open the clamp when the urethral probe is introduced up to the delimited limit. Remove the probe slowly, with circular movements; Repeat the procedure as many times as necessary; Do not remain with the probe inside the nasal cavity for more than 10 to 15 seconds; Do the same in the other nasal cavity. Read: Introduce the clamped urethral probe into one of the nostrils and open the clamp when the urethral probe is introduced up to the delimited limit. Remove the probe slowly, with circular movements; Do the procedure again, as many times as necessary; Do not remain with the probe inside the nostril for more than 10 to 15 seconds; Do the same in the other nostril. b) To think about: the best term would be "lucid patients" or "conscious patients"?	a) Attended. b) Attended. Upon reflection, the following changes were made: Where it reads: SOP items 17, 18, and 19 should not be performed on lucid patients. Read: SOP items 17, 18, and 19 should be avoided in conscious patients. Where it reads: SOP items 17, 18, and 19 should not be performed in lucid patients as introducing the urethral probe into the nasal cavities can cause a lot of discomfort and pain. Read: SOP items 17, 18, and 19 should be avoided in conscious patients as introducing the urethral probe into the nostrils can cause much discomfort and pain.
19) Removal of secretions from the external part of the tube	a) Where it reads: SOP items 17, 18, and 19 should not be performed on lucid patients. Read: The performance of SOP items 17, 18, and 19 should be avoided in lucid patients. Because there are cases, that even in lucid patients, nasal cavity aspiration will be necessary. b) To think: the best term would be "lucid patients" or "conscious patients"? c) There is no difference between cleaning the external region of the tube with antiseptic solutions, with saline solution, or with dry gauze. The tube will be reintroduced into the colonized oral cavity and discarded after use.	a) Attended. b) Attended. Upon reflection, the following changes were made: Where it reads: SOP items 17, 18, and 19 should not be performed on lucid patients. Read: SOP items 17, 18, and 19 should be avoided in conscious patients. Where it reads: SOP items 17, 18, and 19 should not be performed in lucid patients as introducing the urethral probe into the nasal cavities can cause a lot of discomfort and pain. Read: SOP items 17, 18, and 19 should be avoided in conscious patients because introducing the urethral tube into the nostrils can cause a lot of discomfort and pain. c) Attended.
20) Cleaning and lubrication or hydration of parched lips and oral mucous membranes	a) Oral hygiene itself lubricates the lips, since hygiene should start from the outside (lips), I consider this item a bit out of the technical/practical reality.	a) Partially attended to. Sanitizing the lips with distilled or filtered water + 0.12% chlorhexidine or hydrogen peroxide is not enough to obtain lubrication or hydration of lips and prevent lesions and/or cracks during the oral hygiene procedure. Lip hygiene using distilled water and 0.12% chlorhexidine or 1% hydrogen peroxide will be added to item 20. The removal of crusts on lips after lubrication or hydration will be added. The use of AGE, Glycerin, or Dexpanthenol leaves the crusts softened for later removal.
21) Opening the mouth and parting the lips	a) If there is no Minnesota retractor you can use the tongue depressor.	a) Not attended to. There is nothing to contraindicate the use of a sterile, rounded-edge tongue depressor for lip-spreading. However, the tongue depressor is not intended for such a purpose.

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Table 3: Continuation.

SOP item*	Suggestion	Attendance and/or nonattendance with justifications
22) Removal of the oropharyngeal cannula	a) Remove the oropharyngeal cannula if there is no contraindication.	a) Not Attended. If it is contraindicated for the patient to be without the use of the oropharyngeal cannula, it must be removed so that oral hygiene can be done satisfactorily. The Guedel cannula should be decontaminated with 0.12% Degermante Chlorhexidine and running water and placed back in the oral cavity after the oral hygiene procedure. The oropharyngeal cannula is not used in intubated or tracheostomized patients to prevent the tongue bases of these patients from obstructing the oropharynx since such patients are either under mechanical ventilation or conscious.
23) Initial aspiration of the oral cavity	a) Attaching the probe to the forceps does not facilitate the procedure.	a) Not Attended. The Kelly forceps (rigid material with a firm grip) help the professional guide the probe to specific sites within the oral cavity and oropharynx.
25) Detection and removal of orthoses/prostheses in the oral cavity	a) Register/document the viewing of the prosthesis, the removal, cleaning, and especially the return/replacement. In my practice, lost prostheses or even patients who arrive without using them (unnoticed by the family) generate uneasiness between the team family and even a lawsuit.	a) Partially attended to. These suggested procedures should not be performed at this point in the SOP. They should be performed after oral hygiene. These suggested procedures should be included in items 38 and 42 of the SOP. The suggestion of recording/documenting the visualization of the dental prosthesis will be included in item 42 of the SOP.
28) Reconnection of the probe fitted to the kelly clamp into the suction circuit	a) I suggest revising item 26 because, in my understanding, it is repeating information from this item in that one and vice versa.	a) Partially attended Item 28 says to remove the brush with suction and reconnect the probe #12 or #14 + Kelly type forceps in the suction circuit. And, item 26, says to remove the urethral probe from the suction circuit hose and connect it to the brush. There is no repetition of information in the two items. The text will be corrected in item 26: remove the urethral probe from the suction circuit hose and connect the hose to the brush.
32) Chemical decontamination of the oral cavity	a) Today the suggestion in the literature is to use 0.12% chlorhexidine even in patients with COVID-19.	a) Attended.
34) Drying and lubrication or moisturizing lips	a) I suggest adding after the end of oral hygiene, considering that in task 20, you have the same orientation, but before starting the procedure.	a) Not Attended. There will be no such need because the titles of the items will be different. Also, there is no lip drying step in item 20.
36) Positioning of gases in places prone to pressure or friction of the lace/attachment	a) There is also the possibility of using transparent adhesives, especially for COVID patients, due to the pronation technique, to prevent PPL. b) In cases where the patient has lesions in the region, I suggest not putting gauze, because it sticks to the lesion, making removal difficult and aggravating the lesion.	a) Attended. b) Attended. Will be added to the text: avoid putting gas on lesions. Gases sticking to lions should Only be removed after being lubricated with oil.
37) Lifting the bedside grid	a) Besides maintaining proper patient positioning, sheets covering the patient, and tidiness of the environment. b) Insert the term "lateral" after the description "Raise grid".	a) Attended. b) Attended.
38) Hygiene of the dental orthosis/prosthesis or obturator	a) Standardize the terminology "chlorhexidine degerming" in all situations instead of using "chlorhexidine degerming".	a) Attended.
39) Toothbrush processing	a) Standardize the terminology "chlorhexidine degerming" in all situations instead of using "chlorhexidine degerming".	a) Attended.
40) Disposal of PPE and disposable materials	a) To think: use the term "infectious waste garbage can" instead of "infectious waste"	a) Attended.
42) Checking the prescription and writing the report in the medical record	a) The report should have: in patients with TOT, tube height at labial rima level. b) The report must contain the presence of upper, lower, or both prostheses.	a) Attended. b) Attended.
43) Registration and communication of intercurrency	a) Besides "communicating" the interurrences, it is fundamental that They are duly registered in the evolution by the professional who performed the procedure, thus supporting his performance.	a) Attended.

* Missing items from SOP did not receive suggestions from experts

It is noteworthy that the toothbrush with suction is indicated for intubated and tracheostomized patients under MV, and is important in the prevention of VAP because it enables aspiration concomitant with hygiene²⁹, which prevents translocation of plaque, crusts, debris, saliva, and dental paste to the oropharynx and subglottic regions. The item regarding the use of the brush with suction received a CVI of 1.00, attesting to the unanimity among the judges, however, it is known that, unlike the institution for which the SOP was prepared, this material may not be found in all institutional realities.

A study covering the five regions of Brazil showed that 42.2% of the ICU surveyed used toothbrushes for all patients, in 37.2% the brushes were used only in conscious patients and/or those able to perform their hygiene, and 20.3% of the ICU the toothbrushes were not used. The same study showed that when toothbrushes were used, they were disposable in 23.7% of the cases, disinfected with antiseptic in 22.6%, washed only with water in 37.3%, and no disinfection care was practiced in 16.4% of the cases¹⁵. Therefore, the items regarding toothbrushing (CVI 0.92) and toothbrush processing (CVI 1.00) show satisfactory consensus among the judges about brushing technique and bristle hygiene, of the toothbrush in running water and Chlorhexidine 2% degerming agent, besides the importance of drying and keeping it in a closed container with the patient's name and date of the 1st day of use, and on the use of the brush with aspiration for a maximum period of 30 days, as recommended in the validated SOP²⁵.

A British randomized clinical trial compared two HB interventions in MV patients: one using foam *swabs* and the other using toothbrushes, and cleaning efficacy was based on plaque index scores, gingival index, and dental plaque counts (DPC). There was no significant change in DPC between the two approaches, and no statistically significant difference in plaque removal and reduction in gingival inflammation between the two interventions; both were equally effective³⁰.

It has been found in other studies that although the use of foam swabs is effective in keeping the oral mucosa moist and in preventing tissue trauma, they are not very effective in cleaning external surfaces and controlling plaque³¹⁻³³. In this regard, the SOP built and validated²⁵ suggests, in addition to toothbrushes, the use of roll-up gauze pads and Kelly-type forceps for removal of crusts and plaque from the external surface of the orotracheal tube (IVC 0.92), mucous membranes (IVC 0.98) and also for chemical decontamination of the oral cavity (IVC 0.85).

Tongue scraping with the use of a tongue cleaner/scraper is recently recommended by an Indian study as an effective means of reducing the bacterial load on the dorsum of the tongue³⁴. From this perspective, the judges unanimously agreed on this item (CVI 1.00).

Recent studies show that bacterial species related to VAP may migrate rapidly from the mouth and upper airways during the MV period, which contributes greatly to its pathogenesis^{7,35}. Thus, upper airway aspirations are indispensable steps in the routine OH of intubated patients. Corroborating this idea, the items "Delimitation of the amount of urethral probe to be introduced into the patient's nasal cavities", "Lubrication of urethral probe", "Suction of upper airways", "Initial aspiration of oral cavity" and "Final aspiration of oral cavity", received the respective CVI: 0.89; 0.96; 0.81; 0.99; and 1.00.

Although wooden spatulas with gauze attached by crepe tape or adhesive tape at one end, known in Brazil as "little gauze dolls" or "pi", are not effective for removal of bacterial plaque from the oral cavity³⁶⁻³⁸, they are still used in the routine practice of oral hygiene of critically ill patients in many ICUs. The CVI of 0.97 referring to the item "collection of materials needed for the procedure" confirms the importance of an oral hygiene kit with materials for this care, avoiding improvisation and ineffective procedures.

It is noteworthy that the satisfactory metrics found in the SOP validation process do not replace the need for training for its use and implementation in a shared and rational way. Although not directly linked to the proposed validation, the last step of the study related to the planning of training for the ICU nursing team and the institutionalization of the SOP is also important, besides the presentation of the final version in the format of an illustrative infographic, which can facilitate and/or streamline the use of the SOP in the care dynamics, as well as in the teaching of the technique of OH in professional training. It is important to reinforce that, although the SOP was built for a specific reality, its construction was duly supported by the best scientific evidence, therefore, its adaptation concerning the available institutional resources is a future possibility.

The limitations of this study are the non-consideration of nursing technicians in the SOP validation, although they are the target of training for its use, and also the absence of professionals representing class entities, such as associations, and leaders of the Hospital Infection Commissions. However, it is believed that the study presents the following direct contributions: the social return of a feasible product for the use of OH based on scientific evidence that may favor the safety of the critically ill patient and the possibility of using the validated SOP as an interventional means to verify its effect on the incidence of VAP and other aspects that are correlated to the oral hygiene of patients in the ICU. Furthermore, the research has the indirect contribution of raising interdisciplinarity in the construction of evidence-based instruments that enhance the work process in health and may subsidize the teaching and training in loco on the oral hygiene of tracheostomized and intubated patients.

Conclusion

The SOP has a face and content validity since all items obtained CVI above 0.80, and the overall CVI was 0.95 so it can be used by the nursing team associated with the multi-professional team of the Intensive Care Unit for which it was built for oral hygiene of intubated and tracheostomized patients. Therefore, it is considered that the established objectives were reached and its adaptation to other intensive care realities is suggested.

The validated version of the SOP has 43 procedural items, in addition to a checklist of materials needed for the execution of oral hygiene. The verification of the effects under its use is strongly encouraged, as well as updates and revisions about the different institutional realities, although due appropriation of recent scientific evidence and revalidation are pertinent for this.

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