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ORIGINAL ARTICLE

Construction and validity of a bundle to prevent skin infections due to burns: a methodological study

Construção e validação de bundle para prevenção de infecção de pele por queimaduras: estudo metodológico

Construcción y validación de un paquete para prevenir infecciones de la piel por quemaduras: estudio metodológico

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ABSTRACT

Background and Objectives: skin infections can occur in burn patients due to the loss of the main protective and immunological barrier. Although there are general protocols for treating burns and preventing infection, few are suitable exclusively for children and adolescents. Aiming to prevent and improve routine care, this study aimed to build and validate a bundle for the management and prevention of skin infections due to burns in children and adolescents. **Methods:** a methodological study developed at a Burn Treatment Center in northern Paraná from March 2021 to December 2023. The research was developed in three phases, theoretical, empirical and analytical, through statistical analysis in the Statistical Package for the Social Sciences. **Results:** bundle content validity was performed by seven professionals who were experts in the subject. Regarding the bundle content validity, there was 100% agreement among all participants regarding the dimensions assessed: objectivity; layout; simplicity; clarity; relevance; variety; breadth; credibility; and balance. The Content Validity Index was used to verify the bundle content validity. Of the nine items in validity with judges, the Content Validity Index was equal to 1.0. In accordance with the results and minimal suggestions in the bundle, only one round of validity with judges was carried out. **Conclusion:** the bundle was validated to support the treatment of severe burns given the complexity of careful and multidisciplinary management.

Keywords: *Burn Units. Hospital Infection Control Program. Patient Care Bundles. Burns.*

RESUMO

Justificativa e Objetivos: infecções de pele podem ocorrer em pacientes com queimaduras devido à perda da principal barreira protetora e imunológica. Apesar de existir protocolos gerais para tratamento de queimaduras e prevenção de infecção, poucos são adequados exclusivamente para crianças e adolescentes. Visando prevenir e aprimorar a rotina na assistência, o objetivo do estudo foi construir e validar um *bundle* para o manejo e prevenção de infecção de pele por queimaduras em crianças e adolescentes. **Métodos:** estudo metodológico desenvolvido em um Centro de Tratamento de Queimados no norte do Paraná de março de 2021 a dezembro de 2023. A pesquisa foi desenvolvida em três fases, teórica, empírica e analítica, mediante análise estatística no *Statistical Package for the Social Sciences*. **Resultados:** a validação de conteúdo do *bundle* foi realizada por sete profissionais *experts* na temática. Quanto à validade de conteúdo do *bundle*, houve uma concordância de 100% entre todos os participantes diante das dimensões avaliadas: objetividade; *layout*; simplicidade; clareza; relevância; variedade; amplitude; credibilidade; e equilíbrio. Para a verificação da validade de conteúdo do *bundle*, foi utilizado o Índice de Validade de Conteúdo. Dos nove itens na validação com os juízes, o Índice de Validade de Conteúdo foi igual a 1,0. Em conformidade com os resultados e mínimas sugestões no *bundle*, foi decorrida apenas uma rodada na validação com os juízes. **Conclusão:** o *bundle* foi validado para subsidiar o tratamento de queimaduras grave devido à complexidade do manejo cuidadoso e multidisciplinar.

Descritores: *Unidades de Queimados. Programa de Controle de Infecção Hospitalar. Pacotes de Assistência ao Paciente. Queimaduras.*

RESUMEN

Justificación y Objetivos: las infecciones de la piel pueden ocurrir en pacientes con quemaduras debido a la pérdida de la principal barrera protectora e inmunológica. Aunque existen protocolos generales para tratar quemaduras y prevenir infecciones, pocos son adecuados exclusivamente para niños y adolescentes. Con el objetivo de prevenir y mejorar la atención de rutina, el objetivo del estudio fue construir y validar un paquete de medidas para el manejo y la prevención de la infección de la piel por quemaduras en niños y adolescentes. **Métodos:** estudio metodológico desarrollado en un Centro de Tratamiento de Quemados del norte de Paraná de marzo de 2021 a diciembre de 2023. La investigación se desarrolló en tres fases, teórica, empírica y analítica, mediante análisis estadístico en el *Statistical Package for the Social Sciences*. **Resultados:** la validación de contenido del paquete fue realizada por siete profesionales expertos en el tema. En cuanto a la validez de contenido del paquete, hubo 100% de acuerdo entre todos los participantes respecto de las dimensiones evaluadas: objetividad; disposición; sencillez; claridad; pertinencia; variedad; amplitud; credibilidad; y equilibrio. Para comprobar la validez del contenido del paquete, se utilizó el Índice de Validez del Contenido. De los nueve ítems validados con los jueces, el Índice de Validez de Contenido fue igual a 1,0. De acuerdo con los resultados y las sugerencias mínimas del paquete, solo se realizó una ronda de validación con los jueces. **Conclusión:** el paquete fue validado para apoyar el tratamiento de quemaduras graves dada la complejidad del manejo cuidadoso y multidisciplinario.

Palabras Clave: *Unidades de Quemados. Programa de Control de Infecciones Hospitalarias. Paquetes de Atención al Paciente. Quemaduras.*

INTRODUCTION

According to the World Health Organization, burns are considered the fourth most common type of trauma in the world. They constitute a major global health concern, significantly impacting the affected population's quality of life, affecting all age groups, and can cause minor, serious injuries and death.[1]

Most of the burns reported in Brazil occurred in the victim's home, with half of them involving children. According to data from the Brazilian Health System Department of Information Technology[2], between September 2020 and August 2021, there were more than 9,000 hospitalizations of newborns, children and adolescents who were victims of burns.[2] The most affected age group was 1 to 4 years.[2] It is estimated that approximately 1 million Brazilians suffer burn accidents annually. Of these cases, approximately 100,000 require hospitalization and approximately 2,500 result in death.[3]

Those who suffer extensive and severe burn injuries require intensive care and are often admitted to Burn Treatment Centers (BTCs) for prolonged hospital stays.[4-5]

Thus, the need to develop simplified protocols and packages of measures, based on high-standard evidence literature, is essential to guide and improve professional practice and, consequently, improve care, given the positive impacts on care contributing to the improvement of care provided.[6-7]

As a result, in the mid-2000s, in the United States of America, standardized bundles emerged, with the aim of implementing protocols for the prevention of infection, aiming to improve care and hospitalized individuals' quality of life.[8]

Therefore, to facilitate the teaching-learning process, the use of educational technologies is essential to raise awareness and encourage new evidence-based practices in the construction of knowledge, in addition to enabling decision-making. Such educational tools can be booklets, folders, pamphlets, leaflets and manuals, serving as a guide for health promotion.[9]

In Brazil, this topic is considered relatively recent and some hospital units are still in the process of implementation. Although studies present some conducts, there is still no systematic evidence in literature of bundles regarding the prevention and management of infection in skin lesions due to burns in children and adolescents.

This age group undoubtedly presents unique challenges due to their thinner skin and still developing immune system, as well as the specialized center where this study was conducted, not having a bundle for children and adolescents with burns. Thus, the importance of its construction and validity is justified. Therefore, the construction and validity of a specific bundle for burns in pediatrics are essential to ensure the best adherence of professionals.

Considering the importance of preventing and managing infection in burn skin injuries in children and adolescents to aid daily practice and improve the quality of care provided, the question is: is the construction of a bundle valid and feasible for implementation in a specialized center to improve care planning and promote benefits in the therapeutic process? Therefore, this study aimed to construct and validate a bundle for the management and prevention of burn skin infections for children and adolescents.

METHODS

This is a methodological study developed in a specialized center in a public tertiary university hospital, in the northern region of the state of Paraná, from March 2021 to December 2023.

This study was conducted at a referral hospital in the northern region of Paraná that provides specialized care to children, adolescents, adults and elderly victims of first- to third-degree burns. This unit has been in existence for over 15 years, with capacity for ten ward beds, six Intensive Care Unit (ICU) beds, a balneotherapy room, two surgical rooms, an outpatient clinic (Emergency Care) and a hyperbaric oxygen therapy room.

The research was developed in three phases: (a) theoretical phase consisting of literature review, prototype construction, layout development, design and texts; (b) empirical phase consisting of a dialogued expository class and bundle assessment by professionals working in care and experts in the area; (c) analytical phase consisting of the application of statistical analysis.

Theoretical phase: the first phase was carried out from March to June 2021. The following descriptors (DeCS/MeSH) were used for literature review: “Burn Units”, “Hospital Infection Control Program”, “Patient Care Bundles” and “Burns”, combined with the Boolean operator AND. Original studies, systematic reviews, open access, published between 2010 and 2023 were included, with the aim of covering the most recent studies in the area of interest, in the Virtual Health Library, Scientific Electronic Library Online and Latin American and Caribbean Literature in Health Sciences databases. Gray literature was also used, consisting of manuals and protocols on healthcare-related infections from the Ministry of Health and the Brazilian Burn Society. Duplicate studies were excluded. The instrument was constructed in a diagram, in which each structured figure has the main aspects and relevant content to guide decision-making in clinical practice.

Empirical phase: in the second phase, the sample of professionals was intentionally selected, with the following inclusion criteria: being a professional working at BTC for more than one year in the categories: nursing technicians, nurses and physiotherapists. It should be noted that the bundle is applicable to children ≤ 12 years of age and adolescents (between 12 and 18 years of age).

Subsequently, participants were approached through successive conversations with the team involved and professionals who were experts in the area. The invitation was made in person by the main researcher and explained their participation in the research, the research objectives and methods, guaranteeing anonymity through the signing of the Informed Consent Form. After that, professionals were scheduled for classes according to their availability during the morning, afternoon and evening work shifts.

To assist in the bundle construction and improvement, the researcher held a 30- to 40-minute lecture to guide the team during each work shift. Afterwards, a questionnaire with two open-ended questions was applied for participants to describe the skin infection prevention measures carried out in the sector and what other measures would be feasible to implement.

After analyzing the feasibility, available literature and meetings with experts, considering the exchange of knowledge, five measures were defined to compose the bundle, namely: 1 – Room cleaning twice a day, a terminal cleaning when the room is unoccupied or weekly in prolonged hospitalizations; 2 - Strict hand hygiene; 3 - Use of personal protective equipment; 4 - Early excision and grafting of full-thickness burns; 5- Use of topical antimicrobial dressings.

Throughout the period of the dialogued intervention, participants were free to contribute to discussions on the topic, integrating knowledge and perspectives permeating exchange of knowledge. The entire process of construction and elaboration took place between April and August 2022.

Data collection and expert participation took place in an online round. The link was sent via WhatsApp®, using the Google Forms® electronic tool, and the bundle was attached to the questionnaire, which included data related to expert characterization (age, gender, current occupation, professional category, time since graduation, title and time working in the burns area) and the Content Validity Instrument, composed of 9 items that assessed objectivity, layout, simplicity, clarity, relevance, variety, breadth, credibility and balance. Each item contained affirmative sentences on a 5-point Likert scale and, after reading the material and assessing the bundle, judges could assess the item as (5) totally agree, (4) partially agree, (3) neither agree nor disagree, (2) partially disagree and (1) totally disagree. Judges were instructed

to justify the scores 1, 2 and 3. This assessment and validity phase took place in December 2023.

Analytical phase: data organization and analysis were performed using the Statistical Package for the Social Sciences version 19. To characterize professionals, descriptive analysis was used, available in numbers and percentages, and judges were characterized. A descriptive data analysis was performed, with the calculation of absolute and relative frequencies. To verify the bundle content validity, the Content Validity Index (CVI) was used, with the calculation of the Item-Level Content Validity Index for each item of the instrument and the overall CVI. The bundle was considered valid when each item obtained a CVI equal to or greater than 0.80.

This study was conducted in accordance with the recommendations set out in Resolution 466/2012 of the Brazilian National Health Council. The study is part of a research project entitled "*Avaliação das infecções relacionadas à assistência à saúde em crianças e adolescentes*", approved by the *Universidade Estadual de Londrina* Research Ethics Committee on April 26, 2020, under Opinion 3.991.033 and Certificate of Presentation for Ethical Consideration 28068119.6.0000.5231.

RESULTS

The theoretical phase allowed for a literature review, which enabled the bundle construction, and after consensus meetings with the entire BTC team, in the empirical phase, the intervention was carried out through a dialogued class with the participation of 53 professionals. However, of these, 30 met the inclusion criteria for the protocol elaboration, being 18 nursing technicians (60%), seven nurses (23.3%) and five physiotherapists (16.7%), with an average age of 44.5 years. As for the most frequent qualification was higher education (40%), followed by specialization (23.3%), technical education (16.7%) and master's and doctoral degrees (10%). Concerning the time of professional experience in the research sector, 53.3% had 11 to 15 years, 26.7%, 1 to 5 years, and 20%, 6 to 10 years.

The content was structured based on scientific evidence, practical experience of the researcher, healthcare professionals and experts, all working in the research scenario, considering the individual needs and distinct specificities of children and adolescents who are victims of burn injuries. The material was developed by the researcher using the Microsoft PowerPoint - Microsoft 365® program to create illustrations and a textual diagram structured in topics (Figure 1).

After the construction and intervention were completed, banners containing the bundle were created and installed in the different BTC units (ward, ICU, balneotherapy and surgical

rooms) for access and visibility by the entire team. The same printed material contained a QR Code so that the protocol could be circulated both among the BTC team and in the scientific community, configuring itself as a safe and effective tool for multidisciplinary assistance to individuals who are victims of burns (Figure 2).

It is important to emphasize that the bundle was presented to all healthcare professionals involved in the study so that the protocol's relevance and usefulness could be emphasized and, consequently, implemented through continuous adherence through team collaboration and involvement working at the BTC.

After the theoretical and empirical phase, the final version of the bundle for management and prevention of skin infection due to burns for children and adolescents was created, consisting of five measures:

1) Room cleaning twice a day, a terminal cleaning when the room is unoccupied or weekly in prolonged hospitalizations

Critical areas are where there is an increased risk of infection transmission, where immunocompromised patients are found:[10-11]

- BTC;
- ICU;
- Operating Room.

2) Strict hand hygiene

In critical areas such as units with immunocompromised patients, the hands of healthcare professionals can be colonized by pathogenic microorganisms.[12]

- Rubbing antiseptic on hands: 20 to 30 seconds;
- Hand hygiene with soap and water: 40 to 60 seconds;
- Antiseptic hand hygiene: 40 to 60 seconds;
- Surgical antisepsis or preoperative hand preparation:

  3 to 5 minutes – first surgery;

  2 to 3 minutes – subsequent surgeries.

3) Use of personal protective equipment

Personal protective equipment is one of the measures in the prevention and control of infections in sectors that care for critical patients with bacterial resistance due to the high frequency of antibiotic use and disruption of the tissue barrier.[13]

4) Early excision and grafting of full-thickness burns

Excision and closure of deep wounds help prevent sepsis, decrease systemic inflammation, and speed healing. The wound may be covered with:[14]

- Autograft,
- Allograft;
- Synthetic substitute fabric.

5) Use of topical antimicrobial dressings

- Protect the damaged epithelium;
- Minimize bacterial and fungal colonization;
- Provide immobilization to maintain the appropriate functional position;
- Be occlusive to minimize heat loss and cold aggression;
- Provide comfort to the painful wound.[15]

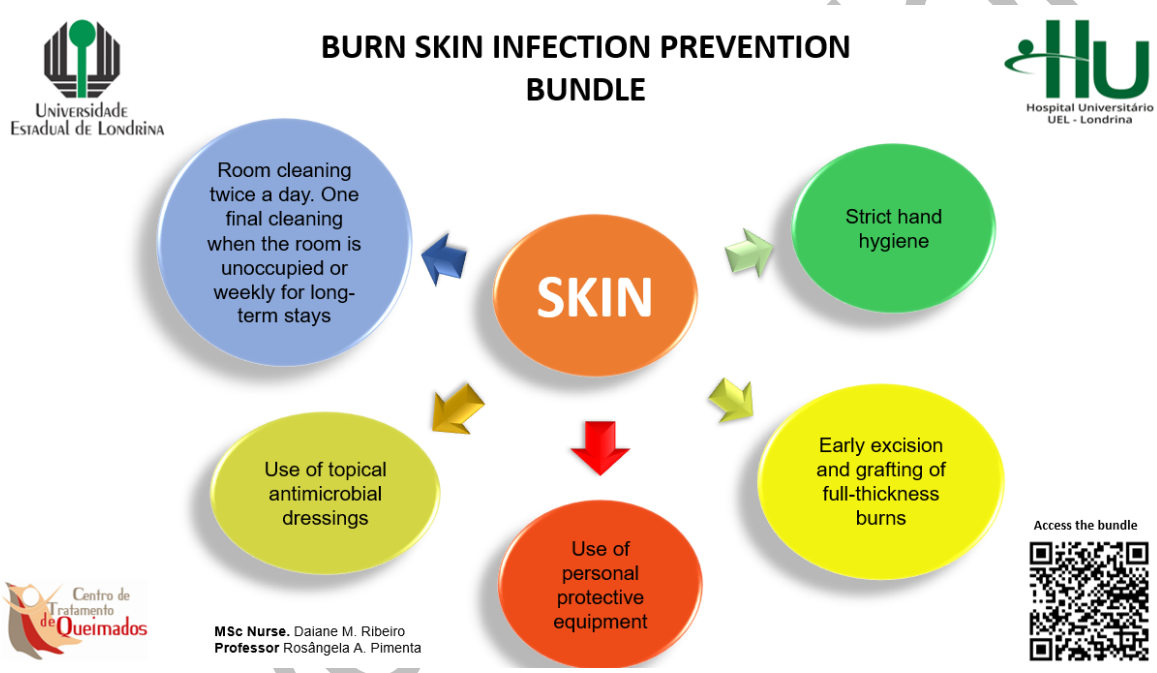

Figure 1. Burn skin infection prevention bundle. Londrina, Paraná, Brazil, 2024

Figure 2. Bundle installed in the Burn Treatment Center units (ward, Intensive Care Unit, balneotherapy and surgical rooms). Londrina, Paraná, Brazil, 2024

Also in the empirical phase, the bundle underwent content validity by seven professionals considered experts on the subject, including one physician (14.3%), three nurses (42.8%) and three physiotherapists (42.8%), with an average age of 44.5 years. As for qualifications, four had master's degree and three had doctoral degree.

In relation to professional time at the research site, 42.9% had 6 to 9 years, and 57.1% had ≥10 years, with 57.1% working in management, 28.6% in care, and 14.3% in care and management simultaneously. Regarding training time, 85.7% had ≥20 years.

As for the bundle's content validity, there was 100% agreement among all participants regarding the dimensions assessed: objectivity; layout; simplicity; clarity; relevance; variety; breadth; credibility; and balance. The CVI of the nine items in validity with judges was equal to 1.0. In accordance with the results and the minimum suggestions in the bundle, only one round of validity with experts was carried out.

Experts' suggestions referred to adjustments in the text, in the simplicity item, replacing the term "skin" with "injury, burn or lesion". The suggestion was not accepted, since the protocol addresses burn injuries to the skin, considering that the skin is the site of infection and other terms are defined as trauma. Furthermore, in the clarity item, it was requested that the action verb be in the infinitive to intensify the instruction. The suggestion was not accepted, considering that the protocol is intended to guide and direct care practice, aiming to list subsidies for the prevention of infection and not to establish conduct.

Furthermore, it was suggested in the variety item that the types of antimicrobial dressings and their respective change times could be exemplified. In accordance with the other items, this was not accepted, as the study sector already has a protocol of recommendations for covering injuries according to the type of burns.

It is worth noting that experts' suggestions did not invalidate the protocol already assessed and validated. From the same point of view, interviewees showed good acceptance of the instrument due to the topic, which promotes quality of care with better benefits, ensuring patient safety.

As a result, the bundle validity protocol Item-Level Content Validity Index showed a maximum agreement of 1.0 among all judges/experts, in the nine dimensions, namely objectivity, layout, simplicity, clarity, relevance, variety, breadth, credibility and balance.

DISCUSSION

Burn patients are exposed to organic changes that make them vulnerable to infectious conditions, increasing their susceptibility to infection due to trauma, such as the breakdown of

the protective barrier, the skin, which becomes a predisposing factor for microbial colonization and growth. Moreover, prolonged hospitalization and invasive procedures intensify systemic inflammation. Thus, morbidity is high and alarming, with sepsis being the main cause of death.[16] In view of this, care for critically ill burn patients and prevention of infection are of utmost importance for their outcome; therefore, knowledge of the signs and symptoms of infection is essential for a good prognosis.[17-18]

In this sense, it is essential to clean the wound by applying dressings to burn injuries, thus stimulating the healing process and preventing infection associated with the injury. To achieve these goals, dressing technologies that individualize care must be used.[19]

In view of this, the appropriate management of burn victims, combined with the application of specific protocols and ongoing training of the multidisciplinary team, underpins a fundamental strategy for preventing infections.[20] It is important to highlight that the available studies were conducted mostly with adult patients, highlighting a gap in research aimed at the child and adolescent population.

From the same point of view, literature expresses that bundles have been widely applied in the standardization of protocols as a crucial strategy to improve quality of care and prevention of infections in burn patients in contemporary times.[21]

Thus, there is evidence that healthcare professionals can contribute to validity processes of materials as resources in health education as a pertinent point in the teaching-learning process, especially in therapeutic mediation. Furthermore, the bundle enriches knowledge, improves attitudes, skills and autonomy, encouraging adherence to essential treatments, according to the findings.[22]

Therefore, the instrument validity process demonstrates in practice that the material produced may be capable of improving clinical practice and allowing the target audience to be presented with material that has relevant, clear, understandable content and is based on scientific evidence.[23]

As a result, item construction and content validity, the first stage, were carried out based on the theoretical basis of the construct, involving the definition of properties, the determination of the dimensionality of attributes and the elaboration of constitutive and operational definitions. In the second stage, data collection was carried out to assess the properties and applicability of the instrument. Finally, the third stage consisted of the execution of analytical procedures.

The instrument was constructed based on behavioral criteria, with objectivity, simplicity, relevance in content, accuracy and variety, transmitting credibility and clarity in the

information provided, presenting breadth on the topic exposed, balance between the content cited and the definition of the instrument.[24]

Thus, the protocol emerges as a fundamental instrument to guide clinical practice, by offering objective and accessible information as a therapeutic tool endorsed as a safe and effective resource. In addition, it is recommended to be used by the multidisciplinary team in specialized centers as a teaching-learning resource, providing continuous updating in health practices according to innovations in the theoretical, methodological, scientific and technological fields, consequently, significantly collaborating with improvement and qualification of care.

Furthermore, new studies can be produced from the application of the bundle in the BTC of the aforementioned institution and in others, which will presumably enable new and valuable contributions to the topic of treatment, also benefiting adult patients with burn injuries.

It is worth noting that, due to the implementation, an institutional protocol was created for the management and prevention of skin infections due to burns in children and adolescents. A WebQuest will be developed in order to assist daily practice, improve the quality of care provided based on evidence and encourage teaching and learning in pedagogical practice as a strategy, recognizing the knowledge that exists in everyday life and strengthening the development of the work process.

A limitation of this study is the fact that it was developed at a local level and was not applied in other units for comparison purposes. Another point is the need for continued assessment and adherence to the bundle by professionals, as well as ongoing health education by the hospital, since the intervention was carried out to begin the implementation process for research purposes. It is also worth emphasizing that there are still few literary findings regarding the use of the bundle as a preventive measure for skin infection due to burns in specialized treatment centers.

It was concluded that the research provided the construction and validity of a bundle for the prevention of skin infections due to burns, developed in collaboration with judges who are experts in the subject. It is expected that the bundle will be used as an educational tool, contributing to the strengthening of health education in several BTCs, including for the adult population. The implementation of educational interventions for health promotion requires specific practices adapted to the needs and particularities of each individual. The bundle construction is valid as a teaching-learning tool to develop educational actions in healthcare practice focused on the subject, since it obtained agreement from all judges regarding objectivity, layout, simplicity, clarity, relevance, variety, breadth, credibility and balance.

Therefore, by validating the protocol as an educational strategy in health, it was able to facilitate motivation and understanding, in addition to supporting the management in treatment of children and adolescents who are victims of burns.

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