

## REGULATIONS IN THE CARE OF PRESSURE ULCERS: AN INTEGRATIVE REVIEW



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## **ABSTRACT**

Pressure ulcers (PU) represent a serious health problem, especially in the hospital environment. Knowledge of legal instruments is vital for health professionals, as it contributes to the creation of a safe environment. Objective: to describe the legal norms involved in nursing care for pressure injuries. Method: This is a qualitative and quantitative integrative review. Results and discussions: 8 publications were selected for the construction of the booklet related to the care and responsibility of the team regarding pressure injuries. Conclusion: The care of pressure injuries goes beyond a technical obligation; It is an ethical commitment to the dignity and well-being of the patient.

**Keywords:** Patient safety. Pressure injury. Legislation

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## INTRODUCTION

Pressure injury (LP) is characterized as localized damage to the skin and/or underlying tissues, often over a bony prominence due to prolonged exposure to pressure or a combination of patient-related intrinsic and extrinsic factors, and may also be linked to the use of medical devices (NPIAP, 2023).

In this context, the history of pressure injury (PU) spans several decades and is intrinsically linked to the evolution of medicine and health care. Knowledge about the emergence of pressure injuries began in the nineteenth century, when Florence Nightingale observed the connection between the patient's position in bed and the appearance of these injuries (Peça, 2016).

From then on, in 1950, the first descriptions of LP in hospitalized patients appeared, the first terms used to describe them were: "decubitus ulcers" and "bedsores". By 1980, the terminology was standardized and the term "pressure injury" was widely circulated. By the 1990s, knowledge about LP prevention had increased significantly. Thus, risk assessment and patient rehabilitation have been incorporated into health care (Soares *et al*, 2023).

In light of this, the Guidelines for Clinical Practice PUayed a crucial role, providing systematized recommendations aimed at guiding health professionals and patients in making decisions related to their care. In 1994, the US Health Policy and Research Agency presented the first specific guideline on PU, which considered the organizational flow, procedures, decision points, and management of the problem (Caliri, 2020).

The release of the report "To Err Is Human: Building a Safer Health System" by the United States Institute of Medicine (IOM) in 1999, marked a significant advance in the field of patient safety, highlighting concerns about medical errors and their consequences on the health system. This has resulted in subsequent initiatives to promote a robust safety culture in healthcare systems globally (Romero *et al*, 2018).

Still on the historical framework of LP, in 2009, the European Pressure Ulcer Advisory Panel (EPUAP) and the National Pressure Ulcer Advisory Panel (NPUAP), currently known as the National Pressure Injury Advisory Panel (NPIAP), produced an expanded version of the existing guideline. This effort was supported by collaborators and specialists, including recommendations for the prevention and treatment of LP (Caliri, 2020).

Soon after, in 2014, the EPUAP and NPUAP, in partnership with the Pan Pacific Pressure Injury Alliance (PPPIA), launched the second guideline for the prevention and treatment of LP. This update has broadened its scope to include medical device-related pressure injury. The recent edition, published in 2019, incorporated contributions from Brazil through the Brazilian Society of Stomatherapy (SOBEST), emphasizing the inclusion of the perspective of patients and informal caregivers (Jansen; Silva; Moura, 2020).

Nursing encompasses a set of scientific and ethical knowledge, developed from social, ethical and political practices, which are manifested through teaching, research and care. In this context, ethical-professional knowledge involves both individual and collective conscience, in addition to social and professional commitment (CONSELHO FEDERAL DE ENFERMAGEM, 2007).

The Nursing Code of Ethics (CEPE) recognizes the population's need and right to nursing care, as well as professional interests, assuming that workers are allied with users through care without risks and damage to health. This normative document has a set of principles necessary for development in the professional field, in the rights, duties, and prohibitions that guide the exercise of the profession (Silva, 2021).

The Law of Professional Nursing Practice aims to protect the professional and the patient, in order to ensure that care is carried out in a competent and responsible manner. This legislation establishes the guidelines and responsibilities of nurses, nursing technicians and auxiliaries, regulating their functions and ensuring that they act in accordance with ethical and scientific standards. In addition, it favors professional appreciation and recognition in the context of the health system (Pereira, 2014).

However, regulations establish technical standards and requirements to ensure the quality and safety of healthy services. Knowledge of these legal instruments is vital for health professionals and hospital managers, as it contributes to the creation of an environment that promotes patient safety and the quality of care offered (Kottner, 2020).

This study reveals its importance by searching the scientific literature for the legal norms involved in the professional practice of nursing in the care of pressure ulcers. Pressure ulcers (PU) represent a serious health problem, especially in the hospital environment. Although its origin is multifactorial, the nursing team carries a significant responsibility, both in prevention and in the maintenance of care. Thus, the study aims to understand the legal regulations pertinent to this area of knowledge and their implications for the promotion of care and the quality of care provided.

In view of the above, the present study aims to describe the legal norms involved in nursing care for pressure injuries.

## METHOD

### TYPE OF STUDY

This is an integrative review and a translational study. To delineate the theme and question of the study, the PICO method was applied, a mnemonic method for identifying the key topics: Population/problem, intervention, comparison, and outcome (Roever *et al*, 2022). Using the aforementioned strategy, the following guiding question was elaborated: *What are the norms identified in the care of Pressure Injuries?*

The bibliographic survey will be carried out in a virtual location, through a database, including: **Virtual Health Library (VHL)**, **Google Scholar** and **SciELO**, in addition to materials that address legal content on the performance of nursing, such as standards and resolutions of the nursing regulatory body and its municipal representatives.

The search strategies were carried out by crossing the Health Sciences Descriptors (DeCS/MeSH): pressure injury; legal liability; Brazil, in a combined manner, to facilitate the search through the Boolean operator "AND", considering the following search parameter "patient safety" AND "pressure injury" and "legislation" AND "pressure injury".

### STUDY LOCATION AND SAMPLE

The study site took place through the analysis of legal norms and articles found in full, related to preventive measures and care for pressure injuries and their interface in Brazilian legislation. In addition, Florence Nightingale's environmentalist theory and ANVISA's 2013 National Patient Safety Program were used as a theoretical framework.

There will be no sample calculation, since the sampling was probabilistic of the intentional type.

### METHODOLOGICAL PROCEDURES

The formulation of the research question was developed through the application of the PICO strategy. Evidence-based practice (EBP) advocates the placement and organization of clinical problems presented in care, educational, or research practice, using the PICO mnemonic as a methodological guide. PICO represents an acronym for

Patient (P), Intervention (I), Comparison (C), and Outcomes/outcome (O) (GALVÃO et al., 2021).

**Table 1** presents the four elements of the PICO strategy, accompanied by their respective descriptions.

**Table 1** – Elements of the PICO of the study.

Acronym	Definition	Description
<b>P</b>	Population	A patient or group of peoPUe with a specific health problem or condition.
<b>I</b>	Intervention	It comprises the intervention of interest, which can be therapeutic (e.g., types of dressings), preventive (e.g., preventive measures for PF), diagnostic (e.g., staging of the LP), prognostic, administrative (e.g., ordinances, resolutions and/or norms) or related to economic matters.
<b>C</b>	Comparison or Control	ImPUementation Of standard intervention, most prevalent intervention or absence of intervention.
<b>O</b>	Outcome (outcomes)	A result that is expected to be achieved.

**Source:** Authors (2023).

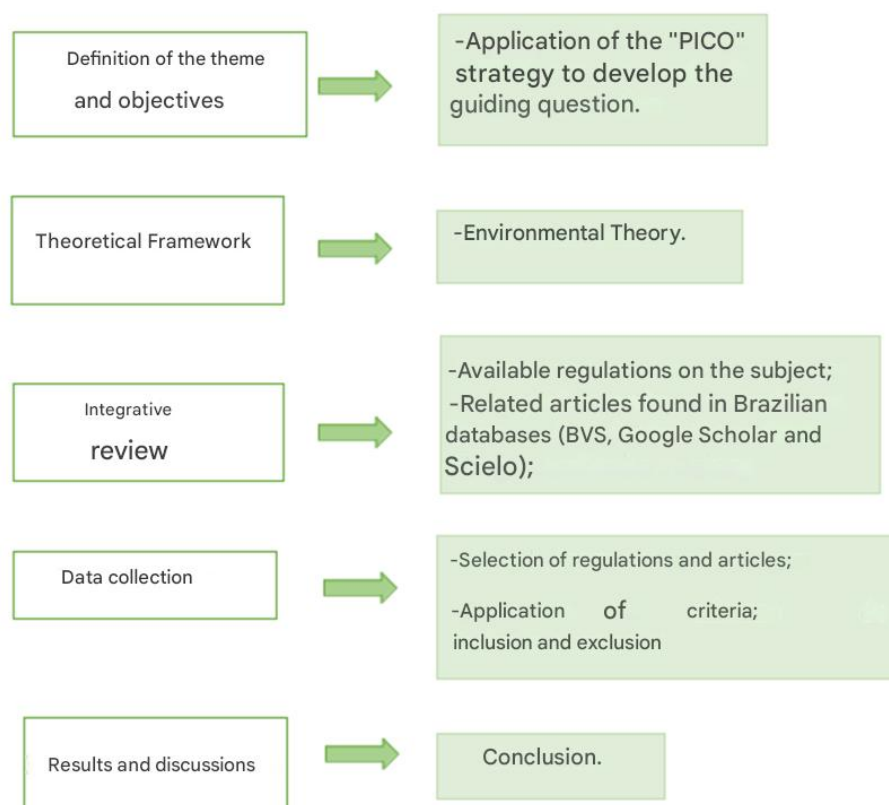
For the formulation of the question in this study, component 'P' encompasses the population with pressure injuries. As for "I", it covers the intervention of interest (preventive, diagnostic and administrative). Regarding the "C", it comprises the legal norms available for Brazilian nursing, including those less known, the most widely used in health institutions. Finally, the "O" component refers to the existing legal aspect in favor of health care related to the prevention of pressure injuries and its apPUication.

To design the research, a survey was carried out about the legal regulations present in Brazil. First, a list was prepared covering each of the standards related to pressure injury, and they were listed as follows: 1- COFEN/COREN; 2- MINISTRY OF HEALTH/ANVISA/Patient Safety; 3- Code of Ethics for Nursing Professionals/Law of Professional Practice. Then, the reading and separation of those that fit the objectives of

the research was carried out. Finally, those related to pressure injuries and patient safety were incorporated into the study.

The methodological sequence for data collection in the research will be presented in the following flowchart, facilitating the understanding and exemplification of the methodology.

**Figure 1:** Methodological flowchart



**Source:** Authors (2023).

The inclusion parameters adopted in the research include articles published over the last 10 years, in English, Portuguese and Spanish; full text available; Keywords related to pressure injuries, pressure injury care, prevention and laws of professional practice.

On the other hand, the exclusion criteria will be applied to articles not available in full, repeated review articles; gray literature.

## ETHICAL ASPECTS

The study will involve only documentary and bibliographic issues, and does not require consideration by the Research Ethics Committee of the Federal University of Sergipe and by the Teaching and Research Management of the HU-SE.

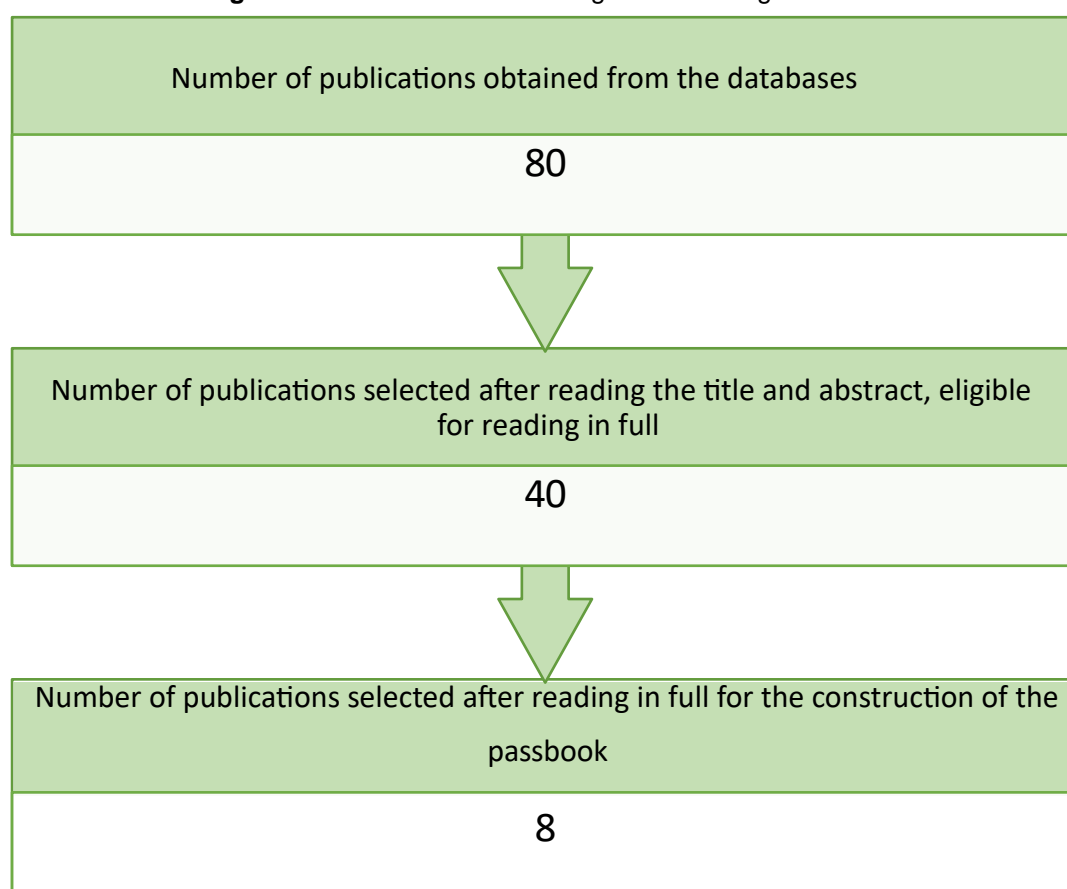


## RESULTS

### INTEGRATIVE REVIEW

80 publications were found from the search in the databases, of which 30 were identified in the VHL, 40 in Google Scholar and 10 in Scielo, 40 were chosen for full reading. Of these, 8 publications were selected for the construction of the work

**Figure 2** – Flowchart for selecting and choosing articles.



**Source:** Authors (2023).

Table 1 summarizes the articles selected for the construction of the work, which are ordered in descending order according to the year of publication. Information regarding the authors, title, objective and conclusion of the respective study were also included. It is noted the presence of one article published in 2016, three published in 2018, one published in 2019, one published in 2020 and two published in 2021. Most of the articles refer to the care and responsibility of the team regarding pressure injuries.



**Table 3** – Articles selected from the integrative review used in this study.

AUTHORS/ YEAR OF PUBLICATION	TITLE	GOAL	CONCLUSION
<b>Silva et al, 2016</b>	Patient safety in the hospital environment: Integrative Review of Literature.	Identify the main themes addressed in the environment hospital for patient safety.	The analysis allowed us to highlight that, it is necessary to to research in order to meet the wishes of professionals about appropriate methods of conducting and improve the quality of care through the control and prevention of adverse events, in order to achieve a better assessment of the quality of care.
<b>Tonole; Brandão, 2018</b>	Human and material resources for the prevention of pressure injuries.	Describe recommendations on human and material resources directed to the prevention of pressure injuries.	No specific recommendations and instruments were identified to assess the adequate quantity of Human and material resources in the prevention of pressure injuries, demonstrating the need for develop and imPUement technologies.
<b>Romero et al, 2018</b>	Patient safety, quality of care and ethics of health systems.	Patient safety is a key component of quality of care. In 2003, the Hastings Center published the report "Promoting Patient Safety: An Ethical Basis for Policy Deliberation."	The ethical obligations surrounding the prevention of medical errors and the promotion of patient safety are configured by the four princiPUes of bioethics. These obligations are not only personal duties of each of the professionals, but also of the health institutions as a whole.

<b>Sokem et al, 2021</b>	Knowledge of the team Nursing on pressure injuries.	Assess the level of knowledge of the nursing staff of a hospital's medical clinic university student on pressure injury.	A weakness in knowledge about pressure injuries was identified. The Health Institutions must implement educational actions on this problem.
<b>Leão; Silva; Lanza, 2019</b>	Prophylaxis of pressure injuries: a look at the accountability of Team of nursing.	Patient safety is an important topic that should always be A concern of health professionals and one of the goals of care delivery. The prevention of pressure injuries is considered essential in this context. Therefore, the prophylaxis of PF is an ethical and legal commitment of the team nursing.	Education is the most effective means to be developed by the nursing team, stimulating critical action, reflective, purposeful, committed and technically efficient, the that assists in the impUementation of the measures of safety of the patient.
<b>Jansen; Silva; Moura, 2020</b>	The Braden Scale in the assessment of risk for pressure injury.	Analyze the ApPUicability of the Braden Scale with the nursing diagnosis "impaired bed mobility", in its potential for predicting development of pressure injury.	The performance of the Scale of Braden presented a balance between sensitivity and specificity, proving to be the best predictive instrument of risk in this clientele.
<b>Silva, 2021</b>	New Code of Ethics for Nursing professionals: an innovative document.	To analyze, in comparison with its previous versions, the innovations presented in the new Code of Ethics for Nursing Professionals.	The changes in the latest edition reveal an updated document incorporating constitutional provisions in force at the national and international levels.

<b>Galetto <i>et al</i>, 2021</b>	Perception of nursing professionals about medical device-related pressure injuries.	To know the perception of nursing professionals working in intensive care units about pressure injuries related to medical devices.	Nursing's perception of pressure injuries related to medical devices is linked to the types of devices, the care offered and the impact of injuries on the peoPUe's lives.
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**Source:** Authors (2023).

For the elaboration of the work, there was also the reading and selection of the current regulations on the subject. Therefore, legal content on nursing performance was listed, such as norms and resolutions of the nursing regulatory body and its municipal representatives, listed in Table 2.

**Table 4** – Regulations included for the preparation of the work.

<b>Regulatory</b>	
<b>COFEN Resolution 240/2000</b>	Approves the nursing code and gives other Arrangements.
<b>COFEN Resolution No. 567/2018</b>	Resolution expands the role of Nursing in the wound care.
<b>Ordinance GM/MS No. 1,377 of July 9, 2013</b>	Approves patient safety protocols.
<b>GVIMES/GGTES Technical Note No. 5 of 2023</b>	Patient Safety Practices in Services Health Department: Prevention of Pressure Injuries.
<b>Integrated PUan for Sanitary Management of Patient Safety 2021 – 2025</b>	Prepared by Anvisa with the objective of integrating the actions of the National Health Surveillance System (SNVS) to promote quality of care and patient safety with a view to risk management and the improvement of health services.
<b>Law No. 7498/1986 on the Professional Practice of Nursing</b>	Provides for the regulation of the exercise of the nursing and provides other provisions.

**Source:** Authors (2023).

## STANDARDS AND REGULATORY CONTENT

According to the Code of Ethics for Nursing Professionals (CEPE), approved by COFEN Resolution 240/2000, professionals must ensure care free of damages resulting from malpractice, negligence or imprudence, as well as update their technical-scientific knowledge for the benefit of the clientele and their professional development, as stated in articles 16 and 17 of the responsibilities (Silva, 2016).

It should be noted that the work of nursing professionals in the care of peoPUe with wounds is regulated by the Federal Nursing Council, through COFEN Resolution No. 567/2018, which evidences the autonomy of nurses for the evaluation, elaboration of protocols, selection and indication of technologies for care, in addition to the opening of a Clinic/Office for the Prevention and Care of PeoPUe with Wounds (COFEN, 2018).

In addition, it is necessary to respect technical and legal competences, so COFEN Resolution No. 567/2018 details the participation of nursing professionals in the prevention and treatment of peoPUe with skin wounds in line with the technical competencies of each category provided for by the Law of Professional Nursing Practice and Nursing Code of Ethics (COFEN, 2018).

Patient safety is a global public health challenge and pressure injury is considered a worldwide health problem. Sometimes, the onset is associated with clinical and comPUications of the patient's health condition, and is inevitable. However, in other circumstances, it may be related to malpractice, recklessness and/or negligence during the execution of care, and is avoidable. To minimize this, there are rules that deal with the subject, which require care records and notification to start the investigation process (Romero *et al*, 2018).

It is known that if a pressure injury is detected, it should be immediately treated and notified. Therefore, for this to be effective in clinical practice, it is necessary to have institutional protocols based on scientific evidence, as well as training and qualification of emPUoyees on the routines developed in care (Soken *et al*, 2021).

The National Patient Safety Program, through Ordinance GM/MS No. 1,377 of July 9, 2013, instituted basic protocols for client safety, highlighting among them, the reduction of the risk of PU in health institutions (MINISTRY OF HEALTH, 2014).

The GVIMES/GGTES Technical Note No. 5 of 2023, updates the note published in 2017, listing as objectives to guide managers and professionals, scheduled in the patient safety center, on the general measures for monitoring and surveillance of adverse events (AE) related to health, as well as in the promotion of PU prevention practices. In addition to strengthening information regarding surveillance, monitoring, and reporting of AEs, especially those related to PU (ANVISA, 2023).

This Technical Note reinforces the Integrated PUan for the Sanitary Management of Patient Safety 2021 – 2025, which aims to unite the actions of the National Health

Surveillance System to provide quality of care and patient safety, providing opportunities for risk management and optimizing care indicators (ANVISA, 2022).

Every health unit must adopt organizational protocols, including pressure injury (PU) preventive measures, according to the guidelines of the Patient Safety Center. Technical Note GVIMS/GGTES/ANVISA No. 05/2023 reinforces the role of States, Municipalities and Federal Districts in supporting NPS and Health Surveillance in PU monitoring and prevention actions, according to the Integrated PUan for the Sanitary Management of Patient Safety in Health Services 2021-2025 (Galetto *et al*, 2021).

Prevention of pressure injuries is essential when it comes to patient safety. In 2022, the Regional Nursing Council of São Paulo launched an informative booklet addressing the ten steps to promote patient safety, with pressure injuries being the ninth step, constituting an ethical-legal commitment of nursing (Rocha *et al*, 2023).

The accountability of nursing professionals in relation to pressure injuries is based on the ethical and technical standards of the Federal Nursing Council (COFEN) and the Regional Nursing Councils (COREN). The responsibility of the nursing team for the appropriate management of these injuries involves both prevention and effective treatment, and non-compliance with these practices can have ethical and legal implications (Leão; Silva; Lanza, 2019).

Article 11 of the Law of Professional Nursing Practice deals with the competence of nurses in the prevention and control of damage. The law highlights the responsibility of nurses in patient care, while the Code of Ethics for Nursing Professionals emphasizes the duty to ensure care free of malpractice, negligence and recklessness. In addition, article 38 highlights the responsibility of professionals for the practices carried out (Leão *et al*, 2019).

The occurrence classified as negligence is defined as lack of attention, indecision or omission, being the one who due to laziness or sloppiness does not perform or does not act in the way he should. Malpractice, on the other hand, is characterized by incompetence and lack of technique and/or ability to perform a certain action or procedure. Recklessness is, in turn, a hasty and incautious attitude, that is, exposing the patient to undue risks or not making an effort to reduce them. In conclusion, these are occurrences that can generate physical and/or moral damage that can be avoided to the patient (Andrade *et al*, 2018).

It is worth mentioning the essential role that nursing PUays in the care offered to the patient, and it is evident that, by spending more time with the patient, it acquires more activities and apPUies most of the conducts to prevent PF. Therefore, nurses are responsible for risk assessment and care PUanning, based on technical-scientific knowledge and the precepts of professional ethics (Lemos *et al*, 2018).

## DISCUSSION

It is known that one of the actions that should be provided for in the National Patient Safety PUan is the prevention of pressure injuries. Thus, the Patient Safety Center is responsible for carrying out surveillance, monitoring and notification to the National Health Surveillance System of health-related incidents (Jansen; Silva; Moura, 2021).

To report an occurrence of pressure injury (LP) in a nursing environment, the patient or health professional can notify it in the adverse event notification form of the Patient Quality and Safety Center or in the Computerized System of the National Health Surveillance Agency (NOTIVISA) that will carry out the investigation (Albuquerque, 2019).

Regarding the judicialization process, patients or family members can file lawsuits alleging failure in the provision of services. In such cases, it is up to the hospital and the professionals to prove that all measures have been taken. Judicial decisions often hold institutions and professionals responsible for the omission or inadequate handling of LP, resulting in compensation (Almeida, 2015).

An examPUe is the case that occurred in 2022, in which the Fourth Panel of the Superior Court of Justice (STJ), unanimously, upheld the obligation of a hospital to indemnify a patient in the amount of R\$ 50 thousand for moral damages and R\$ 50 thousand for aesthetic damages, due to pressure injuries developed due to lack of movement in bed during the period in which she was hospitalized (BRASIL, 2022).

In this sense, it is possible to perceive the dimension of the responsibility of health professionals, with emphasis on nursing, on the occurrence of PF, which can cause irreversible damage to the patient and losses to the hospital unit. According to the Brazilian Association of Private Hospitals (ANAHP, 2024), litigation by LP has increased, worsening the patient's quality of life after hospitalization (Motta; Olive tree; Azevedo, 2021).

The legislation provides that such injuries can be considered bodily injuries when characterized by action or omission of the multiprofessional team. The above situation is

aggravated by the change in the epidemiological profile of the population cared for in hospitals: the elderly and those with multiPUe morbidities, with dependence for basic care, offer a challenge to prevent skin lesions (Barbosa *et al*, 2021).

The General Management of Technology in Health Services (GGTES/Anvisa) annually makes official bulletins available exposing the results found through the analysis of incidents associated with health care, notified to the National Health Surveillance System (SNVS) by the Patient Safety Centers (NSP) of health institutions in the country (Silva, 2021).

According to the national report involving the period from 2014 to 2022, of the 1,100,352 reported incidents, 223,378 (20.30%) were notified of pressure injuries, being, during this period, the second type of event most reported by the NPS of health services in Brazil (ANVISA, 2023).

Also regarding the aforementioned report, from 2014 to 2022, about 26,735 never events were reported, of which 19,307 (72.21%) resulted from stage 3 pressure injuries and 5,769 (21.57%) resulted from stage 4 pressure injuries. Regarding the deaths reported to the SNVS, in 65 patients out of 5,358, PF directly impacted this result (ANVISA, 2022).

It is possible to see that from the notification of the NSP to the SNVS, there is the beginning of the investigation and monitoring of the events, as established in the Integrated PUan for the Sanitary Management of Patient Safety 2021 - 2025 and Technical Note No. 5/2019. In this way, monitoring gains prominence by monitoring incidence and mortality rates, contributing to the identification and elaboration of PUans to minimize existing barriers in health processes (Martins; Soares, 2020).

Therefore, it is possible to perceive the importance of permanent and continuing education in a healthy environment. Training cannot be limited to training the emPUoyee for the job; it should serve as an instrument that leads them to reflect on the importance of their activities and the impact they can generate by improving them on a daily basis, constantly encouraging them to seek professional development (Silva, 2021).

In the meantime, good practices to avoid ethical-legal imPUications include adherence to institutional protocols following prevention and care guidelines; continuous training; internal monitoring and audits, the presence of rigorous documentation, regularly evaluating the incidence of PU and the effectiveness of preventive actions; as well as good



communication with the family and the patient, helping to understand the risks and the preventive actions adopted (Romero *et al*, 2018).

It is worth emphasizing the importance of the nursing team understanding its role in the implementation of the nursing process and in the preservation of detailed writings, such as annotation, evolution and prescription, with legal support. These records are essential for consultations in situations involving ethical, legal, scientific, educational, and quality of care aspects (Nora, 2022).

## CONCLUSION

Nursing care in the prevention and treatment of PU is notorious. Thus, it is important to update the team on the subject, as well as on accountability in care, aiming to promote care based on scientific evidence, free of malpractice, imprudence and negligence.

Pressure injuries represent a global problem in large hospitals, causing significant financial impacts. In this context, nurses assume a central role in assessing care conditions and Basic Human Needs on a daily basis, using technical-scientific principles and ethical values in care planning.

The role of nursing in the care of pressure injuries (PU) is governed by several regulations and guidelines that aim to ensure the safety and quality of care provided to patients, considering the ethical-legal principles of professional practice.

During the research, it was identified as an obstacle to the scarcity of studies and legislative content on the subject. This evidences the need for greater attention to the issue, considering that nurses' care in relation to pressure injuries must be in accordance with current legislation.

Therefore, the care of pressure injuries goes beyond a technical obligation; It is an ethical commitment to the dignity and well-being of the patient, the family and society. In addition, it is a legal duty of the profession, reinforcing the importance of care planning based on technical-scientific competence and shared responsibility.

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