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SYSTEMATIC REVIEW PROTOCOL ON RISK FACTORS FOR PRESSURE INJURY: EXPERIENCE REPORT

PROTOCOLO DE REVISIÓN SISTEMÁTICA DE FACTORES DE RIESGO DE LESIÓN POR PRESIÓN: REPORTE DE EXPERIENCIA

PROTOCOLO DE REVISÃO SISTEMÁTICA SOBRE FATORES DE RISCO PARA LESÃO POR PRESSÃO: RELATO DE EXPERIÊNCIA

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Submission: 24-04-2023
Approval: 12-07-2023

ABSTRACT
Objective: To report the construction process of a systematic review protocol and its registration in the PROSPERO database on risk factors for pressure injuries among adult patients in intensive care units. **Method:** This is an experience report, with a descriptive character and a qualitative approach, of research nurses in the field of stomatherapy on the construction of a systematic review protocol, whose objective is to identify and analyze the risk factors for injury by pressure among adult patients in intensive care units. The experience was presented in two thematic axes: 1) Elaboration of the systematic review protocol; 2) Registration in the PROSPERO online database. **Results:** The protocol consisted of the following steps: elaboration of the research question, search for relevant publications, selection of studies found, data extraction, analysis and synthesis of evidence. With regard to registration, this was carried out during submission to PROSPERO in accordance with the requested information regarding the 38 items of the systematic review study protocol. **Final considerations:** The report allowed presenting the steps followed for the development of the systematic review protocol and its registration in PROSPERO, contributing to support the steps to be followed by researchers in the development of studies of this nature in the nursing area.
Keywords: Nursing; Risk Factors; Pressure Ulcer; Intensive Care Units.

RESUMEN
Objetivo: Reportar el proceso de construcción de un protocolo de revisión sistemática y su registro en la base de datos PROSPERO sobre factores de riesgo para lesiones por presión en pacientes adultos en unidades de cuidados intensivos. **Método:** Se trata de un relato de experiencia, de carácter descriptivo y abordaje cualitativo, de enfermeras investigadoras del área de estomaterapia sobre la construcción de un protocolo de revisión sistemática, cuyo objetivo es identificar y analizar los factores de riesgo de lesión por presión entre pacientes adultos en unidades de cuidados intensivos. La experiencia fue presentada en dos ejes temáticos: 1) Elaboración del protocolo de revisión sistemática; 2) Registro en la base de datos en línea PROSPERO. **Resultados:** El protocolo constó de los siguientes pasos: elaboración de la pregunta de investigación, búsqueda de publicaciones relevantes, selección de estudios encontrados, extracción de datos, análisis y síntesis de evidencia. En cuanto al registro, este se realizó durante el envío a PROSPERO de acuerdo con la información solicitada sobre los 38 ítems del protocolo del estudio de revisión sistemática. **Consideraciones finales:** El informe permitió presentar los pasos seguidos para la elaboración del protocolo de revisión sistemática y su registro en PROSPERO, contribuyendo a sustentar los pasos a seguir por los investigadores en el desarrollo de estudios de esta naturaleza en el área de enfermería.
Palabras clave: Enfermería; Factores de Riesgo; Úlcera por Presión; Unidades de Cuidados Intensivos.

RESUMO
Objetivo: Relatar o processo de construção de um protocolo de revisão sistemática e seu registro na base de dados PROSPERO sobre fatores de risco para lesão por pressão entre pacientes adultos em unidades de terapia intensiva. **Método:** Trata-se de um relato de experiência, com caráter descritivo e abordagem qualitativa, de enfermeiros pesquisadores da área da estomaterapia sobre a construção de um protocolo de revisão sistemática, cujo objetivo se propõe a identificar e analisar os fatores de risco para lesão por pressão entre pacientes adultos em unidades de terapia intensiva. A experiência foi apresentada em dois eixos temáticos: 1) Elaboração do protocolo de revisão sistemática; 2) Registro na base de dados online PROSPERO. **Resultados:** O protocolo contou com a composição das seguintes etapas: elaboração da questão de pesquisa, busca de publicações relevantes, seleção dos estudos encontrados, extração de dados, análise e síntese das evidências. No que se refere ao registro, este foi realizado durante a submissão na PROSPERO de acordo com as informações solicitadas referentes aos 38 itens do protocolo de estudo de revisão sistemática. **Considerações finais:** O relato permitiu apresentar as etapas seguidas para o desenvolvimento do protocolo de revisão sistemática e seu registro na PROSPERO, contribuindo para subsidiar as etapas a serem seguidas pelos pesquisadores no desenvolvimento de estudos desse cunho na área de enfermagem.
Palavras-chave: Enfermagem; Fatores de Risco; Lesão por Pressão; Unidades de Terapia Intensiva.

REVISTA ENFERMAGEM ATUAL IN DERME

INTRODUCTION

Pressure injury (PI) had its first records of studies described by physicians with surgical expertise. In 1593, Fabricius Hildanus, a surgeon from Leiden, described the clinical characteristics of PI for the first time in Holland. He identified as probable causes factors called external natural and internal supernatural, as well as the interruption in the supply of blood and nutrients. In 1722, the French surgeon de La Motte noted that mechanical pressure and incontinence played an important role in the evolution of PI[1].

Pressure and shear forces alone do not fully explain LP formation. Other factors, known as risk factors, seem to play a key role in the process. A better understanding of risk factors and their interaction would allow a more adequate detection of patients whose risk was genuinely increased[1].

PI classification takes place through stages depending on the level of involvement and associated characteristics, based on the consensus of the National Pressure Ulcer Advisory Panel (NPUAP). In stage 1, LP presents as non-blanchable erythema of intact skin. In stage 2, there is loss of skin integrity in its partial thickness, reaching the dermis, in which the wound bed is pink or red in color, with a moist appearance and in the form of a bubble. In stage 3, there is total loss of the skin, with the presence of slough, with impairment of the adipose tissue depending on the location[2]. In stage 4 LP, there is full-thickness skin loss, with involvement and exposure of fascia, muscle, ligaments or bones, containing the presence of slough or necrotic tissue[2].

Another stage considered is deep tissue LP, characterized by a dark red, non-blanchable, brown or purple discoloration. It is the result of intense and prolonged pressure and interfacial presentation of bone and muscle. It also describes the additional definitions: LP related to medical devices and LP in mucous membrane[2].

In addition to this classification, there are cases in which a PI is not stageable, being understood when there is a total loss of skin and tissue thickness, with its area of inexact extension obscured by necrotic tissue[2]. The prevention of stage evolution, from the implementation of an effective therapy in the recovery of the affected tissue, with the least generation of damages[3].

The international literature presents an incidence rate of PI between 5.1% and 12.8% in different hospital settings[4]. National studies report a variation between 6% and 62% depending on the service and sectors evaluated, with the Intensive Care Units (ICU) being the sector with the highest number of occurrences of these injuries[5].

The ICU is a hospital sector with an intense routine, and the nursing team must be prepared to assist patients with important changes in their clinical status at any moment, which require specific skills and practical skills for decision-making and implementation in a timely manner[6].

REVISTA ENFERMAGEM ATUAL IN DERME

Thus, the vulnerability of ICU patients to PI puts their safety during hospitalization at risk. LP is considered an adverse event, since it can be avoided. Its incidence in health institutions is an indicator of quality of care and reflects the quality of nursing and multidisciplinary care[7].

This topic will be the object of scientific investigation by research nurses in the field of stomatherapy based on the development of a systematic review to identify and analyze risk factors for pressure ulcers among adult ICU patients. To this end, a systematic review protocol was constructed and registered on the International Prospective Register of Systematic Reviews platform (PROSPERO).

The prospective recording of systematic review protocols has been increasingly requested by health journals, with the aim of making explicit the entire methodological process followed to carry out the study and avoid duplication of efforts by researchers. Therefore, it is recommended that this disclosure be made in PROSPERO, which consists of a database of systematic review protocols with health outcomes[14].

In view of the above, the objective of this study was to report the process of building a systematic review protocol and its registration in the PROSPERO database on risk factors for PI in adults in the ICU. In this sense, knowing the experience of building the systematic review research protocol is important for the development of future research on this topic or method, so that they meet the main ethical precepts and methodological rigor necessary for quality science.

METHOD

This is an experience report, of a descriptive nature with a qualitative approach, of research nurses in the field of stomatherapy on the construction of a systematic review protocol, whose objective is to analyze the risk factors for PI in adults in the ICU.

The construction activities were carried out in the meeting room of a stomatherapy nursing clinic at the Regional University of Cariri located in the city of Crato, in the state of Ceará, Brazil, during the month of March 2023.

Initially, the following research question was delimited for the development of the systematic review: what are the risk factors for pressure injuries in adults in the ICU? This search aimed to identify whether there was already a systematic review on the subject and whether it was up to date. After the searches carried out, the existence of a systematic review of the same thematic nature was verified, but it was outdated and without registration of any protocol in the main databases of available accesses.

Thus, the description of the experience was divided into two thematic axes: 1) Elaboration of the systematic review protocol; 2) Registration in the PROSPERO online database.

The study followed the ethical standards, national and international, in research involving human beings. However, as the objective of the

REVISTA ENFERMAGEM ATUAL IN DERME

research is to report on the construction of the systematic review protocol, submission to the Ethics Committee for Research with human beings was waived.

RESULTS AND DISCUSSION

Elaboration of the systematic review protocol

The construction of the protocol for the systematic review of observational studies was structured following the recommendations of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P)[8]. And also, in line with the steps of the "Methodological Guidelines: elaboration of a systematic review and meta-analysis of comparative observational studies on risk factors and prognosis", prepared by the Ministry of Health[9].

The choice to carry out a systematic review was based on the need to gather and evaluate the data obtained individually, in order to publish the evidence found on a certain area of interest, in order to collaborate with decision-making and the construction of knowledge when faced with a question. elaborated and use of controlled and free vocabulary in the searches[10].

The protocol included the following stages of study construction: definition of the research question; definition of eligibility criteria for selection of primary studies; database selection; search for eligible studies; screening of articles found by reading the title and abstract; complete reading of the studies selected in the previous step; evaluation of the eligibility of studies; data extraction; evaluation of the methodological quality of the included studies; synthesis of results and assessment of the quality of evidence[9].

Chart 1 presents the construction process of the guiding question for the systematic review, using the acronym PECO: "What are the risk factors for PI in adult ICU patients?". The structural basis of the elaboration was idealized as follows: Population (P) corresponding to adult patients in the ICU; Exposure (E) to risk factors; Comparator (C) not applicable in this context; and Outcome (The) development of LP.

Chart 1 – Elaboration of the systematic review question according to the PECO strategy. Crato, Ceará, Brazil, 2023.

Acronym	Definition	Descriptors
P	Pacient or Problem	Adult Pacients in ICU
E	Exposition	Risk Factors
C	Comparator	Not aplicable in this context
O	Outcome	Lesion for pressure

Scientific articles selected by two reviewers, separately, will be included. In cases where there are differences, a third reviewer will carry out the joint analysis; The articles will

REVISTA ENFERMAGEM ATUAL IN DERME

come from primary studies (observational-analytical cohort, retrospective and/or prospective, and case-control) that have tested the hypothesis of the relationship of some risk factor to PI among adult critically ill patients (critical patients will be considered those adult individuals aged 18 years or over admitted to the ICU); that are available in their entirety free of charge; published in Portuguese, English or Spanish and publication in the last five years (2019-2023) in view of the publication date of the last systematic review on the subject without updating. Studies with risk factors for PI related to medical devices, patients who were admitted to the ICU already with the presence of PI, who do not clearly indicate the age range of the study population and duplicates will be excluded.

For the bibliographic search, access will be carried out through the periodicals portal of the Coordination for the Improvement of Higher Education Personnel (CAPES). The databases selected to be consulted will be: Medical Literature Analysis and Retrieval System Online (MEDLINE), ExcerptaMedica Database (EMBASE), Latin American and Caribbean Health Sciences Literature (LILACS), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Nursing Database – Brazilian Bibliography (BDENF), Web of Science (WoS). To meet the recommendation to include gray literature, Google Scholar will be used.

The corresponding indexed descriptors will be used in each database. Descriptors extracted from the controlled vocabulary Medical Subject Headings (MeSH) will be used: Pressure Ulcer; Risk factors; Intensive Care Units; adults. And the Descriptors in Health Sciences (DeCS): Pressure Injury; Risk factors; Intensive Care Units; Adult. The terms of the Excerpta Medica Tree (EMTREE): Decubitus; Risk Factor; Intensive Care Unit; Adult. The combination with Boolean operators AND and/or OR will be adapted in each database according to the need, as well as free vocabulary. The search strategies in each selected database are shown in Chart 2.

Chart 2 – Search strategies used in each corresponding database. Crato, Ceará, Brazil, 2023.

Database	Controlled vocabulary / free vocabulary
	("intensive care units"[MeSH Terms] OR ("intensive care units"[MeSH Terms] OR Intensive Care Unit[Text Word])) OR "intensive care units"[MeSH Terms] OR ("intensive care units"[MeSH Terms] OR Intensive Care Units[Text Word]) AND "risk factors"[MeSH Terms] OR "risk factors"[MeSH Terms] OR ("risk factors"[MeSH Terms] OR Risk Factor[Text Word]) OR ("risk factors"[MeSH Terms] OR Social Risk Factors[Text Word]) OR "risk factors"[MeSH Terms] OR "risk factors"[MeSH Terms] OR "risk factors"[MeSH Terms] OR "risk factors"[MeSH Terms] OR ("risk factors"[MeSH Terms] OR Social Risk Factor[Text Word]) OR ("risk factors"[MeSH Terms] OR Health Correlates[Text Word]) OR "risk factors"[MeSH Terms] OR ("risk factors"[MeSH Terms] OR Population at Risk[Text Word]) OR ("risk factors"[MeSH Terms] OR Population at Risk[Text Word]) OR ("risk factors"[MeSH Terms] OR Risk Scores[Text Word]) OR ("risk factors"[MeSH Terms] OR Risk Score[Text Word]) OR "risk

REVISTA ENFERMAGEM ATUAL IN DERME

MEDLINE	factors"[MeSH Terms] OR ("risk factors"[MeSH Terms] OR Risk Factor Scores[Text Word]) OR ("risk factors"[MeSH Terms] OR Risk Factor Score[Text Word]) OR "risk factors"[MeSH Terms] AND "pressure ulcer"[MeSH Terms] OR ("pressure ulcer"[MeSH Terms] OR Pressure Ulcers[Text Word]) OR "pressure ulcer"[MeSH Terms] OR "pressure ulcer"[MeSH Terms] OR ("pressure ulcer"[MeSH Terms] OR Bedsore[Text Word]) OR ("pressure ulcer"[MeSH Terms] OR Bedsores[Text Word]) OR ("pressure ulcer"[MeSH Terms] OR Pressure Sore[Text Word]) OR ("pressure ulcer"[MeSH Terms] OR Pressure Sores[Text Word]) OR "pressure ulcer"[MeSH Terms] OR "pressure ulcer"[MeSH Terms] OR ("pressure ulcer"[MeSH Terms] OR Bed Sores[Text Word]) OR ("pressure ulcer"[MeSH Terms] OR Bed Sore[Text Word]) OR "pressure ulcer"[MeSH Terms] OR "pressure ulcer"[MeSH Terms] OR ("pressure ulcer"[MeSH Terms] OR Decubitus Ulcer[Text Word]) OR ("pressure ulcer"[MeSH Terms] OR Decubitus Ulcers[Text Word]) OR "pressure ulcer"[MeSH Terms] OR "pressure ulcer"[MeSH Terms]
LILACS	((“unidades de terapia intensiva” OR “cti” OR “centro de terapia intensiva” OR “centros de terapia intensiva” OR “uti” OR “unidade de terapia intensiva” OR “unidade de terapia intensiva especializada” OR “unidade de terapia intensiva de adulto” OR “unidade de terapia intensiva do tipo ii” OR “unidades de terapia intensiva uti” OR “adulto” OR “adultos”) AND (“fatores de risco” OR “correlatos de saúde” OR “fator de risco” OR “fatores sociais de risco” OR “fatores de risco sociais” OR “fatores de risco não biológicos” OR “fatores de riscos não biológicos” OR “pontuações de fatores de risco” OR “pontuações de risco” OR “pontuações do fator de risco” OR “pontuações dos fatores de risco” OR “população em risco” OR “populações em risco”) AND (“lesão por pressão” OR “escara de decúbito” OR “úlcera de decúbito” OR “úlcera de pressão” OR “úlcera por pressão” OR “úlceras por pressão”)) AND fulltext:("1") AND db:("LILACS") AND type_of_study:("observational_studies") AND (fulltext:("1" OR "1") AND db:("LILACS") AND type_of_study:("observational_studies")) AND (year_cluster:[2018 TO 2023])
EMBASE	decubitus OR 'bed sore' OR 'bedsore' OR 'decubital ulcer' OR 'decubital ulcus' OR 'decubitus ulcer' OR 'decubitus ulceration' OR 'decubitus ulcers' OR 'decubitus ulcus' OR 'decubus ulcer' OR 'pressure injury' OR 'pressure sore' OR 'pressure ulcer' OR 'sore, pressure' OR 'ulcer, pressure' OR 'ulcus decubitus' AND risk factor OR 'relative risk' OR 'risk factors' AND intensive care unit OR 'close attention unit' OR 'combined medical and surgical ICU' OR 'combined surgical and medical ICU' OR 'critical care unit' OR 'intensive care department' OR 'intensive care units' OR 'intensive therapy unit' OR 'intensive treatment unit' OR 'medical-surgery ICU' OR 'medical/surgical ICU' OR 'unit, intensive care' OR ‘adult’ OR 'adults' OR 'grown-ups' OR 'grownup' OR 'grownups'
WEB OF SCIENCE	((“Intensive Care Units” OR “Intensive Care Unit” OR “Unit, Intensive Care” OR “ICU” “Intensive Care Units” OR “Adult” OR “Adults”) AND (“Risk Factors” OR “Factor, Risk” OR “Risk Factor” OR “Social Risk Factors” OR “Factor, Social Risk” OR “Factors, Social Risk” OR “Risk Factor, Social” OR “Risk Factors, Social” OR “Social Risk Factor” OR “Health Correlates” OR “Correlates, Health” OR “Population at Risk” OR “Risk Scores” OR “Risk Score” OR “Score, Risk” OR “Risk Factor Scores” OR “Risk Factor Score” OR “Score, Risk Factor”) AND

REVISTA ENFERMAGEM ATUAL IN DERME

	(“Pressure Ulcer” OR “Pressure Ulcers” OR “Ulcer, Pressure” OR “Ulcers, Pressure” OR “Bedsore” OR “Bedsores” OR “Pressure Sore” OR “Pressure Sores” OR “Sore, Pressure” OR “Sores, Pressure” OR “Bed Sores” OR “Bed Sore” OR “Sore, Bed” OR “Sores, Bed” OR “Decubitus Ulcer” OR “Decubitus Ulcers” OR “Ulcer, Decubitus” OR “Ulcers, Decubitus”))
CINALH	((“Intensive Care Units” OR “Intensive Care Unit” OR “Unit, Intensive Care” OR “ICU” “Intensive Care Units” OR “Adult” OR “Adults”) AND (“Risk Factors” OR “Factor, Risk” OR “Risk Factor” OR “Social Risk Factors” OR “Factor, Social Risk” OR “Factors, Social Risk” OR “Risk Factor, Social” OR “Risk Factors, Social” OR “Social Risk Factor” OR “Health Correlates” OR “Correlates, Health” OR “Population at Risk” OR “Risk Scores” OR “Risk Score” OR “Score, Risk” OR “Risk Factor Scores” OR “Risk Factor Score” OR “Score, Risk Factor”) AND (“Pressure Ulcer” OR “Pressure Ulcers” OR “Ulcer, Pressure” OR “Ulcers, Pressure” OR “Bedsore” OR “Bedsores” OR “Pressure Sore” OR “Pressure Sores” OR “Sore, Pressure” OR “Sores, Pressure” OR “Bed Sores” OR “Bed Sore” OR “Sore, Bed” OR “Sores, Bed” OR “Decubitus Ulcer” OR “Decubitus Ulcers” OR “Ulcer, Decubitus” OR “Ulcers, Decubitus”))
BDENF	((“unidades de terapia intensiva” OR “cti” OR “centro de terapia intensiva” OR “centros de terapia intensiva” OR “uti” OR “unidade de terapia intensiva” OR “unidade de terapia intensiva especializada” OR “unidade de terapia intensiva de adulto” OR “unidade de terapia intensiva do tipo ii” OR “unidades de terapia intensiva uti” OR “adulto” OR “adultos”) AND (“fatores de risco” OR “correlatos de saúde” OR “fator de risco” OR “fatores sociais de risco” OR “fatores de risco sociais” OR “fatores de risco não biológicos” OR “fatores de riscos não biológicos” OR “pontuações de fatores de risco” OR “pontuações de risco” OR “pontuações do fator de risco” OR “pontuações dos fatores de risco” OR “população em risco” OR “populações em risco”) AND (“lesão por pressão” OR “escara de decúbito” OR “úlcera de decúbito” OR “úlcera de pressão” OR “úlcera por pressão” OR “úlceras por pressão”)) AND type_of_study:("observational_studies") AND (fulltext:("1" OR "1") AND db:("BDENF") AND type_of_study:("observational_studies")) AND (year_cluster:[2018 TO 2023])
Gray Literature	
Google Scholar	(“lesão por pressão” “unidade de terapia intensiva” “fatores de risco” “adulto” “estudo de coorte” “estudo de caso-controle”)

The citations found in the databases will be exported to the Rayyan® Systematic Review online application/software from the Qatar Computing Research Institute - QCRI[11]. Then, duplicate publications will be excluded so that titles and abstracts can be read by two independent reviewers. If there is doubt or disagreement between the reviewers regarding the inclusion of any material, a third reviewer will be consulted. To confirm the inclusion of selected articles, all eligible articles will be read in full.

The entire search process and eligibility of the materials found and included will also be presented in a flow diagram, as recommended by the Preferred Reporting Items for Systematic

REVISTA ENFERMAGEM ATUAL IN DERME

Reviews and Meta-Analyses 2020 Statement (PRISMA)[12].

Data extraction will take place through a standardized form, in which an independent pair of trained reviewers will confront the results obtained and, in case of disagreement, a third reviewer will be contacted. If necessary, the authors of the articles will be contacted for the purpose of requesting missing or additional data regarding any stages of the study.

The form for data extraction was prepared according to items suggested by the Joanna Briggs Institute (JBI) for extracting data from systematic reviews of etiology and risk, namely: authors, year of publication, journal name, objective of the study, type of study, study location, population and characteristics of the study sample, procedures performed in subject recruitment, study and follow-up duration, exposure factors (independent variables), dependent variables, data analysis, adjustment for confounding factors, results of the study and comments[13].

The methodological quality of the articles included in the review will be assessed using the instruments recommended by the JBI for each type of study carried out, through which it will be possible to identify the number of items addressed in the studies according to the number of items provided by the instruments[13].

Registration in the PROSPERO online database

PROSPERO is a database of systematic reviews, free of charge, maintained by the Center of Reviews and Dissemination (CRD), at the University of York, and funded by the National Institute for Health Research (NIHR) presenting the requirement to fill in a form containing 38 items during online registration. The prospective registration of these protocols is already recommended by many health journals in order to minimize the risk of publication bias and the duplication of reviews to answer the same clinical question[14].

The registration of this systematic review protocol in the PROSPECTO database fulfilled the fulfillment of the 38 items required in the register, which makes the process of research development more transparent and enlightening, previously presenting the analyzes that will be carried out. This process enables the evaluation of possible selective reporting of subsequent results[14].

The information necessary for registering the protocol includes the data that make up the systematic review, such as the research question, the strategies for searching and analyzing the data, the language and location of the study, the expected start and end date of the research, as well as plans for disseminating the results of the review. Author identification information, institution and funding, and the status of the study at the time of filling out the platform are also requested, whether under construction or

REVISTA ENFERMAGEM ATUAL IN DERME

completed(14). After carrying out the steps of this protocol, the data were inserted and will be continuously updated in the PROSPERO database, in order to ensure the transparency of the systematic review and use the platform as a safe repository of the results found.

Also, it is worth mentioning that the protocol was registered in the same generating a registration number (CRD42023403934). The registration number of systematic review protocols has already been requested by many scientific journals during the submission process [(14)]. It is noteworthy that, in a preliminary search on this database, no similar protocol was found, demonstrating the importance and originality of the review on the subject in question.

FINAL CONSIDERATIONS

The present work allowed reporting the experience of researchers during the elaboration and registration of a systematic review protocol, expressing its importance due to its potential guiding effect in relation to other stakeholders in the development of high-impact evidence.

Fortunately, health care is continuously looking for better practices in order to promote better patient safety, and, regarding the development of PI, this is an investigation proposal with recent data. The detection of its association, or not, with predisposing risk factors may contribute positively to the global health system, which has been dealing with this growing problem, especially in countries with low purchasing power in a post-pandemic scenario.

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Conflict of interest: the authors declared that there is no conflict of interest.

Sponsorship: not applicable

Acknowledgment: Ambulatório de Enfermagem em Estomaterapia do Hospital Regional Inácio de Sá - HRIS, Salgueiro, Pernambuco, Brazil.