

## Nursing care and techno vigilance in safe care

### Enfermagem e tecnovigilância na assistência segura

#### ABSTRACT

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**Introduction:** The use of technology in health care has become more common evidencing the need for surveillance and development of barrier policies in favor of safe care. **Objective:** To elucidate the prevention of adverse events in the Nursing care linked to the implementation of techno vigilance monitoring. **Method:** Integrative literature review of Brazilian journals published between 2012-2017, using free access databases with publications in Portuguese structuring evaluation according to the steps proposed for this study mode. **Results:** From the 06 articles found (three in Lilacs, two in BDNF and one in Medline), four were excluded because they did not meet the inclusion criteria. **Conclusions:** Nursing is experiencing difficulties in the understanding the prevention and occurrence of adverse events especially when related to the use of equipment, determining the lack of these policies for safe care.

**KEYWORDS:** Patient Safety; Risk Management; Patient Harm; Nursing

#### RESUMO

**Introdução:** O uso de tecnologia na atenção em saúde tornou-se mais corriqueiro evidenciando a necessidade de vigilância e desenvolvimento de medidas de barreira em prol de uma assistência segura. **Objetivo:** Elucidar as ações de prevenção de eventos adversos na assistência de enfermagem vinculado a implementação do monitoramento da tecnovigilância. **Método:** Revisão integrativa da literatura realizada em periódicos nacionais publicados entre 2012 e 2017, utilizando bases de dados de livre acesso com publicações em português, sendo estruturada avaliação segundo as etapas propostas para essa modalidade de estudo. **Resultados:** Dos seis artigos encontrados (três no Lilacs, dois no BDNF e um no Medline), quatro foram excluídos por não atender aos critérios de inclusão. **Conclusões:** A enfermagem vivencia dificuldades sobre a compreensão para prevenção e ocorrência dos eventos adversos especialmente quando relacionados ao uso de equipamentos, determinando a carência destas medidas para uma assistência segura.

**PALAVRAS-CHAVE:** Segurança do Paciente; Gestão de Riscos; Dano ao Paciente; Enfermagem

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## INTRODUCTION

Significant technological progress has been made in healthcare settings, enabling the improvement of diagnoses and establishing a link between scientific knowledge and the quality of care<sup>1</sup>. This progress may add risks to the care process, and this highlights the importance of patient safety, as it is often jeopardized by the professionals' unpreparedness in handling high-complexity medical-hospital equipment<sup>2,3</sup>.

Much harm is caused to patients' health as a result of poor care rather than because of the underlying disease. In the hospitals of the United States, after retrospective studies of medical records, there was a prevalence of about 100,000 deaths due to adverse health events (AE)<sup>2,3</sup>.

Over the years and with the increasing use of technologies associated with care, the need for actions aimed at creating barriers and mitigating risks related to patient safety has emerged. The creation of the *World Alliance for Patient Safety* in 2004 has evidenced the need to follow international safety recommendations prepared by the World Health Organization (WHO). In Brazil, these actions culminated in the elaboration and establishment of Ordinance n. 529, of April 1, 2013, which implements the National Patient Safety Program (PNSP)<sup>3,4</sup>.

The PNSP, in line with the objectives of the World Alliance for Patient Safety, encompasses other public policies that corroborate the implementation of safety promotion initiatives at the various levels of healthcare. Among other measures, this includes the implementation of Patient Safety Centers in health services, the management of the organization processes of the departments, notifications of the occurrence of AE and interventions in this scope<sup>5</sup>.

Among the interventions based on and planned in the articulation of strategies for the reduction of AE in hospitals, RDC n. 36, of July 25, 2013, lists the need for an action plan based on patient safety and a patient safety plan in health services. This includes, among several actions, the creation of safety barriers in the use of equipment and materials through technovigilance measures<sup>6</sup>.

Technovigilance measures mean monitoring AE and technical complaints of health products, with a view to recommending measures to ensure the protection and promotion of the health of the population. After the enactment of RDC n. 67 of December 21, 2009, technovigilance actions have been incorporated with a view to the design, implementation, monitoring and ongoing evaluation of protocols for the use of hospital equipment, as well as the continuing education of professionals engaged in procedures that use these resources<sup>7</sup>.

Nursing professionals, directly linked to patient care, use the equipment as a means of optimizing care actions in several care settings. These are also included in the risk scenario associated with technovigilance measures, since the

risk posed to the patients or the products used in their care may reflect the quality of professional actions and the safety offered in their support<sup>8</sup>.

Given this reality, the correlation between technovigilance and patient safety is of paramount importance, to the detriment of the care provided, with impact on the quality of care based on processes, techniques, materials and equipment properly and/or improperly used by the nursing staff. This study aims to shed light on AE prevention actions in nursing care related to the implementation of technovigilance monitoring.

## METHOD

This is an integrative literature review study, which includes systematic analysis and synthesis to contribute to the improvement of the researched topic. Its objective is to synthesize research on a particular subject, guide the practice and base it on knowledge<sup>9</sup>.

For the conduction of the study, the following guiding question was chosen: how does the knowledge of the nursing staff about the prevention of adverse events affect patient safety? In the preparation of this review, the following methodological steps were taken: definition of the topic and of the guiding question, literature search, data collection, critical analysis of the selected articles, discussion and interpretation of results<sup>9</sup>.

The following virtual databases were defined as the research environment: Latin American and Caribbean Health Sciences Literature (Lilacs), Medical Literature Analysis and Retrieval System online (Medline) and the Nursing Database (BDENF). The following descriptors in Health Science (DeCS) from the Latin American and Caribbean Center on Health Sciences Information (Bireme) were used: "Patient safety"; "Risk management"; "Harm to the patient"; "Nursing". The descriptors used boolean connector "AND" for their crossing.

For the selection of articles in the databases, the following criteria were established: original and full-text articles, published in Portuguese, from the last five years (2012-2017), which addressed the defined topic. *Lato* and *stricto sensu* postgraduate training studies, government health program manuals, dissemination of practices developed in health institutions, best practice manuals recommended by specific agencies and literature reviews were excluded from the sample.

The selected studies were critically analyzed through variables including the level of evidence of the articles, namely: Level I - evidence comes from a systematic review or meta-analysis of all relevant randomized controlled clinical trials or derived from clinical guidelines based on systematic reviews of randomized controlled clinical trials. Level II - evidence derived from at least one well-designed randomized controlled trial; Level III



- evidence obtained from well-designed clinical trials without randomization; Level IV - evidence from well-designed cohort and case control studies; Level V - evidence from systematic review of descriptive and qualitative studies; Level VI - evidence derived from a single descriptive or qualitative study; and Level VII - evidence from the opinion of authorities and/or expert committee report<sup>10</sup>.

For data analysis, the following process took place: initially, in the first stage, we read the titles of the publications, in the second stage, we read the abstracts, and in the third and final stage, we read the full article, including the studies that fit the objective of this review, as well as the guiding question. Those that did not fit this parameter were eliminated.

Repeat studies were considered only once. The peer review method was also adopted, since it enables the journals to improve quality, accuracy, readability, and credibility of the content to be published, as well as compliance with the standards for publication established by the journals, ethical and legal norms<sup>11,12</sup>. As for the type, we chose the open review system, where the identity of the authors and reviewers is known to both parties<sup>13</sup>.

## RESULTS

After searching the databases, the selected studies began to be addressed. The initial sample consisted of six articles (three indexed in Lilacs, two in BDNF and one in Medline), four of which were excluded because they did not fit the inclusion

criteria, leaving only two articles for the reading steps (title, summary and full text) to constitute the final analysis sample. The treatment of the articles followed the proposal of evaluation of the studies based on staged-reading and considering the level of evidence of the publications (Figure). There were no occurrences of articles deleted because of repetition in the searched databases.

Despite addressing the researched theme, the scientific evidence of the analyzed articles has a low recommendation level, since these are descriptive studies considered to be fast and easy to prepare, and therefore have little impact on the scientific field. This is because they do not contain a clinical trial, they are not randomized nor are they systematic reviews of cohort studies<sup>14</sup>.

We observed a small occurrence of publications on the theme, with no correlation with the emergence of standardization of policies and resolutions that regulate the use of hospital equipment aligned with patient safety practices. The Table shows the details of the articles included for analysis, in summary.

## DISCUSSION

One of the attributes for achieving quality of care is patient safety, which aims to reduce the risk of unnecessary harm associated with healthcare to an acceptable minimum<sup>3,15</sup>. The enactment of a specific policy to address patient safety issues highlights concerns of national health regulatory bodies about good

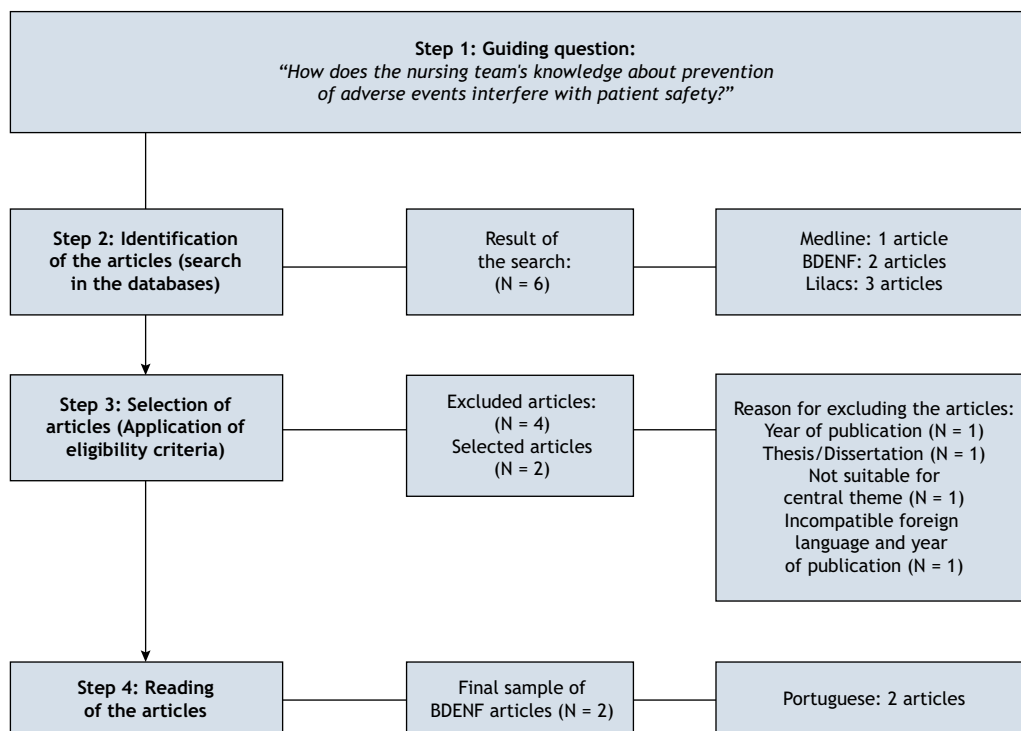


Figure. Flowchart of treatment of review data.



Chart. Synthesis of studies on technovigilance and knowledge of the nursing staff about the prevention of adverse events, 2018.

Database	Article Title	Authors	Journal	Objective
BDEF	Patient safety in the perspective of nurses: a multiprofessional issue	Araújo, MAN; Lunardi Filho, WD; Nanci da Silva, T; Silveira, RS; Souza, JC; Barlem, ELD	Enfermagem em Foco	To identify how nurses perceive patient safety in the health institution where they work, correlated to the multiprofessional team.
Lilacs	Failure Mode and Effects Analysis (FMEA) and International Patient Safety Goals: Pilot Study	Hinrichsen, SL; Possas, L; Oliveira, CLF; Ramos, DM; Vilella, TAS	Revista de Administração em Saúde	To define, list and create a set of recommendations regarding quality and patient risk according to tolerance matrices based on international patient safety goals.

BDEF: Nursing Database; Lilacs: Latin American and Caribbean Health Sciences Literature

practices for the proper functioning of establishments, in order to ensure the adequacy and quality of the services<sup>2,3</sup>.

It is up to the nurse, during the provision of care, to adopt measures that reduce the occurrence of AE. These measures should be guided by the creation of barriers that reduce the risks to which the patient is exposed during care at different levels. Risk management is defined as control measures, assessment of barriers and control practices as well as the management of AE that interfere with human health safety, professional integrity, the environment and institutional reputation<sup>15</sup>.

To implement risk management based on patient care outcomes, it is necessary to create a culture of investigation and identify possible failures that may occur during the provision of care. The patient safety culture is directly related to risk management, since there is a number of factors observed in the occurrence of harm to the patient, and this link favors learning to repair failures, contributing to the prevention of new incidents. In this sense, the practice of care is not only about expertise, rather, it includes attributes related to the qualification and rationalization of nurses to provide care.

Nursing measures related to technovigilance are incipiently evidenced by studies in which professionals are advised to perform their care based on international safety goals and through actions provided for in the risk matrices. The use of the risk matrix to manage the likelihood of the occurrence of AE has gained space in the debate on health quality, since it is extremely necessary in the identification and treatment of risks to which patients are exposed during the course of the therapy.

When the questions of technovigilance in health are detailed, we observe that the legal normative instruments direct the practice to create a stronger system in which professionals are not only reproducers of equipment use, but realize the interference of their purpose in the care of the people<sup>7</sup>. Measures related to the control of preventive maintenance of equipment, traceability of the institutional technological field and calibration are highly effective in safe nursing care.

The sample shows how nursing teams are part of the context of comprehensive care. Some authors even suggest that these

teams are the main responsible parties for the occurrence of harm to patients, considering that the use of hospital equipment is still empirical and routinely associated with nursing professionals. Oftentimes, however, these professionals do not have specific knowledge of these activities and fail to adopt the proper security measures.

These prerogatives require that nurses have more specific knowledge about the application of technovigilance actions in order to standardize procedures, ensure compliance with protocols and act in notification and control of AE<sup>16</sup>.

Together with nursing care, technovigilance plays a fundamental role in ensuring patient safety, collaborating with methods to contain risks related to professional practice and all the apparatus that is involved. The development of this field of knowledge and practice promotes the implementation, monitoring and evaluation of these professionals' continuing education, as well as the management of the care they provide<sup>17</sup>.

## CONCLUSIONS

The articulation of risk prevention and mitigation measures through technovigilance actions triggers reflections that enable significant changes and impact in the context of care involving technology, in addition to representativeness of the nursing class. This supports the maintenance of safety in care settings, together with the healthcare professional, with the help of the institutional structure, other healthcare professionals, patients and families.

Most of the analyzed studies are of the descriptive type. They contribute in a unique way to the transformation of empirical nursing into rationalized nursing, as they point out the obstacles faced by nurses in the understanding of the context related to the prevention and occurrence of AE, as well as their interference in this area.

There is a need for concrete discussions about patient safety starting at the academic education of the nursing professional in order to better train this professional in accordance with the premises of safe care.



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## Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.



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