

# CUIDADO É FUNDAMENTAL

Escola de Enfermagem Alfredo Pinto – UNIRIO

RESEARCH

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## PERCEPTION OF NURSING MANAGERS ABOUT TECHNOVIGILANCE IN THE LIGHT OF PATIENT SAFETY

*Percepção dos gestores de enfermagem sobre a tecnovigilância à luz da segurança do paciente**Percepción de los gerentes de enfermería sobre la tecnovigilancia a la luz de la seguridad del paciente***Carla Rayane Santos Dutra<sup>1</sup>** **Luan José de Queiroz Lima<sup>1</sup>** **Millena Rebeca Pereira de Oliveira<sup>1</sup>** **Carla Sandyele Tavares Galvão de Pontes<sup>1</sup>** **Gabriela Fernanda dos Santos<sup>1</sup>** **Diego Augusto Lopes Oliveira<sup>2</sup>** 

### ABSTRACT

**Objective:** to describe the perception of nurses involved in nursing management about technovigilance in the light of patient safety. **Method:** a descriptive study, with a qualitative approach, carried out with managing nurses based in a reference hospital in trauma in Pernambuco. Data were collected through semi-structured interviews from April to May 2020 and analyzed using Bardin's content analysis technique. **Results:** the analysis led to the emergence of two thematic categories: "Actions of care with the equipment and its relationship in caring for the patient" and "Use and handling of equipment by the nursing team and its consequences on patient safety". **Conclusion:** it was evident that managers demonstrate understanding about the importance of developing actions aimed at technovigilance, as well as their influence in relation to the nursing team in promoting safer and more quality care in health institutions.

**DESCRIPTORS:** Nursing; Hospital nursing staff; Patient safety; Hospital nursing service; Biomedical technology.

<sup>1</sup> Centro Universitário Tabosa de Almeida (ASCES-UNITA), Caruaru, PE, Brazil.

<sup>2</sup> Universidade Federal de Pernambuco, Recife, PE, Brazil.

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**Corresponding Author:** Diego Augusto Lopes Oliveira, Email: diegoaugusto.enf@gmail.com

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## RESUMO

**Objetivo:** descrever a percepção de enfermeiros envolvidos na gestão de enfermagem sobre a tecnovigilância à luz da segurança do paciente. **Método:** estudo descritivo, com abordagem qualitativa, realizada com enfermeiros gestores lotados em um hospital referência em trauma de Pernambuco. Os dados foram coletados por meio de entrevista semi estruturada de abril à maio de 2020 e analisados por meio da técnica de análise de conteúdos de Bardin. **Resultados:** a análise levou ao surgimento de duas categorias temáticas: “Ações de cuidado com o equipamento e sua relação no cuidar do paciente” e “Uso e manuseio de equipamentos pela equipe de enfermagem e suas consequências na segurança do paciente”. **Conclusão:** evidenciou-se que os gestores demonstram entendimento acerca da importância do desenvolvimento de ações voltadas a tecnovigilância, como também de sua influência frente à equipe de enfermagem na promoção de uma assistência mais segura e de qualidade nas instituições de saúde.

**DESCRITORES:** Enfermagem; Recursos humanos de enfermagem no hospital; Segurança do paciente; Serviço hospitalar de enfermagem; Tecnologia biomédica.

## RESUMEN

**Objetivo:** describir la percepción de los enfermeros involucrados en la gestión de enfermería sobre la tecnovigilancia a la luz de la seguridad del paciente. **Método:** estudio descriptivo, con abordaje cualitativo, realizado con enfermeras gestoras de un hospital de referencia en trauma en Pernambuco. Los datos se recopilaron a través de entrevistas semiestructuradas de abril a mayo de 2020 y se analizaron utilizando la técnica de análisis de contenido de Bardin. **Resultados:** el análisis dio lugar a la aparición de dos categorías temáticas: “Acciones de cuidado con el equipo y su relación en el cuidado del paciente” y “Uso y manejo del equipo por parte del equipo de enfermería y sus consecuencias en la seguridad del paciente”. **Conclusión:** se evidenció que los gerentes demuestran comprensión sobre la importancia de desarrollar acciones orientadas a la tecnovigilancia, así como su influencia en relación con el equipo de enfermería en la promoción de una atención más segura y de mayor calidad en las instituciones de salud.

**DESCRIPTORES:** Enfermería; Recursos humanos de enfermería en el hospital; Seguridad del paciente; Servicio de enfermería hospitalaria; Tecnología biomédica.

## INTRODUCTION

The implementation of new technologies in the hospital environment is constantly growing, being the result of the most diverse advances achieved in recent decades, thus, hospital managers are faced with new challenges arising from their innovative proposals facing the assistance offered to customers. Technovigilance is understood as “the set of preventive and corrective measures adopted by clinical institutions in the different biomedical technology management processes, in order to minimize the risks associated with the use of such technologies”.<sup>1</sup>

As we evolve technologically, the requirements to obtain more safety in the use of equipment in hospital environments increase, making the rational use of health technologies and the training of professionals to handle them necessary, knowing that the assistance provided by the nursing professional requires knowledge and skills to implement the technology together with the adopted therapy, which contributes to obtaining an effective practice based on consolidated scientific bases.<sup>2</sup>

It is necessary for hospital institutions to have good management in all areas and complexities of care, and this is no different with respect to technovigilance, because the lack of methodologies to manage, identify, evaluate, and control risks with hospital medical equipment can cause severe and irreversible damage to the patient.

The use of equipment and materials in nursing care contributes substantially to the care, treatment, and recovery of hospitalized patients; however, it also represents risks when used incorrectly,

disrespecting the specifications and/or recommended preventive maintenance.<sup>3</sup>

However, it is understood that a well-structured care management has strategies aimed at improving the quality of the service provided and provides good safety conditions for patients and other professionals who make up the hospital team.<sup>4</sup>

Understanding that patient safety is one of the main attributes of quality of care worldwide, and being of great importance in reducing injuries and risks, nursing managers should guide their actions both in the rational use of health technologies, as in the active search and reporting of adverse events, which are the basis for the development of prevention and correction actions aimed at reducing damage to the patient from the use of such equipment, as well as improving the care offered. It is important to explore the theme, considering the scarcity of studies in the literature, and its relevance as an innovative research proposal in the hospital context.<sup>5</sup> Thus, the objective of this study was to describe the perception of nurses involved in nursing management about technovigilance in the light of patient safety.

## METHODS

This is a descriptive study with a qualitative approach carried out with Nursing managers who work in a reference trauma hospital in the interior of Pernambuco.

Five nurses who held a hospital management position (managers, coordinators and supervisors) participated in the research. Nurses involved in hospital management with more than one

year in the position were included in the research, and nurses involved in management in another hospital institution were excluded. The selection of participants was based on the criteria of sample saturation. The delimitation of the number of interviewees occurred when the content was sufficient to allow the deepening, the comprehensiveness, and the diversity of the comprehension process of the studied theme.

To collect the participants' reports, the Hospital's board of directors was asked to schedule a meeting with the professionals eligible for the study. On this occasion the identification data and the signatures of the Free and Informed Consent Form were collected, and the days for the interviews were scheduled. Due to the social isolation defined by the Brazilian Ministry of Health among the several prevention and control actions against the Coronavirus pandemic (COVID-19), it was not possible to collect the data in person. These adaptations were communicated to the participants and they were given the right to withdraw from the research without personal burden by not participating.

Data were collected using a semi-structured interview divided in two parts: in the first, sociodemographic questions were asked to characterize the profile of managers and in the second, open questions related to the objectives proposed by the study, as follows: 1- What is the importance of hospital equipment surveillance for patient safety?

As the participants answered the questionnaire, the answers were grouped until no different conceptions were observed that could add new inferences, to the point of allowing innovations in the registration units. After the whole process of organizing the answers, a critical reading of the information about the nursing managers' perception of techno-surveillance and its implication in patient safety took place. The participants were identified with the letter "G", followed by a cardinal number, relative to the order of receipt of the answers, with the purpose of preserving anonymity.

Bardin's Content Analysis technique was used for data analysis,<sup>6</sup> where three fundamental phases were developed: pre-analysis, exploration of the material, and treatment of the results obtained (inference and interpretation). From the answers, clippings were made in units of meaning, by means of analysis and selection of the fragments of the reports that expressed the perception of the nurse managers. After the identification, the meaning units were gathered in an orderly manner, to enable the representativeness, comprehensiveness, and diversity in the process of understanding the object under study. The last stage, inference, allowed the treatment and interpretation of the results. After the analysis, two thematic categories emerged, namely: Care actions with the equipment and their relationship in patient care and Use and handling of equipment by the nursing team and its consequences on patient safety.

The research was developed after consideration and approval by the Research Ethics Committee (CEP) of the Caruaruense Association for Higher Education (ASCES - UNITA) under Opinion No. 2,492,773, CAAE: 25434919.8.0000.5203, on February 4, 2020, meeting the standards for research involving human beings, according to Resolution No. 466/2012 of the

National Health Council. All participants were informed about the study and signed the ICF, being informed about the measures to ensure anonymity and confidentiality about the origin of the data obtained. Data collection occurred between the months of April and May 2020.

## RESULTS

Five nurses participated in the study, 4 female and 1 male having the age range of 35 to 50 years. The participating professionals held nursing management positions, being 1 coordinator and 4 supervisors, all had been in the profession for more than 10 years, but the time in the management area ranged from 2 to more than 10 years.

The categories emerged from the core meaning of the reports in the analysis and explain nurse managers' perceptions of technovigilance in light of patient safety.

### Category 1 - Use and handling of equipment by the nursing team and its consequences on patient safety

This category expresses the vision of nursing managers about the role of nurses for the operation of the service and the management of care with hospital equipment, covering key aspects for patient safety.

*Hospital equipment needs quality, and care in its handling, to ensure good care. (G1)*

*I believe that continued education to handle equipment and maintenance are indispensable actions, but unfortunately this is not a common practice in the service.*

*To avoid that failures occur at the time of use and compromise the care given to the patient. The patient needs to be assured of quality care. (G3)*

*Equipment surveillance is of extreme importance for the safety of care and prevention of adverse events to patients, considering that such equipment is used in care processes. (G5)*

### Category 2 - Care actions with the equipment and its relationship with patient care

In this category, the context units reveal that the development of actions related to the use of hospital equipment, aimed at minimizing risks through surveillance, maintenance and training of professionals reflect in a safe care.

*Surveillance is necessary to avoid or minimize errors that compromise care. (G2)*

*Of utmost importance, considering that the equipment is directly involved in maintaining the life and health of patients. Not having surveillance on the equipment is to neglect lives. (G4)*

*The team must be trained for the use of each piece of equipment and the continuing education in this sense makes the handling of the equipment as responsible and safe as possible, otherwise the patient's safe care will be jeopardized. (G4)*

*Directly due to misuse or lack of knowledge regarding operation and, indirectly, because if there is no calibration, preventive and/or corrective maintenance we cannot ensure the effectiveness of the equipment, which consequently may result in harm to patient safety. (G5)*

*The actions are punctual and more in the corrective form. Unfortunately there is no care regarding calibration, as well as investment in preventive maintenance of the technological park by clinical engineering. (G5)*

## DISCUSSION

Technovigilance, associated with nursing care, exercises a direct commitment to ensuring patient safety through the use of methods to contain risks related to professional practice and the devices used in the dynamics of care. With the constant implementation of technological devices in health, risk management and the development of a systematized organization for monitoring adverse events, as well as the development of actions to control and eliminate damage, become essential.<sup>7</sup>

RDC No. 67/2009,<sup>8</sup> provides about the general requirements of techno-surveillance to be adopted by all holders of health product registrations based in the national territory, guiding professionals about the standards of care with hospital equipment, handling, notifications and risk management. Moreover, it determines as a duty the preparation of protocols, development of continuing education activities, and documentation of complaints and/or adverse events.<sup>7-8</sup>

It was evident in the reports that the minimization of failures and care during equipment handling contribute to guarantee quality care, avoiding compromising clinical evolution. It is understood that institutions are directed to the creation of a strengthened system where professionals, in addition to using the equipment, are able to observe the interference of its purpose in the moment of care. RDC nº 36/20139 provides about patient safety actions, among them the creation of Patient Safety Centers (PSC) in hospitals; these centers are the main form of collaboration to strengthen interventions aimed at patient safety, due to its normative principles that aim at the continuous improvement of the assistance process and use of hospital equipment, as well as the articulation and integration of risk management processes and dissemination of the culture of good practices in the services, in order to enable the reduction of risks from the use of such technologies and eventually a safer and quality assistance.<sup>9</sup>

Quality, according to the World Health Organization is defined as "a set of elements that include: a high degree of professional

competence, efficiency in the use of resources, a minimum of risks, a high degree of patient satisfaction, and a favorable effect on health. The quality of the products available in an institution is directly linked to the process of acquisition and use of these materials. Then there is the need for planning, execution, and control, in more efficient and economical conditions from the purchase to the delivery of the product, because the administration of these resources has been a concern for health organizations, both in the public and private sectors that are part of the complementary network of the Unified Health System (SUS). Knowledge about the process of management and use of medical-hospital supplies is of utmost importance, since this process significantly influences the work of professionals who work directly or indirectly in health care. The lack of interaction between the sectors responsible for this process ends up hindering the final result and, in this way, compromising the quality of care.<sup>10-11</sup>

Technological advances have driven the constant increase in the complexity of care, demanding an increasingly higher level of attention from health professionals, creating a growing demand for material resources. The performance of nursing managers in the administration of these resources is an achievement in the decision making spheres, highlighting the importance of their role in the technical-administrative dimension inherent to the process of care and management. It becomes necessary to enable safer assistance that promotes the reduction of risks to the patient, through the development of strategies based on normative and regulatory requirements, to favor the minimization of errors, as well as to promote continuing education actions for its team, since these actions, from the managers' point of view, play an important role in the practice of more responsible and safer assistance, which enables the prevention of damage related to the incorrect handling of equipment during care.<sup>12</sup>

Healthcare equipment and devices can be a source of risk for errors. The variety of devices, manufacturers, and technical specifications of each piece of equipment gives complexity to the health care environment and demands a great deal of knowledge and attention from the worker when operating the equipment. Risk is present as a result of human interaction with products, tools, processes, and procedures in the clinical environment.

Some professionals considered of extreme importance the relation of equipment handling associated to patient safety, taking this aspect into account, one notices that an inadequately programmed infusion pump, for example, where the infusion will occur at a higher or lower speed than the prescribed volume/hour or a mechanical ventilation device that does not offer precision in operation may also cause adverse events in the patient, demonstrating a failed or ineffective nursing care, since the patient's needs are not only related to his/her health condition, but also include the guarantee of functioning of all equipment that help the moment of hospitalization and improvement of the clinical condition.<sup>13</sup>

To achieve a safety scenario, it is necessary that the services adopt a continuous learning behavior, where the notification of events, the analysis of their causes, and a present management

act as triggering elements for the improvement of care processes in order to avoid the recurrence of unwanted situations and harm to patients.<sup>14</sup>

As expressed in the managers' speech, it is observed that there is a need for constant maintenance of this equipment in order to prevent and correct failures that can lead to its inefficiency, as established by the RDC No. 02/2010, highlighting the minimum criteria to be followed by health establishments, for the management of technologies used in the provision of services, which must ensure its traceability, quality, efficacy, effectiveness and safety and, where appropriate, performance, from the entry into the health establishment until its final destination, including the planning of physical, material and human resources, as well as the training of professionals involved in their process.<sup>15</sup>

The insertion of new technology causes great concern in hospital management, because it can reflect in great benefits, increasing the expectation and quality of life of the population, but it can also cause numerous organizational problems, such as: lack of local planning for its incorporation, little training, high costs, unsatisfactory quality, which will reflect severely in the hospital organizational environment and consequently in safe patient care.<sup>14-15</sup>

With regard to the assistance offered by health professionals, the RDC No. 02/2010 is clear when it says that The health establishment must have, for the execution of health technology management activities, norms and technical routines of standardized procedures, updated, registered and accessible to the professionals involved, for each step of management, that is, they must be described in a clear and concise way avoiding that each professional understands in his own way, leading to damage to the patient.<sup>15</sup>

## CONCLUSION

It was verified that the nurse involved in management is a fundamental part in the success of a humanized care, free of damages, and the importance of his/her contribution regarding the mentioned aspects is unquestionable. It is undeniable that the hospital equipment is necessary for the good functioning of the hospital and its management must be shared with the nursing team, because the nursing professionals and the technical team are directly involved in the handling and management of this equipment.

Thus, we observed the need for remodeling the actions developed by nursing managers, since it is understood that the materials should always be used to favor greater efficacy to the patient's clinical condition. We considered limitations for this study the scarcity of articles involving the theme in question, as well as the low adherence of the nurses to participate in the research via online form. It is important to take into consideration that a reality of the current scenario of health services was exposed, and that a small group of professionals was presented, leading to the understanding that more in-depth research should be done about the perception of these professionals.

Thus, it is perceived the need for professionals to improve in the search to offer safe care to patients through updates and compliance with protocols arranged about the handling and/or correct conduct on equipment, thus being essential the joint action of frontline staff and managers to promote patient safety during the period that the patient is under care in health institutions.

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