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INTEGRATIVE REVIEW OF LITERATURE

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DIFFICULTIES AND STRATEGIES OF PATIENT SAFETY CENTERS IN REPORTING ADVERSE EVENTS IN HOSPITALS

Dificuldades e estratégias dos núcleos de segurança do paciente na notificação de eventos adversos hospitalares
Dificultades y estrategias de los núcleos de seguridad del paciente en la notificación de eventos adversos hospitalarios

Monica Maria de Melo Andrade¹ 

Adane Domingues Viana² 

Gisella de Carvalho Queluci³ 

Jackeline Franco Couto⁴ 

Teresa Tonini⁵

RESUMO

OBJETIVO: Identificar desafios e facilidades dos Núcleos de Segurança do Paciente no gerenciamento de eventos adversos.

Método: Revisão integrativa de literatura de artigos publicados entre 2013 e 2023, com busca realizada em março de 2023.

Resultados: Dez artigos foram incluídos. Destaca-se a necessidade de compreender a importância da notificação do evento adverso e a utilização de indicadores de qualidade para traçar estratégias de segurança do paciente. O aprendizado com erros deve ter um enfoque não punitivo, promovendo melhorias contínuas. **Conclusão:** A notificação do evento adverso é essencial para a segurança do paciente, exigindo apoio da gestão ao Núcleo de Segurança do Paciente. É fundamental identificar fragilidades no processo, garantindo uma abordagem educativa e não punitiva.

DESCRITORES: Instalações de saúde; Hospitais; Assistência hospitalar; Gestão de riscos; Segurança do paciente.

^{1,5}Universidade Federal do Estado do Rio de Janeiro, Rio de Janeiro, Rio de Janeiro, Brazil.

²Instituto Municipal de Vigilância Sanitária do Município do Rio de Janeiro, Rio de Janeiro, Rio de Janeiro, Brazil.

³Vigilância Sanitária do Estado do Rio de Janeiro, Rio de Janeiro, Rio de Janeiro, Brazil.

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CORRESPONDING AUTHOR: Monica Maria de Melo Andrade

E-mail: monica.andrade@edu.unirio.br

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ABSTRACT

OBJECTIVE: identify challenges and facilitators of Patient Safety Centers in adverse event management. **Method:** integrative literature review of articles published between 2013 and 2023, with a search conducted in March 2023. **Results:** ten articles were included. The need to understand the importance of adverse event reporting and the use of quality indicators to develop patient safety strategies is highlighted. Learning from errors should adopt a non-punitive approach, promoting continuous improvements. **Conclusion:** adverse event reporting is essential for patient safety, requiring management support for the Patient Safety Center. Identifying weaknesses in the process is crucial to ensuring an educational and non-punitive approach.

DESCRIPTORS: Healthcare facilities; Hospitals; Hospital care; Risk management; Patient safety; Quality indicators in healthcare.

RESUMEN

OBJETIVO: identificar desafíos y facilidades de los Núcleos de Seguridad del Paciente en la gestión de eventos adversos. **Método:** revisión integrativa de literatura de artículos publicados entre 2013 y 2023, con búsqueda realizada en marzo de 2023. **Resultados:** se incluyeron diez artículos. Se destaca la necesidad de comprender la importancia de la notificación del evento adverso y el uso de indicadores de calidad para desarrollar estrategias de seguridad del paciente. El aprendizaje de los errores debe tener un enfoque no punitivo, promoviendo mejoras continuas. **Conclusión:** la notificación del evento adverso es esencial para la seguridad del paciente, requiriendo apoyo de la gestión al Núcleo de Seguridad del Paciente. Es fundamental identificar debilidades en el proceso, garantizando un enfoque educativo y no punitivo.

DESCRIPTORES: Instalaciones de salud; Hospitales; Atención hospitalaria; Gestión de riesgos; Seguridad del paciente; Indicadores de calidad en la atención sanitaria.

INTRODUCTION

Patient safety is a global issue, considered by the World Health Organization (WHO) to be a key factor in health care, since during the care process there is evidence of insecurity for the patient, causing an increase in preventable morbidity and mortality.¹ In hospital environments, there are daily adverse events that affect patient safety. Preventing these adverse events means improving the quality of healthcare and achieving this by prioritizing a culture of safety.²

The adverse event characterizes incidents (an event or circumstance that could have resulted, or did result, in unnecessary harm to the patient), which result in harm to the patient, compromising the structure or function of the body and/or any effect deriving from it, including injury, suffering, death, incapacity or dysfunction, and may be physical, social or psychological.³ Notifying the occurrence of these events is fundamental for patient safety. The National Health Surveillance Agency (Anvisa) defines notification as the act of communicating the occurrence of events, problems or situations associated with products and services. Adverse events and technical complaints about products and services related to health surveillance can be notified to Anvisa. This notification helps the Agency to take measures to protect and promote health.⁴

Following the global movement, Brazil instituted the National Patient Safety Program (PNSP), through the publication of Ordinance 529/2013 of the Ministry of Health (MS) and put into force by Consolidation Ordinance 5/2017, which in its Chapter VIII (articles 157 to 166), determines "the rules on health actions and services of the Unified Health System", aiming to "mitigate the risk of adverse events by qualifying health care in all health establishments in the national territory (article 2)".^{3,5}

The general objective of the National Patient Safety Program is to "contribute to the qualification of health care in all health establishments in the national territory". It establishes strategies such as: "promoting a culture of safety with an emphasis on learning and organizational improvement, engaging professionals and patients in the prevention of incidents, with an emphasis on safe systems, avoiding processes of individual accountability".³

Also in 2013, the Ministry of Health established the National Hospital Care Policy (PNHOSP), defining hospitals as "complex institutions, with specific technological density, of a multiprofessional and interdisciplinary nature, responsible for caring for users with acute or chronic conditions, which present the potential for instabilization and complications of their state of health, requiring continuous inpatient care

and actions that cover health promotion, disease prevention, diagnosis, treatment and rehabilitation". It is up to the hospital to set up "Patient Safety Centers, drawing up a Patient Safety Plan, guaranteeing the implementation of the Basic Patient Safety Protocols". The care provided requires "actions that ensure the quality of care and good health practices should be implemented to ensure patient safety with a reduction in unnecessary and avoidable incidents, as well as safe acts related to care".⁶

Patient safety has achieved greater visibility in the hospital area, seeking to provide excellent care in health services, developing interventions that promote quality in the care provided. For these interventions to take place, it is necessary to change the behavior of hospital workers, with a view to patient safety. In order to disseminate these behaviors in the hospital environment, it is necessary for all the institution's professionals to take an active part in this process of providing safe care, based on the conception of a culture of safety in the hospital environment.⁷

BACKGROUND

It is important for the hospital to offer its employees a space of reliability so that they can spontaneously communicate failures during the care provided to the patient, discussing what happened, jointly observing the context of the situation, knowing the vulnerabilities that triggered these failures in order to strengthen this bond, perfecting dialog techniques.⁸

The structuring of this culture in health institutions is characterized by the effective contribution of quality management in the applicability of care with excellence. It is based on five cultural characteristics: co-responsibility of workers and managers; not prioritizing financial rewards; learning from mistakes, without blame; and providing effective maintenance of patient safety.⁹

In Brazil, the definition of safety culture is the "set of values, attitudes, skills and behaviors that determine commitment to health and safety management, replacing blame and punishment with the opportunity to learn from failures and improve health care".¹⁰

The Agency for Healthcare Research and Quality (AHRQ) defines patient safety culture in healthcare as the product of values, attitudes, perceptions, competencies and behavior patterns of groups and individuals.²

Considering the implementation of a patient safety culture in hospitals, this research shows the importance of the topic

when we observe the need to understand adverse event (AE) reporting and the operationalization of quality indicators with the aim of improving Patient Safety Centers (PSC). Thus, the aim is to identify the challenges and facilities of PSCs in managing AE.

MATERIALS AND METHODS

An integrative literature review was carried out based on the following stages: objectives, definition of the guiding question, search for evidence in the literature, establishment of inclusion and exclusion criteria for articles, analysis, discussion and presentation of results. The purposes of this type of study range from defining concepts, reviewing theories and evidence, and analyzing methodological problems on a particular topic, to generating a consistent and comprehensible overview of complex concepts, theories or health problems relevant to nursing.¹¹

In order to develop the guiding question "What are the difficulties and facilities of NSPs in managing incident reports in healthcare institutions?", the PICo strategy (acronym for Patient, Intervention, Context) was made up of descriptors, in English and Portuguese, as follows: Population = healthcare institutions, Intervention = NSP management and Context = difficulty and ease. Boolean operators were used to combine the descriptors in the databases, namely: ("Health facilities, Hospitals, Hospital care" AND "Risk management, Patient safety" AND "Quality indicators in health care, Quality of health care, Evaluation of processes and results in health care").

The choice of health sciences descriptors (DeCs) facilitates bibliographic research through the classification and hierarchization of terms, standardizing the search. The Boolean operator OR was used between the terms of the same acronym, and the Boolean operator AND was used between each acronym.

Once the time frame of articles published between 2013 and 2023 had been defined, data collection took place in March 2023 on the PubMed, Medline, Scielo and Web of Science databases of the CAPES Periodicals Platform, as the results were broader when compared to other databases, including articles that were electronically accessible in full text and free of charge, with primary data and available in English, Spanish or Portuguese. Dissertations and theses were excluded. The selection and eligibility criteria for the studies identified in the databases are shown in the PRISMA flowchart (Figure 1).

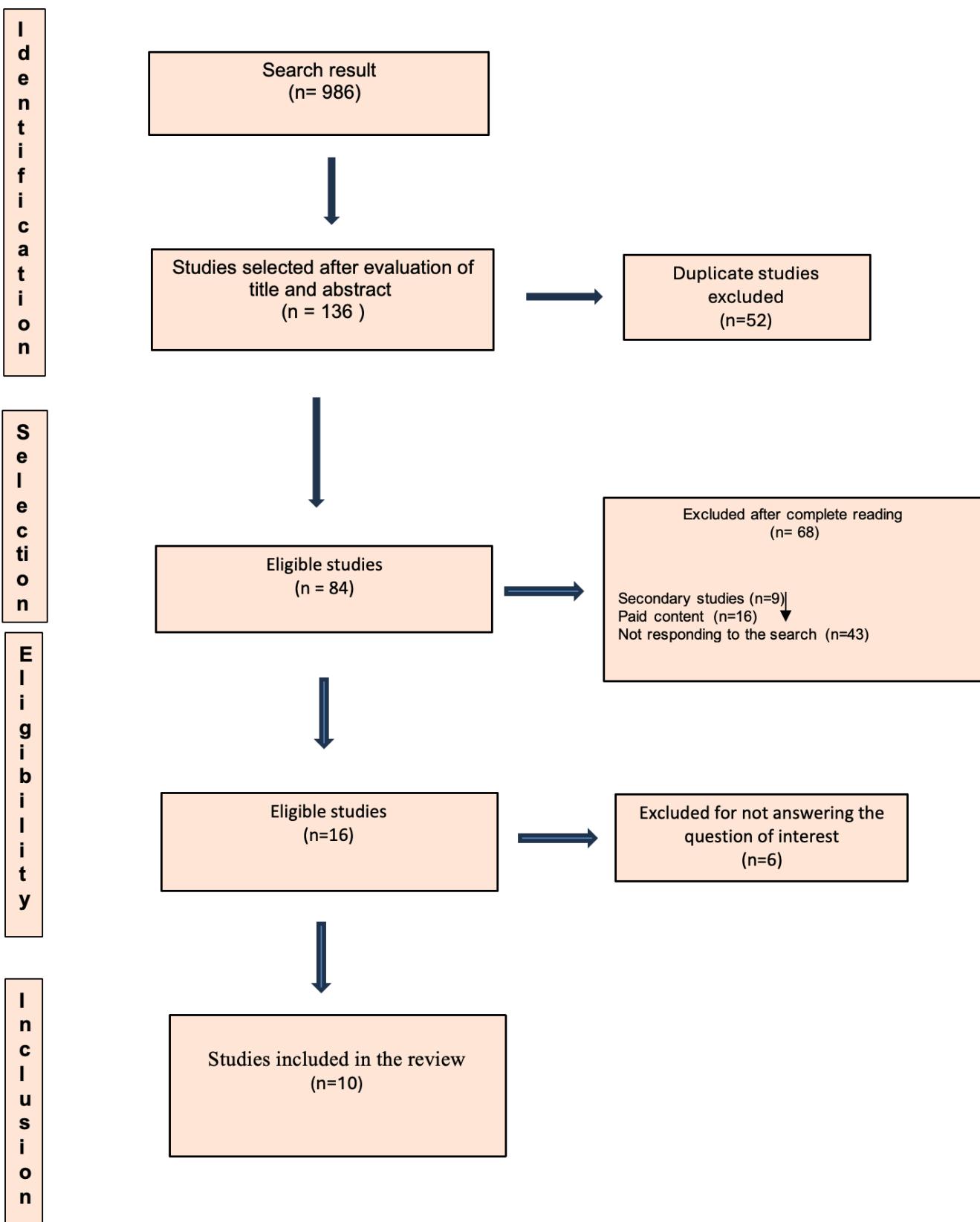


Figure 1 - Flowchart for selecting the articles included in the review

Source: From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n7

RESULTS

The data was processed in an Excel 2010® spreadsheet for analysis and subsequent discussion of the articles, considering information such as: objective, method, results, discussion and conclusion.

Initially, 986 studies were found and, after the entire selection process, 10 articles met the criteria established in this review, with 3 articles published in 2018, 2 in 2017 and one (1) article per year in 2013 to 2015 and in 2019 and 2020. As for the countries where the studies were carried out, five were Brazilian studies, one Spanish, one Iranian, and three English articles. Half of the articles selected are Brazilian, which may point to the concern and difficulties experienced in managing event notifications.

In order to improve the information collected, there have been changes to the notification form, from the manually completed questionnaire containing open questions, where professionals often report their technical complaints regarding pharmacovigilance, to the checklist with objective questions about AEs where the professional could remain anonymous, highlighting the computerized system as an advance in information collection.

Research into reporting using a computerized system shows evidence of an increase in the quality of reports. However, not all hospital institutions have this resource. Another important factor identified was that the drafting of SOPs (Standard Operating Procedures) to guide the notification of adverse events does not achieve the proposed objective, and it is plausible that communication problems are identified, due to the lack of clarification about the meaning of patient safety, the adverse event, how to carry out the notification and the predominance of a punitive culture, leading to an increase in underreporting.¹²

In the workers' understanding of the reasons for underreporting, the following were identified: indifference, mistrust, lack of knowledge and guilt for having been responsible for the incidents or for reporting them.¹³ Vulnerability in retrieving health information was observed, and is related to the poor quality, or even absence, of the notes and the lack of communication between computerized programs.¹⁴

The analysis of notifications at the hospital showed a significant increase in notifications between 2011 and 2014, from 20.4% to 48.2% respectively. With regard to the degree of damage, temporary damage, near misses or incidents without damage were found in 79.6% and 17.9% of cases respectively,

reflecting non-compliance with the routine/protocol in force at the institution. International data shows that between 2.9% and 16.6% of hospitalized patients suffer an adverse event. The obstacles encountered were the lack of a computerized system, fear of punishment, hesitation on the part of professionals to expose their mistakes, and a lack of understanding about the importance of reporting.¹⁵

In order to achieve improvements in the quality of patient safety, the implementation of promotional actions is essential, such as: educational activities in the professional's sector, a restructured digital notification model with objective and clear items.¹³

The research shows possibilities for improvement based on explicit and transparent goals, observing positive points in which teams and professionals show care, compassion, cooperation, civility and commitment to learning and innovation. On the other hand, the negative points are related to the obligation for professionals to provide care with overlapping bureaucratic demands, leading them to feel tormented. There are reports of computerization systems that are not suited to the demands, as well as a lack of communication between systems. Even so, the professionals emphasized the importance of client-centred care and not of chores.¹⁶

Identifying the challenges that Dutch hospitals faced in the processes of developing, implementing and refining HWQS dashboards and how they overcame them, it was found that hospitals have a certain variety of HWQS dashboards, including various subjects and responding to numerous objectives. Even with divergences in the system implemented, any hospitals bring in the safety indicators from the Dutch national safety program, admitting that the dashboard has a responsibility to show important indicators clearly, providing monitoring and possibilities for improvement.¹⁷

Evaluating the patient safety culture, establishing the system's strengths and weaknesses in order to define measures for improvement, highlights the growth in understanding of patient safety according to professional category, noting that service managers are responsible for increasing understanding of this issue, given their relationship with managers in quality policies. Considering the importance of identifying weak points with prospects for progress, the analysis correlated the errors with the precariousness of the laboratory's physical structure, reflecting negatively on the work environment, and consequently on health workers' understanding of organizational adaptation.¹⁸

Table 01 - Summary of the articles included in the review (objective/discussion)

Title / Authors	Journal / Year of publication / Country	Objective	Discussion
Art. 1. Analysis of incidents notified in a general hospital /	Revista Brasileira de Enfermagem – REBEn/ 2018 / Brazil Figueiredo, Mirela Lopes de; Silva, Carla Silvana de Oliveira E; Brito, Maria Fernanda Santos Figueiredo; D’Innocenzo, Maria	Analyzing adverse events reported in a hospital unit.	They point out that the measures used, such as educational activities and non-punitive attitudes, encounter obstacles in the process, such as: lack of a computerized program; fear of penalties; difficulty for professionals to expose their faults; lack of information within the service about AEs; And a lack of appropriate modifications after notification;
Art. 2. Quality indicators: tools for the management of best practices in Health /	Revista Brasileira de Enfermagem – REBEn / 2019 / Brazil Báio, Ana Cristina Pretto; Amestoy, Simone Coelho; Moura, Gisela Maria Schebella Souto de; Trindade, Letícia de Lima	To check with nurses how they characterize and apply “quality indicators” in their daily professional practice.	They found that quality indicators are capable of advising on clinical conduct, providing a comprehensive view; Highlighting the relevance of nurses’ understanding of these management tools and their applicability in the care provided.
Art. 3. Indicators of effectiveness of nursing care in the dimension of patient safety /	Rev. Bras. Enferm, 2020 / Brazil Seiffert, Leila Soares; Wolff, Lillian Daisy Gonçalves; Ferreira, Maria Manuela Frederico; Cruz, Elaine Drehmer de Almeida; Silvestre, Alexandra Lunardon	To validate “nursing care effectiveness indicators” in the context of “patient safety”, covering “availability, reliability, simplicity, representativeness, sensitivity, comprehensiveness, objectivity, low cost, usefulness, stability and timeliness”.	They point out the availability of clarifications to management, making it possible to screen indicators assessed by specialized technicians, assimilating the product of nursing demand during care, demonstrating an increase in patient safety.
Art. 4. The practice of reporting adverse events in a teaching hospital /	Revista da Escola de Enfermagem da USP / 2017 / Brazil Siman, Andréia Guerra; Cunha, Simone Graziele Silva; Brito, Maria José Menezes	What is the routine notification of AE by healthcare workers?	They identified weaknesses in reporting using printed forms, such as poor information on how to fill them out, pointing to computerized reporting, which proves to be more useful and improves the quality of information.
Art.5. Incidents reporting: barriers and strategies to promote safety culture /	Revista da Escola de Enfermagem da USP, 2018 / Brazil Varallo, Fabiana Rossi; Passos, Aline Cristina; Nadai, Tales Rubens de; Mastroianni, Patricia de Carvalho	Verifying the reasons associated with under-reporting of incidents by health workers.	Reveals a recent obstacle to reporting in the understanding of health workers: the recklessness of health workers regarding the culture of adverse event reporting, resulting in underreporting.

Title / Authors	Journal / Year of publication / Country	Objective	Discussion
Art.6. Quality in intensive care units: proposal of an assessment instrument / de Carvalho, Alexandre Guilherme Ribeiro; de Moraes, Ana Paula Pierre; Tanaka, Lilian Maria Sobreira; Gomes, Renato Vieira; da Silva, Antônio Augusto Moura	BMC Research Notes / 2017 / England	It demonstrates the true situation of health care, its interaction with current local regulations and the results encountered by intensive care medicine in the shortage of appropriate qualified resources.	There are fewer formal instruments for measuring health services in Brazil and other developing countries, compared to Europe and the USA.
Art.7. Developing a hospital-wide quality and safety dashboard: a qualitative research study / Weggelaar-Jansen, Anne Marie J W M; Broekharst, Damien S E; de Bruijne, Martine	BMJ - Quality & Safety / 2018 / London	To identify the challenges that hospitals face in the processes of developing, implementing and refining HWQS panels and how they overcome them.	It was observed that hospitals maintain the production of beneficial information for the dashboards, even with difficulties, considering the diversity of their clients.
Art.8. Assessment of patient safety culture among personnel in the hospitals associated with Islamic Azad University in Tehran in 2013 / Moussavi, Fatemeh; Moghri, Javad; Gholizadeh, Yavar; Karami, Atiye; Najjari, Sedigheh; Mehmandust, Reza; Asghari, Mehdi; Asghari, Habib	Electronic physician / 2013 / Mashhad (Iran)	To ascertain the perceptions of professionals in the area of diagnosis and treatment in hospital institutions.	The advance in the commitment of health institutions to improving qualified care can be identified, with the undeniable emphasis on expanding a culture of safety.
Art.9. Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study / Dixon-Woods, Mary; Baker, Richard; Charles, Kathryn; Dawson, Jeremy; Jerzembek, Gabi; Martin, Graham; McCarthy, Imelda; McKee, Lorna; Minion, Joel; Ozieranski, Piotr; Willars, Janet; Wilkie, Patricia; West, Michael	BMJ - Quality & Safety / 2014 / London	To extract high-level learning about culture and behaviour in NHS organizations in England.	It is observed that institutions must consider the dynamism of the process at its different levels, frequently monitoring the improvement of this process; It has been identified that in order to achieve quality and safety in NHS organizations, a consistent action plan is needed from a uniform perspective.

Title / Authors	Journal / Year of publication / Country	Objective	Discussion
Art.10. Assessment of patient safety culture in clinical laboratories in the Spanish National Health System / Gimenez-Marín, Angeles; Rivas-Ruiz, Francisco; García-Raja, Ana M.; Venta-Obaya, Rafael; Fuste-Ventosa, Margarita; Caballe-Martin, Inmaculada; Benítez-Estevez, Alfonso; Quinteiro-García, Ana I.; Bedini, Jose Luis; Leon-Justel, Antonios Torra-Puig, Montserrat	Bioquímica Médica / 2015 / Zagreb	To evaluate the patient safety culture in clinical laboratories in public hospitals in Spain. To establish the strengths and weaknesses of the system in order to establish measures for improvement.	Presents the processes in which technological tools should be used to improve knowledge and intensify the patient safety culture.

AE (Adverse Event); HWQS (information delivery systems that present a clear overview of the QS indicators needed to achieve the desired objectives and thus enable users to manage the QS performance of hospitals); QS (Quality and Safety); NHS (National Health Service).

DISCUSSION

It was noted that quality indicators are presented as one of the axes of improvement in health services. And that applied in an orderly fashion, these indicators make it possible to identify situations of "improvement and deviations from pre-established standards"¹⁹. They are also seen as necessary tools in the management of "good health practices" in hospital institutions.²⁰ Patient safety is described as the key to providing qualified healthcare.²¹

All the articles identify the need to understand the importance of adverse event reporting and the use of quality indicators, based on the premise that with the information collected it is possible to describe the situation in each sector and develop strategies to promote patient safety. In addition, co-responsibility is attributed to the entire team of health professionals and the patient, in order to create protective barriers and implement preventive actions to minimize harm in health care. Learning from mistakes is emphasized, with the assumption of a non-punitive stance.

Other important factors observed were: inefficient communication, excessive working hours, a shortage of professionals, specifically nurses, resulting in an increase in the occurrence of adverse events.^{21,14} However, these professionals are able to see the relevance of reporting as a tool to improve patient care.¹² But we still see many difficulties in the professionals' understanding of the importance of reporting to improve care, i.e. caring without causing harm.

Verifying how nurses portray and use quality indicators, affirming the understanding of the relevance

of quality indicators, contributing to the understanding as a management tool capable of measuring the quality of care promoting changes in compliance with good care practices. She goes on to say that nurses need to be supported by management to operationalize the "quality indicators", improving learning in the workplace. It is important that governance provides the health team with favorable circumstances, based on the results of the instruments used.²⁰

It is important to highlight the importance of the number of systematized tools to qualify health services in Brazil and in developing countries, which until then had been lower than in European countries and the USA. By demonstrating the true situation of health care and its interaction with local regulations, it can be seen that efficient tools for accurate measurements in different areas are indispensable for the qualification of health care.¹⁹

The scarcity of these tools, coupled with the lack of management support in developing them, is an obstacle to improving the quality of healthcare. Developed countries experience a different reality in terms of the quality of patient safety compared to developing and underdeveloped countries, considering the availability of management resources and the adequate dimensioning and qualification of people to evaluate hospital care in developed countries, as well as taking into account socio-cultural differences.

The importance of the topic can be seen in the objectives of the papers included in this study, considering the need to understand adverse event (AE) notification and the operationalization of quality indicators with the aim of

improving PHNs. The PSNs promote and support the establishment of actions aimed at patient safety, promoting the prevention, control and reduction of incidents, as well as bringing together the various environments in hospital institutions; promoting harmonization in the organizational and information systems that result in risks to the patient; with the primary objective of promoting quality and safety in health institutions.¹⁰

With a view to qualifying the care provided in Brazil, it can be said that the year 2013 was fundamental, given the institution of the PNSP and the creation of the Patient Safety Centers (NSP), contributing to the qualification of health care in all health services in the national territory, instituting actions to promote patient safety and improve health quality, respectively.¹⁰

I think there is a correlation between the articles selected and the research question. We have many more difficulties (fear, a punitive culture, difficulties with manual or electronic records, under-reporting, distant governance), but strategies have emerged in the form of welcoming/participation by the teams in the PSN, the creation of measuring instruments and records, sharing information on patient safety, indicators, and management participation.

CONCLUSION

In this study, the reports emphasizing the importance of the search for knowledge and scientific evidence in the area of patient safety and the advances made by the teams at the NSP in creating tools for reporting adverse events in order to measure quality indicators.

It is considered essential for health professionals to understand the importance of reporting adverse events, with the participation of management throughout the process, offering the necessary support to the NSP in drawing up strategies to promote patient safety. It is important to identify the weaknesses faced by the NSP, de-characterizing the punitive nature of adverse event reporting.

Considering the PNSP, we can see the need to notify adverse events in order to avoid exposing patients to avoidable risks. Health professionals therefore need to have scientifically-based knowledge of the patient safety culture.

The advances that have taken place in recent decades in relation to reporting with the aim of promoting patient safety can be seen. The technology applied in this process shows the diversity of possibilities we have for providing safe patient care. But we need to learn about the culture of patient safety in order to achieve good results.

It is therefore essential for the professional team, NSP and management to learn from studies and guidelines, establishing ways to provide care without causing harm.

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