Structure and activities of Patient Safety Centers in hospitals: an integrative review

Estrutura e atividades dos Núcleos de Segurança do Paciente em hospitais: uma revisão integrativa

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ABSTRACT

Introduction: Since the establishment of the National Patient Safety Program (NPSP) in Brazil, the implementation of Patient Safety Centers (NSP) in health establishments has become mandatory. Although many studies on implementation of the NSP in hospitals have been published, until now, there is not any synthesis of the literature to inform how to improve NSP's effectiveness. **Objective:** To synthesize the knowledge of Brazilian scientific publications on the structuring and functioning of patient safety centers in Brazilian hospitals. **Method:** Integrative literature review based on the guiding question: "What does scientific production present about the structuring and functioning of NSP in hospitals?". The searches were carried out in June 2020, in the LILACS, MEDLINE and BDENF databases, through services of the following descriptors: Patient Safety; Risk Management, Safety Management and Hospitals. **Results:** Twelve studies were selected for inclusion. In general, NSP partially comply with NPSP's guidance. Failures related to NSP material and human resources structures were identified, as well as in relation to the NSP activities. Local contextual aspects that represented barriers or facilitators for the effective activity of NSP comprise: material (e.g., staffing and training), symbolic (e.g., culture of blame), relational (e.g., senior management support) and institutional (e.g., quality improvement tools) issues. **Conclusions:** NSP implementation at hospitals have presented some achievements. Improving NSP effectivity requires creating a supportive context for safety improvement efforts.

KEYWORDS: Patient Safety; Risk management; Safety Management; Hospitals

RESUMO

Introdução: A partir da vigência do Programa Nacional de Segurança do Paciente (PNSP) no Brasil, tornou-se obrigatória a implantação de Núcleos de Segurança do Paciente (NSP) nos estabelecimentos de saúde. Apesar dos estudos sobre a implantação dos NSP em hospitais, até o momento, não há uma síntese que apresente pontos para orientar ações para melhoria de sua efetividade. **Objetivo:** Sintetizar o conhecimento disponível em publicações científicas brasileiras sobre a estruturação, funcionamento e atuação de NSP em hospitais. **Método:** Revisão integrativa de literatura realizada a partir da questão: "O que a produção científica apresenta sobre a estruturação e funcionamento de NSP em hospitais?". As buscas foram realizadas em junho de 2020, nas bases de dados LILACS, MEDLINE e BDENF, por meio de combinações dos seguintes descritores: Segurança do Paciente; Gestão de Riscos, Gestão de Segurança e Hospitais. **Resultados:** Doze artigos foram selecionados para inclusão. No geral, os NSP nos hospitais atendem parcialmente às diretrizes do PNSP. Foram identificadas falhas relacionadas às estruturas materiais e de recursos humanos dos NSP, bem como em relação às suas atividades. Aspectos do contexto local que representaram barreiras ou facilitadores para atuação efetiva dos NSP incluem questões materiais (por exemplo, dimensionamento e treinamento da equipe), simbólicas (por exemplo, cultura punitiva), relacionais (por exemplo, apoio da alta gestão) e institucionais (por exemplo, ferramentas para gestão

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da qualidade). **Conclusões:** A implantação de NSP nos hospitais tem apresentado avanços, mas ainda há muitos desafios para sua atuação efetiva. Melhorar a efetividade dos NSP exige criar um contexto mais favorável para o desenvolvimento de ações de melhoria da segurança.

PALAVRAS-CHAVE: Segurança do Paciente; Gestão de Riscos; Gestão de Segurança; Hospitais

INTRODUCTION

Ensuring patient safety (in other words, reducing the risk of unnecessary harm associated with healthcare[1]) is an ongoing challenge for health systems. In order to establish strategies to improve the quality of care, in 2013 the Brazilian Ministry of Health published the National Patient Safety Program (PNSP)[2]. Seeking to encourage a systemic approach to improve patient safety, PNSP actions were planned in four major areas: (1) activities in health services; (2) citizen engagement; (3) education and (4) research[3]. The activities for patient safety in health services were instituted by Joint Board Resolution (RDC) n. 36, of July 25, by Brazil's National Health Surveillance Agency (Anvisa), which made the implementation of Patient Safety Centers (NSPs) mandatory in health establishments, except individual offices, clinical laboratories, and mobile and home care services[4].

NSPs are responsible for strategies to improve the quality of care and for managing healthcare risks within health services[4]. They are also responsible for implementing processes to identify, assess, evaluate, and monitor risks, with subsequent communication to all stakeholders[4]. Other competences include strengthening the culture of safety, implementing Patient Safety Plans (PSPs) according to the local reality, and reporting adverse events to the national system[4].

PSPs contain the standardization of actions established by NSPs for risk prevention and management in the process of patient care within healthcare facilities[3]. Among them are the basic patient safety protocols, which include strategies for the correct identification of patients, the safe performance of surgical procedures, the correct practice of hand hygiene, the prevention of pressure injuries[5], prevention of falls, and the safe use, administration, and prescription of medications[6]. In addition, PSPs should also have protocols for safe prescription, use, and administration of blood products, safe use of equipment and materials, involvement of patients and families in care, promotion of a safe environment, promotion of effective communication between professionals and between health services, safety in the use of prosthetics and orthotics and safe use of enteral and parenteral nutrition therapies, and prevention and control of adverse events (including healthcare-related infections)[4].

The implementation of PNSP in health services has been slow. According to data from Anvisa, in November, most of these (4,285) were in hospitals[7]. Eight years after the publication of RDC n. 36/2013, of the 7,196 hospitals registered in the National Healthcare Establishment Registry (CNES)[8], approximately 60% had established NSPs.

The patient safety landscape in Brazilian hospitals is quite challenging and includes understaffing, limitations related to adverse event reporting, problems in continuing training programs, and lack of standardized processes for patient care, among others[9]. The shortage of material and human resources can interfere with the work of nursing professionals[10] and negatively impact the performance of safety strategies[11] and the internal work processes of NSPs[4].

In recent years, several studies focusing on the structure and activities run by NSPs in hospitals have been published[12,13]. However, an overview is still missing. In order to recommend actions to improve the performance of NSPs in hospitals, a more detailed understanding of this issue is required.

This integrative review aimed to synthesize the knowledge available in Brazilian scientific publications about the structuring, functioning, and performance of NSPs in hospitals.

METHOD

It is an integrative review, which consists of a synthesis of the information available at a given time, on a specific problem, in an objective and reproducible way. This type of research presents a method for searching and selecting studies, assessing the relevance and validity of the findings, collecting, synthesizing, and interpreting the data. Thus, a protocol was used to ensure thoroughness in the research process, which had the following components: review question, inclusion and exclusion criteria, strategies for the search, guidelines for material selection, data analysis and synthesis. The method was chosen because it enables the synthesis of studies with more than one approach, providing a more comprehensive approach to the thematic situation[14].

The research was conducted based on the following guiding question: "What does scientific literature present about the structuring and functioning of Patient Safety Centers (NSPs) in hospitals?" The search was conducted by two researchers in June 2020, in the following databases: *Medical Literature Analysis and Retrieval System Online* (MEDLINE), Latin American and Caribbean Literature in Health Sciences (LILACS), and the Nursing Database (BDENF). The following descriptors registered in the Descriptors in Health Sciences (DeCS) and *Medical Subject Headings* (MeSH) were used: "*Patient Safety*", "*Risk Management*", "*Safety Management*", and "*Hospitals*"; as well as the keywords "*Brazil*" and "*Brazilian*", in Portuguese and English. "*Patient Safety*" was the main descriptor and it was

also used in combination with each of the other descriptors with the Boolean operator "AND".

Original articles, published in Spanish, English, or Portuguese and for which the full text was available, were included. The inclusion of original articles was chosen because an overview of the situation of the centers in Brazil after the publication of the RDC n. 36/2013 is desired. Studies published with data collection prior to November 2013, the start of mandatory NSP implementation in healthcare facilities, were excluded.

The selection of the articles was made in three stages by the researchers: first the title was analyzed, then the abstract, and finally the full article.

The selected articles made up the *corpus* of the analysis. Relevant data were extracted from each article based on an instrument designed for research, including database, language, authors, title, methodology, results (or findings), implications, level of evidence (ranging from 1 to 6, with 1 being the best evidence), and identified limitations[14].

The findings from the articles were analyzed descriptively to characterize the structure and activities performed by the NSPs based on the guidelines established in RDC n. 36/2013. Additionally, the barriers and facilitators for the execution of patient safety actions by NSPs were identified. These were then grouped according to four dimensions of the social context, namely: material (i.e., concrete opportunities for people to put their skills and initiatives into practice), symbolic (i.e., meanings and worldviews), relational (i.e., leadership processes, teamwork), and institutional (i.e., structures and mechanisms for safety)[15].

RESULTS

A total of 2,556 articles were found, 382 from the MEDLINE database, 1,511 from LILACS, and 663 from BDENF. After applying the inclusion and exclusion criteria, 13 articles were selected. One article was excluded for presenting data similar to another, that is, they were performed in the same hospital and presented similar methodology, results, and discussion. In the end, 12 articles were selected (Figure). It is noteworthy that five articles corresponded to the products of two surveys. The results therefore corresponded to nine unique research and/or experience reports.

Regarding the design of the studies, five are qualitative descriptive, five are quantitative, and two are experience reports (Table). Data from the qualitative articles were collected by semi-structured interviews[12,16,17,18,19], document analysis[12,19] and non-participant observation[12,19], and addressed the perspective of professionals on factors that influenced the implementation of safety strategies. Quantitative data were collected through
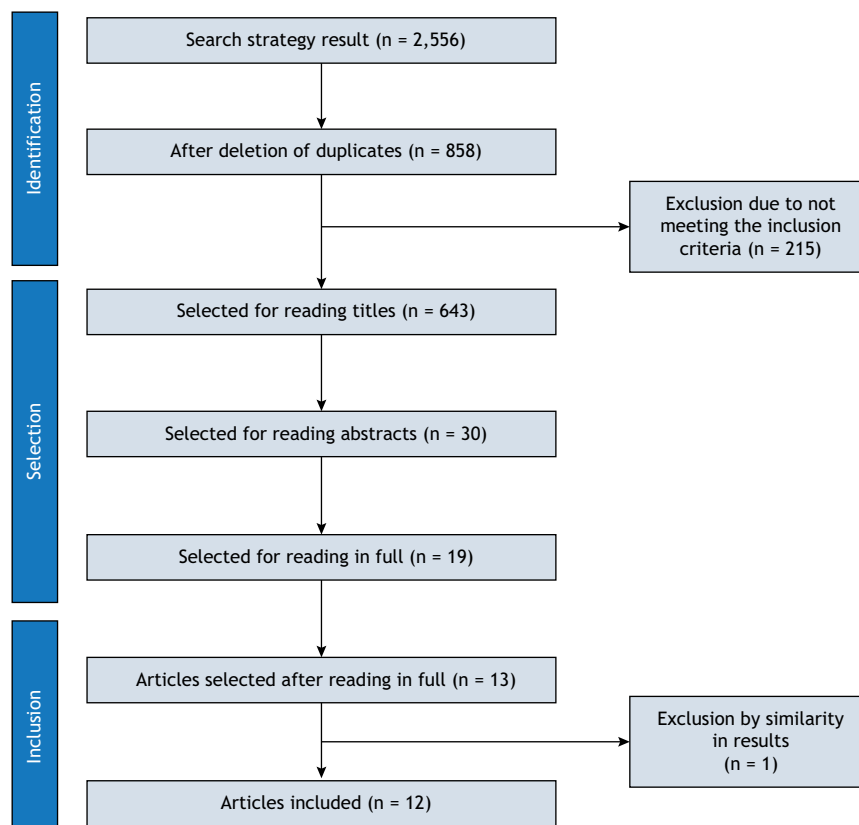
Source: prepared by the authors, 2020.

Figure. Article selection flowchart.

Table. Title, research design/participants and main findings of the articles included in the review.

Authors (year)	Title	Design / participants	Main findings
Cavalcante et al. (2019)[21]	*Implementação dos núcleos de segurança do paciente e as infecções relacionadas à assistência à saúde*	Quantitative cross-cutting/ 12 hospitals, 28 infection-control professionals, data collected by interview	Most hospitals had NSPs, and the protocols of hand hygiene, patient identification, and fall prevention were the most implemented.
Costa et al. (2020)[23]	*Segurança do paciente em serviços de saúde: uma análise na cidade de Salvador, Bahia*	Quantitative/members of the NSP of 12 large hospitals	The studied hospitals had NSPs and most of them had implemented all the basic protocols. Weaknesses in training processes in patient safety.
Macedo and Bohomol (2019)[13]	*Análise da estrutura organizacional do núcleo de segurança do paciente dos hospitais da Rede Sentinela*	Quantitative exploratory and descriptive/12 hospitals, 12 NSP coordinators, data collected by self-completion of form	The institutions had NSPs. Weaknesses were found in NSP processes, risk management in ongoing training programs and in the availability of resources.
Macedo et al. (2018)[22]	*Implantação do núcleo de segurança do paciente em hospital universitário*	Quantitative descriptive /one hospital, data collected by interview	NSP implemented, there was support from senior management, adequate physical structure and human resources. Risk management was performed for the protocols. Communication protocols and involvement of patients in their safety were not implemented.
Oliveira et al. (2017)[18]	*Fatores facilitadores na implantação das estratégias de segurança do paciente: estudo descritivo-exploratório*	Qualitative exploratory descriptive/four hospitals, 72 nurse managers	The support of senior managers and ward managers, risk management initiatives and continuing education processes were mentioned as facilitators.
Prates et al. (2019)[24]	*Núcleo de segurança do paciente: o caminho das pedras em um hospital geral*	Experience report/one hospital, document analysis and experience report of the authors	Implemented actions to strengthen the safety culture, implemented basic protocols, risk and incident management, and monitoring of patient safety indicators.
Reis et al. (2019)[16]	*Dificuldades para implantar estratégias de segurança do paciente: perspectivas de enfermeiros gestores*	Qualitative exploratory descriptive/four hospitals, 72 nurse managers	Difficulties included nursing understaffing, low compliance with care professionals.
Reis et al. (2017)[17]	*Nurse manager perceptions of patient safety strategy implementation*	Qualitative exploratory descriptive/four hospitals, 72 nurse managers	The delay in implementation caused disappointment in some professionals. Others were happy to be involved in safety strategies.
Santos et al. (2019)[25]	*Avaliação da implantação de um núcleo de segurança do paciente*	Experience Report / an NSP from a hospital	NSP has implemented actions for hand hygiene protocols, safe surgery, patient identification, and pressure injury prevention.
Serra et al. (2016)[20]	*Situação dos hospitais de referência para implantação/ funcionamento do núcleo de segurança do paciente*	Descriptive quantitative / six hospitals, data collected by direct observation and verification of records	One hospital had no NSP. Identified problems included shortage of professionals, equipment, and materials.
Siman and Brito (2018)[12]	*A dimensão prescrita e real de práticas de profissionais de saúde no contexto da segurança do paciente*	Qualitative study type Case/hospital, 31 participants NSP members and nurses, data saturated with 12 interviews	There was distance between prescribed protocols and reality, deficit of human and material resources, and failures in the continuing training program.
Siman et al. (2019)[19]	*Desafios da prática na segurança do paciente*	Qualitative type of study case/31 professionals hospital	There were NSPs and prescribed protocols and difficulties to implement the actions. Deficits in human and material resources posed challenges.

Source: prepared by the authors, 2020.
NSP: Patient Safety Center.

interviews[20,21,22,23], direct observation[20], and record checking[20], and data collection was carried out with the same instrument validated in two articles[13,22]. These studies addressed the characterization of the structure and activities conducted by NSPs. The selected set of articles has a low level of evidence, since they are mostly descriptive studies (level 4).

Data were collected from hospitals in the Southeastern (four articles, 14 hospitals), Central-Western (one article, six hospitals), Southern (five articles, five hospitals), and Northeastern (two articles, 24 hospitals) regions of Brazil, corresponding to data from public (n = 32), philanthropic (n = 11), private (n = 6), and public-private partnership (n = 1) hospitals.

The synthesis of the findings of the articles selected for the review was organized into two themes/topics: structure and activities of the NSP, and barriers and facilitators for the execution of patient safety activities.

Structure and activities of NSPs

Most of the studies point out that the NSPs had limitations related to their work structures and processes. Problems in the availability of basic equipment[12,20,23], lack of space and equipment dedicated to the NSP[13,21,23], and scarcity of resources for the implementation of PSP activities[13,19,20,23] stood out. The lack of professionals and personnel trained in quality or patient

safety[13,19,20,23] was a frequent finding, in addition to the absence of professionals with exclusive dedication to the work at the NSP[23]. Nurses[12,19,21,23], pharmacists[12,19,21,23] and physicians[21,23] were the professionals who most often made up the NSPs. Nevertheless, the number of NSPs without the presence of physicians was significant[12,19,22,23,24].

Regarding activities, the studies pointed out weaknesses in process management[20], communication problems among the teams[12,21], and lack of reporting of adverse events, both internally[23] and in the national system[13].

The implementation of the protocols established by RDC n. 36/2013 in the hospitals proved to be variable. The most frequently implemented protocols were patient identification, hand hygiene, fall prevention[13,21,22,23], healthcare-related infection control, safe surgery, pressure injury prevention, and orthosis registration[13,21,22]. The other protocols—effective communication[21,22,25], safe prescription, use, and administration of medications[21], patient involvement in patient safety[21,22], enteral and parenteral nutrition safety, blood transfusion safety, and safe use of equipment and materials[13,22]—have been implemented by fewer NSPs. In some hospitals, the implementation of the protocols was accompanied by follow-up on their indicators[21,23]. Still regarding the protocols, some articles highlighted the distance between what was formalized in the institutional documents and the practices that were actually performed by the care teams[12,19].

The training of professionals in quality and patient safety, a fundamental strategy for improving safety, received little attention from the NSPs. Not all hospitals provided training[12], while others did it in a deficient manner: they did so only upon admission of professionals[13] or did not cover all professionals[20]. Even hospitals that conduct training activities have weaknesses in activities related to patient safety, such as the non-active participation of the nursing care team in the management and surveillance of risks[21].

Barriers and facilitators for the execution of patient safety actions by Patient Safety Centers

Patient safety actions, coordinated by the NSP team, are influenced by aspects of the local context that can function as barriers[12,16,19,20,21,24] or facilitators[17,18,24] to their execution. Barriers related to the material context identified in the studies included lack of training on patient safety[12,24], understaffed care teams, work overload, compensation problems, stress, turnover, poor structural conditions in inpatient facilities, insufficient and poor-quality materials, lack of maintenance and/or absence of equipment[19]. These aspects impair both the structure and internal work of the NSP and the actions that the NSP conducts with the care teams, like the implementation of protocols. In some hospitals, this situation was associated with the lack of financial[20] and material[21] resources.

Regarding the symbolic and relational aspects of the context, the following were considered barriers to the progress of actions: low

support from senior management[16], the existence of a punitive culture within hospitals, and the resistance of some healthcare professionals to comply with safety processes [12,24]. The resistance of the care team, manifested by their non-compliance with safety practices, was referred to as a cause of demotivation in professionals who managed the actions[16]. Another demotivating factor for nurse managers was related to frustration for noticing that actions in their hospitals were lagging behind those of other hospitals that started their NSPs in the same period[18].

Facilitating aspects for the execution of patient safety actions in hospitals were presented by a smaller number of the analyzed studies. In the symbolic and relational dimensions, they included support from top management and the existence of committed leaders[18]; in the institutional dimension, implemented hospital accreditation processes[17] and the use of quality and risk management tools in the work routine[18,24]; and in the material dimension, the performance of continuing training[18]. A motivating factor for the teams involved in the implementation of new practices was the satisfaction caused by the positive impact of the actions[17].

DISCUSSION

This article presents the findings of a literature review on the structure and activities of NSPs in hospitals as components of the "activities in health services" area of the PNSP. The literature review identified that NSPs in hospitals partly meet the guidelines of Anvisa RDC n. 36/2013. Many of the formally established NSPs struggle to advance in the proposed activities because they do not find a favorable context for the execution of actions to improve patient safety. The barriers range from the lack of support from senior management, understaffing, insufficient training, inadequate equipment and supplies to a punitive culture and care teams that are resistant to the actions proposed by the NSPs. Many of these barriers impact both the NSPs and the care teams. The enablers identified by this review correspond to the opposite end of the spectrum, including support from top management, committed leaders, consistent adoption of quality and risk management practices, and adequate training.

System improvement regarding patient safety in healthcare organizations involves cultural, structural, and process issues[1]. Senior management plays an essential role in improving the system, since its engagement with safety initiatives can produce positive results in the safety environment, in the engagement of teams and in the results of safety initiatives[26]. Characteristics of leaders of safe organizations include a systemic look at safety problems and the incorporation of practices aimed at minimizing risks[27]. It is the role of management to provide adequate human resources, equipment, materials and funds[4], in addition to setting goals and initiatives aimed at increasing safety[28].

Senior management should adopt a rational vision when setting up NSP teams because these professionals need to play an

articulation role within the health service[3,29]. For this purpose, these teams should ideally be multidisciplinary, including at the bare minimum pharmacists, doctors and nurses[29]. This minimal composition was not reported in many of the NSPs we studied. This fact may have contributed to the process weaknesses found in these NSPs, such as problems in the reporting process (internal and external) and the lack of robustness in the practical implementation of safety protocols.

Most of the protocols that were considered implemented correspond to basic protocols, except for infection control protocols, whose minimum actions were established in a period prior to patient safety, in 1998[30]. The difference between the time of mandatory implementation of infection control protocols and patient safety protocols (approximately 15 years) may explain the higher frequency of positive results found in infection control.

The finding that patient safety protocols may be expressed more in their prescribed dimension than in their actual dimension (i.e., existing in written documentary form but not being executed in practice)[12] demonstrates the need for NSPs to know more about how care teams put protocols into practice. This approach enables us to know what steps of the protocol are less complied with by the teams and why this occurs, and then guide the planning, together with the professionals at the front end, of initiatives to increase compliance.

One of the reasons for the low compliance with safety protocols seems to be related to the sizing of care teams[11,31]. The high workload may contribute to professionals having a greater perception of stress and a greater probability of generating losses to the quality of patient care[32]. In addition, poor working and remuneration conditions, internal conflicts in teams and conflicts between professionals and the institution can generate burnout[33] and contribute to the low compliance and underreporting of adverse events[34].

Implementing effective strategies to increase compliance with safe practices is a challenge. It can include educational strategies[35] and effective communication[36] and requires the active participation of NSPs[4]. This comprises actions to constantly encourage the participation of professionals in the processes and to strengthen the culture of fairness, since work processes that do not promote the inclusion of professionals may be associated with low rates of adverse event reporting[34]. In addition, actions aimed at promoting good relationships within teams can contribute to a lower perception of overwork among the staff[37].

Continuing education strategies play a key role in the evolution of positive perceptions about patient safety[35,38]. Even hospitals that conduct training activities have weaknesses in activities related to patient safety, such as the non-active participation of the nursing care team in the management and surveillance of risks[21]. This finding suggests that even if properly conducted, training does not generate immediate results. It also reinforces the notion that, although it is a fundamental strategy,

the training of teams is not enough to ensure compliance with safe practices[26].

The results draw attention to the unmet need to strengthen the safety culture within hospitals. This includes fostering a fair culture based on human behavior in the face of the incident, with a distinction between human error, risky behavior and recklessness, and the adoption of a systematic view of the occurrence of these events[4]. Failure to address the punitive culture may be an aggravating factor for the failure of actions to promote a safety culture[39]. Strengthening the safety culture includes actions aimed at valuing professionals, implementing safety protocols, supporting managers, and promoting good working conditions[40,41]. The incorporation of these improvement actions requires active NSPs[29], which emphasizes the importance of properly structuring these centers.

The methodological diversity of the studies included in this review allowed greater breadth in the identification of factors related to the object of study and is a strength of this article. The review was also comprehensive with respect to the nature of the hospitals, including studies that presented results referring to public, philanthropic, and private hospitals. However, the sample of facilities was relatively small when considering the totality and diversity of hospitals in Brazil, which is a limitation of this review. Moreover, the findings were not homogeneously distributed across Brazilian regions and states. The Northern region of Brazil was not included in any of the studies. The regions have differences in relation to the availability of hospital resources and most of the large hospitals are concentrated in the Southeast[42], while the Northern region concentrates the lowest number of inpatient beds in relation to other regions[43]. A study suggested that the North had lower rates of hospital technical efficiency in 2014 and 2015 when compared to other regions of Brazil[44]. These facts may be involved in the scarcity of published articles on structured NSPs in hospitals in that region. Another limitation of the present study refers to the low level of evidence of the papers included in the review.

In addition, the results indicated that the topic is still rarely addressed in the scientific environment, which highlights the need to conduct more research on the subject in Brazil, including with greater coverage of geographical regions. Thus, the knowledge on how to provide more effective performance of NSPs in hospitals would increase.

The findings of this review suggest issues that should be addressed by health policy makers, hospital directors, and NSP teams in order to favor efforts to improve patient safety. As a starting point, more attention should be paid to the proper staffing and training of care and quality and safety management teams. In addition, the inadequate conservation of equipment and the lack of supplies must be addressed. Together with understaffing, these problems strongly affect the ability and motivation of healthcare professionals to provide safe care[45]. Considering the critical role of senior leaders in encouraging and creating a favorable context for patient safety, efforts aimed at the development and

engagement of directors, coordinators and managers are also necessary. Finally, the challenges of complying with safe practices require NSP teams to implement protocols that go beyond writing a document and training staff. They also reveal the need to adopt logics for monitoring protocols that, more than data, generate intelligence, favoring the active search for weaknesses and the use of multiple methods without depending on the completion of forms[46].

This review aimed to present an overview of the structure and activities of NSPs in hospitals. Among the selected studies, few addressed activities related to the monitoring of safety protocols and the involvement of patients and families in their safety. Original studies or literature reviews focusing on specific activities are important to generate knowledge about practices

in the Brazilian scenario and identify lessons learned. Studies that assess the results of the implemented practices are also of essence for a better understanding of the subject.

CONCLUSION

The implementation of NSPs in hospitals has made some progress, but there are still many challenges for its effective performance. Improving the effectiveness of NSPs requires creating a more favorable context for the execution of safety improvement actions. Addressing the barriers identified in this study is a good starting point, and so is recognizing the essential role of top managers in promoting patient safety as a priority and in ensuring the appropriate sizing and training of both care teams and the NSPs.

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Authors' contribution

Coslop S - Conception, planning (study design), acquisition, analysis, interpretation of data and writing of the manuscript. Portugal FB - Conception, planning (study design) and writing of the manuscript. Pereira MSR - Data acquisition, analysis, and interpretation. Calazans MSC - Data analysis and interpretation. Caldas BN - Analysis, interpretation of data and writing of the manuscript. Lima EFA - Writing of the manuscript. All authors approved the final draft of the manuscript.

Disclosures

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