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PROTOTYPE FOR MONITORING INCIDENTS IN THE HEALTH SERVICES: INNOVATION FOR PATIENT SAFETY

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ABSTRACT

Objective: to describe the participatory process of building a prototype to support the development of an information management system for notification, investigation and monitoring of health incidents.
Method: a methodological research study on technology development, carried out in two stages: 1) documentary analysis of primary and secondary sources related to forms and legislation on incident notification systems, from September to October 2018; 2) deliberative dialog in two sessions, with 12 managers and coordinators of the Quality and Patient Safety Center of public hospitals in the Federal District, held in November 2018. In the deliberative session there was a presentation of the prototype and discussion of its applicability and functionality for the development of an information system for risk management in the health services.
Results: creation and prototyping of a tool with 4 (four) screens representing the systematic flow of data. Screen 1: Simplified notification for patients and companions. Screen 2: Notification for the health professional. Screen 3: Investigation of the event and action plan. Screen 4: Intervention and monitoring by means of indicators.
Conclusion: this is a tool capable of integrating actions to reduce the occurrence of incidents based on the identification and timely intervention on the risk factors. It can be used as a facilitating basis for the development or improvement of new instruments for risk management in the health services.

DESCRIPTORS: Patient safety. Health information systems. Notification. Risk management. Quality of health care.

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PROTÓTIPO PARA MONITORAMENTO DOS INCIDENTES NOS SERVIÇOS DE SAÚDE: INOVAÇÃO PARA A SEGURANÇA DO PACIENTE

RESUMO

Objetivo: descrever o processo participativo de construção de um protótipo para subsidiar o desenvolvimento de um sistema de gestão de informação para notificação, investigação e monitoramento de incidentes em saúde.
Método: pesquisa metodológica de desenvolvimento de tecnologia, realizada em duas etapas: 1) análise documental de fontes primárias e secundárias relativas a formulários e legislação sobre sistemas de notificação de incidentes, no período de setembro a outubro de 2018; 2) diálogo deliberativo em duas sessões, com 12 gestores e coordenadores de Núcleo de Qualidade e Segurança do Paciente de hospitais públicos do Distrito Federal, realizado em novembro de 2018. Na sessão deliberativa houve apresentação do protótipo e discussão sobre a sua aplicabilidade e funcionalidades para o desenvolvimento de um sistema de informação para o gerenciamento de riscos nos serviços de saúde.
Resultados: criação e prototipagem de uma ferramenta com 4 (quatro) telas representando o fluxo sistemático dos dados. Tela 1: Notificação simplificada por pacientes e acompanhantes. Tela 2: Notificação por profissional de saúde. Tela 3: Investigação do evento e plano de ação. Tela 4: Intervenção e monitoramento por meio de indicadores.
Conclusão: ferramenta capaz de integrar ações para reduzir a ocorrência de incidentes a partir da identificação e intervenção oportuna sobre os fatores de riscos. Poderá ser utilizada como base facilitadora para o desenvolvimento ou aprimoramento de novos instrumentos para gestão de riscos nos serviços de saúde.

DESCRITORES: Segurança do paciente. Sistemas de informação em saúde. Notificação. Gestão de riscos. Qualidade da assistência à saúde.

PROTOTIPO PARA EL CONTROL DE LOS INCIDENTES EN LOS SERVICIOS DE SALUD: INNOVACIÓN PARA LA SEGURIDAD DEL PACIENTE

RESUMEN

Objetivo: describir el proceso participativo de construcción de un prototipo para respaldar el desarrollo de un sistema de administración de la información para la notificación, investigación y control de incidentes en el ámbito de la salud.
Método: investigación metodológica de desarrollo de tecnología, realizada en dos etapas: 1) análisis documental de fuentes primarias y secundarias relativas a formularios y legislación sobre sistemas de notificación de incidentes, durante el período de septiembre a octubre de 2018; 2) diálogo deliberativo en dos sesiones con 12 administradores y coordinadores de los Centros de Calidad y Seguridad del Paciente de hospitales públicos del Distrito Federal, realizado en noviembre de 2018. En la sesión deliberativa se presentó el prototipo y se analizó su capacidad de aplicación y sus funcionalidades para el desarrollo de un sistema de información para la administración de riesgos en los servicios de salud.
Resultados: se crea y diseña el prototipo de una herramienta con 4 (cuatro) pantallas que representan el flujo sistemático de los datos. Pantalla 1: Notificación simplificada por parte de pacientes y acompañantes. Pantalla 2: Notificación por parte del profesional de la salud. Pantalla 3: Investigación del evento y plan de acción. Pantalla 4: Intervención y control por medio de indicadores.
Conclusión: la herramienta puede integrar acciones para reducir la cantidad de incidentes a partir de la identificación e intervención oportuna sobre los factores de riesgo. Se podrá utilizar como base facilitadora para el desarrollo o la mejora de nuevos instrumentos para la administración de riesgos en los servicios de salud.

DESCRIPTORES: Seguridad del paciente. Sistemas de información en salud. Notificación. Administración de riesgos. Calidad de la asistencia a la salud.

INTRODUCTION

Health institutions are complex structures of high risk for the occurrence of incidents during care. The literature points out that thousands of people are victims of preventable harms while receiving health care, many of them with irreparable losses and even death, which justifies the concern at a global level with the patient safety in these environments.[1–2]

Patient safety means reducing the risk of unnecessary harm associated with health care to an acceptable minimum. Safety incidents are events or circumstances that could have resulted in unnecessary harm to the patient. When the incident results in harms, it is considered an adverse event.[3]

In addition to its cost in terms of human life, the occurrence of incidents has an important social and economic impact, as it causes an increase in morbidity, mortality, treatment time for patients and care costs,[3–4] to which loss of confidence and dissatisfaction of the population with the health services is added.[4]

There is currently an awareness of the problem with incidents and/or adverse events and, in recent years, considerable efforts have been made to prevent or at least reduce the harm caused to the patients. Among the strategies to improve patient safety, the creation of programs for notification and monitoring of incidents in the health services stands out.[3–5]

The notification consists of the communication of the event that occurred and added to the surveillance and monitoring practices as indispensable components for the reduction of the health risks and the promotion of patient safety.[6–8]

In 2000, the report published by the Institute of Medicine of the United States of America drew the attention to the implementation of a computerized system for the notification of incidents as a fundamental strategy to learn from errors, prevent their recurrence and, consequently, improve patient safety in the health services.[9]

The political guidelines for patient safety of the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA), through Resolution of the Collegiate Board (*Resolução da Diretoria Colegiada*, RDC) No.36, and the National Program for Patient Safety (*Programa Nacional de Segurança do Paciente*, PNSP) of the Ministry of Health (MoH), through Ordinance No.529, recommend the implementation of tools that enable the notification of incidents. With this, the aim is to learn about and monitor incidents so that they can be used as a source of learning and as a basis for supporting preventive actions and for reducing the risks of harms resulting from health care.[2–3,10–11]

These two Brazilian entities are in line with the guidelines of the World Health Organization (WHO), which launched the preliminary guidelines with recommendations for the development of systems for reporting adverse events and learning for patient safety. The WHO has also published a standard model of categories of minimum information that should make up an incident reporting system.[3,8]

A number of studies have pointed out that one of the major challenges of the reporting systems lies in the difficulties in extracting adequate and practical information amidst the large volume of data collected.[8] The following is mentioned as a recurring problem: the existence of incomplete, inadequate, untimely data, and often, unrelated to priority activities.[12]

The literature describes numerous benefits of a computerized system to report incidents, among them, the increase in the number of notifications, better adherence by the professionals in reporting events, improvement in the quality of records, and optimization of the investigation process.[2,12] Another important aspect is that they allow analyzing information in an organized manner, helping to identify problems in the workflow, infrastructure or processes, in addition to planning and implementing improvement actions.[13]

Health institutions must have an internal reporting system capable of identifying and analyzing events that justify forwarding reports to external agencies.[7] However, not all public hospitals have an internal system to operationalize the notification, investigation and monitoring process of events.

This process is carried out in different ways, using electronic and printed forms, which makes the risk management model diversified, as well as culminating in different work processes among the sectors responsible for monitoring the indicators.[12] Therefore, the creation of computerized systems inserted in the workplace that facilitate the registration and standardization of this information becomes essential for the management of risks in these hospitals.[11–13]

In the care dimension, innovation involves management tools, products and processes that aim to increase the quality and effectiveness of the services developed in these environments and certainly in the care attributed to the patient.[14] These processes correspond to the invention and implementation of new ideas, which are driven by people based on simple strategies derived from the need and the search for solutions to everyday problems in a given institutional context.[14–15]

In this sense, a proposal was elaborated to create a system for incident management in hospitals designed based on the ongoing experience of the Quality and Patient Safety Centers of the State Health Secretariat of the Federal District (*Núcleos de Qualidade e Segurança do Paciente da Secretaria de Estado de Saúde do Distrito Federal*, NQSP-SES-DF). The prototype was the result of an integration process between academy and services, with a view to producing applicable knowledge, whether in the generation of products or in the increment of processes.[15]

The purpose of this article is to describe the participatory process of building a prototype to support the development of an information management system for notification, investigation and monitoring of health incidents.

METHOD

A methodological research study was conducted based on incremental technological production. Methodological research develops instruments and usually involves complex and sophisticated methods, in which the researcher aims to develop a reliable, accurate and usable instrument that can be used by other researchers and other individuals.[16]

The operationalization of the study took place in two sequential but complementary stages, through documentary analysis and deliberative dialog.

Documentary analysis

Documentary analysis is a procedure that uses methods and techniques for the apprehension, understanding and analysis of documents of the most varied types.[17] It consists of an intense and wide examination of several materials that have not yet undergone any analysis work, or that can be re-examined, seeking other interpretations or complementary information.

The selection of documents occurred with the application of authenticity, credibility, representativeness and meaning criteria, both for primary and secondary documents.[17] Primary sources (without previous analytical treatment) were analyzed, considering those documents elaborated by members of the NQSP-SES-DF team that contained guidelines on notification, investigation and monitoring processes regarding health incidents. Documents published by 2 (two) public hospitals of the SES-DF were selected, chosen because they already had NQSPs with consistent work processes, with implementation of forms for notification and monitoring, and had established dynamics of risk management and intervention in the causes of the incidents. The primary documents analyzed were as follows: forms for notification and investigation of incidents and risks, documents guiding the completion of the forms, models of action plans, and technical data sheets for indicators.

Secondary sources (published bibliography) were those related to patient safety legislation and to the current context of incident notification systems, such as handbooks, resolutions, protocols, instructions, ordinances, published in physical or electronic media, in the years 2005 to 2018, by the MoH, ANVISA and SES-DF, as shown in Chart 1.

Documentary analysis followed the next stages: selection of the documents based on the objectives and on the criteria of authenticity, credibility, representativeness and meaning; analysis of the material by reading the complete documents; extraction of excerpts that described the incident notification, investigation and monitoring process and the categorization of the identified key elements.

This procedure was carried out from September to October 2018 and resulted in the inclusion of eight documents (Chart 1), which were used as sources of information to support the content described in the prototype.

With the data obtained in the documentary analysis, a low-fidelity prototype was elaborated, which consists in the graphic representation of the idea to assist in the definition of the project, survey of the necessary requirements and essential functions to evaluate some specific scenarios.[18] The prototype was created using Microsoft Word from the Office 2016 package and then Pencil, which is a free prototyping software that allows for the creation of mockups of websites.

Chart 1 – Classification of the sources of documentation. Brasília-DF, Brazil, 2019.

Title	Type of document	Year	Author	Characterization of the material
1.Who draft Guidelines for adverse event reporting and learning systems	Guideline	2005	World Health Organization	Recommendations for the development of information systems.
2. Conceptual structure of the International Classification on Patient Safety.	Technical report	2011	World Health Organization	Own terminology for patient safety and its practical applications.
3. Resolution of the Collegiate Board-RDC No. 36	Resolution	2013	Ministry of Health ANVISA*	Establishes actions for patient safety in the health services.
4. Notification and investigation form for incidents and/or adverse events	Internal protocol	2014	Team NQSP-SES-DF†	Instructions for notification of incidents, adverse events, technical complaints, nutritional therapy and blood products.
5. Electronic forms for notification of incidents and/or adverse events	ANVISA Information System - NOTIVISA	2015	Ministry of Health ANVISA*	National computerized system for registering problems related to the use of technologies, products and care processes.
6. General guidelines for notifying adverse events related to health care.	Technical note	2015	ANVISA*	Presents the flow of information for the notification process of incidents and adverse events
7. Minimum information model for incident notification and patient safety learning systems	Guide	2016	World Health Organization	Categories of minimum information that must be collected when notifying an adverse event
8. Risk management and investigation of adverse events related to health care	Handbook	2017	ANVISA*	Instrument on the surveillance and monitoring of care-related incidents

*ANVISA: National Health Surveillance Agency; †NQSP-SES-DF: Quality and Patient Safety Center of the Health Secretariat of the Federal District.

Deliberative dialog

Deliberative dialog is a knowledge translation strategy characterized by intentional conversations, in which the participants (stakeholders) collectively create new understandings using scientific evidence and their own tacit knowledge to address a particular challenge or problem that affects the health system.[19–20]

The method includes elaborating a synthesis of evidence, careful selection of the participants, neutral and skillful facilitation, constructive meeting environment with innovative approaches, and data analysis with integrated methods.[20] It is noteworthy that, due to the characteristics of this research, the synthesis of evidence was replaced by the prototype of the system containing the forms and requirements for the stages of notification, investigation and monitoring of incidents.

Two sessions were held in November 2018, which enabled the participation of twelve stakeholders. The deliberative dialog followed these stages:

- Selection of the participants: health professionals working in the hospital management and in the NQSP-SES-DF for at least six months.
- Definition of facilitators and location: the sessions were moderated by two researchers with mastery of the content of the prototype and the work processes of the NQSPs, in order to enable the debate on the technical aspects of the prototype. The sessions were held on the premises of the Health Sciences College (*Escola Superior de Ciências da Saúde*, ESCS).
- Technique used during the sessions: exhibition of the prototype in PowerPoint format and printed handouts delivered to the participants, for notes relevant to the recommendations emerging during the session.
- Data analysis: the contributions were extracted from the notes of the handouts and those made by the researchers themselves. Each document collected was reviewed, and all handwritten field notes were transcribed and listed in a report. Subsequently, they were analyzed according to their applicability for the remodeling of each screen of the prototype, so that it was consistent with what was practiced in the NQSP and with the recommendations of the national and international guidelines.
- Evaluation: a debriefing session was carried out, in which the results obtained and the recommendations for the construction of the system were analyzed and discussed.

RESULTS

The requirements for preparing the forms were based on the WHO guidelines for building reporting and learning systems. The linguistic adequacy adopted followed the criteria established in the International Classification for Patient Safety, developed by the WHO to facilitate the comparison, measurement, analysis and interpretation of information and to improve patient care.

The selected documents established the theoretical bases that supported the content described in the prototype, containing the three operational stages of risk management: notification, investigation and monitoring. The prototype served as the axis of the project for creating a product that would give users a prior idea of the system.

The deliberative dialog provided a moment of collective construction, decisive for defining the requirements, functionalities and main attributes of the system. During the sessions, many modifications and adaptations were made until a consensual version of the prototype was reached.

The deliberative dialog generated 78 different records in order to add modifications to the prototype, and these records referred to the registration/profiles of users of the system (6), necessary information for notification (50) and investigation (5). Some other suggestions for changes were specific to technical complaints (8), falls (3), medication errors (1) and hemovigilance (5). All were analyzed and considered for the final prototype.

The prototype resulted in 4 (four) forms and follows the systematic flow of data from the notification, investigation and monitoring stages, allowing risk management, as described below.

Notification stage

For the notification, it was decided to elaborate two types of forms: the simplified module - intended for notification by any citizen (patient, family member, companion, outsourced worker), and in which the questions are asked in a simple and understandable way; and the notification module for the health professional - developed with specific questions covering the four categories of the type of most frequent incidents in the health services.

The simplified notification form (Figure 1) stands out by its simple, practical, confidential, and anonymous nature. It consists of three categories: incident data, notifier data, and incident description. All of these fields were designed following the flow of questions that leads to the collection of minimal elements when reporting an incident. It is also possible to report if there was harm to the person involved in the event and to classify its severity. The description of the event is carried out in a free text field so that the notifier describes the incident in a simple way.

Incident data		
Where did it	Hospital:_____	Hospital_____ Bed:____
When did it happen?	Event occurrence date:___/___/_____ Time___:___ Notification date:____/____/_____.	
Who were involved?	( )Patient ( )Family member ( )Companion ( )Outsourced worker ( )Other _____	Name of the_____ Date of birth:___/___/____ Medical record No.:_____ Gender: ( ) Male ( ) Female
Was there harm to the person	( )No ( )Yes	Classify the type of harm: ( ) Slight ( ) Moderate ( ) Severe ( ) Death ( ) I don't
Notifier data		
Who is notifying?	( ) Patient ( ) Family	( ) Companion ( ) _____ ( ) Outsourced worker
Description of the incident		
Describe what happened		

Figure 1 – Simplified notification. Brasília, DF, Brazil, 2019.

The form for the health professional (Figure 2) was designed with screens that represent the categories corresponding to the type of incident. It is possible to notify problems with products, equipment, hospital medical supplies, medication, blood, blood products and health care-related problems.

As it is a form aimed towards the health professional, the fields include a more detailed and specific data record for each type of incident, inserted in a practical and objective way, in order to assist in the investigation process. It is noteworthy that both the user and the professional can opt for anonymous and confidential notification.

Incident data

Where did it happen? Hospital:_____ Hospital sector:_____ Bed:____

When did it happen? Event occurrence date:____/_____/____ Time:____:____
Notification date:_____/_____/_____.

Who were involved? ( )Patient ( )Family member ( )Companion ( )Outsourced worker ( )Other:_____
Name of the involved:_____
Date of birth:____/_____/_____
Medical record No.:_____
Gender: ( ) Male ( ) Female

Was there harm to the person involved? ( )No ( )Yes
Classify the type of harm: ( ) Slight ( ) Moderate ( ) Severe ( ) Death

Notifier data

Who is notifying? ( ) Health professional Professional category:_____

Classify the type of incident

( ) Care

( )Fall ( )Infection ( )Flebitis ( )Nutrition ( )Burn
( ) Pressure injury ( ) Bleeding ( ) Contention injury ( ) Escape/Evasion ( ) Surgical procedure
( )Lack/Failure of identification ( )Loss of probe/catheter/tube ( )Failure in communication ( )Administrative failures ( )Other:_____

( ) Technosurveillance

Type of Material: _____
( ) Lack of units ( ) Label missing ( ) Obstruction ( ) Presence of foreign body ( ) Expired material
( ) Change in smell ( ) Change in color ( ) Change in consistency ( ) Technical problems ( ) Other:_____
MS/ANVISA Registration:_____ Manufacture date: __/__/__ Batch:____
Manufacturer/Brand:_____ Validity date:___/___/__

Type of Equipment: _____
( ) Does not turn on ( ) Does not turn off ( ) Leak ( ) Obstruction of gas outlet ( ) Electric shock ( ) Current leakage ( ) Frequent breakage ( ) Alarm goes off ( ) Provides incorrect data ( ) Overheating ( ) Battery failure ( ) Other ____
Equity number_____ Serial:_____ Batch No.:_____

( ) Hemovigilance

( ) Anxiety ( ) Shivering ( ) Cyanosis ( ) Dispnea ( ) Tachycardia ( ) Tachypnea ( ) Cough ( ) Tremors ( ) Abdominal pain ( ) Chest pain ( ) Vomits ( ) Fritema ( ) Fever ( ) Nausea ( ) Jaundice ( ) Hoarseness
( ) Backache ( ) Hives ( ) Hypertension ( ) Other: _____

( ) Pharmacosurvailance

Adverse reactions/signs and symptoms:

( ) Nausea ( ) Vomits ( ) Dispnea ( ) Itching ( ) Hives ( ) Tremors ( ) Anaphylactic reaction ( ) Pyrogenic reaction ( ) Pain ( ) Other _____

Technical complaint of the medication

( ) Change in color/smell ( ) Change in viscosity ( ) Similar packaging/bottle ( ) Presence of foreign body ( ) Problem in label ( ) Other _____

Incident related to the prescription and/or administration of medications:

( ) Administered but not recorded
( ) Administered was not the same as prescribed (change)
( ) Administered in wrong patient
( ) Administered, but not prescribed
( ) Administered wrong medication prepared
( ) Dose administered was not the prescribed (wrong dose)
( ) Administered in higher/lower dose than prescribed due to calculation error
( ) Error in the prescription
( ) Administered an extra dose
( ) Administered in the wrong place
( ) Outdated prescription
( ) Administered at a wrong time
( ) Other:_____

Figure 2 – Notification for the health professional. Brasília-DF, Brazil, 2019.

Investigation stage

The investigation form (Figure 3) represents a list of the factors, by type, that may have contributed to the occurrence of the event. It should be noted that this stage is intended for professionals from the NQSP, who will carry out the investigation of the event.

The design of the investigation process was based on the analysis recommended in the London Protocol, which consists of a systematic investigation to organize the stages, improve the quality of data collection, and assist in the elucidation of the causal factors, in order to identify the causes and to propose strategies so that they do not occur again.

Type of factor	Contributing factor
Patient	( ) Attention/Perception problems ( ) Emotional factors ( ) Risky/Negligent behavior ( ) Fatigue/Exhaustion ( ) Sabotage/Criminal act ( ) Overconfidence ( ) Non-compliance of the guidelines ( ) Linguistic difficulties ( ) Difficulty understanding ( ) Other_____ ( ) Problems with substance use/abuse ( ) Severity and complexity of the clinical condition
Task or Technology	( ) Organization of the work process ( ) Lack of resources ( ) No instruments ( ) Unstable information system ( ) Protocol is Inexistent/Unavailable/Not implemented ( ) Other_____
Individuals (professional)	( ) Emotional factors ( ) Attention/Neglect/Distraction/Omission problems ( ) Systematic non-compliances ( ) Exhaustion/Work overload/Burnout ( ) Criminal sabotage act ( ) Problems with substance use/abuse ( ) Lack of training/experience ( ) Risky behavior/overconfidence ( ) Technical error in the execution of the activities ( ) Breach of rules/violation of routines/recklessness ( ) Other_____
Team (teams)	( ) Inadequate organization of the teams ( ) Missing/Inadequate information during shift change ( ) Problem understanding the guidelines (written or verbal) ( ) Absence of notes and/or unreadable information in the medical record ( ) Absence of standardized communication methods ( ) Linguistic difficulties (non-standard acronyms and/or language) ( ) Difficulty in using the information to make decisions ( ) Other_____
Work Environment	( ) Inadequate infrastructure/physical environment for working ( ) Interruptions and distractions due to use of tablets, TV, cell phones and others ( ) Inadequate staffing ( ) Lack of maintenance and/or inadequate maintenance ( ) Inadequate design/model of equipment/supplies ( ) Lack of administrative and managerial support in the work environment ( ) Other_____
Organizational and Managerial	( ) Conflict reconciliation/mediation ( ) Destocking of material/supplies ( ) Media management difficulties ( ) Unclear and/or inexistent rules ( ) Stress management/Psychological follow-up ( ) Other_____
Institutional Context	( ) Absence of care flows regulation ( ) Insufficiente funding ( ) Decision-making conflicts between management levels ( ) Difficulty in the relationships with other services ( ) Other_____

Figure 3 – Health incident investigation Brasília-DF, Brazil, 2019.

Monitoring and intervention stage

After the identification of the contributing factors, the Patient Safety Plan follows, elaborated from the 5W2H methodology, whose acronym refers to the following questions: What?, Why?, Where?, Who?, When?, How?, and How much? This method contributes to the identification of critical points and risk situations, in addition to assisting in the planning of the actions that will be implemented for risk management.

In the action plan model, a form with minimal information was proposed, but which can be edited by the NQSP team together with the professionals of the unit where the event took place.

The monitoring of incidents will be carried out by means of indicators that will allow representing, in a quantitative way, the evolution and performance of a given process. The objective is to provide NQSP managers and professionals with information about the current situation of institutional safety and of the quality of the services provided. The indicator panel is composed of six items, and the rates can be monitored by the type of event, by sector and period (Chart 2).

The indicators chosen were derived from the recommendations of the MoH, SES-DF protocols and the six international targets for patient safety proposed by the WHO in partnership with the Joint Commission International, and constitute a comprehensive and measurable guiding model that allows assessing the degree of progress and compliance with the goals established by the PNSP.

Chart 2 – Indicators of health incidents. Brasília-DF, Brazil, 2019.

1. Rate of errors in the prescription of notified drugs, by sector and period
2. Rate of errors in the administration of notified drugs, by sector and period
3. Incidence of notified pressure injuries in the patient
4. Rate of falls reported, by sector and period
5. Number of adverse events due to failures in patient identification, by period and sector
6. Rate of incidents with reported harms, by sector and period

DISCUSSION

This study corresponds to one of the stages in the development of a tool to support health services in order to make it possible to record information for the management of incidents in SES-DF hospitals. It is the improvement of work processes and care outcomes linked to the use of tools and science to develop, implement and disseminate the changes that result in better outcomes.[21]

The current reality of health institutions makes care delivery systems complex and prone to errors, and most of the organizations lack a comprehensive method to correct this situation.[22] In this perspective, the implementation of tools and methods for risk management in the health services is presented as one of the primary strategies for promoting safety and improving health care.[7]

In this study, the creation of a prototype in a participatory manner was privileged, with teams from the NQSPs, managers and researchers to facilitate the understanding of the institutional contexts so that the developed tool represented an incremental innovation applicable to the work processes of these centers. The literature describes that any innovation, even if well designed, requires active participation and support from those involved, in addition to attention to the various organizational characteristics and their objectives.[14,23]

This model, based on active participation, values learning and relationships between managers, decision makers and researchers, and contributes to the promotion, adherence and diffusion of innovation.[14,22]

Documentary analysis was fundamental so that the proposal to create the prototype was aligned with the recommendations established in the national and international protocols and guidelines, especially from the MoH and the WHO, in relation to the methods, indicators, instruments and tools for the development of the notification and learning system for patient safety.[3,7–8,11,22–24]

Processes involving incremental innovations are characterized by the improvement or refinement of products, processes and services already existing in the organization.[15]

A number of studies suggest that hospitals create local solutions in order to know the types of errors and adverse events that occur in care.[5,24] Therefore, the incorporation of tools inserted in the workplace helps to identify risks to which patients are exposed, and they are essential for these risks to become known and shared nationally.[2,5,24]

The literature describes a situation similar to that observed in SES-DF hospitals, in which a health organization was composed of seven institutions and each of them had their own reporting processes based on printed reporting systems. This resulted in several problems, including inconsistencies in what was being reported, different forms, delays in notification, incomplete forms, and lack of feedback to the employees. Therefore, the institution recognized the need to improve and standardize the incident reporting process.[24]

A system for recording incidents and/or adverse events, investigation and monitoring is based on several national and international studies and recommendations that guide the implementation of tools to report events that have occurred as a result of health care. It is an essential component for risk management and one of the main actions in promoting safety and improving the practices and processes carried out in these environments.[12,23]

The experts recommend that reporting systems be used to describe the types of safety issues with accessible, practical, and streamlined data reporting without excessive data, and that it be anonymous and confidential.[5,8] In this respect, the prototype adopts such recommendations and is characterized by being a simple and practical tool that does not require a lot of time from the notifier, with easy access, in which all users can report incidents anonymously and confidentially, whose notifications will be investigated by specialists with the production of reports, alerts and recommendations, in addition to not having a punitive character, as it focuses on learning.[22,24–25]

Another important aspect of a system is to involve different actors in the new technology.[26] Countries that already have a national patient safety policy, such as England, the United States, Australia and Canada, allow, in addition to health professionals, users of the system and their caregivers to notify about risks and incidents in the health services.[12] The availability of this resource allows for the involvement of patients, family members and other caregivers in the process of monitoring health risks and incidents. These actors are important sources of voluntary notification and essential for promoting quality of care and for improving the health systems.[12]

The investigative method adopted, based on some stages of the London Protocol, reveals a number of factors that contributed to the occurrence of the event. This procedure is essential to elucidate the causes of the event and the subsequent implementation of barriers to prevent the recurrence of similar events.[7]

The Patient Safety Plan assists in organizing the strategies and recommendations implemented in the service and promotes changes in the behavior of the professionals and in the remodeling of work processes.[7,11]

Monitoring through indicators allows for the evaluation of the performance of health services and for the programming of improvement actions.[10] It represents a risk management tool, through which managers will be able to identify critical areas and plan strategies for coping with problems and decision-making.[26]

The challenges faced in the process of creating and developing the prototype were related to the apprehension of the NQSP teams regarding obtaining support from managers and the involvement of the teams in the work process, affected by the frequent rotation of professionals in these sectors. The need for support from the top management of hospitals is essential in maintaining teams in the NQSP because, as they accumulate learning, they create tools for this work, which is relatively new in the Unified Health System.

The lessons learned resulted in recommendations for other experiences, which can use the forms for the development or improvement of new instruments for risk management.

The limitations of the study refer to the absence of patients and family members in the deliberative dialog for the validation of the forms and the prototype, considering that the notification stage is also aimed at this population.

To guarantee access to safe and quality care, it is essential to acquire a better understanding and greater knowledge about the risks arising from the care practices.[2] Therefore, the implementation of innovative tools in the health services is an essential factor for the maintenance of activities, growth and development of the health systems, so that they are able to meet the needs of the population.[14–15]

CONCLUSION

This research, of a methodological nature, resulted in the prototyping of a tool to collect, investigate, systematize and disseminate essential information for the promotion of safety in the health services. The participatory creation of forms for notification, investigation and monitoring of health incidents, as well as the prototyping of the tool, is supporting the creation of the information system. It will seek to facilitate the capture of incident notification and investigation data, as well as the monitoring of indicators through reporting.

The development of the information system is in progress, and the validation process will be carried out at each screen and stage of development, namely: user registration, notification screens, investigation screens, indicator panel, and data export and report generation features. Validation takes place in new rounds of deliberative dialogs with the participation of hospital managers, NQSP technical teams, patients and companions. It is intended to incorporate it into the routine of the workers of the NQSP-SES-DF, in order to homogenize the work process and to promote the effective improvement of the services provided in these hospitals.

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NOTES

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CONTRIBUTION OF AUTHORITY

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CONFLICT OF INTERESTS

There is no conflict of interests.

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