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ORIGINAL ARTICLE

PATIENT SAFETY AN ANALYSIS TO EVENT NOTIFICATION SEGURIDAD DEL

Segurança do paciente uma análise acerca da notificação de eventos

Paciente un análisis de la notificación de eventos

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ABSTRACT

Introduction: patient safety is a global issue in management agendas, justified by the incidence of failures related to health care. **Method**: retrospective, descriptive and quantitative study, carried out in a type II Polyclinic of specialized care in the State of Ceará. Data were collected in January 2023. The sample consisted of 21 spontaneous notifications, made from June to December 2022. After collection, the data were organized in the Microsoft Excell® 14.0 version 2010 program, analyzed by simple descriptive statistics and presented in graphs. The research was approved by the Ethics Committee under the Opinion number: 5.969.403. **Results**: Regarding the causes of errors, notifications related to methods prevailed (47.6%), followed by methods and people (28.6%), and people-related (14.3%). The predominant types of events were nonconformities (81%), followed by events without harm and minor harm (9.5% each). Regarding the sectors notified, the ones that stand out are those with direct management by nursing, observation and invasive exams (28.6% of the notifications), and the Sterilization Material Center (14.3%). Regarding the notifying sectors, the warehouse made 28.6% of the notifications, the pharmacy 23%, quality 14.3%, reports, colonoscopy and endoscopy made 9.5% each. **Conclusion**: failures and errors can be associated mostly with causes linked to people and methods, that is, directly related to behavioral attitudes.

Keywords: Patient Safety; Event Notification; Health Care.

RESUMO

Introdução: a segurança do paciente é pauta mundial nas agendas de gestão, justificada pela incidência de falhas relacionados à assistência à saúde. **Método**: estudo retrospectivo, descritivo e quantitativo, realizado em uma Policlínica tipo II de assistência especializada no Estado do Ceará. Os dados foram coletados em janeiro de 2023. A amostra foi composta por 21 notificações espontâneas, realizadas de junho a dezembro de 2022. Após a coleta, os dados foram organizados no programa Microsoft Excel® 14.0 versão 2010, analisados pela estatística descritiva simples e apresentados em gráficos. A pesquisa foi aprovada pelo Comitê de Ética sob o número do Parecer: 5.969.403. **Resultados**: Quanto as causas dos erros, prevaleceram as notificações relacionadas a métodos 47,6%, seguido de métodos e pessoas com 28,6 % e relacionado as pessoas com 14,3 %. Os tipos de eventos predominantes, foram as não conformidades em 81% das notificações, em seguida os eventos sem danos e dano leve com 9,5% cada. Quanto aos setores notificados, destacam-se os que possuem gerenciamento direto pela enfermagem, observação e exames invasivos com 28,6% das notificações, e a Central de Material de Esterilização com 14,3%. Relativamente aos setores notificantes, o almoxarifado realizou 28,6% das notificações, a farmácia 23%, a qualidade 14,3%, os laudos, colonoscopia e endoscopia realizaram 9,5% cada. **Conclusão**: as falhas e erros podem estar associadas em sua maioria com causas ligadas a pessoas e métodos, ou seja, diretamente relacionado a atitudes comportamentais.

Palavras-chave: Segurança do Paciente; Notificação de Eventos; Cuidados em Saúde.

RESUMEN

Introducción: la seguridad del paciente es un tema global en las agendas de gestión, justificado por la incidencia de fallas relacionadas con la atención sanitaria. **Método**: estudio retrospectivo, descriptivo y cuantitativo, realizado en un Policlínico de asistencia especializado tipo II en el Estado de Ceará. Los datos fueron recolectados en enero de 2023. La muestra estuvo compuesta por 21 notificaciones espontáneas, realizadas de junio a diciembre de 2022. Luego de la recolección, los datos fueron organizados en el programa Microsoft Excell® 14.0 versión 2010, analizados mediante estadística descriptiva simple y presentados en gráficos. La investigación fue aprobada por el Comité de Ética con el número de dictamen: 5.969.403. **Resultados**: En cuanto a las causas de errores, prevalecieron las notificaciones relacionadas con métodos con un 81%, seguidas de métodos y personas con un 28,6% y relacionadas con personas con un 14,3%. El tipo de eventos predominante fueron las no conformidades con un 46,20% de las notificaciones, seguido de los eventos sin daño y con daño leve con un 9,5% cada uno. En cuanto a los sectores notificados, destacan los de gestión directa por enfermería, observación y exámenes invasivos con el 28,6% de las notificaciones, y el Centro de Material de Esterilización con el 14,3%. En cuanto a los sectores declarantes, almacén realizó el 28,6% de las notificaciones, farmacia el 23%, calidad el 14,3%, informes, colonoscopia y endoscopia realizaron el 9,5% cada uno. **Conclusión**: las fallas y errores pueden estar mayoritariamente asociados a causas ligadas a personas y métodos, es decir, directamente relacionadas con actitudes comportamentales.

Palabras clave: Seguridad del Paciente; Notificación de Eventos; Cuidado de la salud.

INTRODUCTION

Ensuring safety in healthcare is a critical global priority that demands focused management attention. In Brazil, the issue of patient safety within healthcare institutions is a significant public health concern. Epidemiological studies, particularly those carried out by the Health Surveillance Notification System (NOTIVISA), are essential for analyzing and improving patient safety indicators.

The report on health-related incidents in Brazil, covering the period from 2014 to 2021, as detailed by NOTIVISA, indicates a significant increase in the number of reported incidents across various health services. Notably, incidents with minor damage account for 45.5% of total reports, with outpatient services showing a higher rate of 50%. In contrast, the average incidence of serious damage and fatalities stands at 5%. A substantial proportion of these incidents approximately 250,000 cases are attributed to failures during the delivery of health care, which has consequently resulted in a heightened number of associated deaths. Importantly, it has been determined that 50% of the reported incidents are preventable.

In the state of Ceará, the issue of patient safety is of significant concern. The most frequently reported healthcare failures involve pressure injuries, with approximately 1,500 cases recorded in 2020 and an increase to 3,200 cases in 2021/2022. Furthermore, these healthcare failures have had serious repercussions, leading to 8 fatalities in 2020 and 62 in the subsequent years of 2021/2022. These statistics highlight the critical need for diligent monitoring of adverse events and the urgent implementation of measures to enhance patient safety within healthcare settings.

To ensure effective monitoring of adverse events, it is essential to implement an institutional notification system within the healthcare service, as mandated by the Resolution of the Collegiate Board (RDC) 36 of 2013. This resolution outlines a structured approach for identifying events that occur within the healthcare institution, analyzing these occurrences, and developing a comprehensive action plan to address the adverse events, ultimately striving for continuous improvement. When the action plan is meticulously crafted and executed by all team members involved in any potential error during patient care, it significantly enhances the likelihood of adherence to preventive measures. The action plan typically identifies specific actions that serve as barriers to ensure safe and reliable healthcare. Furthermore, research underscores the critical importance of feedback derived from these notifications, as it provides valuable insights that contribute to the ongoing enhancement of quality and safety in patient care.

Reportable incidents encompass all potential situations that may pose a risk of harm or near misses for patients. A near miss refers to an event that, whether intentional or unintentional, was averted before impacting the patient and may or may not have resulted in harm. An incident that does cause harm to a patient is classified as an adverse event. By Ordinance MS 529/13, adverse events can be categorized as mild, moderate, severe, or potentially resulting in death.

The systematic reporting of events and the subsequent analysis of these reports to develop health indicators focused on patient safety are critical for the effective monitoring and management of risks associated with adverse events in both hospital and outpatient health services, as well as in Primary Health Care and various other healthcare institutions. This approach not only facilitates the prioritization of events for investigation but also enhances the overall capacity to promote patient safety.

The research presents a comprehensive framework encompassing various studies, epidemiological bulletins, and data on patient safety within the hospital setting. This analysis underscores the critical necessity to enhance the monitoring and evaluation of patient safety across all levels of care. It is essential to recognize that the risk of errors in healthcare is a pervasive issue throughout the entire Health Care Network (RAS).

In light of these scenarios, it is crucial to analyze adverse event reports. This analysis facilitates learning from both errors and near misses that impact patients within healthcare services. The publication of studies related to patient safety and event reporting plays a vital role in enhancing the scientific body of knowledge. It supports evidence-based practices and aims to provide high-quality services while minimizing potential harm to patients, all within a framework that emphasizes health promotion.

This study focuses on the analysis of event notifications within a secondary service of the Unified Health System (SUS) at a level II Polyclinic. It highlights the significance of implementing a notification system for adverse events over six months. This work is particularly noteworthy as it contributes to a limited body of research that primarily addresses notifications within hospital settings. The study examines the various types of incidents reported, investigates the underlying causes of these events, details the immediate actions taken following the notification of an adverse event, and outlines proposed action plans aimed at enhancing processes within the service.

The importance of this publication is underscored by the necessity to enhance the dissemination of patient safety indicators. It aims to expand knowledge and foster awareness among both readers and professionals regarding the significance of a Patient Safety Center (NSP). Highlighting its critical role in promoting the health of individuals receiving care in health services, this publication also seeks to encourage the development of a safety culture. This is achieved through a thorough analysis of event notifications related to their types, occurrences, and underlying causes.

METHOD

This document presents a retrospective and descriptive study with a quantitative approach, conducted at a type II secondary-level Polyclinic in the Cariri Region of Ceará, which operates with 100% adherence to the Unified Health System (SUS). The Polyclinic offers an average of 18 medical specialties and provides 15 medium to high-complexity diagnostic exams, facilitating approximately 15,000 appointments each month, encompassing consultations, exams, and therapeutic follow-ups. Notably, this facility is recognized as a pioneer in implementing the Center of Specialties in Rehabilitation - CER IV within the region and is currently pursuing quality-level certification. As a vital component of the health care network, the Polyclinic delivers services through collaborative public partnerships between the State and municipal authorities. It serves a population encompassing seven municipalities within the Health Region, catering to a total of 221,831 inhabitants.

The state of Ceará is home to twenty-two polyclinics that serve five health macroregions, namely Fortaleza, Norte, Cariri, Sertão Central, and Litoral Leste/Jaguaribe. Notably, the National Health Policy (NSP) has been implemented in only 50% of these facilities. This particular unit was inaugurated in 2020 amidst the challenges of the pandemic and has initiated operations dedicated to providing quality healthcare to the population, alongside pursuing quality certification for its services. Additionally, the unit is equipped with a quality office, which oversees the implementation of quality and risk management guidelines to enhance the standards of care within the Polyclinic.

Incident notifications can be submitted either spontaneously or anonymously through the completion of an event notification form, which is available across all sectors of the institution. Upon submission, the form initiates a comprehensive event analysis process that includes the following steps: classification of the event by the quality office, thorough investigation, implementation of the action plan by the relevant sector, and providing feedback to the notifying sector via the quality office. Subsequently, the notifying sector evaluates the effectiveness of the action plan, leading to the closure of the incident with proper archiving and

monitoring of data conducted by the quality department. In instances of serious adverse events, the analysis is carried out by the Patient Safety Center of the Polyclinic. Following an analysis period of approximately five days, the quality department communicates the results back to the notifying sector.

The study examined various categories of incidents, including non-compliance, adverse events (classified as mild, moderate, and severe), events without harm, and fatalities. Notably, the notifications incorporated in this study excluded any cases resulting in serious adverse events or deaths. The focus was limited to non-compliance issues, adverse events that did not result in harm and mild adverse events. These variables were systematically analyzed within the framework of incident types. An incident can be defined as an event or circumstance that has the potential to, or has indeed, caused unnecessary harm to a patient. This includes non-compliance, process failures, and breaches of contractual agreements. Additionally, events without harm are characterized as occurrences that could have led to unnecessary health implications for the patient. Mild adverse events are those that result in minor symptoms, temporary loss of function, or minimal to moderate damage, typically requiring only minimal interventions and accompanied by necessary investigations into the underlying causes.

The analysis included an investigation into the underlying causes of the reported events, utilizing a cause and effect diagram (Ishikawa) for systematic identification and categorization of these issues. The causes were classified into several categories: Methods – (Inadequate procedures or approaches to task execution). Machines (Insufficient maintenance and reliance on outdated equipment). Materials (Use of inadequate or defective materials, including those not sourced from approved suppliers). People (Factors such as haste, carelessness, or insufficient qualifications, experience, or training). Environment (Conditions including pollution, dust, heat, inadequate space, and insufficient lighting). Measurement (Use of inadequate metrics for work measurement and definition). System (Issues related to system failures within SIGES or slow performance). Furniture (Presence of oxidized or worn furniture that may pose risks to patients). Medication (Instances of expired or missing medications). This comprehensive approach ensures that all possible factors contributing to the reported events are systematically evaluated.

Upon collection, the data were systematically organized within a database utilizing the Excel® program and subsequently subjected to analysis through basic descriptive statistics, with findings presented in graphical format.

We adhered to ethical procedures by Resolution No. 466, dated December 12, 2012. The research project received approval from the Research Ethics Committee of the Regional University of Cariri, with the approval report numbered 5969403. Additionally, a formal authorization was secured from the Polyclinic involved in the study through a duly signed consent form.

RESULTS

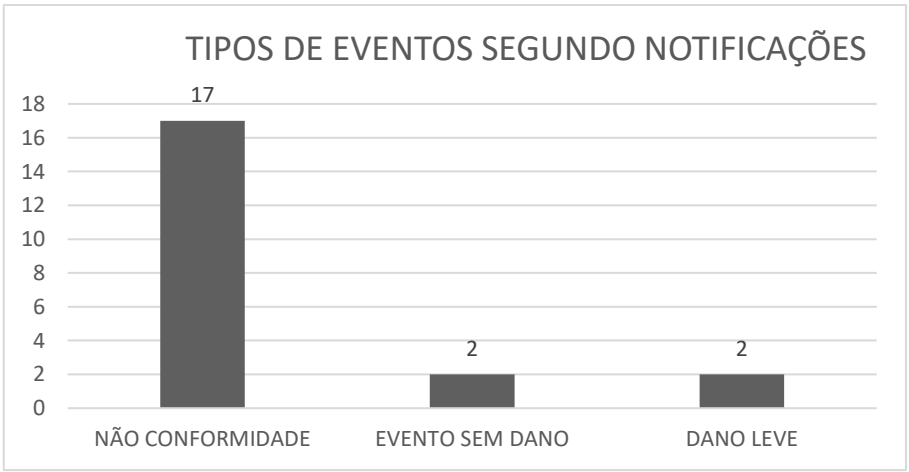
An analysis was conducted of 21 incident reports from a Level II polyclinic in the state of Ceará during the first six months following the implementation of the National Safety Program (NSP). The investigation focused on identifying the causes of the reports based on the variables outlined in the Ishikawa diagram, which include methods, machines, materials, personnel, environment, measurement, system, furniture, and medication. Additionally, the types of reports were categorized by the sector that reported them. In terms of causative factors identified, those linked to methods were the most prevalent, representing 47.6% of the reports (n=10). This was followed by a combination of methods and personnel, accounting for 28.6% (n=6), while reports solely related to personnel constituted 14.3% (n=3). The findings are illustrated in Figure 1:

Figure 1 – Causes of reports from the Level II polyclinic in the Cariri region of Ceará, analyzing the outcomes of the proposed intervention. Crato, CE, Brazil, 2023 (n=21).

Source: authors' archive, 2023

Upon analysis of the event types reported by various sectors within the institution, there is a notable prevalence of nonconformities, accounting for 81% (n=17) of the total notifications. Additionally, the data indicates that there were two incidents (9.5%) categorized as events without damage and two incidents (9.5%) classified as events with minor damage, as illustrated in Figure 2.

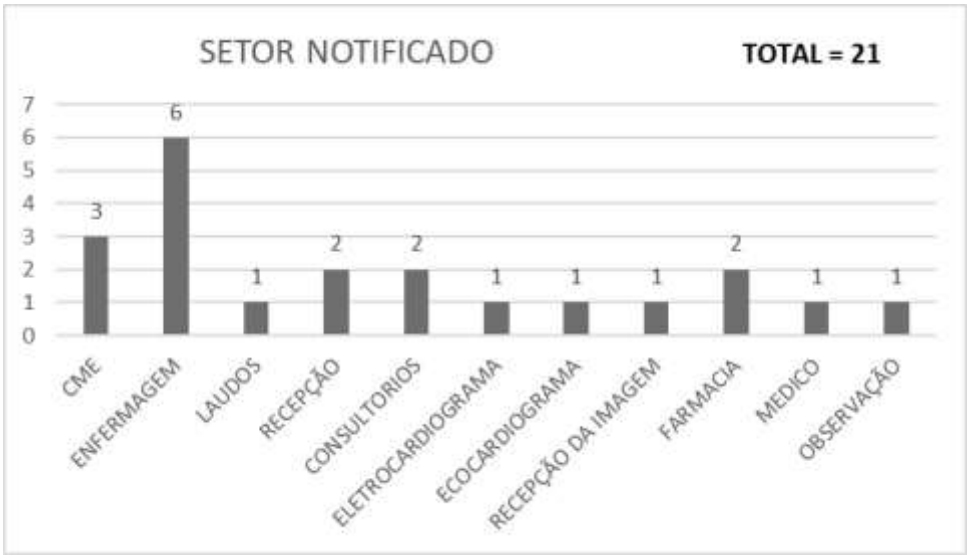
Figure 2 – Distribution of event types based on notifications from a Level II polyclinic in the Cariri Region of Ceará, reflecting the outcomes of the proposed intervention. Crato, CE, Brazil, 2023 (n=21).



Source: authors' archive, 2023

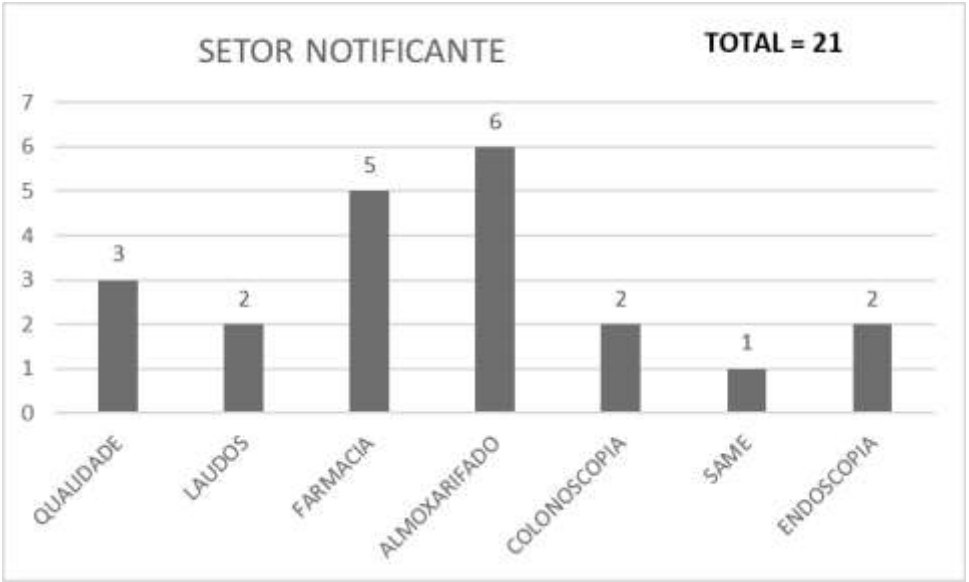
Figures 3 and 4 illustrate the sectors responsible for notifications and those receiving notifications. About the notified sectors, those directly managed by nursing are prominently highlighted, with six notifications (28.6%) attributed to nursing. Following this, three notifications (14.3%) were linked to the Central Sterilization Material (CME). Concerning the notifying sectors, the warehouse accounted for six notifications (28.6%), while the pharmacy recorded five notifications (23%). Additionally, the quality sector contributed three notifications (14.3%), and both the colonoscopy and endoscopy sectors each reported two notifications (9.5%).

Figure 3 - Illustrates the sectors notified based on the analyzed notifications from a Level II polyclinic located in southern Ceará, about the outcomes of the proposed intervention. Crato, CE, Brazil, 2023 (n=21).



Source: authors' archive, 2023

Figure 4 – Notification Sector Based on Analyzed Outcomes from a Level II Polyclinic in Southern Ceará Regarding the Proposed Intervention. Crato, CE, Brazil, 2023 (n=21)



Source: authors' archive, 2023

DISCUSSION

The research conducted aimed to analyze adverse event reports in terms of type, occurrence, and underlying causes. This study underscores the significance of these findings for healthcare services, as it provides critical data necessary for implementing improvements in patient care.

Upon investigating the causes of the reported events, and utilizing the criteria of the Ishikawa diagram, it was found that methods were the predominant factor (n=10; 47.6%),

followed by a combination of methods and personnel issues (n=6; 28.6%). This reaffirms that a considerable portion of errors, failures, and non-conformities within healthcare services are associated with behavioral factors. Addressing these issues through the development of a robust safety culture is essential for enhancing patient safety.

The utilization of the Ishikawa diagram for classifying causes has significantly enhanced the quality office's understanding of the issues reported within the institution. This approach has been instrumental in developing a targeted action plan aimed at improving patient safety. This experience underscores the importance of employing this tool for investigating the underlying causes of events and incidents occurring in healthcare settings.

In the analysis of notification types, a significant prevalence of non-conformities was observed, accounting for (81%) of the total events (n=17). This was followed by notifications of events without damage (n= 2; 9.5%) and events with minor damage (n=2; 9.5%). The existing literature supports these findings, indicating a similar representation of minor damage in the context of adverse event notifications. Specifically, it has been noted that minor damages are categorized as incident notifications with minimal severity, comprising 39.2% of a total of 704 verified notifications.

The notifications concerning non-compliance associated with health events highlight the significance of the issue and underscore the urgency for implementing measures that mitigate unnecessary and preventable harm to patients. It is important to note, however, that comparing the results of this study with others may be challenging due to the varying institutional contexts, as the research identified was conducted within hospital settings.

Upon reviewing the sectors involved in the notifications, both those issuing notifications and those receiving them, it is noteworthy that the warehouse sector emerged as the most active, reporting a total of six notifications (n=6; 28.6%). This was followed by the pharmacy sector with five notifications (n=5; 23%), while the quality sector contributed three notifications (n=3; 14.3%).

The ability to compare findings across different studies is limited by their focus on the hospital sector. According to research conducted by Prates8, the medical clinic emerged as the area with the highest rate of adverse event notifications, accounting for 47.3% of reported incidents within the hospital. Additionally, it has been established that, on average, 1 in 10 hospitalized patients experiences an adverse event during their care11. Despite this alarming statistic, there are still significant challenges regarding healthcare professionals' adherence to reporting these events. It is posited that in secondary care services, the variance in reporting adherence may not be as pronounced.

The study acknowledges the limitations posed by the relatively scarce research focused on patient safety in secondary and outpatient health units. To address this gap, we have thoroughly explored the existing studies, as well as the guidelines, manuals, and regulations set forth by the Ministry of Health, ensuring that the research maintains its representative quality. It is crucial to emphasize the need for increased interest from researchers and initiatives aimed at scientifically investigating the domain of patient safety and the reporting of adverse events across all types of healthcare institutions. This concerted effort will promote safe and quality care, with the ultimate goal of fostering a culture of safety within healthcare settings and enhancing overall health outcomes.

CONCLUSION

The research indicates that the causes of errors or patient insecurity were primarily related to procedural methods, including flow disruptions, adherence to protocols, and various factors linked to work processes. The findings reveal that, within the outpatient service under examination, the predominant type of incident was identified as non-compliance. Nonetheless, there were instances of errors in healthcare delivery that resulted in patient harm, predominantly of a minor nature. Notably, the nursing profession accounted for the highest number of reported incidents, while the quality management sector was responsible for the majority of notifications.

This study underscores the critical importance of published research on event notifications and adverse events within secondary and outpatient health services, as there remains a notable gap in studies focused specifically on this level of care. Traditionally, the focus on patient safety has been predominantly directed towards hospital settings.

The findings of this research make a significant contribution to the field and enhance awareness of the necessity for safer patient care through the implementation and analysis of event notifications for effective care planning. It reaffirms the need for further exploration of studies in this area and supports the development of policies aimed at enhancing patient safety and improving care across the healthcare network.

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