Incident notification and patient safety in times of a pandemic

Notificação de incidentes e a segurança do paciente em tempos de pandemia

Notificación de incidentes y la seguridad del paciente en tiempos de pandemia

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Abstract

Objective: To review notification of incidents that occurred during the COVID-19 pandemic.

Methods: This is a cross-sectional, exploratory descriptive quantitative study. A total of 1,466 notifications to risk management of a private hospital were analyzed from September 2020 to September 2021. Descriptive statistical analysis was used, applying Pearson's chi-square test or the likelihood ratio test. The margin of error used was 5%.

Results: Communication failure (358 - 24.5%), probe and catheter use failure (232 - 15.9%) and article and equipment use failure (132 - 9.1%) were identified as prevalent incidents. The notifiable circumstance totaled 55.9% of reports, and, of these, 33.4% were communication failure. Adverse events were 416 (28.6%), and fall was related to mild damage (43.9%), health care-associated infections, to moderate harm (31%), and medication use failure (50%), to severe harm and death.

Conclusion: Communication failure was the most reported risk circumstance, followed by medication use failure as an adverse event with severe harm. The nursing unit showed the possibility of a greater number of adverse events, while in Intensive Care Units, the degree of harm from adverse events was higher.

Resumo

Objetivo: Analisar as notificações de incidentes ocorridos durante a pandemia de COVID-19.

Métodos: Estudo com delineamento transversal de abordagem quantitativa do tipo descritivo exploratório. Foram analisadas 1.466 notificações à gerência de risco de um hospital privado, no período de setembro de 2020 a setembro de 2021. Utilizou-se a análise estatística descritiva, aplicando o teste Qui-quadrado de Pearson ou o teste da Razão de Verossimilhança. A margem de erro utilizada foi de 5%.

Resultados: Identificou-se como incidentes prevalentes a falha na comunicação (358 - 24,5%), falha no uso de sondas e cateteres (232 – 15,9%) e falha no uso de artigos e equipamentos (132 – 9,1%). A circunstância notificável totalizou (55,9%) dos relatos e destas, (33,4%) eram falha na comunicação. Os eventos adversos foram em número de 416 (28,6%) e a queda esteve relacionada a dano leve (43,9%); Infecção relacionada à assistência à saúde ao dano moderado (31%) e a falha no uso de medicamentos a (50%) como dano grave e óbito.

Conclusão: Falha na comunicação foi a circunstância de risco mais notificada, seguida de falha no uso de medicamentos como evento adverso com dano grave. A unidade de enfermaria evidenciou a possibilidade de maior número de eventos adversos; enquanto que nas unidades de terapia intensiva o grau de dano dos eventos adversos foi superior.

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Resumen

Objetivo: Analizar las notificaciones de incidentes ocurridos durante la pandemia de COVID-19.

Métodos: Estudio con diseño transversal de enfoque cuantitativo del tipo descriptivo exploratorio. Se analizaron 1.466 notificaciones de la gestión de riesgo de un hospital privado, en el período de septiembre de 2020 a septiembre de 2021. Se utilizó el análisis estadístico descriptivo, aplicando la prueba χ^2 de Pearson o la prueba de razón de verosimilitud. El margen de error utilizado fue del 5 %.

Resultados: Se identificaron como incidentes prevalentes la falla en la comunicación (358 - 24,5 %), falla en el uso de sondas y de catéteres (232 – 15,9 %) y falla en el uso de artículos y equipos (132 – 9,1 %). Las circunstancias que pueden ser notificadas totalizaron (55,9 %) de los relatos y, entre ellas, (33,4 %) era una falla en la comunicación. Los eventos adversos totalizaron 416 (28,6 %) y la disminución estuvo relacionada con el daño leve (43,9 %); infección relacionada con la atención a la salud al daño moderado (31 %) y a la falla al usar medicamentos (50 %) como daño grave y defunción.

Conclusión: La falla en la comunicación fue la circunstancia de riesgo más notificada, seguida de falla al usar medicamentos como evento adverso con daño grave. La unidad de enfermería evidenció la posibilidad de un número más elevado de eventos adversos; mientras que en las unidades de terapia intensiva el grado de daño de los eventos adversos fue superior.

Introduction

The health system has been challenged from a managerial, structural and human resources point of view due to the COVID-19 pandemic. In this scenario, patient safety has a greater dimension and importance in health institutions due to the work process reorganization, protocol adequacy and unit overcrowding.

In the second half of 2020, Brazil was the third country with the highest number of infections worldwide, with 4,123,000 confirmed cases and 126,203 deaths from COVID-19.[1] With a focus on quality of care, the Italian Network for Safety in Healthcare (INSH) recommends encouraging adverse event notification by health staff that is on the front line of COVID-19 care, in order to maintain safety climate, to promote corrective and continuous actions.[2]

According to the taxonomy used in patient safety, the World Health Organization (WHO) includes, in the concept of incident, the following situations: notifiable circumstances; near miss; harmless incidents; and adverse events (incident that results in harm to patients).[3] It is estimated that 10% of hospitalized patients suffer some type of adverse event (AE), promoting an increase in hospitalization time and additional costs to the health system.[4] In this regard, Ordinance 529 institutes the Brazilian National Patient Safety Program, in order to ensure patient safety priority in health institutions, with the establishment of principles and guidelines that integrate all care processes in articulation with the management organizational health services.[5]

Thus, incidents must be communicated and notified to the institution's management bodies, including the Patient Safety Center (NSP - *Núcleo de Segurança do Paciente*), which aims to institute actions to promote patient safety and improve quality in health services.[6] The NSP seeks to meet the concept of patient safety established by the WHO, which is a structure of organized activities that creates cultures, processes, procedures, behaviors and technologies in care environments, aiming at reducing risks in a consistent and sustainable way, in addition to minimizing the impact when they occur.[7]

From May 2019 to April 2020, 153,126 incidents related to health care were reported in Brazil: failures during health care (38,673, 25.25%); pressure injury (29,356, 19.17%); failures involving venous catheters (22,993, 15.01%); patient fall (16,053, 10.48%); patient identification failure (11,651, 7.60%); failures involving probes (9,694, 6.33%); patient evasion (3,841, 2.50%). In this period, the total number of deaths associated with AE was (65.61%) related to failures during care.[8] However, most of these notifications were made before the COVID-19 pandemic.

Therefore, in the pandemic period, it was necessary to question which care management protocols should be intensified to reinforce patient safety. The importance of proper risk management monitoring is highlighted by local incident notifications, since each institutional reality demands on-site actions. There is a scientific gap on the subject due to scarcity of published studies on AE in times of a pandemic, which bring robustness in the implementation

of actions that eliminate or reduce AE risks to care practice in the current scenario.

This study aimed to analyze the notifications of incidents that occurred during the COVID-19 pandemic.

Methods

This is a cross-sectional, exploratory descriptive quantitative study, which used the Risk Management notification system database of a private hospital in the city of Recife, Pernambuco, from September 2020 to September 2021. This period was considered by the start of care for patients diagnosed with COVID-19 and the structuring of the institution's notification system for this new scenario.

The hospital has 300 active beds, divided into two units: a ward with 160 beds and an Intensive Care Unit (ICU) with 140 beds, the latter intended for the care of highly complex cases. The hospital was activated on April 15, 2020, and currently has 1,448 employees to exclusively meet the demand for care for patients with COVID-19.

The notifications sent to the study hospital's risk management service were assessed through voluntary notification forms on the computerized hospital management platform. Data collection during the mentioned period obtained 1,515 notifications. We excluded 49 notifications that were classified as "non-compliant", i.e., incomplete notifications, as well as those that were not related to patient safety, making a final sample of 1,466 notifications.

For incident classification, the theoretical framework used was the WHO International Classification for Patient Safety, which is described in 10 classes that provide a global understanding of patient safety. Regarding the definition of an incident, it is understood by: notifiable circumstance, the situation with significant potential to cause harm, but the incident did not occur; near event or near miss, an incident that did not reach patients, but that there was their interception before reaching them; harmless incident, an incident that reached patients but did not result in harm and harm incident, or AE, which is an incident that results in harm to patients.[3]

As for the class consequences for patients attributed partially or completely to an incident, it can be classified according to the type of damage, degree of damage and the social and/or economic impact caused. The degree of damage can be classified into: mild, a situation in which patients have mild symptoms and minimal damage, without the need for intervention; moderate, in which patients require intervention, or prolonged hospital stay, loss of function, and damage is permanent or long-term; severe, when intervention is needed to save patients' life, damage is severe or permanent or long-term, and death caused by the AE.[3,9]

Data collection was carried out by two independent researchers, in a private place, previously trained by the safety center of the hospital under study and oriented to standardize notifications according to patient safety classification in the Health Surveillance Information System (NOTIVISA - *Sistema de Informações em Vigilância Sanitária*).[10]

Data were recorded in an Excel® spreadsheet and descriptively analyzed using absolute frequencies and percentages. To assess the significant difference between the ICU and the ward, Pearson's chi-square test was used, or the likelihood ratio test, when the condition for using the chi-square test was not verified. The margin of error used in statistical test decision was 5%. The program used to obtain the statistical calculations was the IMB SPSS version 25.0.

The study followed the ethical recommendations issued by Resolution 466/12 of the Brazilian National Health Council, guaranteeing confidentiality and secrecy terms, obtaining favorable Opinion 4,857,674 and CAAE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 49157121.2.0000.51931.

Results

Thus, 1,466 incident notifications were assessed, which were voluntarily made to risk management.

Table 1. Notifications and classification of incidents in a COVID-19 care hospital

Root cause	Notifications made			Adverse event				
	Notifiable circumstance	Near miss	No harm incident	Mild damage	Moderate damage	Severe damage	Death	Total
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Accident with sharps	0(0.0)	0(0.0)	0(0.0)	1(0.6)	2(1)	1(2.5)	0(0.0)	4(0.27)
Bronchoaspiration	0(0.0)	0(0.0)	0(0.0)	1(0.6)	1(0.5)	0(0.0)	2(10.0)	4(0.27)
Extubation	0(0.0)	0(0.0)	5(2.5)	23(14.6)	59(29.5)	1(2.5)	0(0.0)	88(6)
Diet administration failure	33(4.0)	2(6.9)	26(13.1)	4(2.5)	1(0.5)	0(0.0)	0(0.0)	66(4.5)
Blood component administration failure	1(0.1)	0(0.0)	3(1.5)	2(1.3)	0(0.0)	0(0.0)	0(0.0)	6(0.4)
Communication failure	272(33.4)	3(10.3)	57(28.9)	6(3.8)	12(6)	4(10)	4(20.0)	358(24.5)
Patient identification failure	62(7.6)	3(10.3)	6(3)	1(0.6)	1(0.5)	0(0.0)	0(0.0)	73(5)
Surgical procedure failure	0(0.0)	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.06)
Patient transport failure	32(3.9)	0(0.0)	5(2.5)	1(0.6)	1(0.5)	0(0.0)	2(10.0)	41(2.7)
Article and equipment use failure	91(11.1)	1(3.4)	22(11.1)	6(3.8)	7(3.5)	3(7.5)	2(10.0)	132(9)
PPE use failure	85(10.4)	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	86(5.8)
Medication use failure	37(4.5)	18(62.1)	20(10.1)	12(7.6)	11(5.5)	10(25.0)	5(25.0)	113(7.7)
Oxygen and other gas use failure	15(1.8)	1(3.4)	9(4.5)	8(5.0)	6(3)	3(7.5)	2(10.0)	44(3)
Probe and catheter use failure	153(18.7)	1(3.4)	35(17.7)	21(13.3)	12(6)	7(17.5)	3(15.0)	232(15.9)
Health care-associated infection	1(0.1)	0(0.0)	0(0.0)	0(0.0)	62(31)	1(2.5)	0(0.0)	64(4.3)
Pressure injury	8(1.0)	0(0.0)	0(0.0)	2(1.3)	22(11)	4(10.0)	0(0.0)	36(2.4)
Fall	1(0.1)	0(0.0)	7(3.5)	69(43.9)	13(6.5)	5(12.5)	0(0.0)	95(6.4)
Use of adornments	23(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	23(1.5)
Overall total	814(100.0)	29(100.0)	197(100.0)	157(100.0)	210(100.0)	39(100.0)	20(100.0)	1466(100)

*PPE - Personal Protective Equipment.

Table 1 shows the types of notifications made and the types of damages according to AE. The prevalence of extubation (29.5%) was observed as an AE with moderate damage and (14.6%) as an AE with mild damage; communication failure (33.4%) as a notifiable circumstance, (28.9%) as incidents of damage and (10.3%) as a near miss; patient identification failure (10.3%) as a near miss; medication use failure (62.1%) as a near miss and (25%) as an AE with severe harm resulting in patient death; probe and catheter use failure (18.7%) as a notifiable circumstance, (17.7%) as an incident without harm, (17.5%) as an AE with severe damage and (15%) as an AE with death; fall (43.9%) as AE with mild damage.

Table 2 shows incident classification and degree of harm caused to patients by wards and ICU. In the ward, with the exception of the notifiable circumstance, all incidents were prevalent compared to the ICU, with statistical significance p<0.001. However, regarding the degree of damage, a higher prevalence of moderate and severe damage is observed in the ICU when compared to the ward, with statistical significance p<0.001.

Table 2. Classification of incidents notified to management and severity of damage to patients by wards and Intensive Care Unit

Incidents	Wards n(%)	ICU* n(%)	Total n(%)	p-value
Notifiable circumstance	196(49.9)	618(57.6)	814(55.5)	p(1)<0.001(2)
Near miss	18(4.5)	11(1.0)	29(2.0)	
No harm incident	60(15.3)	137(12.8)	197(13.4)	
AE with damage**	119(30.3)	307(28.6)	426(29.1)	
Total incidents	393(100.0)	1073(100.0)	1466(100.0)	
Degree of harm from adverse events				
Mild damage	69(58.0)	88(28.7)	157(36.9)	p(1)<0.001(2)
Moderate damage	38(31.9)	172(56.0)	210(49.3)	
Severe damage	7(5.9)	32(10.4)	39(9.2)	
Death	5(4.2)	15(4.9)	20(4.7)	
Total adverse damage	119(100.0)	307(100.0)	426(100.0)	

(1) Significant difference at 5%; (2) Pearson's chi-square test; **AE - adverse event; *ICU - Intensive Care Unit.

Discussion

Incident notification represents a simple way to quantify AE during care practice, which aims to bring quality care. However, its underreporting has still been a challenge for many health institutions before, during and after the pandemic.[10]

As for the root cause of incidents reported in the analysis of this study, extubation stands out as an

AE with mild to severe damage to patients. Early intubation of COVID-19 patients was recommended along with prone position implementation. This consists of providing ventilatory support with patients lying in prone position, being a therapeutic tool for severe hypoxemia treatment.[11,12] However, accidental extubation was one of the most frequent occurrences because it presents a high risk of traction and orotracheal tube (OTT) displacement. This occurrence requires greater attention from the health staff to OTT fixation and positioning as well as vigilance regarding patient sedation.[13-15]

Communication failure was prevalent as a notifiable circumstance and incident without harm, including the potential to cause death to patients. Non-communication of exam with critical patient result in a timely manner was an example of AE involving communication failure that led to patient death. Studies indicate that ineffective communication is among the root causes of more than 70% of errors in health care.[16,17] It is evident that failures in communication include the absence, incompleteness or error of communication, situations that contribute to misinterpretation or non-understanding of relevant information about patient care.[17]

The pandemic revealed important instabilities in working relationships between health professionals and patients, such as mask and face shield use, which made verbal and non-verbal communication difficult, as well as conveying important information related to the conducts management and assistance between health staff. In this sense, those related to the term "handover" stand out, which represents the practice of the professional transferring to another management of the cases under his/her responsibility, as well as the communication with the patient.[18]

In addition to increased pace, intensity and speed of activities expressed in the number of patients seen, the possible deficit in staff sizing and function accumulation also aggravated communication failures due to the pandemic.[11] Emphasis is placed on the elaboration of numerous scales for the absence of professionals with emergency replacements, an increase in the number in communicating bad news due to the high lethality of the disease and the absence of families in person, introducing new communication formats through cell phones or tablets, for instance.[17] Regarding patient identification, this has a dual objective for the safety of patients and professionals who assist them: to safely determine the treatment or procedure recipient and also ensure that the procedure to be performed is effective for patients.[19]

In the hospital, incorrect patient identification may be associated with the work method, material and human resources, in addition to characteristics associated with the institution itself that, in times of a pandemic, hampered its effectiveness.[20] It is worth noting the lack of standardization and monitoring of the process. It was also noticed the lack of resources such as bracelets and identifiers in beds, directly interfering in quality of care and promoting openings for AE occurrence.[19,20] Patient identification in this study was prevalent as a near miss, for instance, in situations of sectoral transfers or patient transport for exams that were intercepted shortly before their execution. However, data from other studies were not found for comparison.

According to the Brazilian National Coordinating Council for Medication Error Notification and Prevention, medication administration failures or medication errors consist of preventable events that cause or induce the inappropriate use of a medication that is under responsibility of healthcare professional, patient or consumer.[21] Such errors may occur in medical prescription, product labeling, composition, or failures in distribution, administration and monitoring, and they can be caused by communication failures.[22] In this study, these events were predominant, such as near miss, AE with severe damage and patient death.

The situations that involved failure in medication use evidenced in this study as a near miss were: prescription error that was corrected shortly before its administration as severe AE: administration of wrong dose of hypotensive and as AE that caused death: wrong route of administration of enteral drug by parenteral.

In this regard, during the pandemic, there was a high demand for drugs popularly called "intubation kit", composed of sedatives, anesthetics and

muscle blockers. Such drugs are necessary for orotracheal intubation, especially in ICUs and emergency units. Thus, the Brazilian National Health Regulatory Agency (ANVISA - *Agência Nacional de Vigilância Sanitária*) published Resolution RDC 483 of March 19, 2021, allowing these and other medications imported without health regulation by ANVISA to be used in Brazil temporarily, with labels, packaging and package inserts in languages other than Portuguese.[23]

This fact exposed the nursing staff, responsible for the preparation and administration of medications, to greater vulnerability to possible AE. In many scenarios, there was no recommended backup, so that hospital pharmacies could forward documents in Portuguese to care areas. These would be defensive barriers to the safe use of these drugs.[23]

Resolution 564/2017 of the Federal Nursing Council (COFEN) prohibits, in Art. 78, administering medication without knowing the indication, action of the drug, route of administration and potential risks, respecting professionals' training levels. This determination aims to favor care safety both for patients and for health professionals, preventing professionals from incurring in situations of malpractice, recklessness or negligence.[24]

Some elements contribute to medication error occurrence, such as work overload, lack of professional attention, a sector with high demands for the movement of people, deficiencies in the training or qualification of professionals, illegible prescription, wrong dispensing by pharmacy, dispensing of medications within 24 hours and punitive attitude in incident notification.[20] In France, during the pandemic, the pharmacy staff portrayed the need for daily and individual automated dispensing of medications, for greater monitoring of safety for patients and staff involved in the process of taking medication.[25]

Probe and catheter use failure was highlighted in risk circumstances and harmless AE. These devices are widely used in hospital environments and are allies in treatment of critically ill patients. A study carried out in São Paulo, aiming at analyzing the AE caused by tube and catheter use revealed that the loss of nasogastric tubes was due to unscheduled removal of the tube by the patients themselves in a context of agitation and disorientation, or its obstruction (macerated pills and/or failure to wash the tube after diet or medication).[25] Regarding catheters, the loss was also due to patient agitation and disorientation, or their obstruction (inadequate handling and/or heparinization).[26]

Regarding AE with mild damage, there was an emphasis on patient fall in hospitals. Falls can be considered a multifactorial event, in which risk factors can be associated with physiological changes, skin fragility and medication use.[16] There are intrinsic factors related to patients, such as agitation, dizziness, confusion, muscle weakness, unsteady gait, hypovolemia and hypotension. Extrinsic factors are related to the hospital environment, such as inadequate lighting, furniture in inappropriate places, slippery floors, unsuitable bathrooms and use of stairs.[17,18]

A comparative study on fall notifications before and after the COVID-19 pandemic in Italian hospitals revealed an increased number of falls, which could be associated with the high number of patients being attended, lack of adequate structural resources, such as hospital beds, or nursing staff undersizing. However, clinical aspects of patients were statistically relevant, such as hypoxia and metabolic disturbances.[27]

However, the Brazilian reality is quite different when compared to physical structures, equipment and professional training of European countries. What was observed in care practice was disorderly overcrowding with use of stretchers and professionals with little technical skill. Therefore, no studies were identified that showed Brazilian data on fall incidence in the face of the pandemic.

This study found that most notifications recorded occurred in the ward when compared to the ICU. It is inferred that, as in the ICU, there are severe and at-risk patients who require uninterrupted medical care, with specialized technological and human resources, in addition to being a more controlled environment, with greater staff engagement and safety culture, which allows greater surveillance of incident occurrence.[28]

According to AE damage degree, moderate and severe damage were higher in the ICU when compared to the ward. According to data from the research hospital system, the mean length of stay of

a patient was around 10 days in this sector, which makes patients susceptible to incidents, which differs from the ward, even because of the clinical condition that patients present. Additionally, during the study period, ICUs were overcrowded due to the accelerated spread of COVID-19.

This research had some important limitations, such as data collection having been carried out after the risk management implementation period and a new staff that received little training to start the work process, a fact that may have contributed to underreporting.

Conducting this research during the pandemic in a specialized unit for patients with COVID-19 ensures that failures can be analyzed and corrected for quality care in times of a pandemic. Adversities faced in care, especially in the last two years, reinforce the importance of intensifying safety climate in health institutions.

Conclusion

The types of incidents identified in this study indicate that communication failure was the most reported risk circumstance, with AE with mild, moderate damage and death. The most prevalent severe harm was medication use failure, also for death AE. Despite the reference to COVID-19 in the study hospital, the profile of ICUs shows the possibility of a greater number of AE, mainly due to the loss of devices and medication use failure. The experiences of the COVID-19 pandemic, from the accelerated spread of the virus, overcrowding of services and high mortality, emphasize the importance of reporting incidents. We recommend conducting more research on AE for greater visibility and encouragement of notifications by healthcare professionals, especially in pandemic scenarios.

Collaborations

Silva FP, Correia KC, Araujo RMD, Oliveira ECS, Oliveira RC, Pereira EB, Holanda GM and Ventura CAA collaborated with study design, data analysis and interpretation, article writing, relevant critical review of the intellectual content and approval of the final version to be published.

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