

Characterize the main adverse events with harm reported in a Teaching Hospital in Minas Gerais

Caracterizar os principais eventos adversos com danos relatados em um Hospital Universitário de Minas Gerais

Caracterizar los principales eventos adversos con daño informados en un Hospital Universitario de Minas Gerais

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ABSTRACT

Background and Objectives: adverse events are a major public health problem. The purpose of the study was to characterize the main adverse events with harm reported in a teaching hospital in Minas Gerais. **Methods:** this is a retrospective cross-sectional descriptive study with quantitative approach, which assessed the reports on adverse events, carried out between January 2015 and December 2018. Pearson's chi-square test was applied in order to verify the association between categorical variables. Cramer's measure V was calculated to assess the degree of association between the respective variables. In the observation of statistically significant results, the Z test was applied to compare proportions with adjustments by the Bonferroni method. **Results:** a total of 445 adverse events were reported, being the highest number in 2018 (61.8%) involving "Abrasion and friction" process (44.7%), which correspond to grades 3 and 4 pressure injuries. Most adverse events were reported by the Emergency Unit (29.2%), and serious harm (7.6%) and deaths (1.3%) were more prevalent in this place. There was a statistically significant association between types of harm and types of incidents ($p < 0.001$), types of harm ($p < 0.001$) and years of occurrence, and also between the harm and the hospital sectors ($p = 0.003$). **Conclusion:** adverse event reports back institutional risk management by strengthening the patient safety culture.

Keywords: Risk Management; Quality of Healthcare; Patient Safety.

RESUMO

Justificativa e Objetivos: os eventos adversos são um importante problema de saúde pública. O objetivo do estudo foi caracterizar os principais eventos adversos com dano notificados em um hospital universitário de Minas Gerais. **Métodos:** trata-se de um estudo descritivo transversal retrospectivo com abordagem quantitativa, que avaliou as notificações de even-

tos adversos, realizado entre janeiro de 2015 e dezembro de 2018. Aplicou-se o teste qui-quadrado de Pearson para verificar a associação entre as variáveis categóricas. A medida V de Cramer foi calculada para avaliar o grau de associação entre as respectivas variáveis. Na observação de resultados estatisticamente significativos, foi aplicado o teste Z para comparação de proporções com ajustes pelo método de Bonferroni. **Resultados:** foram notificados um total de 445 eventos adversos, sendo o maior número em 2018 (61,8%) envolvendo o processo "Abrasão e fricção" (44,7%), que correspondem às lesões por pressão graus 3 e 4. A maioria dos eventos adversos foi notificada pela Unidade de Pronto Atendimento (29,2%), sendo os danos graves (7,6%) e óbitos (1,3%) mais prevalentes nesse local. Houve associação estatisticamente significativa entre tipos de danos e tipos de incidentes ($p < 0,001$), tipos de danos ($p < 0,001$) e anos de ocorrência, e também entre o dano e os setores do hospital ($p = 0,003$). **Conclusão:** os relatórios de eventos adversos retroalimentam a gestão de risco institucional fortalecendo a cultura de segurança do paciente.

Palavras-chave: Gestão de Riscos; Qualidade da Saúde; Segurança do paciente.

RESUMEN

Justificación y objetivos: los eventos adversos constituyen un importante problema de salud pública. El objetivo del estudio fue caracterizar los principales eventos adversos con daño informados en un hospital de enseñanza en Minas Gerais. **Métodos:** se trata de un estudio descriptivo transversal retrospectivo con enfoque cuantitativo, que evaluó los informes de eventos adversos, realizados entre enero de 2015 y diciembre de 2018. Se aplicó la prueba de chi-cuadrado de Pearson para verificar la asociación entre variables categóricas. Se calculó la medida V de Cramer para evaluar el grado de asociación entre las respectivas variables. En la observación de resultados estadísticamente significativos se aplicó la prueba Z para comparar proporciones con ajustes por el método de Bonferroni. **Resultados:** se reportaron un total de 445 eventos adversos, siendo el mayor número en 2018 (61,8%) el proceso de "Abrasión y fricción" (44,7%), que corresponden a lesiones por presión grados 3 y 4. La mayoría de los eventos adversos fueron informados por la Unidad de Emergencia (29,2%), y los daños graves (7,6%) y las muertes (1,3%) fueron más prevalentes en este lugar. Hubo asociación estadísticamente significativa entre tipos de daño y tipos de incidentes ($p < 0,001$), tipos de daño ($p < 0,001$) y años de ocurrencia, y también entre el daño y los sectores hospitalarios ($p = 0,003$). **Conclusión:** los informes de eventos adversos respaldan la gestión de riesgos institucional mediante el fortalecimiento de la cultura de seguridad del paciente.

Palabras clave: Gestión de Riesgos; Calidad de la Atención Médica; Seguridad del paciente.

INTRODUCTION

The occurrence of incidents and adverse events (AE) is considered a problem related to patient safety that reflects problems in the quality of care provided worldwide. An important point both for evaluating AE and for designing strategies aimed at improving quality of care is the systematic investigation of errors, the approach of a professional team and management, requiring the measurement of hospital safety culture.^{1,2}

Incidents are situations where errors or failures occur that may (or may not) cause harm to patients. AE are defined as those that result in damage or injury, and may represent temporary, permanent or death.^{3,4}

It is known that the healthcare context is complex and the daily care routine often establishes situations that are not always expected. Care is constantly developed in an environment pressured by results, in constant transformation, involving complex activities, various types of technologies, increasing the probability of errors. With this, care actions can generate undesirable results, as opposed to helping to solve patients' problems.⁵

The classification of incident types includes: clinical administration, clinical process/procedure, documentation, healthcare-associated infections, medication/intravenous fluids, blood/blood products, nutrition, oxygen/

gas/steam, medical devices, behavior, patient accident, infrastructure/buildings/facilities and resources/organizational management.⁶

AE are classified in terms of severity/severity into four categories, namely: mild, which are short-term reactions that may require treatment; moderate, which alter patients' normal activity, which results in transient incapacity without sequelae, and prolongs hospitalization; severe, reactions that directly threaten patient's lives, that cause permanent disability and that require intervention to prevent sequelae; and lethal, which are the reactions that lead to death.⁷ The Brazilian National Patient Safety Program (PNSP - Programa Nacional de Segurança do Paciente) was established by the Ministry of Health (MoH) in 2013, through MoH Ordinance 529, of April 1st, with the objective of creating in Brazil a contribution program for the qualification of healthcare in all services.⁷

In the last decade, this context has encouraged the promotion of initiatives that provide safer healthcare. Among these initiatives, we highlight the creation of programs to monitor the quality of care provided, directly interfering with patient safety.⁶

Notifying health errors is an important element for improving patient safety and the quality of care provided. Therefore, it must be an integral part of the organizational culture, considered as progress towards

achieving a positive safety culture.⁹ Knowing the characteristics of these AE is important to mitigate them and adopt interventions that minimize the risk and encourage the promotion of safer healthcare.

Therefore, the Empresa Brasileira de Serviços Hospitalares (Ebserh) made available the application called Vigilância em Saúde e Gestão de Riscos (Vigihosp). This application aims to computerize, monitor the notifications of incidents in hospitals, technical complaints, diseases and health problems and streamline the knowledge and solution of problems occurring in the hospital, facilitating the decision-making process in actions to improve the quality of services provided to patients.⁸

Thus, the aim of this research was to characterize the main AE with damage reported in a teaching hospital in Minas Gerais.

METHODS

This is a descriptive study, carried out in a cross-sectional and quantitative approach in a teaching hospital in Minas Gerais that serves 27 municipalities that make up the Triângulo Sul macroregion.

The study population was constituted through the records of notifications of incidents and AE with damages carried out in the Vigihosp app between January 2015 and December 2018.

This application allows voluntary notification by users in a confidential manner from the notifier and is composed of notification forms, an investigation module and another one for issuing management reports in real time.

A survey of the variables was carried out: year of occurrence of incidents and AE, types of incidents, notified processes, classification of AE in terms of severity/severity, professional category that made the notification of AE and hospital unit where AE occurred.

The quality of notifications was evaluated according to the presence of the criteria: description of incident, causality, description of patient or product, as proposed in the study carried out by Capucho.¹⁰

Data analysis was performed using descriptive statistics, where categorical variables were analyzed using measures of absolute and relative frequencies. Bivariate analysis included Pearson's chi-square test in order to verify the existence of association between groups defined by categorical variables. Cramer's V measure was calculated to assess the degree of association between the respective variables. Cramer's V values between 0.00 and 0.30 suggest a weak association observed between variables, between 0.30 and 0.70, a moderate association between variables, and between 0.70 and 1.00, a strong association between variables. In the observation of statistically significant results, the Z test was applied to compare proportions with adjustments using the Bonferroni method. Data were tabulated and analyzed using Microsoft Office Excel and Statistical Package for Social Sciences (SPSS), version 21.0.

The research ensured commitment to data privacy and confidentiality, fully preserving the anonymity and

image of the subject. The project was submitted for consideration and approval by the Institutional Review Board, under Opinion 2483424 and CAAE (Certificado de Apresentação para Apreciação Ética - Certificate of Presentation for Ethical Consideration) 79279717.6.0000.5154.

RESULTS

During the study period, there were 445 notifications of AE with damage to Vigihosp, the highest number in 2018 (61.8%).

The analysis of items related to the quality of notifications showed that 82.5% reported harm to patients, 63.8% have information about the incident outcome, 80.4% contain information about how the incident occurred and 65.2% indicate the causes for it to occur.

The most prevalent incidents and AE with damage were the notifications of "Patient accident" (44.7%), involving the process "Abrasion and friction", which correspond to grade 3 and 4 pressure injuries (Table 1).

For mild damage, lower proportions were observed in 2017 and 2018 compared to 2016, with 2015 being intermediate behavior between the other years. For moderate damage, the proportions observed in 2018 were lower compared to 2015, with 2016 and 2017 being intermediate values. On the other, severe scans observed in 2017 and 2018 were higher than those observed in 2015 and 2016.

The most prevalent death incidents involved "Clinical processes/procedure" using the "Procedure and treatment" process (failures during patient treatment), followed by the "Healthcare-Associated Infection" incident involving the topographies of primary bloodstream infection and pneumonia.

Nurses were the professional who most notified AE (79.1%), followed by the doctor (8.1%). Other professional categories, nursing technicians, physiotherapists, medical residents, pharmacists, social workers, nutritionists, biomedical and nursing residents reported, but at a lower frequency. Notification anonymity occurred in 2.2% of the notifications.

The association between the type of damage and the types of incidents (Table 3) was statistically significant (Pearson chi-square test, p-value<0.001), but presented an association of weak to moderate intensity (V-Cramer, C*≈0.39).

There is also a statistically significant association between the types of damage and the years of occurrence (Pearson's chi-square test, p-value<0.001), but with a weak association (V-Cramer, C*≈0.23).

No statistical difference was found in the proportion of deaths during these four years (Table 4).

Regarding the variables damage and hospital units, the statistically significant association was observed (Pearson's X² test, p-value= 0.003), but with a weak association between the two variables (V-Cramer, C*≈ 0.17). A difference was observed between the proportions only for deaths that occurred in the "Inpatient Unit - Infant" sectors (20.0%) of the "Inpatient Unit - Adult" sectors (1.3%) and "ICUs" (0.0%) (Table 5).

Table 1. Characterization of adverse events with damage and their respective processes notified in Vigihosp in a teaching hospital in Minas Gerais between 2015 and 2018.

Incident / AE	Process	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Patient accident	Abrasion/friction	5	12	21	161	199 (44.7)
Healthcare-Associated Infection	Intravascular catheter	8	29	7	58	102 (22.9)
Clinical process/procedure	Procedure/treatment and general care	6	16	15	20	57 (12.8)
Medical device/equipment	User offset and fail-ure and error	5	13	9	6	33 (7.4)
IV Medication/fluid	Administration	3	7	2	7	19 (4.2)
Clinical administration	High	0	0	4	11	15 (3.3)
Blood/blood products	Side effects	1	4	2	1	8 (1.7)
Resources/organizational management	Availability of hu-man resources and adequacy of proto-cols	1	0	0	5	6 (1.3)
Behavior	Non-compliant/non-cooperative	0	0	0	4	4 (0.8)
Diet/food	Administration	0	0	0	1	1 (0.2)
Infrastruc-ture/building/facilities	Damaged/defective	0	0	0	1	1 (0.2)
Total		29 (6.5)	81 (18.2)	60 (13.5)	275 (61.8)	445 (100.0)

Source: Vigihosp, 2018.

Table 2. Distribution of adverse events considering the damage in a teaching hospital in Minas Gerais between 2015 and 2018.

Damage	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Mild	17 (58.6)	67 (82.7)	28 (46.6)	151 (59.1)	263 (59.1)
Moderate	9 (31.0)	11 (13.5)	10 (16.6)	18 (6.6)	48 (10.7)
Severe	0 (0.0)	2 (2.4)	20 (33.3)	100 (32.3)	122 (27.4)
Death	3 (10.3)	1 (1.2)	2 (3.5)	6 (1.9)	12 (2.6)
Total	29 (6.5)	81(18.2)	60 (13.5)	275 (61.8)	445 (100.0)

Source: Vigihosp, 2018.

Table 3. Distribution of incidents and damage in a teaching hospital in Minas Gerais between 2015 and 2018.

Incident	Damage				Total n (%)
	Mild n (%)	Moderate n (%)	Severe n (%)	Death n (%)	
Patient accident	83 (41.7)	19 (9.5)	96 (48.2)	1 (0.5)	199 (44.7)
Healthcare-Associated Infection	95 (93.1)	3 (2.9)	1 (1.0)	3 (2.9)	102 (22.9)
Clinical pro-cess/procedure	31 (54.4)	15 (26.3)	5 (8.8)	6 (10.5)	57 (12.8)
Medical device/equipment	28 (84.8)	3 (9.1)	2 (6.1)	0 (0.0)	33 (7.4)
IV Medication/fluid	9 (47.4)	6 (31.6)	2 (10.5)	2 (10.5)	19 (4.3)
Clinical administration	0 (0.0)	0 (0.0)	15 (100.0)	0 (0.0)	15 (3.4)
Blood/blood products	7 (87.5)	1 (12.5)	0 (0.0)	0 (0.0)	8 (1.7)
Organizational re-source/management	4 (66.7)	1 (16.7)	1 (16.7)	0 (0.0)	6 (1.3)
Behavior	4 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
Diet/food	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
Infrastructure	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
Total	263 (59.1%)	48 (10.8%)	122 (27.4%)	12 (2.7%)	445

Pearson's chi-square test, p -value<0.001 (V-Cramer, $C^*=0.39$). Source: Vigihosp, 2018.

Table 4. Distribution of damages, according to the year in a teaching hospital in Minas Gerais between 2015 and 2018.

Damage	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	Total n (%)
Mild	17 ^{a,b} (58.6)	67 ^b (82.7)	28 ^a (46.7)	151 ^a (54.9)	263 (59.1)
Moderate	9 ^a (31.1)	11 ^{a,b} (13.6)	10 ^{a,b} (16.7)	18 ^b (6.5)	48 (10.8)
Severe	0 ^a (0.0)	2 ^a (2.5)	20 ^b (33.3)	100 ^b (36.4)	122 (27.4)
Death	3 ^a (10.3)	1 ^a (1.2)	2 ^a (3.3)	6 ^a (2.2)	12 (2.7)
Total	29 (100.0)	81 (100.0)	60 (100.0)	275 (100.0)	445 (100.0)

Pearson's chi-square test, p -value<0.001 (V-Cramer, $C^*=0.23$). The letters *a* and *b* show statistically significant difference. Source: Vigihosp, 2018.

Table 5. Distribution between the association of hospital units and year damage in a teaching hospital in Minas Gerais between 2015 and 2018.

Damage	Hospital Units						Total n (%)
	Emergency Unit n (%)	Outpatient Unit n (%)	Support Unit n (%)	Inpatient Unit - Adult n (%)	Inpatient Unit - Children n (%)	ICUs n (%)	
Mild	75 ^a (54.0)	3 ^a (60.0)	11 ^a (52.4)	107 ^a (66.9)	8 ^a (80.0)	58 ^a (54.2)	263 (59.1)
Moderate	19 ^a (13.7)	1 ^a (20.0)	4 ^a (19.0)	14 ^a (8.8)	0 ^a (0.0)	10 ^a (9.3)	48 (10.8)
Severe	37 ^a (26.6)	1 ^a (20.0)	6 ^a (28.6)	37 ^a (23.1)	0 ^a (0.0)	39 ^a (36.4)	122 (27.4)
Death	8 ^{a, b, c} (5.8)	0 ^{a, b, c} (0.0)	0 ^{a, b, c} (0.0)	2 ^c (1.3)	2 ^b (20.0)	0 ^{a, c} (0.0)	12 (2.7)
Total	139 (31.4%)	5 (1.1%)	21 (4.8%)	160 (36.2%)	10 (2.3%)	107 (24.2%)	445 (100.0%)

The letters a, b and c show statistically significant difference. Source: Vigihosp, 2018. Pearson's chi-square test, p-value=0.003

DISCUSSION

The results of this study showed an increase in notifications of incidents and AE with damage over the years, with 6.5% of notifications in 2015 and 61.9% in 2018. One factor that can contribute to this increase is the awareness campaigns for employees carried out since the beginning of the program, disclosing Vigihosp in the hospital sectors. These results are similar to a study carried out that showed a considerable increase in the number of incidents in 2008 (103) to 2012 (239), and developed a patient safety culture policy through the dissemination of notification system campaigns.¹¹ The increase in notifications contributes to the improvement of safety culture and allows the implementation of improvement actions based on the most prevalent incidents.

Another similar study, carried out in the surgical wards of a university hospital in Japan, showed that brief educational meetings lasting 15 minutes for 6 months on patient safety increased the notification rate; however, the effect of the intervention diminished after 6 months of completion of education, reinforcing the need for long-term continuing education to maintain positive outcomes.¹²

Understanding the importance of an electronic surveillance system that facilitates the registration of notifications in a hospital institution is essential for the control, reduction and prevention of injuries such as incidents and AE. From this information, protection and control measures can be taken.

Regarding the AE with more prevalent damage, in this study, the incident "Patient accident - Abrasion and friction" was highlighted, corresponding to pressure injury, similar to another study¹³ and which could be prevented or mitigated through continuous assessment and reassessment of risk by the care team, highlighting the role of the nursing team in this assessment.¹³

In this study, the type of damage of the AE with the highest prevalence was the "mild" damage, with 59.1% of the notifications; and the harm that had a lower prevalence was "death", with only 2.6% of all notifications. These data are divergent from an integrative review that identified in scientific publications on AE in hospital care, that 83.9% of the incidents are responsible for moderate harm to the patient and 16.1% of the harm resulted in

patient death.¹⁴

Regarding the location with the highest number of incidents with reported damage, the Emergency Unit stood out (29.2%). Studies comparing the proportions of AE attributed to negligence according to the different hospital sectors reveal that the emergency room represents the sector where the largest portions of these events are identified.¹⁵ This unit is characterized by the need for quick decisions and where information about the patient is lacking, which can contribute to the occurrence of AE.

The high burden of patient safety incidents is particularly true in emergency departments, fast-paced healthcare environments with complex communication areas and a high rate of distractions and work interruptions. Moreover, healthcare providers are required to manage different types of patient care with conditions of varying severity.¹⁶

Regarding the professional category that performed the notifications of the AE most frequently, it was found that nursing practitioners performed 79.1% of the notifications. Other studies carried out with multidisciplinary teams also showed greater participation of the nursing staff in reporting.¹⁷⁻¹⁹ The nursing team uses AE notifications as an instrument to aid in healthcare management, problem identification and search for alternatives to solve problems related to healthcare.

It is believed that low notifications from other professional categories are associated with a deficit in knowledge about notification, emphasizing the importance of equipping them to change attitudes. International studies indicate that underreporting may be related to the fact that it is restricted to registration by nurses and also to the voluntary, non-mandatory nature, linked to lack of time and the lack of the habit of notifying.^{17,20}

In this context, it is important to emphasize that it is relevant to implement a continuing education process on patient safety that involves all professionals in the institution to encourage and maintain the habit of notifying. The encouragement and motivation of professionals to notify an AE develop the perception of collaboration with the institution, generating an expectation of having a return, especially in relation to the resolvability of hospital management.^{17,20,21} Patient safety must be the responsibility of all professionals involved in care, with education

as an essential practice for quality of care.^{17,21}

Regarding the quality of notifications, the description of the incident, causality, description of patient or product had satisfactory results. It is noteworthy that notifications that present complete information allow an effective analysis of incidents, generating knowledge so that efficient interventions are carried out, in order to prevent the same from happening again. Given the above, notifications from all sectors of the hospital institution allow identifying, knowing and classifying the characteristics of AE. The production of this knowledge subsidizes decision-making and healthcare risk management stimulated by the patient safety culture. Despite the existence of Vigishop for reporting AE, underreporting is a reality still experienced by health services and represents a limitation of this study.

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AUTHORS' CONTRIBUTIONS

Luciana Paiva, Patrícia Borges Peixoto, and Sergio Antonio Zullo were responsible for designing the project and analyzing and interpreting the data.

Joyce Assunção Barros and Cristina da Cunha Hueb Barata de Oliveira were responsible for writing the article or critically reviewing the relevant intellectual content.

Luciana Paiva, Patrícia Borges Peixoto, Eva Claudia Venancio de Senne, and Cristina da Cunha Hueb Barata de Oliveira approved the final version to be published.

Eva Claudia Venancio de Senne and Cristina da Cunha Hueb Barata de Oliveira were responsible for all aspects of the work in ensuring the accuracy and completeness of any part of the work.

All authors have approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.