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Notifications of adverse events: characterization of the events that occurred in a hospital complex



Notificação de eventos adversos: caracterização dos eventos ocorridos em um complexo hospitalar

Notificación de eventos adversos: caracterización de los eventos ocurridos en un complejo hospitalario

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ABSTRACT

Objective: Analyze incident notifications related to the patient's safety.

Method: Cross-sectional study with quantitative approach, based on data from the risk Management of a hospital complex, located in northwest São Paulo, from August 2015 to July 2016.

Results: 4,691 notifications were analyzed. Nurses were the professionals who notified the most (71%), followed by physicians (8%). The most frequent period in which the notifications occurred was the daytime. There was significant difference in the proportion of notifications between the days of the week. The notifications were classified by reason and the most prevalent were those related to medication (17%), followed by skin lesions (15%), and phlebitis (14%). The highest frequency of notifications occurred in the hospitalization units. In relation to severity, 344 events caused damage to the patient, most of which were of mild intensity (65%).

Conclusion: Spontaneous notifications are an important source of information, and highlight the magnitude of the problem related to health incidents.

Keywords: Notification. Patient safety. Quality of health care.

RESUMO

Objetivo: Analisar as notificações de incidentes relacionados à segurança do paciente.

Métodos: Estudo transversal com abordagem quantitativa, baseado nos dados do Gerenciamento de Risco de um complexo hospitalar, localizado no noroeste paulista, de agosto/2015 a julho/2016.

Resultados: Foram analisadas 4.691 notificações. O enfermeiro foi a categoria profissional que mais notificou (71%), seguido do médico (8%). O período mais frequente em que ocorreram as notificações foi o diurno. Houve diferença significativa da proporção de notificações entre os dias da semana. As notificações foram classificadas por motivo, com destaque para os medicamentos (17%), seguido de lesões de pele (15%) e flebite (14%). A maior frequência de notificações ocorreu nas unidades de Internação. Quanto à gravidade 344 eventos ocasionaram dano ao paciente, sendo a maioria de intensidade leve (65%).

Conclusão: As notificações espontâneas são uma importante fonte de informações e evidenciam a magnitude do problema relacionado aos incidentes em saúde.

Palavras-chave: Notificação. Segurança do paciente. Qualidade da assistência à saúde.

RESUME

Objetivo: Analizar las notificaciones de incidentes relacionados con la seguridad del paciente.

Métodos: Estudio transversal con abordaje cuantitativo, basado en los datos del Gestión de Riesgos de un complejo hospitalario, ubicado em el noroeste paulista, de agosto de 2015 a julio de 2016.

Resultados: Se analizaron 4.691 notificaciones. El enfermero fue la categoría profesional que más notificó (71%), seguido del médico (8%). El período más frecuente en que ocurrieron las notificaciones fue el diurno. Hubo una diferencia significativa de la proporción de notificaciones entre los días de la semana. Las notificaciones se clasificaron por motivo, con destaque para los medicamentos (17%), seguido de lesiones de piel (15%), flebitis (14%). La mayor frecuencia de notificaciones ocurrió en las unidades de Internación. En cuanto a la gravedad 344 eventos ocasionaron daño al paciente, siendo la mayoría de intensidad leve (65%).

Conclusión: Las notificaciones espontáneas son una importante fuente de información, y evidencia la magnitud del problema relacionado con los incidentes en salud.

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■ INTRODUCTION

Healthcare processes must be able to diminish, to an acceptable minimum level, the risk of failure, and as a consequence, reduce the preventable damage associated to the assistance, guaranteeing the safety of the patient. Adverse events in healthcare are a public health problem, recognized by the World Health Organization (WHO)⁽¹⁾.

Quality improvements are actions that make possible a safe, effective, patient-focused, adequate, efficient, and equal healthcare. The theme of patient safety got attention in 1999 through the report "To err is human", by the American Institute of Medicine (AIM), which estimated that from 44,000 to 98,000 deaths take place every year in the United States due to failures in medical and hospital care⁽²⁾. However, one decade after the publication of said report, the number of Adverse Events (AE) did not fall as expected and desirable, despite the implementation of some recommended strategies, especially those related to reports and to the analysis of incidents as a way to promote learning from mistakes⁽³⁾.

The severity of AE related to healthcare has such a social impact that health systems throughout the world have been impacted by it, leading to a large mobilization of government and non-government organs to control and prevent such occurrences, which also happened in Brazil⁽⁴⁾.

The consequences of patient insecurity go beyond deaths and include health problems and more subtle damages to health, such as the loss of dignity and respect, and psychic suffering⁽⁵⁾ The importance of the theme stands out, since studies estimate that the occurrence of AE associated to healthcare affects from 4% to 16% of hospitalized patients in developed countries⁽³⁻⁴⁾. In the United States, one of every 10 hospitalized patients have some AE⁽⁶⁾. One in every two surgeries has a mistake or an AE related to medication use⁽⁷⁾.

In Brazil, the most common causes of AEs are falls, incorrect administration of medication, failure to identify the patient, mistakes in surgical procedures, infections, and the inadequate use of medical devices and equipment⁽³⁾. In this context, the Ministry of Health instituted the National Program of Patient Safety, whose aim is contributing for the qualification of care in every health establishment in the national territory⁽⁸⁾.

The notification of these events is relevant for patient safety, since it allows professionals to report health incidents and/or AE. The analysis of the notifications enables organizational learning, making it possible for causes to be identified and avoided, from the revision and improvement of healthcare processes⁽⁹⁻¹⁰⁾.

Therefore, in Brazil, in order to know the reality of the country and carry out a situational diagnostic of the incidents that took place, the notification and inspection of healthcare related incidents was regulated, and is conducted through the Information System for Sanitary Surveillance (NOTIVISA)⁽¹¹⁾.

The concern about the theme started with an understanding of how relevant the problem was, and by believing that undernotification, that is, the notification of less than all events that took place, is a lost opportunity for correcting the possible shortcomings in the process, which risk the safety of the patient. Due to the above, this study aims at analyzing the notifications of incidents related to the safety of the patient.

METHOD

Cross-sectional study, resulting from a dissertation⁽¹²⁾, with a quantitative approach, using the database of the Risk Management notification system of a university hospital complex in the countryside of São Paulo, from August 2015 to July 2016. The hospital complex has 877 beds, divided in two units, the A Unit with 706 beds for high-complexity elective healthcare, and the B Unit, with 171 beds for high-complexity and urgency/emergency healthcare. The sample included 4691 notifications of incidents and AE sent to the Risk Management Service of the hospital that participated in the study, through the information system of voluntary notification. No exclusion criterion was defined. Therefore, all incidents notified during the study were included in the research.

To discuss the results found, when pertinent, the comparisons between variables were carried out with statistical analyses, using the Chi-square test for 2 proportions (Z test), in which the values were represented by differences in them, with confidence intervals of 95% (Cl95%). Spearman's correlation coefficient was also calculated. The significance level used was 5%. The analysis used the software MedCalc Statistical Software version 18.5 (MedCalc Software byba, Ostend, Belgium; http://www.medcalc.org; 2018).

The research was approved by the Research Ethics Committee of the institution, under CAAE 59976116.6.0000.5440. There was no need for a Free and Informed Consent Form, since the study was retrospective and did not involve interventions.

RESULTS

From August/2015 to July/2016, Risk Management received 4691 notifications of incidents related to patient

safety. The mean was that of 391 notifications/month (standard deviation 27.83), with a median 394 notifications (1° quarter 383,75 and 3° quarter 409,25).

The nurses were the responsible for most notifications 70.60% (n=3312), followed by physicians 7.95% (n=373), administrative officials 4.73% (n=223), and pharmacists 4.35% (n=204), considering the two units as a whole.

In Unit A, the morning presented 45.42% (n=1,566) occurrences, while the afternoon presented 40.66%

(n=1.402) of cases and 15.54% (n=480) took place at night. That may indicate that, in the hospital being analyzed, most procedures are conducted during the day, which is related to the working hours of the ambulatory and the intense activity of the teams, which is not true in the period of the night. On the other hand, in Unit B, the afternoon had the most incidents, 40.87% (n=508), while the morning presented 39.10% (n=486) and the night 20.03% (n=249).

Table 1 - Number, percentage, and significance level of the notification of incidents related to the safety of the patient, according to the period of the hospital occurrence and day of the week, as specified by a hospital unit, from Aug. 2015, to July 2016. Ribeirão Preto - SP

	Unit A	P ¹	Unit B	P ¹	Total	P ¹
Time of occurrence	n (%)		n (%)		n (%)	
Morning	1566 (45.42)	<0.05 ^(a)	486 (39.10)	>0.05 ^(d)	2052 (43.74)	<0.05 ^(g)
Afternoon	1402 (40.66)	<0.05 ^(b)	508 (40.87)	<0.05 ^(e)	1910 (40.72)	>0.05 ^(h)
Night	480 (13.92)	<0.05 ^(c)	249 (20.03)	<0.05 ^(f)	729 (15.54)	<0.05 ⁽ⁱ⁾
Day of the week						
Sunday	241 (6.99)	<0.05	123 (9.90)	< 0.05	364 (7.76)	<0.05
Monday	598 (17.34)	>0.05	196 (15,77)	>0.05	794 (16.93)	>0.05
*Tuesday	656 (19.03)	-	242 (19.47)	-	898 (19.14)	-
Wednesday	576 (16.71)	>0.05	193 (15.53)	>0.05	769 (16.39)	>0.05
Thursday	603 (17.49)	>0.05	205 (16.49)	>0.05	808 (17.22)	>0.05
Friday	499 (14.47)	<0.05	163 (13.11)	>0.05	662 (14.11)	<0.05
Saturday	275 (7.98)	<0.05	121 (9.73)	< 0.05	396 (8.44)	<0.05

Source: Research data, 2018.

Caption: P1 Pearson's Chi-square test;

Comparison between the periods in Unit A: (a) morning x afternoon; (b) morning x night; (c) afternoon x night; Comparison between the periods in Unit B: (d) morning x afternoon; (e) morning x night; (f) afternoon x night; Comparison between Unit A and Unit B: (g) Morning (h) afternoon (i) night.

As data from Unit A was analyzed, a significant difference was found between the proportion of the three periods, that is, morning versus afternoon, morning versus night, and afternoon versus night. In Unit B, a significant difference was found between night and afternoon, and between afternoon and night. The comparison between morning and afternoon was not significant, that is, the proportion found in these two periods were found to be the same.

When the total of the units A and B was analyzed, differences were found between the proportion of notifications

in Unit A and B in the morning and in the evening. The comparison between units A and B in the afternoon was not significant, that is, there was no difference.

In the general analysis, regarding the day of the week in which notifications took place, 19.14% (n=898) took place on Tuesday, followed by Thursday, which had 17.22% (n=808) of notifications, Monday, with 16.93% (n=794), Wednesday, with 16.39% (n=769), Friday, with 14.11% (n=662), and a lower incidence on Saturdays 8.44% (n=396) and Sundays 7.76% (n=364), according to table 1.

^{*}Reference (Tuesday) - comparison between days of the week.

Table 2 - Reason for the notification of incidents related to patient safety according to amount and frequency, from Aug. 2015 to July 2016. Ribeirão Preto - SP

Reason for the notification	n (%)	
Medication	807 (17.20)	
Skin lesions	695 (14.82)	
Phlebitis	650 (13.86)	
Medical/Hospital Article	630 (13.43)	
Fall	299 (6.37)	
Blood related/Transfusion process	207 (4.41)	
Surgery Related Events	100 (2.13)	
Device losses	46 (0.98)	
Sanitary, Cosmetics, and Personal Hygiene products.	30 (0.64)	
Medical/Hospital Equipment	26 (0.55)	
Vaccines and Immunoglobulin	6 (0.13)	
Anesthetic Event	5 (0.11)	
In vitro diagnostic reaction toolkit	3 (0.06)	
Others	1,187 (25.30)	
Total	4,691	

Source: Research data, 2018.

Table 2 shows the reason for the notifications of incidents related to patient safety, according to total number and frequency. The main reasons for notification were: "Others", with 25.30% (n=1187), followed by medication, with 17.20% (n=807) of notifications, skin lesions, with 14.82% (n=695), phlebitis, with 13.86% (n=650), medical/hospital articles 13.43% (n=630) and falls 6.37% (n=299). Blood related events represented 4.41% (n=207) of notifications, and surgery related events, 2.13% (n=100) of them.

Regarding the place in which the notifications took place, Chart 1 shows the notification services of hospital units A and B in the period of the study.

Chart 1 shows the notifications of incidents related to the safety of the patient according to the overarching area.

In unit A, the incidents notified were mostly frequent in the units of Hospitalization 47.19% (n=1,627), Diagnostic and Therapeutic Support 7.66% (n=264), Intensive Care 7.28% (n=251). The Surgical Center is in fourth place, with 6% (n=207), followed by the Administrative and Technical Support (3.48% - n=120) and by the Ambulatory (3.22% - n=111). Unidentified notifications represet 25.17% (n=868) of the total.

In unit B, Hospitalization units also stood out as the ones with the most notifications, with 42.48% (n=528), followed by the Intensive Care unit 30.49% (n=379) and the Attention sector 9.41% (n= 117). The Surgical Center is also in the fourth position 5.07% (n=63), and the lowest results are in the Diagnostic and Therapeutic Support (0.72% - n=9) and in Administrative and Technical Support 0.56% (n=7). 25.17% (n=869) notifications in unit A and 11.26% (n=140) in unit B were not identified regarding their unit.

Regarding the type of incident, 344 were classified as Adverse Events. These were classified according to the severity of the damage.

According to chart 2, 67.90% of the events in unit A and 54.79% of those in unit B were identified as of light degree, while 28.04% in unit A and 34.35% in unit B were classified as of moderate degree, meaning they caused some type of temporary or reversible disability, generating longer periods of hospitalization, losses of function, permanent or long-term damage. 3.69% of cases in unit A and 4.11% in unit B were classified as severe, requiring medical/surgical interventions or leading to permanent damage to the patients. 0.37% of cases in unit A and 6.85% in unit B resulted in death.

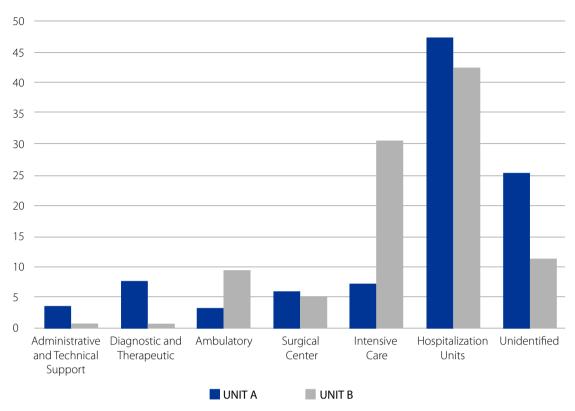


Chart 1- Percentage of patient-safety related incident notifications per overarching services/areas in units A and B, from Aug 2015. to Jul. 2016. Ribeirão Preto - SP

Source: Research data, 2018.

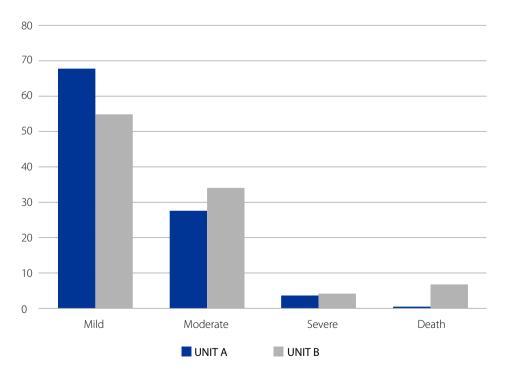


Chart 2 - Severity of the damage of adverse events related to patient safety, in units A and B, from Aug. 2015 to July 2016. Ribeirão Preto - SP

Source: Research data, 2018.

DISCUSSION

According to the place where the notifications took place, unit A was responsible for 73.50% of notifications, followed by unit B, with 26.50%. These percentages are coherent with the size of the two units, since unit A has 706 beds and was the place of 573,253 consultations and 25,294 hospitalizations, while unit B, with 171 beds, attended 38,182 walk-in patients and received 9,888 hospitalizations, data from 2016.

Regarding the professional category of the notifiers, a study conducted in 2012 in the same hospital identified that the nurses were also those who notified the most 76.6% (n=512) in the implantation of the electronic notification system. Physicians, on the other hand, contributed with 16.6% of the hand-written notifications, contributing with only 2.5% of electronic ones⁽¹⁷⁾.

In an analysis of the incidents notified in a public hospital at the Federal District, nurses were found to be responsible for most notifications (26.3%), followed by physicians 5.7%⁽¹⁰⁾. All professional categories are authorized to notify incidents. According to the Nursing Professional Ethics Code, the nursing professional has the responsibility and duty of: "Guaranteeing to the person, family and collectivity an attention free from harm resulting from lack of ability, negligence, or carelessness"⁽¹⁸⁾.

From the point of view of the nursing team, the issues of patient safety and incident notification cannot be solely responsibilities of the nurses, even if they are the responsible for healthcare coordination and management. Nurses are the professionals who spend the most time beside the patient, in addition to being more numerous within hospitals than other professionals and being trained on the importance of reporting the process of patient healthcare⁽¹⁷⁻¹⁸⁾.

Physicians reported only 7.95% of the events, corroborating other researches^(10,17). The scarcity of notifications carried out by physicians is probably due to a series of reasons based on cultural factors, fear, lack of knowledge, expectation of being blamed or punished, alleged lack of time, lack of understanding regarding how to report, or the perception that the notification may not lead to improvement^(9-10,17). The results point at the need for evaluating the reasons due to which the physicians do not notify, in addition to reiterating the need for strategies that can encourage these professionals to notify.

The notifications carried out by other professionals is a sign of their involvement in the patient safety policies.

When the period in which the total incidents of the units A and B was analyzed, differences were found between the proportion of notifications in Unit A and B in the morning and in the evening. The comparison between units A and B in the afternoon was not significant, that is, there was no difference. Most notifications made during the day are coherent with data from ANVISA, according to which 58.9% of notifications were reported during the day⁽¹³⁾.

During the characterization of a medium-sized hospital in the state of Minas Gerais, Brazil, it was found that 40.2% of notifications were created in the night period, and 22.2% in the morning period, a result that is different from the one found in the hospital analyzed here⁽¹⁴⁾.

Another analysis in a surgical clinic found that, from 2,396 occurrences, 57% (n=1,365) took part in the morning, 17.4% (n=416) in the afternoon, while 25.6% (n=615) took place during the night shift⁽¹⁵⁾. These findings are similar to those found by this study. This data can be related to the moment in which many actions, such as consultations, procedures, attention, exams, and medical visits are carried out, to the high number of professionals in the units — especially nurses, who are more numerous during the day and are responsible for most notifications.

Regarding the day of the week in which most notifications took place, in unit A, the Spearman's correlation coefficient found was: - 0.0714; p=0.8790, com IC95%: -0.782; -

0.720. The comparison between weekdays was significant, meaning there was a difference between their results. The reduction in the number of notifications in the weekends might be related to the fact that the ambulatory is not active in those days.

In unit B, the Spearman's correlation coefficient found was -0.286; p=0.5345 com IC95%: -0.855; 0.595. The comparison between weekdays was significant, meaning there was a difference between their results. Healthcare is offered every day of the week, but according to data from the institution, in the period of the study, the number of patients per weekday diminishes on Saturdays and Sundays, and the average number of people attended is 2,365 in weekdays and 1,855 on weekends.

Regarding the notification of incidents, the option "Others" was the most commonly reported in the original data from the institution, with 1,689 notifications. However, the analysis of notifications made it possible for 504 notifications to be re-classified in a more adequate and specific place in the database of this research. Despite the system making it possible to classify the motive of the incident, the notifiers opted to mark the option "Others", perhaps because it is easier.

A study in Brazil described similar results, with 3,209 studies having marked the option "Others" in the information system, and later being reclassified according to each specific system category⁽¹³⁾. Even after reclassification, there was a

high number of incidents classified as "Others" (n=1,187). This can be due to the great variety of types of events that took place and to the difficulty to classify this group of diverse incidents which can be or not associated to healthcare.

In this study, it was possible to highlight adverse events due to medication (MAE) in 17.2% of cases, meaning this was the most frequent motive for notifications and involved many different causes. The MAEs, in most cases, are preventable. The continued commitment of the health professionals involved in each step of the medication process is essential, and together they can prevent these events, each being responsible for their own role.

In 2012, a study conducted in the same hospital analyzed hand-written and electronic notifications and found medication mistakes to be the most commonly reported incidents in both systems⁽¹⁷⁾.

In the findings of other researches, however, medication mistakes corresponded to 63.6% of the mistakes found⁽¹⁵⁾. A similar study in a large-sized hospital found that MAEs were the second most frequent type of incident, with 16.7%⁽¹⁹⁾. To prevent and avoid MAEs, it is necessary to evaluate the causes and the human and structural factors involved in this process, as to prevent the implementation of preventive barriers and diminish risks for the patient^(3,11).

Pressure lesions (PL) and falls are preventable incidents, that is, can be prevented through the adoption of preventive measures and institutional strategies. In this study, they represented, respectively 14.8% and 6.37%. These occurrences can bring problems to the patients, families and institutions, making it more difficult for the patient to recover, increasing the chance of infections, the length of hospitalizations, in addition to diminishing the independence and functionality of patients and their performance of daily activities, not to mention their physical and emotional suffering.

PLs stand out as the third most notified event by the Patient Safety Centers in the health services of the country. 10,210 (18.9%) of the 53,997 incidents reported in 2016 were due to this type of lesion⁽¹³⁾. Despite being related to the quality of care, intrinsic factors influence in the results found.

In a study conducted in a university hospital in the south of Brazil, falls were responsible for 45.5%⁽¹⁹⁾, being among the most reported incidents in NOTIVISA⁽¹³⁾. They are associated to many risk factors, especially involving hospitalized elder patients, highlighting the need for constant surveillance^(3,19).

In the notification system of the hospital complex studied here, providing the place in which the situation happened is not mandatory, though the specialty under which the patient was, is. Identifying the location is important for preventive measures that refer to the incidents to be

carried out, and professionals should be better advised to complete this part of the form. The data found corroborate previous studies, in which hospitalization units were responsible for most notifications^(13,19), followed by Intensive Care Units⁽¹³⁾. In another research, 59.3% of notifications also did not notify the location of the event⁽¹⁰⁾.

A study conducted in a hospital of similar size found that the ICUs were responsible for most of the incidents notified in 2012 (34.4%), followed by the hospitalization units (21.2%)⁽²⁰⁾. The ICUs are complex environments destined to attend patients in severe conditions. Emergency care, on the other hand, is an environment where many mistakes may happen, since the professionals may not have time to offer the best possible care and surveillance, due to the overload of patients in most services and the lack of continued care.

This study found that 9.41% of notifications took place in Emergency Care, more than what was found by other authors (2.5%)⁽¹⁹⁻²⁰⁾. The emergency and urgency unit is a specialized service, which offers immediate care to many health problems that risk severe complications or death.

Regarding the severity of events in unit A, more severe events took place than in unit B, despite there being more deaths in unit B. Considering the statistical analysis, it was found that there was no difference in the number of events in units A and B, with the results: moderate x mild 0.92 (IC95%: 0.81 - 1.04; p>0.05), severe x mild 0.94 (IC95%: 0.69 - 1.27; p>0.05) and severe x moderate 1.02 (IC95%: 0.74 - 1.41; p>0.05).

A university hospital from the Sentinela Network, with 309 beds of medium and high complexity, the analysis of incident notifications, throughout one year, found 5,672 incident reports, 218 of which were characterized as adverse events, from which 170 (77.98%) were mildly damaged, 36 (16.51%) received moderate damage and five (2.29%) received severe damage. With a low prevalence, but higher impact, seven (3.21%) events resulted in death⁽¹⁶⁾. This percentage is higher than the one found in this study. In a recent study, among the incidents notified, there was a predominance of AE, and regarding the level of the damage, it was mostly mild or moderate, corroborating this study⁽¹⁰⁾.

CONCLUSION

The analysis regarding days of the week showed a significant difference between them, with a reduction in the number of notifications in weekends in both units. The day of the week with most notifications was Tuesday in both units, and the days with the lowest were Sunday, in unit A, and Saturday, in unit B.

The notifications were mostly created by the nurses, indicating that the responsibility for patient safety is not equally shared by the teams. It stands out that the notification of incidents is not a responsibility of only one professional category. The notification of undesirable factors should be made by professionals working with the client, physicians, nurses, and nursing technicians and auxiliaries. The scarcity of notifications made by physicians was clear, adding up to only 8% of the ones reported in the period. This number is too low considering the role of this professional in the therapy of the patient.

In the notification system of the hospital complex, there is no option to indicate a Potential Adverse Event, being necessary to check once again the possibility of including this classification among the incidents, since it is important to improve these processes. The damage resulting from health care has many consequences, both for the patient and for the hospital institutions, such as the increased hospitalization times, permanent disabilities, processes, and the expressive impact in hospital expenses.

This study contributes for the production of knowledge on the theme of adverse events in health. Considering the data analysis, spontaneous notifications are an important way to detect health incidents, since it is a low cost method, involves professionals that offer direct assistance to the patient, and raises awareness for the promotion of patient safety in hospital environments, while also highlighting certain aspects regarding the management of quality in the services.

Among the limitations of this study, stand out the different realities of each unit, since data can change from one hospital to the other due to their profile and to a high number of variables, although these limitations do not compromise the results found here. Therefore, other studies are suggested that can further these investigations, so that new strategies can be created to avoid incidents and adverse events.

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