

Analysis of healthcare-related incidents in the city of Porto Alegre, Rio Grande do Sul, between 2016 and 2017

Análise dos incidentes relacionados à assistência à saúde no município de Porto Alegre, Rio Grande do Sul, nos anos de 2016 e 2017

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ABSTRACT

Introduction: Health care incidents represent a serious public health problem since they are associated with increased mortality, length of hospitalization and treatment costs. In this context, the continuous monitoring and surveillance of incident occurrence by the health services are important prevention tools. **Objective:** To describe and evaluate the quality of the incident notification related to healthcare occurred in the city of Porto Alegre, RS, between 2016 and 2017. **Method:** A descriptive study that proposes to calculate the prevalence of notified incidents and to analyze their variables from secondary data. **Results:** A total of 1,059 events occurred among the studied years, most of them in hospitals, with mild damage and during healthcare. The most affected age group was the elderly and the most frequent incidents were produced by falls. The most frequent *never event* were pressure ulcers and the quality of the notification was generally low. **Conclusions:** It is important risk monitoring and incident notification to be permanent practices in health services and the notified data to be used as a tool for constant improvement of healthcare processes.

KEYWORDS: Public Health Surveillance; Patient Safety; Health Surveillance

RESUMO

Introdução: Os incidentes relacionados à assistência à saúde representam um sério problema de saúde pública por estarem associados ao aumento da mortalidade, tempo de internação e custos no tratamento. Nesse contexto, o monitoramento e vigilância permanente da ocorrência de incidentes por parte dos serviços de saúde são importantes ferramentas de prevenção. **Objetivo:** Descrever e avaliar a qualidade das notificações dos incidentes relacionados à assistência ocorridos no município de Porto Alegre, Rio Grande do Sul, entre os anos de 2016 e 2017. **Método:** Estudo descritivo que se propõe a calcular a prevalência de incidentes notificados e analisar suas variáveis a partir de dados secundários. **Resultados:** Um total de 1.059 eventos foi notificado entre os anos pesquisados, a maioria em hospitais, com grau de dano leve e durante a prestação de cuidados. A faixa etária mais acometida foi a de idosos e os incidentes mais frequentes foram as quedas. Os *never events* mais frequentes foram as úlceras por pressão e a qualidade das notificações mostrou-se baixa em geral. **Conclusões:** É importante que o monitoramento de riscos e a notificação de incidentes sejam práticas permanentes nos serviços de saúde e que os dados notificados sejam utilizados como ferramenta para a melhoria constante dos processos de cuidado.

PALAVRAS-CHAVE: Vigilância em Saúde; Segurança do Paciente; Vigilância Sanitária

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INTRODUCTION

The provision of care is not free of risks and healthcare institutions are complex facilities, where several factors can contribute to the occurrence of healthcare-associated incidents¹. The World Health Organization (WHO) defines an incident as an avoidable event or circumstance, resulting from care, not associated with the underlying disease². Studies estimate that the occurrence of these incidents, and in particular of adverse events (AEs), affects 4% to 16% of hospitalized patients in developed countries. This has encouraged health systems around the world to design strategies to enhance patient safety³.

This mobilization began after the publication of the *To Err is Human: building a safer health system* report, of the Institute of Medicine (IOM)⁴, which estimated between 44,000 to 98,000 deaths per year in the United States due to errors in patient care. Ever since then, health results or outcomes have been the subject of study, once the occurrence of AEs involves considerable social and economic costs and can result in irreversible damage to patients and their families⁵.

In view of what was said in the report, in May 2002, the 55th World Health Assembly adopted Resolution WHA n. 55.18, "Quality of care: patient safety", which urged the member states to pay more attention to the matter of patient safety⁶.

Then, in 2004, the WHO established the World Alliance for Patient Safety in order to design strategies to improve patient care and increase the quality of health services. With an international scope, the Alliance has the mission to coordinate, spread and expedite improvements in patient safety worldwide. In 2005, the Alliance set some priority issues for research in the area of patient safety that are highly relevant to countries at all levels of development: healthcare for mothers and newborns; healthcare for the elderly; AEs related to medication errors; poor safety culture, focused on the process of accountability for the errors; inadequate competences and skills among healthcare professionals; healthcare-associated infections⁷.

According to the WHO, the safety culture has three components: a fair culture, in which the difference between unacceptable acts and errors due to system failures is clear. A culture that is fair, open and blame-free has the potential to create a virtuous circle that encourages more reporting, which, in turn, results in more efforts to improve services and consequently optimize standards related to patient safety⁸; a reporting culture, in which information about healthcare-associated incidents is collected, analyzed and shared; a culture of learning from mistakes, driven by monitoring, analyses and feedback, enabling reflection on incidents in health services. Finally, this culture is the foundation of further improvement actions⁹.

Regarding the classification of healthcare-associated incidents, reportable occurrences are situations with significant potential to cause harm, but which did not result in an incident (for

example, a defibrillator in the emergency room that is not working); a near miss is an incident that did not affect any patient, but had this potential before its occurrence (errors in prescriptions, fixed before the product was administered to the patient); a no harm incident is an incident that the patient suffered, but did not result in discernible harm (transfused blood unit, but the blood was incompatible with the patient's); a harmful incident (AE) is an incident that results in healthcare-associated harm. It is unintentional and unrelated to the natural evolution of the underlying disease and results in longer hospitalization and/or death (transfusion of a wrong blood unit and death from hemolytic reaction)¹⁰.

As for their severity, AEs can be classified as: mild, moderate, severe and death, according to the intensity of the complications¹¹.

AE reporting is important to help identify healthcare-associated incidents. In addition to being a low-cost method, it is widely recognized as an important method for the continuous improvement of healthcare safety. Many countries have established their own surveillance and reporting systems^{12,13}. Among its possible uses, the reported data can generate information to identify patterns and trends on patient safety, encouraging continuous learning, inducing the resolution of the identified problems and adopting risk-based measures. With that, solutions can be created to prevent the recurrence of harm to patients in healthcare services, thus improving the quality and safety of patients in these services¹⁴.

In Brazil, an important milestone in healthcare was the creation of the National Patient Safety Program (PNSP) by the Ministry of Health (MS) through the publication of Ordinance n. 529, in April 1st, 2013. The objective of the program is to contribute to the improvement of healthcare in all health facilities in Brazil. Among the objectives of the PNSP, the implementation of risk management plans and the Patient Safety Centers (NSP) in health facilities stand out¹⁴.

Still in 2013, RDC n.36, of July 25, 2013, established actions for patient safety in healthcare services and defined concepts like safety culture, harm, AE, incident, risk management, among others. Among these definitions, highlights to the NSPs as "healthcare instances created to promote and support the implementation of initiatives focused on patient safety" and the Patient Safety Plan (PSP), a document that points out situations of risks in healthcare services and describes the strategies and actions defined by the healthcare service for risk management aimed at preventing and mitigating incidents, from admission to transfer, discharge or death of the patient¹⁵.

The reporting of AEs to the National Health Surveillance System (SNVS) is an instrument to support health management¹⁶ and is an important attribution of the NSPs to the SNVS. This reporting must be done in the specific module of the Health Surveillance Notification System (Notivisa)¹⁷.



In the city of Porto Alegre, health surveillance initiatives are conducted by the General Health Surveillance Coordination (CGVS), a department linked to the Municipal Department of Health (SMS), whose main objective is the promotion of health and prevention programs - one of the guidelines of the Brazilian Unified Health System (SUS). The CGVS has sought to consolidate articulated actions between the areas of epidemiological, sanitary, environmental and worker health surveillance, dividing itself into different teams within these areas¹⁸.

The Health Service Surveillance Team (EVSIS) - part of the health surveillance body - works with a focus on patient safety with a view to preventing AEs. To this end, it inspects and provides guidance to adapt healthcare facilities to the current health legislation¹⁸. This team is composed of the Municipal Patient Safety Center (NMSP), created in view of the importance of AEs related to healthcare, as well as the great relevance of the topic of patient safety and quality of care. The NMSP is responsible for monitoring AE reports, consolidating, evaluating and analyzing reported cases, doing investigations, supporting the implementation of safety practices in institutions, promoting and collaborating in people training, and more¹⁹.

The objective of the present study was to assess the quality and describe incident and AE reports, as well as to analyze their variables informed on Notivisa during the years 2016 and 2017.

METHOD

This is an observational, descriptive study of healthcare-associated incident reports in Porto Alegre. It aimed at estimating the prevalence of these incidents and study their variables from secondary data, that is, reports of healthcare-associated incidents from the NSPs of all healthcare facilities in Porto Alegre (public, private, philanthropic, civil or military, including those that carry out teaching and research actions) to the SNVS, found in the Notivisa 2.0 System, from January 2016 to December 2017. The study presents the data of healthcare-associated incidents analyzed by the researcher in an aggregated manner, maintaining the confidentiality of the reporting healthcare facilities.

A limitation of this research is underreporting. Since we worked with secondary data, the information could only be computed when the institutions filed a report. Any cases that were not reported were omitted from the study.

The collection was done by exporting the data related to the reports made in the period covered by the research. The Notivisa 2.0 system allows the choice of the desired variables, the export to an electronic spreadsheet compatible with Microsoft Excel® and the download of the spreadsheet.

NMSP credentials, which are part of EVSIS with CGVS, were used.

The database used to study the variables (type of incident; consequences for the patient; patient's characteristics; characteristics of the incident/adverse event; contributing factors;

consequence to the organization; detection; mitigating factors; improvement initiatives); and initiatives to reduce the risk) was tabulated with Microsoft Excel®.

In order to assess the quality of the reports, we used the criterion of missing information, which has already been applied in other studies²⁰. We considered the proportion of information ignored in the non-mandatory fields of the form (contributing factors; consequence to the organization; identification of the adverse incident/event; mitigating factors; improvement initiatives; and initiatives to reduce risk). The scores used to assess the quality of the information were: excellent (less than 5% of the fields not filled in), good (between 5% and 10%), average (between 10% and 20%), bad (between 20% and 50%) and very bad (50% or more).

With regard to ethical aspects, this study was approved by the Research Ethics Committee of the School of Public Health of Rio Grande do Sul, Opinion report n. 2.570.491, in accordance with the Resolution of the National Health Council n. 466, of December 12, 2012. The research project was also evaluated by the Research Ethics Committee of the Municipal Department of Health of Porto Alegre, as a co-participant institution, and approved under Opinion report n. 2.616.212.

RESULTS AND DISCUSSION

Incident characteristics

Between January 2016 and December 2017, health institutions in Porto Alegre reported 1,059 healthcare-associated incidents.

A study done in Brazil between March 2014 and March 2017 found that only 36.87% of the NSPs registered in the country made at least one report, totaling an average of 123.67 incidents reported by NSPs²¹. During the investigation period of the present study, 20 NSPs were registered in Porto Alegre, of which 12 (60.00%) reported at least one incident, resulting in an average of 88.25 incidents reported by each reporting NSP.

The most frequently reported events were falls, which accounted for 50.00% of the reports. Falling is an event that causes the individual to involuntarily end up on the floor or at a lower level and is capable of causing trauma and fractures, which have great potential to influence daily activities and quality of life, especially for elderly patients. Furthermore, falls are associated with increased mortality, greater medical expenses, longer hospitalization period and lawsuits^{22,23}.

A retrospective study done in hospitals of Porto Alegre between 2003 and 2013 found that there were 26 deaths from falling out of bed, with a majority of female patients (65.39%) over 70 years old²⁴.

During the surveyed period, falls occurred mostly in the area of the patient's room (33.80%), from the bed (28.70%) and in the bathroom (21.70%). Less frequently, falls were also reported from chairs (6.40%), stairs or steps (2.30%), while using therapeutic



or diagnostic equipment (2.30%) and while being transported by another individual (1.90%). Still, among the total of reports, 36.10% of the falls were from their own height, 32.90% were caused by slips, 17.30% by loss of balance, 7.40% by tripping and 5.50% by fainting.

The second most frequent type of incident was failure during the provision of care (24.30%), with highlights to procedures, treatments and interventions performed in an incomplete or inadequate manner (23.70%), which were wrong or untimely (16.30%) or outside the indicated schedule (14.40%).

Because of their general nature, failure during the provision of care hampers interventions and the implementation of strategies of improvement²⁵.

A study done in the operating theater of a hospital, through the analysis of 1,717 reports previously registered in a patient safety reporting system, found that the most frequent determining factors in the reports made by physicians, nurses and assistants were related to equipment, supplies and devices (27.20%), procedures, treatments and tests (24.90%) and medication errors (12.40%). It also noted that among physicians there was a greater proportion of reports related to professional conduct²⁶.

In the present study, reports of pressure injuries (PIs) also stood out, with 12.20% of the total of reports. PIs are injuries on the skin and/or on the underlying tissue or structure, usually on a bony prominence, resulting from isolated pressure or pressure combined with friction and/or shear²⁷. Among these, the most frequent were stage II (74.40%). Stage III and IV injuries are classified as never events and were the second most frequent type of pressure injury (24.00%), followed by stage I injuries (1.60%).

A study with patients under palliative care has shown that, of 475 reported events, 266 were related to pressure injuries²⁸, which confirms the greater vulnerability of these patients, especially when submitted to unsafe care and practices²⁹.

Although less frequently, the study in question also found reports of patient accidents, failures in patient identification, during surgical procedures, in administrative activities, in clinical or pathology laboratories, in documentation, in the administration of diets, in the administration of O₂ or medicinal gases, and in the care or protection of the patient. These occurrences accounted for 8.40% of the reports and are detailed in Table 1.

Nevertheless, 54 reports were classified under the “Other” category, where most events were related to leakage, allergic reactions to contrasts, medications and complications during diagnostic tests (Figure 1).

According to data released by the National Health Surveillance Agency (Anvisa) through the Patient Safety and Quality in Health Services Bulletin n. 15: Healthcare-associated incidents. In 2016, 28.00% of the incidents reported in Brazil were classified in the “Other” category, 26.00% as failures during healthcare, 18.90%

as pressure ulcers, 10.90% as falls and 8.20% as failure in patient identification³⁰. These data are very different from those from Porto Alegre, where falls and pressure ulcers accounted for approximately 62.00% of the total of reports, while the “Other” category corresponded to 5.10% of the incidents.

As for the severity of the incidents, 47.20% were classified as mild, 26.80% no harm, 17.70% moderate, 7.10% severe and 1.20% resulted in death of the patient. In the analyzed period, in Porto Alegre, the proportion of deaths was higher than the national average observed between June 2014 and June 2016 (0.60%)²⁴ and the majority of deaths occurred due to failure during the assistance, especially during treatments, procedures and interventions (46.10%) and failure during surgical procedures (23.10%).

Three deaths were because of incidents classified as “Other”; one due to the inadvertent catheterization of the subclavian artery, another resulted from cardiorespiratory arrest in an out-patient, and the last occurred in a patient classified as low risk.

Types of procedures

The survey found that incidents were more frequent while treatment (80.50%) and diagnosis (13.10%) procedures were performed and less frequent in procedures such as childbirth or puerperium (1.60%), rehabilitation (0.60%), prevention (0.30%) and other (3.90%).

Characteristics of the patients

Regarding gender, of the patients who suffered an incident, 51.60% were male and 48.40% female.

As for the age group, the most affected were individuals between 26 and 85 years of age (84.30%), with the most frequent groups being 66 to 75 years of age (16.40%), 56 to 65 years of age (16.00%) and 26 to 35 years of age (13.50%). In 15.70% of the incidents, children, adolescents and young patients up to 25 years old were affected.

The most frequent race/color was white (20.40%), followed by black (1.30%), yellow and brown (0.60% each). The race/color attribute was not informed in 77.10% of the reports.

Regarding the diagnosis, 21.40% of the patients were affected by diseases of the respiratory system, 11.80% by neoplasms, 8.90% by infectious and/or parasitic diseases, 7.60% by diseases of the cardiovascular system, 7.00% by mental and behavioral disorders and 6.00% by diseases of the nervous system. We also observed that 11.00% of the patients were affected by symptoms, signs and abnormal findings from clinical and laboratory exams, not classified elsewhere. Less frequently, diseases of the genitourinary system, endocrine, nutritional and metabolic diseases, diseases of the digestive system, diseases of the musculoskeletal system and connective tissue were observed, among others, totaling 26.30% of the total of reports.



Table 1. Other healthcare-associated incidents reported in the city of Porto Alegre, Brazil, 2016-2017.

Type of incident	N	%
Patient accidents	9	0.85
Piercing/penetrating force (scratch, cut, break)	2	0.19
Blunt force (crushing, abrasion or friction)	2	0.19
Another type of specific injury mechanism	5	0.47
Documentation failure	8	0.76
Document delivered to wrong patient or wrong document	5	0.47
Missing or unavailable document	1	0.09
Delay in accessing the document	1	0.09
Ambiguous/illegible/incomplete information in the document	1	0.09
Failure during surgical procedure	18	1.70
Hemorrhage after surgery	5	0.47
Organ injury during surgery	5	0.47
Unintentional foreign body retention in a patient after surgery (never events)	5	0.47
Surgical procedure performed on the wrong side of the body (never events)	2	0.19
Deep venous thrombosis after surgery	1	0.09
Failure in patient identification	20	1.89
Switching patients' names	20	1.89
Failure in diet administration	6	0.57
Enteral (oral, oral or nasal catheter, ostomies)	5	0.47
Not informed	1	0.09
Failure in the administration of O2 or medicinal gases	1	0.09
Wrong mode of administration	1	0.09
Failure in administrative activities	13	1.23
Marking	6	0.57
Patient transfer	2	0.19
Patient identification	2	0.19
Regulation/referencing	1	0.09
High	1	0.09
Not informed	1	0.09
Failure in patient care/protection	1	0.09
Discharge or release of a patient of any age who is unable to make decisions, to another unauthorized person(never events)	1	0.09
Failure in clinical or pathology laboratories	13	1.23
Wrong result	10	0.94
Wrong collection	2	0.19
Wrong processing	1	0.09
Total	89	8.40

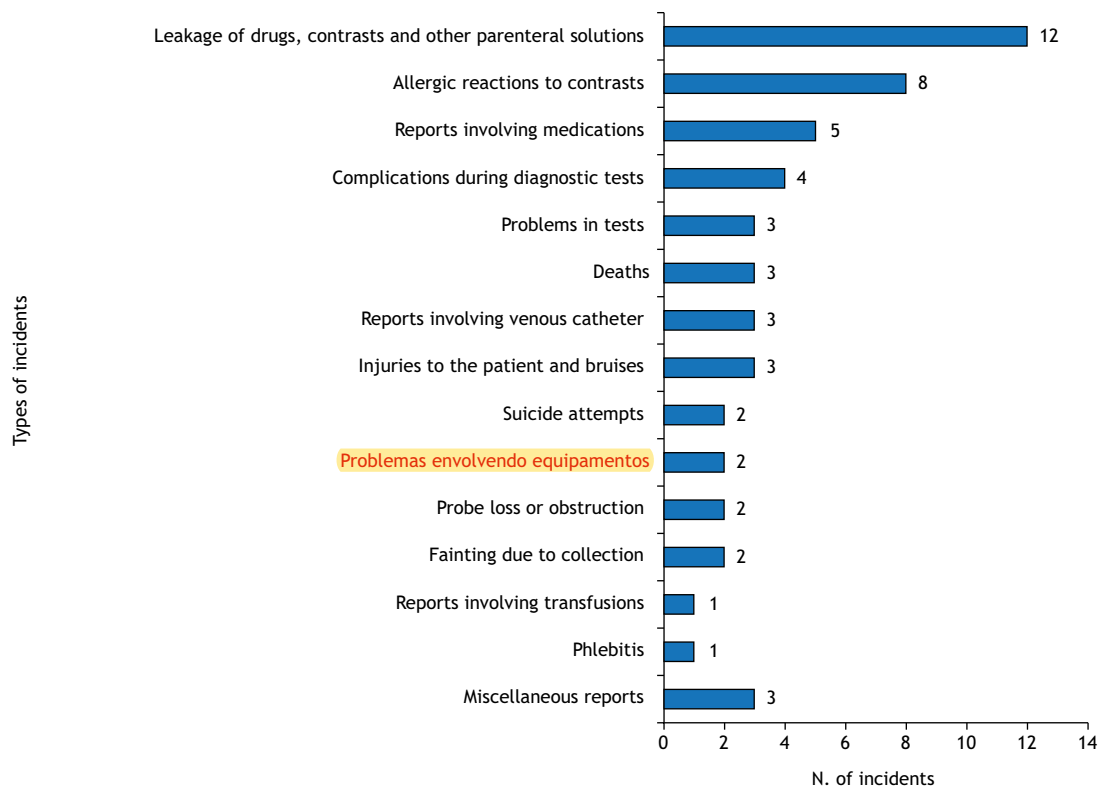
Source: Notivisa, 2018.

Origin of the incident, period and phase of assistance

Hospitals were the institutions that most reported healthcare-associated incidents (86.20%), followed by outpatient services (5.20%), radiology services (3.40%), laboratories of clinical, microbiological and/or pathology analyses (2.40%), clinics (1.10%), urgent and emergency services (0.80%), hemodialysis services (0.10%) and others (0.80%). According to the latest Brazil-wide survey published by Anvisa, hospitals account for 94.00% of incident reports, followed by urgent and emergency services (2.30%) and outpatient services (0.90%)³⁰.

It is noteworthy that during these two years, only two incidents were reported by health centers and basic health units. Although primary care serves less complex patients, a study has shown that 82.00% of the events caused harm to the patient, 25.00% of them with high severity and 7.00% resulting in death³¹.

Among hospital health units, 73.70% of incidents occurred in inpatient units, 17.30% in intensive care units (adult, pediatric or neonatal) and 3.30% in operating theaters. Less frequent events were recorded in urgent and emergency units (1.70%) in



Source: Notivisa, 2018.

Figure 1. Number of healthcare-associated incidents classified as “Other” (n = 54). Porto Alegre, Brazil, 2016-2017.

the radiology and clinical analysis laboratories (0.90% each), outpatient service (0.40%) and day hospital (0.10%).

Most of the incidents occurred during the provision of care, such as diagnosis, evaluation, treatment or surgical intervention (89.10%). In 8.50% of cases, the patient was not hospitalized and the rest of the incidents occurred during the appointment, at the time of admission, at discharge or during transfer to another healthcare service (2.40%).

We also noticed that the majority of incidents occurred during the day, from 7 am to 7 pm (49.50%), and 28.30% occurred in the evening and night, from 7 pm to 7 am. 22.20% of the institutions did not know the period of occurrence.

Never events

The term *never events* was created in the United States in 2001, by an important agency that promotes patient safety and quality of care (National Quality Forum). By definition, a never event consists of a preventable incident, resulting from an error in medical care, which in general has serious consequences for patients, suggesting the existence of a real problem in the safety and credibility of the healthcare facility. These events are common in surgeries (wrong place, wrong person, wrong procedure, foreign body retention in the patient after surgery)^{32,33,34,35}.

During the survey period, 39 never events were reported, most of them with moderate harm (74.30%), followed by severe (20.50%) and no harm (5.20%). Table 2 illustrates the most frequent types and delimits the problem that occurred.

Never events in surgeries are not uncommon, even though they are completely preventable and avoidable³⁵. In Brazil, in 2016, 1.60% of these events were related to failure during surgical procedures³⁰. In Porto Alegre, this proportion was higher both in 2016 (50.00%) and in 2017 (12.50%).

Quality of the reports

Non-mandatory fields are important tools that help elucidate factors that can compromise the quality of services and patient safety, as well as an opportunity to record the measures adopted by the institutions to prevent errors from occurring again.

Considering the non-mandatory fields that were not filled out and the application of the chosen methodology, both in 2016 and 2017 the reports were rated as very bad. Figure 2 illustrates the proportion of non-mandatory fields that were not filled out in the reports of incidents that occurred during the surveyed period.

CONCLUSIONS

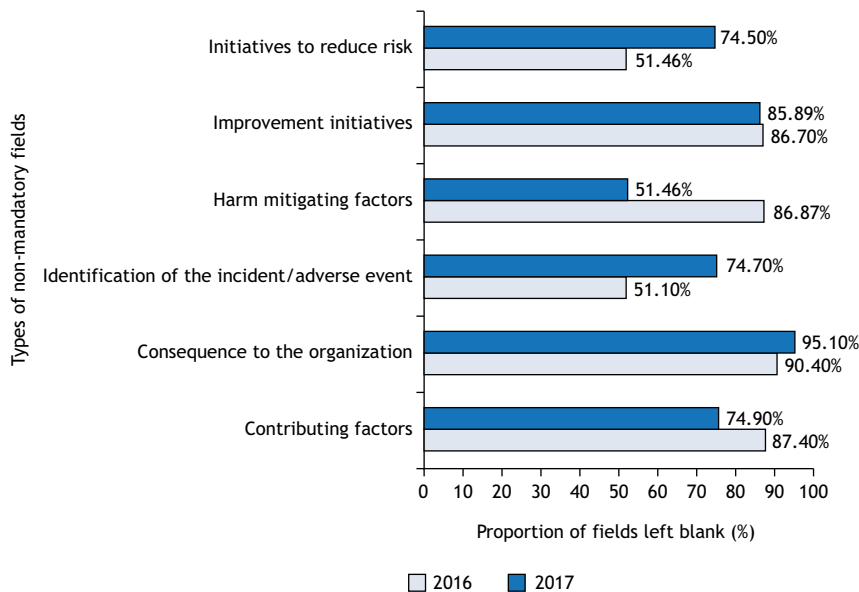
Incident reporting by the NSPs is an important tool that can be used by Health Surveillance services, since it enables the analysis



Table 2. Frequency of never events as to the type and problem that occurred. Porto Alegre, Brazil, 2016-2017.

Type of never event	Problem occurred	2016	2017	Total
Failure during surgical procedure	Unintentional foreign body retention in a patient after surgery	2	3	5
	Surgical procedure performed on the wrong side of the body	1	1	2
Pressure ulcer	Stage III	4	25	29
	Stage IV	-	2	2
Failure in patient care/protection	Discharge or release of a patient of any age who is unable to make decisions, to another unauthorized person	-	1	1

Source: Notivisa, 2018.



Source: Notivisa, 2018.

Figure 2. Proportion of non-mandatory fields left blank on Notivisa in the years 2016 and 2017. Porto Alegre, Brazil.

of the distribution of these occurrences and their contributing factors, in addition to the identification of critical points for action to mitigate the occurrence of AEs and improve the quality of care in a given area.

The study helped to understand the local epidemiology with regard to the occurrence of healthcare-associated incidents. The data obtained confirm the need to enforce public policies aimed at patient safety, as well as to improve the protocols for the prevention of incidents in health services.

The lack of reports from other types of facilities, like basic health units, blood centers, hemodialysis services and mental or psychiatric health services, was evident. We also observed

that, few of the NSPs of Porto Alegre reported incidents during the surveyed period, which suggests that the results of this study only show the tip of the iceberg of events that occurred in this state capital.

The need to expand the safety culture in healthcare institutions is reinforced, with an emphasis on education and communication, through the commitment of managers and professionals, the involvement and empowerment of users and family members and the collaboration between different departments and categories. A punishment-oriented culture should also be avoided, since it is an important factor that increases underreporting.

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Authors' Contributions

Cartana JB - Conception, planning (study design), acquisition, analysis, interpretation of data and writing of the work. Breier A - Conception, planning (study design) and writing of the work. Anelo TFS - Analysis, interpretation and writing of the work. All authors approved the final version of the paper.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.



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