



ISSN: 2230-9926

Available online at <http://www.journalijdr.com>

IJDR

International Journal of Development Research

Vol. 11, Issue, 03, pp.45655-45661, March, 2021

<https://doi.org/10.37118/ijdr.21443.03.2021>



RESEARCH ARTICLE

OPEN ACCESS

CHARACTERIZATION OF PATIENT SAFETY INCIDENTS REPORTED BY PATIENTS OR FAMILIES TO THE BRAZILIAN HEALTH REGULATORY SYSTEM - 2014 - 2019

Heiko Thereza Santana^{1,*}, Magda Machado de Miranda Costa¹, Maria Dolores Santos da Purificação Nogueira¹, Ana Clara Ribeiro Bello dos Santos¹, André Anderson Carvalho¹, Cleide Felicia de Mesquita Ribeiro¹, Humberto Luiz Couto Amaral de Moura¹, Lilian de Souza Barros¹, Luciana Silva da Cruz de Oliveira¹, Mara Rubia Santos Gonçalves¹, Andressa Honorato Miranda de Amorim¹, Silvano Barbosa de Oliveira² and Fernanda Raphael Escobar Gimenes de Sousa³

¹Management of Health Services Surveillance and Monitoring (GVIMS), General Management of Health Services Technology (GGTES), Brazilian Health Regulatory Agency (ANVISA), Brasilia, Brazil

²Ministry of Health (Brazil), Brasilia, Brazil

³Department of General and Specialized Nursing - University of São Paulo at Ribeirão Preto, College of Nursing, São Paulo, Brazil

ARTICLE INFO

Article History:

Received 25th January, 2021

Received in revised form

17th January, 2021

Accepted 20th February, 2021

Published online 30th March, 2021

Key Words:

Adverse Events, Health Services, Incident Reporting, Patient-Centered Care, Patient Engagement, Patient Safety, Sanitary Surveillance.

*Corresponding author:

Heiko Thereza Santana

ABSTRACT

Patient safety incidents, especially adverse events (AEs), are a global public health issue. The objective of the study was to characterize patient safety incidents reported by patients or families to the Brazilian Health Regulatory System (SNVS). This is a descriptive, retrospective study with a quantitative approach, using a database from the Brazilian Health Regulatory Agency (ANVISA), NOTIVISA - Citizen module, 2014 to 2019. A total of 1355 safety incident were reported, a majority from the Southeast region (45.3%), occurred more frequently among women (58.0%) aged between 26 and 35 (16.7%) and 56 and 65 years (16.5%). Healthcare-associated infections (HAIs) (36.3%) were the most frequently notified event, followed by medication/intravenous fluid (IV) incident (36.2%). Injury was mostly classified as mild (32.0%) and moderate (23.7%). From a total of 33 deaths, the majority (51.5%) were due to HAI. There was a significant association between the proportion of deaths and age group (p-value = 0.032). Most notifications were related to HAIs, followed by drugs or IV fluids and most reported incidents resulting in death were due to HAIs, with a significant difference observed in the proportion of deaths in relation to age group. The study demonstrates the need for greater encouragement and participation of patients and family members in reporting incidents, valuing their experiences for continuous learning from errors in health services.

Copyright © 2021, Heiko Thereza Santana et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Citation: Heiko Thereza Santana, Magda Machado de Miranda Costa, Maria Dolores Santos da Purificação Nogueira et al. "Characterization of patient safety incidents reported by patients or families to the Brazilian Health Regulatory System - 2014 - 2019", *International Journal of Development Research*, 11, (03), 45655-45661.

INTRODUCTION

Patient safety incidents, especially adverse events (AEs), are a global public health issue requiring corrective and preventive action to minimize injury to patients (WHO, 2021). About 10% of patients in health services are affected by AEs, resulting in thousands of deaths annually, with 1% suffering serious consequences. Half of these events are subject to preventive measures (Baker et al., 2004; WHO,

capable of avoiding unnecessary suffering and preserving the economy of households, health care, society and the state. In this context, patient safety is an essential component of quality management, and should be considered a fundamental principle of patient-centered care (WHO, 2002). Efforts should also be made to learn from mistakes, based on a safety culture that involves professionals, organizations and patients (IOM, 2001). Since 2004, the World Health Organization (WHO) has been leading the global movement for patient safety and ensuring a voice for users of health

been systematically developed by the Brazilian Health Regulatory Agency (ANVISA) (Santana *et al.*, 2020), having been reinforced in 2013 with the guidelines established by the National Patient Safety Program (PNSP) (Brasil, 2013a). Following recommendations by the WHO and considering that “a patient more engaged in their own health care can help prevent safety incidents”, the Ministry of Health included the parameter “Involvement of citizens in their safety” (Brasil, 2013b) in the PNSP (Brasil, 2013a). However, since 2011, health services have been expected to establish best practices and implement actions to promote patient participation in the care provided (Brasil, 2011). In 2013, it was reinforced that Patient Safety Centers (NSPs) should encourage the participation of patients and family members in all levels of care (Brasil, 2013c).

An additional precaution adopted by the Brazilian Health Regulatory System (SNVS) was to support the participation of patients and family members in the voluntary safety incident reporting process (Notivisa, 2021a). It is known that patients hold a unique position, being able to contribute to the safety improvement of health systems by sharing information about safety issues they have experienced in health services and reporting incidents in local or national information systems (Ward *et al.*, 2011; EC, 2010). Several studies have shown that patients and families can provide experiences and expertise that are useful, and possibly rich learning opportunities from errors and improvements in health care (Longtin *et al.*, 2010; Khan *et al.*, 2018). Nevertheless, there are few studies documenting the analysis of safety incidents reported by patients and family members in different countries. In Brazil, despite the topic’s relevance, there are also knowledge gaps in this field and studies remain scarce, requiring research that discloses the results of incident reports made by citizens. As a result, there was an interest in investigating how the main safety incidents reported by Brazilian citizens are characterized. The objective of the study was to characterize patient safety incidents reported by patients and family members to the SNVS in the period between March 2014 and December 2019. Secondary objectives include: assessing associations between safety incidents and explanatory variables (sex, age group, race, geographic region, number of cases per year, phase of care, place and period of occurrence of the event) and evaluating associations between deaths and other explanatory variables (sex, age group, race, geographic region, period of occurrence and detection of the event).

METHODS

Study design and duration: This is a descriptive, retrospective study following a quantitative approach. The data used in the study are secondary, obtained from a national database (NOTIVISA, Citizen Module) and include safety incidents reported by patients or relatives to the SNVS between March 2014 and December 2019.

Population and data collection: Safety incident reports to the SNVS were made by hospitalized or not hospitalized patients (or family members) who received care / treatment by health services in the country, since the national implementation of NOTIVISA (Citizen Module). These incident records were included in the study.

Data analysis: The following variables of interest were analyzed to characterize the incidents reported: year of report, geographic region, sex, age group, race / color, phase of care, place and period of occurrence of the event, detection, and injury severity (Notivisa, 2021a). Taking into consideration the most frequently reported incidents, grouping was done into four main categories: 1) Health care-related infections – HAIs; 2) Incidents related to medications or intravenous fluids (IV); 3) Incidents related to clinical process or procedure (procedure / treatment / intervention; diagnosis / evaluation; complementary diagnostic); medical errors / failure to protect (evasion, accident, fall and pressure ulcers) and other incidents that occurred during surgical procedure; and 4) Incidents related to clinical administration (admission; discharge; transfer; scheduling of appointments; resources and organizational management; documentation; patient identification; and infrastructure

/ facilities). Incidents reported as “other” have been reclassified, when possible, considering the specific incident options available on the notification form. Exclusion criteria adopted were: lack of information / incomplete form, adverse reaction to drugs and vaccines, technical complaints, therapeutic ineffectiveness and when not applicable (did not characterize an incident). Descriptive statistics were used, and aggregate data analysis was conducted. It was therefore not possible to identify the source of information, maintaining confidentiality of the reporting citizen’s data in accordance with ANVISA requirements. For association analysis between the type of incident and variables of interest (sex, age group, race, geographic region, number of cases per year, phase of care, place and period of occurrence of the event) and the event of death and variables of interest (sex, age group, race, geographic region, place and period of occurrence of the event, and detection), p-value was calculated using the chi-square test. The confidence interval (CI) was 95% and a 5% significance level ($\alpha = 0.05$) was considered in all analyses. Treatment and analysis of data were performed using Stata version 16 statistical software.

RESULTS

A total of 1355 safety incident reports by patients and family members were registered during the analysis period. In general, it was found that a majority originated from the Southeast region (45.3%), occurred more frequently among women (58.0%) aged between 26 and 35 (16.7%) and 56 and 65 years (16.5%), and belonging to the white race, as shown in Table 1. Most incidents occurred during provision of care (35.5%) and when the patient was not hospitalized (31.2%). The type of health service where most incidents took place was the hospital (38.2%). Incident rate was higher during daytime (61.0%). With respect to adverse event detection, patients and family members reported that they were informed by health professionals (64.4%). The types of incidents reported were HAIs (36.3%), followed by incidents related to IV fluids or medications (36.2%), clinical process / procedure (16.1%) and clinical administration (11.4%). In general, injury was mostly classified as mild (32.0%) and moderate (23.7%). Grouped frequency distribution of incidents was statistically different in relation to all variables studied (p-value <0.001) (Table 1). Evaluation of reports over the years shows a tendency for the number of reported events to increase, except for 2017, which displayed a decrease in incidents. In 2018 and 2019, 420 event notifications were made each year. In 2018, most incident reports were associated with medications or IV fluids, totaling 200 cases and comprising approximately 50.0% of all notifications. In 2019, there was a decrease in the reporting of these incidents, but an increase in HAIs notifications (55.5%) (Table 1).

A higher percentage of incident reports related to medications or IV fluids was observed in all geographic locations excluding the Southeast region, where more HAIs cases were reported (48.5%). With respect to the most frequently reported incident categories and sex, men were more affected by HAIs (40.1%), while events involving medications or IV fluids were mostly described in women (40.5%). As for the degree of harm, higher percentages of mild (35.3%), moderate (47.5%), and severe (42.5%) injury were seen in notifications related to medications or IV fluids (Table 1). Among the reported events that resulted in deaths, 17 (51.5%) were due to HAIs, 11 (33.3%) resulted from clinical process / procedure and 5 (15.2%) were associated with medications or IV fluids, totaling 33 deaths (Table 1). Taking proportion into consideration, the results also show that the majority of death reports came from the Midwest region (4.8%), followed by the Northeast (2.6%), and occurred mostly among men (3.2%) aged 65 and older (4.3%) belonging to the Asian race (16.0%). Although daytime was the period with the greatest number of incident notifications, deaths were more frequently reported at night (3.8%). In regard to detection and disclosure of the event to patients and family members, a majority of patients answered “I am not sure” (5.3%). There were no statistically significant differences in the proportion of deaths in relation to year, sex, period, and detection.

Table 1. Distribution of incidents according to patient and incident characteristics

Brazil, 2014 to 2019

Variables	Total	Clinical Administration		Medication/IV fluids		Process/clinical procedure		HAIs		p-value*
	n	n	%	n	%	n	%	n	%	
Total	1355	154	11.4	491	36.2	218	16.1	492	36.3	-
<i>Year</i>										
2014	84	3	3.6	55	65.5	11	13.1	15	17.9	<0.001
2015	110	12	10.9	40	36.4	24	21.8	34	30.9	
2016	218	30	13.8	92	42.2	38	17.4	58	26.6	
2017	103	16	15.5	40	38.8	14	13.6	33	32.0	
2018	420	41	9.8	200	47.6	60	14.3	119	28.3	
2019	420	52	12.4	64	15.2	71	16.9	233	55.5	
<i>Geographic region</i>										
North	63	9	14.3	31	49.2	9	14.3	14	22.2	<0.001
Northeast	269	38	14.1	110	40.9	47	17.5	74	27.5	
Southeast	614	57	9.3	190	30.9	69	11.2	298	48.5	
South	220	33	15.0	95	43.2	35	15.9	57	25.9	
Midwest	189	17	9.0	65	34.4	58	30.7	49	25.9	
<i>Sex</i>										
Male	569	57	10.0	173	30.4	111	19.5	228	40.1	<0.001
Female	786	97	12.3	318	40.5	107	13.6	264	33.6	
<i>Age group</i>										
younger than 29 days	58	13	22.4	12	20.7	11	19.0	22	37.9	<0.001
29 daysto 1 year	34	4	11.8	11	32.4	9	26.5	10	29.4	
2 to 4 years	21	3	14.3	12	57.1	2	9.5	4	19.0	
5 to 11 years	35	9	25.7	9	25.7	4	11.4	13	37.1	
12 to 17 years	22	2	9.1	13	59.1	2	9.1	5	22.7	
18 to 25 years	146	14	9.6	91	62.3	8	5.5	33	22.6	
26 to 35 years	226	24	10.6	101	44.7	14	6.2	87	38.5	
36 to 45 years	189	27	14.3	67	35.4	27	14.3	68	36.0	
46 to 55 years	147	14	9.5	46	31.3	21	14.3	66	44.9	
56 to 65 years	224	22	9.8	70	31.3	32	14.3	100	44.6	
66 to 75 years	123	9	7.3	33	26.8	37	30.1	44	35.8	
76 to 85 years	101	9	8.9	24	23.8	38	37.6	30	29.7	
Over 85 years	29	4	13.8	2	6.9	13	44.8	10	34.5	
<i>Race</i>										
White	713	82	11.5	299	41.9	98	13.7	234	32.8	<0.001
Black	101	9	8.9	19	18.8	18	17.8	55	54.5	
Brown	360	34	9.4	120	33.3	64	17.8	142	39.4	
Asian	25	3	12.0	7	28.0	8	32.0	7	28.0	
Indigenous	4	1	25.0	1	25.0	1	25.0	1	25.0	
Not informed	152	25	16.4	45	29.6	29	19.1	53	34.9	
<i>Phase of Care</i>										

Continue ...

During the diagnostic phase/assessment	270	26	9.6	57	21.1	43	15.9	144	53.3	<0.001
Assistance/treatment	481	39	8.1	108	22.5	132	27.4	202	42.0	
During or after blood donation	5	0	0.0	0	0.0	5	100.0	0	0.0	
Admission	120	50	41.7	23	19.2	18	15.0	29	24.2	
Discharge	18	1	5.6	4	22.2	9	50.0	4	22.2	
Transfer of care	10	6	60.0	0	0.0	0	0.0	4	40.0	
Patient was not hospitalized	423	28	6.6	287	67.8	10	2.4	98	23.2	
Post-discharge	28	4	14.3	12	42.9	1	3.6	11	39.3	
Care Setting										
Ambulatory	202	15	7.4	25	12.4	10	5.0	152	75.2	
Blood bank/Hemotherapy Service	2	0	0.0	0	0.0	2	100.0	0	0.0	
Health Center	65	12	18.5	23	35.4	4	6.2	26	40.0	
Pharmacy/Drug Store	65	3	4.6	43	66.2	1	1.5	18	27.7	
Outside health care/other	364	34	9.3	255	70.1	9	2.5	66	18.1	
Hospital	517	54	10.4	91	17.6	180	34.8	192	37.1	
Clinical Laboratory	18	11	61.1	2	11.1	1	5.6	4	22.2	
Nuclear Medicine	38	6	15.8	28	73.7	2	5.3	2	5.3	
Radiology Service	18	3	16.7	4	22.2	4	22.2	7	3.9	
Urgent and Emergency Service	47	13	27.7	17	36.2	3	6.4	14	29.8	
Hemodialysis Services	15	1	6.7	1	6.7	2	13.3	11	73.3	
Mental Health Services or Institutions	4	2	50.0	2	50.0	0	0.0	0	0.0	
Period										
During the day	827	103	12.5	252	30.5	127	15.4	345	41.7	<0.001
At night	234	26	11.1	92	39.3	52	22.2	64	27.4	
Patient was not able to inform	294	25	8.5	147	50.0	39	13.3	83	28.2	
Detection										
Yes	873	84	9.6	266	30.5	175	20.0	348	39.9	<0.001
No	369	53	14.4	174	47.2	34	9.2	108	29.3	
... I am not sure	113	17	15.0	51	45.1	9	8.0	36	31.9	
Degree of harm										
None	265	28	10.6	52	19.6	33	12.5	152	57.4	<0.001
Mild	434	51	11.8	153	35.3	82	18.9	148	34.1	
Moderate	322	26	8.1	153	47.5	48	14.9	95	29.5	
Severe	301	49	16.3	128	42.5	44	14.6	80	26.6	
Death	33	0	0.0	5	15.2	11	33.3	17	51.5	

p-value of the chi-square test Source: NOTIVISA/ANVISA - Citizen Module (Mar/2014 to Dec/2019). Abbreviations: IV, intravenous fluids; HAIs: Health care-related infections.

Table 2. Distribution of incidents according to patient and incident characteristics Brazil, 2014 to 2019

Variable	Total	Death		p-value*
	n	n	%	
Total	1355	33	2.4	-
<i>Geographic region</i>				
North	63	0	0.0	0.114
Northeast	269	7	2.6	
Southeast	614	15	2.4	
South	220	2	0.9	
Midwest	189	9	4.8	
<i>Sex</i>				
Male	569	18	3.2	0.139
Female	786	15	1.9	
<i>Age group</i>				
Up to 17 years	112	4	3.6	0.032
From 18 to 65 years	932	16	1.7	
Over 65 years	253	11	4.3	
<i>Race</i>				
White	713	14	2.0	0.028
Black	101	2	2.0	
Brown	360	10	2.8	
Asian	25	4	16.0	
Indigenous	4	0	0.0	
<i>Period</i>				
During the day	827	16	1.9	0.231
At night	234	9	3.8	
Patient was not able to inform	294	8	2.7	
<i>Detection</i>				
Yes	873	17	1.9	0.078
No	369	10	2.7	
I am not sure	113	6	5.3	

*p-value of the chi-square test; Source: NOTIVISA/ANVISA - Citizen Module (Mar/2014 to Dec/2019).

There was a significant association between the proportion of deaths and age group (p-value = 0.032) as well as race / color (p-value = 0.028) variables, as shown in Table 2.

DISCUSSION

The present study characterizes safety incidents notified to the SNVS from 2014 to 2019 –being significant for providing a general distribution analysis of incidents reported by patients and family members. A majority of incidents occurred in the hospital (about 40%), which is consistent with most findings showing a higher occurrence of events in these institutions, due to high care-associated risks and better documentation of safety improvement strategies (WHO, 2002). An analysis of notifications made to the Incident Report Resulting from Medical Error system in Mexico revealed that 84% of reported events occurred in hospitals (Rodríguez-Suárez *et al.*, 2012a). The study's findings showed that incidents occurred primarily among women (58.0%) of working age (26 to 35 – 16.7% and 56 to 65 years – 16.5%). In Mexico, incidents also occurred more in women (2:1 ratio) and notifications increased with patient age. Nevertheless, approximately 64 to 74% of events happened with people aged 18 to 65 years (Rodríguez-Suárez *et al.*, 2012a). As for the fact that most incidents occurred during the day, this may be due to routine practices in health institutions, where procedures performed by health care professionals are mainly conducted during this period, possibly leading to adverse events if patient safety practices are not adopted (Shojania *et al.*, 2001). In regard to types of incidents most frequently reported, HAIs predominated, similar to other studies (EC, 2010; Rodríguez-Suárez *et al.*, 2012b), since they affect hospitalized patients worldwide (Flanagan *et al.*, 2011; WHO, 2011a; WHO, 2009b). A study carried out between 2011 and 2012, involving 781 events reported voluntarily by 22 Mexican hospitals through the Automated Registration System of Health Incidents (SIRAI), based on the International Classification for Patient Safety (WHO & WHO Patient Safety, 2010), showed that HAIs were the most frequently disclosed incident (35.9%), followed by those related to clinical process / procedure (28.8%), and medication / IV fluids (12.5%) (Rodríguez-Suárez *et al.*, 2012b).

Another study showed that HAIs were reported by 8.2% of hospitalized patients (Agoritsas *et al.*, 2005). Evidently, HAIs are a challenge for health services around the world. It is estimated that more than 4 million patients in Europe and 1.7 million in the United States annually develop some type of HAIs, with higher prevalence in low- and middle-income countries. However, approximately 20 to 30% of HAIs can be avoided with the implementation of control and prevention measures in health care facilities, including adherence to standard precaution by health care workers, such as hand hygiene, epidemiological surveillance of HAIs (Central Line-associated Bloodstream Infection - CLABSI, Catheter-associated Urinary Tract Infections - CAUTI, Surgical Site Infection - SSI and Ventilator-associated Pneumonia – VAP), implementation of antibiotic stewardship programs, cleaning, disinfection, and sterilization of medical equipment, and cleaning environmental (Brasil, 1998; WHO, 2009b; WHO, 2016a; ANVISA, 2017).

The second most recurrent type of incident involved medications or IV fluids, a finding that supports several studies (Weingart *et al.*, 2005; Hasegawa *et al.*, 2011; Harrison *et al.*, 2015; O'Hara *et al.*, 2018). Patients seem to report more medication-related safety incidents than any other category (Ward, Armitage, 2012). For instance, a study found that 71% of events reported by patients were medication errors (Weingart *et al.*, 2005). Two other studies showed that patients reported medication-associated problems in 33 and 39% of cases, respectively (Hasegawa *et al.*, 2011; Friedman *et al.*, 2008). In addition, one in ten patients admitted to English hospitals disclosed at least one incident involving medication (O'Hara *et al.*, 2018). Such events can be avoided throughout the medication-use system (prescription, dispensing/distribution, preparation/administration and monitoring) (WHO, 2016b), with multidisciplinary work by medical, nursing, and pharmaceutical teams (Keers *et al.*, 2014; Goedecke *et al.*, 2016; Janmano *et al.*, 2018; Cohen, Smetzer, 2018). Incidents reported by patients using medications are known to support the identification of new events not previously notified by health professionals to regulatory agencies (Harmark *et al.*, 2015; Aslani *et al.*, 2018). However, health care teams have not routinely asked patients to report incidents that may have occurred during care (Harrison *et al.*, 2015).

The number of incidents reported by citizens has increased over the study period, the Southeast region being responsible for most notifications – possibly for having the greatest concentration of health services in the country. Nevertheless, despite a reporting system made available by ANVISA, the number of notifications remains low. A study conducted in 2009, involving 27 EU member countries, showed that 7,031 interviewed citizens claimed to have been affected by AEs when hospitalized, although 70% did not report these events (EC, 2010). In regard to incident detection, patients and family members reported that they were informed by health professionals in most cases (64.4%). By contrast, approximately 70 to 90% of AEs that occurred in Mexico were not communicated to patients or their families (Rodríguez-Suárez *et al.*, 2012a). Traditionally, health professionals have avoided discussing safety incidents with patients and family members, partly due to fear of legal proceedings for negligence and embarrassment or discomfort communicating the event (AHRQ, PSNet, 2021). Hence, the importance of transparent and timely communication surrounding incidents in improving patient and family confidence in health care. From this perspective, the Canadian Patient Safety Institute has developed guidelines that symbolize a commitment to patients' right to be informed if they are involved in a patient safety incident. Such guidelines promote a clear and consistent approach to communication of the event, emphasizing the importance of teamwork and continuous learning (CPSI, 2011). As for the 33 notifications of death due to AEs, significant differences were found in the proportion of deaths in relation to age group (p -value = 0.032). It is well documented that the incidence of AEs increases with age, with patients aged 65 years and over having twice the risk of suffering some type of AE compared to those aged 16 to 44 years, with no difference between the sexes. The degree of injury caused by AEs depends on several factors and may even affect patient mortality, requiring preventive action by health services, given that 40% of AEs can be avoided (Villanueva-Egan *et al.*, 2012). A secondary study, using ANVISA's database with respect to NOTIVISA registered reports (Health Care module), showed that 417 AE-related deaths were recorded by health professionals from 2014 to 2016, mostly in young and older adults (85%), with no differences between sexes.

Incident notification is a strategy to mobilize patients for their own protection and encourages them to share safety problems. However, patients may assume their reporting will not result in any satisfactory response, thus potentially omitting disclosure (Rodríguez-Suárez *et al.*, 2012a). In the SNVS system, notifications are not analyzed individually, avoiding the punishment of those involved. Nevertheless, according to ANVISA, the information gathered is used to institute general preventive measures and reduce future harm to patients using the country's health services (Brasil, 2017). Patients are an important source of learning, but still neglected in determining and assessing the quality and safety of health care (O'Hara *et al.*, 2018). In its Global Patient Safety Action Plan, the WHO reinforced the importance of citizen involvement and empowerment for the strengthening of health systems and the provision of safer care free of preventable injury (WHO, 2020). However, several barriers hinder patient empowerment and engagement in safety initiatives, such as inadequate infrastructure for quality management, excessive organizational hierarchy in health institutions, communication difficulties and the discredited information reported by patients. Therefore, patient involvement should be encouraged at all levels of health care (Saturno, 2009). To enable the effective and timely participation of citizens in the notification process, it is necessary for them to understand the definition of incidents, feel motivated to report, and most importantly, be aware of available reporting systems (Aslani *et al.*, 2018). However, systems must have forms that contain terminology that is understandable to patients, yet also reflect prevailing patient safety language (WHO & WHO Patient Safety, 2010; Larizgoitia *et al.*, 2013), in order to improve event reporting and optimize its use in health care. Sharing results from the analysis of incident notifications with patient associations can help disseminate and increase reporting by raising citizen awareness about its importance. Although not every report leads to a sanitary measure, whether regulatory or not, a set of notifications arising from this civic

responsibility, added to information reported by health services, may be able to generate consistent data and incite recommendations focused on reducing unnecessary harm (Notivisa, 2021a; Brasil, 2017). In addition, more investment in patient safety training of health professionals and the general public, as well as research development, can support patient safety improvement (WHO, 2011b) and citizens' compliance with incident reporting. This study had several limitations. First, information bias is highlighted given that data were obtained from a national database with incidents being reported voluntarily by patients or family members. Another limitation includes incomplete records and the notification form itself, which has pre-defined options and categories for safety incidents, potentially hindering responses. Furthermore, since underreporting is a possibility, the results obtained may not reflect the real picture of notifications in the system. A further limitation is the inability to use the results presented to make epidemiological estimates or for national monitoring of safety issues, since they depend on the level of awareness and topic knowledge of those who made the notification.

Conclusion

The present study showed the currently known distribution of incidents reported by citizens to the SNVS. Most notifications were related to HAIs, followed by medications or IV fluids. The majority of reported incidents resulting in death were due to HAIs, with a significant difference observed in the proportion of deaths in relation to age group. The study allows for learning from mistakes and can help managers, professionals, and researchers propose improvements in care systems, based on knowledge of the most frequent safety incidents reported by patients and family members. New challenges emerge from health initiatives already developed by the SNVS to promote patient participation in health care, including the opportunity for a reporting system. Nevertheless, it is necessary to expand strategies that encourage the notification of events by citizens as a complementary tool, supporting the promotion of a safety culture that values continuous learning from errors as a result of greater patient and family participation in health care.

REFERENCES

- Agency for Healthcare Research and Quality, Patient Safety Network. Disclosure of errors. 2021. Available online at <https://psnet.ahrq.gov/primer/disclosure-errors>
- Agoritsas, T., Bovier, P.A., Perneger, TV. 2005. Patient reports of undesirable events during hospitalization. *J Gen Intern Med.*, v.20, n.10, pp. 922-8.
- Agência Nacional de Vigilância Sanitária. 2017. Diretriz Nacional para Elaboração de Programa de Gerenciamento do Uso de Antimicrobianos em Serviços de Saúde. Disponível em: <https://www.gov.br/anvisa-pt-br/centraisdeconteudo/publicacoes/servicosdesaude/publicacoes>
- Aslani, P. *et al.* 2018. Consumer opinions on adverse events associated with medicines and vaccines. *Patient Preference Adherence*, v.12, pp. 1383-92.
- Baker, G.R. *et al.* 2004. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ.*, v. 170, n. 11, pp.1678-86.
- Brasil. Ministério da Saúde. 2013b. Documento de referência para o Programa Nacional de Segurança do Paciente. Ministério da Saúde; Fundação Oswaldo Cruz; Agência Nacional de Vigilância Sanitária. Brasília: Ministério da Saúde, pp 27-28.
- Brasil. Agência Nacional de Vigilância Sanitária. 2017. Como posso contribuir para aumentar a segurança do paciente? Orientações aos pacientes, familiares e acompanhantes. ANVISA, Brasília, Brasil.
- Brasil. Agência Nacional de Vigilância Sanitária. Resolução da Diretoria Colegiada. RDC nº 63 de 25 de novembro de 2011. Dispõe sobre os requisitos de Boas Práticas de funcionamento para os serviços de saúde. *Diário Oficial da União, Brasília, DF*, 28 nov. 2011.

- Brasil. Agência Nacional de Vigilância Sanitária. Resolução da Diretoria Colegiada. RDC nº 36 de 25 de julho de 2013 que institui ações para a segurança do paciente em serviços de saúde e dá outras providências. Diário Oficial da União, Brasília, DF, 26 jul.2013c.
- Brasil. Ministério da Saúde. Portaria nº 2616, de 12 de maio de 1998. Expede, na forma dos anexos I, II, III, IV e V, diretrizes e normas para a prevenção e o controle das infecções hospitalares. Diário Oficial da União, Brasília, DF, 13 mai. 1998.
- Brasil. Ministério da Saúde. Portaria nº 529 de 1º de abril de 2013. Institui o Programa Nacional de Segurança do Paciente PNSP. . Diário Oficial da União, Brasília, DF, 23 abr. 2013a.
- Canadian Patient Safety Institute. 2011. Canadian disclosure guidelines. Being Open with Patients and Families. cited 2021 Feb 24. Available online at <https://www.patientsafetyinstitute.ca/en/toolsResources/disclosure/Documents/CPSI%20Canadian%20Disclosure%20Guidelines.pdf>
- Cohen, M.R., Smetzer, J.L. 2018. ISMP Medication Error Report Analysis. *Hosp Pharm.*, v.53, n.4, pp. 217-9.
- European Commission. 2010. Patient Safety and Quality of Healthcare. Special Eurobarometer 327 European Opinion Research Group: Brussels, Belgium, pp. 5-10.
- Flanagan, M.E. *et al.* 2011. A national collaborative for reducing health care-associated infections: Current initiatives, challenges, and opportunities. *Am J Infect Control.*, v.39, n.8, pp.685-589.
- Friedman, S.M. *et al.* 2008. Errors, near misses and adverse events in the emergency department: what can patients tell us? *CJEM.*, v.10, n.5, pp. 421-7.
- Goedecke, T. *et al.* 2016. Medication Errors: New EU Good Practice Guide on Risk Minimisation and Error Prevention. *Drug Saf.*, v. 39, n.6, pp. 491-500.
- Härmark, L., van Hunsel, F., Grundmark, B. 2015. ADR Reporting by the General Public: Lessons Learnt from the Dutch and Swedish Systems. *Drug Saf.*, v.38, n.4, pp. 337-47.
- Harrison, R. *et al.* 2015. The missing evidence: a systematic review of patients' experiences of adverse events in health care. *Int J Qual Health Care.* v. 27, n.6, pp. 424-42.
- Hasegawa, T. *et al.* 2011. Patients' identification and reporting of unsafe events at six hospitals in Japan. *Jt Comm J Qual Patient Saf.*, v. 37, n. 11, pp. 502-8.
- Institute of Medicine. 2001. Crossing the Quality Chasm. A New Health System for the 21st Century. National Academy Press, Washington, EUA, 2001.
- Janmano, P., Chaichanawirote, U., Kongkaew, C. 2018. Analysis of medication consultation networks and reporting medication errors: a mixed methods study. *BMC Health Serv Res.*, v.18, n.221. Available online at <https://doi.org/10.1186/s12913-018-3049-2>
- Keers, R. *et al.* 2014. Impact of interventions designed to reduce medication administration errors in hospitals: a systematic review. *Drug Saf.*, v.37, n.5, pp.317-32.
- Khan, A. *et al.* 2018. Engaging Families as True Partners During Hospitalization. *J Hosp Med.*, v.13, n. 5, pp. 358-60.
- Larizgoitia, I., Bouesseau, M.C., Kelley, E. 2013. WHO Efforts to Promote Reporting of Adverse Events and Global Learning. *J Public Health Res.*, v.2, n.3, pp.e29.
- Longtin, Y. *et al.* 2010. Patient participation: current knowledge and applicability to patient safety. *Mayo Clin Proc.*, v.85, n. 1, pp.53-62.
- Maia, C.S. *et al.* 2018. Registry of adverse events related to health care that results in deaths in Brazil, 2014-2016. *Epidemiol Serv Saude.* v.27, n.2, pp. e2017320.
- O'Hara, J.K. *et al.* 2018. What can patients tell us about the quality and safety of hospital care? Findings from a UK multicentre survey study. *BMJ Quality & Safety.* v.27, pp.673-682.
- Rodríguez-Suárez, J. *et al.* 2012b. Patient safety incidents notified by 22 Mexican hospitals by way of the Sirais system. *Rev CONAMED.* v.17, n.2, pp.52-58.
- Rodríguez-Suárez, J. *et al.* 2012a. Sistemas de notificación y registro de incidentes en México: Aprendizajes. *Rev CONAMED.* v.17, n.2, pp.81-86.
- Santana, H.T. *et al.* 2020. The Protagonism of the Brazilian Health Regulatory System in the Evolution of Patient Safety in the Country: History, Dilemmas, and Current Challenges. *J Patient Saf.*, v. 16, n. 4. pp. e260-e266.
- Saturno, P.J. 2009. Estrategias para la participación del paciente en la mejora continua de la seguridad clínica. *Rev Calid Asist.*, v.24, n.3, pp.124-130.
- Shojania, K.G. *et al.* 2001. Making health care safer: a critical analysis of patient safety practices. *Evid Rep Technol Assess Summ.* 43:i-x, pp.1-668.
- Sistema de Notificações em Vigilância Sanitária. NOTIVISA. Módulo Cidadão. acesso em 23 mar 2021a. Disponível em: <http://www16.anvisa.gov.br/notivisa/Servicos/cidadao/notificacao/evento-adverso/formulario>.
- Sistema Nacional de Notificações em Vigilância Sanitária - NOTIVISA. acesso em 22 mar 2021b. Disponível em: <http://antigo.anvisa.gov.br/notivisa>.
- Villanueva-Egan, L.A., Rodríguez-Suárez, J., Lucero-Morales, J.J. 2012. Analysis of adverse events in hospital facilities in adults by age and gender. *Rev CONAMED.* v. 17, n. 3, pp.109-13.
- Ward, J.K. *et al.* 2011. Patient involvement in patient safety: Protocol for developing an intervention using patient reports of organisational safety and patient incident reporting. *BMC Health Serv Res.*, v. 11, pp.130.
- Ward, J.K., Armitage, G. 2012. Can patients report patient safety incidents in a hospital setting? A systematic review. *BMJ Qual Saf.*, v.21, n. 8, pp. 685-99.
- Weingart, S.N. *et al.* 2005. What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J Gen Intern Med.*, v.20, n. 9, pp. 830-6.
- World Health Organization. 2002. Quality of care: patient safety report by the Secretariat. cited 2021 Mar 20. Available online at <https://apps.who.int/iris/handle/10665/78467>
- World Health Organization. 2004. World Alliance for Patient Safety forward programme 2005. WHO press, Geneva, Switzerland.
- World Health Organization. 2009a. Global priorities for patient safety research. WHO press, Switzerland.
- World Health Organization. 2011b. WHO Multi-professional Patient Safety Curriculum Guide. WHO, Malta.
- World Health Organization. 2016a. Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level. WHO press, Geneva, Switzerland.
- World Health Organization. 2016b. Medication Errors: Technical Series on Safer Primary Care. WHO press, Geneva, Switzerland.
- World Health Organization. 2020. Global patient safety action plan 2021–2030: towards zero patient harm in health care. WHO press, Geneva, Switzerland.
- World Health Organization. 10 Facts on Patient Safety. cited 2021 Mar 23. Available online at <https://www.who.int/news-room/facts-in-pictures/detail/patient-safety>
- World Health Conceptual .2010 .WHO Patient Safety & Organization framework for the international classification for patient safety version 1.1: final technical report January 2009. World Health Organization. Available online at <https://apps.who.int/iris/handle/10665/70882>
- World Health Organization. 2011a. Report on the burden of healthcare-associated infection worldwide: a systematic review of the literature. WHO press, Geneva, Switzerland.
- World Health Organization. 2009b. WHO guidelines on hand hygiene in health care. First global patient safety challenge. Clean care is safer care. WHO press, Geneva, Switzerland.