

# Patient safety incidents and adverse events reported by Brazilian citizens: a descriptive study, 2014-2018

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## Abstract

**Objective:** To describe incidents related to healthcare services reported by Brazilian citizens on the Health Surveillance Notification System. **Methods:** This was a descriptive study, using the database from the Health Surveillance Notification System (Notivisa) of the Brazilian Health Regulatory Agency (Anvisa), 'citizen' module, between 2014 and 2018. **Results:** 935 incidents were reported, most of them occurred among females (60.9%), the elderly (20.1%) and those of white race/skin color (51.0%). The majority of the reported incidents were related to the use of medications (50.8%), falls (7.5%) and healthcare-associated infections (HAIs) (7.2%), which occurred during provision of healthcare, treatment or surgery (37.3%), in daytime (58.3%) and in hospital setting (37.4%). **Conclusion:** It could be seen a low adherence to the notification system among the citizens. There was a higher frequency of incidents related to medications, falls and HAIs. This shows that citizens have the capability to recognize and report these incidents as patient safety issues.

**Keywords:** Patient Safety; Information Systems; Patient Participation; Quality of Health Care; Descriptive Epidemiology.

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## Introduction

The importance of patient participation and engagement in all levels of care to ensure his or her safety and quality of healthcare provision, has been increasingly recognized, especially in the international scenario.<sup>1</sup> Patient-centered care and perception play an important role, often a distinct or complementary perspective to that of the health professional.<sup>2</sup> Notifications of incidents related to healthcare, made by patients, family members and caregivers, provide useful information necessary for improving patient's safety and quality of the care. These notifications may include incidents that are not recognized or reported by health professionals on notification systems.<sup>3</sup> The analysis of these incidents also showed that their occurrence may be due to the accumulation of failures over a long time period related to the care delivered, from the hospital to the home environment and the community where the patient lives.<sup>2</sup> In a study conducted in England in 2018, patients identified incidents related to communication (21.7%), care provided by health professionals (13.2%), problems with the care environment (12.2%) and medications (9.9%).<sup>4</sup> According to another study, conducted with 80 patients in a surgical clinic in Brazil, 17.5% of them identified some types of incidents during their hospitalization, the most frequently occurring during the medication process (78.5%).<sup>5</sup>

*Notifications of incidents related to healthcare, made by patients, family members and caregivers provide useful information necessary for improving patient's safety and quality of the care. They may include incidents that are not recognized by health professionals.*

The World Health Organization created the Patients for Patient Safety program in order to ensure that the patient voice is heard and promote patient's perception at all levels of care, aiming at bringing together patients, families and caregivers to improve health care safety.<sup>6</sup> To join this initiative, several organizations have developed strategies aimed at strengthening patient participation and engagement, and implemented different actions, involving not

only patients but also their families.<sup>7,8</sup> Among these strategies for the promotion of patient participation, incident reporting systems were made available, built and adopted in several countries.<sup>9-12</sup>

In the Brazilian context, the National Patient Safety Program<sup>13</sup> implemented a voluntary incident reporting system due to patient safety concerns. The Brazilian Health Regulatory Agency (Anvisa) developed the Health Surveillance Notification System (Notivisa) in order to receive notifications of incidents, adverse events and technical complaints. Recognizing the importance of health professionals and patients in providing care, Notivisa offers two notification modules for different target audiences: (i) professionals working at the Patient Safety Centers and (ii) citizens – patients, family members, caregivers, friends and 'other'.<sup>14</sup> The so-called 'citizen' module records voluntary notifications of incidents and adverse events reported by patients, family members, caregivers, friends and 'other'. In recent years, studies based on information from Notivisa have been published; however, there were no analyses performed using the 'citizen' module.<sup>15,16</sup>

Given the challenge of ensuring the safety during provision of healthcare, such initiatives to promote the active participation of patients need to be checked; among them the magnitude and characteristics of incidents related to health services based on patients' and family members' perspective, recorded in notification systems. The objective of this study was to describe the incidents related to health services reported by Brazilian citizens on Notivisa.

## Methods

### *Study design*

This was a cross-sectional descriptive study, based on the notifications recorded on Notivisa - 'citizen' module.<sup>12</sup>

### *Participants*

All notifications made on Notivisa - 'citizen' module, between January 2014, the year of its implementation, and December 2018 were analyzed.

### *Variables*

Considering the system variables and the predefined and immutable categories, the variables analyzed were:

- a) Year of notification;
- b) Federative Unit (notifying municipality);
- c) Individual responsible for the notification (friend; caregiver; family; patient; others);

d) Age group (in years:  $\leq 1$ ; 2-4; 5-11; 12-17; 18-25; 26-35; 36-45; 46-55; 56-65;  $\geq 66$ );

e) Gender (male; female);

f) Race/skin color (white; brown; black; Asian; indigenous; had no information);

g) Type of incident (medication use; patient falls; healthcare-associated infections (HAIs); administrative activities; health products; pressure ulcer; use of blood and derivatives; patient identification; surgery; patient protection and care failures; clinical or pathology laboratories; patient accidents; radiological service; blood donation or blood components; transplantation, grafting or fertilization; dietary management; other);

h) Levels of care (during the provision of care, treatment or surgery; patient was not hospitalized; during diagnosis; during the admission or access to health service; in follow-up after discharge; at the time of discharge; during transfer to another institution or service; provision of care or surgery; during or after blood donation);

i) Incident location (hospital setting; outside the health service; outpatient clinic; pharmacy or drugstore; primary health center [PHC]; emergency care center; nuclear medicine; radiological service; hemodialysis service; clinical analysis laboratory and pathological anatomy; hemotherapy service; mental and psychiatric health service or institution);

j) Period of the day (in daytime; during the night or at dawn; had no information); and

k) Degree of damage (none; mild; moderate; severe; death).

#### *Data sources and measurement*

The data analyzed, obtained from Notivisa-'citizen' module, were requested through the Access to Information Law and forwarded to the principal researcher on December 12, 2019, via e-mail. Data were made available according to the structure of the system. In addition to the pre-categorized variables, the system has a field for open-ended questions called 'other', used frequently to report incidents foreseen in closed categories, especially those related to medications, surgeries, health products, HAIs and falls. The variable 'incident type' has one more category named 'other'; this was reclassified by reading the recorded information, based on the International Classification for Patient Safety.<sup>17</sup> First, we sought to reclassify the category 'other' in the previously defined

fields. For the notifications whose reclassification of the type of incident did not fit the defined categories, we decided to group and name them according to activities or characteristics. To illustrate this grouping, examples of the most frequent and serious notifications recorded as 'other', showed in the results, were selected.

#### *Data analysis*

A descriptive analysis of the frequency distribution of variables related to incidents in health services available in the 'citizen' module was performed using the SPSS program version 24.0.

#### *Ethical aspects*

This research was approved by the Research Ethics Committee of Escola Nacional de Saúde Pública Sergio Arouca, Fundação Oswaldo Cruz. Opinion No. 3,492,606, issued on August 7, 2019 – Certificate of Submission for Ethical Appreciation 17593419.7.0000.5240.

## **Results**

In Brazil, citizens reported 935 incidents related to health services between 2014 and 2018. Of the 197 notifications whose type of incident was categorized as 'other', 92 were reclassified (Table 1). The most frequently notified incidents and adverse events were related to medication use (50.8%), patient falls (7.5%) and healthcare-associated infections (7.2%) (Table 1). Of the 105 reclassified notifications, 70 described types of incidents that had not been foreseen on the Notivisa system – 'citizen' module. This description made it possible to allocate the incidents in new groups, such as those related to clinical process or procedure, behavior and structure (Table 2). However, 35 notifications were not reclassified or grouped due to inaccuracy or incompleteness of the answers.

The highest frequency of notifications was found in 2018 (44.9%), followed by 2016 (23.3%), 2015 (11.8%), 2017 (11.0%) and 2014 (9.0%). The majority of notifications came from the Southeast (37.5%), followed by the Northeast (24.2%), South (16.5%), Midwest (15.8%) and North (6.0%). With regard to the Federative Unit, the highest frequencies were observed in the states of São Paulo (15.5%), Minas Gerais (15.4%) and Maranhão (10.9%), and the lowest frequency of notifications was found in Paraíba and Roraima.

**Table 1 – Types of incidents reported on the Brazilian Health Surveillance Notification System (Notivisa), 'citizen' module (n=935), Brazil, 2014-2018**

Types of incidents	n	%
Medications uses	475	50.8
Patient falls	70	7.5
Healthcare-associated infections	67	7.2
Administrative activities	56	6.0
Health product	40	4.3
Pressure ulcer	36	3.9
Use of blood and derivatives	24	2.6
Patient identification	18	1.9
Surgery	17	1.8
Patient protection and care failures	7	0.8
Clinical or pathology laboratories	6	0.6
Patient accidents	5	0.5
Radiological service	4	0.4
Blood donation or blood components	2	0.2
Transplantation, grafting or fertilization	2	0.2
Dietary management	1	0.1
Other	105	11.2
<b>Total</b>	<b>935</b>	<b>100.0</b>

**Table 2 – Incidents reported as 'other' on the Brazilian Health Surveillance Notification System (Notivisa) and reclassification adopted (n=70), Brazil, 2014-2018**

Types of incidents that were reported and reclassified	n	Examples of reported incident
Clinical process/clinical procedure	29	Poorly fixed central venous access, leading to procedure failure. Phlebitis due to venous puncture
Behavior	9	Aggressive patient companion Violence toward staff
Human resource and organizational management	8	Lack of pediatric care. Employees not qualified for the job or workplace deviation
Structure	6	Improperly disposed of medical waste. Female infirmary without bathroom for patient's selfcare, due to the need for a bathroom renovation, by order of the manager. Lack of supply (bed sheet, soap, alcohol; employees).
Neurological disorders	5	Patient presenting with agitation and confusion, trying to leave the healthcare sector. Convulsion
Vaccines	5	Vaccine administration error. Vaccine side effects, fever over 40° C.
Allergy	4	Allergy due to ultrasound gel
Circulatory System diseases	2	Cardiogenic shock
Gastrointestinal disorders	1	Bloody diarrhea
Protocol adherence failure	1	No hand hygiene
<b>Total</b>	<b>70</b>	

**Table 3 – Individual responsible for the notification and characteristics of patients who were victims of incidents (n=935), Brazil, 2014-2018**

Variable	N	%
<b>Individual responsible for the notification</b>		
Other	462	49.4
Affected person	239	25.6
Family member	146	15.6
Friend	48	5.1
Caregiver	40	4.3
<b>Sex</b>		
Female	569	60.9
Male	366	39.1
<b>Age group (years)</b>		
≤1	58	6.2
2-4	17	1.8
5-11	14	1.5
12-17	20	2.1
18-25	116	12.4
26-35	167	17.9
36-45	115	12.3
46-55	94	10.1
56-65	146	15.6
≥66	188	20.1
<b>Race/skin color</b>		
White	477	51.0
Brown	245	26.2
Black	46	4.9
Asian	22	2.4
Indigenous	4	0.4
Had no information	141	15.1
<b>Total</b>	<b>935</b>	<b>100,0</b>

**Table 4 – Characteristics of reported incidents (n=935), Brazil, 2014-2018**

Variables	n	%
<b>Care steps or moment</b>		
During the provision of care, treatment or surgery	349	37.3
The patient was not hospitalized	346	37.0
During diagnosis	107	11.5
During the admission or access to health service	88	9.4
During follow-up after discharge	22	2.4
At the time of discharge	14	1.5
During transfer to another institution or service	5	0.5
During or after blood donation	4	0.4

To be continued

Continuation

**Table 4 – Characteristics of reported incidents (n=935), Brazil, 2014-2018**

Variables	n	%
<b>Incident location</b>		
Hospital setting	350	37.4
Outside the health service	279	29.8
Outpatient clinic	85	9.1
Pharmacy or drugstore	61	6.5
Primary Health Center	49	5.3
Emergency care center	39	4.2
Nuclear medicine	35	3.7
Radiological service	12	1.3
Hemodialysis service	11	1.2
Clinical analysis laboratory and pathological anatomy	10	1.1
Mental and psychiatric health service or institution	4	0.4
<b>Period of the day</b>		
In daytime	545	58.3
During the night or at dawn	166	17.7
Had no information	224	24.0
<b>Incident severity</b>		
Mild	308	32.9
Moderate	247	26.4
Severe	225	24.1
None	133	14.2
Death	22	2.4
<b>Total</b>	<b>935</b>	<b>100.0</b>

Individuals responsible for the notification identified themselves as 'other' (49.4%), followed by the 'affected person' (25.6%). Most incidents occurred among female patients (60.9%),  $\geq 66$  years (20.1%) and of white race/skin color (51.0%); 15.1% of individuals who reported the incidents did not mention the patient's race/skin color (Table 3). With the exception of these cases with no variable information, patients of white race/skin color represented almost twice as many (60.1%) as those of brown race/skin color (30.9%), and black race/skin color that together accounted for 36.6%.

Most incidents and adverse events occurred during the provision of care, treatment or surgery (37.3%), in daytime (58.3%). Hospital setting was the 'location of the incident' with the majority of notifications (37.4%); 32.9% of the incidents were considered mild and 2.4% resulted in deaths (Table 4).

## Discussion

Most of the reported incidents were related to the use of medications, followed by patient falls and healthcare-associated infections. These incidents affected most women, the elderly and citizens of white race/skin color, and occurred more frequently during the provision of care, treatment or surgery, in the hospital and in daytime. Regarding the degree of damage, for one-third of the notifications the damage was considered mild, severe damage was the least frequent, and the proportion of deaths was less than 2.5%. The general adherence to the notification system was considered low, five years after its implementation.

The high proportion of incidents categorized as 'other' and the inaccuracy or lack of information in the open fields made the analysis difficult and therefore limited this study. After the reclassification of the

incidents originally reported in the category 'other', it could be seen that most of these notifications could have been recorded in specific fields predefined in the system.

There was a low general adherence to the notification system, even five years after its implementation. During the study period (2014 to 2018), 57,281,573 hospitalizations were carried out only in the Brazilian National Health System.<sup>18</sup> Given the incidence of adverse events, which ranges from 7.6% to 10.0%, approximately 4 million adverse events that resulted in damage could have occurred.<sup>19,20</sup> Taking into consideration this number of hospitalizations, 935 notifications of incidents over a five-year period seems to be below expectations. This evidence is related to patients' and family members' perception and knowledge of health, they may be unaware of the opportunity to report to notification systems that are not well known locally and also to the fact that individuals do not have an obligation to record these incidents. Among the factors that may affect the involvement of patients and family members in notifications are issues related to the characteristics of the notification system, such as ease of notification, the use of comprehensible terms and well-elaborated questions,<sup>9</sup> and the knowledge of patients who should perceive some kind of benefit of reporting the incidents.<sup>10</sup> Studies that used patient-centered notification systems as a source of information analyzed a number of notifications lower than that performed here, but with circumscribed time cuts.<sup>9-11</sup> Rethinking the system design in partnership with users, in addition to Notivisa dissemination campaigns, may be strategies capable of increasing their participation in the notification of incidents during the provision health care. Similarly, the development of new methodological approaches aiming at capturing patient report, would facilitate the patient and his or her family engagement in the notification of incidents.<sup>2</sup>

In addition to the reduced number of notifications, they were geographically circumscribed. The Southeast region concentrated most of them, comparatively, especially the states of São Paulo and Minas Gerais. This finding is important because the Southeast is the most populous region. It is more economically developed and has a larger number of health facilities, compared to other regions in the country, and consequently has a higher volume of consultations and hospitalizations.<sup>21</sup> On the other hand, it presents the lowest number of incident notifications. The North region presents a geographical, demographic, economic and service scenario diametrically opposed to that of the Southeast.

This difference should be taken into consideration when analyzing the results that were found, given that these may reflect the perspective of the users from the Southeast, although the scope of this study was national.

The most frequently reported incidents on Notivisa- 'citizen' module were related to medication, falls and healthcare-associated infections with low-severity clinical condition, findings similar to those of two other studies conducted in the United States<sup>9,10</sup> and Finland,<sup>11</sup> published between 2017 and 2018, which used notification systems aimed at patients and family members based on medication-related problems,<sup>9,10</sup> falls<sup>11</sup> and infections,<sup>10</sup> and did not reported damage.<sup>9,11</sup>

Citizens reported perceptible incidents related to healthcare, which poses a serious challenge to patient's safety and quality of the care around the world. Medication-related problems were the most frequently reported by patients and family members, inside and outside health organizations.<sup>1,22</sup>

Falls were found to be the second most frequent type of incident. They can lead to prolonged hospital stay, treatment costs, in addition to generating severe sequelae in the patients.<sup>23</sup> Similarly, healthcare-associated infections were the third most frequently notified event,<sup>24</sup> they also represent a major challenge for patient safety in low- and middle-income countries,<sup>25</sup> capable of causing harm to all individuals involved, excessive spending for the health system and families, and even deaths.<sup>25-27</sup>

Most of the reported incidents occurred among the elderly, finding similar to a medical record-based observational study, conducted in Brazil in 2019,<sup>21</sup> partially explained by the higher number of comorbidities, longer hospital stay, and use of multiple medications.<sup>28-30</sup> Regarding the degree of damage, mostly mild, the result was similar to that of other studies that used data from notification systems aimed at patients, family members and caregivers.<sup>9,11</sup> However, citizens were also able to report serious incidents that resulted in death. In general, patient reports seem to be more detailed and explicit than those of health professionals, constituting a valuable source of information for the analysis and improvement of health services.<sup>30</sup>

There was a low number of notifications during the study period. It could be seen a higher frequency of incidents related to the use of medications, followed by patient falls and healthcare-associated infections. These findings show that citizens have the capability to recognize and report such incidents as patient safety



issues. In order to better understand the dynamic use of this type of platform by the citizen and, consequently, improve patient and family adherence, further studies on Notivisa should be conducted based on the perspective of patient-centered care.

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## Authors' contributions

Villar VCFL collaborated with the study conception, data analysis and interpretation, drafting and critical reviewing of the manuscript content. Martins M and Rabello ET collaborated with data analysis and interpretation and critical reviewing of the manuscript content. All authors have approved the final version of the manuscript and declared themselves to be responsible for all aspects of the work, including ensuring its accuracy and integrity.



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