Original article

Registry of adverse events related to health care that results in deaths in Brazil, 2014-2016

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Abstract

Objective: to describe the adverse events related to health care resulting in death. **Methods**: a descriptive study of reports recorded in the Brazilian Health Surveillance Notification System (Notivisa) in Brazil from Jun 2014 to Jun 2016; notifications recorded as 'other' in the 'incident type' were recoded. **Results**: 417 cases were recorded, mostly in adults and the elderly (85%), with no sex differences; the states of São Paulo (N=92), Paraná (N=75) and Minas Gerais (N=66) were the main reporter; hospitals contributed to 97% of the records, principally in the intensive care and hospitalization sectors; the investigation by the notifying unit occurred in 5% of cases; in the recode of the type of incident, 52 records were recovered; the most common type of incident was 'failures during health care' (50%). **Conclusion**: notifications resulting in death occurred mainly in hospitals; were identified failure to register and need to investigate the large proportion of deaths.

Keywords: Patient Safety; Information Systems; Death; Health Services; Epidemiology, Descriptive.

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Introduction

Studies in several countries warn about the high frequency and severity of damage caused by health care.[1,2] This movement, corroborated by complaints of victims of health services, have resulted in the launch in 2004, by World Health Organization (WHO), the World Alliance for Patient Safety, and in 2013, the Brazilian Program for Patient Safety.[3] One of the strategies of this program is the surveillance and monitoring of incidents in health care.[4]

In Brazil, with the publication of the Resolution of Collegiate Directorate (Resolução de Diretoria Colegiada - RDC) of Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária - Anvisa) RDC No 36 of 25 July 2013,[5] was determined the creation of the of Divisions of Patient Safety (Núcleos de Segurança do Paciente - NSP) in health services. Among the competences of NSP is the analysis of the data on incidents arising out of the provision of the service, as well as its notification in the Brazilian Sanitary Surveillance System (Sistema Nacional de Vigilância Sanitária - SNVS). This RDC of Anvisa defines incident as 'event or circumstance that could have resulted, or resulted in unnecessary harm to health' and adverse event caused any harm.[6]

> *One of the strategies of the Brazilian Program for Patient Safety is the surveillance and monitoring of incidents in health care.*

The study of the global burden of disease, conducted between the years of 2007 and 2011, from a review of the literature and using data from previous epidemiological studies commissioned by the WHO, revealed that occurred approximately 421 million hospitalizations in the world every year with approximately 42.7 million of adverse events related to health care.[7] Such events led to 23 million years of life lost disability-adjusted per year. It is estimated that two-thirds of these events occur in middle and low income countries.[7]

Several studies have shown the association among the occurrence of adverse events in health services and death.[8,9] Retrospective research conducted in 2003, in three hospitals of Rio de Janeiro, about 1,103 randomly selected records, showed an incidence of adverse events of 7.6% and in-hospital mortality rate of 8.5%. The association between death and adverse event was statistically significant, with an odds ratio of 9.5.[10] A case-control study analyzed three Brazilian hospitals that served exclusively to private health care of high complexity and with more than one certification of quality (a total of 57,215 hospital discharge), among the years of 2012 and 2014, and found an incidence of 4% of adverse events. The mortality rate was 3.3 times higher in patients with adverse events.[11]

The incidence of adverse events related to health care in Brazil is few investigated.[3] Nevertheless, the reports are mandatory since June 2014 and should be recorded in the Brazilian Health Surveillance Notification System (Sistema de Notificações para a Vigilância Sanitária - Notivisa) version 2.0, under the responsibility of the Anvisa.

The database of adverse events related to health assistance of Notivisa can constitute an important source of information about where and when the patient is more vulnerable and what security measures are more urgent.

The objective of this study was to describe the adverse events related to health care resulting in death in Brazil.

Methods

This is a descriptive study of adverse events related to health care that resulted in deaths reported in the Brazilian Health Surveillance Notification System (Notivisa), under the responsibility of Anvisa.

The Notivisa version 2.0 was created with the purpose of connecting the Brazilian Sanitary Surveillance System (Sistema Nacional de Vigilância Sanitária – SNVS) and the information on the occurrence of adverse events related to health care (not infectious), generated by the NSP in health services.[12]

The events must be reported until the 15th day of the month following the occurrence of the event - with the with exception of deaths, which must be reported within 72 hours after the occurrence of the event.[12] According to the WHO definition, deaths recorded in Notivisa are result of that incident and refer to death caused or anticipated - by incident - in a short term.[13]

All health services when reporting deaths or other serious events that should never occur in health services - never events -, in addition to register the ten steps provided for in the Notivisa, must fill out a specific form containing the report of the investigation. This form is available in the service FormSUS (creating web forms service, offered by IT Department of the Brazilian National Health System) and can be accessed simultaneously by coordination of sanitary surveillance of Distrito Federal, states, municipalities and Anvisa, in a hierarchical manner.[12]

The present study comprised all notifications with date of registration on Notivisa between June 2014 and June 2016 that resulted in death.

We opted for this period of analysis since the Notivisa version 2.0 was deployed in March 2014 and its first three months of existence, amounted to a small number of records, denoting that the system still had a lower acceptability and stability, justifying the exclusion, in this research, in the first quarter of function of Notivisa.

The information on the investigations were obtained from the database of FormSUS. Included all notifications of research recorded in the database of FormuSUS that could be related to the respective notification of Notivisa. For this relationship between the records of the two databases, used the variable 'notification number'.

The following variables related were studied:

a) Person
- sex (male; female);
- age (in age ranges: <28 days, 28 days to 1 year; 2-7 years; 18-25 years; 26-55 years; 56-85 years; >85 years);
- ethnicity (White, Black, Brown, Asian, Indigenous); and
- finding that led the patient to the health service, based on the chapters of the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) (only the five groups of finding more frequent among the notifications, which are: (i) certain infectious and parasitic diseases, (ii) respiratory diseases, (iii) diseases of the digestive system, (iv) diseases of the circulatory system and (v) pregnancy, childbirth and the puerperium).

b) Place
- place of hospitalization, per unit of the federation.

c) Time
- date of admission;
- date of occurrence of the event; and
- date of notification.

d) Adverse Event
- type of incident (failures in administrative activities; failure during health care; failures during surgical procedure; failure in the administration of diets; failure in the administration of O_2 or medical gases; failure in care/protection of the patient; the patient to fall; pressure ulcer; patient accidents; healthcare-associated infection; medication/intravenous fluids; blood/blood products; medical articles/equipment; infrastructure/building/premises;other).

e) Type of health establishment
- outpatient clinic;
- clinic;
- hospital
- radiology
- emergency service;
- dialysis service; and
- other.

f) unit of the health establishment where the event occurred
- outpatient clinic;
- operating theater;
- hospital-day;
- radiology
- ambulance;
- units of hospitalization;
- intensive care units (ICU);
- urgency/emergency; and
- other.

g) phase of assistance in the event occurred
- during the provision of care;
- at admission;
- at hospital discharge;
- in the consultation;
- in the transfer;
- was not hospitalized; and
- monitoring after discharge.

h) period of the day on which the event occurred (7:00-19:00; 19:00-7:00)

With the aim of improving the quality of the descriptive analysis about the type of incident, we proceeded to the reclassification of the type of incident notifications in this variable was filled with the option 'others'. The notification form presents 14 categories of types of incidents related to health care, as well as the option 'others'. Whenever the user selects the option 'others' this variable, it opens the option of filling of the variable 'description of the adverse event'. For the reclassification, we used the information contained in

the variable 'description of the adverse event' and/or variables ´antecedents and context of the event' and 'description of the first strategy for reducing risks', being that these last two listed in the form of FormSUS. These three pieces of information are open fields, in which the notifier must describe information about the adverse event and their research.

The information of the three aforementioned variables were evaluated by two different examiners, with the purpose of establishing - where possible - a new classification of the type of incident. A third examiner was called to participate when the presence of disagreement.

If it was impossible to find in the system a category in which the adverse event could be classified,[12] we opted for classification of incident type defined by the WHO.[13]

Descriptive analyzes were performed with presentation of proportions and measures of central tendency. The opportunity of notification on Notivisa was evaluated by the median time interval between the date of the occurrence of the adverse event resulting in death and the date of the notification system. It was also calculated the median time interval between the date of admission and the date of the incident. The interquartile ranges were calculated from these measures.

The analysis of data occurred with the support of the Epi Info 7.2.0.1 and Microsoft Excel® 2010.

The present study has complied with the principles of ethics in research involving humans, prescribed in the Resolutions of the National Health Council (CNS) No. 466 of 12 December 2012, and No. 510, from 7 April 2016. By based on secondary data of events not nominated, available in databases of the Brazilian National Health System (SUS) - to preserve the identity of individuals -, the study was exempted from consideration by the Ethics Research Committee. The institutional consent was obtained from the General Management of Technology in Health Services (GGTES/Anvisa) by electronic manifestation, on 18/07/2017.

Results

Were recorded 63,933 adverse events related to health care in the period from June 2014 to June/2016. These events, 417 (0.6%) progressed to death. Of the 417 records of deaths, in 22 (5.3%) cases it was possible to find the respective research recorded in the database of FormSUS. There are other 392 records on Formsus of investigations of deaths not identified in the notification database, and other never events, which could not be quantified separately because there is no such distinction in the database.

The opportunity of notification on Notivisa was 63 days (1st quartile=29; 3rd quartile=133 days). The median time interval among the date of admission and the date of the incident was four days (1st quartile=0; 3rd quartile=12 days [data not presented in table]).

The distribution of notifications over time, by epidemiological week, shows fluctuations in the number of reporters, typical of surveillance systems with recent deployment and whose accession and permanence of the notifiers could vary greatly at the beginning of your deployment process (Figure 1).

The distribution of cases in the country can be observed in Figure 2. Of the 27 units of the federation, the state of Amapá was the only one not to register notification of death in the period studied. Five states recorded one death (Alagoas, Paraíba, Pernambuco, Rondônia and Roraima), and two (Bahia and Mato Grosso) recorded two deaths. Minas Gerais (N=66), Paraná (N=75) and São Paulo (N=92), together were responsible for 55.8% (N=233) of records on Notivisa, being that the São Paulo state accounted for 22.1% of the total number of notifications.

The records were mainly in the state capitals (Figure 2B), responsible for 321 records (77%). In the states of Minas Gerais and São Paulo, we observed greater decentralization of records, performed by nine municipalities in the state capital. Belo Horizonte accounted for 54.6% and 21.2% of Montes Claros in the records of Minas Gerais and São Paulo; the capital accounted for 69 (75,0% of the records) and the second municipality with the largest number of records has been Sorocaba, with eight (8.7%).

Adults from 26 years and older (60 years or more) accounted for the largest proportion of deaths (85%). Diseases of the circulatory system and the respiratory system accounted for 35.5% of diagnoses at the time of admission, among these age groups (Table 1).

The type of incident was classified as 'other' in 133 notifications (31.9%), of which 52 were reclassified. This process resulted in the inclusion of the following types of incidents: 'healthcare-associated infections', 'medicine/intravenous fluids', 'blood/blood products', 'medical articles/equipment' and 'infrastructure/building/premises' (Table 2).

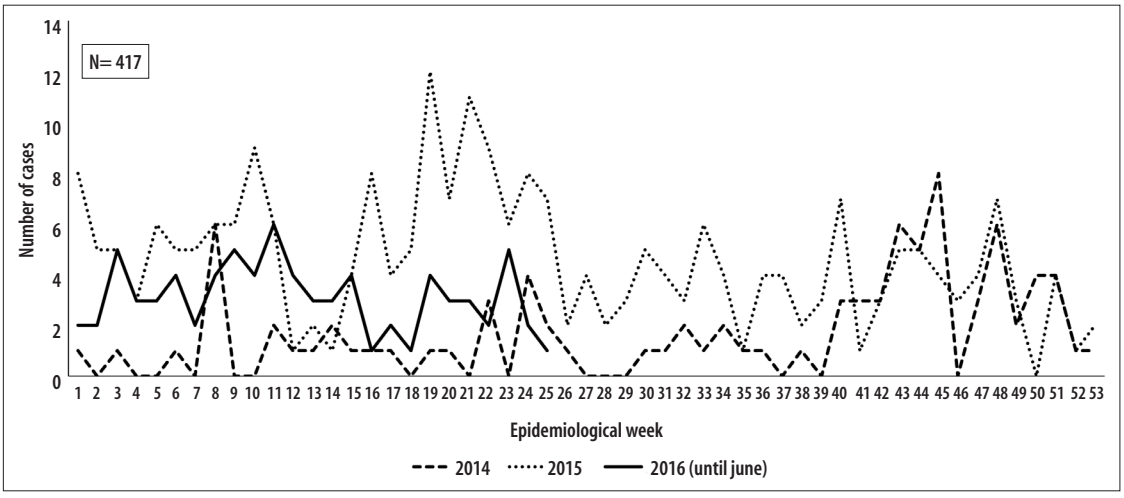
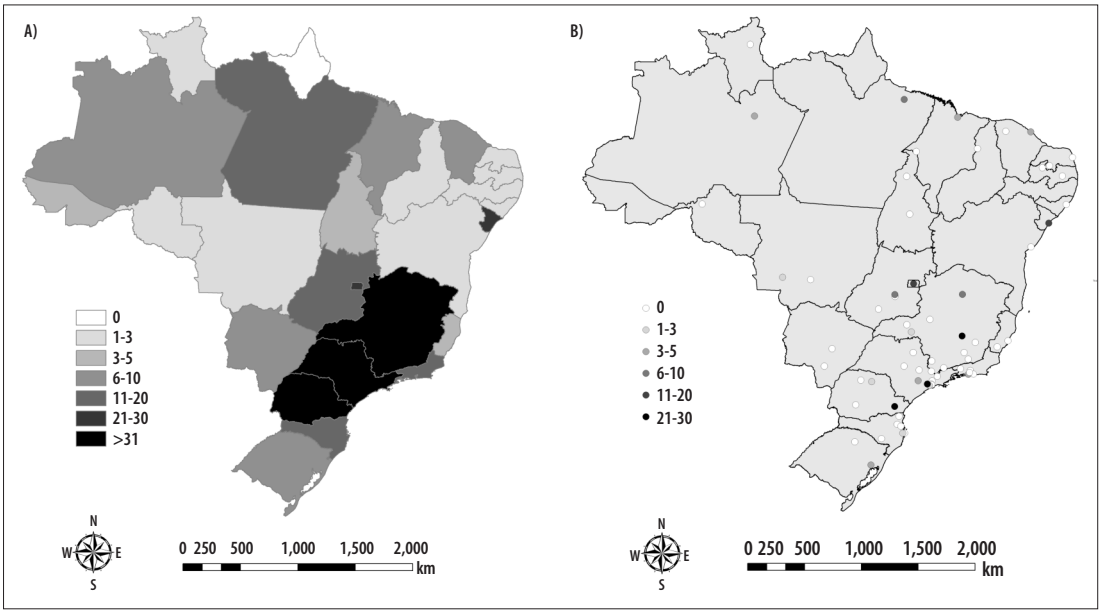


Figure 1 – Epidemic curve of adverse events related to health care resulting in death recorded in the Brazilian Health Surveillance Notification System (Notivisa) version 2.0, according to epidemiological week from date of occurrence of event, Brazil, June/2014-June/2016



a) Absolute frequency of cases recorded per unit of the federation.
b) Absolute frequency of cases recorded by municipality.

Figure 2 – Adverse events related to health care resulting in death recorded in the Brazilian Health Surveillance Notification System (Notivisa) version 2.0, Brazil, June/2014-June/2016

The notifications of cases came mostly from hospitals (96.9%) and occurred during the provision of care (diagnosis, evaluation, treatment or surgical intervention = 89%), followed by admission (3.1%) and transfer to another unit or to another service health system (2.9%).

Discussion

The deaths resulting from adverse events accounted for 0.6% of the total events recorded in the first two years of mandatory reporting. Most of the deaths occurred in adult and elderly patients who were

Table 1 – Characteristics of people who have suffered adverse events related to health care resulting in death recorded in the Brazilian Health Surveillance Notification System (Notivisa) version 2.0, Brazil, June/2014-June/2016

Variables	N	%
Sex		
Male	203	48.7
Female	214	51.3
Age Group		
<28 days	24	5.8
28 days to 1 year	11	2.6
2-17 years	13	3.1
18-25 years	15	3.6
26-55 years	120	28.8
56-85 years	208	49.9
>85 years	26	6.2
Ethnicity/skin color		
White	140	33.6
Black	12	2.9
Brown	100	24.0
Asian	1	0.2
Indigenous	1	0.2
Not informed	163	39.1
Diagnostic Group[a]		
Diseases of the circulatory system	90	21.6
Diseases of the respiratory system	58	13.9
Diseases of the digestive system	42	10.1
Pregnancy, childbirth and puerperium	35	8.4
Certain infectious and parasitic diseases	27	6.5

a) Based on the chapters of the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) at the time of admission. Were included only the five most frequent diagnostic groups.

hospitalized when of occurrence of the event. São Paulo, Paraná and Minas Gerais were the states with the highest number of notifications. Failures during the assistance were the main cause of the events.

Probably, healthcare adverse events are underreported in Brazil, whereas the national estimates of incidence of events.[10.11] Reporting of adverse events for products subject to health surveillance - including medicines, health products, blood and components, and transplants - are collected in the Notivisa 1.0 and not entered in these analyzes. Also do not take part of the scope of Notivisa version 2.0, system that served as the basis for the study on screen, the records of healthcare-associated infections referred to Anvisa through specific FormSUS electronic forms. Such factors represent limitations to the present study and potentially, reduce the external validity of the results. However, this is a first attempt with this design, whose objective was to evaluate such notifications since the deployment of the PNSP.

Half of the incidents analyzed in this study were failures during the assistance to health, which, by its generality, does not allow interventions and search for more specific improvements in services.

To Notivisa fulfills its purpose, it is necessary to evaluate their attributes, especially with regard to the representativeness of data quality and complexity. The multitude of systems for recording of adverse events can cause confusion - as can be seen in cases

Table 2 – Characteristics of adverse events related to health care resulting in death, recorded in the Brazilian Health Surveillance Notification System (Notivisa) version 2.0, Brazil, June/2014-June/2016

Variables	Type of incident: N (%)															Total N (%)
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	
	2 (0.5)	207 (49.6)	36 (8.6)	6 (1.4)	3 (0.7)	8 (1.9)	27 (6.5)	28 (6.7)	6 (1.4)	8 (1.9)	2 (0.5)	1 (0.2)	1 (0.2)	1 (0.2)	81 (19.4)	417 (100.0)
Health unit in which the incident occurred																
Operating theater;	–	12	23	–	–	–	–	1	–	–	–	1	–	–	4	42 (10.1)
Units of hospitalization	1	71	1	4	–	4	16	1	3	3	–	–	–	–	9	113 (27.1)
Intensive care unit (adult/pediatric/neonatal)	1	54	8	2	2	–	2	11	3	5	–	–	1	1	51	141 (33.8)
Urgency/emergency	–	40	1	–	–	3	3	14	–	–	1	–	–	–	5	67 (16.1)
Others	–	19	1	–	–	1	5	1	–	–	-	–	–	–	4	31 (7.4)
No filling (blank)	–	11	2	–	–	–	1	–	–	–	1	–	–	–	8	23 (5.5)
Period in which the incident occurred																
During the day (7:00 to 19:00)	–	105	23	2	1	3	12	–	2	–	1	–	1	–	42	192 (46.0)
During the night/early morning (19:00 to 07:00)	2	83	12	4	1	5	15	1	4	–	1	1	–	1	38	168 (40.3)
Did not inform	–	19	1	–	1	–	–	27	–	8	–	–	–	–	1	57 (13.7)

Types of incident: A - failures in administrative activities; B - failures during a health care; C - failures during surgical procedure; D - flaws in the administration of diets; E - flaws in the administration of O_2 or medical gases; F - failures in care/protection of the patient; G - the patient to fall; H - pressure ulcer; I - accidents patient; J - healthcare-associated infections, K - medication/intravenous fluids; L - blood/products derived from Blood; M - medical articles/equipment; N - infrastructure/building/facilities; and O - another.

mistakenly recorded in Notivisa, although dispense as categories described in the reference document of the WHO,[13] may lead to low adherence and motivation.[14] Even before the release of version 2.0 of Notivisa, has already indicated the challenge of improving the system, which must be based on the use, in the critique and in relation to the users, notifiers and interested.[15]

The largest part of the events came from hospitals. It should be considered that the notification is performed by NSP, established a few years ago, and that require resources for its operation, possibly are most commonly found in hospitals than in smaller companies. Furthermore, it is recognized that the culture and the search for data on patient safety have been concentrated in hospitals, with few studies conducted in primary care and home care.[3] However, it is emphasized in primary care the incidents related to patient safety are mostly preventable, causing the measures adopted in this level of attention to health are of great impact.[16]

A significant amount of fillings as 'others' points to limitations in the description and/or availability of types listed on the form. The reclassification carried out in this study indicates the need to better target the reporter, with the publication, for example, of technical manuals with more detailed description and citation of examples. A study conducted in 2015, in pediatric public hospital in the South region of the country, showed gaps in the knowledge of professionals in relation to the safety of the patient, the concepts and examples of incidents and/or adverse events in health, impairing the reporting process.[17]

The records on the investigations of cases that resulting in death, which could supplement the information, are scarce, suggesting that this step, as relevant to the institutional learning, is not being performed, or entered into the system. It is important to highlight that, as defined in current legislation,[5] these data should be reported in the SNVS in up to 72 hours after its occurrence. In addition, the investigation of events is seen as one of the pillars of the response to incidents in patient safety, whose findings are the basis for the identification of latent conditions and subsequent implementation of improvements in the system of care, in order to prevent the repetition of the incident.[18]

In Brazil, the reporting is made on a per incident basis and not per individual, which limits the comparison with the results of the large international studies based on medical records, including studies

that cite multiple adverse events suffered by the same person during their hospitalization.[9,19] Important research conducted in the United States, on the incidence of adverse events between the population hospitalized in the northeast in that country, showed 13.6% of lethality in cases in which adverse events occurred.[20] Another study carried out in two British hospitals, found an incidence of 10.8% of adverse events, of which 8% of the individuals came to death.[19] Canadian study in 2004 showed that 20.8% of adverse events analyzed resulted in death.[8] A research, conducted in the Netherlands in 2009, found that 12.8% of adverse events resulted in permanent incapacity or contributed to the death of the patient.[9] A systematic review, included eight studies on adverse events in patients hospitalized and, recorded 7.4% of adverse events found as lethal.[21]

A research conducted in Brazil, on estimates of deaths extrapolated for the number of hospitalizations in the SUS and private healthcare, concluded that in the year 2015, occurred among 104,187 and 434,112 possible deaths associated to in-hospital adverse events. If it were a group of cause of death, this factor would be among the five major causes of deaths in the country.[22] This result it should be noted on the need to better understand the context in which people are injured during the attention to health, to direct the public policies directed to the quality of services.

The findings of this study show, also, the lack of opportunity in the notification. The surveillance of adverse events related to health care is recent in Brazil. It is believed, therefore, that its incorporation in the routine work of health services should take some time, leading to a gradual increase in the number of notifications. However, in 2016, when to maintenance or increase of notifications was expected, there was a reduction, which may point to the need for investments in maintaining the sensitivity of the current notifiers and in the greater adhesion of new services.

The results presented indicate the low amount or even absence of records in the system in some localities, especially outside of South-Southeast axis and the Brazilian state capitals. This fact certainly is reinforced by the greater availability of hospital services in these municipalities. It is very important that Anvisa watch out for this situation and promote actions by the accession of health services to the system of monitoring in locations silent.

The characteristics of the people who suffered the adverse events resulting in death show similarities with other studies, as the similar distribution among sexes[8] and an important percentage of elderly - which corroborates their greater proportion among the hospitalized population.[9]

In intensive care, which require a greater use of technologies and procedures, predispose to a higher incidence of adverse events.[23] Adverse events that resulted in deaths were more frequent in intensive care units. It should be noted that the complexity of the unit may predispose to greater surveillance of cases by the professionals. An observational study carried out in 2002 and 2003, in intensive care unit and coronary care unit of Boston, United States, found a high incidence of adverse events (20%). Among these adverse events found, 13% were threatening to life or death.[23]

The systems for notification of incidents in patient safety are known to be useful in cases of severe events, which require decisions of state.[24] The national commitment is crucial in managing data about events that led to the death, is to respond to the relatives and friends of the victims , is to promote improvements in services, making health care safer. The achievement of these goals, the quality and timeliness of research are essential and deserve investments on the part of the SNVS. The promotion of a safety culture, motivating learning from the notifications should be another important tool for health surveillance and management of health services.

The predominance of hospitals as reporters and the shortage of data on investigations, added to the low opportunity registration, draw attention to the importance of actions of SNVS along these services, in order to ensure more effective and rapid approaches in cases that lead to death.

Authors' contributions

Maia CS and Araújo WN contributed in the conception and design, analysis and interpretation of data and the final revision of the manuscript. Maia CS drafted the first version of the manuscript. Freitas DRC and Galo LG contributed to data analysis and interpretation, and critical revision of the manuscript. All authors approved the final version and are responsible for all aspects of the study, ensuring its accuracy and integrity.

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