

Evolution of the national patient safety program: an analysis of the public data made available by the National Health Surveillance Agency


Evolução do programa nacional de segurança do paciente: uma análise dos dados públicos disponibilizados pela Agência Nacional de Vigilância Sanitária

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ABSTRACT

Introduction: The Brazilian Patient Safety Program (PNSP, in Portuguese), was established in 2013 in Brazil and, with it, a legislation that turns the formation of Patient Safety Committees (NSP, in Portuguese) and incidents notifications by health services compulsory. Since then, the Brazilian Health Surveillance Agency (Anvisa) publishes newsletters that contain compiled information of the notifications received; however, it does not compare it over time. **Objective:** Analyze the evolution of the Brazilian Patient Safety Program in five years. **Method:** Retrospective study, based on documents analysis. It is a review of Anvisa's publications, that are called Patient Safety and Quality in Healthcare Newsletters (*Boletim Segurança do Paciente e Qualidade em Serviços de Saúde*), from 2015 to 2019. **Results:** There was an increase of 416.00% on the NSP; however, this number represents less than 50.00% of Brazilian hospitals. Notifications have enhanced over 900.00%, but it is still necessary to qualify the information before submitting it to Anvisa. The comparison of cases proportions has shown that there was a slight decrease of severe damage and death, but 1,491 lives were lost due to adverse events in health on the studied period. Studies that assess national action's impact on healthcare results must be encouraged. **Conclusions:** Coordinated actions of health surveillance and assistance must be intensified, in order to patient safety become into a real priority of the Brazilian public healthcare system. Despite not having a perennial action financing policy, PNSP has caused a positive evolution over the years, and Brazilian institutions and health professionals have a huge potential for saving lives.

KEYWORDS: Patient Safety; Quality Assurance; Healthcare; Health Surveillance; Unified Health System

RESUMO

Introdução: O Programa Nacional de Segurança do Paciente (PNSP) foi instituído em 2013 no Brasil e, com ele, legislação que torna obrigatórias a constituição de núcleos de segurança do paciente (NSP) e a notificação de incidentes em estabelecimentos de saúde. Desde então, a Agência Nacional de Vigilância Sanitária (Anvisa) publica boletins contendo compilado das informações contidas nas notificações, porém não faz comparação ao longo do tempo. **Objetivo:** Analisar, a partir de dados públicos da Anvisa, a evolução do PNSP, em cinco anos. **Método:** Estudo retrospectivo, de análise documental, a partir da revisão das publicações da Anvisa denominadas Boletim de Segurança do Paciente e Qualidade em Serviços de Saúde, publicadas entre 2015 a 2019. **Resultados:** Houve aumento no número de NSP em 416,00%, porém representa menos de 50,00% dos estabelecimentos hospitalares brasileiros. As notificações aumentaram em mais de 900,00%, mas ainda se faz necessário qualificar as informações previamente ao envio à Anvisa. A comparação da proporção dos casos mostrou que houve discreta redução dos danos graves e óbitos,

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porém foram perdidas 1.491 vidas por eventos adversos na assistência à saúde no período avaliado. Estudos que avaliem o impacto de ações nacionais nos resultados do cuidado devem ser estimulados. **Conclusões:** Ações coordenadas de vigilância sanitária e de assistência à saúde devem ser intensificadas, a fim de tornar a segurança do paciente uma real prioridade de saúde pública no Brasil. Apesar de não haver uma política com financiamento perene de ações, nota-se que o PNSP provocou evolução positiva ao longo dos anos e que a mobilização das instituições e profissionais de saúde brasileiros tem potencial de salvar vidas.

PALAVRAS-CHAVE: Segurança do Paciente; Garantia da Qualidade; Cuidados de Saúde; Vigilância Sanitária; Sistema Único de Saúde

INTRODUCTION

It is estimated that 2.6 million deaths every year are due to healthcare-associated adverse events (AEs) in hospitals all over the world. One of the main causes of death and disability of patients are AEs, which are health incidents that cause harm to patients.¹ Nevertheless, most AEs are preventable, so implementing public strategies and policies to reduce harm to patients is of the utmost importance.

In Brazil, the Ministry of Health (MS) established, through Ordinance MS/Minister's Office (GM) n. 529, of April 1, 2013², the National Patient Safety Program (PNSP), whose general objective is to enhance the quality of healthcare in all healthcare facilities in Brazil—both public and private—and whose specific objectives are to promote and implement initiatives to improve patient safety, with the creation of Patient Safety Committees (NSPs) in healthcare facilities.²

Moreover, MS/GM Ordinance n. 529/2013² determines the need to design and implement protocols, guidelines, and manuals aimed at patient safety. These PNSP implementation strategies are the first step to promote safe care and are described in the Patient Safety Plan in Health Services (PSP), RDC n. 36, of July 25, 2013³, of Brazil's National Health Surveillance Agency (Anvisa), and so are the mandatory monitoring and monthly reporting of AEs, done by the NSPs.

Since 2014, Anvisa has been publishing a report based on reported health incidents,⁴ which compiles the data for each year. No time-based comparative analysis has been performed yet. This hinders the analysis of the effects of the initiatives that have implemented within the scope of the PNSP, which is to reduce healthcare-associated harm. The objective of this study was to analyze the evolution of the PNSP over time, based on information published by Anvisa.

METHOD

This is a retrospective study of documentary analysis, based on the review of Anvisa's publications entitled "Patient Safety and Quality in Health Services Newsletter" and its "Healthcare-associated Incidents" sub-titled editions. The newsletters are published by the Health Services Surveillance and Monitoring Management (GVIMS), of the Health Services Technology General Management (GGTES/Anvisa). Their objective is to share the results achieved with the analysis of healthcare-associated data reported throughout the year by the NSPs to the National Health

Surveillance System (SNVS) on the Health Surveillance Reporting System (Notivisa). The data are presented in an aggregated manner and the reporters' confidentiality is ensured. We studied all the newsletters published until January 2020 on the cases of patient harm occurred in 2014 (n. 10),⁴ 2015 (n. 13),⁵ 2016 (n. 15),⁶ 2017 (n. 18),⁷ and 2018 (n. 20).⁸

We analyzed the following pieces of information, which are common to the five newsletters: number of registered NSPs by Brazilian state; distribution of incident reports according to patients' age and gender; incident reports according to the period/shift of the day, type of incident and degree of harm; reported healthcare-associated incidents in the "other" category; deaths due to AE, according to cause.

The data were arranged in an Excel® spreadsheet and a descriptive statistical analysis was performed. As for the ethical aspects, this work analyzed public data made available by Anvisa in an aggregated form, so it is impossible to identify the source that generated each piece of information. This ensures the confidentiality of the data, so the study did not require prior authorization from the Research Ethics Committee and complies with the Resolutions of the National Research Ethics Committee (Conep) n. 510, April 7, 2016, and n. 466, of December 12, 2012.

RESULTS AND DISCUSSION

The total number of registered NSPs between 2014 to 2018 increased by 416%, from 784 to 4,049 in the last year (Table). The Southeast region currently concentrates about 44.00% of Brazil's NSPs, which is expected since this region is also home to most healthcare facilities in the country.

The average number of committees per state in these five years ranged from 3.4 in the state of Amapá to 396.8 in the state of Minas Gerais. There are already some government initiatives for better and increased distribution of healthcare facilities in the country, so coordinated action is essential to make sure these facilities have internal groups to manage the safety of the patients assisted there.

Comparing the number of hospitals registered in the National Registry of Healthcare Facilities (CNES) with the number of NSPs, less than 50% of the hospitals have patient safety committees, which shows that there is still a lot to be done to set up formal groups to address the issue of patient safety in hospitals.



Table. Number of patient safety committees registered by Brazilian state from 2014 to 2018.

State	Years					Period 2014-2018		
	2014	2015	2016	2017	2018	Average NSP	Max n. of NSP	Min n. of NSP
AC	5	7	8	9	11	8.0	11	5
AL	4	5	10	11	19	9.8	19	4
AM	5	12	29	35	49	26.0	49	5
AP	1	2	2	5	7	3.4	7	1
BA	26	48	80	108	154	83.2	154	26
CE	17	27	38	55	108	49.0	108	17
DF	17	44	71	80	103	63.0	103	17
ES	34	48	71	90	107	70.0	107	34
GO	60	109	170	248	378	193.0	378	60
MA	30	44	59	73	97	60.6	97	30
MG	109	233	393	523	726	396.8	726	109
MS	6	19	43	57	78	40.6	78	6
MT	11	21	29	40	47	29.6	47	11
PA	9	14	24	33	40	24.0	40	9
PB	9	10	22	41	54	27.2	54	9
PE	25	40	57	67	111	60.0	111	25
PI	3	8	33	38	59	28.2	59	3
PR	70	130	210	293	362	213.0	362	70
RJ	70	102	203	241	346	192.4	346	70
RN	9	18	29	32	44	26.4	44	9
RO	13	21	35	42	49	32.0	49	13
RR	1	1	6	6	10	4.8	10	1
RS	30	62	141	192	244	133.8	244	30
SC	41	86	142	172	202	128.6	202	41
SE	5	9	15	19	24	14.4	24	5
SP	170	244	354	431	593	358.4	593	170
TO	4	8	12	19	27	14.0	27	4
Brazil	784	1,372	2,286	2,960	4,049	2,290.2	4,049	784

Source: Anvisa^{4,5,6,7,8}.

States. AC: Acre; AL: Alagoas; AP: Amapá; AM: Amazonas; BA: Bahia; CE: Ceará; DF: Federal District; ES: Espírito Santo; GO: Goiás; MA: Maranhão; MT: Mato Grosso; MS: Mato Grosso do Sul; MG: Minas Gerais; PA: Pará; PB: Paraíba; PR: Paraná; PE: Pernambuco; PI: Piauí; RJ: Rio de Janeiro; RN: Rio Grande do Norte; RS: Rio Grande do Sul; RO: Rondônia; RR: Roraima; SC: Santa Catarina; SP: São Paulo; SE: Sergipe; TO: Tocantins; Min: Minimum number of patient safety committees in the period; Max: Maximum number of patient safety committees in the period; Max: Patient Safety Committees.

Although much still needs to be done to encourage the creation of NSPs and incorporate their activities into the routine of healthcare facilities, what we have seen over the years was the continuous expansion of NSP numbers. This increase suggests some improvement in information flows and, consequently, improvement in decision-making processes and in the quality of care.⁹

The amount of information sent from healthcare facilities to Anvisa via Notivisa increased by more than 900.00% over the period evaluated: 8,435 reports in 2014; 31,774 in 2015; 53,997 in 2016; 66,552 in 2017; and 103,275 in 2019. The increase in the number of reports does not necessarily mean a decrease in the quality of the services provided. Although reports have been mandatory since 2013, there are still some

obstacles, like the lack of a reporting culture in case of negative incidents, as shown by an integrative literature review done with Brazilian studies.¹⁰

The biggest disadvantages in using reporting systems to assess the reality of patient safety are the variable number of reporting institutions and the impossibility to ensure that 100% of incidents are reported, which hinders the direct comparison of numbers. Therefore, this study assessed the main characteristics of the incidents according to their proportions, considering the total number of reports every year.

In relation to the site where the incidents occurred, inpatient wards accounted for 52.45% (n = 13.4235) of the cases and intensive care units corresponded to 28.84% (n = 73.825) of the



reported cases when all years are combined. In a year by year comparison, the profile was the same.

In a study of a patient safety program in England,¹¹ first-aid rooms accounted for 66% of the cases and intensive care units corresponded to roughly 4% of the cases, which is quite different from data reported in Brazil. There are more than 4,500 reports without any information on where the incident occurred, which shows the need to educate reporters to inform the incident sites, as well as the need to encourage NSPs to qualify the information before submitting it to Anvisa. These missing data may hinder the design of risk mitigation policies, programs, and initiatives targeted at the places where the incidents occur more often.

As for the period in which the incidents occurred, in the five years we analyzed, an average of 60.00% of the AEs occurred from 7 am to 7 pm (Figure 1). The data found in this study are similar to those from two recent studies, one carried out in the state of Santa Catarina¹² and the other in a hospital complex in the state of São Paulo,¹³ in which the morning and afternoon shifts accounted for the highest percentage of incidents. This may be due to the fact that most procedures, like appointments, surgeries, assistance, and exams, are done in the morning. Other studies have reported a higher frequency of AEs at night,^{14,15} which may be associated with the excess workload and sleep deprivation of some professionals, which affects their ability to make decisions in emergency situations, for example. Once again, it is noteworthy that an average 19.00% of the reports—more than 50,000 over the years—did not bear any information about the shift in which the incident occurred.

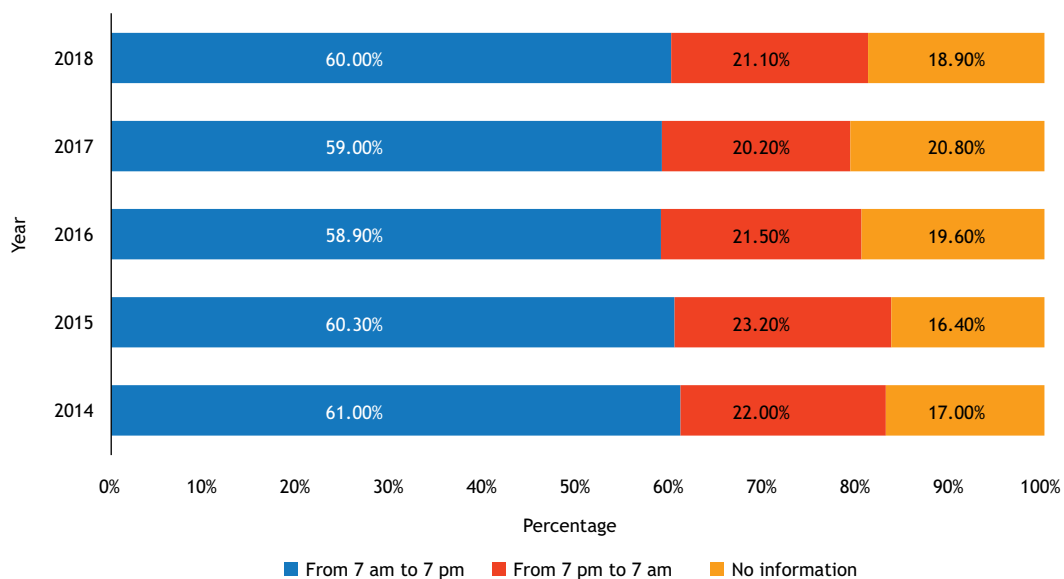
The Brazilian Network of Sentinel Hospitals was created by Anvisa in 2001¹⁶ to assist the agency in the post-approval surveillance of health technologies. Participating hospitals were

frequently encouraged to qualify information with due analysis of cases before filing a report in the national system. Like this project, in the PNSP the NSPs should also be made aware that the reports are of little use if they are not properly filled out. This culture of analysis and improvement of information is necessary to support internal action plans to enhance the quality of care that must be implemented by the NSPs. The lack of knowledge about the incidents' shift limits the analysis of the variables that contributed to the occurrence and, as a consequence, the implemented measures may be insufficient to prevent recurrence.

As for the age group of patients involved in the incidents, newborns corresponded to 3.53% of the reported cases and children accounted for 7.58%, on average. About 54.00% of cases involved patients over 56 years of age. Within five years, there was no change in the profile of patients affected by incidents, according to the cases reported in Anvisa's newsletters. Based on these data, we suggest that patient safety initiatives involve the participation of adult patients in their own care, whenever possible, as well as the adoption of specific protocols for this group, since it represented the largest share of patients affected by incidents in Brazil.

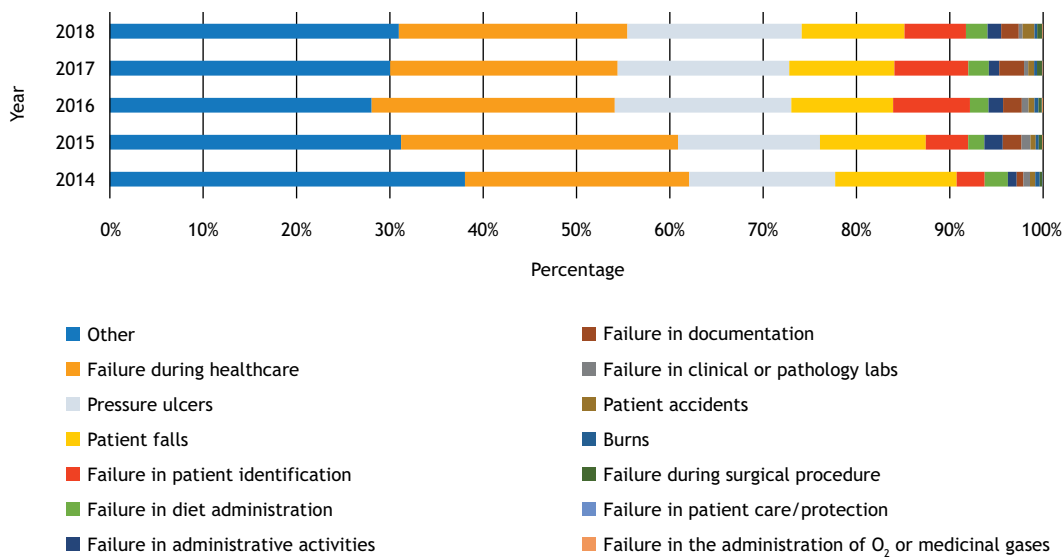
Regarding gender, there have been no changes in the profile of patients over the years. The average number of male patients was 52.58%, whereas female patients accounted for 47.42%. The results do not suggest the design of programs aimed at a specific gender to avoid incidents, rather, they favor the inclusion of all patients and professionals in campaigns, protocols, and other initiatives.

Figure 2 shows healthcare-associated incident reports by type of incident. Failure during care, including lack of screening, incomplete diagnosis, intervention or procedure performed



Source: Anvisa^{4,5,6,7,8}

Figure 1. Reports of healthcare-associated incidents according to the period/shift, from 2014 to 2018.



Source: Anvisa^{4,5,6,7,8}

Figure 2. Reports of healthcare-associated incidents according by incident type, from 2014 to 2018.

on the wrong patient, pressure injuries, and the “other” category corresponded to most incidents reported in the years under study.

As of 2015, Anvisa began to detail the classification of “others” (Figure 3), which corresponded to most types of incidents reported. In addition, the increase in the “miscellaneous reports” subcategory is worrisome: in 2015, it corresponded to 5.76% of the reports, and in 2018 this rose to 15.81% (increasing every year). This undermines the analysis and, consequently, the design of an action plan. Clear-cut categories are important for reporters to stop using the “other” field, since it is meant only for incidents that do not have specific records. If a particular type of incident is increasing within this category, a specific record must be created for it. According to newsletter n. 20, from 2018, as of 2019 Anvisa was supposed to remove “other” from the options and the most reported incidents included in this option were to be presented in the list of incidents to be reported by the NSPs.⁸ Until January 2020, however, this change had not been made yet.

The proper classification of AEs is essential to enable the detailed analysis of the cases. For example, the loss or obstruction of probes and phlebitis, which together account for almost 50.00% of all reports in the “other” category, should have a specific reporting form, with detailed data about this type of incident, so that an action plan to prevent their recurrence in healthcare facilities can be devised. Therefore, the recurrent request that information be qualified prior to its submission to Anvisa must be accompanied by initiatives from the agency to enable more qualified reports. This can be done through specific electronic reporting forms for the most frequent incidents in Brazil.

A good way to learn whether or not a patient safety program is effective is to compare the proportion of events with and

without harm. The flattening of the Bird Pyramid, widely used for the analysis of occupational accidents,^{17,18} indicates that the action plan to reduce incidents with harm is effective.^{19,20} In this study, we could see a significant increase in reporting, with an increase in the proportion of events with moderate harm too. There was also a decrease in the proportion of severe harm and death, indicating that the work done by the NSPs and other agents—municipal, state and especially federal government, which coordinates the PNSP—may in fact help reduce harm (Figure 4). Serious AEs corresponded to 1.00% in 2014, increased to 2.91% in 2015, but decreased in the following years, with 2.57% in 2018. The proportion of deaths due to incidents also decreased: 1.00% in 2014; 0.73% in 2015; 0.51% in 2016; 0.66% in 2017; 0.47% in 2018. The decrease in serious AEs may indicate that the implementation of protocols and other risk management initiatives in health services in Brazil has contributed to less harm to the users of the Brazilian healthcare system in recent years. Fewer AEs is an expected result of the implementation of basic patient safety protocols, according to studies by the World Health Organization (WHO). This effort resulted in campaigns for the global challenge of patient safety in the 2000s, which, in turn, encouraged the adoption of hand hygiene and safe surgery protocols.^{21,22}

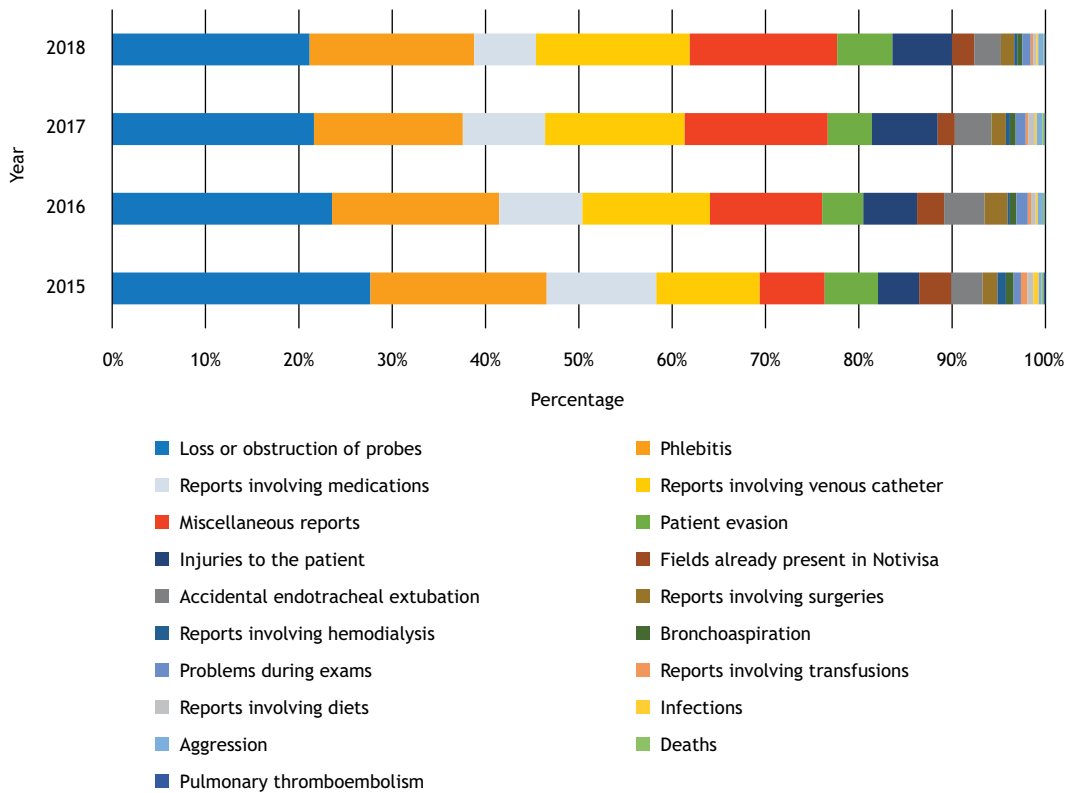
The increase in information on health incidents by almost 1,000.00% seems to have contributed to reducing harm, which in 2014 represented 71.99% of incidents and, in 2018, 68.16%. The increase in the number of reports—together with the decrease in severe harm and deaths—shows that healthcare professionals are better prepared to identify AEs, as well as to report them.²³ Preventing and predicting all harm is impossible. Healthcare is unpredictable and complex, as is human behavior. Some harm will never be fully eliminated, but it can be dramatically reduced with the adoption of evidence-based health tactics.²⁴



During the study period, according to data from the analyzed newsletters, 1,491 patients died of AEs in public and private healthcare services in Brazil. Despite these worrisome data, the study also revealed a decrease in deaths from 1.00% in 2014 to 0.47% in 2018. In order to improve the quality of the data available on deaths, entering detail into the “other” category is of the utmost importance. Anvisa started to classify the AEs that led to death in 2015 in a standardized fashion (Figure 5). Even

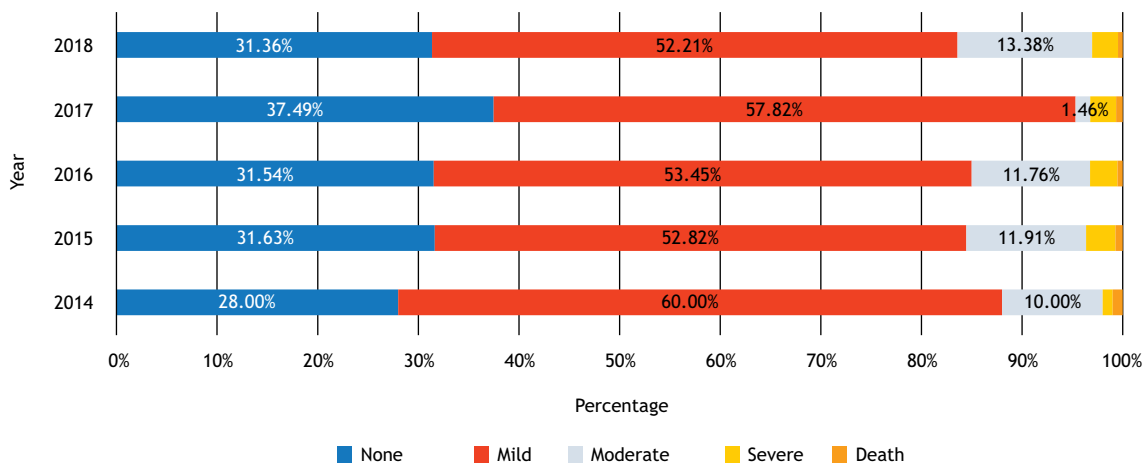
though the newsletters mention the problems and processes involved, they do not accurately describe them nor explain the right classification for reporting purposes.

There is scarce research on the occurrence of healthcare-associated AEs in Brazil. A study done from 2014 to 2016²⁵ to describe healthcare-associated AEs that resulted in death observed that, of 63,933 healthcare-associated AEs, 417 (0.6%) ended in death.



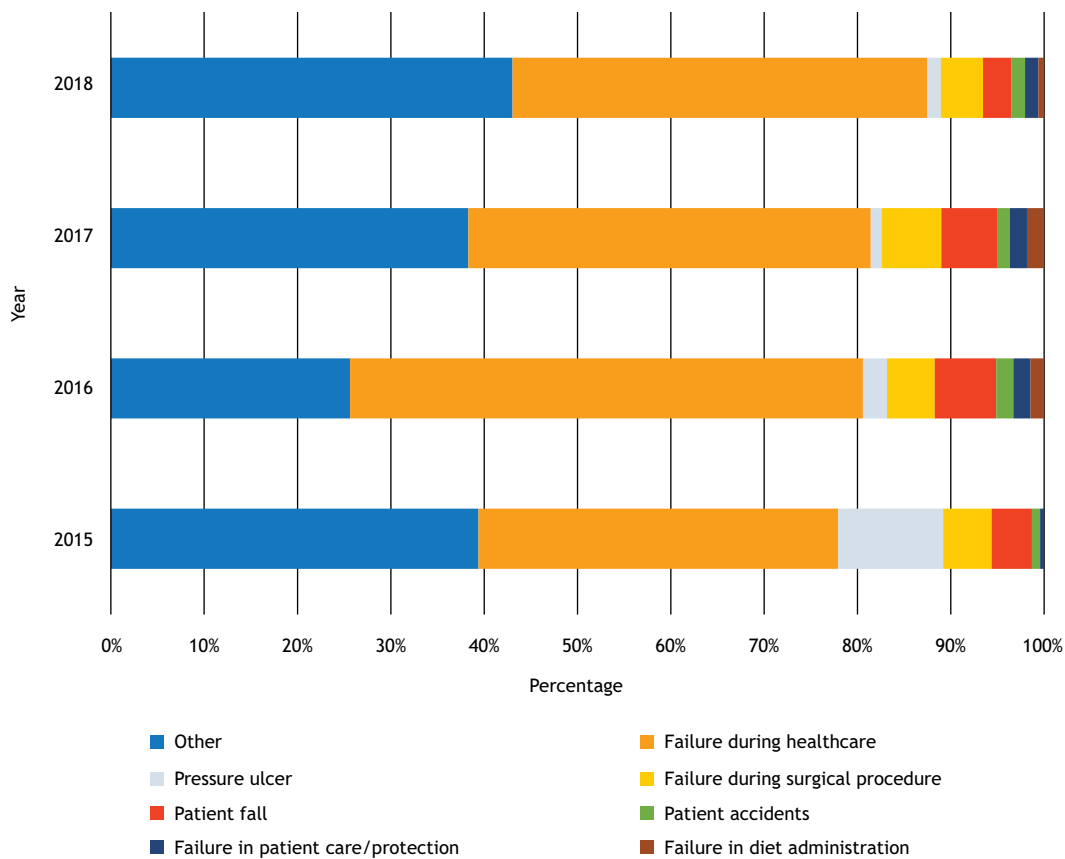
Source: Anvisa^{4,5,6,7,8}

Figure 3. Healthcare-associated incidents reported under the “other” category, from 2015 to 2018.



Source: Anvisa^{4,5,6,7,8}

Figure 4. Reports of healthcare-associated incidents according by degree of harm, from 2014 to 2018.



Source: Anvisa^{4,5,6,7,8}

Figure 5. Reported deaths resulting from healthcare-associated adverse events, according to cause, from 2015 to 2018.

The data are similar to those in this study, so we can conclude that the category of “failure during healthcare” is not specific and prevents the search for targeted improvement. It is essential that deaths be classified according to the International Classification for Patient Safety (ICPS),²⁶ detailing AE data to enable local and national efforts to improve processes and practices, enhance care results, and prevent deaths. Health surveillance inspection supported by educational methods can go beyond law enforcement. It can help improve the quality of data. In a national program, proper classification according to WHO guidelines is essential for benchmarking with other UN member countries, like Brazil itself.

The decrease in the proportion of deaths from pressure injuries, previously called pressure ulcers and thus classified in the analyzed newsletters, suggests that the adoption of the basic protocol for the prevention of this type of AE has been effective. Efforts like the publication of Technical Note GVIMS/GGTES n. 03/2017²⁷ by Anvisa aim to guide NSP professionals and promote safe practices to prevent pressure injuries. This type of initiative may have contributed to the decrease in this type of AE.

This work was based on the information found in the newsletters published by Anvisa and not on information directly from the reports. This may have limited our data analysis and correlations of variables. However, we find the presented data and

reflections important for future adjustment of the strategies used within the scope of the national patient safety program.

The data analyzed in this study does not reflect any significant improvement since the creation of the World Alliance for Patient Safety in 2004. In 2019, during the 72nd World Health Assembly, the WHO recognized patient safety as a global priority, reinforcing that signatory countries should design and enforce public policies to strengthen patient safety in all healthcare settings.¹

Patient safety programs in healthcare facilities have been adopted for a long time in several countries, like England, Canada, and Australia.²⁸ A quasi-experimental study done in a large pediatric hospital in the United States, after the implementation of a patient safety program with methods similar to those established under the PNSP, like culture change, training, and introduction of good practices (protocols), found that: safe environment scores across the hospital increased significantly; there was an 83.3% reduction in the rate of serious AEs; preventable harm decreased by 53% and in-hospital mortality by 25%.²⁹

Another important finding of the American study was that, as a result of improved quality and patient safety, hospital costs decreased by 22.00%. This corroborates the findings of an important Brazilian study³⁰ conducted in public hospitals in Rio de Janeiro, which estimated a difference of 200.5% between the



care costs of patients with AEs compared to those who did not suffer any harm.

There are no studies by the Brazilian government that estimate the costs of AEs in the country. A study with countries of the Organization for Economic Cooperation and Development (OECD) found that approximately 15% of hospital expenses are for after-effects caused directly by harm to patients and that the cost of six types of AEs in English hospitals is equivalent to the wages of over 3,500 nurses every year.³¹

Therefore, establishing continuous programs and processes to promote patient safety should not be seen by healthcare managers as an expense, but as an investment. Brazil seems to have made some progress in recent years, but there is still the need to encourage the creation of more NSPs across the country. More than that, these committees must be able to actually design and carry out effective patient safety plans to reduce incident under-reporting.¹⁰ Additionally, the data generated by the reports sent to the SNVS should be used for decision making and to inform the design of national and local indicators and policies for more effective and safer care.

In addition to increased inspections by the local health surveillance body, in accordance with current Brazilian legislation, and further training of healthcare managers at the three levels of government, the current program should be promoted to a public health policy, of national coverage and with a clear budget forecast. Furthermore, a public policy aimed at enhancing the quality of care should encourage investment in process improvement, with changes in the compensation model, since the fee-for-service model does not encourage sustained good practices over time.²⁸

Inside the institutions, the implementation of initiatives for patient safety, as well as for quality management in general, requires strong support from the organization's leaders ever

since the beginning. This can enable the adoption of an institutional model of safety culture and, consequently, help reduce AEs and mortality rates.^{32,33,34,35}

For these reasons, systematic public health initiatives, with a budget forecast for the implementation of patient safety strategies, are fundamental for the achievement of long lasting and increasingly robust results. Efforts should be made to turn the PNSP into a Brazil-wide policy supported by health surveillance legislation, so as to promote and protect the health of the population.

CONCLUSIONS

From the first edition of the patient safety newsletter to 2018, more than 1,400 citizens died because of AEs while receiving care in public and private healthcare institutions in Brazil. The 416.00% increase in the number of registered NSPs and the increase in information about health incidents by almost 1,000.00% seem to have helped reduce harm, especially severe and fatal occurrences.

Despite some signs of progress, the data show that the PNSP should be further strengthened and prioritized, as recommended by the WHO in 2019, since Brazil is a signatory to this international organization. Additionally, we have to discuss strategies to reduce underreporting and improve data qualification. We should also consider that healthcare professionals are often afraid to report, claiming lack of time, access or knowledge and feedback, which severely limits the analysis. Brazil should review and update its national patient safety plan, modify the health compensation model, discuss the permanent allocation of funds for the execution of the program, in a permanent and continuous manner, so as to promote and protect the health of Brazilians.

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Authors' Contribution

Andrade AM, Capucho HC - Conception, planning (study design), data acquisition, analysis and interpretation, and writing of the manuscript. Rodrigues JS, Lyra BM, Costa JS, Braz MNA, Sasso MA - Data interpretation, and writing of the manuscript. All authors approved the final draft of the manuscript.

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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