

Patient Safety: Adverse events notified in the Southern Region of Brazil, 2014-2019

Rochele Maria Zugno¹, Bruna Campos De Cesaro¹, Paulo Antônio Barros Oliveira², Ronaldo Bordin¹

¹ Graduate Program in Administration - PPGA, Federal University of Rio Grande do Sul (UFRGS), Brazil

² Graduate Program in Collective Health, Federal University of Rio Grande do Sul (UFRGS), Brazil

Abstract— *Introduction: One in ten inpatients suffers damage from healthcare, most of which is preventable. Objective: To describe the occurrence and characteristics of adverse events or incidents recorded in the National Health Surveillance System (Notivisa) for the three southern states of Brazil, between March 2014 and January 2019. Methods: Use of data from Notivisa's Adverse Events Reports for the three states of the Brazilian South Region (n=55.536 records). Variables studied: type of incident and year of occurrence; processes involved and problems occurred in incidents involving failures during assistance; types of services and hospital units; patient profile; shift in which the incident occurred; degree of damage and deaths per incident. Results: Of the total records, 56.7% occurred in male people, 57.7% in the age group above 56 years of age, 54.3% in the day shift and 50.7% resulted in mild damage. The three main reasons for incidents and adverse effects were: Failures during healthcare (24.5%), pressure ulcers (21.6%) and patient falls (15.0%). In "failures during health care", the procedures, treatment and / or intervention predominate (64.5%); in problems, incomplete or inadequate assistance (36.3%). The number of notifications four times higher in Paraná and twice in Santa Catarina suggests possible underreporting in Rio Grande do Sul. Conclusion: Failures predominated during health care in Paraná and Santa Catarina, and the patient's fall in Rio Grande do Sul.*

Keywords— *Health Information System, Health Management, Patient Safety, Risk Management.*

I. INTRODUCTION

Patient Safety is defined as “the reduction, to an acceptable minimum, of the risk of unnecessary harm associated with health care” [1]. Although the main objectives of health institutions are aimed at recovery and health promotion of patients, the occurrence of errors that imply damage to them is not uncommon [2]. According to data from the Latin American Study of Adverse Events, one in ten hospitalized patients suffers damage from health care, most of which may have been prevented [2].

Health errors can be characterized as acts of negligence or recklessness that, when they result in damage to the patient's health, are defined as an adverse event (AE) [1,3]. It is important to differentiate from the definition of incident, which would be an event or circumstance that could have resulted, or resulted, in unnecessary damage to health [1]. There are estimates that the occurrence of incidents related to health care affects 4% to 16% of hospitalized patients in developed countries, which has stimulated health systems around the world to seek improvements in patient safety [4,5,6].

A study covering 27 countries on six continents identified an average of 10% of patients affected by at least one adverse event during the hospitalization period,

51.2% of which were preventable [7]. In the United States, it is estimated that the error related to health care is the third cause of death, reaching up to 400.00 deaths per year, behind only cardiovascular diseases and cancer [8].

In Brazil, there is no overview of the real magnitude of the occurrence of AEs related to health care, however, data show that, every three minutes, more than two patients die in a Brazilian hospital, whether public or private, due to errors and other AEs related to the professional assistance provided to the patient [9]. A study carried out in three teaching hospitals in Rio de Janeiro found that 7.6% of patients were affected by some type of AE, 67% considered to be preventable [10].

In this context, notifications provide information that allows the identification of patterns and trends on patient safety, in order to prioritize continuous learning and the solution of identified problems, as well as to encourage the adoption of measures that can manage risk [11]. Thus, the objective of this study is to describe the occurrence and characteristics of events and incidents recorded in the National Health Surveillance System (Notivisa), in the three southern states of Brazil, between March 2014 and January 2019.

II. METHODS

The study was developed directly on the National Health Surveillance System (Notivisa), based on data from the Adverse Events Report of the three states in the South Region of the country (Rio Grande do Sul, Santa Catarina and Paraná), from March 2014 to January 2019, published and made available at:

<http://www.anvisa.gov.br/hotsite/notivisa/relatorios/index>.

Notivisa is a computerized system created by the National Health Surveillance Agency (ANVISA) to receive notifications of incidents, adverse events and technical complaints related to the use of products and services under health surveillance, allowing the monitoring, dissemination and monitoring of this data [12].

The following variables were used for this study: number of incidents by type; processes involved and problems occurring in failures during assistance; number of hospitals that reported each year; number of incidents per year; types of services versus number of incidents; hospital units versus number of incidents; number of incidents by sex and age group of the patient; occurrence shift; number of incidents per degree of damage; number of deaths per incident.

After collection, the data were entered into an electronic spreadsheet, using descriptive statistics for their management.

It should be noted that the use of a secondary data source from Notivisa is one of the limitations of the study, since it is a voluntary notification system, with the possibility of underreporting. Estimates are that a maximum of 15% of events are reported [13].

III. RESULTS AND DISCUSSION

In Brazil, from March 2014 to January 2019, 281,613 incidents and adverse effects were reported, with

55,536 (19.7%) in the South Region (Table 1). Of these, 29,802 (56.7%) occurred in males and 30,038 (57.7%) in the age group above 56 years of age, with no statistical difference between the states. Data similar to a study carried out in the states of São Paulo and Minas Gerais [14], but diverging from a study carried out in the context of primary care, where there was a predominance of females and between 20 and 59 years of age [15].

Of the total number of reported incidents and adverse effects, 30,150 (54.3%) occurred during the day shift (7 am to 7 pm), unlike the study that demonstrated a predominance of occurrences in the night shift [16].

Regarding the degree of damage, the highest number of incidents and adverse effects resulted in mild damage (50.7%), followed by no damage (33.3%), moderate damage (13.2%) and severe damage (2.5%) and deaths (0.3%). Similar data to another study in the area [7].

Table 1 shows the number of incidents and adverse effects according to the type in the three states of the Southern Region. It is observed that the three main reasons were: Failures during health care (24.5%), pressure ulcers (21.6%) and patient fall (15.0%), totaling 61.1% of the total. By state, Paraná and Santa Catarina differed regarding the ordering of these reasons when compared to Rio Grande do Sul, when the rubric of patients falls from third to first place.

Several studies have pointed out reasons related to the drug chain as the most frequent [16-20]. A Canadian study, on the other hand, found falls and pressure ulcers among the most frequent incidents and adverse effects [21].

Table 1 - Number of incidents / adverse effects reported by type in the three states of the South Region (Paraná - PR, Santa Catarina - SC and Rio Grande do Sul - RS), March 2014 to January 2019

Type of incident / adverse effects	States (n)		
	Paraná	Santa Catarina	Rio Grande do Sul
Failures during health care	8.769	3.405	1.452
Pressure ulcer	7.136	2.848	1.998
Patient's fall	3.392	1.852	3.089
Patient identification failed	2.781	1.264	179
Documentation failure	833	142	107
Failures in diet administration	617	321	118
Failures in administrative activities	481	105	85
Patient accidents	363	66	46
Failures in clinical or pathology laboratories	161	81	26
Burns	72	64	24
Failures during the surgical procedure	55	113	56
Failures in the administration of O ₂ or medicinal gases	19	10	2
Others	7.671	4.839	894
Total n	32.350	15.110	8.076
%	58,3	27,2	14,5

Source: Notivisa.

As for the processes involved and problems occurring in the “failures during health care”, the procedure, treatment and / or intervention (64.5%) and general assistance (28.3%) in the processes predominate; incomplete and / or inadequate assistance (36.3%) and not performed when indicated (26.4%) in the problems (Table2).

Table 2 - Processes and problems involved in failures during health care in the three states of the South Region (Paraná - PR, Santa Catarina - SC and Rio Grande do Sul - RS) from March 2014 to January 2019

	PR	SC	RS	Total	
				n	%
Processes involved					
Procedure / treatment / intervention	4.751	2.797	1.114	8.662	64,5
General assistance	3.090	471	241	3.802	28,3
Physical containment	413	12	4	429	3,2
Diagnosis / Complementary means of diagnosis	342	95	53	490	3,7
Screening / check up	26	5	6	37	0,3
				13.420	100,0
Problems Occurred					
Incomplete / inadequate	481	105	85	671	37,3
Not done when indicated	363	66	46	475	26,4
Wrong procedure / treatment / intervention	161	81	26	268	14,9
Out of stock	72	64	24	160	8,9
Wrong patient	55	113	56	224	12,5
				1.798	100,0

Source: Notivisa.

Studies carried out in several countries in the Middle East and Ireland have shown that therapeutic and diagnostic errors / events were the most commonly found [22, 23], corroborating what was found in this study.

Failures during care are generally considered to be avoidable errors, among which work processes and organization stand out, followed by technical capacity and

personal issues, such as distraction and anxiety during the prescription, dose or preparation [24].

There was a progressive increase in the number of hospitals that reported incidents and adverse effects, as well as the number of notifications made in the period and states under study. In 2014, only 78 hospitals made notifications, reaching 1,121 institutions in 2018 (increase of 1,337%). Notifications went from 866 in 2014 to 10,141 in 2018 (increase of 1,071%). This increase may be due to the establishment of a culture of safety among health professionals [16].

Hospitals concentrated notifications by type of service, with 53,594 (95.5%) records, followed by outpatient clinics, with 525 (0.9%) cases. A study in primary health care services found 125 (1.1%) incidents in 11,233 visits made [15].

As for hospital units, there was a predominance of hospitalization sectors (n = 28,654), in adult, pediatric or neonatal intensive care units (n = 14,905), in urgency and emergency units (n = 4,246) and surgical center (n = 1,615), accounting for 92.4% of valid records. Similar data to other studies [6,16].

IV. CONCLUSION

The three states that make up the South Region of the country were responsible for 19.7% of the total notifications made in the country in the period under study. Failures predominated during health care in Paraná and Santa Catarina, and patient falls in Rio Grande do Sul.

In the other variables, there are similarities between the three states. There was a progressive increase in the number of hospitals that carried out notifications over the years studied, with incidents and adverse effects focusing on the hospital area and, in these, in the sectors of hospitalization, intensive care units and urgency and emergency, in the shift daytime. Incidents and adverse effects affected both sexes equally, mainly in the age group above 56 years of age, resulting in a greater number of minor injuries.

REFERENCES

- [1] Brasil. Agência Nacional de Vigilância Sanitária. Resolução de diretoria colegiada nº 36, de 25 de julho de 2013. Institui ações para a segurança do paciente em serviços de saúde e dá outras providências. Brasília: ANVISA, 2013.
- [2] WHO – World Health Organization. IBEAS: a pioneer study on patient safety in Latin America - towards safer hospital care. Geneva: WHO, 2011.
- [3] Wachter RM. Compreendendo a segurança do paciente. 2ª ed. Porto Alegre: AMGH, 2013.
- [4] Brasil. Agência Nacional de Vigilância Sanitária. Gestão de riscos e investigação de eventos adversos relacionados à assistência à saúde. Brasília: Anvisa, 2017.
- [5] Sousa P, Uva AS, Serranheira F, Nunes C, Leite E. Estimating the incidence of adverse events in Portuguese hospitals: a contribution to improving quality and patient safety. *BMC Health Serv Res* 2014;14:311.
- [6] Somella L, Waure C, Ferriero AM, Biasco A, Mainelli MT, Pinnarelli L, et al. The incidence of adverse events in an Italian acute care hospital: findings of a two-stage method in a retrospective cohort study. *BMC Health Serv Res* 2014; 14:358.
- [7] Schwendimann R, Blatter C, Dhaini S, Ausserhofer D. The occurrence, types, consequences and preventability of in-hospital adverse events – a scoping review. *BMC Health Serv Res* 2018;18:521.
- [8] Makary MA, Daniel M. Medical error - the third leading cause of death in the US. *BMJ* 2016;353:1-5.
- [9] Couto RC, Pedrosa TMG, Rosa MB. Instituto de Estudos de Saúde Suplementar. Erros acontecem: a força da transparência no enfrentamento dos eventos adversos assistenciais em pacientes hospitalizados. Belo Horizonte: IESS, 2016.
- [10] Mendes W, Martins M, Rozenfeld S, Travassos C. The assessment of adverse events in hospitals in Brazil. *Int J Qual Health Care* 2009;21:279–84.
- [11] Brasil. Ministério da Saúde. Documento de referência para o programa nacional de segurança do paciente. Brasília: MS, 2014.
- [12] Brasil. Agência Nacional de Vigilância Sanitária. Notificação em vigilância sanitária. 2018. Disponível em: <http://portal.anvisa.gov.br/notivisa>. Accessed on Sep 4, 2018.
- [13] Prates CG, Stadnik M. Segurança do paciente, gestão de riscos e controle de infecção hospitalar. Porto Alegre: Moriá, 2017.
- [14] Maia CS, Freitas DRC, Gallo LG, Araújo WN. Notificações de eventos adversos relacionados com a assistência à saúde que levaram a óbitos no Brasil, 2014-2016. *Epidemiol Serv Saude* 2018; 27: e2017320.
- [15] Marchon SG, Mendes Jr WV, Pavão ALB. Características dos eventos adversos na atenção primária à saúde no Brasil. *Cad Saúde Pública* 2015;31: 2313-30.
- [16] Figueiredo ML. Análise da ocorrência de incidentes notificados em hospital-geral. *Rev Bras Enferm* 2018;71:121-30.
- [17] Aranaz-Andres JM, Aibar-Remón C, Limón-Ramírez R, Amarilla A, Restrepo FR, Urroz O et al. Prevalence of adverse events in the hospitals of five Latin American countries: results of the 'Iberoamerican study of adverse Events' (IBEAS). *BMJ Qual Saf* 2011;20:1043-51.
- [18] Akbari AS, Doshmangir L, Torabi F, Rashidian A, Sedaghat M, Ghomi R, Prasopa-Plaizier N. The incidence, nature and consequences of adverse events in Iranian hospitals. *Arch Iran Med* 2015;18:811-5.
- [19] Grira M, Larbi T, El Ouni A, Bouslama K, Abdallah M, Harmel A, Hamzaoui S, M'rad S. The incidence of

serious adverse events in a tunisian hospital: a retrospective medical record review study. *Tunis Med* 2015;93:795-9.

- [20] Halfon P, Staines A, Burnand B. Adverse events related to hospital care: a retrospective medical records review in a Swiss hospital. *Int J Qual Health Care* 2017;29:527-33.
- [21] D'Amour D., Dubois CA, Tchouaket E, Clarke S, Blais R. The occurrence of adverse events potentially attributable to nursing care in medical units: cross sectional record review. *Int J Nurs Stud* 2014; 51:882-91.
- [22] Wilson RM, Michel P, Olsen S, Gibberd RW, Vincent C, El-Assady R, Rasslan O et al. Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital. *BMJ* 2012;344:e832.
- [23] Rafter N, Hickey A, Conroy RM, Condell S, O'Connor P, Vaughan D et al. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals-a retrospective record review study. *BMJ Qual Saf* 2017;26:111-9.
- [24] Hoefel HHK, Echer I, Lucena AF, Mantovani VM. Incidentes de segurança ocorridos com pacientes durante o cuidado de enfermagem. *R Epidemiol Control Infec* 2017;7:174-80.