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Factors associated with adverse drug events reported in Brazil from 2014 to 2018

Factores asociados a eventos adversos de medicamentos notificados en Brasil entre 2014 y 2018

Fatores associados aos eventos adversos a medicamentos notificados no Brasil no período de 2014 a 2018

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Abstract

Adverse drug events generate an estimated cost of US$42 billion annually, corresponding to approximately 1% of total global health expenditures. ADEs are estimated to be associated with approximately 6.3% of hospitalizations in developing countries. This study aimed to analyze the profile and occurrence of adverse drug events reported in the national online reporting system in the five Brazilian regions. This epidemiological study analyzed reports of adverse drug events from the NOTIVISA database from March 2014 to December 2018. A total of 6,289 reports were analyzed, and a steady increase in the number was observed until 2016. The frequency was highest in the Southeast region (3,010; 47.8%), and adverse drug events mostly involved women (52.2%) and those aged 18 to 65 years (58.6%). Furthermore, 43% resulted in minor harm. The study highlighted the direct impact on safe patient care due to the increase in minor harm in the in-hospital setting, as these are preventable complications during drug treatment.

Descriptors: Adverse Events; Information System; Patient Safety; Pharmacovigilance; Medication.

Resumén

Los eventos adversos a medicamentos generan un costo estimado de US$42 mil millones anuales, lo que corresponde a aproximadamente el 1% del gasto total mundial en salud. Se estima que los EAM están asociados con aproximadamente el 6,3% de las hospitalizaciones en países en desarrollo. Este estudio tuvo como objetivo analizar el perfil y la ocurrencia de eventos adversos a medicamentos informados en el sistema nacional de informes en línea en las cinco regiones brasileñas. Este estudio epidemiológico analizó los informes de eventos adversos a medicamentos de la base de datos NOTIVISA de marzo de 2014 a diciembre de 2018. Se analizaron un total de 6.289 informes y se observó un aumento constante en el número hasta 2016. La frecuencia fue más alta en la región Sudeste (3.010; 47,8%), y los eventos adversos a medicamentos involucraron principalmente a mujeres (52,2%) y personas de 18 a 65 años (58,6%). Además, el 43% resultó en daños menores. El estudio destacó el impacto directo en la atención segura al paciente debido al aumento de daños menores en el entorno intrahospitalario, ya que estas son complicaciones prevenibles durante el tratamiento farmacológico.

Descriptores: Eventos Adversos; Sistema de Información; Seguridad del Paciente; Farmacovigilancia; Medicamento.

Resumo

Os eventos adversos a medicamentos geram um custo estimado de US$ 42 bilhões anuais, o que corresponde a aproximadamente 1% do total das despesas globais em saúde, estima-se que os EAM, estão associados a cerca de 6,3% das internações nos países em desenvolvimento. Objetivou-se analisar o perfil e ocorrência de eventos adversos a medicamentos notificados no sistema nacional de notificação on-line nas cinco regiões brasileiras. Trata-se de um estudo epidemiológico realizado a partir da análise das notificações relacionadas a eventos adversos a medicamentos do banco de dados do sistema NOTIVISA, no período de março de 2014 a dezembro de 2018. Um total de 6.289 notificações foram analisadas e foi verificado um crescente aumento em seu número até o ano de 2016. Houve maior frequência na região sudeste (3.010; 47,8%) e os eventos adversos a medicamentos envolveram, na maioria, pessoas do sexo feminino (52,2%) e faixa etária dos 18 a 65 anos (58,6%). Ainda, 43% resultaram em danos leves. O estudo evidenciou o impacto direto na assistência segura ao paciente, devido ao aumento de danos leves no ambiente intra-hospitalar, por se tratar de intercorrências evitáveis durante o tratamento medicamentoso.

Descritores: Eventos Adversos; Sistema de Informação; Segurança do Paciente; Farmacovigilância; Medicamento.

Introduction

Adverse drug events (ADEs) generate an estimated cost of US$42 billion annually, which corresponds to approximately 1% of total global health expenditure[1]. In the US, approximately 1.3 million people experience AMI each year, and such events are responsible for nearly 700,000 emergency department visits and 100,000 hospitalizations[2]. These numbers reinforce the hypothesis that ADEs are a significant and challenging public health problem, despite years of investment in research and technologies over the past two decades[3].

In low-income countries, patients are twice as likely to experience ADE compared to those in high-income countries[4]. In Brazil, a population-based cross-sectional study showed a 6.6% prevalence of ADEs.5 Furthermore, from 2010 to 2013, 17 medication errors were reported in the Brazilian media, and 14 resulted in severe harm[6].

In this context, pharmacovigilance is described by the World Health Organization (WHO) as the study of activities related to the detection, evaluation, and prevention of adverse events (AE) or any other events related to medicines, including post-marketing surveillance, which is considered crucial to control the safety of medicine use and patient safety[7]. In Brazil, the National Health Surveillance Agency (ANVISA) is responsible for managing activities related to pharmacovigilance, including ADEs[3].

Since 2008, records related to ADE have been carried out through the Health Care module of the Health Surveillance Notification System (NOTIVISA), updated in 2019 to VigiMed, where every health professional and consumer is able to report[8-12]. In this process, the Patient Safety Centers (NSP) of health services are responsible for reporting the occurrence of adverse events related to medications to the National Health Surveillance System (SNVS) managed by ANVISA[13].

The notification system plays a key role in patient safety, enabling continuous learning from errors and care failures through the analysis of notifications, in order to avoid harm to the patient[10,13,14]. According to ANVISA[15], since 2016, an increase in the number of ADE notifications has been recorded; however, the annual occurrence, associated factors, and damage caused by ADE in the population are unknown, facts that encourage us to investigate due to the impact on patient safety.

The presence of ADE in hospitals and the community compromises patient safety[16,17] due to risk factors such as polypharmacy, advanced age, and previous comorbidities, which is why the WHO launched the Global Action Plan for Patient Safety 2021–2030, which supports the Third Global Challenge called “Medication without harm” by encouraging the use of tools, technologies, and continuous learning among health professionals, engaging patients and their families in managing their own medications, and encouraging the reporting of AEs[11,18]. Thus, improving patient safety aimed at the safe use of medications is constantly in evidence nationally and internationally.

Given the above, the study aimed to characterize the clinical-epidemiological profile and identify the factors associated with ADE reported in NOTIVISA in Brazil, from 2014 to 2018.

Methodology

This is a cross-sectional population-based study, with analysis of information regarding ADE reported in NOTIVISA 2.0, from March 18, 2014, to December 4, 2018, the period preceding the change of the ADE reporting system to VigiMed.

Conceptual definitions

Medication errors

Any preventable event that may lead to inappropriate use of the medication or compromise patient safety[19].

Adverse drug events

They are defined as harm to a patient resulting from medication, whether due to a pharmacological reaction to a normal dose or a preventable adverse reaction to a medication resulting from an error. ADEs are categorized according to the WHO classification methodology[19]:

- Prescription error: A medication error that occurs during the prescribing of a medication, whether in the prescription or the therapeutic decision, due to an involuntary deviation from the reference standard.
- Transcription error: This involves the nursing staff making a copy of the prescription. The transcription is forwarded to the pharmacy for dispensing, and the original document is retained by the medical and/or nursing staff.
- Dispensing error: Erroneous dispensing of medication concerning the prescription.
- Administration error: Any type of failure in the medication administration process.
- Monitoring error: Failure to analyze the appropriateness and ability to identify problems with a prescribed treatment, or failure to use appropriate clinical or diagnostic data to adequately analyze the patient's response to the prescribed treatment.

Pharmacovigilance

Science is a set of activities related to the detection, evaluation, understanding, and prevention of the adverse effects of pharmaceutical products[19].

Population and sample

The study population consisted of 264,590 general incident reports, of which 16,383 (6.1%) were related to AEs and 6,289 (2.3%) were related to ADEs nationwide. These events were reported by healthcare professionals, service users, and companies/manufacturers. Reports not specifically related to harm caused by medication use were excluded. ADEs were classified according to the WHO classification, namely: (i) prescribing errors, (ii) transcription errors, (iii) dispensing errors, (iv) administration errors, (v) monitoring errors, and (vi) others[19].

Variables

Outcome: Number of ADE notifications.

Predictors:

- Patient characteristics – Sex: Female or male; Age range: < 18 years, 18 to 65 years, and > 65 years (according to WHO classification); Ethnicity: White, black, and others; Medical diagnosis (according to ICD-10).
- Variables related to ADE: Period of occurrence (Daytime - 7 am to 7 pm; Nighttime - 7 pm to 7 am and not informed); Phase of care (during care provision; at admission or consultation; at discharge, transfer, post-discharge follow-up; not hospitalized); Type of service (hospital; outpatient clinic and others) and health unit (inpatient departments; intensive care units; emergency and urgency; radiology; outpatient clinic; surgical center; not informed and others).
- Brazilian regions: North, Northeast, Southeast, Central-West, and South.
- Degree of damage: None, mild, moderate, severe, and death[19].
- ADE Classification: Prescription, transcription, dispensing, administration, monitoring, and other errors[19].

Data analysis

Initially, the data were analyzed and presented as absolute (n) and relative (%) frequencies. The association between ADE and the predictor variables was verified using the chi-square test and the odds ratio. Yes/no response variables were used to categorize the data according to the WHO (2009) medication error classification. To categorize the degree of harm, cumulative logits were used, as 1 (None), 2 (Mild), 3 (Moderate), and 4 (Severe/Death). To determine the degree of harm (None, Mild, Moderate, Severe/Death), multinomial logistic regression analysis was conducted.

To address missing data, data imputation was used. For each of the imputed models, a multinomial logistic proportional odds model was fitted. In this model, the inclusion and exclusion of predictor variables were selected using the Bayesian Information Criterion (BIC). In the final model, the corresponding odds ratios (ORs) were calculated based on the model parameters. All analyses were performed using R program[20], with a significant level of 5% ($\alpha = 0.05$).

Ethical aspects

The study was approved by the Research Ethics Committee (CEP) of the Ribeirão Preto School of Nursing at the University of São Paulo under CAAE: 39892620.8.0000.5393, and opinion no. 4,499,833.

Results

Of the 264,590 general reports of patient safety incidents, 16,383 were related to AEs, and of these, 38.3% (n=6,289) were related to medication use. Regarding the profile of patients who suffered ADEs, more than half were female (3,278; 52.1%), aged 18 to 65 years (3,686; 56.8%), white (1,877; 60.3%), and had comorbidities (2,760; 43.8%), with neoplasia being the most prevalent (1,442; 22.9%). Furthermore, 96.0% (6,038) occurred during the provision of care to inpatients and during the daytime (4,449; 70.7%) (Table 1).

Table 1. Distribution of ADE cases reported to NOTIVISA at the national level, by sex, age group, ethnicity, medical diagnosis, and ADE-related variables. Ribeirão Preto, SP, Brazil, 2014–2018 (N = 6,289)

Predictor variables	Frequency	
	n	%
Patient characterization		
Sex		
Feminine	3,278	52.2
Masculine	3,011	47.8
Age*		
< 18 years	804	12.7
From 18 to 65 years	3,686	58.6
> 65 years	1,799	28.7
Ethnicity *		
White	1,877	60.5
Black	1,200	38.6
Others	31	0.9
Medical diagnosis, according to ICD-10*		
Others	2,760	43.9

Neoplasms	1,442	22.9
Respiratory system diseases	672	10.7
Diseases of the circulatory system	617	9.8
Diseases of the digestive system	473	7.5
Diseases of the nervous system	325	5.2
Variables of adverse drug events		
Period of occurrence		
Daytime (7am to 7pm)	4,449	70.7
Night (7pm to 7am)	1,234	19.6
Not informed	606	9.7
Assistance phase		
During the provision of care	6,038	96.0
Not hospitalized	115	1.8
Upon admission or consultation	100	1.6
At discharge/ Transfer/ Post-discharge follow-up	36	0.6
Type of service		
Hospital	5,348	85.1
Others	623	9.9
Outpatient clinic	318	5.0
Health unit		
Inpatient sectors	3,122	49.7
Not informed	943	15.0
Intensive Care Units (Adult/ Pediatric/ Neonatal)	869	13.8
Others	372	5.9
Urgency and emergency	305	4.8
Radiology	285	4.5
Outpatient clinic	281	4.5
Surgical center	112	1.8

Note: *Missings: database made available with gaps in detailed information, not mandatory at the time of notification, and not reported by the notifier via the system.

The results also reveal that the frequency of ADE notifications was higher in 2016 (1,502; 23.9%) when compared to the other periods, followed by a decline in 2017 (1,451; 23.1%) and 2018 (1,315; 20.9%). The southeast region was responsible for 48% (n=3,010) of the notifications (Figure 1).

Of the 6,289 ADEs reported in Brazil between 2014 and 2018, the majority did not result in direct harm to the patient, according to the WHO classification. However, 140 (2.2%) caused severe harm or death. Furthermore, the highest occurrence of ADEs (3,010; 47.8%) was in the southeast region of the country. Furthermore, Table 2 reveals that the largest number of medication errors were classified as others, representing 21.1% (n=1,322) of cases. Furthermore, such errors resulted in severe harm or death in nine patients (0.7%). Administration errors (1,312; 21%) resulted in minor harm in 448 (34%) and severe harm or death in 94.

Figure 1. Frequency of ADE notifications, according to the region of the country. Ribeirão Preto, SP, Brazil, 2014-2018 (N = 6,289)

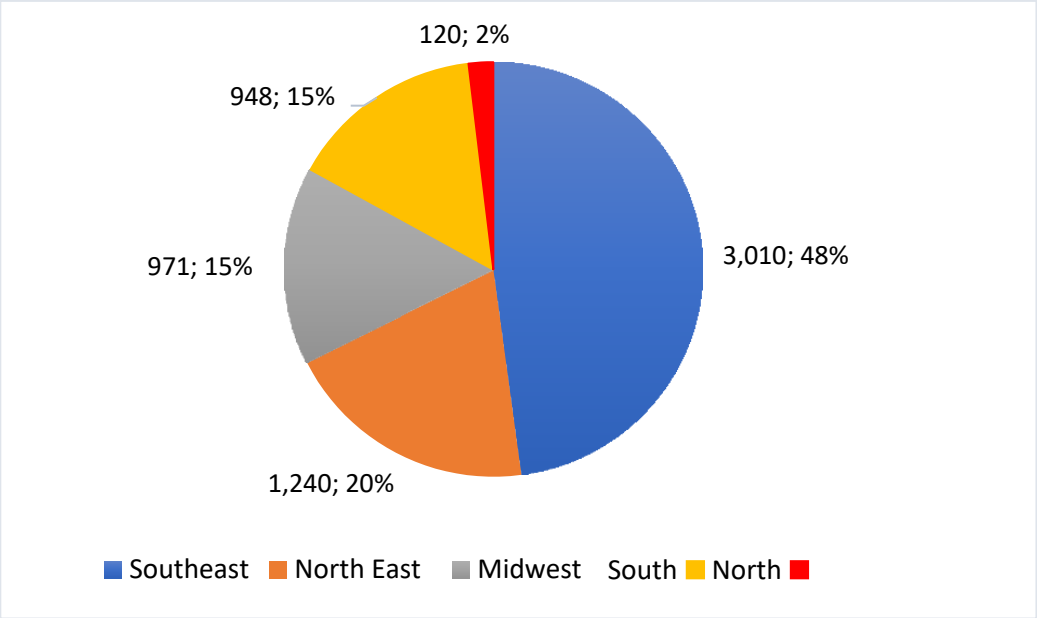
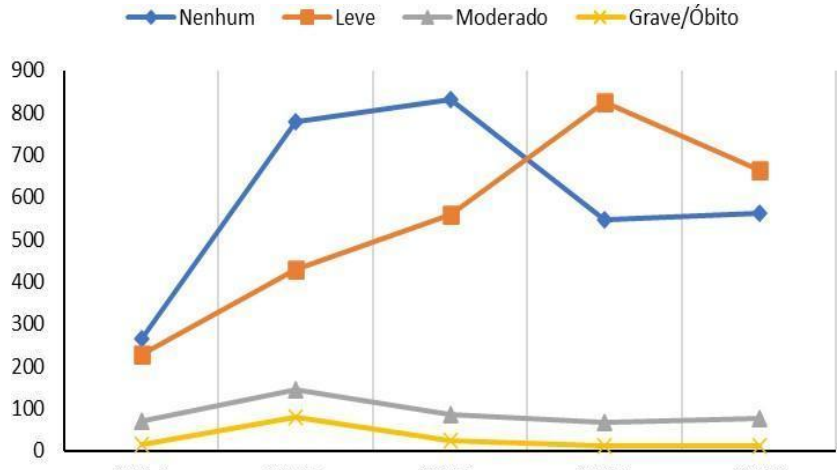


Table 2. Distribution of the degree of harm from adverse drug events reported in NOTIVISA, according to the region of the country and type of medication error. Ribeirão Preto, SP, Brazil, 2014–2018 (N = 6,289)

	Level of Damage									
Variables	**None**		**Light**		**Moderate**		**Severe/Death**		**Total**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Region of the country										
Southeast	1,401	46.5	1,281	42.6	227	7.5	101	3.4	**3,010**	**47.8**
North East	627	50.6	553	44.6	47	3.8	13	1	**1,240**	**19.7**
Midwest	513	52.8	367	37.8	80	8.2	11	1.1	**971**	**15.4**
South	382	40.3	470	49.6	84	8.9	12	1.3	**948**	**15**
North	70	58.3	42	35	5	4.2	3	2.5	**120**	**1.9**
Total	**2,993**	**47.5**	**2,713**	**43**	**443**	**7**	**140**	**2.2**	**6,289**	**99.8**
Type of medication error	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Prescription Error										
Yes	533	73.2	118	16.2	46	6.3	32	4.4	**729**	**11.5**
No	2,460	44.2	2,595	46.7	397	7.1	108	1.9	**5,560**	**88.4**
Transcription Error										
Yes	14	63.6	5	22.7	2	9.1	1	4.5	**22**	**0.4**
No	2,970	47.5	2,708	43.2	441	7	139	2.2	**6,267**	**99.6**
Dispensing Error										
Yes	617	87.5	73	10.4	12	1.7	3	0.4	**705**	**11.3**
No	2,376	42.6	2,640	47.3	431	7.7	137	2.5	**5,584**	**88.7**
Administration Errors										
Yes	616	46.7	448	34.0	160	12.1	94	7.1	**1,318**	**21**
No	2,377	47.8	2,265	45.6	283	5.7	46	0.9	**4,971**	**79**

Monitoring Error										
Yes	4	50.0	3	37.5	1	12.5	0	0	**8**	**0.2**
No	2,989	47.6	2,710	43.1	442	7	140	2.2	**6,281**	**99.8**
Others										
Yes	320	24.2	910	68.8	83	6.3	9	0.7	**1,322**	**21.1**
No	2,673	53.8	1,803	36.3	360	7.2	131	2.6	**4,967**	**78.9**

Figure 2. Distribution of ADE cases reported to NOTIVISA, according to the degree of harm and period of occurrence. Ribeirão Preto, SP, Brazil, 2014 to 2018 (N = 6,289)



Note: Nenhum: None. Leve: Light. Moderado: Moderate. Grave/Óbito: Severe/Death.

There was also an increase in the number of mild injuries, along with a stabilization of moderate and severe cases over time (Figure 2).

The variables were imputed and adjusted 10 times, with the following frequencies selected using the BIC: year (n=8), diagnosis (n=10), ethnicity (n=7), age group (n=3), phase of care (n=7), period of occurrence (n=7), health service (n=10), administration error (n=10), dispensing error (n=10), other errors (n=10), prescription error (n=10) and region of the country (n=7).

Table 3 shows that patients treated at health services in 2017 who were of black ethnicity had a lower chance of ADE (OR = 0.68; 95% CI: 0.48-0.95; p-value: 0.02). Dispensing error (OR=8.35; 95% CI: 5.80-12.03; p-value: 0.00) and residence in the Northeast region (OR=5.03; 95% CI: 3.47-7.30; p-value: 0.00) were factors that increased the chances of ADE occurring between 2014 and 2018.

Table 3. Multinomial logistic regression model of variables associated with the degree of harm from adverse drug events. Ribeirão Preto, SP, Brazil, 2014-2018 (N = 6,289)

Predictor variables *	Estimate	SE	Statistic	p-value	CI 95%		OR
Year							
2015	-0.26	0.17	-1.55	0.12	0.54	1.07	0.76
2016	-0.03	0.17	-0.22	0.82	0.68	1.34	0.96
2017	-0.37	0.17	-2.22	**0.02**	0.48	0.95	0.68
2018	-0.27	0.17	-1.59	0.11	0.53	1.06	0.75
Ethnicity							
Black	-0.43	0.09	-4.50	**0.00**	0.53	0.78	0.64
Others	0.28	0.39	0.73	0.46	0.61	2.88	1.33
Diagnosis							
Digestive System	0.66	0.20	3.30	**0.00**	1.31	2.90	1.95

Respiratory System	0.57	0.19	2.92	**0.00**	1.20	2.59	1.76
Nervous System	0.76	0.23	3.29	**0.00**	1.36	3.40	2.15
Neoplasms	0.02	0.17	0.11	0.91	0.71	1.45	1.02
Others	0.67	0.16	4.17	**0.00**	1.43	2.70	1.97
Assistance phase							
Admission/Consultation	0.20	0.32	0.61	0.53	0.64	2.33	1.22
Discharge/Transfer/ Post-discharge	-0.09	0.49	-0.19	0.84	0.34	2.38	0.90
Not hospitalized	-0.93	0.34	-2.71	**0.00**	0.20	0.77	0.39
Period of occurrence							
Day (7am – 7pm)	0.25	0.10	2.50	**0.01**	1.02	1.56	1.28
Health service							
Hospital	-0.52	0.16	-3.20	**0.00**	0.42	0.81	0.58
Others	0.48	0.23	2.07	**0.04**	1.02	2.54	1.61
Error classification							
Prescription	0.57	0.15	3.71	**0.00**	1.31	2.41	1.78
Dispensing	2.12	0.18	11.41	**0.00**	5.80	12.03	8.35
Administration	-0.19	0.10	-1.84	0.06	0.66	1.01	0.82
Others	-0.39	0.10	-3.89	**0.00**	0.55	0.82	0.67
Region							
North East	1.61	0.18	8.52	**0.00**	3.47	7.30	5.03
North	0.54	0.26	2.05	**0.04**	1.02	2.89	1.72
Southeast	0.478	0.12	3.68	**0.00**	1.25	2.08	1.61
South	0.16	0.15	1.08	0.27	0.87	1.58	1.18

Notes: *Levels of freedom (lf) = 98.0484 for all variables; SE: Standard Error; CI: 95% Confidence Interval; OR: Odds Ratio. Boldface was used to highlight statistically significant results. Data missing from certain regions did not contain sufficient information for inclusion in the multinomial logistic regression and estimation via R.

Discussion

The study aimed to analyze the profile of ADE reports received from the Brazilian online system. The results showed that these events were more frequent among females, aged 18 to 65, white, hospitalized during the daytime.

According to study[21], women are up to 1.7 times more likely to experience an AMI compared to men, indicating that women are more likely to report and therefore contribute to the higher overall rate of events among women. Similar findings were identified in research[22], making explicit the need for greater attention from health professionals to this group when providing health care.

The Southeast Region was responsible for most notifications, while the North Region was for the minority, corroborating the research findings[22,] which analyzed ADE reports from 2014 to 2018. Caution is needed when interpreting these results, as Brazil has diverse realities and a diverse economic situation. It is worth noting that NOTIVISA is an electronic system for reporting patient safety incidents, and that the process requires internet access. According to the authors[23], Numerous hospitals in Brazil still lack computers, making reporting impossible. Furthermore, the Southeast region is more populous and economically more developed, accounting for 55.2% of the country's Gross Domestic Product (GDP), 44.2% of registered NSPs compared to the entire country, and possessing a greater supply of healthcare facilities than other regions[24]. Therefore, it has a higher volume of consultations and hospitalizations, a factor that may explain the results found.

The results also showed an increase in the number of notifications from 2014 to 2017, followed by a decline. These findings converge with those of authors[22] who analyzed reports of all patient safety incidents in the same period, but differ from the research conducted in India, which observed a higher number of reports in 2018[25]. With patient safety in the spotlight in recent years, the prevention

of preventable events such as those related to medications can only be achieved if known, that is, through reporting, which has been increasingly encouraged by health agencies. Variations in the number of national reports highlight the individualities of each country and the creation of local strategies[11,26]. In Brazil, 2018 was the transitional year for the implementation of the new VigiMed system, a factor to be considered in the impact on the number of notifications to ANVISA during this period[10].

Regarding the types of medication errors most involved in ADEs, a higher prevalence of the other category (21.1%) was observed, followed by administration errors (21%), in contrast to those in the study[27], which aimed to analyze medication errors reported on the African continent between 1968 and 2018. According to the researchers, errors in scheduling and dose administration were the most common errors. The WHO noted that the irrational or inappropriate use of medications is a major challenge for countries, as medications are often responsible for severe and potentially fatal harm. However, such errors are considered preventable.

In this sense, the WHO proposed twelve key interventions to promote safe medication use: 1) Inclusion of this topic in formal undergraduate curricula; 2) Creation of a multidisciplinary national body to coordinate policies related to medication use; 3) Use of clinical guidelines; 4) Development and use of the national list of essential medicines; 5) Creation of medicines committees in hospitals and districts; 6) Continuing education of in-service medical professionals as a requirement for licensure; 7) Audit, supervision, and feedback; 8) Use of independent information on medicines; 9) Public education on medicines; 10) Avoidance of perverse financial incentives; 11) Use of adequate and enforced regulations; 12) Sufficient government expenditure to ensure the availability of medicines and professionals[28,29].

According to NOTIVISA notification reports, most ADEs resulted in mild harm to the patient (43%). However, 7% of reports resulted in moderate harm, and 2.2% resulted in severe harm and death. Study[30] pointed out that more than half of the medications administered result in harm that can be avoided through the implementation of active pharmacovigilance in hospitals to improve awareness of the unwanted effects of medications and patient safety.

Conclusion

Based on the study's results, it can be concluded that analyzing and understanding the profile of adverse drug events according to demographic characteristics can support the planning of actions to improve care and mitigate preventable errors. Improvements are still needed in the country's pharmacovigilance process to address the gaps left by underreporting. Furthermore, future studies should compare data from Brazilian regions after the transition to the new VigiMed reporting system.

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