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Analysis of the notifications of adverse drug events in a Brazilian public hospital

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Abstract

Objective: to describe the adverse drug events (ADE) reported to the Brazilian Health Regulatory Agency (Anvisa) by a public hospital of the Sentinel Network in Belo Horizonte. **Method**: descriptive observational study, with analysis of the complete ADE notifications registered at VigiMed by the Permanent Committee for Hospital Sanitary Risk Management from January 2021 to May 2022. The notified ADEs were described according to their distribution by month, by sector and according to their classification as adverse drug reaction (ADR) or medication error. The drugs involved in the notifications were classified according to the first level of the Anatomical Therapeutic Chemical (ATC) code from World Health Organization. **Results**: 74 notifications were analyzed, with a median of five notifications each month. Of those, 14 (18.9%) were ADR; seven (9.4%) were prescription errors; 11 (14.9%) were dispensing errors and 42 (56.8%) were administration errors. The sectors with the highest number of notifications were adult ward- inpatient, oncology - outpatient and pharmacy units. The class of drugs most involved in ADE was "Blood and Blood-forming Organs" (20.3%), followed by "Anti-infectives for systemic use" (18.9%). **Conclusion**: In this study, the ADEs notified to Anvisa at a public hospital of the Sentinel Network of Belo Horizonte were described qualitatively and quantitatively. Most of the ADEs were drug administration errors and there was a reduced number of ADR notifications. The analysis of these notifications can help the institution with the implementation of preventive and corrective measures to improve the safety in the prescription, use and administration of medicines. It is important to encourage the notification culture to better understand the profile of errors related to the drug chain and act effectively to reduce them.

Keywords: Drug-Related Side Effects and Adverse Reactions; Medication Errors; Pharmacovigilance; Notification; Patient Safety.

Análise das notificações de eventos adversos relacionados a medicamentos em um hospital público brasileiro

Resumo

Objetivo: descrever os eventos adversos relacionados a medicamentos (EAM) notificados à Agência Nacional de Vigilância Sanitária (Anvisa) por um hospital público da Rede Sentinela de Belo Horizonte. **Método:** trata-se de estudo observacional descritivo, no qual foram analisadas as notificações de EAM completas, realizadas pela Comissão Permanente de Gerenciamento de Risco Sanitário Hospitalar no VigiMed, entre janeiro de 2021 a maio de 2022. Os EAM notificados foram descritos de acordo com sua distribuição mensal, por setor e, também, conforme sua classificação como reação adversa a medicamento (RAM) ou erro de medicação. Os medicamentos envolvidos nas notificações foram classificados de acordo com o primeiro nível da Classificação Anatômico Terapêutico Químico *(Anatomical Therapeutic Chemical)* (ATC) da Organização Mundial de Saúde. **Resultados:** Foram analisadas 74 notificações, com mediana de cinco notificações a cada mês, sendo 14 (18,9%) classificadas como RAM; sete (9,4%) como erros de prescrição; 11 (14,9%) como erros de dispensação e 42 (56,8%) como erros de administração. Os setores com maior número de notificações foram a unidade de internação-enfermaria, oncologia-ambulatório e farmácia. A classe de medicamentos mais envolvida nos EAM foi "Sangue e Órgãos hemoformadores" (20,3%), seguida por "Anti-infecciosos para uso sistêmico" (18,9%). **Conclusão:** Neste estudo foram descritos, de forma qualitativa e quantitativa, os EAM notificados à Anvisa em um hospital público da Rede Sentinela de Belo Horizonte. A maioria dos EAM foram erros na administração de medicamentos e houve número reduzido de notificações de RAM. A análise dessas notificações pode auxiliar a instituição na tomada de decisões, na adoção de medidas preventivas e corretivas a fim de promover melhorias no processo de implementação do protocolo de segurança na prescrição, uso e administração de medicamentos. É importante estimular a cultura da notificação, para melhor conhecer os danos relacionados a cadeia medicamentosa e atuar de maneira efetiva com o objetivo de reduzi-los.

Palavras-chave: Efeitos Colaterais e Reações Adversas Relacionados a Medicamentos; Erros de Medicação; Farmacovigilância; Notificação; Segurança do Paciente.

Introduction

During healthcare delivery, errors may occur that often compromise patient safety. Adverse drug events (ADEs) are harms caused by the use of medications. ADEs can result from medication errors, which are preventable incidents leading to improper use of medications, causing harm, prolonging hospital stays, and increasing healthcare system costs. Therefore, it is essential to identify the nature of medication errors to develop actions that can prevent and mitigate[1,2] them. ADEs can also occur with all medications, even when used appropriately, constituting adverse drug reactions (ADRs)[2].

The global prevalence of ADEs among hospitalized patients, calculated in a systematic review, was 12%, being higher in low-income countries (14%) compared to high-income countries (12%)[1]. Studies conducted in Latin American countries identified a median rate of medication administration errors of 32%, ranging from 9% to 64%[3]. A study evaluating Brazilian ADE data reported a rate of 5.2 ADEs per 1,000 admissions between 2008 and 2012[4].

In Brazil, the monitoring of medications and other products has been strengthened through the creation of the Sentinel Network, which comprises approximately 270 hospitals to develop actions in pharmacovigilance, hemovigilance, and technovigilance[5]. This network contributes to national regulatory actions by identifying incidents and reporting them through VigiMed. The VigiMed system, provided by Anvisa, records ADE notifications. It was adopted in Brazil in December 2018 to better classify ADEs in the Brazilian context and is an adapted version of the system used by the World Health Organization (WHO), known as Vigiflow[6,7].

The Sentinel Network is a strategy to enhance the reporting and investigation of adverse events related to products under health surveillance in Brazil, such as medications[5]. Conducting studies that evaluate notifications from Sentinel Network hospitals contributes to understanding ADEs in the national context, strengthening pharmacovigilance activities, and improving patient safety[5,8]. Thus, analyzing ADE notifications reported to Anvisa by a Sentinel Network hospital, including their occurrence profile and main characteristics, enables the development of strategies to prevent and mitigate medication-related harm, fostering a culture of reporting and safety. Therefore, the aim of this study is to describe ADEs reported to Anvisa by a public Sentinel Network hospital in Belo Horizonte.

Methods

Study Design

This is a descriptive observational study with retrospective data collection covering the period from January 2021 to May 2022.

Study Setting

The study was conducted in a public hospital managed by an indirect public administration agency that provides healthcare services to government employees of the State of Minas Gerais, Brazil. The hospital specializes in urgent care and high-complexity inpatient and outpatient services in the following areas: angiology, cardiology, general surgery, thoracic surgery, vascular surgery, internal medicine, palliative care, endocrinology, gastroenterology, geriatrics, gynecology/obstetrics, hematology, neurology, neurosurgery, orthopedics/trauma, oncology, pediatrics, proctology, psychiatry, and urology. The hospital is a large facility with 344 beds and an average of 12,000 admissions annually.

The Pharmacovigilance Service and the notification process have been part of the institution's routine since 2009, with the hospital being a member of the Sentinel Network[9]. The institution's Permanent Commission for Hospital Health Risk Management (CPGRSH) is responsible for policies, procedures, practices, and resources for evaluating risks and adverse events that affect safety, human health, professional integrity, the environment, and the institution's reputation. CPGRSH receives ADE notifications from the institution's professionals, analyzes them, and records the data in the VigiMed system. For this purpose, notifications are organized in Microsoft Excel® spreadsheets, which served as the data source for this study.

Data Collection and Study Variables

Data on complete ADE notifications made by CPGRSH in the VigiMed system during the period from January 2021 to May 2022 were collected. The database was reviewed by the researchers to identify inconsistencies. As all data were obtained from digital sources, no intermediate data collection instrument was used. No data regarding patients or healthcare professionals involved in the events were collected.

The reported ADEs were described according to their monthly distribution and subclassification as ADRs or medication errors (prescription, dispensing, and administration errors). Prescription errors included wrong timing, prescribing a medication to which the patient is allergic, incorrect dosage, ambiguous or illegible prescriptions, and incorrect frequency. Dispensing errors encompassed incorrect medication, excessive dosage, errors in kit assembly, delays in dispensing, labeling errors, and medications dispensed with quality deviations. Notifications involving administration errors included incorrect dosage, medication extravasation, expired medications, administration without a prescription, errors by the patient or caregiver, incorrect administration route, wrong timing, failure to check the prescription, and errors related to substances. Regarding ADRs, the clinical manifestations, as recorded in the notifications, are described in Supplementary Material, Table 1.

Additionally, the institutional departments responsible for reporting ADEs were described. These departments were identified and grouped based on service characteristics: surgical center, obstetric center, adult intensive care unit (ICU), pediatric ICU, pharmacy, gynecology/obstetrics ward, hemodynamics, neurosurgery ward, oncology outpatient clinic, pediatrics ward, and inpatient unit ward. The medications involved in the notifications were classified according to the first level of the World Health Organization's[10] Anatomical Therapeutic Chemical (ATC) classification.

Data Analysis

In the descriptive analysis, absolute frequency, relative frequency, median, minimum, and maximum values were presented according to the behavior of the variables.

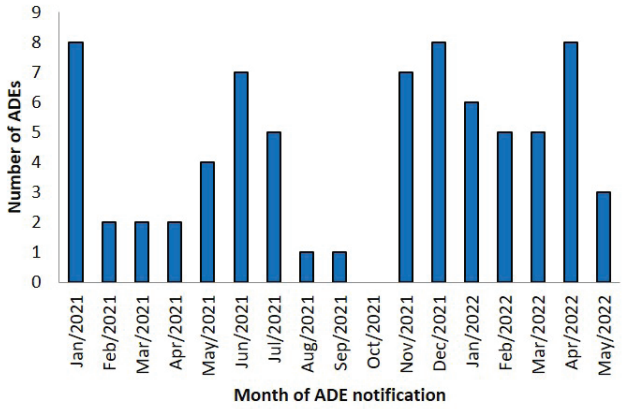
Ethical Aspects

This study was conducted in accordance with the guidelines of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) and approved by the Research Ethics Committee (REC) of UFMG (Federal University of Minas Gerais) and the REC of IPSEMG (Institute for Social Security of State of Minas Gerais Employees) (CAAE 61664722.0.0000.5149).

Results

A total of 74 notifications were analyzed, of which 47 (63.5%) were made in 2021 and 27 (36.5%) in the counted months of 2022. The median number of monthly notifications was five, with a minimum of zero notifications in October 2021 and a maximum of eight notifications in January and December 2021 and April 2022 (Figure 1).

Figure 1. Monthly number of ADEs reported to Anvisa in a public hospital of the Sentinel Network. Belo Horizonte, 2021 and 2022.

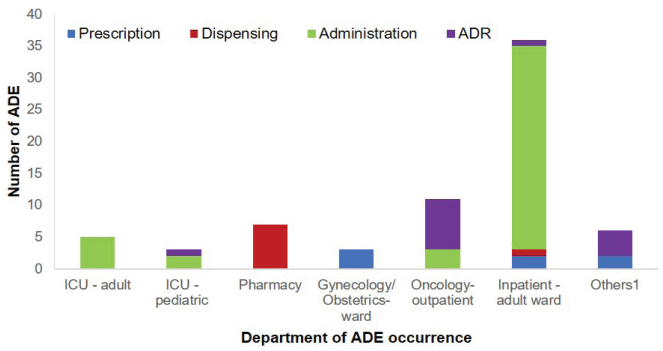


Legend: ADE – Adverse Drug Event; Jan- January; Feb- February; Mar- March; Apr- April; Jun- June; Jul- July; –Aug- August; –Sep- September; Oct- October; Nov- November; Dec- December .

Of these, 14 (18.9%) notifications were related to ADRs (Supplementary Material – Table 1), while the remaining 60 (81.1%) were medication errors (Supplementary Material – Table 2). Among medication errors, administration errors were the most frequent (n=42; 56.8%), followed by dispensing errors (n=11; 14.9%) and prescription errors (n=7; 9.4%).

The department with the highest number of notifications (n=36; 48.6%) was the adult inpatient unit, where administration errors prevailed (n=32; 88.9%), as well as in the adult ICU (n=5; 100%) and pediatric ICU (n=2; 66.7%). Notifications from pediatric, neurosurgery, and gynecology/obstetrics wards referred to prescription errors. In the pharmacy, reported errors were related to dispensing. The department with the highest number of ADR notifications was the oncology outpatient clinic (n=8) (Figure 2).

Figure 2. ADE notifications stratified by type and by the institutional sector where the event occurred. Belo Horizonte, 2021 and 2022.



Legend: ICU – Intensive Care Unit; ADE – Adverse Drug Events; ADR – Adverse Drug Reactions. [1]Sectors with two or fewer notifications were grouped as "Others" (Surgical Center, Obstetric Center, Hemodynamics, Neurosurgery- ward, Pediatrics- ward).

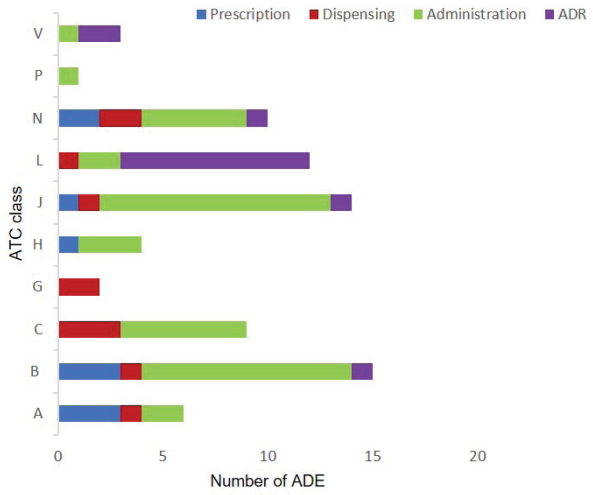
The number of identified medications exceeded the total number of reported ADEs (n=74) because seven ADEs involved the concomitant use of two or more medications. Most notifications involved drugs belonging to the following pharmacological groups: B – Blood and blood-forming organs (n=15); J – Antiinfectives for systemic use (n=14); L – Antineoplastics and immunomodulating agents (n=12) (Table 1).

Table 1. ADE notifications stratified by medication according to ATC classification. Belo Horizonte, 2021 and 2022.

ATC (1st level)	Class	Medication	n
A	Alimentary Tract and Metabolism	Butylscopolamine+ Metamizole	1
		Insulin NPH (isophane)	1
		Insulin Regular soluble	1
		Mannitol	1
		Metoclopramide	1
		Ondansetron	1
B	Blood and Blood Forming Organs	Potassium chloride	1
		Sodium chloride	4
		Enoxaparin	2
		Heparin	2
		Ferric hydroxide	1
		Glucose 5%	1
		Magnesium sulfate	1
		Trometamol	1
		Warfarin	2
C	Cardiovascular System	Furosemide	2
		Hidralazine	1
		Nifedipine	2
		Norepinefrine	4
G	Genito Urinary System and Sex Hormones	Misoprostol	2
H	Systemic Hormonal Preparations	Dexamethasone	2
		Prednisone	1
		Octreotide	1
J	Antiinfectives for Systemic Use	Amoxicillin	1
		Ampicillin	1
		Cefazolin	3
		Clindamycin	1
		Meropenem	3
		Metronidazole	1
		Oxacillin	1
		Piperacillin+ tazobactam	1
		Teicoplanin	1
		Hepatitis B vaccine	1
L	Antineoplastic and Immunomodulating Agents	Carboplatin	2
		Cetuximab	1
		Docetaxel	2
		Doxorubicin	1
		Hydroxycarbamide	1
		Ifosfamide	1
		Paclitaxel	1
		Rituximab	3
N	Nervous System	Metamizole	2
		Phenytoin	2
		Fentanyl	2
		Levodopa + benserazide	1
		Midazolam	1
		Morphine	1
		Ropivacaine	1
		Tramadol	2
P	Antiparasitic Products, Insecticides And Repellents	Ivermectin	1
V	Various	Contrast media, iodinated	2
		Parenteral nutrition	1

The notifications corresponding to groups B (Blood and blood-forming organs) and J (Antiinfectives for systemic use) were primarily related to administration errors (66.7% and 78.6%, respectively). Conversely, notifications related to class L (Antineoplastics and immunomodulators) were mostly associated with ADRs (75%) (Figure 3).

Figure 3. ADE notifications stratified by type and by drug according to Level 1 of the ATC classification. Belo Horizonte, 2021 and 2022.



Legend: ATC - Anatomical Therapeutic Chemical classification; ADE – Adverse Drug Events; A - Alimentary tract and metabolism; B - Blood and blood-forming organs; C - Cardiovascular system; G - Genitourinary system and sex hormones; H - Systemic hormonal preparations, excluding sex hormones and insulins; J - Anti-infectives for systemic use; L - Antineoplastic and immunomodulating agents; N - Nervous system; P - Antiparasitic products, insecticides, and repellents; V - Various.

Discussion

In this study, it was observed that most of the 74 voluntarily reported ADEs during the evaluated period were medication errors and occurred in adult inpatient units. The most frequent ADEs were related to the administration of medications and predominantly involved drugs from the Blood and blood-forming organs and Antiinfectives for systemic use classes.

In 2019, 2,771 medication errors were reported to Anvisa. These data cover the entire Brazilian country and likely reflect underreporting of ADEs. Although voluntary reporting of ADEs is an important strategy for promoting patient safety, it remains considerably limited[6]. A systematic review identified several strategies, albeit with low evidence levels, that have the potential to increase ADE reporting compared to voluntary practices. These include using reminders, specific reporting forms, and active ADE detection by clinical pharmacists[11].

Despite limitations, a gradual increase in voluntary reporting by healthcare professionals[6,12] has been observed. In some cases, this increase occurs following the implementation of specific strategies, such as creating voluntary reporting forms for prescription errors by pharmacists reviewing prescriptions in healthcare services[13]. The rise can also be attributed to growing awareness of the importance of ADE reporting and the use of technologies that facilitate the identification of medication errors[12]. According to data from Anvisa, between January 2021 and May 2022, 3,944 notifications were received through the VigiMed system from the state of Minas Gerais[14]. In a study conducted in a hospital specializing in oncology, an average of 287 ADE notifications were reported annually between 2018, 2019, and 2022[15].

In the present study, the number of ADE notifications sent to Anvisa was lower than that observed in other contexts. It is known that the number of identified ADEs varies significantly depending on the identification method used. Studies based on voluntary reporting, like this one, tend to underestimate ADE[3,16] prevalence. The low number of notifications may also be associated with measures implemented in the institution that increase the visibility of registered ADEs and help minimize their occurrence. Periodic training sessions on the importance of notifications are conducted, and online forms are available in the institution's system to facilitate and encourage reporting to CPGRSH. A monthly ADE report is sent to the coordination of the sector where the ADE occurred, and an action plan for addressing and preventing future events is requested. Promoting ADE reporting and sensitizing the multidisciplinary team about its importance contributes to improving patient safety[17].

Among the ADE notifications described in this study, there was a low number of ADRs. Drugs from class L (Antineoplastics and immunomodulating agents) tend to be more frequently associated with ADRs due to their high potential to induce hypersensitivity reactions, hematological toxicity, peripheral sensory neuropathy, gastrointestinal symptoms, cardiac issues, myalgia, and hand-foot[18,19] syndrome. Still, only eight ADR notifications were recorded in the oncology outpatient clinic of the studied hospital. Underreporting of ADRs is a global issue, making it even more important to implement initiatives that encourage healthcare professionals[6] to document these ADEs. The availability of simple systems and knowledge about pharmacovigilance are factors that facilitate reporting by healthcare professionals. However, some professionals base their reporting on the severity of the event or certainty that it is an ADR, which increases the risk of underreporting[20,21].

Underreporting also occurs in the context of medication errors, with frequently cited causes including workload and fear of embarrassment[22]. In this study, administration errors were the most frequent medication errors. Similarly, a study conducted from 2002 to 2007 in a Brazilian general hospital found that most medication errors (64.3%) were related to preparation and administration errors[23]. Similar to the present study, errors were most frequently associated with antineoplastic (24.3%) and antiinfective (20.9%)[23] medications. In another study, based on the observation of 484 doses administered by nursing technicians, errors were identified in 69.5% of cases[24].

The highest number of ADEs occurred in the inpatient unit. This result may be associated with the larger number of beds in this sector, with an annual average of 204 active beds. However, it is known that ADE occurrence is high in sectors treating patients with complex clinical conditions and where intravenous drug administration is frequent. A systematic review found a median of 14.6 medication errors per 100 prescriptions in pediatric[25] ICUs. In a study conducted in the surgical center of a teaching hospital, one ADE was reported for every 20 medications administered[26].

The types of medications used in each sector can also influence the frequency of ADEs. In this study, a high number of notifications

were related to drugs from group B (Blood and blood-forming organs) in the ATC classification. A systematic review of 585 studies showed that the drugs most involved in severe ADEs belong to class B, represented by warfarin, heparin, and antithrombotics[19]. Various strategies have been developed to minimize medication errors involving these high-alert medications, such as electronic prescribing systems, anticoagulant management programs, and specialized teams. However, the number of notifications has not significantly decreased, reinforcing the importance of monitoring errors associated with these medications[12].

Different strategies are used to reduce medication errors, all starting with identifying ADE occurrences. Educational measures and training for the healthcare team on pharmacotherapy and appropriate medication use[27] can then be implemented. Improved communication between professionals, patients, and caregivers can foster cooperation, contributing to medication safety. Psychological support and listening to healthcare professionals, who are often fatigued and overburdened[6], have also been identified as valid strategies. The implementation of technologies such as artificial intelligence systems and bedside carts assists in medication prescription evaluation and administration, becoming increasingly feasible in some institutions[28,29].

Reducing ADEs is encouraged by various international initiatives, such as the WHO's third Global Patient Safety Challenge, aimed at reducing medication errors[30]. Additionally, most of the six International Patient Safety Goals established by the Joint Commission International (JCI), in partnership with the WHO, are directly or indirectly related to reducing ADEs[31]. In the field of pharmacovigilance, healthcare professionals should monitor, evaluate, and prevent existing risks. Pharmacists, as medication specialists, can collect, record, analyze, and report information from ADEs or ADRs reported by patients, other healthcare professionals, and the public[7,27]. In doing so, they contribute to educating patients and other professionals and promoting the safe use of medications[7].

Some limitations of the study include the lack of a standardized taxonomy in the system for medication errors and the small number of complete notifications identified during the investigated period. Strengths include the fact that the evaluated setting is part of the national Sentinel Network and has a Permanent Committee for Hospital Health Risk Management, which enhances the reliability of the collected data.

Conclusion

This study qualitatively and quantitatively described the ADEs reported to Anvisa in a public hospital of the Sentinel Network in Belo Horizonte. It was identified that most ADEs were medication administration errors, and there was a low number of ADR notifications. The analysis of these notifications can expand knowledge about ADE reporting in the Brazilian context and assist the institution in decision-making, adopting preventive and corrective measures, and improving the process of implementing the safety protocol for prescribing, using, and administering medications. Additionally, it is pertinent to evaluate measures that can encourage a culture of reporting to better understand the damages related to the medication chain and act effectively to reduce them.

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Contributors

LDS, HMM, and CMB participated in the project design, data analysis and interpretation, and manuscript drafting. CLF, GGR, and MGN contributed to the critical review of the text. All authors approved the final version of the manuscript for publication.

Conflicts of Interest

The authors declare no conflicts of interest.

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