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Incident analysis occurrence related to potentially dangerous medicines distributed in teaching hospital

Análise das ocorrências de incidentes relacionados aos medicamentos potencialmente perigosos dispensados em hospital de ensino

Análisis de las ocurrencias de incidentes relacionados a los medicamentos potencialmente peligrosos suministrados en hospital de enseñanza

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ABSTRACT

Objective: To analyze the reports of incidents related to potentially hazardous medications distributed at a teaching hospital in the interior of São Paulo.

Methods: A descriptive, retrospective study with a quantitative approach of data from the analysis of pharmacovigilance notifications that occurred between January 2009 and December 2014, from tables and graphs, showing the absolute/relative frequencies.

Results: From 786 reports of pharmacovigilance, 188 were related to potentially hazardous medicines, 36.7% of which were ineffective, 32.44% were technical complaints, 15.95% were adverse reactions, 7.44% were phlebitis, 5.13% were extravasation , 1.06% dispensing error, 0.53% administration error and 0.53% medication error. The professionals who most notified were nurses. The most commonly reported pharmacological groups were drugs with action on the nervous system (35.63%).

Conclusion: The analysis showed that there were a significant number of reports and the need to adopt strategies to ensure greater patient safety.

Keywords: Patient safety. Pharmacovigilance. Medication errors. Quality indicators, health care.

RESUMO

Objetivo: Analisar as notificações de incidentes relacionados aos medicamentos potencialmente perigosos dispensados em um hospital de ensino do interior de São Paulo.

Métodos: Estudo descritivo, retrospectivo com abordagem quantitativa dos dados provenientes da análise das notificações em farmacovigilância que ocorreram no período de janeiro de 2009 a dezembro de 2014, a partir de tabelas e gráficos, apresentando as frequências absolutas/relativas.

Resultados: Das 786 notificações de farmacovigilância, 188 foram relacionadas aos medicamentos potencialmente perigosos, sendo 36,7% de ineficácia terapêutica, 32,44% queixa técnica, 15,95% reação adversa, 7,44% flebite, 5,13% extravasamento, 1,06% erro de dispensação, 0,53% erro de administração e 0,53% erro de medicação. Os profissionais que mais notificaram foram enfermeiros. Os grupos farmacológicos de maior notificação foram drogas com ação sobre sistema nervoso (35,63%).

Conclusão: A análise demonstrou que houve um número de notificações expressivo e necessidade de adoção de estratégias a fim de garantir maior segurança do paciente.

Palavras-chave: Segurança do paciente. Farmacovigilância. Erros de medicação. Indicadores de qualidade em assistência à saúde.

RESUMEN

Objetivo: Analizar las notificaciones de incidentes relacionados a medicamentos potencialmente peligrosos suministrados en un hospital de enseñanza del interior de San Pablo.

Métodos: Estudio descriptivo, retrospectivo, con abordaje cuantitativo de los datos provenientes del análisis de las notificaciones en farmacovigilancia que ocurrieron en el período de enero de 2009 a diciembre de 2014, a partir de tablas y gráficos, presentando las frecuencias absolutas/relativas.

Resultados: De las 786 notificaciones de farmacovigilancia, 188 fueron relacionadas a los medicamentos potencialmente peligrosos, siendo 36,7% de ineficacia terapéutica, 32,44% queja técnica, 15,95% reacción adversa, 7,44% flebitis, 5,13% extravasación, 1,06% error de dispensación, 0,53% error de administración, y 0,53% error de medicación. Los profesionales que más notificaron fueron enfermeros. Los grupos farmacológicos de mayor notificación fueron drogas con acción sobre el sistema nervioso (35,63%).

Conclusión: El análisis demostró que hubo un número de notificaciones expresivas y necesidad de adopción de estrategias a fin de garantizar mayor seguridad al paciente.

Palabras clave: Seguridad del paciente. Farmacovigilancia. Errores de medicación. Indicadores de calidad de la atención de salud.

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INTRODUCTION

Pharmacovigilance is an essential tool for the monitoring of medicines that are on the market, with the aim of identifying possible injuries caused to the human health[1].

The adverse drug events (ADE), according to the World Health Organization (WHO), can be described as damage to the health of a user or a patient who is under treatment with a medicine, from this perspective, it is said that some of the major problems in the area of pharmacovigilance monitoring include adverse reactions to medicine (ARM), the therapy inefficiency or ineffectiveness (TI), the deviations of the quality of medicines or technical complaints (TC) and medication errors (ME). All these incidents may be responsible for the occurrence of a harmful effect to the patient and thus, an adverse reaction to the medicine; the presence of damage is a necessary condition to characterize the incident as an adverse event[2].

The ADE are responsible for an adverse impact on hospital health, since this type of problem occurs with great frequency in patients hospitalized resulting in increased time of patients hospitalization, hospital costs, mortality, in addition to generating changes of emotional aspects in the health team and affect the credibility of the institution in the society[1,3]. Studies indicate that in Brazil there was the incidence of 7.6% of hospitalized patients who were affected by adverse events, being that 66.7% of these events were preventable. These incidents should be informed or notified to the health services managers so that preventive measures can be carried out with the objective of reducing this demand. Incidents can be classified into incident without damage, incident with damage (it is observed the occurrence of the adverse event) and "*near miss*" (could have hit the patient, but it was intercepted in advance from the occurrence of the damage and it can also be called potential adverse event)[4].

The voluntary or spontaneous notification is the most widely adopted method to collect information about the incidents, and it becomes extremely helpful with the involvement of the whole health staff, with emphasis to the nursing staff, responsible for the largest numbers of notifications. Fact justified by the greater permanence beside the patient and frequent trainings about the importance of the care provision register. However, the difficulty found by this voluntary or spontaneous method is the underreporting, a common characteristic found in several countries, and it occurs due to several factors, such as, for example, fear, guilt, shame and punishment, the fear of receiving criticism from others in addition to the dispute and the difficulty in performing a notification in relation to what to report, the type of notification system, the existence of incentives and obstacles[4].

It is well known that in the hospital context, the use of drugs is a complex system and several health professionals from different areas are involved (physicians, nursing staff, pharmacists and pharmacy technicians). Thus, the medication error may be involved with the professional practice, and it includes flaws in the prescription, in the preparation, dispensation, distribution, administration and education, and use of medicines[5-6].

It is necessary to emphasize that nursing is involved in the direct care to the patient, being responsible for the steps of preparation and administration of medicines, one of the activities of greatest relevance to the team. Failures that were not detected during the process, often are assigned to the team that holds the last opportunity to interrupt an error[7].

Factors such as work overload, inadequate environment, a deficit of professional training, communication failures, non-adherence to protocols and incorrect handling of medicines often work as triggers for the occurrence of medication errors[5]. However, there is a tendency to the detail of the errors concerning the nursing staff, due to the fact that these do not entail serious consequences to patients, resulting in underreporting. In addition to this belief, it is possible to consider the fear of ethical-legal sanctions as one of the reasons for the underreporting by the staff[4-5].

There is a subgroup of medications that can increase the possibility of significant damages to the patient, although it is known that any medication used improperly can result in adverse impact on them. These medications are classified as potentially dangerous drugs (PDD) - Annex 1, this designation was proposed by the Institute for safe practices in the use of medications (ISPM), which provides an updated list of PDDs based on event reports submitted by two tools: The MEDMARX International Reporting and the program of the own ISPM named Medication Error Reporting[8].

The PDDs can be considered high risk medicines and should receive special attention when planning actions of prevention measures and reduction of errors are proposed. Medication errors that involve PDDs are extremely complex and serious in a hospital environment compared to the ambulatory environment. The patient who is in a hospital environment is subjected to therapeutic procedures of greater complexity and aggressiveness. Therefore, it is necessary that there are methods and measures of preven-

tion in the entire chain of medication use, which includes: packaging, identification, storage, prescribing, dispensing, preparation and administration[9].

Therefore, the importance in identifying and analyzing the incidents that involve the PDDs such as ARM, TI, TC or even an adverse event, highlight the need of conducting studies on the subject, once an incident with a PDD can lead to a permanent or fatal injury to the patient, increasing the time of hospitalization and consequently the hospital expenses.

The objective of this study was to analyze the reports of incidents related to potentially dangerous medications distributed in a teaching hospital in the interior of São Paulo.

METHODS

This is a descriptive and retrospective study. The source of secondary data was the database of notifications received by the Hospital Sentinela and the Patient Safety Center of a general hospital, of public character, from the university and teaching in the interior of São Paulo. The analysis of the notifications of medicine corresponds to the period from January 2009 to December 2014.

The technical notifications of complaints, adverse reactions to medication and inadequate treatment received by the area of pharmacovigilance in hospitalization units, intensive care and emergency were included. Other notifications of medications related to care provision have been included from 2014 on, because it was in this year that there was the creation of the Patient Safety Center in the hospital.

All data concerning the number of notifications related to DPPs were analyzed and tabulated; as well as the number of technical complaints, ARM, TI and other notifications related to potentially dangerous medicines; notifiers according to professional category; notifications by hospitalization units of the hospital; profile of patients, age and sex, involved in the notifications; number of notifications by pharmacological groups of DPPs in accordance with the first level of classification *Anatomical Therapeutic Chemical* (ATC); number of notifications of potentially dangerous drugs per month, during the study period; occurrences related to technical complaints of DPPs (inadequate bottle, broken pill, empty blister, foreign body, aspect different from the usual, among others).

The data were tabulated by the Software Microsoft Office Excel 2007, being performed a descriptive analysis of the data from tables and graphs, showing the Absolute/Relative frequencies and percentages.

This research is derived from a monography of the "Programa de Residência Multiprofissional em Saúde do Adulto e do Idoso" (Multiprofessional Residency Program in Adult and Elderly Health[10] and it was approved by the Ethics Committee of the Medical School of Botucatu under protocol No. 2382/15.

RESULTS

In the period studied, 786 notifications in the area of pharmacovigilance were analyzed. Of this total, 188 (23.9%) were notifications related to potentially dangerous medicines. It is worth highlighting that the total number of notifications received in the interval of the study was 1971, being 786 (39.9%) of pharmacovigilance.

In relation to the DPPs notifications, 69 (36.7%) are related to the ineffectiveness of the therapy (TI), 61 (32.44%) to technical complaints (TC), 30 (15.95%) to the adverse reactions to the medication (ARM), 14 (7.44%) to notifications of phlebitis, 10 (5.13%) of extravasation, two (1.06%) of error of dispensation, one (0.53%) of administration errors, one (0.53%) of medication error.

The professionals responsible for the notifications were 78 (41.49%) nurses, 54 (28.73%) physicians and 31 (16.49%) pharmacists and 25 (13.29%) professionals who did not identify themselves.

The hospitalization units that performed notifications related to DPPs are surgical centers 44 (23.40%), central pharmacies 24 (12.76%), computed tomography sectors 19 (10.10%), adult ICU 11 (5.85%) and coronary ICU 10 (5.31%), as illustrated in figure 1.

According to analysis of the profile of patients who used the DPPs, the data obtained show that 226 (28.72%) are males and 226 (28.72%) are females, 75 (9.57%) of the notifications do not show the patient's sex and 259 (32.97%) notifications of DPPs are technical complaints, consequently, they were not used in patients, therefore it is not applied the definition of sex.

Still according to the profile of the patient, the age group, observed in the notifications, was of 10 (5.31%) notifications from zero to 12 years old, six (3.19%) from 13 to 18 years old, 61 (32.44%) from 19 to 59 years old, 43 (22.87%) from 60 years old on and six (3.19%) do not show age, as seen in figure 2.

Table 1 shows the ATC classification *(Anatomical Therapeutic Chemical)* of the medicines. It was found that the most frequent occurrences are related with medicines that act on: N - Nervous System 67 (35.63%); V- Several 30 (15.95%); C – Cardiovascular System 29 (15.42%) and B - Blood and hematopoietic organs 28 (14.89%).

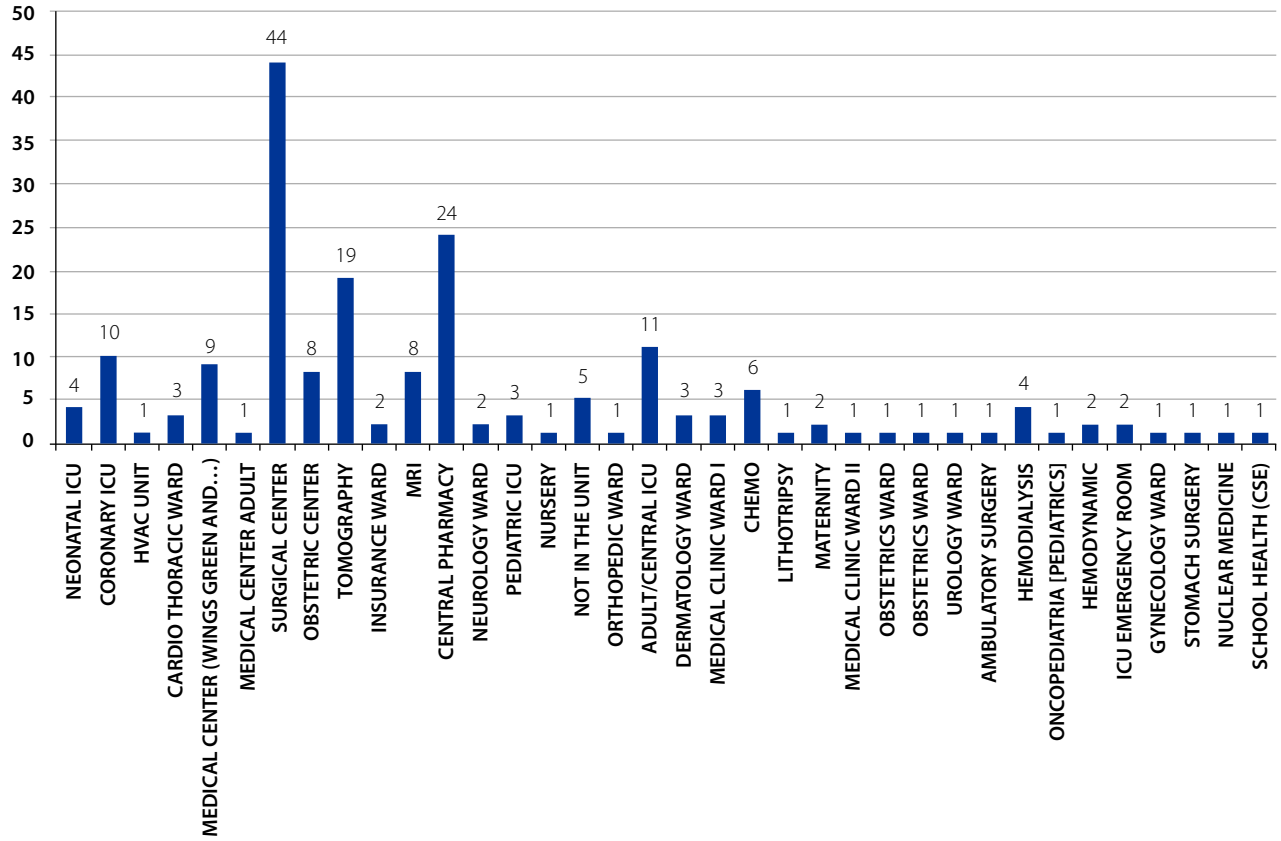

Figure 1 - Rate of incidents notifications related to the DPPs by Sector/Hospitalization Unit. Botucatu, SP, Brazil, 2014
Source: Research data, 2014.

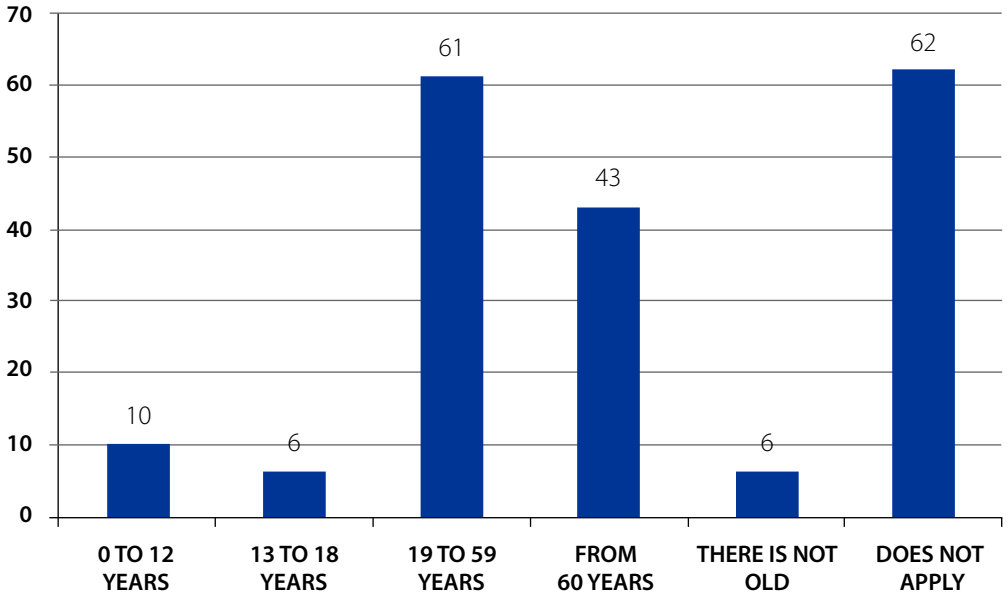

Figure 2 - Distribution of DPPs notifications by age of hospitalized patients. Botucatu, SP, Brazil, 2014
Source: Research data, 2014.

Table 1 - Distribution of DPPs reported in the area of Pharmacovigilance in accordance to the ATC categorization (*Anatomical Therapeutic Chemical*). Botucatu, SP, Brazil, 2014

ATC Classification*	n	%
- Digestive tract and Metabolism	6	3.19
B - Blood and hematopoietic organs	28	14.89
C - Cardiovascular System	29	15.42
H - Systemic hormonal preparations, excluding sex hormones and insulin	3	1.59
L - Antineoplastic and immunomodulating agents	8	4.25
M - Musculoskeletal system	1	0.53
N - Nervous system	67	35.63
P - Antiparasitic, insecticides and repellent products	1	0.53
R - Respiratory Tract	2	1.06
V - Several	30	15.95
Unclassified	13	6.91
Total	**188**	**100**

Source: Research data, 2014.
Caption: *ATC - *Anatomical Therapeutic Chemical*

In relation to the studied period, according to figure 3, the years that had the greatest number of DPPs notifications were 2014 with 49 (26.06%) and 2009 with 43 (22.87%).

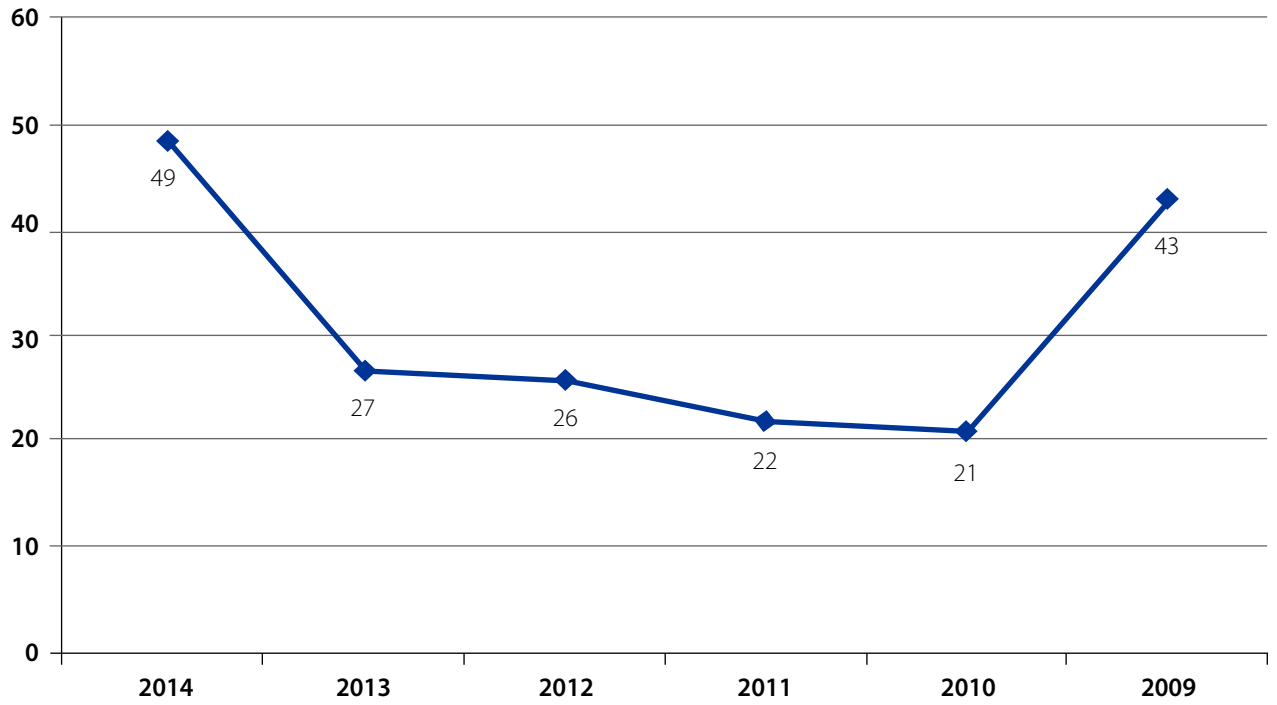

Figure 3 - Annual distribution of Pharmacovigilance notifications of DPPs. Botucatu, SP, Brazil, 2014
Source: Research data, 2014.

The most reported technical complaints related to DPPs were flask or ampoule without label 13 (21.31%), followed by the difficulty of the bottle seven opening (11.47%), as shown in table 2.

Table 2 - Distribution of Pharmacovigilance notifications of DPPs technical complaints according to the type of occurrence. Botucatu, SP, Brazil, 2014

Description of the occurrences of technical complaint	n	%
Flask/ampoule without label	13	21.31
Difficulty opening the flask/ampoule.	7	11.47
Presence of foreign body	5	8.19
Different coloring from the usual	5	8.19
Content below than the one described on the packaging	5	8.19
Inadequate bottle	4	6.55
Different aspect from the usual	4	6.55
Broken or missing ampoule inside the sealed box	4	6.55
Lack of pills inside the blister	4	6.55
Absence of product in the flask/ampoule.	3	4.90
Broken pill	2	3.27
Leakage	2	3.27
Content above than the one described on the packaging	1	1.63
Bottle with problems	1	1.63
Difficulty to inhale the contents of the flask	1	1.63
Total	**61**	**100**

Source: Research data, 2014.

DISCUSSION

There was a total of 786 notifications, equivalent to an average of 131 notifications per year. Compared to another study, conducted in a teaching hospital in the interior of São Paulo, it is possible to observe a similar result in which the total number of notifications recorded in a period of one year was 113[5].

In a study conducted in a teaching hospital of Ribeirão Preto, in 2012, it was recorded during a period of 6 months 48.7% of notifications related to potentially dangerous medicines. In our study, it was observed a smaller percentage of 23.9%. This may reveal that one of the factors possibly responsible for the low number found may be the underreporting[4].

The majority of studies found that involve the DPPs are those that specifically analyze medication errors related to this class. It has not been found, for example, studies on other adverse events of potentially dangerous medicines such as ARM, TI and the TC. Only from 2014 on, the period of deployment of the Patient Safety Center in the Hospital of this publication, it was possible to identify notifications on medication error (ME). Therefore, the available literature is of character and general content of medications, and not only on DPPs, which hindered the comparison with the findings of this study.

In a hospital located in Paraíba, a study was conducted on the notifications sent to Risk Management. In this case, only the ARM and TC notifications were used as the primary source of data. Notifications of greatest prevalence are TC (61.8%) and ARM (38.2%). It is not included in the study the TI notifications[11]. At the place where this research was conducted, it was also possible to observe a greater quantity of TC notifications in relation to ARM. According to the NOTIVISA (System of Notifications in Health Surveillance) database, the evolution of the notifications, in the period from 2006 to 2013, show that the TC obtained a higher number in all the years analyzed. Perhaps the reason for the lower number of ARM notifications can be explained by the difficulty in recognizing and making sure that the occurrence presented by the patient is derived from a possible ARM[12].

In the hospital studied, it is observed that the professional category predominantly responsible for the notifications registered during the period of this research was Nursing. In a study conducted in a teaching hospital located in the interior of the state of São Paulo, it was possible to also check that most of the notifications were performed by the Nursing professional[5]. According to Capucho, this professional is the majority in a hospital institution and remains for a longer time in contact with the patients, justifying the predominant category in relation to the notification of incidents. In addition, the nursing tends to notify more than the medical staff due to time constraints, uncertainty about what to report, fear and lack of awareness on the part of the medical staff[4].

Another factor that justifies this finding is the fact that the nursing team is involved in most of the cases involving the administration of medicines. A study carried out in a hospital located in the South of Minas Gerais showed that professionals who have made more errors were nursing technicians responsible for 68.5% of the notifications[7]. Another study showed that 51.3% of the errors reported were related to the correct five (patient, medication, dose, administration and right schedule) stages of preparation and administration of medications that are often performed by nursing[5].

In relation to the hospitalization units/sectors that most notified, the surgical center stands out, with the highest number of notifications, followed by the central pharmacy, tomography and central ICU. In another study, carried out in a hospital of similar profile, located in the south of Minas Gerais, it was observed that the sector that notified the most in 2012 was the medical clinic. The surgical center was the second sector with the highest number of notifications. Another sector that stood out and that also presented a high number of notifications was the pediatric ICU[7]. Other literature data showed that the sectors that notified the most were also the medical clinic and hospital pharmacy[13]. Therefore, it is possible to observe a similarity of prevalence among the units that most notify to the pharmacovigilance.

The distribution of notifications related to the sex of the patient shows equality between the genders. Besides the gender of the patients, it was observed a significant notification occurrence of the adult age group (19 to 59 years old) and elderly, showing greater care provision in the areas involved in order to prevent or reduce the incidents related to care and/or health products, including medicines.

A study by the Fortaleza Hospital, conducted in 2007, used as a secondary source the ARM suspicion files. The research showed a predominance of male patients (81.8%). In addition, in the same study, in accordance with the age of the patients, the most predominant age group was between 15 to 29 years old and 30 to 59 years old, thus showing similarity with the data obtained[14]. In other Brazilian studies, it was observed similar data from notifications between genders and predominance of age above 40 years old[5,15]. Eventually, this similarity can be explained by the greater prevalence of population in this age group. According to IBGE, in 2010, 55.9% of the Brazilian population is in the age range from 20 to 59 years old[16].

After the categorization of the medications in accordance with the ATC classification, in our study it was possible to identify that the most notified groups were: N (Nervous System), V (Several), C (Cardiovascular System) and B (Blood and Hematopoietic Organs). At the Clinical Hospital of Porto Alegre (HCPA), by means of a retrospective cross-sectional study, in which were analyzed notifications of medication errors during the period of two years, it was observed that the medicines that appear the most are also group N and B medicines[17]. The results show that the health staff must be attentive and adopt measures for the prevention or reduction of damage to the nervous and cardiovascular systems.

The technical complaint notified the most was related to the packaging of the medicine about the absence of a label on the flask or ampoule. It is in the label the information that allows traceability of the product, such as the name of the medication, dosage, batch, manufacturing date, expiration date, responsible pharmacist, laboratory, among others. Another type of TC reported with frequency, also related to the medication packaging, was the difficulty of opening the flask or ampoule. In a survey of the Pharmacovigilance notifications in the Clementino Fraga Filho Teaching Hospital, of the Federal University of Rio de Janeiro and the Clinical Hospital of Porto Alegre, also showed similar occurrences, corroborating our findings[18].

Concerned about the safety of the patient, the ISMP (Institute for Safe Practices in the Use of Medications), from the United States, performs consulting to databases of medication errors notifications regularly. On these occasions, the reports in the literature about mistakes that have resulted in harmful consequences to the patient are evaluated. In addition, studies are held to identify which medications are most frequently involved in medication errors[19].

In Brazil, the Law 13.236 of 29 December 2015, amending the Law 6.360 of 23 September 1976, has the purpose to establish measures to inhibit medication errors[20]. The new law stipulates new rules for packaging and labeling of medicines. One of the determinations is the differentiation of medicines for child and adult use. Thus, medicinal products for pediatric use must have specific characteristics that

allow the immediate and accurate distinction of medicinal products for adult use. In addition to this measure, others will also be required as, for example, the clear differentiation of medicines by means of labels and packaging[19].

From this study, in which it was possible to identify the DPPs involved in notifications of occurrences, new strategies should be adopted in the hospital to reduce or prevent medication errors and adverse events regarding these medications.

Besides the monitoring of adverse events and technical complaints, other measures should be adopted as the introduction of barriers that reduce the occurrence of errors (example: identification of DPPs to be dispensed to hospital units), use of protocols and communication standardization on the treatments, supply and improvement of access to information, centralization of processes considered of greater risk of errors, the incorporation of automatic alerts in computerized systems, use of procedures of dual checking of medications, among others[17].

Thus, it becomes evident the importance of monitoring occurrences involving medicines, especially DPPs, and the need for the adoption of preventive measures in health care, in order to ensure the rational use of medicines and, mainly, the patient safety.

CONCLUSION

It is concluded that the number of notifications in the area of pharmacovigilance was expressive, being that nearly a quarter of these occurrences was of potentially dangerous medicines.

The notification types that had higher occurrence rates were ineffective therapy, technical complaints and adverse reactions to medicines. The professionals who performed the highest number of notifications were nurses, doctors and pharmacists; and the notifying units were the surgical center, pharmacy and the tomography sector.

The predominant group of medicines was that of the nervous system. In relation to the age of the patients involved in adverse events, predominated the adult age, followed by the elderly.

The most reported technical complaints were the flask or ampoule without label and the difficulty of the bottle opening.

In addition, through the monitoring of notifications it will be possible to adopt preventive strategies regarding the safe use of medicines, especially for potentially dangerous drugs, thus ensuring greater patient safety.

This study presents limitations because it was not found specific studies on potentially dangerous medicines, which made it difficult to compare the data with greater detail. However, the studied period preceded the creation of the Patient Safety Center, preventing the identification of medication errors notifications.

It is worth mentioning that the notifications received after this period are still being registered, analyzed and tabulated in the database. As the study focused on the period before the implementation of the Patient Safety Center, the data after this date will result in further research.

On the other hand, the findings of this study may contribute to the adoption of preventive measures in health care, in addition to providing data for research foundation, since it is still a subject little explored.

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