MEDICATION DISPENSING ERRORS AT A PUBLIC PEDIATRIC HOSPITAL

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Objective: assess the safety of medication dispensing processes through the dispensing error rate. Method: Cross-sectional study carried out at a pharmaceutical service of a pediatric hospital in Espírito Santo, Brazil. Data collection was performed between August and September 2006, totaling 2620 prescribed medication doses. Any deviation from the medical prescription in dispensing medication was considered a dispensing error. The categories of medication errors were: content, labeling, and documentation errors. The dispensing error rate was computed by dividing the number of errors by the total of dispensed doses. Results: From the 300 identified errors, 262 (87.3 %) were content errors. The rate of errors in the labeling and documentation categories was 33 (11%) and 5 (1.7%), respectively. Conclusion: The total dispensing error rate was higher than rates reported in international studies. The most frequent category was “content error”.

DESCRIPtoRES: medication errors; pharmacy; medication system; pharmaceutical care

ERRORES DE DESPACHO DE MEDICAMENTOS EN UN HOSPITAL PÚBLICO PEDIÁTRICO

Objetivo: Evaluar la seguridad en el despacho de medicamentos a través de la determinación de la tasa de errores de despacho. Métodos: Estudio transversal que evaluó 2620 dosis de medicamentos despachados entre agosto y septiembre de 2006 en un servicio de farmacia de un hospital pediátrico del Estado de Espíritu Santo, Brasil. Los errores de despacho fueron definidos como cualquier desvío ocurrido entre lo despachado y lo prescrito en la receta médica. Los errores fueron categorizados en contenido, rótulo y documentación. La tasa de error de despacho fue calculada dividiendo el número de errores total por el número total de dosis despachadas. Resultados: de los 300 errores identificados, 262 (87.3 %) fueron de contenido. En las categorías errores de rótulo la tasa fue de 33 (11%) y 5 (1.7%) en la de errores de documentación. Conclusión: la tasa total de errores de despacho fue elevada cuando se compara con la descrita en estudios internacionales. La categoría de error más frecuente fue la de "error de contenido".

DESCRIPtoRES: errores de medicación; farmacia; sistemas de medicación, atención farmacéutica

ERROS DE DISPENSAÇÃO DE MEDICAMENTOS EM UM HOSPITAL PÚBLICO PEDIÁTRICO

Avaliar a segurança na dispensação de medicamentos através da determinação da taxa de erros de dispensação constitui o objetivo deste trabalho. O método utilizado foi o estudo transversal que avaliou 2 620 doses de medicamentos dispensados entre agosto e setembro de 2006, em um serviço de farmácia de um hospital pediátrico do Espírito Santo. Os erros de dispensação foram definidos como qualquer desvio entre o dispensado e o prescrito na receita médica. Os erros foram categorizados em conteúdo, rotulagem e documentação. A taxa de erro de dispensação foi calculada dividindo o número de erros total/total de doses dispensadas. Os resultados mostraram que, dos 300 erros identificados, 262 (87,3%) foram de conteúdo. Nas categorias erros de rotulagem a taxa foi de 33 (11%) e 5 (1,7%) na de erros de documentação. Concluiu-se que a taxa total de erros de dispensação foi elevada quando comparada à descrita em estudos internacionais. A categoria de erro mais frequente foi a de erro de conteúdo.

DESCRIPtoRES: erros de medicação; farmácia; sistemas de medicação, assistência farmacéutica
INTRODUCTION

Medication error is a difficult topic to address. Discussions about it are generally directed at seeking the culprit and do not provide system improvement opportunities with a view to preventing failures (1). Some authors suggest that the occurrence of errors in different social and professional systems might originate in system failures (systemic errors). Medication errors are considered human errors and, thus, can be caused by these failures (2-4). They represent a severe social and health problem with important economic repercussions (3) and are classified as medication prescription, dispensing and administration errors. Dispensing errors occur during the medication dispensing process (4-6).

Literature suggests that the incidence of medication errors in pediatrics is twice or three times as high as in adults, and also that pediatric patients are at higher risk of death when compared to adults (7-11). These errors also represent an important economic cost and measures to reduce and prevent them are necessary (2,10). Discovering their frequency and defining ways to prevent them is an important strategy to reduce risks, especially in special populations like children. The Brazilian Health Surveillance Agency (ANVISA) recently included medication errors in its pharmacosurveillance program as a strategic area for patient safety in the process of medication use (4).

The pharmacy service is responsible for the safe and efficient use of medication in hospitals and plays an essential role in integrating the prescription, dispensing and administration processes and should have policies and procedures to prevent errors (4-5,8). The rate of errors is considered one of the best indicators of quality of medication distribution systems and is still used to evaluate the safety of these systems (4,6,9).

Some studies, published in the United States and England, showed an incidence of dispensing errors of about 10%, even in hospitals with advanced medication distribution systems, such as unit doses (7,11).

A few studies were carried out in Brazil, specifically on medication dispensing processes, and presented high rates of errors, above 10% (5,8). In the pediatric area, especially in Brazil, no study was found on dispensing errors and, to date, their cause and epidemiology are unknown.

Therefore, this study aims to evaluate the dispensing process of the pharmacy service at a public pediatric hospital. Important indicators were used to measure the dispensing process and the rate of total dispensing errors was the global indicator of its quality.

MATERIAL AND METHODS

Study design

Cross-sectional, descriptive study, carried out in the dispensing sector of the Pharmacy service at a public pediatric hospital in Espírito Santo, Brazil from August 25 to September 20, 2005.

Characteristics of the study site

Public pediatric hospital with 96 beds distributed in three hospitalization units; pediatric outpatient, neonatal and pediatric intensive therapy unit, surgical center and emergency care. The Pharmacy service is divided in the following sectors: material and medication storage, dispensing, total parenteral feeding, and medication splitting.

Description of the medication distribution system

Dispensing medication is performed through a mixed distribution system (collective and individual doses) for a period of 24 hours. Medication is dispensed through carbonated copy of medical prescriptions to the nursing wards. The prescription copies are collected by the pharmacy technicians in the hospitalization units until 11am, and are forwarded to pharmacists for interpretation and evaluation. In this stage, the pharmacist, when possible, evaluates dosage, administration route, frequency of administration, duration of treatment, etc. After evaluating the prescription, the pharmacy auxiliaries separate medication dosages and put them in plastic bags. The plastic bags are put in the dispensing sector and then forwarded to pharmacists for checking.

After identification and correction of potential errors in the preparation of dosages by the pharmacists, medications are separated for each unit and the nursing auxiliaries go to the pharmacy and check, for the second time (control), after which the medication is forwarded to the units until 3pm.

The medications are dispensed in different pharmaceutical presentations according to the prescriptions (injectable, oral solid, oral liquid, semi-
solid, etc), put in plastic bags and identified with the drug name according to the Brazilian Common Denomination (DCB), dosage, lot number and expiration date. These medications are usually bought from the industry in blisters, glass or plastic containers. Oral solutions, elixirs, syrups, oral suspensions, creams, ointments and lotions are dispensed by the distribution system by unit dose, while parenteral medications and sterile liquids, suppositories, ophthalmic, auricular, nasal and oral preparations, aerosols and inhalants are collectively dispensed in their original packages.

Inclusion criteria

All dispensed medication in solid presentation for oral use, oral solutions, elixirs, syrups, oral suspensions, creams, ointments, lotions, ophthalmic, auricular, nasal and oral preparations, aerosols, parenteral solutions of small volume, inhalants and medication not standardized in the hospital, but available at its pharmacy.

Exclusion criteria

- prescribed medication that was out of stock in the hospital during the period of data collection;
- medication illegibly prescribed;
- medication that was dispensed but the researcher did not observe its preparation or separation and dispensing.

Sample

The sample was composed of 239 prescriptions that met the inclusion criteria. The selection and dispensing of 655 medications, totaling 2620 doses, were followed between August 25 and September 20, 2005 at a pediatric hospital in Espírito Santo, Brazil.

Pilot Test

To estimate the sample and validate the data collection form, 10 medical prescriptions per day were randomly selected for five days (10 prescriptions were randomly drawn from each 30 that arrived at the pharmacy), totaling 50 prescriptions during the pilot test. A total dispensing error rate of 10% was found in the pilot sample, considering approximately 5% of precision, 95% of confidence interval, and prevalence of 10%. The sample size was 139 prescriptions + 10% of losses = 153 prescriptions.

Data collection

Data collection was carried out between August and September 2005 in two stages: before and after the pharmacist’s inspection, when inspection was performed. Thus, errors of pharmacy technicians when preparing medications and errors of pharmacists when dispensing were identified. The prescriptions were randomly selected during the study period. Each day, 20 prescriptions were randomly drawn, totaling 239 prescriptions during data collection. After selection, prescriptions were identified with a number for posterior evaluation of errors. After pharmacy technicians prepared medications, the medication name, concentration, dosage form and quantity prepared were recorded in a data collection form. The same procedure was performed after the pharmacist’s inspection, before medications were sent to the units. Because there was no access to the prescriptions at the moment of data collection, the researchers had no previous knowledge of dispensing errors. Medications with questionable quality (altered color, violated container, no label, disintegrated or fissured solid oral) or with expired date were reported to the pharmacist and were not considered errors. A pharmacist, with more than two years of experience in hospital pharmacies, and a pharmacy student collected data; the main researcher previously trained both.

Variables Operationalization

Errors were classified according to the criteria used in a previous study in:

Content errors

Incorrect medication – Drug dispensed differs from the one prescribed. Excluding therapeutic substitution of medication due to hospital standards or procedures;
Incorrect concentration – dispensing drug with correct quantity of medication (Mg or mL) but with incorrect adjustment of dosing instructions;
Incorrect dosage form – Dispensing correct medication but in a dosage form different from that prescribed. It includes providing a modified release formulation when a standard formulation was prescribed;
Dose added – Dispensing a larger quantity of medication (in number, units, or times a day) than that prescribed.
Missing doses – Dispensing a quantity smaller (in number, units, or times a day) than that prescribed.
Omission of medication – not dispensing the prescribed medication;
Deteriorated medication – Dispensing expired medication or medication stored in inappropriate temperature (not complying with the manufacturer’s specifications) or medication whose primary package was damaged;
Other errors of content – All other errors not included in previous categories.

Labeling errors

Incorrect patient’s name – Omitting the patient’s name or name different from the one in the medical prescription.
Incorrect name of medication – The name of the medication on the label is different from that prescribed, except when observations are necessary to comply with the hospital standards (e.g. prescription with brand name and dispensation by generic name);
Incorrect dosage of medication – Dosage of medication on the label is different from the one prescribed, when more than a dose is available on the market, except when observations are necessary to comply with the hospital standards;
Incorrect quantity of medication – Quantity of medication on the label is different from prescribed, expect when adjustments are necessary to comply with the hospital standards;
Incorrect dosage form – the dosage form on the label is different from the one prescribed (e.g. tablets dispersed as capsules);
Incorrect date – omission of dispensing date or wrong dispensing date;
Incorrect instructions – Instructions different from those prescribed, except when adjustments are necessary to comply with the hospital standards (e.g. take the medication after meals);
Additional warning – Omission or incorrect use of warnings according to the bibliographic references.
Pharmacy address – Fail to include the correct pharmacy address on the label;
Other labeling errors – Any labeling error not included in the previous categories; for instance, illegible name or number.

Documentation errors

Absent or incorrect controlled medication documentation – Absent or incorrect documentation of controlled drug registration according to law;
Other documentation errors – Any documentation errors not included in the category above.

Statistical analysis

Statistical Package for the Social Sciences (SPSS Chicago - IL, version 9.0, 1998) was used to build the database and make statistical calculations. Categorical variables were expressed as proportions (relative frequency).

Ethical aspects

This study was approved by the hospital direction. The pharmacists and pharmacy technicians filled out the informed consent term, allowing the observation of dispensing activities, and were informed about the study aims to evaluate the dispensing system. They were not aware of the objectives and method used; these aspects were kept blind to the pharmacy team to avoid known biases[6-7]. All errors that occurred during the study were codified and kept confidential. They were corrected only after the last control performed by the pharmacist-researcher[7].

RESULTS

During the study, 239 prescriptions were evaluated and included 655 prescribed medications, totaling 2620 dispensed doses.

The total rate of errors including the three criteria (content, labeling and documentation errors) was 11.5% (300 errors/2620 doses). Table 1 shows the frequency of dispensing errors in each of the categories. The content category presented the highest rate of error, followed by labeling and documentation errors.

Table 1 – Distribution of errors by category at a pediatric hospital in Espírito Santo, Brazil - 2005

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of errors</th>
<th>% of errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content error</td>
<td>262</td>
<td>87.3</td>
</tr>
<tr>
<td>Labeling error</td>
<td>33</td>
<td>11.0</td>
</tr>
<tr>
<td>Documentation error</td>
<td>05</td>
<td>1.7</td>
</tr>
<tr>
<td>Total</td>
<td>300</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2 presents the results for the category “content errors”. The most frequent errors in this category were “too high doses”, “missing doses” and
omission errors; incorrect dosage and deteriorate medication errors were not registered. On the other hand, the most common errors in "labeling errors" were the subcategory "other labeling errors" and "incorrect dosage", as shown in Table 3. There was no occurrence for the items: medication name, quantity, pharmaceutical presentation, date, instructions, warning, and incorrect pharmacy address.

Table 2 – Distribution of errors according to the category “content errors” at a pediatric hospital in Espírito Santo, Brazil – 2005

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Number of Errors</th>
<th>Frequency of Errors (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect medication</td>
<td>01</td>
<td>0.38</td>
</tr>
<tr>
<td>Incorrect pharmaceutical presentation</td>
<td>03</td>
<td>1.15</td>
</tr>
<tr>
<td>Dose Added</td>
<td>75</td>
<td>28.62</td>
</tr>
<tr>
<td>Missing doses</td>
<td>130</td>
<td>49.62</td>
</tr>
<tr>
<td>Omission</td>
<td>40</td>
<td>15.27</td>
</tr>
<tr>
<td>Other content errors</td>
<td>13</td>
<td>4.96</td>
</tr>
<tr>
<td>Total</td>
<td>262</td>
<td>100</td>
</tr>
</tbody>
</table>

The total error rate of the category "labeling error" was 1.7%. The most frequent errors in this category were: "other labeling errors" with 75% and "incorrect dosage" with 21.2%. (Table 3).

Table 3 – Distribution of errors according to the category "labeling errors" at a pediatric hospital in Espírito Santo, Brazil – 2005

<table>
<thead>
<tr>
<th>Type of error</th>
<th>Number of errors</th>
<th>Frequency of errors (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect patient’s name</td>
<td>1</td>
<td>3.03</td>
</tr>
<tr>
<td>Incorrect dosage</td>
<td>7</td>
<td>21.21</td>
</tr>
<tr>
<td>Other labeling errors</td>
<td>25</td>
<td>75.76</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>100</td>
</tr>
</tbody>
</table>

The occurrence of errors in the "documentation errors" category was classified according to criteria included in Table 4. There were errors of absent or incorrect documentation of control in two cases, which represents 40% of errors in this category.

Table 4 – Distribution of errors according to the category "documentation errors" at a pediatric hospital in Espírito Santo, Brazil – 2005

<table>
<thead>
<tr>
<th>Type of error</th>
<th>Number of errors</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent or incorrect control documentation</td>
<td>02</td>
<td>40%</td>
</tr>
<tr>
<td>Other documentation errors</td>
<td>03</td>
<td>60%</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>100%</td>
</tr>
</tbody>
</table>

DISCUSSION

The total dispensing error rate, according to the adopted classification system (content, labeling, and documentation errors), was 11.5% for the total of dispensed doses in the study period. This rate represents one error for approximately nine dispensed doses. Data analysis showed a much higher frequency in the criterion "content errors" 87.3% (262/2620). This higher predominance is due to the fact that errors occur more often during the dispensing process itself than during the labeling and documentation of this activity(3).

When the criterion "content errors" is separately analyzed, the most frequent errors were "too high doses" and "missing doses" with 49.6% and 28.6%, respectively. These data are in accordance with other studies that appoint that dosage errors are the most frequent in pediatrics. Considering only the contribution of this category (content errors) in the total error rate by dispensed doses, an error rate of 10% is found, that is, almost the total error rate found in the sample.

The categories ‘labeling errors’ and ‘documentation errors’ represented 11% and 1.7% of the errors, respectively. In the category ‘documentation errors’, the absence of documentation was the most common error. There are different methods to evaluate dispensing errors, which makes it difficult to compare results between different studies(14). In the study sample, the total error rate was considered high when compared with other studies using a similar method(4-5,10). The causes of errors presented in this study can be of several origins, which require a deeper evaluation with qualitative studies, though some critical points can be raised as possible causes. An important point observed is that, most of the times, the pharmacist did not check doses prepared by pharmacy technicians. Despite the adequate rate of pharmacists per number of beds (30:1), it was verified that the pharmacist’s actions are focused on the administrative aspect of the dispensing process, and not on its care. There is strong evidence that the distribution system of unit doses can reduce the error rate and increase safety in the medication use process(4-8).

Another interesting aspect is that part of the doses is dispensed in 'unit doses'; that is, they are ready for use, with no need for manipulation before administering medication, which represents an
improvement. However, the adopted system does not allow for a reduction in dispensing errors because there are no rigid controls. The majority of errors can be avoided if a distribution system concentrating the process of dosage preparation in the pharmacy service is in place and the pharmacist checks the prescription before it is dispensed\(^4\to^5\). On the other hand, effective interaction between the nursing and the pharmacy services is essential because many errors that occur during the dispensing process can be avoided at the moment the medication is administered by the nurse. A multicenter study involving four hospitals in different regions of the country identified high error rates during medication preparation and administration. Authors suggest that, to improve safety of medication distribution systems, changes need to be adopted in the institutional culture with a view to solid improvements\(^9\).

Results of two Brazilian studies on dispensing errors in adult hospitals showed very high error rates (13.8% and 17%), although pharmacists inspected the doses prepared by auxiliaries in both studies\(^5\to^8\). However, one has to be careful in making comparisons between these two studies because there is an important methodological difference in error classification\(^7\to^10\).

This study presents some limitations, the main of which is that one cannot generalize its results to other hospitals of the same size and specialty, because there are other important variables that can influence the dispensing error rate. Another issue is that a representative sample of Brazilian public hospitals was not used, considering number and type of clinical units as well as their complexity level\(^4\).

**CONCLUSION**

The total dispensing error rate in the study sample is high when compared to international studies\(^12\to^13, 15\). The most frequent error category was the "content error", while "missing doses" and "wrong dose" were the most prevalent in this category. The categories "labeling error" and "documentation error" represented a small influence on the total error rate. Further research is necessary to evaluate this issue, not only on medication dispensing but also on administration and prescription.

**REFERENCES**