Root cause analysis: evaluation of medication errors at a university hospital*

Thalyta Cardoso Alux Teixeira¹, Silvia Helena De Bortoli Cassiani²

ABSTRACT
The objectives of this study were to identify and analyze the types of medication errors observed in doses prepared and administered differently from those prescribed. It is a descriptive study using the root cause analysis method, in which a secondary analysis of data from a previously existing investigation was performed. In the study, 74 medication errors were identified during medication preparation and administration by the nursing staff. Dose errors (24.3%), schedule errors (22.9%) and unauthorized medication administration errors (13.5%) were the most frequent. Hence, medication errors were identified, and root cause analysis was performed, leading to the identification of multiple factors that contributed to error occurrence. Strategies and recommendations were presented for the prevention of errors.

KEY WORDS

RESUMO
Os objetivos deste estudo consistiram em identificar e analisar os tipos de erros de medicação observados nas doses de medicamentos que foram preparadas e administradas de forma diferente daquelas prescritas. É um estudo descritivo, que realizou uma análise secundária de dados de um estudo já existente. O estudo identificou 74 erros de medicação durante a preparação e a administração de medicamentos pelo equipa de enfermagem. Erros de dose (24,3%), de horário (22,9%) e medicamentos não autorizados (13,5%) foram os mais frequentes. Assim, os erros de medicação foram identificados, e estratégias e recomendações foram apresentadas para evitá-los.

RESUMEN
Los objetivos de este estudio consistieron en identificar y analizar los tipos de errores de medicación observados en las dosis de medicamentos que fueron preparadas y administradas de modo diferente respecto del cual fueron prescritas. El estudio fue de carácter descriptivo, se utilizó el método de análisis secundaria de datos de un estudio ya existente. En el estudio, 74 errores de medicación fueron identificados durante la preparación y la administración de medicamentos por parte del equipo de Enfermería. Erros de dosis (24,3%), errores de horario (22,9%) y medicamentos no autorizados (13,5%) fueron los más frecuentes. Así, el análisis de causa raíz fue realizado, identificándose múltiples factores que contribuyeron para la ocurrência dos errores, y estrategias y recomendaciones fueron presentadas para evitarlos.

DESCRIPTORES

DESCRITORES

* Part of the thesis, “Análise de causa raiz: avaliação de erros de medicação em uma unidade de clínica médica de um hospital universitário”, University of São Paulo at Ribeirão Preto College of Nursing, 2007.¹ RN. MSc in Fundamental Nursing at University of São Paulo at Ribeirão Preto College of Nursing, Ribeirão Preto, SP, Brazil. thalytacat@hotmail.com ² RN. Full Professor at General and Specialized Nursing Department, University of São Paulo at Ribeirão Preto College of Nursing, Ribeirão Preto, SP, Brazil. shbcassi@eerp.usp.br
INTRODUCTION

Patient safety involves, in general, preventing errors in care and eliminating any harms to the patient due to those errors. Error in health care results from an unintentional action caused by some kind of problem or failure when providing patient care. That error can be committed by any health team member and can occur at any time of the health care process, as, for instance, in patient medication.

The culture of punishing the professional when medication errors are discovered remains in practice. Therefore, professionals often face disciplinary actions, humiliations, losing jobs, and legal repercussions when medication errors are reported, in addition to the emotional effects they experience, such as feeling guilty and incompetent.

Patient safety involves changing this culture to not punishing the professional and, also, adopting measures regarding the medication system. This way, errors could be reported by the professionals involved and notified so their causes could be investigated.

To help reduce the occurrence of errors, there is a need for health institutions to maintain a continuous careful analysis of the errors that effectively occur. Over the last years, there has been much talk about the investigation of medication errors, as it is essential to promote the reliability of the medication system as well as patient safety.

A method that is currently being used to analyze medication errors is root cause analysis. This method has been used in engineering, in the investigation of industrial, nuclear and aviation accidents, and recently in health institutions to improve patient safety. It was incorporated, in 1997, by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), a private American organization that provides hospital accreditation.

The root cause analysis method is not simple and consists of different techniques, which include barrier analysis, change analysis, Ishikawa diagram, Pareto analysis, cause trees, among others, to elaborate the causal chain based on a final unwanted result with the purpose of finding the root cause. In addition, the proposition of this method is not limited to simply finding the root causes, but in trying to solve the effective fact, with the purpose of preventing and avoiding new episodes from happening.

The United States Veterans Affairs National Center for Patient Safety – NCPS (2004) has worked extensively to develop the root cause analysis into an effective method to identify problems, analyze critical incidents and generate system improvements.

The objectives of the present study were to identify and analyze the types of medication errors observed in the medication doses that were prepared and administered differently from what had been prescribed and propose strategies and recommendations to avoid such errors.

METHOD

This is a descriptive study, of cross-sectional design to elicit the complete nature of the phenomena, performed with the objective to observe, describe, and document the aspects of the situation.

In this study a secondary analysis was performed on the data obtained in the study "Inquérito e análise dos erros de medicação em seis hospitais brasileiros" (Investigation and analysis of medication errors in six Brazilian hospitals) a quantitative, descriptive study, using cross-sectional design that was performed with the purpose to observe, describe, and document the aspects of situations regarding the administration of medications. Data collection was performed during 30 days, through direct and non-participant observation of the preparation and administration of the medications. The direct observation technique was used, as it has been described in the literature as the adequate method to detect medication errors. Results showed that 821 medication doses were observed at the hospital, the present study location, 70 of which contained 74 medication errors, i.e., some doses involved more than one error in their administration.
The present study analyzed the medication errors that occurred at an internal medicine unit of a tertiary public university hospital, located in Ribeirão Preto, São Paulo State.

The study universe consists of 70 medication doses that were prepared and administered differently from what had been prescribed, and containing 74 medication errors that were obtained by means of a database used in a previous study(10).

This study was approved by the Research Ethics Committee at the studied hospital and participants provided informed consent.

An instrument was formulated using the root cause analysis method, with the purpose of understanding what had happened and what factors were involved in the identified medication errors.

In the present study, an adaptation of two root cause analysis methods(4,6) was performed to analyze the medication doses. The first method originated from the Human Performance Enhancement System (HPES), from the energy companies of the United States, and the steps composing this method are the following: process of problem identification and description, analysis of the task, of the change and of control barriers, outlining the causes and problem factors, identifying the root causes, proposing recommendations to avoid the problem from occurring, and implementing the systems(4). In the present study, only the first step of this method was used.

The process of problem identification and description, which comprises the definition and data collection, has the objective to illustrate the identified problem, by describing what happened. Data collection can be performed by reviewing documents, observations and interviews. As soon as the problem was detected, a thorough description of what happened should be provided in an organized manner(4).

The second method used was that proposed by SOURCE, developed by the Department of Energy by the Westinghouse Savannah River Corporation, in 1991. The referred method defines that root causes are the basic causes that can be identified and manage and supervise the actions needed to correct errors, provide effective recommendations to prevent the recurrence of errors and involve four steps: data collection and preservation, causal factors charting, identifying the root causes and developing recommendations and implementation(6).

The steps used in the present study were: data collection and preservation, causal factors charting, and developing recommendations.

The objective of the process of data collection and preservation, as the name defines it, is to collect and preserve error data, as it occurred. With an effective data collection, the error can be illustrated and solved. The data should be obtained as soon as possible, after the error occurred, so as to prevent losses or changes to the data(6).

The causal factors charting is a simple diagram that permits investigators to describe the error from the beginning to the end, using a chart. The causal factors charting technique was originally developed by Ludwing Benner and colleagues in US National Transportation Safety Board to use in accident investigations. This technique was designed to help investigators to make a timeline to describe the events and the involved conditions(6).

Before making the recommendations, it is necessary to evaluate if the corrective action will prevent the recurrence of the event or condition and if it will be achievable according to the institution’s capacity of implementing it. Furthermore, corrective actions should be directed not only to the specific circumstances of the event, but also to the implementation of the system with the objective to reduce the frequency of the problem, reduce the involved staff’s exposition and minimize its consequences(6).

Hence, each medication dose that was prepared and administered differently from what had been prescribed was analyzed. Thus, the table with the frequency of the types of errors was presented in the results section. After performing the analysis of the root of cause analysis using the aforementioned instrument, the causal factors related with the occurrence of medication errors were identified and discussed, and strategies and recommendations were proposed to avoid such errors.

There are several definitions and classifications in the literature about the types of medication errors. Hence, in the present study, the types of medication errors were classified according to the definitions from the literature(10-11), as shown in Chart 1.
RESULTS AND DISCUSSION

Table 1 presents the distribution of the 74 medication errors, identified in the 70 medication doses that were prepared and administered differently from what had been prescribed.

Table 1 - Types of medication errors identified - Ribeirão Preto, SP - 2007

<table>
<thead>
<tr>
<th>Types of errors</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage errors</td>
<td>18</td>
<td>24.3</td>
</tr>
<tr>
<td>Time errors</td>
<td>17</td>
<td>22.9</td>
</tr>
<tr>
<td>Unauthorized medications</td>
<td>10</td>
<td>13.5</td>
</tr>
<tr>
<td>Technique errors</td>
<td>9</td>
<td>12.2</td>
</tr>
<tr>
<td>Administration route errors</td>
<td>6</td>
<td>8.1</td>
</tr>
<tr>
<td>Extra doses</td>
<td>4</td>
<td>5.4</td>
</tr>
<tr>
<td>Prescription errors</td>
<td>3</td>
<td>4.1</td>
</tr>
<tr>
<td>Omissions</td>
<td>3</td>
<td>4.1</td>
</tr>
<tr>
<td>Wrong patient</td>
<td>2</td>
<td>2.7</td>
</tr>
<tr>
<td>Presentation errors</td>
<td>2</td>
<td>2.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>74</td>
<td>100</td>
</tr>
</tbody>
</table>

In the present study, dosage errors (24.3%), time errors (22.9%) and unauthorized medications (13.5%) were the most frequent. In another study, omissions (24%) and errors or wrong quantity (23%) and prescription errors (22%) were the most frequent, reported on the MEDMARX, a database, developed by the United States Pharmacopeia – USP(12) and made accessible on the internet, which collects anonymous data and analyzes medication errors.

In the literature, different studies show different frequencies for the identified medication errors. This occurs because each institution has its own medication process, with specific characteristics that need to be identified by the researchers to help in the error analysis. Therefore, it should be emphasized that the referred hospital uses a computerized prescription system, which is considered a barrier in the medication system, as it avoids error to happen provided it is used correctly, and the medication is stored individually.

Regarding the profession of the health practitioners who were observed preparing and administering medications, 84.3% were nursing aides, 14.3% were nursing technicians and it was not possible to identify the profession of 1.4%. A study performed in Rio Branco, in Acre state, showed that 86.4% of professionals observed while preparing and administering medications were nursing aides and technicians, while only 13.6% were nurses (13).

Nursing aides and technicians are usually the professionals who administer medications because nurses are...
often busy with administrative problems, stepping away from the direct supervision of this process. Therefore, the lack of direct supervision in this process results in risk situations for the patient regarding a safe implementation of the drug therapy.

**Dosage error**

Regarding the 24.3% observed dosage errors, 50% referred to administering twice the prescribed dosage, 27.7% concerned administering half the prescribed dosage and 11.1% referred to administering four times the prescribed dosage. Regarding the presentation of the medications administered in wrong dosages, most were pills, and metoprolol was the most frequently involved drug.

In two studies, dosage errors in the administration of medications was among the three most common types of medication errors, corresponding to 12% and 15%\(^{[11,14]}\). It is observed that a factor that contributes with administering wrong medication dosages is storing the medication in dosages different from what had been prescribed.

In this institution, medications are stored individually, which demands the nursing team to handle and prepare the medication according to the prescription. Therefore, the unitary dose is a strategy capable of avoiding these medication administration errors, and can be adopted by this and other institutions with the purpose of avoiding that similar errors occur again. Among the many advantages of the unitary dose, it should be emphasized that it reduces the time necessary for the nursing team to store and prepare medications and thus also improved health care quality\(^{[15]}\).

**Time errors**

In the study, 22.9% regarded time errors, and the most common classes of medications involved were antibiotics, anti-diabetic drugs, anticoagulants, minerals and cardiovascular agents. Among these errors, 35.3% were related with the fact that the patient had attended another sector for hemodialysis, to perform and exam or to implant an arteriovenous fistula.

In fact, many patients receive medications in times different from what had been prescribed, due to the fact that they go to another sector for some other procedure. Hence, there should be effective communication between nursing and medical teams from the different sectors, to avoid delays, for instance, these medications should be sent along with patients with the objective to increase the safety of its use, especially in cases of antibiotics that can have their altered serum levels, and thus cause harms or illnesses to patients.

A strategy that could help to administer the medication at the prescribed time, when a patient is submitted to some type of procedure or exam, would be the nursing staff control the time of drug administration, thus preventing the moment of performing these procedures, which involves having effective communication among the many sectors of the institution.

**Unauthorized medications**

Of the errors involving unauthorized medication identified in the study (13.5%), most occurred due to the administration of nifedipine instead of nifedipine retard, and amoxacillin instead of amoxacillin combined with clavulanate. Other studies presented a 4% to 13% rate of this type of error\(^{[11,14]}\).

It is known that nifedipine and nifedipine retard belong to the same class (calcium channel blockers), but nifedipine is usually used once a day, because it has a prolonged action, while nifedipine retard is usually prescribed to be used every 12 hours. On the other hand, amoxacillin combined with clavulanate is used to treat infections by amoxacillin-resistant bacteria, as it produces beta-lactamases. Hence, these medication exchanges should not occur.

In the root cause analysis it was questioned whether the medications were correctly stored/dispensed by the pharmacy. Therefore, it was observed that there were mistakes in dispensing the medication, considering that this step of the medication process is responsible for the selection and separation of the medications to be used.

Using bar codes is a way to avoid medication errors, and it is a strategy to intercept those errors, during dispensing as well as when administering the medication.

**Technique errors**

Technique errors involved the steps of medication preparation and administration and represented 12.2% of all errors. These errors concerned wrong medication infusion time, the lack of equipment in the sector and the inadequate programming of the infusion volume, per hour, in an infusion pump. They also involved the non-administration of medications before and after meals, as recommended on the prescriptions, and not using specific material to measure the dosage correctly, such as when a professional measured the nistatin dosage at sight.

The orientations prescribed for administering the medications, such as the use of infusion pumps, before/after meals, should be followed by the nursing team, as it could affect the absorption of the medication by the organism or even cause adverse reactions on the patient.

Therefore, it is important for the institution to promote a safe environment for administering medications, which includes having equipment such as a syringe pump and infusion pumps, training and instructing professionals periodically regarding the techniques to prepare and administer medications, and the presence of protocols and guidelines for administering medications as strategies to avoid those errors.

**Administration route errors**

Of the 74 identified medication errors, 4.1% occurred due to using an administration route different from what had been prescribed. Isosorbide dinitrate was administered
orally instead of sublingual, human recombinant erythropoietin was administered subcutaneously instead of intravenous, and furosemide was administered intravenously instead of orally. The MEDMARX report stated that one of the most frequent errors that caused harms to patients were route errors, as they caused significant and immediate harm to the patients' health condition.

Furthermore, vigabatrin, carbamazepine and bromide were administered by inhalation, instead of orally, to the patient by the person accompanying them at the hospital (companion). The main factor involved in these events was that the professional handed the medication container to the companion, who administered it to the patient, and did not provide any instructions.

Medications should not be left with patients of their companions to be administered, since it increases the chances of occurring medication errors, especially when patients and their companion do not receive appropriate instructions. It is the nurses' duty to administer medications, as they have been prepared to perform the task of administering medications and are, therefore, responsible for this activity in the hospital environment.

To avoid administration route errors, it is recommended that professionals read the medical prescription carefully, identifying the five correct points, which includes the administration route, to guarantee the medication is administered correctly.

**Extra doses**

In the present study, extra doses (5.4%) occurred due to the administration of medications that had been suspended in the medical prescriptions. Medications such as cefepime and enalapril were involved in the errors.

These medications were prescribed, dispensed by the pharmacy, and subsequently suspended by the physician, but the nursing team, which did not check the medical prescription, administered the suspended medications nevertheless. It was observed that the suspension of the medication was not written in the pharmacy order.

The description of the events and the causal factors charting revealed that the contributing factors were disregard for the medical prescription and using the pharmacy order for preparing and administering the medications. In another study, the failure to check the medical prescription resulted in administering extra doses of medications such as antibiotics and anticoagulants.

The lack of integration and cooperation among multi-professional team professionals leads to similar situations. According to a study performed at a university hospital, there was a chance that 16.8% of patients hospitalized in the clinics could have received an extra medication (or dose) that had already been suspended by the physician, unless the nursing team had been communicated sooner or checked the medical prescription.

The verbal communication between health team members is essential in patient care and is directly related with medication errors. A study performed at an intensive care unit found evidence that 37% of the reported errors involved the verbal communication among professionals.

In fact, many times there is no communication between the physician and the nursing team when a change is made to the prescription or a medication is suspended. This increases the chance of errors, especially when the prescription is not used.

In this institution, it is very common for the nursing team to prepare and administer medications consulting the pharmacy order, which does not contain all the information or the changes that were made to the prescription. Therefore, it is recommended that the medical prescription be consulted when preparing and administering medications to avoid such errors, and there should be better cooperation among members of the multiprofessional team, so that any changes to the prescription be informed to the nursing team.

**Prescription errors**

All types of prescription errors (4.1%) were intercepted by the nursing team, and were, therefore, considered near-misses.

In this study, the errors were related with the inadequate timing of omeprazole, which should be administered before meals, and the verbal prescription of one insulin dose and its non-change in the prescription. A limited number of factors, such as the lack of knowledge or information regarding the treatment, wrong evaluation and use of patient information, prescription and confusing medication nomenclature, wrong dosage calculations and inappropriate preparations were the main factors that contributed with the occurrence of prescription errors.

Traditionally, physicians decide the medication to be used by the patient, and pharmacists and the nursing staff implement their decisions. The presence of a clinical pharmacist can avoid errors, since they provide more information and promote optimized medication use, in addition to monitoring the process of prescribing, preparing and administering the medications, and developing educational programs and medication guidelines.

Prescription errors are common and the nursing staff, who have knowledge in this respect, form an important barrier in the medication system for interception, as presented in this study. Furthermore, computerized prescription systems and the clinical pharmacist are strategies that can avoid this type of error.

**Omissions**

Of all error observed, 4.1% regarded omissions related with the difficult access to patients' venous network, changes in the prescribed times and the non-administration of atrovent (ipratropium bromide) with the saline at 0.9% and berotec for inhalation.
Mistakes, misses and lack of attention are some of the factors related with human failures that lead to acts or omissions. Behind those human failures, there is always a system failure that contributes with the occurrence of medication errors.

These omission errors could be avoided, especially regarding the lack of peripheral access and lack of medication at the moment of its administration, if nurses supervised the administration of medications. Nurse supervision could represent one of the defensive barriers in the medication system processes, with the purpose of reducing medication errors. Hence, that supervision performed by nursing aids and technicians provide essential conditions for nursing actions to be developed with quality and without causing any harms to patients, besides preventing errors in the administration of the medications\(^\text{[3]}\).

**Wrong patient**

This type of error corresponds to 2.7% of the identified errors. The description of the events and the causal factors charting showed that the nursing professional confirmed the name of patient Y and administered phenytoin and sodium bicarbonate to that patient in the place of patient X who was in the next bed.

Patient errors are not often reported in the literature, but a case study about one patient error in which the patient was submitted to an electrophysiological procedure in the place of another was presented and by means of root cause analysis, 17 similar errors were found\(^\text{[21]}\).

Identifying the patient at the time of administering the medication, confirming their names, is essential to avoid such errors. Furthermore, using name bracelets and bar codes in the medication administration system are also strategies to avoid this type of error. A study identified that only 6.8% of hospitalized patients used name bracelets, which is alarming, as the bracelet helps to identify the patient, especially when they are unable to communicate\(^\text{[20]}\).

**Presentation errors**

Presentation errors (2.7%) occurred due to the administration of furosemide ampoule instead of tablets, and bromopride capsules instead of tablets. These errors imply questioning whether there was dispensing error or if there was any storage in the nursing unit.

Dispensing errors could be avoided using a bar code system to clear medications, and the institution should avoid the presence of storages in the nursing units, as it would facilitate separating medications in a presentation different from what had been prescribed.

It was also observed that the separation of furosemide ampoule, instead of tablets, caused the occurrence of another error, involving the administration route. Therefore, a presentation error caused a route error, which could harm the patient.

**FINAL CONSIDERATIONS**

In present study, 70 medication errors were identified, and the most frequent involved dose, time, and unauthorized medications. In addition, the root cause analysis method was used, which permitted to identify factors that contributed with the occurrence of medication errors. Strategies and recommendations to prevent these errors were presented, as it is an important issue, especially considering the high incidence of these problems worldwide.

Institutions should adopt root cause analysis because its proposition is not limited to only finding the root causes, but to actually clarify the fact with the purpose of preventing and avoiding new episodes. Hence, the present study contributed with patient safety, presenting medication errors, and strategies and recommendations that could be used by other institutions to avoid them.

The difficulty to study and use the root cause analysis method was one of the present study limitations, as there are no publications on this issue in Brazil. Therefore, the root cause analysis methods used in other countries were adapted for developing the present study.

The only medication system steps observed were medication preparation and administration. The other steps, such as prescription or dispensing and distribution were not included in the study due to the complexity of the system. Therefore, it was impossible to identify other root causes that may have contributed with the occurrence of these errors.


