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Drug adverse effects in a public hospital in Rio de Janeiro: pilot study

ABSTRACT

The results from implementing a strategy for monitoring adverse effects from drugs in a public hospital in the municipality of Rio de Janeiro, Southeastern Brazil, in 2007, were analyzed. Based on retrospective analysis of 32 medical files, adverse effects were found in 16%. To identify these effects, 38 tracking criteria were needed. Among these, the main ones were the use of antiemetics, abrupt cessation of medication and oversedation. Despite the difficulties, especially in relation to access to information and the record quality, application of these tracking criteria seems to be viable. To improve the implementation of the method, it is suggested that the data collection should be computerized and risk adjustment indicators should be sought.

DESCRIPTORS: Adverse Drug Reaction Reporting Systems. Pharmaceutical Preparations, adverse effects. Drug Monitoring. Hospitals. Form and Record Control.

INTRODUCTION

Drug adverse effects that occur in hospitals may increase the length of stay or death rate. The frequency of such effects may reach 19%, and two thirds of them can be avoided.[2]

In Brazil, drug adverse effects among hospitalized patients have been studied by using a longitudinal approach,[3,4] reviewing medical files retrospectively[1] or using the hospital database of the *Sistema Único de Saúde* (SUS – National Health System).[5]

The objective of the present study was to analyze the results from a strategy of monitoring drug adverse effects that was applied in a public hospital.

METHODS

This study formed part of a project of research and teaching activities relating to patient safety and healthcare quality developed by the *Escola Nacional de Saúde Pública* (National School of Public Health) of the *Fundação Oswaldo Cruz*. It was conducted in a large-sized general hospital (450 beds) in the city of Rio de Janeiro, Southeastern Brazil, which has efficient healthcare record storage and medical file retrieval, along with teaching and research activities. In addition, the hospital participated in a network of sentinel hospitals.

A retrospective analysis on the medical files was carried out in June 2007, using tracking criteria to screen for possible adverse effects from drugs.[6] The

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tracking criteria used, which were adapted from the original list,[a] consisted of the following: diphenhydramine; vitamin K; flumazenil; antiemetics; naloxone; antidiarrhetics; sodium polystyrene; blood glucose less than 50; partial thromboplastin time (PTT) greater than 100 seconds; international normalized ratio (INR) greater than six; white corpuscle count less than 3,000; platelet count less than 50,000; digoxin use and signs and symptoms of intoxication (arrhythmia, bradycardia, nausea, vomiting, anorexia or visual disorders); elevated serum creatinine; oversedation, lethargy, low blood pressure and falls; skin rashes; abrupt cessation of medication; and transfer to a higher level of care.

A list of drugs used in the hospital, corresponding to the proposed tracking criteria, was used to signal adverse effects. These drugs (antiemetics and antiallergic agents, among others) were considered to be trackers when they were actually administered, and not just when they were prescribed.

Five hundred and thirty-three medical files relating to patients aged 15 years and over who were hospitalized for two or more days and discharged in January 2007 were eligible for this study. Patients admitted to the obstetrics and emergency departments were excluded. A simple random sample of 34 medical files was extracted. The criteria used for calculating the sample size were an error of 10%, statistical significance of 95%, prevalence of the event studied of 10% and losses of 10%. The need to obtain an overall estimate that was representative of the hospital justified the use of statistical criteria to select the medical files. Out of the 34 medical files drawn, two were not found in the archives. Thus, the results relate to 32 medical files.

The concepts and the tracking criteria were standardized between the reviewers. The harm to the patient was defined as a temporary or permanent disorder of physical or psychological functioning of the human body or its structure. Abrupt discontinuation of medication was taken to such events that had not been foreseen, but excluding the following cases: changing the substance to another one in the same chemical group with similar pharmacokinetic or pharmacodynamic characteristics; prescriptions "if necessary" that were not administered; and administrative reasons (for example, lack of the product in the hospital or absence of records). Adjustments to the dose or the method of administration, according to the clinical evolution or laboratory parameters (for example, adjustment of the insulin dose according to blood glucose levels) could also be tracking criteria.

Only tracking criteria recorded during the hospital stay in the ward were considered. Days spent in the intensive care unit (ICU) were not included, since the risk-benefit relationship of the medication is interpreted differently from in the ward. Because of the severity of the condition of ICU patients, monitoring forms part of the care and mild tracking criteria such as somnolence would not apply.

The medical files were analyzed by a team composed of one clinician, three physicians with training in public health (administration or epidemiology), one nurse and three pharmacists. The data collection instrument was tested on eight medical files that were not included in the sample. Each medical file was examined independently by two members of the team. Divergences were resolved by consensus.

With regard to the stages of identification and measurement of the tracking criteria and adverse effects from drugs, the medical files were reviewed from the discharge summary or from the form for authorization of hospital admission within SUS, in order to collect general information on the following: primary and secondary diagnoses, duration of hospitalization and patient sociodemographic data. The review of the medical files was based on the prescriptions and the laboratory results. The records relating to patient evolution, made by the physician and nursing team, were examined to look for changes in consciousness, rashes, somnolence, falls, low blood pressure, nausea, vomiting and complementary information on the medication. After finding the tracking criterion, occurrences of adverse effects soon afterwards were investigated. If such events were found, they were described and classified. The medications were recorded.

Starting from the indication of possible adverse effects that was signaled by the tracking criterion, a clinical judgement was made regarding the point within the chain of causality (before, during or after) at which the adverse effect from the drug occurred. The nature of the adverse effects varies: it could come from the use of antagonist drugs, from laboratory parameters or from clinical decisions (abrupt discontinuation of medications or referral to a higher level of care). There are cases in which the tracking criteria are also the adverse events (somnolence, falls and low blood pressure, among others). The following examples illustrate the above conditions:

- exposure to drugs → severe adverse event → tracking criterion → "transfer to a more complex level of care"
- exposure to drugs → tracking criterion and adverse effect from drug → "fall"
- exposure to drugs → tracking criterion "platelets < 50,000" → drug adverse effect due to administration of platelet concentrate

[a] The original tracking criteria can be consulted at the website of the Institute for Healthcare Improvement [cited 2009 Aug 13]. Available from: http://www.ihi.org/ihi

Table. Characteristics of drug adverse effects recorded in the medical files of a general hospital. Municipality of Rio de Janeiro, Southeastern Brazil, 2007.

Patient's characteristics (age, sex and diagnosis)	Number of drug adverse effects	Description of the drug adverse effect	Putative cause
57 years, male Inguinal hernia, peritonitis	2	Glucose administration,Bleeding from the operative wound	Insulin Enoxaparin
66 years, female Unilateral inguinal hernia	1	Somnolence	Promethazine
53 years, female Cholelithiasis	1	Nausea, vomiting	Dipyrone Tramadol
33 years, female Cholecystitis, choledocholithiasis	1	Nausea	Ciprofloxacin
61 years, male Occlusion of iliac aorta	4	Nausea and vomiting (3 episodes) somnolence/ disorientation (1 episode)	Paracetamol

The classification of drug adverse effects was based on the criteria of the National Coordinating Council for Medication Error Reporting and Prevention Index for Categorizing Errors (NCC/MERP Index; Rozich[6] 2003). It represents harm to the patient caused by the care, independent of whether it resulted from error.

This project was approved by the Ethics Committees of the *Hospital Federal Público* (Federal Public Hospital) and the *Fundação Oswaldo Cruz*.

RESULTS

Fifty-six percent of the medical files (18/32) were positive for some of the 38 tracking criteria considered. The criteria most frequently found were the use of drugs (such as antiemetics), abrupt cessation of medication and oversedation. After evaluation, possible adverse effects from drugs were identified in 15.6% of the medical files (5/32). There were nine adverse effects from drugs in total (Table). All of the effects met the definition adopted, in that they caused temporary harm to the patient for which intervention was necessary. Among these five patients, only one was less than 50 years of age.

DISCUSSION

An incidence of possible adverse effects from drugs of 15.6% was found, mostly of mild to moderate intensity. Among the drugs involved were analgesics, antipyretics, hypoglycemic agents, anti-inflammatory agents and anticoagulant.

There were difficulties in the study relating to access to the hospital database (existence of more than one database, with inconsistencies between them); examination of the medical files (ordering of the pages according to the time and the record type); quality of the records in the medical files (legibility and use of abbreviations); and time availability among the professionals for them to get involved in the activity of evaluating the medical files. In particular, the fact that most of the events were signs and symptoms of the diseases themselves gave rise to problems with regard to establishing a causal relationship. Furthermore, few tools were available for adjusting the risk according to the severity of the disease.

Despite these barriers, application of tracking criteria as a strategy for monitoring adverse effects from drugs seems to be viable, considering that this would make it possible to follow up the implementation of changes aimed towards reducing the occurrence of such events and improving the quality of care. This method does not require extraordinary resources and evaluations performed using representative samples of medical files can be done in a short time.

Certain facilitating measures for identifying occurrences of adverse effects from drugs may improve the process of hospital evaluation, such as: computerization of data entry (transcription and typing), to save time and diminish data collection errors; searching for risk adjustment strategies that would make it possible to incorporate the severity of the underlying disease as a factor that would affect the relationship between the drug and the adverse effect from it; closer linkage with continual review committees for medical files and deaths; and inclusion of undergraduates in such evaluations. This last measure is being tested in other units and may, in the future enable improvement of students' training and increase the efficiency of the method.

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