Machado-Alba, Jorge E.; Moncada, Juan Carlos; Moreno-Gutiérrez, Paula Andrea
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Biomédica, vol. 36, núm. 2, junio, 2016, pp. 251-257
Instituto Nacional de Salud
Bogotá, Colombia

ORIGINAL ARTICLE

Medication errors in outpatient care in Colombia, 2005-2013

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Introduction: Medication errors outside the hospital have been poorly studied despite representing an important threat to patient safety.

Objective: To describe the characteristics of medication errors in outpatient dispensing pharmacists reported in a pharmaco-surveillance system between 2005 and 2013 in Colombia.

Materials and methods: We conducted a descriptive study by reviewing and categorizing medication error reports from outpatient pharmacy services to a national medication dispensing company between January, 2005 and September, 2013. Variables considered included: process involved (administration, dispensing, prescription and transcription), wrong drug, time delay for the report, error type, cause and severity. The analysis was conducted in the SPSS® software, version 22.0.

Results: A total of 14,873 medication errors were reviewed, of which 67.2% in fact occurred, 15.5% reached the patient and 0.7% caused harm. Administration (OR=93.61, CI 95%: 48.510-180.655, p<0.001), dispensing (OR=21.58, CI 95%: 16.139-28.870, p<0.001), transcription errors (OR=5.64; CI 95%: 3.488-9.142, p<0.001), medicines for sensory organs (OR=2.04, CI 95%: 1.519-2.756, p<0.001), anti-infective drugs for systemic use (OR=1.99, CI 95%: 1.574-2.525, p<0.001), confusion generated with the name of the drug (OR=1.28, CI 95%: 1.051-1.560, p=0.014), and trouble interpreting prescriptions (OR=1.32, CI 95%: 1.037-1.702, p=0.025) increased the risk for error reaching the patient.

Conclusions: It is necessary to develop surveillance systems for medication errors in ambulatory care, focusing on the prescription, transcription and dispensation processes. Special strategies are needed for the prevention of medication errors related to anti-infective drugs.

Key words: Medication errors, inappropriate prescribing, adverse drug reaction reporting systems, pharmaco-surveillance, Colombia.

doi: http://dx.doi.org/10.7705/biomedica.v36i2.2693

Errores de medicación en pacientes atendidos en servicios ambulatorios de Colombia, 2005-2013

Introducción. Los errores de medicación en la atención ambulatoria se han estudiado poco, a pesar de que representan una amenaza importante para la seguridad del paciente.

Objetivo. Describir las características de los errores de medicación en atención ambulatoria reportados por un sistema de farmacovigilancia de Colombia entre el 2005 y el 2013.

Materiales y métodos. Se hizo un estudio descriptivo en el cual se recopilaron, revisaron y categorizaron los reportes de errores de medicación de pacientes atendidos en un servicio farmacéutico ambulatorio a cargo de una empresa nacional de dispensación de medicamentos, entre enero de 2005 y septiembre de 2013. Se consideraron variables que involucraban el proceso (administración, dispensación, prescripción y transcripción), el medicamento, el tiempo para elaborar el reporte, el tipo de error, su causa y su gravedad. El análisis se hizo con el programa SPSS®, versión 22.0.

Resultados. Se recopilaron 14.873 errores de medicación, de los cuales 67,2 % realmente ocurrió, 15,5 % afectó al paciente y 0,7 % causó daño. Los errores de administración (p<0,001; OR=93,614; IC$_{95\%}$ 48,510-180,655), de dispensación (p<0,001; OR=21,585; IC$_{95\%}$ 16,139-28,870), de transcripción (p<0,001; OR=5,647; IC$_{95\%}$ 3,488-9,142), los relacionados con medicamentos para los órganos de los sentidos (p<0,001; OR=2,046; IC$_{95\%}$ 1,519-2,756), y con los medicamentos de uso sistémico contra infecciones (p<0,001; OR=1,993; IC$_{95\%}$ 1,574-2,525), la confusión en el nombre del fármaco (p=0,014; OR=1,281; IC$_{95\%}$ 1,051-1,560) y los problemas en la interpretación de las prescripciones (p=0,025; OR=1,328; IC$_{95\%}$ 1,037-1,702), aumentaron el riesgo de que el error afectara al paciente.

Discusión. Es necesario establecer sistemas de vigilancia específicos para errores de medicación en los servicios ambulatorios, que hagan énfasis en los procesos de prescripción, transcripción y dispensación. Se requieren estrategias específicas para la prevención de los errores de medicación relacionados con antibióticos.

Palabras clave: errores de medicación, prescripción inadecuada, sistemas de registro de reacción adversa a medicamentos, farmacovigilancia, Colombia.

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm, related to unwise or inadequate professional practice from the moment of pre-scription to medical order fulfillment (1,2). These errors include inadequate selection of the drug, dose or route of administration, therapy length or incorrect selection according to the potential harm related to the characteristics or comorbidities of the patient (3,4).

There is strong evidence that all medication error problems seem to be bigger outside the hospital. However, most research has focused on hospitals and the lack of evidence about medication errors in ambulatory care does not allow for an estimation of the incidence and features of such errors that could serve as basis for the development of prevention strategies (3).

Most studies are limited to a specific population or medication error type; in 2003 in the United States, four mistakes per 250 prescriptions per pharmacy/day occurred in the ambulatory setting (1). That same year in México, prescription errors accounted for 15.6% and dispensing errors for 0.4% of all negative outcomes associated with medication (NOM) detected in ambulatory patients (5). In 2013, in Germany the NOM were found in 18.0% of all ambulatory patients and 11.2% of all prescriptions, of which 39.0% occurred during the prescription process. However, 95.0% of all NOM detected could have been solved partially or completely during the initial pharmacy visit (6).

Colombian pharmaco-surveillance system only covers adverse drug events and, therefore, the nation lacks programs and statistics about medication errors. In this context, the aim of this study was to describe the characteristics of all the medication errors in ambulatory pharmacy settings reported to a pharmaco-surveillance system gathering information from patients of the Colombian health system (*Sistema General de Seguridad Social en Salud*, SGSSS) between 2005 and 2013.

Materials and methods

A descriptive study was carried out to gather information on medication errors that occurred between January 1st, 2005 and September 12, 2013 on ambulatory pharmacies owned by the company Audifarma, S.A, which dispenses medications prescribed by physicians to 6.5 million people affiliated to different health care providers. The reports were submitted by the health professional (physician, pharmacist, nurse) that detected the error through an electronic surveillance system and then reviewed by a pharmacist, with the support of a physician specialized on pharmacoepidemiology if needed. The review by the pharmacists is linked to the national pharmaco-surveillance pro-gramme of Audifarma, S.A., which periodically reports results to the (*Instituto Nacional de Vigilancia de Medicamentios y Alimentos*, Invima).

Variables included in the surveillance system were: 1) date of occurrence and report; 2) time delay for the report, 3) place of occurrence (city and pharmacy); 4) process involved (administration, dispensing, prescription and transcription); 5) ordered drug; 6) wrong drug; 7) moment of detection; 8) classification by error type and severity according to the taxonomy developed by the National Coordinating Council for Medication Error Reporting and Prevention *(*NCCMERP) (7) (table 1); 9) contact between the error medication and the patient, and 10) consumption of the drug by the patient. Medicines were grouped by the time of reporting, according to the Anatomical Therapeutic Chemical (ATC) classification.

Information was gathered into a database in Excel 2010 and analyzed using the IBM SPSS® Statistics software, version 22.0 for Windows (IBM, USA). An exploratory data analysis was performed initially, then χ^2 tests were used to select variables significantly related to the primary

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Table 1. Severity of medication errors, Colombia, 2005-2013

Severity of medication errors	n	%
A. Circumstances or events that have the capacity to cause error	4,879	32.8
B. An error occurred but the error did not reach the patient	7,695	51.7
C. An error occurred that reached the patient, but did not cause patient harm	2,136	14.4
D. An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm	84	0.6
E. An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	64	0.4
F. An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	11	0.1
G. An error occurred that may have contributed to or resulted in permanent patient harm	0	0.00
H. An error occurred that required intervention necessary to sustain life	2	0.01
I. An error occurred that may have contributed to or resulted in the patient's death	2	0.01

outcome (reaching the patient), that were later used to create a logistic regression model. A p value of <0.05 was considered to be significant. The research was reviewed by the Bioethics Committee of the *Universidad Tecnológica de Pereira* (Pereira, Colombia), and it was approved as "research without risk" following the principles of the Helsinki's Declaration.

Results

At the time of observation, 14,873 medication errors were reported in 362 ambulatory pharmacies from 71 cities in 21 states of Colombia, most from Bogotá (n=8,917; 60.0%), Antioquia (n=1,304; 8.8%) and Valle del Cauca (n=919; 6.2%). Errors were reported on the day of occurrence in 21.0% of the cases (n=3,116), and 70.4% (n=10,463) of errors were detected between the first and tenth day; the median time for detection was four days (interquartile range: 12; range: 0-390 days). On average, 1.06 errors were notified for every 10,000 prescriptions.

Errors in category A, B and C comprised 98.9% of the total submitted records (n=14,710) (table 1), while 67.2% of all the errors reported really occurred (n=9,994) (categories B to I), of which 23.0% (n=2,299) reached the patient (categories C to I), and the medication was used by 64.1% (n=1,475) of these patients. Approximately 3.4% (n=79) of these cases resulted in harm; in four of the cases (5.1%) (categories G to I) the harm was permanent and might have contributed or been related to the death of two patients (category I). The severity of medication errors is shown in table 1.

The most common process in which errors actually occurred (categories B to I) was dispensation (55.5%; n=5,548), followed by prescription (40.1%; n=4,006), transcription (3.6%; n=355) and administration

(0.9%; n=85). Most errors that reached the patient (n=2,113; 91.9%) and that caused harm (n=72; 91.1%) occurred in the dispensation process. The report rate increased through time until 2011, at which point it started to decrease (figure 1).

Errors in medication name, concentration, dosage form and quantity were the most common. Generally, medication errors were detected during medical prescription review (37.1%), while almost half (48.1%) of those that caused harm were detected by the patient, as shown in table 2.

There were 14,826 reports of 630 substances (table 3) and 268 therapeutic subgroups; eleven of these errors involved multiple medication and forty-seven, illegible prescriptions in which drug identification was not possible. As shown in figure 2,
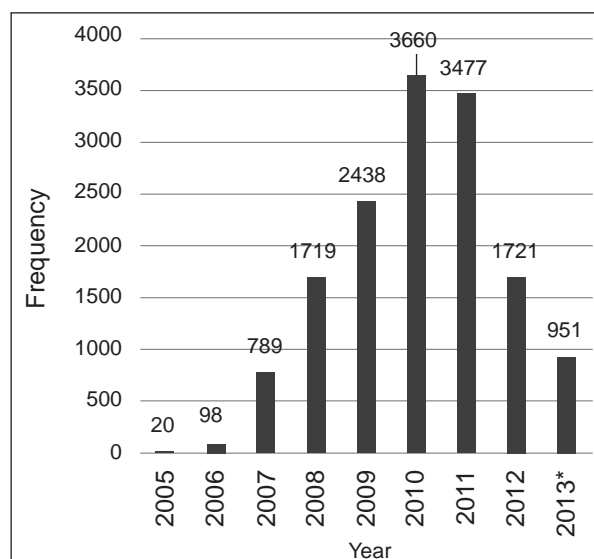
Figure 1. Medication errors reports by year of occurrence, 2005-2013, Colombia
*January to September

Table 2. General characteristics of medication errors, Colombia, 2005-2013

	All errors (A-I)	Reached patients (C-I) n=2299	Caused harm (E-I) n=79
Type of medication error			
Wrong concentration	32.3	38.1	22.0
Improper dose/quantity	26.5	16.9	16.0
Wrong drug	21.2	27.0	48.0
Incomplete formula	3.7	0.9	0.0
Wrong patient	3.6	4.0	2.0
Wrong route	3.5	2.0	2.0
Extra drug	3.4	7.1	4.0
Wrong dosage form	3.2	2.6	4.0
Unreadable formula	2.4	1.2	0.0
Wrong technique	0.01	0.1	2.0
Process where the medication error was detected			
Medical prescription review	37.1	32.6	8.9
Dispensation	31.1	3.0	2.5
By the patient	11.3	27.1	48.1
Delivery or posterior	6.4	20.6	12.7
Enlistment	6.2	0.5	0.0
Patient review	5.0	6.2	8.9
Other	2.4	7.2	0.0
Medical follow-up	0.2	1.5	3.8
Dosing	0.2	0.3	0.0
Emergency room visit	0.1	1.0	15.2

Table 3. Most reported drugs in medication errors, Colombia, 2005-2013

| All errors (A-I) (n=14,826)	%	Reached patients (C-I) (n=2,299)	%	Caused harm (E-I) (n=79)	%
Paracetamol	3.1	Cefalexin	2.4	Prednisolone	8.3
Metronidazole	3.0	Metronidazole	2.1	Butyl scopolamine	4.2
Losartan	2.7	Dexamethasone and anti-infective agents	1.9	Gemfibrozil	4.2
Levothyroxine sodium	2.7	Dicloxacilin	1.8	Metronidazole	4.2
Enalapril	2.1	Amoxiciline	1.8	Metoclopramide	2.8
Loratadine	2.0	Diphenhydramine	1.8	Insulin (human)	2.8
Amoxiciline	1.9	Nifedipine	1.7	Thiamine (vit. B1)	2.8
Metoprolol	1.7	Levothyroxine sodium	1.6	Enalapril	2.8
Chlorpheniramine	1.7	Ciprofloxacin	1.6	Medroxyprogesterone	2.8
Metoclopramide	1.6	Losartan	1.3	Levothyroxine sodium	2.8

66.8% of the errors were related to five ATC groups: C, A, N, R and J. The prescribed drug was different than the selected one in 43.3% of medication errors (n=6,420), of which 77.5% (n=4,974) were from a different subgroup, and 47.7% (n=3,061) were from a different ATC group. Finally, 20.3% (n=1,601) of the mismatched drugs reached the patient.

Multivariate analysis showed that medication errors during the administration, dispensation and transcription processes, sensory organs medications, antibacterials for systemic use, wrong medication name, and concentration, significantly increased the risk for the drug reaching the patient (categories B to I). Conversely, being cared for in Bogotá and wrong dosage form were found to diminish the risk of the error reaching the patient (table 4).

Errors reported in the database were analyzed and corrected, if possible, in the moment of detection by a pharmacist. Actions to prevent further similar errors were also considered and executed.

Discussion

The construction of a national reporting system for medication errors covering as many ambulatory and medical institutions as possible is the first step towards the creation of policies and local actions aimed at preventing medication errors. Most work around medication errors focuses on prevention inside the hospital, but this study shows the relevance of including ambulatory pharmacies in the strategies for medication errors prevention, as they represent a potential risk for patients (1), even though most errors reported were mild.
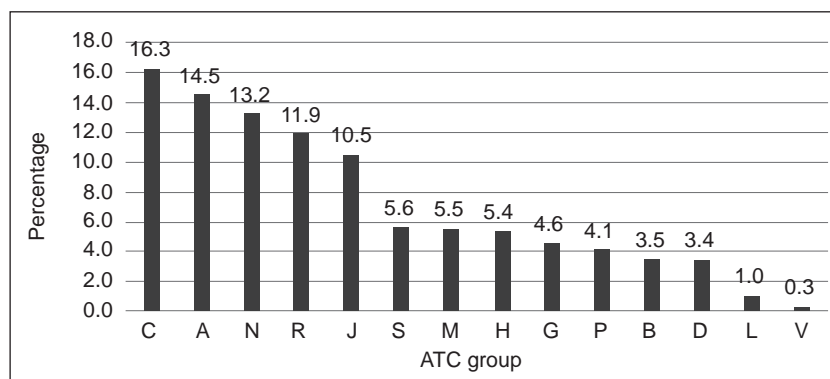
Figure 2. Medication errors by ATC group in ambulatory settings, Colombia, 2005-2013
C: Cardiovascular system; A: Alimentary tract and metabolism; N: Nervous system; R: Respiratory system; J: Anti-infective agents for systemic use; S: Sensory organs; M: Musculo-skeletal system; H: Systemic hormonal preparations excluding sex hormones and insulin; G: Genito-urinary system and sex hormones; P: Antiparasitic products, insecticides and repellents; B: Blood and blood forming organs; D: Dermatological medications; L: Antineoplastic and immunomodulating agents; V: Various

Table 4. Multivariate analysis with variables associated significantly to the occurrence of errors that reach the patient in Colombia during 2005-2013

Variables	n	%	p	OR	CI 95%
Process					
Administration	64	75.29	<0.001	87.49	48.58-171.72
Dispensation	2,113	38.09	<0.001	20.67	15.4-28.02
Transcription	47	13.24	<0.001	5.51	3.38-9.00
ATC group					
Sense organs	203	24.43	<0.001	2.02	1.47-2.78
Anti-infective drugs for systemic use	377	24.15	<0.001	1.98	1.52-2.57
Type					
Wrong concentration	614	15.94	0.05	1.29	1.00-1.66
Wrong drug name	435	17.21	0.01	1.43	1.11-1.86
Wrong dosage form	191	8.18	0.01	0.67	0.50-0.90
Occurrence location					
Bogotá	724	8.12	<0.001	0.61	0.49-0.75

The characteristics of the drug (wrong concentration, dose, quantity and drug) were involved in 80.0% of all errors, 82.0% of those that reached the patient and 86.0% of those that caused harm, contrary to the pharmacopeia report from the United States (US), that stated omission errors as the leading type, while only a small number of errors related to the drug (1,8). Look-alike sound-alike drug names have been identified as a clear cause of medication errors and the strategies to avoid them include both pharmacy practices (e.g., avoid storing drugs by alphabetical order and create "flags" in electronic dispensing systems) and drug labeling regulations to prevent confusions (9,10).

The medication errors found in this study were less severe than those reported in the USA, where 91.3% actually occurred and of those, 64.0% reached the patient (against 67.2% and 23.0% in Colombia, respectively), while in both cases a low number of errors caused damage to the patient (3.0% *Vs.* 0.7%). Further studies are required to determine if this difference is explained by underreport of serious medication errors or more effective functioning of the program, since the errors are reported through surveillance and the rate of report is unknown. The overall percentage of errors reaching the patient (15.5%) could be explained by the difference between a hospital and an ambulatory environment, where the interaction between staff and patient is lower at all stages of drug consumption (1).

Moreover, medication errors that occur in ambulatory settings require different systems for vigilance and control. Efforts should be aimed at preventing errors during the distribution phase, which is the last contact between the health care personnel and

the patient in outpatient settings, and was linked to almost all errors that reached the patient and caused harm.

Administration errors comprised only 0.9% of the total, significantly less than studies performed previously in health institutions in US, Spain, Iran and Southeast Asian countries, which reported percentages between 15.2% and 88.6% (1,10-13). Nevertheless, three quarters of the administration errors that occurred reached the patient. These types of errors have been generally associated with nursing actions (14), and related to factors like a heavy workload, lack of knowledge, wrong calculations and distractions related to work environment in hospitals (13,15), while their occurrence in outpatient care may be related to inadequate prescription by the physician.

In contrast to our findings, more than half (59.1%) of the medication errors that reached the patient in a study performed in Danish community pharmacies were related to the transcription phase. These errors were mainly caused by handwritten prescriptions, similarities in packages or names, "traps" that lead to confusion or misunderstanding of prescriptions, lack of effective control (errors that are not detected by the pharmacist) and lack of concentration caused by interruptions (10). Despite this difference, the prevention of errors during prescription and transcription phases has a significant impact on the incidence of medication errors because problems related to handwritten medical prescriptions have been identified as inducing medication errors (2,16).

Another important strategy for the prevention and detection of medication errors are electronic prescription systems, that offer the possibility of connecting all steps in patient care in addition to preventing errors related to handwriting, dosing interval, dose, and drug interactions, and decreasing errors that happen during transcription; however, in many instances access to this device may be limited (16,17).

In this study, the main drugs involved in medication errors matched the drugs most used for the treatment of common illnesses like chronic diseases, pain and infections. This is similar to data found in Germany, where antibiotics, non-steroidal anti-inflammatory drugs (NSAID), β-blocking agents and inhibitors of the renin-angiotensin system represent 35.3% of NOM detected in ambulatory dispensing. Even when these medications have wide security profiles, they require special attention due to their frequent use (6).

The Agency for Health Research and Quality (AHRQ) identified anti-infective agents as the pharmaceutical group most associated with drug adverse reactions, and different studies have shown these drugs to be among the medications most frequently involved in hospital and ambulatory medication errors (6,18-21). Additionally, in this work they increased the risk of reaching the patient. This pharmaceutical group requires specific approaches that take into consideration the dosage form, monitoring and dissemination of clinical practice guidelines, electronic prescribing systems and surveillance of all processes involved (2,22).

None of the ATC principles stood above the others significantly; moreover, the similar frequency of the ATC groups C, A, N, R and J was probably related to the frequency of use of different groups of medications in ambulatory care. On the other hand, medicines for sensory organs were involved in a small proportion of errors, but they were twice likely to reach the patient than other drugs, therefore, the dosage form must be evaluated and additional risk factors should be identified in order to implement corrective and preventive actions.

Three quarters of the medication errors happened in the biggest states and in the country's capital, where, despite the fact that pharmacies cover a large part of the territory, there is evidence that they have stricter monitoring programs and the staff is watchful and aware of the importance of notification. This may help to explain why having a prescription filled in Bogotá was found to be a protective factor for the error reaching the patient because of frequent reporting of all kinds of errors, while in other cities, only more severe errors were reported.

Based on the findings of this study, we can say that the most common medication errors in ambulatory practice were related to the dispensing and prescription processes, they were of low severity and usually did not reach the patient. On the other hand, medicines for sensory organs, anti-infective agents for systemic use, wrong medicine name or concentration were all identified as error characteristics that increase the risk of the drug reaching the patient.

Medication errors included in this paper were limited to those submitted on a self-report database, which included some of the errors but did not detect the totality of the actual errors that occurred. Besides, the final consequences in harmed patients and corrective measures taken after reviewing the error were not always recorded and, therefore, not

reported. These results are applicable to groups of population with similar socio-demographic characteristics and health insurance affiliation.

According to our results, the creation of a database that follows NCCMERP standards to gather the reports of medication errors occurring in different national institutions would improve health staffs' knowledge and awareness about this issue (1), and increase error detection. These programs should also include the continuous involvement of the pharmacist in the entire process of medication use and the development of systems for evaluation and control of factors that are determinant of severity, with emphasis on high-risk operative procedures and medicines. Finally, it is necessary to improve training and reporting of medication errors, especially in decentralized settings.

Conflicts of interest

The ideas and opinions expressed are the sole responsibility of the authors. No sources of funding were used in the preparation of this article. The authors have no conflicts of interest directly relevant to the content of this article.

Financial support

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