ISSN 1695-6141
Revista electrónica trimestral de Enfermería
Nº 33
Enero 2014
www.um.es/eglobal/

ADMINISTRACIÓN – GESTIÓN - CALIDAD

Adverse drug event reporting system: a university hospital experience

Experiencia de un sistema de reporte de errores de medicación en un hospital docente

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Keywords: Medication Error; Adverse Drug Events; Reports.

Palabras clave: Errores de Medicación; Eventos Adversos de Medicamentos; Reporte.

ABSTRACT

Introduction: The medication error (ME) has an impact in the morbi-mortality of the patients, as this way also the economic consequences for the individual, the systems of health and the society. A way of identifying them is across the system of reports. The aim of this communication is to present the experience of use of reports in an teaching hospital.

Methodology: Descriptive Analysis of ME reports. There were in use as sources of information the system of census and the reports of the ME.

Results: The rate of ME's reports was of 1.2x 1000 patients. The reports principally came from medical services (39 %) and 34% from Intensive Care Units 34 %. More frequent MM was in the administration (47 %) and dispensation (27 %). The notified ME 69 % came to the patient, some type of intervention being needed in 68 % of these cases. The gravity of ME was important in 47 % of the cases, being able to preventable 97 %.

Conclusions: ME is a present reality in our hospital, which it is possible to anticipate. The system of ME reports is a useful tool in the identification that causes root.

RESUMEN

Introducción: Los errores de medicación (EM) tienen un impacto en la morbi-mortalidad de los pacientes, como así también consecuencias económicas para el individuo, los sistemas de salud y la sociedad. Una forma de identificarlos es a través del sistema de reportes.

O**bjetivo:** Presentar la experiencia de uso de reportes en un hospital docente universitario.

Metodología: Análisis descriptivo de reportes de EM. Se utilizaron como fuentes de información el sistema de censo y los reportes de los errores en la medicación.

Resultados: La tasa de reportes de EM fue de 1.2 x 1000 pacientes. Los reportes principalmente provinieron de servicios de tipo médicos (39%) y de Unidades de Pacientes Críticos-Aislamiento (34%). Los EM más frecuentes estuvieron en la administración (47%) y dispensación (27%). El 69% los errores notificados llegaron al paciente, necesitándose algún tipo de intervención en el 68% de esos casos. La gravedad de los EM fue importante en el 47% de los casos, pudiéndose prevenir en el 97%.

Conclusiones: Los EM son una realidad presente en los centros asistenciales, que se puede prevenir. El sistema de reportes de EM es una herramienta útil en la identificación de sus causas.

INTRODUCTION

Attributable to medical errors, among which are the medication errors (ME) deaths, according exceed the Institute of Medicine (IOM) of the Accident USA, Breast Cancer and AIDS [(1)]. These ME, are mainly due to System Drug Utilization increasingly becomes more complex, becoming the main factor of ME, which starts with the selection of a therapeutic drug arsenal at different levels (government, province, hospital), then the act of prescribing by health team professionals, mainly doctors, then the dispensation of medication or preparation by the pharmacy unit, to be administered by the nursing staff. The process ends with monitoring patient's clinical response to the procedure performed and accordingly is continued or modified therapy starting the process again.

The ME incidence in hospitals are between 11.5 x 1,000 patient hospitalizations and 6.2 x 100 [(2, 3)].

It can be said with certainty that adverse events related to ME, carry a significant decline in patients quality of life, sometimes for organic impairment and / or physical disabilities and even death [(4)]. The ME economic consequences are mainly due to compensation for malpractice, prolonged length of hospital stay, need for palliative health care and lost productivity, disability or death [(5)].

Since social point of view increasing the errors in health care intolerance shown. Medication error social impact should be studied from two aspects, first, from patients point of view and their relatives or careers, can be said to be a witness or suffer ME, weakens confidence in the health system and on the other hand, if we consider the health professionals who have made a mistake, we see as being aware it leads them to distrust themselves hereinafter the motivation and fear of making mistakes [(6)]

Due to the health, economic and social connotation of ME, various actions have been implemented in order to reduce the most of this situation. Among which are electronic prescribing [(7)] nursing team dedicated specifically medication administration [(8)], dispensing systems in unit dose [(9)], among others. However, safe medication implementation of use systems by itself does not ensure success, for it is the evaluation of the implemented measures necessary. Some methodologies used for the assessment and detection ME that have been referred to in literature is the review of medical records [(10)] , direct observation of processes [(11)] , monitoring of laboratory parameters ME indicative [(12)] , etc .

The aim of this paper is to present the experience gained in two years implementation ME reports.

METHODOLOGY

The study was conducted in a university hospital with 600 beds, all medical specialties, which has annually about 21,000 hospital discharges.

The information was obtained from the nursing incident report, which contains a section on medication, it is recorded: the type of incident, he or drugs involved, unit, time and action taken to resolve. Apart from the system of general hospital census demographic data such as age and sex of patients, length of stay, and morbidity data were obtained according to the International Classification of Diseases ICD- 10 [(14)]. The drugs involved were classified according to the Anatomical- Therapeutic WHO classification [(15)].

The ME were classified according to the process in which the error (prescribing, dispensing, preparation, dispensing) started and then categorized according to severity by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) [(16)]. The collected data were entered into an MS- Excel ®, spreadsheet for analysis and classification.

RESULTS

During the two years in which the reports were reviewed, 59 were considered ME, corresponding to 1.19 reports per 1,000 patients. Which were generated mainly from type and Medical Services, Critical Unit and Isolation (Table 1). Patients who were involved in a report of ME were mainly women (58 %) with a mean age of 55 years and an average of 17 hospital stay days. The most common diseases according to ICD- 10 were related to the circulatory system (31%) and neoplasms (25%) (Table 2) The drugs involved in ME according to the ATC classification, 19% belonged to Blood System (Heparin (5%), Acenocoumarol (3%)), and 15 % to the group anti-infective (Vancomycin, 3%). (Table 3) Importantly, most of the drugs involved were for intravenous administration.

Table 1. Distribution of ME Report provenance

Type of Hospital Setting	Unit	Reported Incident
Medical	Cardiology	11(19%)
	Nefrology	4(7%)
	Internal Medicine	4(7%)
	Neumology	2(3%)
	Fisiatry	1(2%)
	Endocrinology	1(2%)
Total Medical Unit		23(39%)
Medical-Surgical	Urology	2(3%)
	Ophthalmology	1(2%)
Total Medical-Surgical Unit		3(5%)
Surgery	Surgery	8(14%)
	Coloproctology	1(2%)
Total Surgery		9(15%)
Support	Anesthesiology	2(3%)
	Emergency	1(2%)
	Dialysis	1(2%)
Support Unit		4(7%)
Critical Care Unit and Isolation	Surgery Intermediate Care	9(15%)
	Hematology oncology	4(7%)
	Intensive Care Unit	2(3%)
	Coronary Unit	2(3%)
	Pediatrics Intensive Care Unit	1(2%)
	Neurology-Neurosurgery Intermediate Care	1(2%)
	Medical Intermediate Care	1(2%)
		20(34%)
Total Report		59

Table 2. Demographic and Morbidity Features of Patients involved in ME.

Demographic data	
Gender	
Female	34(58%)
Male	25(42%)
Age (years)	55±21
Stay at hospital(days)	17±19
Main Diagnoses ICD-10	
Diseases of the Circulatory System	18(31%)
Neoplasm	15(25%)
Diseases of the Genitourinary System	7(12%)
Diseases of the Digestive System	7(12%)
Diseases of the Respiratory System	3(5%)
Diseases of the Central Nervous System	2(3%)
Endocrine Diseases	2(3%)
Diseases of pregnancy, delivery and puerperium	1(2%)
Parasitic and infectious diseases	1(2%)
Cutaneous diseases	1(2%)
Diseases of musculoskeletal system	1(2%)
Injuries, wounds	
Intoxications and other external factors	1(2%)

Table 3 Report description as per ATC

Drug Group		Frequency
	Adriamycin	1(2%)
	Ara-C	1(2%)
Antineoplastic and	Cyclophosphamide	1(2%)
Immunomodulating agents	Cyclosporin	1(2%)
	Cetuximab	1(2%)
	Etoposide	2(3%)
Total		7(12%)
	Ampicillin	1(2%)
	Anphoterycin B	1(2%)
	Ciprofloxacyn	1(2%)
Antiinfective Drugs for Systemic Use	Cloxacillin	1(2%)
	Levofloxacyn	1(2%)
	Nitrofurantoin	1(2%)
	Benzylpenicillin	1(2%)
	Vancomicyn	2(3%)
Total Med. Antiinfective Drugs for Systemic Use		9(15%)
Hormone Medication for Systemic	Propilthiouracyl	1(2%)
Use	Somatostatin	1(2%)
Total Hormone Medication for Systemic Use		2(3%)
	Furosemide	2(3%)
Cardiovascular System Drugs	Hydrochlorothiazide	1(2%)
	Nifedipine Retard	1(2%)
Total Med. Cardiovascular System Drugs		4(7%)
	Bupivacaine/Fentanyl	3(5%)
	Phenytoin	2(3%)
Nervous System Drugs	Morphine	1(2%)
	Petidine	1(2%)
	Tramadol	1(2%)
Total Med. Nervous System Drug		8(14%)

Continue Table 3 Report description as per ATC

		Frequency
Drug Group		
Drugs for Blood and Blood forming Organs	Acenocoumarol	2(3%)
	Aminoacids	1(2%)
	Sodium Bicarbonate	1(2%)
	Calcium	1(2%)
	Enoxaparin	2(3%)
	Heparin	3(5%)
	KCl	1(2%)
Total Drugs for Blood and Blood forming Organs		11(19%)
Musculoskeletal System Drugs	Cyclobenzaprine	1(2%)
	Dipyrone	2(3%)
	Ketoprofen	1(2%)
Total Musculoskeletal System Drugs		4(7%)
Respiratory System Drugs	Racemic Epinephrine	1(2%)
	Noradrenalin	1(2%)
Total Respiratory System Drugs		2(3%)
Alimentary Tract Metabolism Drugs	Glibenclamide	1(2%)
	Hidrocortisone	1(2%)
	Cristalline Insulin	1(2%)
	NPH Insulin	2(3%)
	Parenteral Nutrition	1(2%)
	Omeprazole	1(2%)
	Thiamin	1(2%)
Total Tract and Metabolism Drugs		8(14%)
Drugs Used in the Diagnosis	Nonionic Contrast Medium	1(2%)
Total Drugs Used in the Diagnosis		1(2%)
No Information		3(5%)
Total No Information		3(5%)
Total		59(100%)

Forty seven percents ME reports began in administration process, 27% in the dispensing process (Figure 1).

Of Fifty nine ME reports, 69% of them (41) reached the patient, of which 34% required monitoring, and 39 % required more than one action is taken. While there was attributable to ME reported deaths, 47% were classified as type A, and 97% ME reported could have been avoided (Table 5).

In 46 of 59 ME reports. Attempt to set the ME type occurred in each of the processes (Table 5). In the prescription process, the source of the error was because there was not a recipe (42.9 %) or because the prescribed dose was not correct (28.6 %). The delivery of the wrong medication, which was originated 40 % ME occurred in the

dispensing process (35.3%). It occurred in the management process was due to the administration of a drug that is not appropriate.

Table 4 ADE severity and Preventability

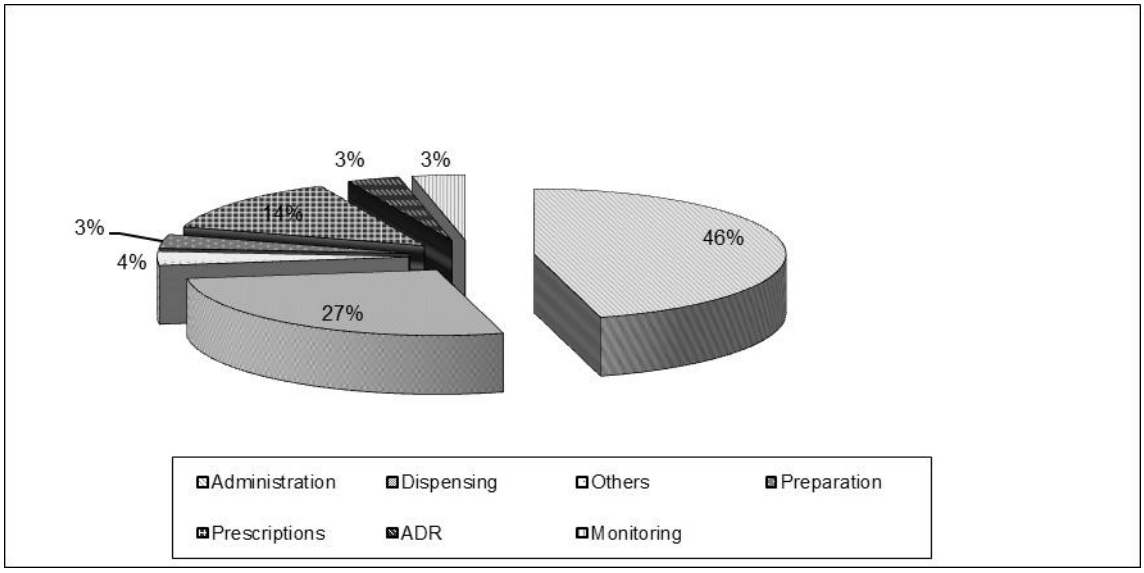
Severity	**Frequency**
A Circumstances or incidents that have capacity to cause error.	8(14%)
B An error occurred but did not reach the patient.	17(28%)
C An error occurred that reached the patient but did not cause patient harm.	6(10%)
D An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.	8(47%)
E An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.	0%
F An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.	0%
G An error occurred that may have contributed to or resulted in permanent patient harm.	0%
H An error occurred that was life threatening and required intervention necessary to sustain patient's life.	0%
I An error occurred that may have contributed to or resulted in the patient's death.	0%

Preventability	
Non-preventable	1(2%)
Preventable	58(98%)

Table 5. Description of ME types reported for which a description was retrieved (N=46)

ME Type	Description	Nº(%)
Administration		
	Wrong patient	4(18.2%)
	Wrong time	3(13.6%)
	Wrong medication	6(27.3%)
	Wrong dose	3(13.6%)
	Wrong route of administration	1(4.5%)
	Wrong rate of infusion	5(22.7%)
Total		22(47%)
Dispensation		
	Delayed dispensation	1(10.0%)
	Wrong medication	4(40.0%)
	Out of stock	1(10.0%)
	Faulty conservation	2(20.0%)
	Faulty labeling	1(10.0%)
Total		10(22%)
Banal		
	Medication loss due to flask breakage	1(100%)
Total		1(2.2)
Preparation		
	Wrong reconstitution	2(28.6%)
	Wrong rate of infusion	5(71.4%)
	Wrong dosage form	1(10.0%)
Total		10(22%)
Prescription		
	Illegible writing	1(14.3%)
	Inexistent order	3(42.9%)
	Non-validated verbal order	1(14.3%)
	Wrong dose	2(28.6%)
Total		7(15.2%)
ADR		
	Skin rash	1(50.0%)
	Poorly tolerated	1(50.0%)
Total		2(4.4%)
Monitoring		
	Medication not indicated	1(50.0%)
	Laboratory parameter Assessment omitted	1(50.0%)
Total		2(4.4%)
Total		46(100%)

Figure 1 Type Medication Error



DISCUSSION

This work is made by the few in our country who describe ME experience.

The ME reporting rate in our hospital were lower than those reported in international studies [17] because the system had little time to implement, so it is little known. Other reasons may be reluctance to report by the health personnel involved in the ME for any penalties that may receive. Other reasons that have been described in literature as barriers to the reporting ME, is lack of feedback after reporting initiatives, lack information to make a report and the difficulty to access report forms [18].

Of note is the high number of ME patient arrived, a value close to 70 %, higher than that reported in literature [19] and figure this is probably why they have reported.

The processes of drug use in which ME reports originated, are similar to other published experiments [20]. During the analysis it was observed that most of the reported ME occurred due to various faults within the system of drug use [21]. It has been estimated that about 50% ME, default procedures and lack of automation in medication use system [22] should be. Among other ME causes are lack of a drug to prescribe or administer, difficulty accessing drug information or protocols, lack of communication between the health team, etc. [23].

The time at which ME occurred (data not shown) in our hospital, concentrated mainly in the daytime, possibly because burden of care that focuses on that schedule (test taking, more frequent drug administration), that is likely to notice at this time is greater for control given by full complement staff, not during night time. These results are similar to other studies in which ME occur between 12pm and 4pm [24], but also because in these times there is more control, as there is fully staffed, it does not occur during at night .

The weakness of this work comes from the quality of the information provided in incidents reports, as many times not complete data patients had not identified precise time incident, and the measures taken to reverse the adverse event, as well as the description of the event itself occurred. We conclude that usefulness of incident reports will be useful only if they contain all the information to be able to identify the causes of ME and take corrective action [25]. Medication error report, detect those high clinical significance and have a low rate of false positives [26].

The situation described in this work may have changed actually, as the hospital has made dissemination of standards of good practice in regard to medication administration, which were developed by a joint committee with the participation of nurses of different services, midwives and pharmacists. This is expected to be a consistency in the process, helping to improve clinical practice.

CONCLUSIONS

The ME actually a cross all services of our hospital. The ME report, are a useful method for detecting the origin of the ME and ME for those that have a high clinical significance for the patient, however, are sub - notified.

Medication error, are included in Security component in Patient Care must be met by all health care providers to achieve accreditation, which can be achieved with implementation standards care (management standards, guidelines clinical practice), working protocols for the use of drugs with high probability of ME (use of insulin, oral hypoglycemic agents, heparin, etc.), and implementing computer systems for prescribing and dispensing. It is important to consider that ME are not only due to human error, but also must consider the poor planning of work systems and drug delivery systems to patient. In addition it should be noted that in ME is not only involved medical personnel (doctors, pharmacists and nurses), but also pharmaceutical industry, health authorities and even patient himself.

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ISSN 1695-6141