Medication Errors in a Tertiary Hospital With Three Different Drug Delivery Systems

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Abstract

Objective: To estimate the proportion of medication errors in a tertiary hospital, global and for each delivery medication system, to describe the error types and the implied medications, and to analyse the factors associated to the same ones.

Methods: Errors were identified from direct observation of 2242 opportunities for error (administered doses or prescribed doses not given) by 6 couples of observers. Delivery medication systems were stock in ward, unit-dose with electronic prescription, and unit dose with computerized transcription. Logistic regression was used to evaluate the association between errors and certain factors.

Results: The medication error rate was 7.2% (95% CI, 6.1-8.3), and 4.4% (95% CI, 3.6-5.3) of them reached the patient. For delivery systems, the error rate was 9.5% (95 CI, 7.4-11.9) for stock in ward, 7.8% (95% CI, 5.9-10.0) for electronic prescription, and 4.7% (95% CI, 3.4-6.4) for computerized transcription. The highest error frequency was observed in the administration phase (58.4%) and the omitted dose was the most prevalent error (31.7%). The error rate was associated with the pharmacotherapeutic process, the schedule of administration, and the unit of hospitalization.

Conclusions: In 1 of each 14 opportunities for error, a medication error takes place. The different delivery medication systems have different error rates.

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Errores de medicación en un hospital terciario con tres sistemas de distribución de medicamentos diferentes

Objetivo: Estimar la proporción de errores de medicación en un hospital terciario, tanto de manera global como por sistemas de distribución de medicamentos, describir los tipos de error y los medicamentos implicados y analizar los factores asociados a los mismos.

Método: Los errores se identificaron mediante la observación directa de 2.242 oportunidades de error (dosis administradas o las prescritas y no administradas de medicamentos) por 6 pares de observadores. Los sistemas de distribución fueron *stock* en planta, dosis unitarias con prescripción electrónica asistida y dosis unitarias con transcripción informatizada. Se utilizó la regresión logística múltiple para valorar la asociación entre errores y determinados factores.

Resultados: El porcentaje global de error de medicación fue del 7,2% (IC del 95%, 6,1-8,3), y un 4,4% (IC del 95%, 3,6-5,3) alcanzaron al paciente. Por sistemas de distribución, el porcentaje de error de medicación fue de 9,5% (IC del 95%, 7,4-11,9) para el *stock* en planta, 7,8% (IC del 95%, 5,9-10,0) para la prescripción electrónica asistida y 4,7% (IC del 95%, 3,4-6,4) para la transcripción informatizada. La mayor frecuencia de errores se observó en la fase de administración (58,4%) y la dosis omitida fue el tipo de error más prevalente (31,7%). El riesgo de error se asoció al proceso farmacoterapéutico, al horario de administración y al tipo de unidad de hospitalización.

Conclusiones: En una de cada 14 oportunidades de error se produce un error de medicación. Los distintos sistemas de administración de medicamentos tienen tasas de error diferentes.

Palabras clave: Error de medicación. Observación directa. Error de administración. Sistemas de distribución de medicamentos.

INTRODUCTION

Since initial works by the ADE Prevention Study Group[1,2] and the publication of the report "To err is human,"[3] interest and concerns about medication errors have been continuously increasing. The diverse criteria for defining medication errors, the disparity of research methods used in the different studies, the variability of the different environments, and changes over time have been serious limitations on the ability to estimate the magnitude of the problem and its real impact on patients.[4,5] However, it is agreed that the initiatives to improve this problem must include having more information available about its prevalence at each specific centre, the most frequent types of error with the greatest impact on the patients, and the factors that could contribute to its control.

In the specific case of hospital care, patients are the final recipients of a complex pharmacotherapeutic process that begins with a pharmacological prescription made by the medical team, followed by validation by the pharmacist, preparation, and dispensation by the pharmacy nursing staff and administration by the nursing personnel on the ward, and includes monitoring aspects by all these workers. Errors can occur in any of these stages, due to act or omission, and it is essential to identify them to develop strategies for improvement.

The purpose of this work is to estimate the proportion of medication errors in a tertiary hospital, overall and for each drug delivery system operating there, to describe the types of error and the drugs involved, and to analyse the factors associated with the same.

METHOD

Scope

A cross-sectional study was carried out during the months of May and June 2005 in the hospitalisation units (HU) caring for adult medical-surgical conditions at a University Hospital with 1500 beds. In the hospital, there were 3 different drug delivery systems: a ward stock system which served 6 units, a unit-dose delivery system with assisted electronic prescription (DUPEA system), via the Prisma® software, which serves 18 hospitalisation units, and a unit-dose delivery system with computerised transcription (DUTI system) using the Farmasyst® programme, which served 11 units. Table 1 sets out the most interesting characteristics of the pharmacotherapeutic processes in each of the 3 delivery systems.

In the ward stock system, the doctor prescribed the medication on the clinical record, the nurses transcribed this to the nursing sheet and prepared the medication from the stock they have in their ward. The medication was replaced based on a weekly order to the pharmacy department, which did not know the identity of the patients nor their corresponding treatments.

In the DUPEA system, the prescription (doctor), validation (pharmacist), and administration (nurse) stages were integrated in the Prisma® application software (APD Compañía Española de Informática, Madrid 2005). Doctors could prescribe from the hospitalisation units, polyclinics, operating theatres and the critically ill patients', and emergency areas. The pharmaceutical validation of the prescriptions was performed before dispensing

Table 1. Characteristics of the Pharmacotherapeutic Process in the 3 Delivery Systems[a]

Process Stage	Stock	DUPEA	DUTI
Medical prescription	Clinical record	Computerised Assisted (Prisma®)	Drug prescription sheet
Transcription by nursing staff in hospitalisation unit	Nursing sheet for medication	No	Nursing sheet for medication
Transcription by nursing staff in pharmacy department	No	No	Computerised (Farmasyst®)
Pharmaceutical validation	No	Computerised Assisted (Prisma®)	Computerised (Farmasyst®)
Dispensing by nursing staff pharmacy department	Manual Weekly By ward	Automated (Kardex®) Daily Per patient	Manual Daily Per patient
Administration by nursing staff hospitalisation unit	Nursing sheet for medication	Computerised administration sheet (Prisma®)	Nursing sheet for medication

[a]DUPEA indicates unit-doses with assisted electronic prescription; DUTI, unit-doses with computerised transcription.

the drugs, every day and 24 hours a day. Once the prescription had been validated, the pharmacy nursing staff prepared the medication on trolleys with Kardex® automated dispensers. The trolleys were delivered to the ward between 15.00 and 17.00 hours every day. The HU nursing staff checked the medication received and administered it to each patient according to the administration sheet issued by Prisma®.

In the DUTI system, the doctor prescribed the medication on the prescription sheet, a copy of which is submitted to the pharmacy. The pharmaceutical validation of the prescriptions was carried out before the drugs were dispensed. The nursing personnel transcribed the prescription onto the Farmasyst® application software (APD Compañía Española de Informática, Madrid 1999). This application generated a medication list from which the medication was manually prepared on the trolleys and then delivered to the ward at 14.00 hours every day. The HU nursing staff checked the medication received and administered it to each patient according to the nursing sheet.

Population and Sample

The unit of analysis was each of the opportunities for error (OE), these being taken to be the doses administered or those prescribed and not administered.[6] Fluid therapy and chemotherapy administrations were excluded from the study. The sample size was calculated as 683 OE for each of the 3 delivery systems, assuming an error rate of 20%, a 95% of confidence level, and a 3% of precision. The observations were distributed proportionally among the hospitalisation units in each system and the most frequent administration times, with 62% of observations in the 9-hour schedule, 22% in the 16-hour schedule, and 16% in the 21-hour schedule.

Measures of the Results

The main measure of the results was the medication error (ME), which, for the purposes of the study, was considered to be any incident in the pharmacotherapeutic process from prescription to administration. This definition was adopted to allow prescription errors to be included (as observers could interpret whether or not the prescription was correct) and register any incidents occurring in the stages prior to administration of the medication as errors, even though the error had been intercepted. The secondary measure of results was "medication error reaching the patient" (MERP), defined as any error not intercepted before giving the medication.

The ME were classified by the stage of the process during which the error occurred and the type of error according to the recommendations of the Ruiz Jarabo working group,[7] exclusively. Monitoring errors were not considered, as they could not be detected with the methodology used. During the data analysis process, difficulties arose to classify 2 groups of errors: *a*) the administration or suspension of drugs and changes of route without medical prescription were classed as prescription errors, as these were considered to have been done verbally or by another procedure (clinical record); and *b*) a missed dose or its unavailability in the medication drawer caused by "not sending" the prescriptions to the pharmacy, was classed as an administration error because of the involvement of the HU nursing staff (in the DUTI system).

The failure to register blood products was also included among the types of errors (a demand established in the protocols for using blood products in the hospital), but the errors relating to speed of administration and physical-chemical incompatibility of mixtures of drugs were not taken into account, because of the variability of this data registration by the observers. Timing errors were defined as a 30-minute difference in dosing regimens of 6 and 8 hours, and 60 minutes in dosing regimens of 12 and 24 hours. The errors were characterised according to the possible severity of harm suffered by the patient. This was done according to the criteria of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)[8] and the medication risk was classified according to the criteria of the Institute for Safe Medication Practices (ISMP).[9]

Error Detection

Following the methodology used in other studies,[6] the ME were identified by direct observation of the medication administration. The method applied did not mask the purpose work to be done to the observers or nursing staff. The observers were pharmacists and specialists doing an internship in Hospital Pharmacy and were given training sessions before starting the field work. The observers did not know which medication the patient was to receive. Six fixed pairs of observers (2 per delivery system), inspected the preparation and administration of the medication in the ward and then compared their notes with the prescription and, additionally, with the validation on the DUPEA and DUTI systems. Prior to this, for these systems, the observers reviewed the drugs prepared on the medicine trolley. The observations were entered into a computerised database in which each register corresponded to an opportunity for error. Once the entire process was finalised, 2 pharmacists from the research group reviewed all the computer registers, comparing them with the data collection sheets and the documentation provided by the observers.

Ethical Aspects

The study, which was of an observational nature, was authorised by the Medical and Nursing Management, as well as the Hospital Research Committee. The computer registers developed contained no information capable of identifying patients. The observers, in spite of the fact that they did not know which medication was prescribed to the patients, intervened whenever they considered an error might occur, to avoid the possible impact on the patients (in these cases, the incident was recorded as an error reaching the patient, even though it had been avoided).

Statistical Analysis

Firstly, the percentage of ME was estimated (errors in comparison to the total opportunities for errors), overall and by delivery systems, as well as the errors reaching the patient (errors not intercepted). In both cases, the corresponding confidence intervals were estimated at 95% using the exact binomial method. The percentage of ME was also calculated in terms of administration schedules, as well as the error distribution among the stages of the pharmacotherapeutic process and the different types of ME. The possible existence of associations between those factors and the percentage of ME was assessed by the χ^2 test. Finally, a multiple logistic regression was performed to assess the independent associations between the existence of ME and the factors analysed: delivery system (stock, DUPEA, and DUTI), administration schedule (9, 16, and 21 hours), type of HU (medical, surgical, mixed medical and surgical and a set of trauma-orthopaedics, rehabilitation, and psychiatry), and number of drugs per patient and per administration (1, 2 to 4, 5 to 7, and 8 or more). The goodness of fit of the model was assessed using the C-statistic and the Hosmer-Lemeshow test. All the calculations were made using the STATA® statistical package.

RESULTS

A total of 2242 opportunities for error were seen, corresponding to 531 different patients, where 161 medication errors were identified (7.2%; 95% CI, 6.1-8.3) of which 99 were not intercepted, leading to a percentage of MERP of 4.4% (95% CI, 3.6-5.3). By delivery systems (Table 2), the DUTI showed a smaller error rate than the stock and the DUPEA systems (4.7% vs 9.5%, and 7.8%, respectively), although the differences between DUTI and DUPEA were not statistically significant. The DUTI system also showed a lower proportion of MERP (0.4% vs 5.5% in the DUPEA system, and 8.1% in the stock system). With regard to the schedules (Table 3), the 16-hour dosing schedule showed a higher proportion of errors than the 9- or 21-hour one, a statistically significant aspect both overall and in the DUPEA system (P<.005).

By the pharmacotherapeutic process stages (Table 4), the administration stage accounted for 58.4% of the ME and 85% of the MERP, while in the prescription stage 22.4% of the ME occurred (in 78% they were verbal medical prescriptions or notes on the clinical record), and 6% of the MERP. The 83%, 100%, and 93% of the errors occurred during the prescription, validation, and dispensation stages, respectively, were intercepted. With regard to errors in administration, 11% were resolved (all in the DUTI system and originating from the HU staff not sending the treatment sheet to the pharmacy).

Table 5 shows the distribution of ME by type and delivery system. Among the 4 most frequent types of ME in each system, the following are worth noting: *a*) for the stock system, the missed dose error (31.7% of the ME) originated in all cases within the administration stage; for the DUPEA system it originated in the administration (73%) and dispensing (27%) stages, and for the

Table 2. Medication Errors, Overall, and by Delivery System[a]

	Overall			*Stock*			DUPEA			DUTI		
	No.	%	95% CI	No.	%	95% CI	No.	%	95% CI	No.	%	95% CI
Opportunities for error	2242	–	–	705	–	–	707	–	–	830	–	–
Medication errors[b]	161	7.2	6.1-8.3	67	9.5	7.4-11.9	55	7.8	5.9-10.0	39	4.7	3.4-6.4
MERP[b]	99	4.4	3.6-5.3	57	8.1	6.2-10.3	39	5.5	3.9-7.4	3	4	0.1-0.9
Total patients	531	–	–	147	–	–	167	–	–	217	–	–
Patients with ME[b]	118	22.2	18.7-26.0	45	30.6	23.1-38.5	40	24.0	17.6-31.1	33	15.2	0.6-20.6

[a]ME indicates medication error; MERP, medication error reaching the patient; DUPEA, unit-doses with assisted electronic prescription; DUTI, unit-doses with computerised transcription; 95% CI, 95% confidence interval.
[b]P<.001 statistically significant difference among the 3 delivery systems.

Table 3. Percentage of Medication Errors According to the Administration Schedule and the Delivery System[a]

Opening Times	Overall[b]			*Stock*			DUPEA[b]			DUTI		
	OE	% ME	95% CI	OE	% ME	95% CI	OE	% ME	95% CI	OE	% ME	95% CI
9 Hours	1401	6.4	5.1-7.6	429	7.9	5.6-10.1	457	5.7	4.0-7.8	515	5.4	3.6-7.7
16 Hours	492	10.6	7.8-13.3	152	13.2	8.9-18.5	172	15.1	10.1-21.3	168	4.2	0.2-8.4
21 Hours	349	5.7	3.3-8.2	124	10.5	6.0-15.0	78	3.8	0.8-10.8	147	2.7	0.1-5.3
Total	2242	7.2	6.1-8.3	705	9.5	7.4-11.9	707	7.8	5.9-10.0	830	4.7	3.4-6.4

[a]ME indicates medication error; OE, opportunity for error; DUPEA, unit-doses with assisted electronic prescription; DUTI, unit-doses with computerised transcription; 95% CI, 95% confidence interval.
[b]P<.005 statistically significant difference among administration schedules, overall and in the DUPEA system.

Table 4. Distribution of Medication Errors According to the Pharmacotherapeutic Process Stage and the Delivery System[a]

Stage	Overall				*Stock*				DUPEA				DUTI			
	ME		MERP		ME		MERP		ME		MERP		ME		MERP	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Prescription	36	22.4	6	6.0	15	22.4	5	8.8	9	16.4	1	2.6	12	30.8	0	0.0
Validation	2	1.2	0	0.0	NA	–	NA	–	1	1.8	0	0.0	1	2.6	0	0.0
Transcription	15	9.3	8	8.0	6	9.0	6	10.5	NA	–	NA	–	9	23.1	2	66.7
Dispensing	14	8.7	1	1.0	NA	–	NA	–	8	14.5	1	2.6	6	15.4	0	0.0
Administration	94	58.4	84	85.0	46	68.7	46	80.7	37	67.3	37	94.8	11	28.2	1	33.3
Total	161	100	99	100	67	100	57	100	55	100	39	100	39	100	3	100

[a]ME indicates medication error; MERP, medication error reaching the patient; DUPEA, unit-doses with assisted electronic prescription; DUTI, unit-doses with computerised transcription; NA, stage not applicable in the delivery system.

Table 5. Distribution of Medication Errors According to Their Type and the Delivery System[a]

Type of Error	Overall, % n=161	Stock, % n=67	DUPEA, % n=55	DUTI, % n=39
Missed dose	31.7	20.4	40.0	38.5
Schedule	17.4	22.4	23.6	0.0
Missed medication	11.2	13.4	1.8	20.5
Administration route	8.7	7.5	9.1	10.3
Incorrect dose	8.1	10.5	9.1	5.1
Treatment duration	7.5	3.0	3.6	20.5
Incorrect drug	6.2	10.4	3.6	2.6
Dosing interval	3.7	7.5	1.8	0.0
Double dose	2.5	1.5	5.4	0.0
Non-registration of blood products	1.9	3.0	1.8	0.0
Double therapy	0.6	0.0	0.0	1.0

[a]DUPEA indicates unit-doses with assisted electronic prescription; DUTI, unit-doses with computerised transcription.

DUTI system, in the administration (45%), dispensing (35%), and prescription (20%) stages; *b*) the missed medication error (11.2%) originated in the prescription stage (65%) and the transcription stage (35%) within the stock system, whilst within the DUTI system, this type of error always originated in the transcription stage; *c*) the incorrect dose error in the DUPEA system originated mainly by administrating whole tablets or vials when only half had been prescribed; and *d*) the error in the duration of treatment within the DUTI system originated from prescription (38%) due to verbal order of the suspension, in the transcription (12%), and in administration (50%) for not sending the treatment sheet to the pharmacy.

The drugs most often involved in ME were those belonging to the analgesic/antipyretic (25%), antibacterial (25%), and anti-ulcer (17%) groups. High-risk drugs were: tramadol ampoules (n=3), pethidine ampoules (n=1), potassium chloride ampoules (n=1), and glibenclamide tablets (n=1). In the error classification according to their potential seriousness, a total of 62 (38.5%) did not reach the patient (category B), 94 (58%) reached the patient without causing harm (category C), and 4 (2.5%) reached the patient and it was considered that they might have required monitoring and/or treatment to avoid harm (category D). The latter consisted of: failure to administer a proton pump inhibitor because it was prescribed by the brand name of a speciality not included in the Hospital Pharmacotherapeutic Guide; failure to administer enoxaparin 40 mg because there was no transcription for it in the HU; administration of a dose of enoxaparin 80 mg instead of 60 mg; and the failure to administer a dose of transdermal fentanyl every 72 hours.

In the bivariate analyses, the type of HU (medical: 7.3%, surgical: 7.4%, mixed: 12.7%, traumatology and others: 4.9%; *P*=.001) was associated with the error rate, as were the delivery system (Table 2) and schedules (Table 3). By contrast, no association was found with the number of drugs. The multivariate analysis (Table 6) reproduced these associations with some slight differences. The evening schedule showed a higher level of risk, the other factors being maintained (OR=1.6), as did the mixed units as opposed to medical units (OR=1.7), while the DUTI system (OR=0.6) reduced the risk of error in comparison to the ward stock system. Taking between 5 and 7 drugs, paradoxically, also reduced the risk of error in comparison to patients taking just 1 medication (OR=0.7). The model showed good calibration

Table 6. Factors Independently Associated With Medication Error Risk. Logistic Regression Analysis[a]

Factors		OR	95% CI	*P*
Medication delivery system	Stock	1.0		
	DUTI	0.6	0.4-0.9	.006
Schedule	9 Hours	1.0		
	16 Hours	1.6	1.1-2.3	.008
Hospitalisation units	Medical units	1.0		
	Mixed units	1.7	1.1-2.7	.066
Number of drugs	0-1	1.0		
	5-7	0.7	0.4-1.0	.013

[a]OR indicates odds ratio; 95% CI, 95% confidence interval.
n=2242; *P*<.0001; pseudoR^2=0.028; C-statistic: 0.625; P (χ^2 Hosmer-Lemeshow)=.224.

(non-significant in the Hosmer-Lemeshow test) although its discriminatory capacity was low (C-Statistic: 0.62).

DISCUSSION

The results of this study show the importance of ME in our hospital environment. When we extrapolate the percentage of ME found to the volume of activity in the Pharmacy Department during 2005, and assuming equivalence between the doses dispensed and opportunities for error, this gives 490 medication errors every day in the DUPEA system (6300 daily doses) and another 87 daily errors in the DUTI system (1860 daily doses), with almost 6000 patients involved of the 25 000 seen every year; this data cannot be estimated in the ward stock system, as it is not an individualised system for delivering drugs and is not computerised.

The percentage of medication errors in other studies that have used similar methodologies varies between 2.4% and 19%.[6,10-14] The comparison of the results of these studies has limitations due to differences in definitions, methods, and environments, including different delivery systems, and to the fact that they refer to errors that reach the patient (discrepancies between prescription and administration). Furthermore, in our study, in contrast to others, errors relating to speed of administration and physical-chemical incompatibility of mixtures of drugs were not considered, because of the variability of this data registration by the observers. Even with these provisos, the results for the stock in ward and DUPEA systems seem consistent with earlier studies, while the percentage of MERP in the DUTI system is much lower than those referred to in the literature, except for a study done in the 1990s, which showed rates of MERP below 1%.[15]

The stock system showed a higher rate of errors than unit-dose systems, although the differences were only significant with regard to the DUTI system. The absence of significant differences between the stock and DUPEA systems may be conditioned by the application of these systems to different HU, with treatments of different complexity. This explanation is suggested by a study performed at our hospital (the results have not been published) which shows an important reduction in errors in the units which changed from the stock system to the DUPEA. However, the error rate in the DUPEA system was especially associated with the 16-hour schedule (in fact, it is the error rate at this schedule the one that increases the percentage of ME in DUPEA in comparison to DUTI). Although associations have been described between the error rate and the schedules of administration,[16] this is an aspect that must be specifically studied to determine rectifiable causes of error.

When analysing the rate of ME by stages, considering drug delivery systems at the same time, it is observed that in the DUPEA system there are no transcription errors by nursing personnel as it is the doctors who put in the prescriptions. Electronic prescriptions seem not to improve safety in the administration stage; in this sense, the importance of teamwork culture in a unit-dose system must be recognised. Indeed, in our hospital the DUTI system has been operating for 15 years (300 beds), while the introduction of the DUPEA system has taken place progressively over the past 5 years (600 beds) in hospitalisation units which had a ward stock system. We must also take into account that even though a great deal of effort is put into training doctors when the DUPEA system is introduced (training is given at the beginning and continuously for 2 months) and pharmacists validate the prescriptions and monitor the already established treatments, the nursing team of the HU, although they also receive initial and continuous training, requires greater support for standardisation and improvement of the activities carried out during the drug administration stage (conformity of the drug sent by the pharmacy, preparation of intravenous mixtures, verification by double checking, etc). This analysis suggests strategies of interest such as incorporating new technologies in the administration stage (bar code and radiofrequency),[17,18] as well as improvements in working practices, which focus on promoting the standardised work culture of the pharmacotherapeutic process.

With regard to other variables associated with errors, there are studies that have not found any relationship with the number of drugs in each dose.[19,20] However, an association has been reported between administration errors and the workload falling on the nursing staff in the HU,[14,21] a variable that could be related to the administration schedules. Given the low predictive capacity of the regression model obtained, it is possible that the workloads of the nursing staff and other variables not included in this study are important to explaining the proportion of medication errors.

Among the limitations of this study, it is essential to note those deriving from the direct observation method, including aspects of validity (changes in the behaviour of people who know they are being observed) and aspects of reliability among and between observers. These are aspects inherent to the method itself that can have an impact on the results in several ways,[5,6,13,22] and which are only partially compensated by their high output to detect defects in quality of the pharmacotherapeutic processes and by the quantitative nature of the results obtained.[23] Secondly, the method chosen is especially suitable for assessing discordances between the drugs administered and those prescribed, but it is less effective for assessing the prescription errors themselves.

Nevertheless, this study shows the substantive importance of ME and MERP in our hospital, the relationship among error rate, administration systems and schedules of administration, and a higher percentage of ME in the administration stage, with missed doses being the most frequent errors.

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