Quality of Drug Treatment Process Through Medication Errors in a Tertiary Hospital

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Abstract

Objective: To assess the quality of drug treatment process in a unit dose and assisted electronic prescription system in a tertiary hospital, by looking at medication errors.

Methods: A prospective, observational study into medication errors was carried out on 308 hospitalized patients. This was done by assessing medical prescriptions, pharmaceutical validation, prepared and dispensed medication, and by directly observing drug administration. The variable, ie, the medication error, was analyzed in the drug treatment process so as to decipher the type and cause of the error. Quality indicators were defined at each stage (percentage relationship between errors and opportunities for error).

Results: Of the 308 patients studied, 107 had at least 1 medication error (34.7%). There were a total of 137 errors: omission of allergy and prescription description (20.4%), prescription/validation (28.5%), dispensing (23.4%), and drug administration (27.7%). The most frequent error was dose omission (19.7%) and choice of pharmaceutical product (16.1%). The most common cause of error was forgetfulness or a lack of attention to detail (53.3%). The quality indicators by stage were: 2.3% for omission of the patient's allergies; 0.9% for prescription; 1.6% for prescription/validation; 8.2% for dispensing; and 2.1% for drug administration.

Conclusions: It is estimated that 35 patients in every 100 experience errors in their drug treatment process. Opportunities for improvement are identified based on standardization and training for professionals in carrying out technical tasks and using technology.

Key words: Medication error. Direct observation. Administration error. Drug distribution systems. Drug treatment process.

Calidad del proceso farmacoterapéutico a través de errores de medicación en un hospital terciario

Objetivo: Evaluar la calidad del proceso farmacoterapéutico en un sistema de dosis unitaria y prescripción electrónica asistida en un hospital terciario, a través de errores de medicación.

Métodos: Se realizó un estudio observacional prospectivo de errores de medicación en 308 pacientes hospitalizados, por revisión de la prescripción médica, la validación farmacéutica y la medicación preparada y dispensada, y por observación directa de la administración de medicamentos. La variable, el error de medicación, se analizó en la fase del proceso farmacoterapéutico, el tipo y la causa de error. Se definieron indicadores de calidad (relación porcentual de errores respecto a oportunidades de error) en cada fase.

Resultados: De los 308 pacientes estudiados, en 107 se detectó al menos 1 error de medicación (34,7%); hubo un total de 137 errores distribuidos en: omisión de alergia y descripción de la prescripción (20,4%), prescripción/validación (28,5%), dispensación (23,4%) y administración de medicamentos (27,7%). El error más frecuente fue la omisión de dosis (19,7%) y la selección de especialidad farmacéutica (16,1%). La causa más común fue fallos de memoria y descuidos con el 53,3%. Los indicadores de calidad por fases fueron: 2,3% para la omisión de alergia del paciente; 0,9% para la prescripción; 1,6% para la prescripción/validación; 8,2% para la dispensación, y 2,1% para la administración de medicamentos.

Conclusiones: Se estima que en 35 de 100 pacientes ocurre un error en su proceso farmacoterapéutico. Se identifican oportunidades de mejora basadas en la normalización y la formación de profesionales para realizar tareas técnicas y manejar la tecnología.

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

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INTRODUCTION

In the area of drug treatment, the patient's safety requires a system of quality and risk management to be established to prevent medication errors (ME) which may occur in the whole drug treatment process in the hospital, that includes prescription, validation, preparation, dispensing, and administration of medications, along with the follow-up of the entire patient's drug treatment.[1]

In 2005, an epidemiological study was carried out to find the proportion and profile of ME in our hospital. The method used was direct observation of medication administered or observing what should be administered to patients[2] by adapting to other authors' methodology.[3] The proportion of ME in 2242 opportunities for error was 7.2% (95% confidence interval [CI], 6.1-8.3), similar results to 12.8% and 14.9%, which were published by Blasco et al[3] and Tissot et al,[4] respectively, who used direct observational methods to medication administration. With this design, ME is detected in the final step of the process (administration), and later, a retrospective analysis is carried out to decipher where the error occurred in the process. This may cause biased error attribution: administration errors are overestimated,[5] and errors which have been resolved before reaching the final stage are no longer registered. In this sense, and from a quality perspective, a method which analyzes each stage of the drug treatment process in real and daily clinical conditions is more interesting for accurately documenting the specific process improvements.

This study's objective is to evaluate the quality of the drug treatment process through ME determination, by patient and in each stage of the process, and from prescription to administration.

METHODS

Ethical Aspects

The observational study received authorization from the Doctor and Nurse management as well as the Commission for Research of our hospital. The computer registries developed contained no information allowing the patients' identification. In spite of not knowing the medication prescribed to the patients, observers from the administration intervened every time they thought an error could occur to avoid its impact on the patients (in these cases, the incident was registered as an error which would have affected the patient even though it was avoided).

Design and Characteristics of the Study

A transversal study was carried out during the months of May and June 2006, in hospital units (HU) treating adult patients with medical surgical pathologies from the General Hospital with 750 beds, of which 550 were treated by unit dose dispensing (UDD) and with a computer assisted prescribing (CAP). This hospital was part of a complex with more than 1500 beds.

Beds from surgery and critical patients' area, and emergency sections were excluded from this study because of their care needs and characteristics of their medication distribution system. Those HU with UDD and CAP recently established were also excluded because they were in a training period for these systems.

Characteristics of the Drug Treatment Process

Stages of prescription (doctor), validation (pharmacist), and administration (nurse) were involved in the CAP (Prisma®) application. There was an alert system connected to the electronic prescription and validation which warned of morbidity risks of prescribed drugs and offered recommendations. Oncological and nutritional drug treatment was administered for patients through Oncofarm® and Nutridata® programs.

Doctors could prescribe from the HU, polyclinics, operating rooms, and critical and emergency areas. Based on established normal work procedure, pharmaceutical validation of prescriptions was carried out before medications were dispensed, daily and within 24 h. Once the prescription was validated, the pharmacy nursing personnel used the Kardex® semi-automated storage with a CAP program interface. From this point, assistant technical personnel prepared and reviewed the medication in carts distributed daily between 15:00 and 17:00 h. The HU infirmary reviewed the medication received, prepared the intravenous medication (IV), and administered it to each patient according to the drug administration sheet issued by Prisma®.

Communication of incidents or problems was done by interview, telephone, and electronically, depending on urgency of resolution or seriousness of the incident. The drug treatment follow-up was supported by the hospital's electronic medical record which provides various modules for clinical reports at admission and discharge, and microbiology, radiology, and laboratory reports, among others.

Population and Sample

The patient sample size was obtained by applying the prevalence of patients with errors of 25% with a 95% CI and precision of observational method of 5% with a total of 288 patients; this number increases to 300 to avoid losses (5%). Patients were randomly selected from all of those attended to under the UDD and CAP system, and were grouped by HU to better organize the study.

Variables and Indicators

Medication error was established as the measurement variable and classified based on the stage of drug treatment process, the type, and cause of the error according to the methodology established by Climent et al.[2] Analysis of causes was carried out using the technique published by Jiménez et al.[6]

Quality indicators were defined as the percentage relationship of ME with respect to opportunities for error in each stage. The

denominators of quality indicators were obtained from opportunities for error in each stage: number of patients and drugs (lines), and of doses dispensed and administered to each patient. This was registered on the prescription's display, the printout on the medication carts, and the medication administration sheet, respectively. It was estimated that between 8:00 and 16:00 h, the number of prescriptions was equal to the number of patients, and daily medical and pharmaceutical validation was obligatory. The indicator was calculated by dividing the numerator by the denominator and multiplying it by 100. Quality assessment was carried out by comparison with a practice standard established based on our experience[2] and available resources.

Process of the Study

The patients were given a follow-up during their whole drug treatment process during a day in hospital, through the revision of medical prescriptions and pharmaceutical validation of the medication dispensed by the pharmacy nurses and by direct observation of medication administration by the infirmary. Fluid therapy and cytostatic agents were excluded.

A data collection sheet was designed for each patient. The follow-up was started by the revisers of the prescription and validation (one specialist pharmacist and another in training in hospital pharmacy) which: *a)* analyzed the patient's prescription selected on the treatment display, and they registered the presence or absence of incidents on the given sheet; *b)* they reviewed the patient's electronic record to detect regular medication, presence of allergies, etc, not recorded on the electronic prescription application; *c)* they revised the corrections and messages sent to the doctor during the validation done by the pharmacist associated with the given HU, and they registered this in the incidents sheet. The revisers communicated to the given pharmacist incidents found which had not been considered by them, to clarify and assign, or not assign quality errors exclusively tied to the prescription or to both (prescription and validation). The revisers printed the treatment label and the dose administration sheet to evaluate the next stages of dispensation and administration, annotating the number of lines of medication in treatment.

There were 8 trainee pharmacists who were revisers of the medication carts. They registered any difference between medications in the data collection sheet which were in the box of the selected patient and the printouts of medication on the cart, and they made note of the number of lines and number of units.

The 6 pairs of observers of medication administration in the hospital units were trainee pharmacists and specialists in training in hospital pharmacy. They carried out various training sessions before beginning their field work and followed the methodology established by Climent et al.[2] Observation of administration was carried out between 8:00 and 9:00 h.

Once the entire process was finalized, the data registered in the data collection sheets were recorded into a computer database by observers. Subsequently, 2 pharmacists from the research group reviewed all computer records and contrasted them with the data collection sheets and documentation provided by the revisers and observers.

Statistics

For the ME measurement variable, its distribution percentage was estimated based on the stage of the drug treatment process and its corresponding 95% CI by exact binomial method. Calculations were carried out using the SPSS 13.0 statistical package.

RESULTS

Of the 308 patients studied, in 107 at least 1 medication error was detected (34.7%; 95% CI, 29.4-40.3), and there was a total of 137 errors distributed as: 7 omission of allergy and 21 description of prescription (both represent 20.4%); 39 prescription/validation (28.5%); 32 dispensation (23.4%); and 38 medication administration (27.7%).

In Table 1, ME distribution is shown by type and stage of the drug treatment process. ME variability of prescription is notable and to a lesser degree, prescription with validation. Both share an error profile related to the management of the computer application of which stands out: selection of pharmaceutical specialties (commercial names, types of presentation, etc), description of prescriptions in the instruction section of the infirmary and hourly guideline. On the other hand, the incidents identified in the stage of preparation and administration of medications were of a technical nature and had to do with handling of medications.

ME causes are shown in Table 2. It is observed that the most frequent ME's were caused by memory and carelessness errors, and failure to maintain standards and protocols for 53.3% and 36.5%, respectively.

Quality indicators are shown in Table 3. It is observed that indicators related to patients show similar values in each stage, staying in the range of 6% to 12%, while those indicators referring to errors show very different results, because each indicator has a specific denominator, and each stage presents different opportunities for error.

DISCUSSION

This study's design allows for comprehensive evaluation of the quality of the drug treatment process and also offers an epidemiological approach to ME prevalence. Also, review and observation of each stage in one patient provides a sequenced perspective of the facts.

In our case, the 137 errors were distributed as: omission of allergy and description of prescription (20.4%), prescription and validation (28.5%), dispensation (23.4%), and administration of medication (27.7%). No defect was detected in the description and identification of patients because the system is electronic and

Table 1. Percentage Distribution of Medication Errors (ME) Based on Type and Stage of the Drug Treatment Process

Type of ME	Patient's Data, % n=7	Prescription, % n=21	Prescription-Validation, % n=39	Preparation, % n=32	Administration, % n=38	Total, % n=137
Patient's data	100	4.8	0.0	0.0	0.0	5.8
Omitted dose	0.0	9.5	2.6	15.6	50.0	19.7
Duplicated dose	0.0	0.0	7.6	12.5	7.9	7.3
Erroneous dose	0.0	0.0	5.1	12.5	5.3	5.8
Omitted medication	0.0	4.8	0.0	31.3	7.9	10.2
Erroneous medication	0.0	4.8	0.0	28.1	5.3	8.8
Schedule	0.0	9.5	0.0	0.0	13.2	5.1
Dosage interval	0.0	4.8	2.6	0.0	0.0	1.5
Route of administration	0.0	14.3	10.3	0.0	7.9	7.3
Method of administration	0.0	0.0	2.6	0.0	0.0	0.7
Medication duplicity	0.0	0.0	2.6	0.0	0.0	0.7
Duration of treatment	0.0	4.8	0.0	0.0	0.0	0.7
Selection of specialty	0.0	14.3	48.7	0.0	0.0	16.1
No suspension	0.0	14.3	5.1	0.0	0.0	3.6
Medication in infirmary instructions	0.0	9.5	12.8	0.0	0.0	5.1
No registered medication	0.0	0.0	0.0	0.0	2.6	0.7
Others	0.0	4.8	0.0	0.0	0.0	0.7
Total	100	100	100	100	100	100

Table 2. Percentage Distribution of Causes of Medication Errors (ME) According to the Stage of the Drug Treatment Process

Type of ME	Patient's Data, % n=7	Prescription, % n=21	Prescription-Validation, % n=39	Preparation, % n=32	Administration, % n=38	Total, % n=137
Errors of memory/carelessness	0.0	28.6	59.0	93.8	36.8	53.3
Failure to maintain standards or protocols	100	33.3	33.3	6.3	55.3	36.5
Lack of knowledge on patient	0.0	28.6	2.6	0.0	0.0	5.1
Lack of knowledge on medication	0.0	9.5	0.0	0.0	2.6	2.2
Inadequate follow-up	0.0	0.0	5.1	0.0	0.0	1.5
Non-fulfilment by patient	0.0	0.0	0.0	0.0	5.3	1.5
Total	100	100	100	100.0	100	100

is connected to the hospital's admission service. This is different than the classic model of medication distribution by unit-doses with a hard-copy of the prescription, presenting 6% of incidents.[7]

These data may be compared with studies carried out by stages such as Leape et al,[8] whose prescription distribution, dispensation, and administration was around 52%, 12%, and 36%, respectively. These differences may be due to varying definitions, methods, and medical settings, including different distribution systems. Furthermore, proportions between stages may be different if the sample includes the same or different patients according to the stage of the process.

On the other hand, in this study, there are a few quality indicators established for each stage whose numerators are expressed as patients with an error or as errors, and these normalize by their own denominator (opportunity for error). This idea avoids the temptation to conclude that quality is similar among professionals because of the fact that the ME study variable is distributed in each stage around 20%-28%. Consequently, from the quality management perspective, the numerator (expressed in number of errors) has to be normalized by its specific denominator: the doctors and pharmacists work on patients' lines of medication, and the pharmacy infirmary

Table 3. Quality Indicators for Evaluation of Quality in the Drug Treatment Process

Indicators	Description	Numerator	Denominator	Calculated, %	Standard, %
Omission of allergy	Omission of allergy in electronic prescription	Number of patients with an error = 7	Total number of patients = 308	2.3	1
Prescription[a]	Quality of description of each of the lines of medications prescribed by the doctor	Number of patients with an error = 21 Number of errors = 21	Total number of patients = 308 Total number of lines of medications = 2408	6.8 0.9	1 1
Prescription and validation	Quality of description of each of the lines of medications prescribed by the doctor and reviewed by the pharmacist	Number of patients with an error = 31 Number of errors = 39	Total number of patients = 308 Total number of lines of medications = 2408	10.1 1.6	1 1
Dispensation	Quality in the preparation of medication carts	Number of patients with an error = 26 Number of errors = 32	Total number of patients = 308 Number of prepared doses = 3885	8.4 0.8	1 0.2
Administration	Quality in the administration of medications	Number of patients with an error = 36 Number of errors = 38	Total number of patients = 308 Number of opportunities = 1789	11.7 2.1	1 1
Overal		Number of patients with an error = 107	Total number of patients = 308	34.7	–

[a]Description of prescription or treatment: description of medications, pharmaceutical method, and/or dosage.

personnel work on dispensed doses and the ward personnel on doses administered.

With this CAP model, 2.5% of the 100 lines of treatment show ME caused by the prescribing doctor (0.9%) or not corrected by the pharmacist in treatment validation (1.6%). This information is similar to the 2.5% published by Delgado et al, but these authors included controls of the patients as lines of treatment.[9] The proportion of ME in preparation of medication for carts was 0.8%, similar to the error percentages of filling the carts (0.6%-1.04%) found in the literature,[10,11] and greater than the 0.2% established by pharmacy technicians in certain states of the United States.[12]

The values obtained from quality indicators were compared with the standards, and these point to a need to improve the drug treatment process. These jointly analyzed comparisons with an error profile (omission of dose [19.7%] and selection of pharmaceutical specialty [16.1%]) and the most common ME causes (memory and carelessness errors [53.3%], failures to maintain standards and protocols [36.5%]), suggest which measures should be established in our system. First of all, professionals' training should be promoted through annual sessions, organized by services, in order to update particular procedures for using technology such as the CAP computer program which integrates prescription, validation, and administration.[13] Secondly, study groups should be created for standardization and improvement of technical tasks which develop in stages of preparation and administration of medications (medication approval sent by the pharmacy, preparation of IV mixtures, verification by double checking, etc)[14] Thirdly, new technologies should be incorporated in the drugs administration stage (bar code and radio frequency).[15,16] Lastly, it is necessary to promote a culture of safety through safety committees,[17] follow-up teams,[18] and with pharmacist participation in the ward.[19] This goes with an initiative towards proof and the principles of quality and security, in an environment of management and planning of health services where quality and safety are strategic elements.[20,21]

Among the limitations of this study, special mention should be made on limitations of review and direct observation methods with validity issues (changes in the persons' behaviour due to knowledge of being observed) and reliability issues within and among observers.[3,4] Furthermore, the method selected is especially recommended for assessing technical errors (especially instruction errors) more than treatment errors, because in daily practice, complementary information is only obtained from modules integrated with the hospital's electronic record (admission reports, biochemistry, microbiology, etc) for patients with a risk of presenting with problems related to medications, such as transplants, and/or with specific multiple therapy with a narrow therapeutic margin.

On the other hand, the methodology of this study, based on detecting, registering, and correcting incidents in each stage of prescription, validation, dispensation (preparation), and medication administration, reflects daily practice. First, every professional involved has the risk of causing ME in the stage where their function is carried out, and mainly, technical ME is due to technology management. Secondly, in daily practice, each stage is improved by professionals who collaboratively participate in the drug treatment chain, and they have the opportunity to detect and analyze ME and suggest clarifications, alternatives, and

recommendations for the other professionals. Therefore, evaluation by stages allows for knowledge of the ME proportion and for precise measures to be established for improvement. On the other hand, direct observation studies on administration (the final step in the drug treatment process) reflect the result of a collection of decisions made and actions taken by professionals and provide epidemiological value to the given field. Observation of administration was carried out between 8:00 and 9:00 h, with no other scheduling, but according to a previous study,[2] this range has a greater number of administrations and has an ME percentage of 6.4%, with an overall ME prevalence of 7.2%.

In conclusion, overall, in 35% of patients it is estimated that an incident occurs in any of the stages of the drug treatment process, with consistent distribution of errors in each stage. Quality indicators show opportunities for improvement for professionals involved in the process, based on standardization and training for carrying out technical tasks and handling technology.

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References

1. Grupo GEPEM (Grupo Español para la Prevención de Errores de Medicación). Mejora de la seguridad del sistema de utilización de medicamentos: funciones del especialista en farmacia hospitalaria. Farm Hosp. 2005;29:384-8.
2. Climent C, Font Noguera I, Poveda Andrés JL, López Briz E, Peiro S. Errores de medicación en un hospital terciario con tres sistemas de distribución diferentes. Farm Hosp. 2008;32:18-24.
3. Blasco Segura P, Mariño E, Aznar Saliente M, Pol Yanguas E, Alós Almiñana M, Castells Molina M, et al. Desarrollo de un método observacional prospectivo de estudio de errores de medicación para su aplicación en hospitales. Farm Hosp. 2001;25:253-73.
4. Tissot E, Cornette C, Limat S, Mourand JL, Becker M, Etievent JP, et al. Observational study of potential risk factors of medication administration errors. Pharm World Sci. 2003;25:264-8.
5. Dean Franklin B, Vincent C, Schachter M, Barber N. The incidence of prescribing errors in hospital inpatients: an overview of the research methods. Drug Saf. 2005;28:891-900.
6. Jiménez Torres NV, Climente Martí M, Font Noguera I. Guía para la práctica clínica orientada a problemas farmacoterapéuticos. 1st ed. Valencia: APHPE. Hospital Universitario Dr. Peset; 2002.
7. García Cortés E, Rodrigo A, Carbajal JA, Carmona PM, Font I. Sistema de distribución individualizada de medicamentos por dosis unitarias: análisis global de la calidad en un hospital terciario. Rev Calidad Asistencial. 2001;16:384-9.
8. Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA. 1995;274:35-43.
9. Delgado Sánchez O, Escrivá Torralba A, Serrano López de las Hazas J, Crespí Monjo M, Pinteño Blanco M, et al. Estudio comparativo de errores con prescripción electrónica versus prescripción manual. Farm Hosp. 2005;29:228-35.
10. Llodrá Ortolá V, Morey Riera MA, Perelló Roselló X, Vaquer Sunyer X. Acreditación de un Servicio de Farmacia según la norma ISO 9002. Experiencia en la Fundación Hospital Manacor. Farm Hosp. 2001;25:229-39.
11. Jornet Montaña S, Canadell Vilarrasa L, Calabuig Muñoz M, Riera Sendra G, Vuelta Arce M, Bardají Ruiz A, et al. Detección y clasificación de errores de medicación en el Hospital Universitari Joan XXIII. Farm Hosp. 2004;28:90-6.
12. Ambrose PJ, Saya FG, Lovett LT, Tan S, Adams DW, Shane R. Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes. Am J Health Syst Pharm. 2002;59:1183-8.
13. Griner PF. Leadership strategies of medical School Deans to promote quality and safety. Jt Comm J Qual Improv. 2007;33:63-72.
14. Desselle SP. Certified pharmacy technicians' views on their medication preparation errors and educational needs. Am J Health Syst Pharm. 2005;62:1992-7.
15. Poon EG, Cina JL, Churchill W, Patel N, Featherstone E, Rothschild JM, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. Ann Intern Med. 2006;145:426-34.
16. Skibinski K, White BA, Lin LI, Dong Y, Wu W. Effect of technological interventions on the safety of a medication use system. Am J Health Syst Pharm. 2007;64:90-6.
17. Otero MJ, Codina C, Robles D. Programa multidisciplinario de prevención de errores de medicación en un hospital. Rev Calidad Asistencial. 2005;20:79-89.
18. Frankel, A, Grillo SP, Baker EG, Huber CN, Abookire S, Grenham M, et al. Patient Safety Leadership WalkRounds at Partners Healthcare: learning from implementation. Jt Comm J Qual Improv. 2005;31:423-37.
19. Kaboli PJ, Hoth A, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care. A systematic review. Arch Intern Med. 2006;166:955-64.
20. Borrell-Carrió F. Ética de la seguridad clínica. Contribuciones desde la práctica médica. Med Clin (Barc). 2007;129:176-83.
21. Lo B, Groman M. Oversight of quality improvement. Focusing on benefits and risks. Arch Intern Med. 2003;163:1481-6.