Analysis of medication errors detected in the dispensing process by the unit dose system in a Spanish hospital

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"When they sin, rebuke them in the presence of all, that the rest also may have fear."
I Timothy 5, 20 Holy Bible.
"Errare humanum est"
"If you close the door to all mistakes, you leave the truth outside."
Rabindranaz Tagore

ABSTRACT

Objective: To detect, describe, calculate and rate any errors produced by a pharmacy department in the course of giving out drugs by the Unit Dose Dispensing System.

The method: Individual patient treatment was checked every day when dispensed before being provided to clinical units. The number and type of errors were recorded and they were corrected. Two ranks of binomial population were established, namely to make an error or not to make one. The error rate for every 100 patients and every 100 drugs dispensed was estimated.

Results: The null hypothesis established "a priori" was tested by the χ^2 test. The probability of committing an error did not depend of the clinical unit where they are detected or on the number of dispensed drugs. In all cases $p > 0.05$. 16 types of errors were found, in order of frequency: surplus drugs remained in 15.8% cases, a drug was changed to another in 15.3% cases, the dosage was changed in 11.2% and drugs were not present in 10.9 %. The frequency was less than 10 % in the rest of the cases. The more common errors cannot be considered as simple trivial errors. The cost of detecting and correcting was 4.455 euros per error.

Conclusion: The goal of everyone is "zero errors". A well trained staff, familiar with all the processes, and continuing quality control prevent and detect errors and enable strategies for improvement to be established.

KEY WORDS:

Data collection; Dispensing; Drug distribution systems; Errors medication; hospital pharmacy .

INTRODUCTION

Quality indicators are parameters that are easily obtained and applied, and which demonstrate important quality aspects of the activities needed to be measured. They are obtainable at particular times or on a continuous basis in order to monitor the Units under evaluation. The indicators are useful for establishing programmes of nursing care quality assurance.

In order to establish nursing care quality assurance it is necessary to assess daily practice, to be willing to accept one's own errors and to reduce subjective appraisals to a minimum.

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The objectives of the Pharmacy Department's unitary dose system for dispensing and distributing drugs are:

- To ensure the correct administration of drugs to the patient.
- To reduce medication errors.

The number of errors committed in the preparation of medicines for hospital departments can be used as a quality indicator. For this, inspections need to be carried out on the preparation of medicines to detect errors and to compile a comprehensive register of those committed.

When evaluating the requirements of medicines dispensing by the unit dose distribution system, we can check whether the following, among others, are complied with:

- Pharmacy auxiliary staff prepare the drug according to the pharmacotherapeutic sheet.
- The drug is always identified. The packaging must be clearly marked with the generic name, dosage, manufacturing batch number and expiry date.
- The pharmacist checks the drug, once prepared.
- A register of the errors detected in preparation is compiled
- Once the drug is prepared and checked, a rapid, safe and effective distribution system is established.

In our case, all requirements are complied with, apart from the record of errors detected.

At present, there is a lot of confusion in publications about the terms used for naming the different negative effects derived from the use of medication. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) has published a taxonomy of medication errors (1), and the American Society of Health-System Pharmacists (ASHP) has put up for discussion a document on the use of definitions and the relationship between medication misadventures, medication errors, adverse events and adverse reactions (2).

Medication misadventures are understood to include all unexpected or undesired incidents, problems or events produced by error or not, during the drug-use system whether or not they cause damage to the patient. Medication errors (ME) are understood to be any drug-use system errors. NCCMERP defines these errors as any preventable event that could be damage-causing to the patient or that gives way to the inappropriate use of medication, when under the control of health care professionals or the patient, or the consumer. These incidents could be related to professional practice, procedures or systems, including mistakes in the prescription, communication, labelling, packaging, designation, preparation, dispensing, distribution, administration, education, follow-up and use [1]. The term used for when medication errors injure a patient is Preventable Adverse Drug Event (ADE). If no injury is caused it is a potential adverse drug event (PADE) or ordinary medication error. A potential ADE is a serious medication error that could have caused harm, but didn't by chance, or because it was intercepted before reaching the patient [3]. The analysis of potential ADEs is useful because it allows for the identification of weak areas in the system where errors are produced, and also those areas that function and where errors are intercepted and avoided.

The function and responsibility of a Medication-use system (MUS) is to assure the public that the medication is efficient, safe and effective [4], that the resources used are optimum, that both errors and preventable adverse effects are avoided, and that the treatments are adequate. It is therefore necessary that the system combines a series of characteristics, among others working with the philosophy of maintaining "zero tolerance" to errors, in order to be considered "ideal" [4]. If we cannot aspire to a zero error standard in the drug-use system, one would ask what standard of error would be acceptable. To establish it at 0.1% would not be sufficient [5].

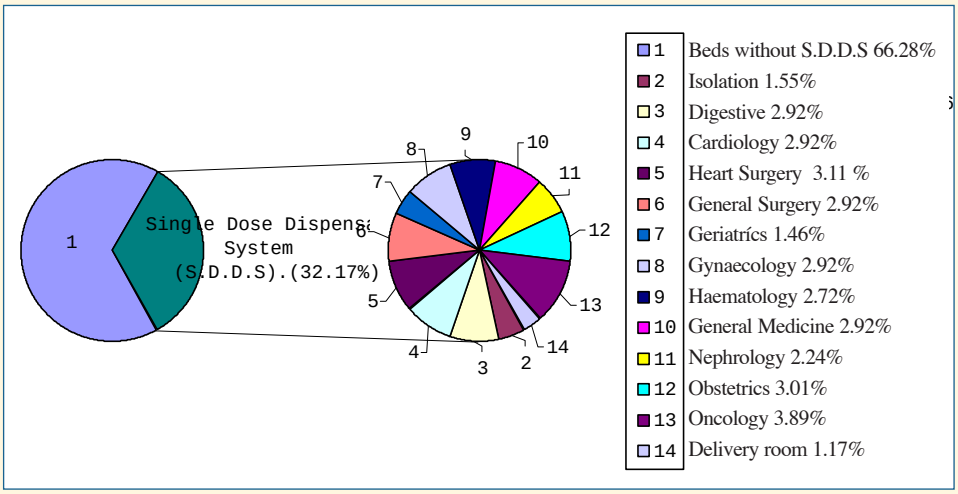

Figure 1
The distribution of the number of beds according to the medication dispensing system in percentages . The left circle represents those with no medication dispensing in unit doses versus those that have. The right circle represents each clinical unit with medication distribution system in unit doses.

Our aim is to propose a new requirement as a quality indicator to record those errors detected in the dispensing of medication by the unit dose system. A study will be performed on the type of errors committed and we will analyse their probable causes.

In this study, we will not deal with non-preventable adverse events produced despite appropriate use of the medication, and which correspond to the so-called adverse reactions.

METHODS

The San Carlos Clinical Hospital has been assigned nursing care, research and educational functions, in Area 7 of the Autonomous Community of Madrid. It has a total of 1659 beds, of which 1029 are in use.

The dispensing of medication from the Pharmacy Department is carried out using a traditional method of stock replacement, except in 13 hospital units, with a total of 347 beds, where it is performed per patient and in unit doses (Figure 1).

The computerised application managing dispensing per patient in unit doses is supplied by "Lands Tools". The specialist pharmacists and section residents transcribe and/or verify by computer the complete pharmacological treatment prescribed daily upon medical orders, of every patient admitted to the clinical units.

Each clinical unit sends out a list, containing the following information for each patient: bed number, patient record number, name and surname, number of units of each drug the patient should take during 24 hours.

As well as the number of units of each drug and the nomenclature in the registered trade mark (the antibiotics, atenolol, captopril, diclofenac, magnesium dipyrone, omeprazole, acetaminophen and ranitidine are called by their generic name), the dosage, pharmaceutical form, and administration route also figure. Drugs not appearing on the list are psychopharmacological and narcotic drugs, cytostatics, solutions for infusion, parenteral nutrition and individually prepared formulations.

A transportation system for the medication is assigned to every clinical unit, consisting of a manual drive trolley with compartments and drawers (one for each bed). Every drawer is identified with the bed number, and a label with the patient's name.

At each clinical unit, and using the lists, Pharmacy Department auxiliary staff check that the patients' names and bed numbers coincide with those on every drawer on the trolley, collect the medication units of each patient from the pharmacy in unit doses and place them in the respective drawers. Large volume medication units that do not fit into the drawers, and refrigerated medication, are noted in a register along with the bed number to which they are assigned, and sent together to a different drawer on the same trolley or an independent container. The auxiliary staff rotates every fifteen days. The pharmaceutical staff is responsible for correcting any errors detected when checking the medication dispensed by the auxiliary staff.

This daily activity is recorded in the Monthly Activity Log Book of the hospital, complying with yet another quality requirement.

Two classes of binomial population are established: error committing and non-error committing.

To analyse the dispensing errors and probable causes during a period of 35 non-consecutive days and to avoid having the same personnel involved with the medication, we proceeded to detect the number of dispensing errors, identify them and classify them into ordered groups. A list was designed to

Clinical unit	(1)Nº PAT.	(2)Nº DRG	(3)Nº ERR.	Error identified
Isolation (iso)				A) one drug changed for for another
Cardiology (h1n1)				B) change of dose
Heart surgery (h7n)				C) change of administration route
General surgery (h3sa)				D) change of pharmaceutical form (same route)
Digestive (h2sa)				E) some medication doses missing
Geriatrics (6ng)				F) some medication units missing
Gynaecology (h5sa)				G) injection solvent missing
Haematology (h2sb)				H) complete treatment of one patient missing
General medicine (h4sa)				I) some prescribed drug units left over
Nephrology (hne)				J) unprescribed drug left over
Obstetrics (h5n)				K) drug with no batch number, expiry date or dose
Oncology (hon)				L) drug not placed on trolley and/or in refrigerator
Delivery room (del)				M) drug drawer wrongly or not identified
				O) no stock shortage catalogued
				P) drawer without medication and unidentified
				R) room temperature drug in refrigerator

(1) Number of patients
(2) Number of drugs
(3) Number of errors

Figure 2 :
Record of errors detected. Every error type has been assigned an identification letter to aid classification.

collect observations or errors (discrete variables), entering each group and clinical unit. An identification code or letter was assigned for every type of error to facilitate collection (Figure 2).

The rate of error was calculated for every 100 patients and for every 100 drugs in each clinical unit. A null hypothesis was established as being that the probability of committing errors is independent to the clinical unit where detected and to the number of drugs dispensed. This was demonstrated using the x^2 test.

The percentage of distribution was calculated of every error type recorded under total errors.

Causes and probable solutions were discussed.

RESULTS

For 22 non-consecutive days (4 hours a day, without interruptions), 4442 drawers of 10 clinical units with medication distribution system in unit doses were checked. The drawers contained 21,978 drugs. A total number of 430 errors were recorded (Table 1) (the information obtained from the Delivery Room and Obstetrics units are included together; General Medicine data is omitted due to the fact that the medication in this unit is dispensed and checked during the afternoon shift, and Geriatrics and Vascular Surgery are also omitted as in these units unit dose dispensing was established after the classification of errors).

The frequency of each class of error was:
(1) One drug changed for another in 68 (15.8%)
(A) Medication units left over on 66 occasions (15.3 %)
(B) Change of dosage in 48 (11.2%)
(F) Medication units for dispensing missing 47 (10.9%)
(E) All doses of one medication missing in 43 (10 %)
(C) Administration route of one medication changed in 41 (9.5%)
(K) Medication dispensed with no identification of dosage, expiry date or batch number in 36 (8.4 %).
(M) The drawer with medication corresponding to a patient recorded on the computer had the name of another patient who had been transferred, discharged, or had the name of the patient of that bed partially identified on 27 occasions (6.3%)
(L) Medication placed outside the drawer (those refrigerated or too large) assigned to wrong locations in 26 cases (6 %)
(H) Entire treatment of one patient missing on 8 occasions (1.9 %)
(O) No annotation of missing medication stock in the Pharmacy for further dispensing or modification on 8 other occasions (1.9 %)
(P) The drawer that should carry medication was without identification and completely empty on 6 occasions (1.4%).
(↓) Unprescribed medication left over on 3 occasions (0.7%)
(G) Medication dispensed without solvent in 1 case (0.2 %)
(R) Medication found that should be kept at room temperature in the refrigerator (0.2%).
(D) Another pharmaceutical form was dispensed for one medication, although of the same administration route (sachets for tablets) (0.2%). (Figure 3).

The null hypothesis was considered valid, that is to say, the probability of committing errors did not depend on the clinical unit, or the number of drugs dispensed in them. On comparing the number of errors found for every 100 patients of each unit, with the number of errors found for every 100 patients in general, the probability is more than 0.05 (Figure 4). On comparing the number of errors found for 100 drugs dispensed in each unit, with the number of errors found of the total dispensed, the probability is more than 0.05 (Figure 5) In both cases the difference is not statistically significant at a 5% level (Table 2).

Table 1. Number of errors recorded over 22 days

Clinical unit	Errors	Nº Errors
Isolation	4A + 4B + 2E + 3F + 6I + 2K + 1M + 1R	23
Digestive	8A + 4B + 6C + 1D + 2E + 2F + 1H + 8I + 6K + 1L + 4M + 2"O"	45
Cardiology	4A + 8B + 4C + 5E + 1G + 9I + 1K + 4M + 2"O"	38
Heart surgery	2A + 2B + 3C + 1E + 5F + 2I + 1K + 2L + 4M	22
General surgery	7A + 2B + 4C + 2E + 4F + 7I + 3K + 2L + 1M + 1P	33
Gynaecology	7A + 7B + 3C + 5E + 6F + 4I + 1J + 6K + 2L + 2M + 1P	44
Haematology	8A +5B + 3C + 6E + 6F + 2H + 10I + 1J + 5K+ 6L + 6M + 4"O" + 1P	63
Nephrology	11A + 9B + 3C + 13E + 7F + 8I + 4K + 1L + 3M	59
Obstetrics-delivery	2A + 4B + 4C + 1E + 4F + 3H + 2I + 1K + 2P	23
Oncology	13A + 3B + 11C + 6E + 10F + 2H + 12I + 1J + 7K + 12L + 2M + 1P	80
Total		**430**

The price per effective working hour of a medical area specialist is 21.77 Euros. The number of dispensing errors detected per hour was 4.886, leading to the inevitable conclusion that the price of detecting dispensing errors in Pharmacy is 4.455 euros per error.

The Global Index of Medication Error (GIME) and the number of errors/drawer of one patient /day were calculated.

Opportunities for error and the number of medicines dispensed are

considered as the number of drawers assigned to different patients of clinical units and instead of number of errors/patient/day we worked with number of errors/patient drawer/day.

GIME= (number of errors/total opportunities for error) x100=1.62%.

Number of errors/patient drawer/day=GIME x number of drug (number of opportunities for error)/patient drawer/day=0.0044

Discussion

The errors detected after dispensing of medication by the unit dosage system in the Pharmacy Department of the Hospital Clínico can be regarded as Potential Adverse Events or ordinary errors. They do not depend on the clinical units or the number of drugs dispensed.

In our study, the incidences found are corrected in the Pharmacy Department and not prior to patient administration. Medication errors according to their nature are called neglect errors, that is to say non-administration and/or dispensing of one prescribed dose to a patient, dispensing/administration errors of one non-prescribed dose, some errors in administration technique and errors of dispensing/administration of an expired drug.

Why are they produced?

Similar packaging of the drug or look-alike appearance [6].The pharmaceutical industry markets numerous specialities where oral dose units lack identification, dosage, expiry date or batch number due to their not being a legal requirement in Spain. The labelling of tablets packaged in the Pharmacy Department in unit doses to aid dispensing to the Clinical Units is the same for all specialities.

Sound-alike specialities [6] with confusion between market names (Prozac and Prograf, Cytotec and Cytotect Biotest), active ingredients (metamizol and metronidazole) or active ingredients and market names (levofloxacin and Levothroid).

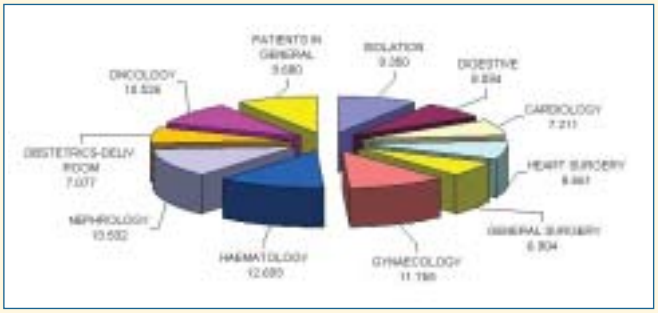

Figure 4
Errors found for every 100 patients of each unit

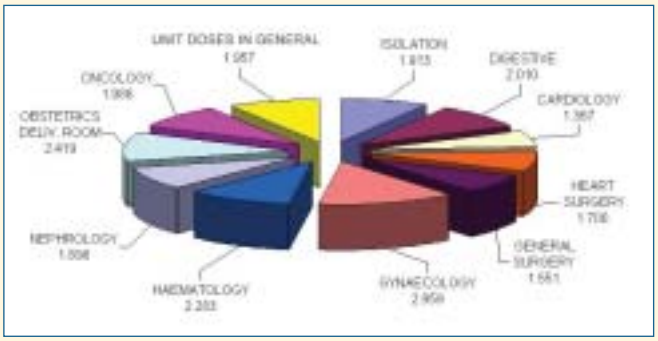

Figure 5
Errors found for every 100 drugs dispensed in each unit

Similar indication. The dispensing of acetaminophen for metamizol or vice versa is frequent due to the association of its analgesic action.

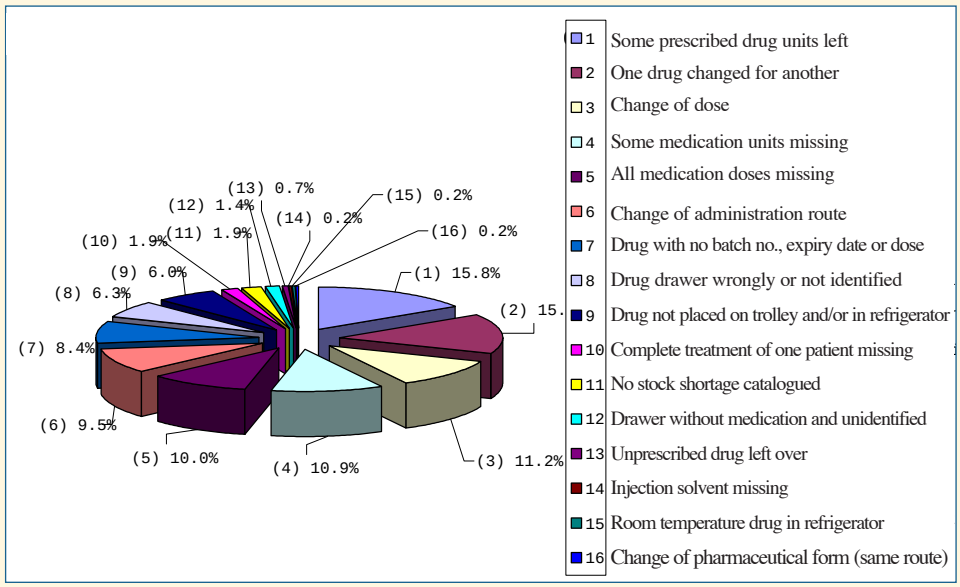

Figure 3
Percentage, according to classification, of errors found in the medication dispensing process before being distributed to the clinical units.

Table 2. . (1) $\chi 2$ test. All results of all Clinical Units were obtained from the errors per 100 patients of the unit and the errors per 100 patients of all the Clinical Units. In all cases $p > 0.05$

(2) $\chi 2$ test. All results of all Clinical Units were obtained from the errors per 100 drugs dispensed to the Unit and the errors per 100 drugs dispensed to all the Clinical Units. In all cases $p > 0.05$

Clinical unit	Nº patients	Nº drugs	Nº Errors	Err/100 pats	χ 2 (1)	Err/100 drugs	χ 2 (2)
Isolation	246	1202	23	9.35	0.026	1.913	0.241
Digestive	556	2239	45	8.094	0.021	2.01	0.23
Cardiology	527	2779	38	7.211	0.14	1.367	0.051
Heart surgery	254	1294	22	8.661	$2.160*10^6$	1.7	0.154
General surgery	478	2128	33	6.904	0.207	1.551	0.102
Gynaecology	374	1487	44	11.765	0.061	2.959	$1.754*10^6$
Haematology	486	2760	63	12.963	0.259	2.283	0.11
Nephrology	436	3109	59	13.532	0.396	1.898	0.234
Obstetrics-deliv. Room	325	951	23	7.077	0.167	2.419	0.067
Oncology	760	4029	80	10.526	0.001	1.986	0.244
Total	**4442**	**21978**	**430**	**9.68**		**1.957**	

The error of changing the administration route is produced when all treatment uses the parenteral route and only one drug is administered orally, or vice versa, indicating that the line was not read to the end.

Errors due to incorrect identification of the medication dispensed (batch number, expiry date or dosage not listed) are committed because they are extra work added to dispensing. Medication should be correctly labelled. The same goes when stock shortage is noted due to lack of medication at that moment. In both cases the staff workload is too great.

We can add to the evident chain of circumstances environmental, professional and personal factors. Errors can be active or errors committed by professionals, and on the other hand latent defects or errors present in the system related to the organisation, work procedures, technical means, working conditions etc. It is therefore important to consider that errors are produced because "mistakes" existing in the system (system approach) and are not the "fault" of the individual or groups of individuals. Therefore, is it appropriate to take punitive measures towards professionals who make errors? Institutions should consider the negative consequences of putting disciplinary action into practice with their employees without having previously considered the consequences. Bauman [7] found that 5% of hospitals took legal action against pharmacists who had committed a serious error. The answers were different depending on whether the hospital was situated in a small town and/or a rural hospital with few pharmacists, or situated in a large city.

Conclusions

We have to progress towards a "zero" error standard; the review of medication dispensed in the Pharmacy Department before its distribution to the clinical units increases the quality of nursing care. Is it possible to evaluate the damage caused to a patient by the wrong administration of a drug?

Dispensing and verification must be carried out by trained personnel familiar with the names of specialities, active ingredients, dosage and outward appearance since great attention and accuracy is needed. From this point of view, pharmacists can look for new mechanisms (the use of dispensing machines) and/or dispensing methods (per medication instead of per patient) to ease work and reduce errors, as well as training nursing professionals to carry out this function..

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