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ORIGINAL ARTICLE

Benefits of Direct Observation in Medication Administration to Detect Errors

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Objectives: To evaluate the nursing process of medication administration in terms of safety to identify frequency and characteristics of errors and to identify possible solutions.

Methods: Descriptive analysis data from a blinded observational study of randomly selected episodes of nursing administration medication, for which some 40 parameters each to be observed had been identified. Seventeen nurses and 88 patients from a university hospital in Navarra (Spain) participated. Patients were given 172 drugs. We measured whether errors, active failures, or latent conditions were present during the medication administration process.

Results: In 1075 possibilities of errors (the total number of medications administered to the patients multiplied by the processes to be observed), we detected 1 error and 474 active failures. Interestingly, no failures were observed in processes that had already been computerized.

Conclusions: Human behavior modifies the process of medication administration. A change is proposed because several processes and infrastructure-related variables can be improved, thus changing the system and conditions under which nurses work. A specific strategy of change has been proposed and is currently being piloted in a ward. This includes structural modifications and nurse training.

Key Words: nursing, medication administration, drugs error, safety

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Medication errors are an issue that worries patients, professional organizations, health systems, regulators, and governments. More importantly, professional awareness is increasing as experts alert us of the importance of medication errors.[1] Such errors are considered a major contribution to adverse events in health systems in the United States,[2] and they are believed to be the cause of most medical mistakes.[3] Despite this fact, the exact incidence of medication errors is still unknown, although the recent Institute of Medicine report suggests that it lies between 2.4% and 11.1%.[4]

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The Ethical Committee of the University Hospital of Navarra approved the study.

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The true frequency of error is likely to be much greater than the usual incident reports indicate. For instance, when institutions begin aggressive searching, errors are found to increase from 10-fold to 100-fold over rates determined by passive reporting.[5] Near misses are often not considered among these errors, although they predict the frequency of harmful errors.[5] In fact, a number of terms have arisen to describe different types of "errors or possible errors."[6,7] *Errors* are considered actions or omissions that lead to deviations from expectations and can take a variety of forms: slips, lapses, jumbles, mistakes, and procedural violations. *Active failures* are unsafe acts committed by key people in direct contact with patients that either lead to or have the potential to lead to harm. *Latent conditions* are consequences of organizational processes and management decisions, which have the potential to introduce pathogens into the system (such as fatigue, inexperience, time pressure, or workload); they can create long-lasting weakness within the organization and provoke error conditions.

The rates of medication errors are influenced by several factors, for example, the operational definition of an error, the denominator used (e.g., patient, dose, day), the methods of surveillance, the variations in safety practices, and the random error. Medication errors can occur at any of the 5 stages[8] involved in the process of drug administration: prescription, transcription, dispensing, administration, and monitoring. Although important drug prescribing or dispensing errors can be discovered because there is a downstream caregiver to intercept them, drug administration errors are not so easily noticed.[9] Drug administration errors are most likely to be made by nurses who are the last step between the drug and the patient.[10] Usually, it is taken for granted that nurses who undertake drug administration are adequately prepared for it.[11] Many nurses, during their training period, have learned about the "five rights" rule of medication use: the right patient, the right drug, the right time, the right dose, and the right route.[12] However, the "five rights" statement is now considered insufficient.[12,13]

There are several studies focused on medication administration errors. Some of them investigate discrepancies between the dispensed drugs and the nurse chart,[14] others focus on intravenous drug preparation and administration,[15] whereas others research on administration issues related to specific units, such as critical or pediatric ones.[16,17] However, we could not identify any study that would encompass the entire process of drug administration in the context of an institution and include slips, lapses, and latent conditions as well as errors.[18]

The aims of this study were to investigate the frequency and characteristics of errors during the medication administration process, to characterize the stage in which they occurred, and to propose mechanisms to reduce them while assigning responsibility to the different teams involved in the process. The findings should help to inform of other efforts and to develop new interventions that help to reduce medication errors.

METHODS

Material

The study was conducted at a 350-bed university teaching hospital in Spain. We used a descriptive observational study. We operationalized drug administration process as those processes occurring between the time when the pharmacy dispenses a medication and the time the patient receives it. This purposely excludes drug prescription and transcription errors because transcription at our institution had been computerized some time ago. The physicians' prescriptions arrive directly and electronically to the Pharmacy department. The hospital uses a unitary dose distribution system.[19] To measure errors or potential errors, we used the "gold" standard measurement technique of direct blind observation in a protocol approved by the institutional ethics review board.

Nurses were unaware (blind) of the intentions of the observer because the observer's presence was disguised with an alternative purpose. The trained observer rounded with the nurses as they went about their medication administration tasks. The observer was a hospital staff female nurse whose primary responsibilities often involve rounds in the building for a number of issues. We used a single observer to enhance the reliability of the findings.

As for the study design, we chose to investigate on a random sample of medication administration times through the hospital, which was composed of 17 units at the time of this research: pediatric intensive care unit, adult intensive care unit, Oncology, Internal Medicine (wards A and B), Surgery (wards A and B), Orthopedics, Neurology, Neurosurgery, emergency room, Pediatrics, Gynecology and Obstetrics, Cardiology, Cardiovascular Surgery, coronary unit, Psychiatry, and day hospital.

Considering the resources available, it was determined that we could undertake 1 observation hour per unit, leading to 17 hours of direct blind observation during a 7-day period (or the equivalent of a 10% sample of the 168 h in a week). The specific selection of these 17 hours was done through a stratification process. On the one hand, 13 hours were randomly chosen from the stratum of the high-volume medication administration hours (i.e., 8 AM, noon, 4 PM, 8 PM, and midnight)—which means that in this stratum, we selected 37% of such times, whereas the other 4 hours were randomly chosen of the low-volume administration stratum with the remaining 133 hours—which means that we sampled 3% of such times.

Once the observation hours were established, the order in which the unit was to be observed was also randomly selected. Furthermore, for each observation hour, the nurse to be observed was randomly selected from a list of all nurses working in that shift and in that unit, thus leading to 17 nurses (of some 300 nurses with medication administration privileges in the institution) observed in the study. Although the institution is a university-based one, no nursing students were included in this sampling frame, and no nursing students were included for observations. All random selections were done using the random number generator function of Excel (Microsoft Windows XP 2004).

For each selected nurse, all patients whom this nurse was responsible for were included for observation. For each patient, we observed the process of delivering and administering all drugs, although structured information on the process was only collected for the up to first 3 delivered drugs because of time constraints related to input of all the observed variables into the recording device.

For our analyses, the nurse was the primary unit of analysis (i.e., the denominator). However, we also present rates in which the patients and dose are the units of analysis.

Elements of Observation

The elements of the structured observation were determined by the research team in advance, taking into consideration the current process of medication administration and The Healthcare Failure Mode and Effect Analysis (HFMEA) framework.[20]

Specifically, some parameters were related to the nurse under observation, although no identifiers were collected to keep anonymity of the results. Some other parameters were related to the patient under observation, and then, a series of parameters were to be collected for each of the up to 3 drugs being recorded for each patient, including structural aspects of the medication administration process. Overall, some 40 parameters were recorded for each patient receiving medication (Tables 3 to 5 and Fig. 1 present some of them).

To enhance the reliability of data collection, parameters of interest were synthesized in a yes/no type of question. The code "not observed" was used when the medication administration process had already taken place and the process had not been observed or as "it is not necessary" such as when the drug was a pro re nata.

No validation of the questionnaire was conducted, in part because the observer was intimately involved in the development of the questionnaire, and the meaning of variables and values had been extensively discussed during its development.

Analyses

All the elements of the structured observation were placed in flow diagrams (see example in Fig. 1 where we portray a selection of observed processes). Because we wanted not only to know if errors occurred and which ones but also to know which professional team was to lead improvements on the situation, we added this information to the diagram. Last, whether changes of structure or process (according to the classification proposed by Donabedian[21]) would best address the problem was also added to the diagram.

As for the frequency distribution of errors, the descriptive analyses included means, medians, and percentages.

TABLE 1. Demographic and Professional Characteristics of All Nurses with Medication Administration Privileges at the Hospital Studied

A. Age: between 20 and 25 yrs, 96 (31%); 26 and 35 yrs, 117 (37.7%); 36 and 45 yrs, 72 (23.2%); 46 and 55 yrs, 23 (7.4%); >55, 2 (0.6%).

B. Sex: 100% female

C. Years working as a nurse: <1, 42 (13.5%); 1–3, 37 (11.9%); 3–5, 21 (6.8%); 5–7, 31 (10%); 7–10, 25 (8.1%).

D. Time working in the hospital (entire years and months working, resting, on maternal leave of absence, or others): 8 years and 9 months (mean)

E. Specialization in nursing: Yes, 281 (90%); No, 28 (9%)
- Intensive care, 18 (5.8%)
- General surgery, 22 (7.0%)
- Psychiatry, 10 (3.2%)
- Pediatric, 36 (11.6%)
- Midwifery, 5 (1.6%)
- Internal medicine, 37 (11.9%)
- Orthopedic, 29 (9.3%)
- Cardiovascular surgery, 52 (16.7%)
- Surgical room, 23 (7.4%)
- Others, 1 (0.3%)

F. Type of contract
- Permanent, 166 (53.5%)
- Temporal, 144 (46.4%)

G. Dedication
- Full time, 216 (69.6%)
- Part time, 78 (25.1%)
- Only weekends, 16 (5.1%)

H. Type of shifts
- Alternating shifts, 256 (82.5%)
- Only nights, 27 (8.7%)
- Only days, 26 (8.3%)

Nurses = 310.
Adapted from Reason.[18]

These were calculated using SPSS version 9 (SPSS Institute, Cary, NC).

RESULTS

All 17 established periods of observation were carried out and all 17 nurses were identified. Although it would have been interesting to provide information on the characteristics of nurses because of the anonymity concern previously indicated, this information is not available. However, Table 1 summarizes the demographic and professional characteristics of the nurses with medication administration privileges staffing the hospital at the time of the study, which we present in another related publication.[22] It is important to note that at the time of this study, nurses had not received any additional training on medication administration.

These 17 nurses had to deliver medication to 87 patients. There was an additional patient who was not scheduled to receive medication but was about to receive one because of an error. This error was caused by the fact that in the nursing medication record, the medication of a prior patient was not eliminated from the system after his discharge, and so the nurse was about to administer that medication to the next patient who occupied the bed. In fact, the presence of the observer prevented this from happening, and this case was labeled as a near miss.

Of the 88 patients included in the study, approximately half were men (51%). There were only 2 patients younger than 20 years. Thirty-four percent of the patients were aged between 51 and 65 years, 33% were older than 66 years, 17% were between 36 and 50 years, and the remaining 11% were between 21 and 35 years.

Thirty-three patients (36.4%) received only 1 medication, whereas 26 (29.5%) received 2 drugs, 10 (11.5%) received 3, and the remaining 19 (21.8%) received more than 3. Thus, our study evaluated a total of 172 drugs. Of these, one was never administered because it was the near-miss case reported above, and 2 others were medications that the patients had brought with them into the hospital. The distribution of frequencies and the route of administration are summarized in Table 2. Two patients took medication (1 drug each) that they had brought from home.

The 171 drugs administered to the patients belonged to the following medication groups (in order of frequency): analgesics and anti-inflammatories (15.7%), antibiotics (14%), sedatives and hypnotics (11.6%), antidepressants and antipsychotic (9.9%), anticoagulants and antiagregants (7.6%), gastric protectors (7%), mucolytics (4%), steroids (3.5%), antihemetics (2.9%), spasmolytics (2.9%), antihistaminics (2.9%), oral diabetic agents and insulin (2.9%), vasodilators (2.3%), antihypertensives (1.7%), oxitocics (1.7%), laxatives (1.7%), diuretics (1.1%), antiparkinsonians (1.1%), vitamins (1.1%), anticonvulsants (0.5%), chemotherapy (0.5%), urinary

TABLE 2. Number of Drugs Administered to Patients by Medium of Administration and Route of Administration (Patients = 88; Drugs = 172)

	Total No. Patients	Total Drugs	Drug Administration Route				
	88	172	Oral	Intravenous	Subcutaneous	Inhalatory	Nasogastric
Prescribed drugs	86*	170	—	—	—	—	—
None in this medium	0	—	33 Patients	46 Patients	81 Patients	87 Patients	88 Patients
1 Drug	31	31	16 Drugs	15† Drugs	0	0	0
2 Drugs	26	52	28 Drugs	21 Drugs	3 Drugs	0	0
3+ Drugs	29	87	42 Drugs	39 Drugs	5 Drugs	1 Drugs	0
Own drugs	2	2	2 Drugs	0	0	0	0

*Two patients (and 2 drugs) were discounted from the total because they had 1 own drug each.
†One patient and his only drug were not delivered after being identified as a near miss.

TABLE 3. Processes Related to Patient Identification and Information on Medication Orders

	Not Observed	Yes	No	NA	Total No. Patients
Patient identification is present on unidosis box	18	65 (74.7%)	2	2	87
All patient drugs are present on the unidosis box	36	49 (56.3%)	1	1	87
The medical order contains all needed information	9	76 (87.3%)	2	0	87
Each patient has its own folder	0	76 (87.3%)	11	0	87
Administration of medication is signed off after delivery	12	1 (1.1%)	69	5	87
Patient allergies are registered	0	86 (98.8%)	1	0	87

n = 87 patients, excluding the near miss case.
NA indicates not applicable.

antispasmodics (0.5%), bronchodilators (0.5%), and β-blockers (0.5%).

Table 3 illustrates data related to the identification of patients and medication records. A box with all medication and proper patient identification is to be prepared at the Pharmacy department. During our observation, 2 such boxes did not contain the identification of the current patient. It could also be noticed that another patient did not have all drugs in the single dose box, and 2 medical orders did not contain all the information because they had not been updated since the last prescription. In all units, all patients had their own folder except for 1 unit where a group of patients shared the same folder. In regard to the signing of medication administration, the medication administration was signed afterward only in 1 patient, whereas for most of patients, the administration had been signed off in advance. Finally, all patients had allergies registered because it is compulsory for electronic prescription. However, in 1 patient, the prescribed drug was the one the patient was allergic to.

After the administration, it was checked whether administration route and doses were understandable from the medical records. Table 4 summarizes several variables related to the first 3 drugs delivered. We must highlight that the time of administration was confusing in 1 drug, needing more specification. More than half of the patients who were given drugs were not informed about the medication they were receiving. In about half of the patients whose medication was oral, there was no verification of intake (the nurse did not wait for the patient to take his/her medication, and neither did the observer).

With regard to the administration of intravenous medication, additional observed parameters are summarized in Table 5. In short, for drugs prepared in the ward, the nurses who prepared drugs were not those who administered them in 5 cases. More than half of intravenous drugs prepared in the wards did not have the patient's name on them, and one third of them did not have the patient's room number. The labels of 2 medications lacked the drug name. Moreover, drug doses were not labeled in 10 cases. The administration route was not specified in the labels of 26 medications. In a total of 37 drugs prepared in the ward, 29 did not fulfill at least one of the required fields (i.e., drug's name, dose, administration route). In contrast, no errors were found in the identification label of drugs prepared at the Pharmacy department. Regarding the administration of multiple intravenous drugs, it must be noted that in 21 instances, the lines were not washed before delivering the second drug. Summing up all the possibilities of error for intravenous medication administration (regardless of whether they were prepared at the Pharmacy department or in the unit), 109 errors (42%, 95% confidence interval [CI], 36.0%–48.4%) of 259 possibilities were found.

Overall, of the 1273 observed items, near errors or errors were detected in 388 instances. Thus, our overall error rate was 30.4% (95% CI, 28.0%–33.1%).

Diagram of Results and Proposal of Changes

A series of diagrams were designed to show which observed variables presented an error during the direct

TABLE 4. Selected Observed Variables Related to the Administration of the Up to 3 Drugs Per Patient

	Drug 1 (No. Patients and Drugs = 88)	Drug 2 (No. Patient and Drugs = 55)	Drug 3 (No. Patients and Drugs = 29)	Total (No. Patients = 88; No. Drugs = 172)
Way of administration is not understandable	0/85 (0%)	0/55 (0%)	0/29 (0%)	0/169 (0%)
Drug dose is not understandable	0/77 (0%)	0/55 (0%)	0/28 (0%)	0/160 (0%)
Time of administration is not understandable	1/82 (1.2%)	0/54 (0%)	0/29 (0%)	1/165 (0.6%)
Patient is not informed about medication	44/65 (67.6%)	33/44 (75.0%)	15/23 (65.2%)	92/132 (69.6%)
There is no verification on oral medication intake	22/38 (57.8%)	14/26 (53.8)	11/12 (91.6%)	47/76 (61.8%)

Cases presenting errors are counted in the numerators; denominators are the total number of patients for whom such drug was needed and for whom that administration process was observed.

TABLE 5. Selected Observed Variables for Drugs Requiring Intravenous Administration

	Drug 1 (No. Patients and Drugs = 42)	Drug 2 (No. Patients and Drugs = 27)	Drug 3 (No. Patients and Drugs = 6)	Total (No. Patients = 42; No. Drugs = 75)
Drugs prepared in the ward				
The nurse who prepares drug is not the one who administers it	2/10 (20%)	1/8 (12.5%)	2/5 (40%)	5/23 (21.7%)
Drug identification label does not…				
…contain patient's name	13/17 (76.4%)	9/13 (69.2%)	4/6 (66.6%)	26/36 (74%)
…have patient's room number	6/17 (35.2%)	4/14 (28.5%)	1/6 (16.6%)	11/37 (29.7%)
…have drug's name	0/16 (0%)	2/14 (14.2%)	0/6 (0%)	2/36 (5.5%)
…have dose	4/16 (25%)	5/14 (35.7%)	1/6 (16.6%)	10/36 (27.7%)
…have drug administration route	11/17 (64.7%)	11/14 (78.5%)	4/6 (66.6%)	26/37 (70.2%)
Label does not fulfill all specifications	12/17 (70.5%)	12/14 (85.7%)	5/6 (83.3%)	29/37 (78.3%)
Cumulative possibilities of error at ward	48/119 (40.3%)	44/98 (44.8%)	17/42 (40.4%)	109/259 (42%)
Drugs prepared in pharmacy				
Drug label does not fulfill all specifications	0/1 (0%)	0/3 (0%)	0/2 (0%)	0/6 (0%)
Regardless of site of preparation				
Medium is not washed if used for another drug	14/14 (100%)	7/7 (100%)	—	21/21 (100%)
There is no administration rate preestablished	16/16 (100%)	6/9 (66.6%)	—	22/25 (88%)

Counts of errors are reflected in the numerators, whereas denominators indicate total number of such administration processes observed.

observation (Figs. 1–3). The diagrams were structured as follows: the first line of the diagram shows the processes observed. The second line indicates the presence or absence of errors/failures: white dots reflect an absence, whereas black ones indicate at least 1 error/failure observed. This fringe also indicates which staff member is responsible for the process and whether the error corresponds to a failure in either the structure or the process of medication administration. The third line of the diagram shows proposed changes from process to structure by the implementation of

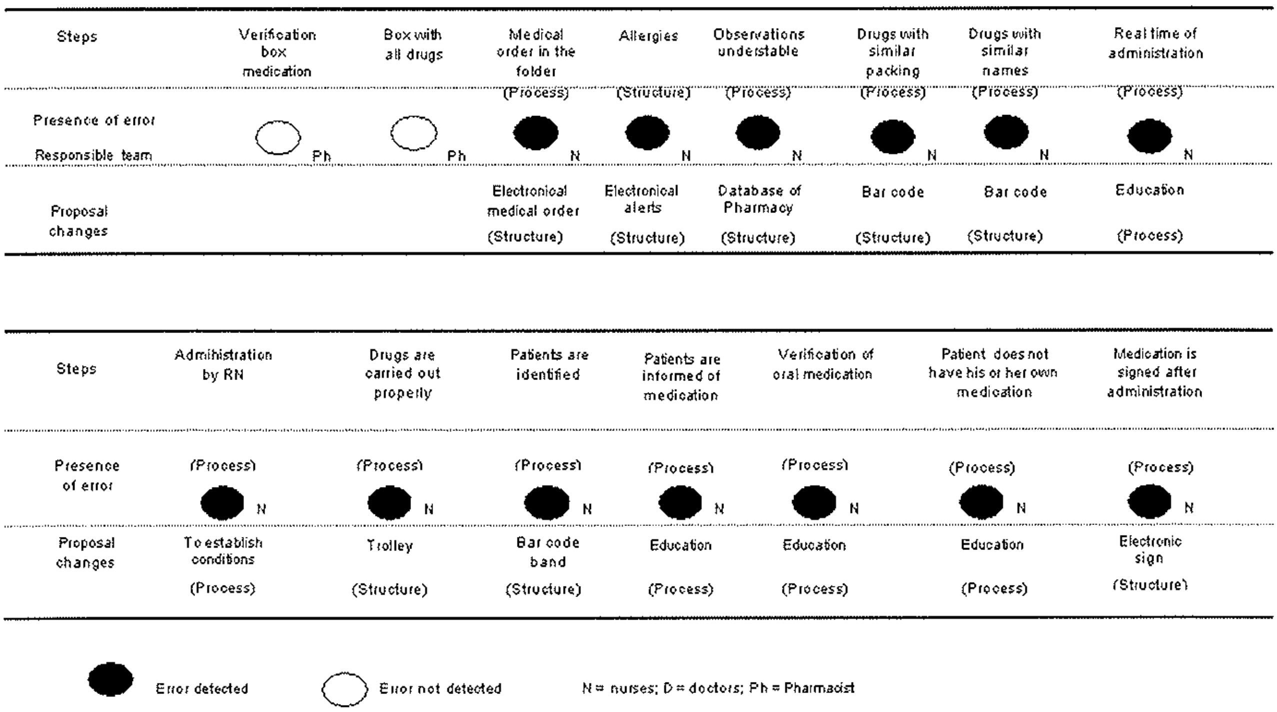

FIGURE 1. General aspects of medication administration. RN indicates registered nurse.

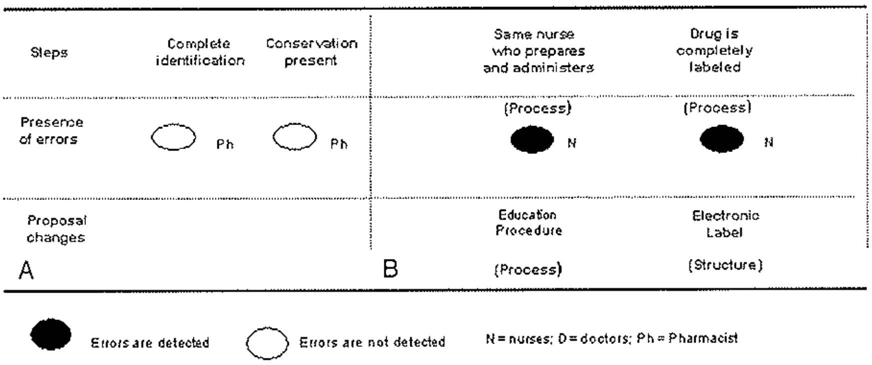

FIGURE 2. Diagram drug intravenously prepared in pharmacy (A). Diagram intravenously prepared in nursing ward (B).

new safety elements when possible or of an education program if needed.

DISCUSSION

In 1075 possibilities of errors (the total number of medications administered to the patients multiplied by the processes to be observed), we detected 1 error and 474 active failures. Interestingly, no failures were observed in processes that had already been computerized.

Improvements in the systems should take into considerations our findings related to imperfect drug identification and labeling, drug administration techniques, and patient identification and assurance of his/her medication intake.

In regard to drug identification and labeling and because medical orders are already computerized in this hospital, a computer on the medication trolley would save printing medical orders each time and would assure that the administration of drugs comes from updated medical orders. A computer on the patient medication trolley would also provide information about drug administration and patient identification; and patient identification could be completed with a code bar. Carrying drugs in the hands or using other elements like trays leads to the loss of patient identification and therefore to committing errors. Problems related to drugs having similar names could be addressed with a code bar system.

Other issues to improve are related to medication allergy identification (presently, allergies are to be recorded in the electronic medical order), yet an allergy database could prove useful, or to intravenous drug administration. For example, to eliminate medication interactions, the route for 1 intravenous medication has to be washed before another medication is passed through. Particular attention needs to be given to intravenous drugs, which should be fully labeled including patient's name, patient's room number, drug's name, drug's doses, and drug's route and time of administration, as it is done with drugs prepared at the Pharmacy department (Fig. 2A). If the drug is not fully labeled and the nurse who prepares the intravenous drug is different from the nurse who administers it, then the possibilities of committing errors increase. To avoid writing down the entire drug information, a printer connected to the electronic medical order would provide a complete label. In fact, this printout could be considered as a medical order because it comes directly from prescription (Fig. 2B). The administration rate has to be verified because different drugs have different rates and have to be predetermined in advance. It is also important to have an order for each intravenous drug if there is more than 1 intravenous drug (Fig. 3).

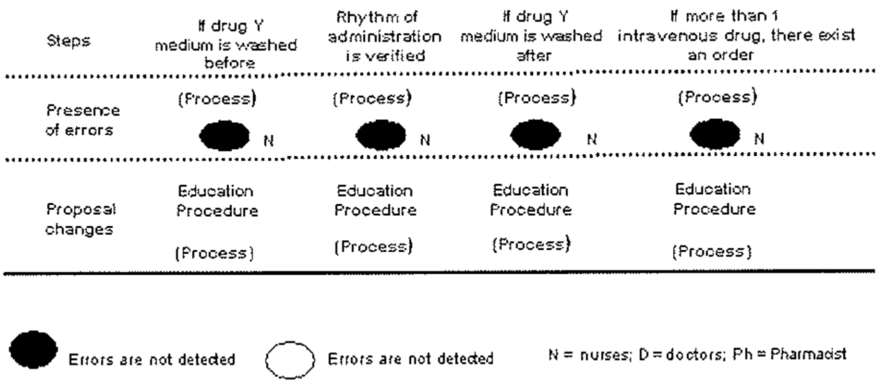

FIGURE 3. Administration of intravenous drugs.

One additional issue to keep in mind regarding the administration process is that, because the hospital is a university teaching one, a registered nurse does not always administer the drugs, but students do. Although nurse students were not included in our study, we believe that it is important to note that we must establish the right conditions for them in advance to avoid errors.

Last, on the issue of patient identification and confirmation of their medication intake, patients should be informed of their own medications. Although it is difficult to check whether a patient takes oral medication, strategies should be implemented to verify the intake of packing and similar medication in many cases. All the medication owned by patients should be checked during admission and should be given to nurses. Medication should always be signed after administration. So everybody would know whether medication has not been administered for any reason.

Strategy of Change

An interprofessional group of pharmacists and nurses has been established to deal with all medication errors with the approval of the general manager of the hospital. Using information derived from this study, a strategy of change has been started in a pilot ward, with changes introduced progressively. In the first stage, a general procedure was designed and discussed with the nurses from the pilot ward. A "quality" nurse was placed in the ward during the implementation, accompanying each observed nurse at least once during the administration process, explaining the procedure in terms of safety, and requiring feedback from her on the procedure and the difficulties found and on suggestions for software improvements. Every patient has a bar code, so the name is always checked before administering medication. All the trolleys have a computer, so nurses can move from one room to another along the corridor with patient's drugs and the medical order information. This system allows them to carry drugs properly without losing the patient's identification. To have the computer on the trolley allows them to check all the drugs before being administered and to sign them immediately afterward. Patients are informed briefly of their medication.

We recognize several limitations to our study. First, the epidemiology of errors varies by the methods used to identify them. We used direct observation, which is thought of as the gold standard. Our results may have varied if we had used different methods to detect errors. Second, we did not include prescription and transcription errors in our analysis. Third, we had a relatively small sample size. Nevertheless, errors were so common that our results are fairly precise (i.e., narrow CIs). Fourth, our results may not be generalizable. We studied 1 hospital in Spain. Further research is needed to see if these results are generalizable. If they are, they could have important implications on organizing the medication use process and training of nurses.

CONCLUSIONS

With this study, we make use of a relatively low-cost but highly valid methodology to assess the frequency and characteristics of medication administration errors in our environment. Real direct blind observation is a gold standard for medication error frequency and near misses, and its implementation in our setting was rather simple and efficient.[23] Interestingly, even with a selectively small observational sampling frame, we prevented errors and detected multiple sources of potential errors. Whether our frequency of medication administration errors is higher or lower than those in other settings is practically impossible to assess because we are not aware of any other direct observational study comparable to ours in breadth and depth. Furthermore, those studies focusing on specific areas of potential errors rely on voluntary error notification, which, we have already noted, presents big discrepancies with our method of direct observation. More important than determining the frequency and type of the incident errors is the fact that the observation allowed identification of structural improvements that have already been implemented in a pilot experience that we will evaluate in the near future.

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