Prevalence of medication administration errors in two medical units with automated prescription and dispensing

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ABSTRACT

Objective To identify the frequency of medication administration errors and their potential risk factors in units using a computerized prescription order entry program and profiled automated dispensing cabinets.

Design Prospective observational study conducted within two clinical units of the Gastroenterology Department in a 1537-bed tertiary teaching hospital in Madrid (Spain).

Measurements Medication errors were measured using the disguised observation technique. Types of medication errors and their potential severity were described. The correlation between potential risk factors and medication errors was studied to identify potential causes.

Results In total, 2314 medication administrations to 73 patients were observed: 509 errors were recorded (22.0%)—68 (13.4%) in preparation and 441 (86.6%) in administration. The most frequent errors were use of wrong administration techniques (especially concerning food intake (13.9%)), wrong reconstitution/dilution (1.7%), omission (1.4%), and wrong infusion speed (1.2%). Errors were classified as no damage (95.7%), no damage but monitoring required (2.3%), and temporary damage (0.4%). Potential clinical severity could not be assessed in 1.6% of cases. The potential risk factors morning shift, evening shift, Anatomical Therapeutic Chemical medication class antacids, prokinetics, antibiotics and immunosuppressants, oral administration, and intravenous administration were associated with a higher risk of administration errors. No association was found with variables related to understaffing or nurse's experience.

Conclusions Medication administration errors persist in units with automated prescription and dispensing. We identified a need to improve nurses' working procedures and to implement a Clinical Decision Support tool that generates recommendations about scheduling according to dietary restrictions, preparation of medication before parenteral administration, and adequate infusion rates.

INTRODUCTION AND BACKGROUND

The importance of proper use of drugs is well documented in numerous publications on patient safety and quality of healthcare, all of which have highlighted the health impact of medication errors and the need for effective safety practices. The Harvard Medical Practice Study,[1] which analyzed the damage caused by common errors in medical care in New York State in 1984, estimated that 3.7% of hospitalized patients experience an adverse event during admission, the most common being medication-related complications (19%, of which 45% were preventable), followed by surgical wound infections (14%) and technical complications (13%). The ENEAS Study in Spain showed that 4% of hospitalized patients experienced medication-related adverse events, that 37% of all adverse events documented were associated with medication, and that 35% of these events were preventable.[2]

The complexity of the medication administration process is such that errors can appear at one, some, or even all the stages between prescription and administration. In fact, the frequency of errors has been estimated to be 39% during the prescription process, 12% during the transcription process, 11% during the dispensing process, and 38% during the administration process.[3 4] However, most errors that actually affect a hospitalized patient occur when a dose of medication is incorrectly administered at the bedside. Thus, technologies such as automated dispensing cabinets (ADCs) at the point of care and the electronic medication administration record (e-MAR) verified using barcode medication administration (BCMA) aim to reduce administration errors.

However, very few studies have shown safer administration with both these technologies,[5–13] especially with ADCs, for which only three studies have been published.[5–7] Furthermore, experience with these technologies is still limited in Spain, where only 13% of hospitals have implemented ADCs, 5% have implemented e-MAR, and none use the BCMA system throughout the hospital, due to the difficulty and cost of developing and maintaining such complex infrastructures.[14]

Since 2003, our institution has effectively used a computerized prescription order entry (CPOE) program with online pharmacy validation and decentralized profiled ADCs for 900 beds. However, administration errors are still a major problem, because, unlike BCMA, these technologies cannot ensure the five rights of the administration process, as it is not possible to automatically cross-check the prescription with the prepared medication just before each administration.

OBJECTIVE

The objective was to identify the frequency of medication preparation and administration errors

as well as the potential risk factors for these errors in two clinical units using a CPOE program and profiled ADCs.

MATERIALS AND METHODS

Design

This was a prospective observational study performed using a disguised observation technique.

Setting

The study was conducted in two gastroenterology units (30 and 29 beds) in a 1537-bed tertiary teaching hospital in Madrid (Spain).

Since 2005, gastroenterologists have entered the prescription in a CPOE system. The pharmacists' role consists of continuous centralized order validation, except during the night shift. Drugs are dispensed using profiled-ADCs (Pyxis System), from which they can be retrieved by nurses once prescribed and validated by the clinical pharmacist. Administration is registered manually in a semielectronic paper format (computer-generated, signed by hand). This patient-specific medication administration record (MAR) is printed once daily and serves as a paper reference for the medications to be given to patients and completed administrations for that day. The hospital's CPOE system has to be checked regularly for new or modified medication orders. Any changes required a new MAR to be printed, as this document is used to retrieve medication from the ADC.

High-volume medication administration times are 09:00, 12:00, 13:00, 16:00, and 20:00; most medications are administered at 09:00.

In both units medication is administered by qualified nurses, except for oral medication at 13:00 and 20:00, which is administered by nursing assistants.

Observation procedures

Observations were scheduled on weekdays and weekends and during all shifts. Six pharmacists and five nurses were trained to make the observations unobtrusively and assess the error rate. Training consisted of two previous informative sessions developed by one of the pharmacists, in which the data collection form and examples of medications errors were discussed.

Before the study began, the team explained the study methodology to the nursing staff of each unit, namely, that the purpose of the study was to examine the functionality of the CPOE and ADCs. The term 'medication error' was deliberately avoided. Only nursing managers knew the real purpose of the study. Nurses were also informed that the observer could not answer any medication-related questions and should be referred to the satellite pharmacy for answers to medication-related questions.

Since nurses were the subjects of our study, informed consent from the patient was not required by the hospital's institutional review board. After contacting the nurse at the beginning of the medication administration round, emphasizing that study participation was entirely voluntary, oral informed consent was obtained.

To prevent interference with nursing workflow, a maximum of two observers were assigned to each study unit during one observation session. Each observer studied the preparation and administration process with the same nurse during one shift per day. The observers were instructed to intervene if they witnessed actions that could lead to an adverse event. The prescribed medication was determined by printing the paper MAR of each observed patient and contrasting it with that of the nurse. The observation period started when a nurse entered the patient's name and began retrieving medication from the ADC.

Definitions

Medication is defined as any ordered drug (except oxygen) and intravenous fluid by any route. A dose of intravenous fluid is the unit that is ordered, even if the contents are administered over hours.

An administation error was defined as any discrepancy between prescription and administration and was categorized according to the Ruiz Jarabo 2008 taxonomy, as follows[15]: wrong patient, wrong drug, wrong dose, wrong pharmaceutical form, wrong route, wrong preparation/manipulation/conditioning technique, wrong administration technique due to food intake, wrong administration technique due to other causes (eg, physicochemical incompatibilites in parenteral administrations, wrong crushing), wrong administration speed, wrong time, wrong frequency, wrong treatment duration, wrong store, damaged drug, omission, and other. The 'other' category was further classified by the investigators after the study was completed. A wrong-time-of-administration error was considered as administration more than 15 min before or after the scheduled administration in the case of emergency prescriptions, 30 min in the case of treatments given every 6 h or more, and 1 h in the case of treatments every 8 h or less. Wrong preparation/manipulation/conditioning technique, wrong administration technique, and wrong administration speed were defined as a discrepancy with the recommendations of the summary of product characteristics. In cases of doubt, the manufacturer was consulted.

In addition, the cause and the severity of the error were evaluated by the observer and two senior pharmacists, respectively, and according to the Ruiz Jarabo 2008 taxonomy.[15] If a disagreement arose regarding the severity of error, a third evaluator reviewed the observation and provided a recommendation.

This study did not include adverse drug reactions or nonpreventable adverse events.

Data analysis

The number of observations needed to adequately power this study was based on the results of a previous study investigating the administration error rate before and after implementing ADC in a French ICU setting.[7] Assuming a similar baseline error rate after implementing this technology of 13.5%, an α of 0.05, and a precision of $\pm 1.5\%$, at least 1994 medication administrations had to be observed.

The medication error rate was calculated by dividing the number of errors by the total opportunities for error (OEs). OEs were defined as the sum of observed administrations and omitted medications. As wrong-time errors were generally considered less severe than other errors, overall results were reported as total errors and errors excluding wrong-time errors.

The variables registered and entered into the database (MS Access 2003) were as follows: patient age and gender; medicine (name, dosage form, and Anatomical Therapeutic Chemical (ATC) class); administration route; number of medicines per shift and patient; whether the expiry date of the medication had been checked or not; whether the medication had been labeled correctly with patient name, drug and dose or not; whether the medication had been retrieved from the ADC just before administration or not; whether the medication was administered by the nurse or the nursing assistant; whether the administration was documented or not; day and shift of administration; age of nurse; type of nurse (career nurse or not); experience in the unit (months); number of beds the nurse is

responsible for; whether an error has been made or not; error category; cause of error; and severity of the error.

Univariate and multivariate logistic regression analyses were performed to study the association between potential risk factors and the occurrence of errors. All p values were two-tailed. Statistical significance was set at $p<0.05$.

The data were analyzed using the Statistical Package for Social Sciences (PAWS Statistics) V.18.0.

RESULTS

Subjects were studied for 1 week in February 2010, during which time 2314 OEs were observed.

Study unit characteristics during the study period and the observation characteristics are summarized in tables 1, 2, respectively.

The total medication error rate was 22.0%—20.7% if 30 cases of wrong-time errors were excluded—and errors involved 70 different drugs. Ten administrations accumulated more than one error. Sixty-eight (13.4%) errors occurred in the preparation process and 441 (86.6%) in the administration process. The inter-rater reliability for classifying severity was moderate (k=0.40). Errors were classified as no damage in 95.7% of cases, no damage with monitoring in 2.3% of cases, and temporary damage in 0.4% of cases. In 1.6% of cases, the potential clinical severity could not be assessed. Only 18 interventions were deemed necessary by the observer.

All types of error—excluding wrong-time errors—and their causes and clinical severity are shown in table 3.

The most common error was wrong technique due to food intake (mainly proton-pump inhibitors (PPIs) (39.9%), immunosuppressive drugs (20.6%), and prokinetics (15.9%)). The main resason was a lack of use of standarized procedures, as nurses or nursing assistants often administer the medication without separating those with dietary restrictions in a different container or warning the patient that it has to be taken on an empty stomach.

The next most common error was wrong reconstitution/dilution of parenteral drugs: in 8.6% of intravenous administrations, the drug was not reconstituted/diluted according to the recommendations of the summary of product characteristics. The main drugs involved in this type of error were vancomycin, piperacillin/tazobactam, omeprazole, and imipenem.

Thirty-two cases of omission were detected, due mainly to a lack of stock in the ADCs, lapse of concentration, lack of use of standardized procedures (when the nurse decided not to administer the drug scheduled), and problems with communication between the physician and the nurse when a modification was made on the prescription. Of these 32 errors, one case (omission of transdermal fentanyl) was categorized as potential temporary damage and five cases (omission of parenteral vitamin K, inhaled ipratropium, propranolol, and two doses of intravenous metoclopramide) as no damage but potential monitoring could have been required. In three cases, the clinical severity could not be determined.

Twenty-seven cases of wrong infusion speed were detected, with albumin, levofloxacin, and paracetamol as the main drugs involved.

The remaining errors had an incidence of less than 1%. In the case of wrong dose, the main causes were withdrawal from the ADC of an amount less than that prescribed due to a lapse of concentration or because the nurse forgot to dispense the exact dose prescribed after retrieval from the ADC. The error would not have harmed the patient, except for the administration of sodium bicarbonate 1 M instead of 1/6 M in one case and near administration of half the dose prescribed for albumin in two cases. Twelve errors of wrong adherence were detected, because the nurse did not verify whether the patient had taken the medication. In the case of wrong route, six out of seven errors were due to the administration of ondansetron intravenously

Table 1 Study units and staffing characteristics during the study period

No of admissions	58
No of patients discharged	64
Occupancy (%)	129.10
Length of stay, days	9.19
Patient/bed rotation	3.58
No of deaths	1
Admissions to ward from emergency room (%)	55.17
No of nurses observed	23
No of beds/nurse, median (p25—p75)	8 (8—10)
Career nurses (%)	52.17
Nurse age, median (p25—p75)	39 (26—42)
Experience in the unit, months, median (p25—p75)	24 (9—246)

Table 2 Observation characteristics of study

No of patients	73
Male (%)	64.4
Age, median (p25—p75)	63 (51—75)
Total no of OE	2314
Median (range) OE per patient during the observational session (p25—p75)	7 (5—9)
Total no of different drugs ordered	213
Anatomical Therapeutic Chemical medication class no (%)	
Gastrointestinal	857 (37.0)
Anti-infective agents	297 (12.8)
Blood	286 (12.4)
Cardiovascular	230 (9.9)
Respiratory	171 (7.4)
Neurological	171 (7.4)
Antineoplastic and immunomodulating agents	116 (5.0)
Musculoskeletal	73 (3.2)
Hormones	57 (2.5)
Various	27 (1.2)
Gynecological	15 (0.6)
Dermatological	6 (0.3)
Antiparasitic agents	8 (0.3)
No (%) of OE per administration route	
Oral	1560 (67.4)
Intravenous	402 (17.4)
Inhaled	125 (5.4)
Subcutaneous	121 (5.2)
Continuous intravenous perfusion	71 (3.1)
Transdermal	17 (0.7)
Rectal	9 (0.4)
Topical	6 (0.3)
Intramuscular	2 (0.1)
Enteral catheter	1 (0.004)
No (%) of observations	
Morning	1134 (49.0)
Evening	1018 (44.0)
Night	162 (7.0)
Weekend observations (%)	33.8
No (%) of observations	
Pharmacist	57.3
Nurse	42.6

OE, opportunities for error, defined as the sum of observed administrations and omitted medications.

Table 3 Administration errors classified by type of error, cause and clinical severity

Type of error excluding wrong-time errors	N	Error rate (%)	Cause	N	Clinical severity	N
Wrong technique due to food intake	321	13.9	Lack of standardized procedures	272	No damage	321
			Lack of knowledge about the drug	49		
Wrong preparation	40	1.7	Lack of knowledge about the drug	40	No damage	40
Wrong reconstitution (volume, fluid)	8	0.3				
Wrong dilution (volume, fluid)	32	1.4				
Omission	32	1.4	Lack of stock in the ADCs	9	No damage	23
			Lapse of concentration	8		
			Lack of standardized procedures	8	No damage but monitoring was required	5
			Communication problems	3		
			Lack of knowledge about the patient	2	Temporary damage and monitoring was required	1
			Stress	2	Unknown	3
Wrong infusion speed	27	1.2	Error in infusion speed calculation	27	No damage	21
					No damage but monitoring was required	2
					Unknown	4
Wrong dose	19	0.8	Lapse of concentration	14	No damage	16
			Communication problems	2		
			Lack of knowledge about the drug	2	No damage but monitoring was required	3
			Error in preparing the drug	1		
Wrong patient adherence	13	0.6	Lack of knowledge about the patient	13	No damage	13
Wrong route	7	0.3	Lack of knowledge about the drug	6	No damage	7
			Lack of standardized procedures	1		
Wrong duration of treatment	6	0.3	Lapse of concentration	3	No damage	5
			Communication problems	3	Temporary damage and monitoring was required	1
Wrong drug	5	0.2	Communication problems	2	No damage	4
			Lack of standardized procedures	2		
			Lack of stock in the ADCs	1	Unknown	1
Wrong frequency	3	0.1	Lack of stock in the ADCs	2	No damage	3
			Communication problems	1		
Wrong technique other reasons	3	0.1	Stress	1	No damage	2
			Lack of knowledge about the drug	2	No damage but monitoring was required	1
Wrong store	2	0.1	Lack of standardized procedures	1	No damage	2
			Lack of packing in unit doses	1		
Wrong pharmaceutical form	1	0.0	Error in preparing the drug	1	No damage but monitoring was required	1
Total	479	20.7	—	479	—	479

ADCs, automated dispensing cabinet.

rather than orally, because nurses were unaware that the vials could be administered by this route. Six cases of wrong duration of treatment and five cases of wrong drug were detected, mainly because the treatment had been modified by the physician but not reported to the nurse (eg, vitamin K was going to be administered despite having being stopped in the CPOE, or tiotropium was stopped by the physician, and the nurse administered tiotropium and ipratropium at the same time). Another error worthy of mention was the administration of intravenous ipratropium solution by inhalation.

Finally, although considered less severe than other errors, 30 cases of wrong-time errors were detected. Antibiotics and fluids were the main drugs involved, and the causes were accumulation of workload, nurse's decision to make her job easier, and lack of drug stock in the ADC.

The correlation between occurrence of administration errors and potential risk factors is shown in table 4 (univariate and multivariate analysis). In the multivariate analysis, the factors associated with a higher risk of administration errors were as follows: morning shift (OR 2.36), evening shift (OR 2.08), ATC medication class antacids (OR 18.09), ATC medication class prokinetics (OR 16.75), ATC medication class antibiotics (OR 3.10), ATC medication class immunosuppressants (OR 17.26), oral administration (OR 2.40), and intravenous administration (OR 2.48).

DISCUSSION

This study focuses on administration error rates and the potential risk factors that can persist in a manual administration process that benefits from automated prescription and dispensing. The study was performed in two units with 10 years of experience using this technology.

The methodology used was direct observation of medication administration, which is the most efficient and practical medication-error-detection method and one that produces valid and reliable results.[16–18] Since a common language was necessary to standardize diagnosis and systematize the detection, analysis, and recording of medication errors, we followed the Ruiz Jarabo Group medication-error taxonomy,[15] which is an adaptation of the National Coordinating Council for Medication Error Reporting and Prevention taxonomy in the Spanish health system. Widely used by hospitals and other healthcare settings within the external medication errors reporting system of the ISMP-Spain, this taxonomy makes it possible to standardize

Table 4 Correlation of administration errors with potential risk factors

	Univariate OR (95% CI)	Multivariate OR (95% CI)
Patient characteristics		
Age (in years)	0.99 (0.99 to 1.00)	0.99 (0.99 to 1.00)
Gender		
Female	Reference category	Reference category
Male	1.19 (0.96 to 1.49)	0.97 (0.73 to 1.30)
Medication characteristics		
Anatomical Therapeutic Chemical medication class		
Antacids	10.42 (7.57 to 14.34)	**18.09 (12.60 to 25.96)**
Prokinetics	7.52 (4.77 to 11.86)	**16.75 (10.10 to 27.79)**
Antibiotics	1.36 (1.00 to 1.86)	**3.10 (1.98 to 4.85)**
Immunosuppressants	8.12 (5.31 to 12.44)	**17.26 (10.80 to 27.59)**
Administration route		
Oral	1.81 (1.44 to 2.28)	**2.40 (1.34 to 4.30)**
Intravenous	1.15 (0.88 to 1.47)	**2.48 (1.28 to 4.81)**
No of medicines/shift/patient	0.97 (0.94 to 1.00)	0.99 (0.95 to 1.03)
Organization characteristics		
Expiry date not checked	3.61 (0.47 to 27.50)	3.30 (0.31 to 34.75)
Medication labeled incorrectly	0.53 (0.36 to 0.81)	1.05 (0.64 to 1.72)
Medication not retrieved from the automated dispensing cabinet just before administration	0.64 (0.52 to 0.79)	0.79 (0.56 to 1.10)
Administration by nursing assistant	0.99 (0.80 to 1.22)	0.94 (0.63 to 1.40)
Administration not documented	1.40 (0.82 to 2.39)	1.22 (0.61 to 2.42)
Time characteristics		
Working day	1.23 (0.99 to 1.52)	1.57 (0.99 to 2.49)
Shift		
Night	Reference category	Reference category
Morning	2.75 (1.58 to 4.77)	**2.36 (1.10 to 5.04)**
Evening	2.93 (1.69 to 5.07)	**2.08 (1.02 to 4.22)**
Nurse's characteristics		
Age (years)	0.99 (0.98 to 1.00)	1.01 (0.99 to 1.03)
Not career nurse	1.08 (0.87 to 1.33)	1.34 (0.97 to 1.86)
Experience in the unit (months)	1.00 (0.99 to 1.01)	0.97 (0.95 to 1.00)
No of beds under charge	0.97 (0.94 to 1.00)	1.01 (0.95 to 1.09)

Statistically significant correlations in the multivariate analysis are shown in bold.

description of the errors detected, the drugs involved, the cause of error, and the consequences and contributing factors involved.

The total error rate was high, as approximately one in five administrations were imprecise. However, this high incidence was due to wrong-technique errors (dietary restrictions); the incidence of other errors, excluding wrong-time errors, was significantly lower (6.8%). The main reason for such a high error rate was the lack of correct nursing working procedures, which generates three problems. First, the time schedule for medication is defined by nurses who often fail to consult administration guidelines; neither the CPOE nor the ADCs provide information about which medicines need to be administered on an empty stomach. Second, even though staff is aware of dietary restrictions, all the medication needed for the shift is retrieved from the ADCs at the beginning of the shift, without separating them in a different container. Third, although all the medication is removed from the ADCs by nurses using their personal fingerprint, oral medication at 13:00 and 20:00 is administered by nursing assistants, who have less knowledge about dietary restrictions.

Other considerations should be taken into account. Since these errors were not prevented—the observers were instructed to prevent only those errors that could produce an adverse event—the same error was repeated throughout the study; hence such a high error rate (128 times for PPIs and 39 and 27 times for tacrolimus and mycophenolate). In clinical terms, these errors could not be considered severe, as, in the case of PPIs, a reduction in bioavailability or a lack of effectiveness is not expected when they are co-administered with food, even though the summary of product characteristics recommends administration on an empty stomach. With immunosuppressive drugs, the clinical significance would have been significantly higher, but plasma concentrations were monitored in all cases. For these drugs, nursing staff did follow the schedule established (09:00 (administration every 24 h) and 09:00 and 21:00 (administration every 12 h)), as this is the schedule that best adapts to the patient's lifestyle outside the hospital.

In any case, we believe it is necessary to improve training in oral administration techniques and to change the way nurses work in the institution (ie, separating medication with dietary restrictions routinely and ensuring that all medications are administered by the nurse responsible for the patient). As a result of this study, the Pharmacy Department has started to adapt and implement the Guidance on the Interdisciplinary Safe Use of Automated Dispensing Cabinets, elaborated by the ISMP, which includes strict quality monitoring of nursing practice using data from the ADC management software.

Errors that may have been of greater clinical significance were much less frequent. No cases of wrong patient were detected, and the low incidence of wrong drug and dose was related to the introduction of profiled ADCs in the organization. However, despite this barrier control in dispensing, these errors still occur

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