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

Carmen Guadalupe Rodriguez-Gonzalez,1 Ana Herranz-Alonso,1 Maria Luisa Martin-Barbero,1 Esther Duran-Garcia,1 Maria Isabel Durango-Limarquez,2 Paloma Hernández-Sampelayo,2 Maria Sanjurjo-Saez1

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 57% of all adverse events documented were associated with medication, and that 55% 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 58% 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 administration 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, physical-chemical incompatibilities 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 non-preventable 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 ±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 administrations. 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
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 (15.4%) errors occurred in the preparation process and 441 (86.6%) in the administration process. The inter-rater reliability for classifying severity was moderate (κ=0.40). Errors were classified as no damage in 95.7% of cases, no damage with monitoring in 2.5% 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) (59.9%), immunosuppressive drugs (20.6%), and prokinetics (15.9%)). The main reason was a lack of use of standardized 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 overdose of wrong medication. In the case of wrong route, six out of seven errors were due to the administration of ondansetron intravenously.
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 been 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. 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, 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...
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 administrations, 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 print, oral medication at 13:00 and 20:00 is administered by nurses who often fail to consult administration using data from the ADC management software. 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.

| 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** |                  |                  |
| 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) |
| **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) |
| 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.
because nurses do not check the electronic prescription just before administration; this could have prevented two drug errors, 18 dose errors, three treatment duration errors, and four omission errors.

The analysis of potential error severity revealed that almost 96% of errors would cause no harm (Ruiz Jarabo 2008 taxonomy category C). Few of the errors were severe, because, as mentioned above, most errors were due to incorrect technique and dietary considerations, and very few errors were due to wrong drug or dose after implementing ADCs. Although this could indicate an excessively precise semantic structure for error reporting, it is the only way to detect non-severe errors that could be indicators of failures in the medication administration process and potentially lead to more severe errors in the long term. Our study is limited in that it did not take adverse events into account.

As for the potential risk factors involved, other than the positive correlation for PPIs, immunosuppressants, and prokinetics, a correlation was found for antibiotics due to problems with the reconstitution and dilution technique; this also explains the positive correlation for the parenteral route. We did not find any correlation between administration errors and nurses’ age, category (career or not), or experience, or between the number of medicines per shift or number of beds under charge. Such a correlation could have been associated with understaffing. Finally, although a statistical association could not be found between organizational characteristics and error rate, we believe it is necessary to improve working procedures in units with automated prescription and dispensing (eg, the expiry date had been checked in only 0.7% of administrations, and 53% of drugs were not retrieved from the ADC just before administration). Another critical point was the poor communication between the physician and the nurse when treatment was modified in the CPOE. This could explain the positive correlation between the morning shift and the evening shift—when more treatment modifications were made—and the error rate. Also important is the fact that nurses do not cross-check the medication prepared with the prescription online just before administration.

Our results cannot generally be compared with those of other studies, mainly because of the error-detection method used (ie, direct observation versus voluntary reporting or medical chart review). Even with direct observation, reported error rates differ. These differences could be related to how medication errors are defined (eg, many studies define the error in relation to food intake as wrong time error, which is then excluded from the overall analysis due to its scant clinical relevance), the denominator used to calculate the error rate (eg, total doses administered vs 1000 patient-days), the type of medication use process (manual or automated), and the specific population evaluated (eg, adults, children, medical patients, surgical patients, ICU patients).

In a multicenter study in six hospitals in Catalonia, only 2% of the 1500 observed administrations involved an error. Omission was the most common, representing 40% of the total, followed by wrong time and wrong frequency. Only nine wrong infusion speed errors were detected, and wrong technique errors were not mentioned. These results differ considerably from ours, possibly because all the errors found were prevented—making it difficult to repeat the same type of error—and its undisguised methodology and multicenter design could have made it difficult to observe and detect the errors consistently in different hospitals. However, other studies show a closer error rate: Barker et al reported a 19% administration error rate in 36 healthcare facilities in Georgia and Colorado (USA). This rate is very similar to ours, except for the 43% in cases of omission, which was an uncommon error in our study. Fontan et al reported a 23% error rate after implementing electronic prescribing and ADC in a pediatric nephrology unit, and Bruce and Wong reported a 25% rate of parenteral drug administration errors by nursing staff on an acute medical admissions unit. Three studies analyzing the effect of implementing ADCs showed a 10.4%, 10.6%, and 13.5% error rate after implementation. However, this technology cannot be implemented in Spain in the short term, not only because of its high cost, but also because of its important infrastructure requirements, as pharmaceutical manufacturers do not provide medications in unit dose packages with symbols that are readily deciphered by commonly used scanning equipment. Furthermore, as is the case with ADCs, BCMA will not prevent all types of preparation and administration error, such as wrong reconstitution or wrong technique, which are the most common errors detected in this study.

Although not connected to this BCMA system, the implementation of the e-MAR itself could reduce the error rate dramatically; as documenting administration in real time requires the prescription to be checked at the bedside and the medication to be administered by the nurse responsible for the patient (instead of a nursing assistant). Furthermore, a Clinical Decision Support tool can be incorporated to generate recommendations for nurses about preparation of medication before parenteral administration, adequate infusion rates, and scheduling according to dietary restrictions. Even though we are aware that the utility of the software depends on use at the bedside and adherence of nurses to recommendations, we expect to reduce administration errors by 80% with this technology. However, it will not prevent 100% of wrong drug and dose errors, or potential wrong patient errors, which are probably the most dangerous.

The limitations of this study are those associated with direct observation and the possibility of the Hawthorne effect. However, previous studies have demonstrated a negligible effect on the observed party through direct observation, and we did not find any differences between the error rate on the first and last day of data collection per nurse. Due to the nature and objectives of the study, adverse events were not taken into account. Finally, the study is also limited by its single-department design and the applicability to other institutions that have different processes for medication prescription and delivery or do not have a clinical pharmacist available.

**CONCLUSION**

Medication administration errors persist in units with ADCs. The information provided by this study indicates the type of errors and potential risk factors. We identified a need to improve nurses’ working procedures and knowledge about drugs, especially in terms of oral administration in relation to food intake and techniques for parenteral administration. The development of technology such as the e-MAR will not only enable us to document administration in real time but also facilitate cross-checking of the prepared medication with the electronic prescription at the bedside and provide information on how to administer each drug. In any case, one should bear in mind that any changes made to improve safety may generate new error risks, thus justifying continuous quality monitoring.
Acknowledgments The authors thank L Cortejoso, A de Lorenzo, V Escudero, C González, P Monts, R Romero, C Sanchidrián, N Trovato, D Vázquez, and C Velasco, for their cooperation in the observational study. We thank JM Bellon for his assistance with the statistical analyses. We thank T O’Boyle for his help in the preparation of the manuscript.

Funding Spanish Ministry of Health and Social Policy, Grant No 9982 (Royal Decree 924/2009, dated May 29) (Official State Bulletin, Tuesday, June 16, 2009).

Competing interests None.

Ethics approval This study was approved by the Ethics Committee of Hospital General Universitario Gregorio Marañón, Madrid, Spain.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES