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Using Healthcare Failure Mode and Effect Analysis to reduce medication errors in the process of drug prescription, validation and dispensing in hospitalised patients

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ABSTRACT

Objectives: To identify actions to reduce medication errors in the process of drug prescription, validation and dispensing, and to evaluate the impact of their implementation.

Methods: A Health Care Failure Mode and Effect Analysis (HFMEA) was supported by a before-and-after medication error study to measure the actual impact on error rate after the implementation of corrective actions in the process of drug prescription, validation and dispensing in wards equipped with computerised physician order entry (CPOE) and unit-dose distribution system (788 beds out of 1080) in a Spanish university hospital. The error study was carried out by two observers who reviewed medication orders on a daily basis to register prescription errors by physicians and validation errors by pharmacists. Drugs dispensed in the unit-dose trolleys were reviewed for dispensing errors. Error rates were expressed as the number of errors for each process divided by the total opportunities for error in that process times 100.

Results: A reduction in prescription errors was achieved by providing training for prescribers on CPOE, updating prescription procedures, improving clinical decision support and automating the software connection to the hospital census (relative risk reduction (RRR), 22.0%; 95% CI 12.1% to 31.8%). Validation errors were reduced after optimising time spent in educating pharmacy residents on patient safety, developing standardised validation procedures and improving aspects of the software's database (RRR, 19.4%; 95% CI 2.3% to 36.5%). Two actions reduced dispensing errors: reorganising the process of filling trolleys and drawing up a protocol for drug pharmacy checking before delivery (RRR, 38.5%; 95% CI 14.1% to 62.9%).

Conclusions: HFMEA facilitated the identification of actions aimed at reducing medication errors in a healthcare setting, as the implementation of several of these led to a reduction in errors in the process of drug prescription, validation and dispensing.

During the past 15 years, numerous organisations have promoted the adoption of strategies to reduce adverse events deriving from healthcare. In Spain, a multicentre nationwide study conducted in 2005 revealed that our country was not foreign to this problem as the rate of hospitalisation-related adverse events stood at 9.3%, a third of which were directly related to medication.[1]

By studying medication errors (MEs) we can assert that these arise mainly from prescribing.[2 3] Some novel information technologies (ITs) are aimed mostly at reducing prescription errors and the implementation of computerised physician order entry (CPOE) in particular reports a reduction of 55–83% in classic studies,[3–5] results which have been confirmed by more recent systematic reviews.[6 7] In this sense, many other ITs have been designed to reduce MEs, such as clinical decision support (CDS) systems, carousel dispensing technology and smart pumps.[8]

However, attention must be paid to errors which might stem from ITs, as numerous new prescription errors have been reported following the implementation of CPOE,[9–11] and a more standardised approach to ME studies is recommended.[12] Authors state these new errors can arise due to deficiencies in the CPOE programme, lack of software customisation, a poor implementation plan or a deficient interface design, among other reasons.[13–15]

Whenever implementing an IT, its potential positive and negative influences on the other elements of the working system should be examined. Technologies change the way

in which work is performed and, since healthcare work and its processes are complex, negative consequences of ITs are possible and expected.[16 17] Once technology is being used, monitoring should be constant to identify potential problems and work-arounds, so that its handling is evaluated in a real context.[18–20]

In this sense proactive hazard analysis (PHA) tools may be of great value, as they are specifically designed to identify hazards and prevent harm. These have been applied to different healthcare areas such as paediatric parenteral nutrition,[21] chemotherapy in adult patients[22] and especially to paediatric patients,[23–25] as well as to different stages of the use of medication such as drug order transcription,[26] distribution[27] and administration.[28] They have also been considered excellent tools for the evaluation of the safe implementation of ITs such as CPOE[29] and semi-automated dispensing robots.[30]

Failure Mode and Effect Analysis (FMEA) in particular is a PHA tool used to evaluate potential failures and their causes, and prioritises them according to the risk they pose. It provides a systematic methodology to categorise risks and investigate in-depth those which are unacceptable. Health Care Failure Mode and Effect Analysis (HFMEA) is an adapted FMEA where the terms and concepts have been adjusted to the healthcare setting.[31] It is a proactive and team based approach that identifies the ways in which a process or design can fail, why it might fail, the effects of that failure, and how it can be made safer. Even though HFMEA is only a tool, its adoption by the healthcare community can facilitate a culture shift towards an increased focus on patient safety.

In our particular setting, two ITs have been implemented recently: a CPOE system provided with CDS, and a carousel dispensing robot. Although the efficacy of the implementation has been evaluated in the past,[32 33] no studies have been carried out to evaluate the safety of the whole process of prescription, validation and dispensing of medication. The complexity of these phases involves different professionals (clinicians, pharmacists, nurses, technicians, porters, etc) with a large number of intermediate steps in which errors may appear to threaten patient safety. Hence, conducting a PHA may be of great value.

Therefore the aim of this study was to identify actions aimed at reducing MEs in the process of drug prescription, validation and dispensing, and to evaluate the impact of their implementation.

METHODS

Hospital setting

A Spanish university hospital with 1070 beds that covers a population of over half a million inhabitants. The Pharmacy Department is made up of 22 pharmacists and is noteworthy for its leadership in patient safety both within the organisation and nationwide, as some members make up the nucleus of several working groups and national scientific societies directly involved in designing and implementing healthcare safety strategies.

CPOE is fully implemented in the hospital for 3 years. The software is provided with CDS such as drug-allergy and drug interaction alerts, dosage range checks, protocol-based prescriptions and a drug information resource. Standardised order prescription procedures are available on the intranet. After prescription, the validation is completed, consisting of online order review for appropriateness in drug, dose, frequency and route of administration, and which is carried out by the pharmacists. Once the electronically-assisted prescriptions have been made, the physicians print and sign the medical records in which the nurses will later document administration.

In the hospital, 73% of the beds are provided with unit-dose distribution system, in which pharmacy technicians prepare the unit-dose trolleys daily aided by a carousel dispensing robot which semi-automates work. These trolleys have drawers in which each patient's medications are placed (one drawer for each patient) and are distributed once a day to the ward with the prescribed drugs for 24 h. Unit-dose trolleys are filled in two ways: by *direct filling*, which consists of preparing the medication for one ward in one step (this is done once physicians have prescribed and pharmacists have validated the prescription); and by *indirect filling*, which consists of preparing the medication with the prescriptions from the day before and then, once physicians have made the order entry and pharmacists have validated the medical order, technicians add the new drugs and remove the suspended drugs for the day. *Direct filling* requires less time and involves fewer robot movements, but it cannot be done for all prescriptions because of time limitations. *Indirect filling* is done first thing in the morning, and immediately before delivering the trolley, the new drugs are added and the suspended drugs removed. After filling, a fill list can be printed to check if the drawers contain the right medication. Any new order entries after the trolley delivery are validated by a pharmacist and delivered in identified individual bags.

Study design

A prospective study following HFMEA procedure was performed to analyse the process of drug prescription, validation and dispensing. The HFMEA was completed with a before-and-after cross-sectional ME study to measure the actual impact in error rates stemming from

the implementation of the corrective actions. This study was conducted in all wards with CPOE and unit-dose distribution system (27 wards). Paediatrics and neonatology were not included. The complete study was carried out over 15 months and was preceded by a pilot study in the endocrine-rheumatology ward to help us design our HFMEA, and by a concordance study using κ Test in order to obtain a score of the homogeneity existing between the two observers in charge of detecting and classifying MEs in the before-and-after study.[34] The concordance study was carried out in one ward for three consecutive days. Prescription, validation and dispensing errors were collected and classified by two observers who had experience in this field, as they had performed previous error studies. The chronology of the complete study is shown in table 1.

Table 1 Chronogram of the study

Phases	Description	2009 JUN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	2010 JAN	FEB	MAR	APR	MAY	2011
Previous	Pilot study in endocrine-rheumatology ward																		
	Concordance study																		
HFMEA	Choosing process/Assembling HFMEA team/																		
	Mapping process																		
	Pre-intervention medication error study (Data collection)																		
	Conducting hazard analysis																		
	Developing /implementing corrective actions and outcome measures																		
	Post-intervention error study (Data collection)																		
	Global analysis																		

HFMEA, Health Care Failure Mode and Effect Analysis.

HFMEA procedure

HFMEA is a five-step process that uses a multidisciplinary team to proactively evaluate a healthcare process. The first step was to choose a highly vulnerable area to study (in our case the prescription-validation-dispensing process).

The second step was to assemble a multidisciplinary team. The team included five pharmacists (the head of quality and risk, the head of pharmacovigilance, a clinical pharmacist specialised in detecting and reporting adverse drug events, and two pharmacists with previous experience in detecting prescription and dispensing errors and who were also in charge of performing the before-and-after error study), a geriatrician (in our hospital geriatricians receive numerous inter-professional consultations to adjust medication for the older polymedicated patients), and a nursing supervisor who had worked in the Pharmacy Department for 7 years and currently works in a medical ward. Two of the pharmacists had knowledge in proactive risk assessment and had previously conducted other HFMEAs. The team was required to meet weekly in sessions of 2 h. Meetings were called via email 1 week in advance. By attaching the agenda, participants could prepare ahead of time for any questions or feedback.

The third step was to develop a flow diagram of the process and sub-processes. The pharmacists built up the diagrams, which were then discussed among the members of the team in a meeting.

The hazard analysis made up the fourth step and took eight meetings in which the members also reviewed the results of the before-study. Potential failure modes (the ways in which the identified process and sub-processes could fail) were unearthed during brainstorming sessions in which each member contributed their personal experience. For all identified potential failure modes,

Table 2 Hazard score matrix in Health Care Failure Mode and Effect Analysis

Severity score	Probability score
Minor: 1	Remote: 1
Moderate: 2	Uncommon: 2
Major: 3	Occasional: 3
Catastrophic: 4	Frequent: 4

Hazard score=severity score×probability score (values; 1–16).

the potential effects and the potential causes were listed. Next, the severity and the probability score for each potential failure mode were determined by team consensus. The severity score is a measure of the potential effect of the failure mode. This score was based on subjective assessment and experience. The probability score is the likelihood of the failure mode occurring. Both scores were calculated using the results of the before-study which were also displayed and analysed in these meetings. The hazard score was obtained by multiplying both scores (table 2). The group then used a decision tree to determine if the failure modes warranted further action (figure 1). If the decision was to proceed for the failure mode being assessed, all its failure mode causes were listed with the help of the results obtained from the error study.

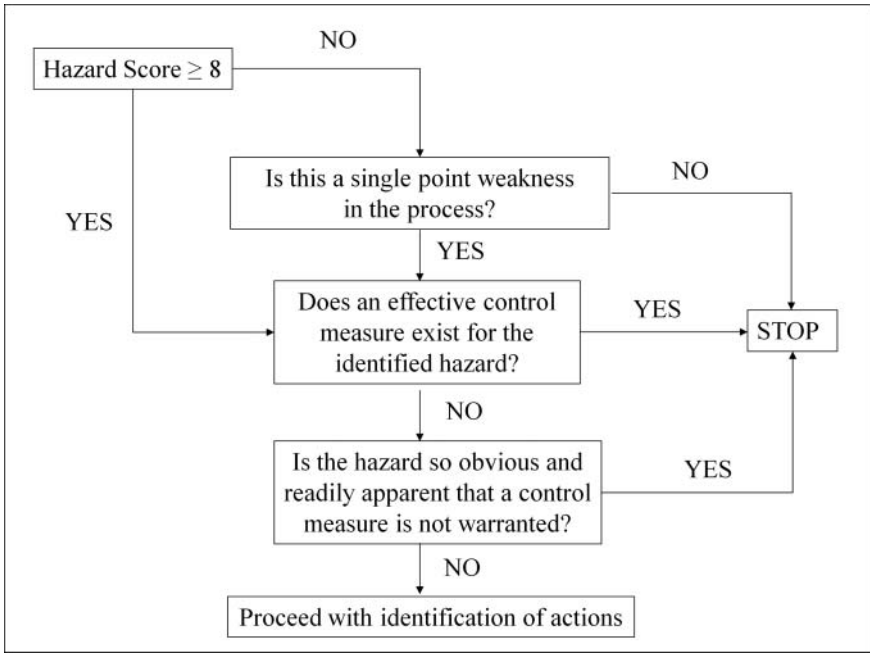
The fifth step consisted of identifying the possible actions aimed at reducing potential failure modes. These were identified during three meetings. The results of the pre-intervention error study focused the team on the errors that prevailed in the actual setting, and therefore, the ones that most need to be solved. The plausibility of the implementation was studied in another meeting in which the Head of the Pharmacy Department was invited. Those actions that were considered in need of the approval of the Hospital Directorate were negotiated in a subsequent private meeting between the Head of the Pharmacy Department and the Hospital Director. In total this step, including implementation, took 5 months.

Error study

As part of the HFMEA, a before-and-after, observational, cross-sectional study was performed to ascertain the rate of prescription, validation, and dispensing errors in all the wards with CPOE and unit-dose dispensing system (27 wards). Two pharmacists, who formed part of the HFMEA team, were in charge of collecting MEs in two periods: before and after the implementation of the corrective actions. The study was blinded for the pharmacists, the physicians and the technicians, so the professionals did not know at any point which day the MEs in a particular ward were going to be measured. The before-study helped in the design of the corrective actions and the prioritisation of their implementation, while the after-study revealed the impact of the implemented actions.

Based on prior data in our setting[32] we determined that 9464 drug prescriptions would have to be analysed to demonstrate a reduction from 9.1% to 8.0% in the prescription error rate, at an α of 0.05 and β of 0.20 (80%) power, after the implementation of the corrective actions. Considering 185 drugs are prescribed daily in each ward, we assumed we had to include 51 wards in

Figure 1 Decision tree.



each period of the before-and-after study (9464 divided by 185). Hence, we decided to analyse each of the 27 wards twice in each period. Two wards were reviewed daily, one per observer, from Monday to Friday.

The definition of a ME given by the *National Coordinating Council for Medication Error Reporting and Prevention* (NCCMERP) was adopted.[35] MEs were classified according to the Ruiz-Jarabo classification, which is an experienced committee that has adapted the NCCMERP taxonomy to our national environment.[36]

A prescription error was defined as 'a failure in the prescription writing process that results in a wrong instruction about one or more of the normal features of a prescription'.[37] The 'normal features' included the appropriateness in the drug (with correct indication and duration, and with no contraindications or relevant interactions), dose, frequency and route of administration. The rate of prescription error was found by dividing the prescription errors by the total number of drugs prescribed. Though CPOE was fully implemented in the hospital, in the pilot study we found manual prescriptions were still being made, mainly when administration records were already printed. These prescriptions required nurse transcription in the ward and pharmacist transcription into the CPOE software if the order was sent to the Pharmacy. Therefore, the total number of drugs prescribed was found by reviewing the CPOE, the printed medical orders, physician progress notes, hospital discharge summaries and any other notes where prescriptions could be drawn up. In case any manual prescriptions were not transcribed into the software by the physician, an omission prescription error was accounted. Drug dose adjustments to renal and hepatic function were not considered, as the CDS of our CPOE software did not provide any help in this sense. In addition, prescription procedures did not include these adjustment aspects, and were mainly aimed towards a correct software operation. Moreover, we had lack of human resources to check laboratory data. Anticoagulant orders made by haematologists and insulin orders by endocrinologists were not taken into account because their prescription followed a different route in which manual prescription was involved.

The rate of validation errors was calculated by dividing the validation errors made by the pharmacists by the total number of validated prescription orders. Observers reviewed all current validated orders in the software with a validation error being considered as such in those cases where a lack in the appropriateness in the prescription of a drug, dose, frequency and route of administration had not been corrected by a pharmacist during the validation process.

The dispensing error rate was calculated by dividing the dispensing errors by the total number of drugs dispensed. A dispensing error was considered as such where a discrepancy existed between the drug prescription and the drug that the technician used to fill the unit-dose trolley. Observers accounted the errors by comparing the fill list against the filled drawers.

The data was analysed with the programme *Evaluación de Tratamientos 1.0.1*, developed by the Clinical Biostatistics Department of the hospital.[38] This allowed us to calculate relative reduction risks with a 95% confidence interval.

The conditions of normal clinical practice were maintained at all times, and the study was approved by the Hospital's Clinical Investigation Ethical Committee, following the standards of observational clinical studies.

RESULTS

The results obtained from the concordance study showed a *substantial agreement* in the detection and classification of prescription errors for the two observers (κ of 0.75 in 508 observations), and an *almost perfect agreement* in validation and dispensing errors (κ of 0.84 in 496 observations and 0.86 in 718 observations, respectively).

The flow diagram elaborated by the HFMEA team is summarised in figure 2. The developed hazard analysis is shown in table 3.

Among the strategies to reduce MEs during the prescription process, four could be applied during the study period. First, CPOE refresher courses were given in each of the 27 wards included in the study. This training was carried out by a pharmacist who was formerly in charge of the implementation of CPOE at the hospital. Courses were obligatory for all physicians. Each week physicians in two wards were trained, and in 5 months all physicians in the 27 wards had received the training. Second, CPOE procedures were updated with particular emphasis on entering drug orders electronically in the medication lines where the software provides CDS (and not in free text-fields, or manually after printing the orders). This update was designed by the HFMEA team and authorised by the Head of the Pharmacy Department. After receiving the approval of the Hospital Director they were distributed via the intranet. These new procedures were taught during the courses. In third place, some aspects of the software's database to reduce MEs in certain drugs were improved (eg, redefining the hours of administration of transdermal nitroglycerin patches to ensure a minimum interval of 10 h without the drug). This action responded to errors that appeared in the before-study and to personal experiences. Lastly, automating the software connection to the hospital admission census was also implemented. This allowed physicians to have an updated database of

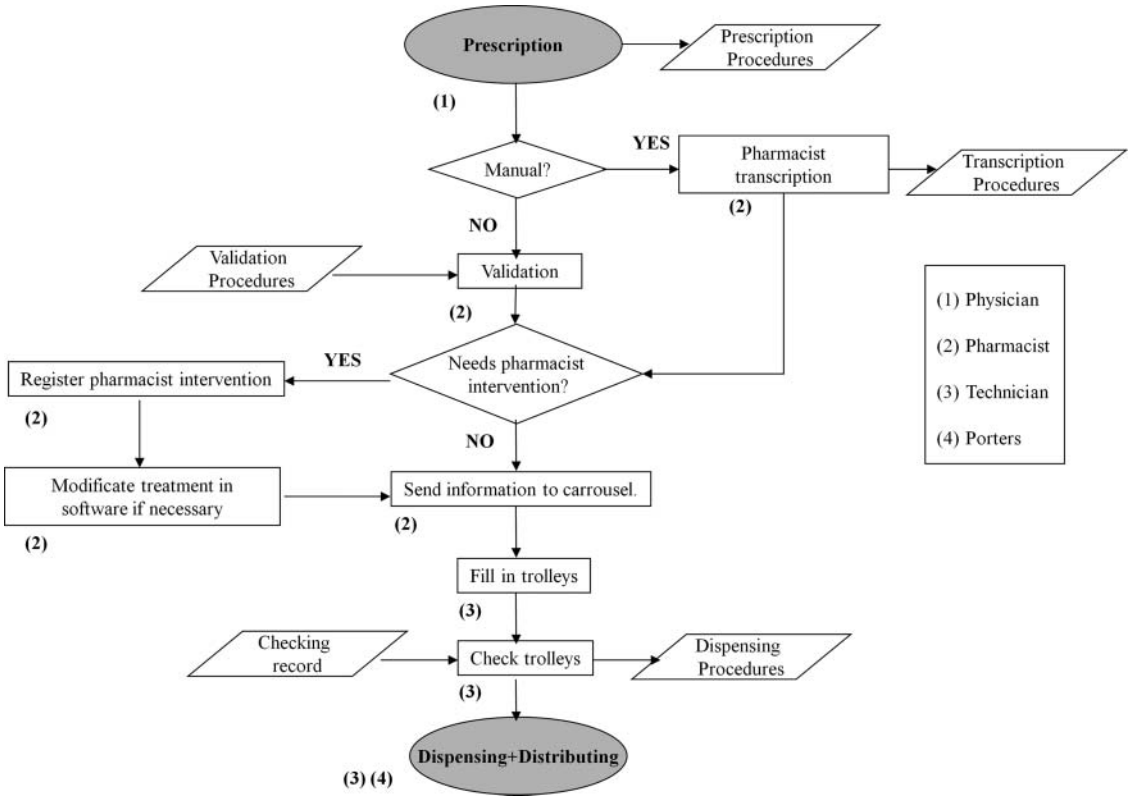


Figure 2 Flow diagram of the prescription, validation and dispensing process.

hospitalised patients and to prescribe medication online at any time. Formerly, this process was done manually by pharmacists and probably caused numerous manual prescriptions due to a lack of continuous updates in the census.

Three main recommendations were applied to reduce validation errors. The first was to distribute wards to be validated among the pharmacists in order to optimise time for teaching pharmacy residents on patient safety. This action came as result of the errors collected in the before-study, in which the main cause was stress and work overload. The distribution allowed pharmacists to specialise in the drug prescriptions of certain wards (eg, one of the pharmacists became responsible for validating traumatology and urology). No formal distribution was carried out previously and validation was often completed randomly. Second, standardised validation procedures were designed because there was no existing procedure to develop this task. These procedures were designed by the pharmacists of the HFMEA team and welcomed by the Head of the Pharmacy Department. Finally, particular aspects of the software were improved to have more CDS when validating. These actions were mainly focused on improving dose, frequency and route of administration help in certain drugs.

Two corrective actions were implemented in the dispensing process. First, the filling of the trolleys was reorganised, by replacing *indirect* with *direct filling* in three wards (endocrine-rheumatology, cardiology and cardiac surgery). Second, a protocol was drawn up for the drug pharmacy checking of four trolleys before delivering by independent technicians. Checking could not be protocolised for more trolleys due to time restriction. In the after-study the *extra dose* and *deteriorated drug errors* diminished.

Manual prescriptions in the before-study represented 4.0% of the total, while in the after study the percentage diminished to 2.4%, despite CPOE. The ME rates are shown in table 4.

DISCUSSION

Actions implemented and medication error reduction

As far as prescription is concerned, training and educating prescribers in CPOE constituted the main action to reduce prescription errors. Shaughnessy and D'Amico,[39] demonstrate that physicians who receive prescription training can improve their prescription writing and reduce their errors. Second, the updating of CPOE procedures was also implemented. Along the same lines, the Institute of Medicine recommendation is to 'standardise prescription writing and prescription rules, and eliminate certain abbreviations and dose expressions'.[40] In third place, CDS and the software's database were also improved. In this sense, some systematic analyses conclude that home-grown softwares with advanced CDS

Table 3 Failure modes and corrective actions

Process and sub-processes	Failure modes	Potential causes	Potential effects	Severity	Probability	Hazard Score	Actions to reduce failure mode	Needs Hospital Director approval?
Prescription	MANUAL prescription (instead of CPOE)	CPOE knowledge deficit. Efficiency-thoroughness trade off. Failure of the computing system. Urgent treatments	Medication errors (omission, duplication)	3	3	9	Nurses not accepting any manual prescription. **Education and training physicians on CPOE**	No
	Prescription with errors	CPOE/drug knowledge deficit. Lapses. Not following standardised procedures. Work overload	Medication errors	4	4	16	**Improving clinical decision support. Improving software's database. Pharmacy validation. Updating CPOE procedures. Education and training on CPOE**. Clinical pharmacist participation on physician round	Yes/No
	Prescribing on wrong patient	Lapses. Software error	Medication errors	4	3	12	**Education and training on CPOE. Solving specific problem in our CPOE software**	No
	Oral prescription; physician to nurse	Urgent treatments. Efficiency-thoroughness trade off. System inertia	Medication errors, in particular administration	3	3	9	**Education and training on CPOE**. Nurses not accepting any verbal orders (except urgent situations)	No
	Patient does not appear as admitted in the CPOE system	Pharmacist has not connected the software to the patient hospitalised census. Ward has not communicated transition/ admission. Fall of the computing system	Prescription is delayed; delay in dispensing; use ward stock before pharmacy validation	1	4	4	**CPOE software improvements. Automating software connection to admission census**	No
Nurse transcription	Transcription error	Illegible order. Ambiguous prescription. Use of abbreviations. Trailing zeroes. Lapses. Inexperience. Work overload. Interruptions	Administration error	3	3	9	**Eliminate/reduce transcription. CPOE printed orders**	Yes
Pharmacist transcription	Transcription error	Illegible/ambiguous order. Use of abbreviations. Lapses. Inexperience. Work overload. Interruptions. Limited staff. System inertia	Dispensing and administration error	3	4	12	**Eliminate trasnscription.** Double checking	No

Continued

Table 3 Continued

Process and sub-processes	Failure modes	Potential causes	Potential effects	Severity	Probability	Hazard Score	Actions to reduce failure mode	Needs Hospital Director approval?
Validation	Validation error	Work overload. Lack of training/ knowledge. Inexperience. Lack of clinical data Interruptions. Distractions. Limited staff. System inertia. Stress	Dispensing and administration error	3	4	12	Minimum of one pharmacist every 100 beds. Environmental improvements	Yes
							Developing standardised validation procedures. Assigning wards to validate. Educate and train pharmacists. Software improvements	No
Preparing medication cart in the pharmacy. (Dispensing)	Dispensing error	Lapses. Inexperience. Look alike products stored near each other. Limited staff. Distractions. Space. Lighting, noise. Inefficient workflow	Administration error	3	4	12	**Drawing up a protocol for the drug pharmacy checking. Reorganising the filling trolleys process**	No
							Environmental improvements	Yes
Deliver medication to patient care ward	Delivered to wrong ward	Lapses. Inexperience	Delay. Use of ward stock medication	3	2	6	–	No
Check medication in the ward	Check not done/not completed/ inadequate	Work overload. Limited staff. System inertia. Efficiency-thoroughness trade off	Administration error	2	3	6	Focal meetings with nurses in the wards	Yes

Although our CPOE system requires no transcription, the process was included in the analysis because transcription continues to be present in certain occasions. Recommendations that were implemented are shown in bold characters.
CPOE, Computerised physician order entry.

Table 4 Medication error rates before and after implementation of corrective actions

	Before			After			
Process	**N**	**Total**	**%**	**N**	**Total**	**%**	**RRR**
Prescription	**618**	**8703**	**7.1**	**568**	**10 248**	**5.57**	**22.0% (12.1%; 31.8%)**
Causes							
Prescription procedures violation	**475**	–	–	**386**	–	–	**31.0% (19.9%; 42.0%)**
Lack of drug knowledge	47	–	–	52	–	–	6.0% (–32.2%; 44.3%)
Lapses	44	–	–	64	–	–	–23.5% (–65.6%; 18.7%)
Incorrect selection from a list	33	–	–	33	–	–	15.1% (–29.6%; 59.8%)
Other	19	–	–	33	–	–	–47.0% (–114.3%; 20.3%)
Validation	**216**	**8383**	**2.58**	**205**	**9866**	**2.08**	**19.4% (2.3%; 36.5%)**
Causes							
Stress, work overload	**184**	–	–	**161**	–	–	**25.7% (7.4%; 43.9%)**
Validation procedures violation	**18**	–	–	**7**	–	–	**67.0% (14.7%; 119.2%)**
Lack of drug knowledge	6	–	–	17	–	–	–140.7% (–280.3%; 1.20%)
Lapses	6	–	–	16	–	–	–126.6% (–236.4%; 10.2%)
Other	2	–	–	4	–	–	–69.9% (–286.6%; 146.7%)
Dispensing	**101**	**12177**	**0.83**	**66**	**12936**	**0.51**	**38.5% (14.1%; 62.9%)**
Types							
Extra dose	**32**	–	–	**15**	–	–	**55.9% (14.7%; 97.1%)**
Dose omission	29	–	–	18	–	–	41.6% (–3.7%; 86.8%)
Wrong patient	17	–	–	18	–	–	0.3% (–65.8%; 66.5%)
Deteriorated drug	**17**	–	–	**3**	–	–	**83.4% (32.3%; 134.5%)**
Other	6	–	–	12	–	–	–88.3% (–221.4%; 44.9%)

RRR, relative risk reduction; Total, number of prescribed drugs, number of prescribed and validated drugs, number of dispensed drugs. Significant reductions are shown in bold characters (95% confidence interval).

are best at reducing prescription errors, because they are better adapted to the specific setting.[6 7] Our software, though commercial, is continuously updated with suggestions made by clinicians, and thoroughly evaluated for security and safety. Fourth, we did not find any study which specifically evaluated the introduction of an automatic connection to the hospital census, but it is known that ITs must acquire integration within the healthcare system in order to provide us with the maximum benefits.[41]

Assigning fixed wards to be validated among the pharmacists was a measure designed to optimise time spent on resident training in managing pharmacotherapy and obtaining clinical proficiency and judgement to reduce validation errors. Some publications insist on lack of education and knowledge of pharmacy staff as the causes of fatal MEs.[42] Second, developing standardised validation procedures was another aspect which we improved in our setting. The review of drug orders by pharmacists leads to the reduction of medication-related errors.[43 44] Joint Commission in particular, requires that 'in non-urgent situations all prescriptions or medication orders must be reviewed by a pharmacist …'.[45] Lastly, specific improvements in the software surely contributed to reducing these errors, as validation was facilitated with more support for the validation of treatments.

Dispensing errors were also reduced. The number of trolleys loaded by *direct filling* increased. This type of filling requires fewer movements of the dispensing robot, therefore, as Abad *et al*[46] conclude in their study, this means fewer errors. We also formalised a series of checks before delivering drugs to the ward. NCCMERP enhances accuracy in the process of dispensing by encouraging the organisation to establish checks whenever possible by independent individuals.[47]

Pros and cons of the methodology

Even after a technology has been implemented and its benefits in patient safety have been proven, it is important to continue monitoring its use in an actual context, as well as to identify potential problems and workarounds. In the particular case of IT in healthcare, the inherent characteristics of MEs require a system approach, strong leadership and multidisciplinary cooperation in order to succeed in preventing them from occurring or reducing their prevalence.[48] Proactive analyses must include testing to ensure that the system works effectively and that new vulnerabilities have not been introduced elsewhere in the system.[31] This testing should be, in our opinion, as objective as possible. HFMEA may be of great value, but there is little evidence to support its use for quantitative prioritisation of process failures because it lacks both reliability and validity.[49 50] We designed this type of study in this specific sense which combines the advantages of the system

approach PHA adapted to the healthcare setting and the objective measures of a classic cross-sectional ME rate study. To our knowledge, there are no publications in which this combined methodology is used to study the process of medication use.

Apart from this novel methodology, we consider that another main strength of our study is the broader view of process of medication use we achieved by analysing the sequence of more than one phase of the medication process (not just dispensing[30] or administration[28]), by including the entire hospital setting with unit-dose system (not just one ward[51 52]), and by including all types of drugs (not just chemotherapy,[22–24] parenteral nutrition[22] or intravenous drugs.[28 53]) The fact that we completed our study with a before-and-after rate ME study to measure the efficacy of the actions taken (instead of using before-and-after hazard score values to measure efficacy[21 54 55]) make it one of the most complete within the bibliography consulted. Using a rate ME study made us overcome limitations that are inherent to the HFMEA method,[56] such as not measuring real failure rates,[23] not contemplating actions to reduce error rates with a low detectability,[57] or trusting outcome measures proposed by the multidisciplinary team which may be biased, as some authors have investigated.[58] In fact, supporting the PHA with other types of studies is a recommendation given by other authors to guarantee objectivity.[59]

Though we suspect the solutions identified are fairly 'common sense' we think that conducting this type of study warrants the sturdiness and objectiveness of the results. Moreover, some of the identified improvement actions could only be identified conducting the baseline error study (eg, some particular improvements in CDS for certain drugs) and others only from the HFMEA step (eg, prescribing for wrong patient that did not occur in the data collection).

Limitations and future lines of investigation

However, we also found some limitations in our study. The main one was not including the administration phase. The shortage in human resources needed to conduct the *direct observation* to collect data made its inclusion impossible. We believe this is a weakness given that the administration phase is considered the second in the process of medication use in terms of number of errors.[2 3] Moreover, it is the last phase before the drug reaches the patient; thus, establishing barriers to prevent any errors from reaching the patient should be prioritised.

In addition, we found the inherent limitations of conducting a before-and-after observational study, in which results may be biased because they lack a control group. In general, uncontrolled studies should not be used to evaluate the effects of guideline implementation strategies, and the results of studies using such designs have to be interpreted with great caution, but these quasi-experimental studies are often conducted when there are practical and ethical barriers to conducting randomised controlled trials, as in our case. It would not have been ethical to implement actions we believed were going to improve patient safety in some wards and not in others.

Our inexperience in assembling multidisciplinary teams could have also been a limitation. In this sense, we think our team was particularly pharmacist focused, and it would have beneficiated from including other professionals such as pharmacy technicians who are responsible for dispensing, as well as a larger variety of physicians (including senior and junior) since prescribing errors were the most prevalent.

Consequently, in future lines of investigation we will include the administration phase if we are provided with the necessary human resources and assemble a more balanced team. We would also like to design a study to evaluate the dispensation through automated dispensing cabinets, which are gradually replacing traditional unit-dose trolleys. In addition, future work should also focus on dosing in renal and hepatic failure since our CDS does not provide this functionality.

In conclusion, this study illustrates the value of completing a PHA with a before-and-after ME study to identify actions aimed at reducing MEs in a healthcare setting. The implementation of the identified actions led to a reduction in the errors in the process of drug prescription, validation and dispensing.

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Using Healthcare Failure Mode and Effect Analysis to reduce medication errors in the process of drug prescription, validation and dispensing in hospitalised patients

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