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ANALYSIS OF ENVIRONMENTAL AND ORGANIZATIONAL ASPECTS AND STRATEGIES FOR PREVENTING RISKS OF MEDICATION ERRORS IN A TEACHING HOSPITAL

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ABSTRACT

The present study was conducted to identify the causes of medication errors (ME) in a public teaching hospital and seeking strategies to reduce them. A prospective, cross-sectional, descriptive, exploratory, and observational study of the physical and organizational structure of 7 different units of the hospital and the level of organization of the processes involved in the medication cycle (from prescription to administration) was performed. The study examined the medication process of 155 patients, including 465 medical prescriptions and 7,080 prescription drugs. Risk factors for ME were more associated with deficiencies of the health system than with individual failures. Deficiency of facilities, inadequate use of space, disorganized drug storage cabinets, poor lighting, excessive noise and failure and/or unavailability of equipment were observed in most of the units. Quantity, distribution and insufficient training of nursing professionals, as well as work overload, double routine activities and frequent interruptions of tasks, were also observed. Errors in the medication process were observed at all stages of the cycle, ranging from failures of communication between team members to operational deviations that endangered patient safety. Efforts by directors and health professionals should be concentrated on creating a work environment that values comfort and adequacy of facilities, hiring an adequate number of employees with high quality and sufficient training, improving the availability and correct operation of the equipment, and adopting operating protocols that guide healthcare professionals at all stages of the medication cycle.

KEY WORDS: Healthcare, Medication administration, Medication errors, Nursing errors, Patient safety.

INTRODUCTION

Medication errors (ME) are considered one of the most common types of errors that affect patient safety, reaching approximately 3 to 6.9% of hospitalized patients.[1] They contribute significantly to the increase in morbidity and mortality and increased costs of the health system.[2] Approximately 30% of hospitalized patients may experience adverse effects due to a ME, and in some cases, the errors may be multiple and/or fatal.[3.4.5]

However, research investigating causes of errors in healthcare are much more focused on the individual[6.7.8] than on the context in which the error occurred. There are few studies in which the environmental and organizational issues of a health system are key factors in securing safe medical and nursing care during the medication process.[9.10.11]

As the majority of adverse events related to ME can be prevented, we hope that this study can help health professionals and institutional directors from other centers to change the paradigm in investigating the causes of these serious errors. Preventive strategies necessary to ensure a high quality of patient care should be adopted in the medication process.

MATERIAL AND METHODS

Study characteristics and research setting

A prospective, cross-sectional, descriptive, exploratory, and observational study was conducted over 18 non-consecutive months at the Clinical Hospital of the Faculty of Medicine, State University of Sao Paulo, UNESP, Botucatu, SP, Brazil (CH/FM – UNESP). This public hospital has 417 hospital beds and is connected to the Health Secretary of the State of Sao Paulo, whose attention is predominantly focused on serving patients of the Unified Health System. The study was conducted according to the standards of the National Board of Health and the Ministry of Health of Brazil and was approved by the Ethics Committee in Research of the Faculty of Medicine of Botucatu, UNESP, Brazil.

Acquisition of data and selection criteria

To identify risk factors for ME, an active search was performed in 7 different units of the CH/FM – UNESP, where there were many patients and a high demand for procedures associated with the medication process, including the Central Intensive Care Unit (Central - ICU), the Intensive Care Unit of Emergency (ICU - Emergency) and the units of General Surgery, Surgical Gastroenterology, Orthopedics and Trauma, Medical Clinic and Pediatrics.

The methods used in the search of information included regular visits to inpatient units, systematic consultation of medical prescriptions and nursing notes, direct observation of procedures performed by nursing staff, and analysis of the workplace, including the exploration of all environmental and organizational variables that could interfere in the medication process.

Due to the high number of patients and demand for medication administration in these 7 inpatient units, the search for risk factors for ME was performed using random sampling, and analysis included the medication procedures of 155 patients, 465 prescriptions and 7,080 prescription drugs. The following factors were excluded from the analysis: the indication and dosage for the drug as prescribed by the treating physician, drug interactions, and steps linked to the internal processes of the hospital pharmacy, including purchasing, receiving, acceptance, storage, preservation and handling of drugs by the pharmaceutical staff.

Analyzed variables

The study was designed to detect risk factors that could lead to ME, involving 1) failures or inadequacies of the physical infrastructure, material and human resources (including availability, location, organization and proper use of the workspace; existence of areas reserved for the preparation of medications; lighting conditions and noise; conditions of storage, organization, identification and separation of drugs; availability, organizing and checking the cart for cardiopulmonary arrest; availability and adequacy of existing technological and material resources; and quantity, distribution and training of human resources); 2) organizational and procedural failures (including the existence of standardized medicines for hospital use and standardized procedures related to the medication process and analysis of variables related to each step of the medication cycle, including a) prescription; b) pharmaceutical dispensing; c) segregation/preparation/dilution of drugs; d) administration/application of medications and solutions; and e) monitoring patients pre-, intra- and post-medication); and 3) complaints of professionals linked to the psychosocial aspect, with the potential to impair performance during the medication process through reports on work overload, stress, fatigue, job dissatisfaction and relationship conflicts with superiors. The collection of descriptive data for all variables was based on protocols specifically prepared for this purpose, based on the literature on the subject.

RESULTS

Physical infrastructure, material and human resources

All assessed inpatients units had an area set aside for the preparation of medications, with the exception of the Central - ICU, where medications were prepared at the patient's bedside.

Most existing medication rooms were within the standards established by the brazilian legislation, which sets standards for the physical environments of health care facilities (RDC No. 50, ANVISA), except for the Pediatric unit (which had no power outlets and no access to hot and cold water) and the Surgical Gastroenterology and Orthopedics/Trauma units, where workstations and storage supplies were located relatively distant from the patient rooms. Inappropriate use of the medication room space was also observed in the Surgical Gastroenterology unit.

The lighting conditions were also considered poor in the Central - ICU and Pediatric unit, where there was excess noise due to the constant movement of people, conversations without purpose and noises produced by mobile phones and alarms generated by the monitoring and ventilating equipment. Interruptions of work hours to care for patients or heeding their families were also frequent in the Central - ICU, ICU – Emergency and the Surgical Gastroenterology and Orthopedics/Trauma units.

The storage, organization, identification and separation of drugs in cabinets were considered inadequate in most of the inpatient units, with the exception of the Central – ICU and ICU – Emergency. The hygiene and cleanliness of the cabinets were also considered poor in the Pediatric and Surgical Gastroenterology units, and the furnishings were old and in poor condition in the Pediatric, Orthopedics/Trauma and General Surgery units. Additionally, there was no appropriate identification of medicinal drugs and solutions stored in these cabinets.

The cart used for cardiopulmonary arrest was inadequate in the Orthopedics/Trauma unit, namely, the absence of seals, lack of notation of the date the cart was last checked and medicines were replenished and lack of information on the medications' expiration dates.

On all the inpatient units, except the Surgical Gastroenterology unit, there were computers to access information about medication, drug interactions and adverse drug reactions, but they were rarely used by health professionals. Bedside terminals for the control and monitoring of vitals of the patient before, during and after the medication process were only available in the Central – ICU and ICU – Emergency. Drug infusion pumps were available in 7 units; however, there was no

printed and available standard operating plan for all professionals. Computerized provider order entry (CPOE) with individualized doses of medications, as well as computerized medical and nursing evaluation of patients, was available in all units. However, no units had electronic devices to increase the security of patients, such as wrist bands with code bars for identification or automated systems for dosing and administration with the ability to alert and detect adverse events.

There is a deficit in the number of nurses, specifically, 93.3%, 85.7% and 80.0% below the recommended number set by the brazilian legislation in the Surgical Gastroenterology, Orthopedics/Trauma and General Surgery units, respectively. Nursing activities were not directly supervised by a nurse in any of the 7 inpatient units at night, on weekends and during holidays. This task was performed by a single nurse on duty, who was responsible for supervising 2-3 inpatient units, concomitantly.

There was a smaller deficit in the number of nursing assistants and technicians in the Surgical Gastroenterology and Medical Clinic units (4.37% and 3.03% below the recommended number, respectively). The number of nursing professionals was also considered deficient by the Federal Council of Nursing legislation in all categories in the Central – ICU and ICU – Emergency.

All the professionals in the 7 units in the study were trained at the level required by their employment contracts, which include an annual plan for formation, training, and continuing education for nurses. Despite being mandatory, not all employees participated in the activities. The same trend occurs with the specific training of professionals in the units, mainly in relation to the execution of tasks related to the medication process.

Organizational and procedural failures

All the medication used at the CH/FM – UNESP was standardized by the Commission of Hospital Pharmacy and individually prescribed and administered electronically, but there were no standardized protocols available to nursing professionals to perform all the steps related to the medication process.

Failures in the steps of the medication cycle in the hospital

a) Prescription

The level of communication among physicians, pharmacists and nursing professionals was considered poor in all inpatient units. Characteristics of poor communication included the lack of clarification of doubts of prescriptions, suspension or switching medications and lack of schedules for early administration of drugs added to the prescription. There were also conflicts in the timing of the medication process, including pharmaceutical dispensing and administration of medications to patients.

No errors were observed in medical prescriptions related to the identification of the patient, bed number or medical records or the hospital unit name, date and time of the prescription, prescriber's name, generic drug name, drug form or drug concentration. However, doctors in all the units wrote changes on printed electronic prescriptions, at times making them confusing to understand. Except for the Pediatric unit, medical prescriptions did not contain information about the care the nursing staff should utilize during the administration of medications to patients, such as measures to protect the active ingredient, speed and manner of administration or the desired monitoring plan for the pre-, intra-, and post-medication stages.

b) Pharmaceutical dispensing

Medical prescriptions were transmitted electronically to the pharmacy in all the units. However, some prescription drugs were not dispensed by the pharmacy due to a lack of available product in the hospital. Frequent delays in the release of prescription drugs by the pharmacy were also observed due to the delay in the release of medical prescriptions. There was no protocol to regulate the dispensing and administration of drugs to be given after a shift ended, and dispensing and administration depended on the willingness of professionals to speed up the process.

All medications released by the pharmacy followed the best practices of dispensing medication, according to the requirements of quality, safety, validity and physicochemical characteristics of the products. However, the pharmacy used identical labels and graphic characters for identifying all medicinal products for oral intake, increasing the risk of errors during the process of dispensing and drug administration.

There were no decentralized units of the pharmacy located near inpatient units. Similarly, pharmacists did not participate in external processes of the pharmacy during prescribing, preparation and administration of medications to patients. Additionally, a pharmacist was not present in the hospital at night, on weekends and during holidays.

c) Organization, identification and preparation of medications

In all inpatient units, nursing professionals were familiar with the techniques of manipulation, preparation and dilution of medications and solutions. However, 100%, 72% and 54% of medications were not double-checked by the nursing staff in the Surgical Gastroenterology, Medical Clinic and Pediatric units, respectively. None of the 7 units had a printed, standardized protocol available to all professionals to ensure the correct organization of medicines, including their identification, manipulation, dosage and requirements for the maintenance of the

physicochemical properties of the drug. There was no systematic concern by professionals in all the units to wash and sanitize their hands each time they handled, prepared and administered medication. Similarly, health professionals did not sanitize when handling vials, ampules, solutions and intravenous access; replace needles used in the process of preparation during drug administration; or change gloves when administering drugs to different patients.

d) Drug administration

Prescriptions were not double or triple checked with the medication administered to the patient and were only checked once at the time of drug administration. There were no printed standard operating procedures that ensured patient safety during medication administration, including the minimum guarantee of the "five rights of medication administration" and other principles.

In the Surgical Gastroenterology, Orthopedics/Trauma and Medical Clinic units, 100%, 76% and 40% of medications were administered at the incorrect time, respectively. Frequent delays in the infusion rates medication pumps were also observed in all the hospital units, primarily due to programming errors or improper preparation of the instruments. In the hospital, there was a standard operating protocol for such equipment; however, it was not available to all the professionals in the 7 inpatient units studied. Nurses in the Surgical Gastroenterology, Orthopedic/Trauma and Medical Clinic units only record the time of drug administration when they are prepared and not immediately after they have been administered.

Except for the Central – ICU and ICU – Emergency, there were failures in the identification of patients using wrist bands, including lack of use and the progressive erasure of the printing.

In all the units except for the Central – ICU, several technical failures of the nursing staff were observed during the medication process, including the use of trays containing medicines from several patients, lack of routinely asking the patient's full name, lack of patient education of the medication and possible side effects and lack of assurance that the medication administered orally was actually ingested by the patient.

e) Monitoring the patient in the pre-, intra- and post-medication stages

The nursing staff in all the units did not routinely note any side effects or adverse events that occurred with the administration of medications to patients, the same occurring with the medical and nursing procedures adopted in these situations. Except for the Central – ICU and ICU – Emergency, nurses did not routinely perform daily patient assessment in relation to their clinical response to the drugs and only noted patients' vitals and possible requests from the medical staff. During the study, ME were not notified, and this issue was not referred to the health risk management of the hospital.

Individual and psychosocial factors

Complaints from nurses about job dissatisfaction, stress, and fatigue were commonly heard by the researcher during the study period in the 7 units. These problems were imputed by nursing staff to work overload, double work shift and limited staff for complete implementation of all essential tasks and possible conflicting relationships with superiors. Embarrassment, fear of losing their jobs, and fear of missing psychological and legal support from the institution were the alleged reasons for not reporting ME to the health risk management of the hospital.

DISCUSSION

Environmental and organizational failures

Medication administration in hospitals remains a high risk task for nurses because of the possibility of errors that can cause damage, sequelae or death of patients.[4.12.13]

Despite the potential for human error, we observed that the risk factors for ME were more associated with failures or deficiencies of the physical and organizational environment of the hospital units than with individual failures.

Studies show that when medication workspaces are inadequate, poorly designed and/or improvised for the implementation of activities or tasks related to the therapeutic cycle, this flaw raises the level of tension, discomfort and stress of professionals, increasing the risk of human and process failures.[14.15.16] The same stress and failures occur if the workstations and/or medical and nursing supplies are centralized in the units and are far removed from the patient rooms.[17]

Medication errors or near-miss events are related to separation, identification and incorrect administration of medications, and these events have been reported in hospitals where medication cabinets are disorganized or there are failures or lack of identification and separation of drugs, including the incorrect form and route of administration. [15.18.19]

Studies also show that ME are more likely to occur when ambient lighting in the preparation and dispensing of medications is poor.[20] Improved lighting of the workplace, especially with the use of natural light, is not only related to lower rates of drug dispensing errors but also improves alertness and quality of life of health professionals.[21.22] ME are also more likely to occur if there is excessive noise because it is a source of distraction and stress to professionals, leading to decreased attention and potential errors.[23]

The absence of certain equipment and electronic systems in the inpatient units may also play a significant role in increasing the prevalence of ME. Studies show that ME decrease and patient safety increases with electronic order entry, drug infusion pumps, and portable electronic

devices used for searching pharmacological information, as well as barcode devices for the identification of patients and drugs, computerized record systems of medication administration, electronic alert systems for detecting adverse events, automated dosing systems and electronic bedside terminals.[20.24.25]

In our study, we noted that inpatient units had problems with identifying patients and drugs to be administered due to the fading of the print on wrist bands. A systematic review published by Young et al.[26] showed that although the use of barcode systems for medication administration did not consistently reduce the overall incidence of ME, the systems can, however, identify other types of errors not previously detected by the traditional approach of the "five rights" of drug administration.

We also noted that there was no standard operating procedure in the units that guides nurses in the proper use of the drug infusion pumps. Studies show that improper use of equipment in health facilities constitutes a potential source of errors and stress for the professional team. In contrast, technological improvements and the ability to track usage and availability of equipment protocols can reduce latent problems, such as breaks and failures in the operation of these instruments, as well as possible errors in the dosage and timing of drug administration.[11.27]

We also observed organizational failures of the health system related to the amount and distribution of nursing staff. According to Mahmood et al.[11], improvement in the composition, distribution and functional organization of the staff and sub-staff, including physicians, pharmacists and nursing professionals working in health care facilities, was considered crucial for reducing rates of ME. This task, however, requires hiring an adequate amount and quality of human resources sufficient to meet the demand and complexity of patient care without compromising workload, function and quality of care.[28]

Improving the level of education and training of the hospital staff also reduces the rates of ME and adverse events associated with drugs.[29] Research performed by Mckeon et al.[30] showed that nurses with a higher level of knowledge about drugs and greater access to reference materials had fewer violations of best practices for administering medications than those who did not have these requirements. Additionally, novice nurses and/or nurses with poor training in performing tasks related to medication had a higher rate of errors than more experienced and trained nurses. [20.31]

Process errors were also observed at all stages of the medication cycle, from the dispensation of the drug by the pharmacy until its administration to patients. Studies show that nurses are less likely to violate procedures when performing their activities in a positive work environment, marked by good communication among team members and adequate training.[32.33.34] However, poor communication occurred among members of the medical, pharmaceutical and nursing teams at the institution under study, and there were no standard operating procedures available to ensure quality nursing practice throughout the medication process.

Individual and psychosocial factors

Personal, psychological and social problems can increase the risk of ME, and many complaints were witnessed among nurses in all the hospital units. Studies conducted by various authors demonstrate that stress, fatigue, distraction, job dissatisfaction and difficult relationships with superiors contribute to decreased alertness and performance and affect the quality of patient care. [10.33.34] In this study, however, we observed that many of the psychosocial risk factors could be closely linked to failures and/or inadequacies of the physical and organizational environment of the workplace, such as work overload, increased routine activities, frequent interruptions of tasks, inadequate number of professionals to complete all activities and accountability for results.[19.35.36.37]

Although risk management existed in the institution, ME were not reported. This failure may possibly be related to guilt and the fear of being punished. According to Kalra[38] and Dekker[39], blaming a person for a ME leads to an attitude of self-defense, inhibiting the willingness of professionals to report the problem as a self-protection mechanism. Therefore, "punitive health systems" are generally ineffective in addressing the range of causes of ME and issues of patient safety because a ME is more likely associated with various factors than with an individual component. According to Hughes[40], this retrospective bias focuses only on the human factor and greatly simplifies the problem by hiding the true causes of the errors.

Anderson and Webster [41] and Wolf et al.[42] stated that the most productive strategy to address human error is the creation of mechanisms that enable health professionals to better understand the impact a medication error can have on themselves and the patient and therefore encourages professionals to report errors or potential errors to the institution. For this reporting to happen, medication errors should be handled in a constructive manner to permit the exploration of all possible error causes, education and training should be required, and necessary support should be provided to enable the professional to create mechanisms to cope with the ME.[43]

Strategies to reduce medication errors

A basic strategy to minimize ME is to double or triple check a medication by multiple nurses during the dispensing of the drug, patient identification, and preparation of solutions, as well as before the drug is administered to the patient.[41.44] Although this strategy does not eliminate the need for other security procedures

[45], it was not practiced by any of the hospital units evaluated in this study.

Another traditional method to ensure patient safety during medication administration is the "principle of the five rights", which involves five essential checks before administering a drug to a patient: the right patient, right medication, right dose, right route and right time.[46] More recently, other principles have been added to this list, including the right form of the drug, the right response, the right patient documentation and the action/indication of the drug, encompassing the "nine right principles".[47] This method was not used in any of the 7 hospital units in this study.

According to Lisby et al.[12}, a medication should always be administered to the patient for whom it was prescribed (principle of "right patient"). However, it is still common to administer medication to the wrong patient. The strategies suggested to reduce this type of error include asking the full name of the patient before medication administration, refraining from suggesting his name to the patient, verifying that the hospital bed number matches the patient's name and their nursing records, and using wristbands with barcodes or identification bands whenever possible.

Studies show that up to one third of medication errors involve administering the wrong medication to a patient.[48] Therefore, to ensure the "principle of the right medication," the following strategies have been suggested: always use the prescription's generic drug name due to the similarities of drug names, dosages, routes, prefixes, suffixes, etc.; adopt an electronic prescribing system that provides individualized doses; require nurses to know why the drug was prescribed; when possible, notify the patient about which drug will be administered; ask patients about their potential allergy history of the drug to be administered; and report/annotate any side effect the patient experiences during the administration or after use of the medication.

In clinical practice, the nursing staff should only administer the prescribed dose of the drug using the correct route of administration (the principles of "right dose and right route"). Numerous medication errors have been reported in the literature because of incorrect dose and/or route.[48.49.50] Strategies to prevent these types of errors include special nursing attention in reading the prescriptions, mainly the doses that use decimal points, zeros, or milligram and microgram units; careful calculation of doses and volumes according to weight; special attention to drugs with exclusive routes of administration (vincristine, for example, is only administered intravenously; intrathecal injection can be fatal); and discussion of any doubt in dose and route of administration with the prescriber prior to administration. The drugs should be administered at the right time ("principle of right time") to ensure its therapeutic serum levels. A study by Barker et al. [51] conducted in 36 healthcare facilities in North America revealed that 43% of ME are due to administering medication at the wrong time and/or interval. The main recommendations for ensuring the effectiveness of the medication and patient safety are the following: all medication should be administered to the patient as close as possible to the time prescribed by the physician; during repeated use of medications, nurses should not deviate from the interval prescribed by more than 30 minutes[52], medications should never be prepared far in advance of its administration and should be prepared in compliance with the chemical composition and the active ingredient of the drug[50], and medications should be administered in accordance with the prescribed guidelines in relation to the infusion rate (bolus, slow infusion, rapid infusion, with particular drip). In our study, however, we observed that the units did not have a structured schedule that was in synch with the flow times of the medical staff, pharmacy and nursing, especially in relation to drugs prescribed or suspended outside the routine schedule of the units.

As the same drug can be available in various forms and administered by different routes, it is necessary to adopt mechanisms to ensure that a drug is administered in its correct form ("principle of right form"). Strategies to avoid that a form of medication can be administered in an incorrect form or route include the following: ensure that the route of administration requested by the attending physician is compatible with the form of the product; always label medications for oral use, when they will be administered with syringes or by nasogastric tube (use expressions such as "use by nasogastric tube only"); and ensure that drugs formulated for intestinal absorption are not absorbed in the stomach.

Medication administration also involves monitoring the patient to verify that the drug produced the desired effect or response ("principle of right response"). Professionals need to be careful with drugs that have therapeutic doses that are very close to iatrogenic or lethal doses, such as anticoagulants, anti-arrhythmics and insulin.[53] Monitoring the "right response" may also involve (besides assessing clinical signs of the patient) blood tests, electrocardiograms and others. All of these controls must be strictly ordered by the attending physician through a prescription.

All administrations of medication must be recorded by the nursing staff, including that the prescribed drug was administered and the time or range of time recommended for administration ("principle of proper documentation"). This record, however, must be done immediately after the medication has been administered and never beforehand because patient refusal to take medication or loss of venous access can prevent that medication be administered. Conversely, omissions of medication administration increase the risk of medications being administered again by another nurse. A medication should not be prescribed "as needed," "if pain" or "if

fever." Medication administration should only be performed after review by the medical staff and the nurse has noted the generic drug name, dose, route used, time of administration, indication and clinical response in the patient record.[54] The nursing staff in this study did not routinely note the patient's response to the medication, including its side effects. During medication administration, nurses should know why the drug was prescribed/indicated ("principle of right action/indication"). To implement this strategy in practice, agreement between the medical and nursing staff on the diagnosis and the clinical condition of the patient must occur. This relationship can prevent the wrong medication being administered to the patient or a medication being given to the wrong patient. Therefore, nursing staff should always tell the patient the name/class of medication and why the drug is being administered (for example, a nurse could state "Here is an antibiotic to treat your pneumonia").[47]

CONCLUSIONS

Failures, deficiencies and/or inadequacies of the physical and organizational environment of a health system are responsible for most of the risk factors associated with ME in this study.

Coordinated efforts of directors and medical, pharmaceutical and nursing professionals should be concentrated on creating a work environment that values comfortable and adequate facilities, hiring enough high quality professionals with sufficient training, ensuring availability and proper operation of equipment, and adopting standard operating procedures that regulate and guide professionals in all stages of the medication process.

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