

Medication Errors in an Internal Intensive Care Unit of a Large Teaching Hospital: A Direct Observation Study

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Abstract- Medication errors account for about 78% of serious medical errors in intensive care unit (ICU). So far no study has been performed in Iran to evaluate all type of possible medication errors in ICU. Therefore the objective of this study was to reveal the frequency, type and consequences of all type of errors in an ICU of a large teaching hospital. The prospective observational study was conducted in an 11 bed internal ICU of a university hospital in Shiraz. In each shift all processes that were performed on one selected patient was observed and recorded by a trained pharmacist. Observer would intervene only if medication error would cause substantial harm. The data was evaluated and then were entered in a form that was designed for this purpose. The study continued for 38 shifts. During this period, a total of 442 errors per 5785 opportunities for errors (7.6%) occurred. Of those, there were 9.8% administration errors, 6.8% prescribing errors, 3.3% transcription errors and, 2.3% dispensing errors. Totally 45 interventions were made, 40% of interventions result in the correction of errors. The most common causes of errors were observed to be: rule violations, slip and memory lapses and lack of drug knowledge. According to our results, the rate of errors is alarming and requires implementation of a serious solution. Since our system lacks a well-organize detection and reporting mechanism, there is no means for preventing errors in the first place. Hence, as the first step we must implement a system where errors are routinely detected and reported.

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Introduction

In Iran, awareness of errors during medical practice is growing. In general, some units such as intensive care units are more prone to errors, because of complex settings. The complexity of intensive care units and medical conditions of patients increases the likelihood of medical errors (1). Medication errors (MEs) are defined as any preventable event that may cause or lead to an inappropriate medication usage, or harms the patient, while in the control of the health care professional, patient or consumer (2). Errors in the medication process can occur at different stages: prescribing, transcribing, dispensing and administration (3).

There are a few reports about MEs in ICUs in Iran (4-7). Errors in the preparation and administration of IV medications in the intensive care unit of a teaching hospital in Iran were 9.4%. Of those 33.6% were related to the preparation process and 66.4% to the administration process (5).

So far no study has been performed in Iran to evaluate all type of possible MEs in ICU. Therefore the objective of this study was to reveal the frequency, type and consequences of all type of MEs in an ICU of a large teaching hospital.

Materials and Methods

This study was conducted in an 11 bed internal ICU ward of a large teaching hospital in Shiraz. Errors were detected by using the disguised observation technique. Nurses were unaware of the goal of the study.

In the practiced ICU ward each patient has a file which the physicians prescribe the ordered medication on the file by hand writing. Then nurses transfer the written medication to the administration charts. Patients were rounded everyday which in each round, an internist, an internal resident and a general physician present. In this study direct observation method were used. The pharmacist as observers was trained how to

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perform the study. The observation conducted in morning and afternoon shifts equally. All data were reviewed by a clinical pharmacist to ensure the type of errors. To become familiar with the disguised observation method in the ICU, the observer followed one week training period at ICU. All observations were recorded on a data collection form specially designed for this study. Observers would intervene only in situations that the medication error cause substantial harm to patients. Errors were categorized by type according to ASHP classification (3). The medication error consequences were classified according to Hartwig *et al.* definition (8), rating from minor effects to fatal effects.

The data was processed using SPSS software version 11.0(SPSS inc., Chicago, IL, USA). The results stated as mean \pm SD and or percentage as appropriate. For categorical variables for each set of data, we used Chi-square or Fischer analysis and for continuous variables for each set of data, we used independent sample t-test. Finally, we used logistic regression for simultaneous

study of the impact of parameters on drug error observation. We considered P -value <0.05 as significant level. In this study two approaches were used for calculating the rate of errors. In the first approach the frequency of errors was calculated by dividing the number of administrations that had one or more errors by the sum of the number of drugs administered (whether ordered or not) and the number of drugs that were omitted. In the second approach the numbers of errors were divided by total number of opportunities for errors.

Results

During the observation 307 doses of prescribed medications administered to 38 patients, through 38 shifts. Duration of each shift was 6 hours. Demographic data of patients and drug characteristics are shown in table 1.

Table 1. Patient demographics (n=38), drug characteristics (n=307).

Age, Mean \pm SD (range), yr	50.63 \pm 19.63(19-80)
Gender, no. (%)	
Male	18(47.4%)
Female	20(52.6%)
Ventilation no. (%)	35(92.1%)
Length of hospitalization, Mean \pm SD (range), day	29.19 \pm 31.74(1-150)
NO. of doses during the day of observation, Mean \pm SD (range)	22.57 \pm 9.30(6-48)
Drug characteristics no. (%)	
Drug class	
Antimicrobials	72(23.5)
Cardiovascular	48(15.6)
Gastrointestinal	42(13.7)
CNS	25(8.1)
Vitamins	25(8.1)
Anticoagulants	19(6.2)
Hormones	19(6.2)
Electrolytes	16(5.2)
Hematologic	9(2.9)
Respiratory	8(2.6)
Sedatives/analgesics	6(2.0)
Others	18(5.9)
Route of administration	
Oral	154(50.2)
Intravenous	
Bolus	115(37.5)
Continuous infusion	12(3.9)
Subcutaneous	14(4.6)
Inhalation	5(1.6)
Rectal	1(0.3)
Intraocular	5(1.6)
Intramuscular	1(0.3)
Number of observed shifts no. (%)	
Morning	20(52.6%)
Afternoon	18(47.4%)

1. Glasgow coma scale

Table 2. Frequency of all type of medication errors separately (number of errors: 442).

Type of error	Number of errors	Percent of errors	Percent of total	Number of opportunities for errors	Corrected percent	Corrected percent of total (%)
Prescription errors						
Wrong drug	33	10.7	7.4	307	10.7	5.8
Wrong dose	26	8.5	5.9	307	8.5	4.6
Wrong dosage form	30	9.8	6.8	213	14.1	7.7
Wrong route	6	2	1.4	211	2.8	1.5
Omission	10	3.3	2.3	297	3.4	1.8
Wrong time	8	2.6	1.8	307	2.6	1.4
Monitoring	42	13.7	9.5	197	21.3	11.6
Total prescription error	155	41.1	35.1	2279	6.8	34.4
Administration errors						
Omission	28	9.1	6.3	307	9.1	4.9
Wrong time	44	14.3	10	213	20.7	11.2
Wrong dosage form	2	0.7	0.4	148	1.4	0.8
Wrong dose	34	11.1	7.7	307	11.1	6
Wrong route	5	1.6	1.1	194	2.6	1.4
Wrong preparation	44	14.3	10.0	159	27.7	15.1
Wrong technique	90	29.3	20.4	257	35	19
Administration of unordered drug	10	3.3	2.3	307	3.3	1.8
Deteriorated drug	13	4.2	2.8	307	4.2	2.3
Total administration error	270	61.6	61.0	2766	9.8	62.5
Transcription error	10	3.3	2.3	307	3.3	1.8
Dispensing error	7	2.3	1.6	307	2.3	1.3
Total	442	79.8	100	5785	7.6	100

In average each patient received 11 different medications in a day. In table 2, errors were divided into categories. Out of 5785 opportunities for error, 442 (7.6%) errors were detected (Table 2). The rate of

administration, prescription, transcription and dispensing errors were 9.8, 6.8, 3.3 and 2.3 percent respectively, which most errors occurs about antibiotics.

Table 3. Severity categories of observed medication errors.

Harm category	Prescription error (n=155)	Administration error (n=270)	Transcription error (n=10)	Dispensing error (n=7)	Total (%) n=442
No error occurred (level 0)	-	5(1.12)	1(0.23)	-	6(1.36)
Error occurred that did not result in patient harm (level 1)	78(17.64)	236(53.38)	6(1.36)	4(0.90)	324(73.30)
Error occurred that resulted in the need for increased patient monitoring, but no patient harm (level 2)	61(13.80)	26(5.9)	2(0.44)	4(0.90)	93(21.04)
Error occurred that resulted in the need for increased patient monitoring with a change in vital signs (level3)	2(0.5)	-	-	-	2(0.44)
Error occurred that resulted in the need for treatment with another drug or an increased length of stay (level4)	14(3.17)	1(0.23)	-	-	15(3.38)
Error occurred that resulted in permanent patient harm (level 5)	-	-	-	-	-
Error occurred that resulted in patient death (level6)	-	2(0.44)	-	-	2(0.44)

Percentage are given within parenthesis

Table 4. Examples of prescription error.

Type of prescription error	Examples
Wrong drug	Ordering enalapril for a patient with hyperkalemia (k:5.2) to control hypertension
Underdose	Forget to readjust the dose of ranitidine for a patient with normal clearance of creatinin who previously had acute renal failure
Overdose	Forget to convert the dose of IV phenytoin to oral form (suspension) , patient received 100 mg IVQ8h ,then 100 mg oral suspension Q8h
Wrong dosage form	Prescribing the tablet of multivitamin instead of syrup of multivitamin for a patient with NG tube
Wrong frequency	Ordering amikacin QD instead of Q24h
Forgot to order	Forgot to order another antiepileptic in place of topiramate for a patient with epilepsy, because topiramate was unavailable
Forgot to define the route of administration	Forgot to define the route of administration of heparin as IV or SC
Monitoring	Prescribing therapeutic dose of heparin with checking PTT every other day despite out of therapeutic range of PTT
Interaction	Ordering imipenem with gancyclovir. This can lead to generalized seizure

The severity of different categories of errors is shown in table 3. Examples of different categories of errors are in table 4, 5 and 6.

Totally 45 interventions were made, out of that 91.12% of interventions were about nursing MEs and 8.88% were about physician MEs. 40% of interventions result in the correction of errors.

Morning shifts were associated with more MEs than evening shifts ($P=0.029$, $OR=0.039$).

Rule violations, slip and memory lapses and lack of drug knowledge were the most common predisposing causes of errors (Table 7).

Table 5. Examples of administration errors.

Types of administration error	Examples
Omission	Forgot to administer atropine to a patient with cardiac arrest
Wrong time	Did not administer antibiotics on time
Under dose	Administration of heparin with lower dose due to wrong calculation of nursing
Upper dose	Administration of two vial of ciprofloxacin 200 mg instead of one vial
Wrong route	Administration of vitamin B12 IV instead of IM
Wrong drug preparation error	Didn't wash premature set containing ceftriaxon with normal saline, vancomycin added to premature set, precipitation occurred
Wrong administration- technique error	Didn't shake phenytoin suspension before administration

Table 6. Examples of transcription errors.

Types of transcription errors	Examples
Omission	Propranolol 10 mg TID has been prescribed however was not transcribed in nursing cardex
Wrong frequency	Ordering heparin 5000 IU Q12h transcribes as Q8h
Wrong dose	Prescribing tab ASA 100 mg transcribed as tab ASA 80 mg

Table 7. Predisposing factors for different category of errors (n=442).

Predisposing factors	Prescribing (n=155)	Administration (n=270)	Transcription (n=10)	Dispensing (n=7)	Total (n=442)
Rule violations	59(13.35)	60(13.56)	0	0	119(26.91)
Slips and memory lapses	33(7.47)	74(16.74)	2(0.44)	0	109(24.65)
Lack of drug knowledge	41(9.28)	58(13.11)	0	0	99(22.40)
Preparation error	1(0.23)	47(10.62)	0	0	48(10.86)
Faulty dose checking	0	16(3.62)	3(0.68)	0	19(4.30)
Faulty interaction with other services	7(1.57)	7(1.57)	0	0	14(3.17)
Lack of patient information	0	12(2.70)	0	1(0.23)	13(2.93)
Drug stocking and delivery problems	0	2(0.44)	0	10(2.25)	12(2.70)
Transcription error	0	4(0.93)	5(1.12)	0	9(2.04)
Inadequate monitoring	6(1.36)	1(0.23)	0	0	7(1.57)
Infusion pump problem	0	2(0.44)	0	0	2(0.44)

Percentage are given within parenthesis

Discussion

The importance of the medication error rate is less considered in Iran. Only few researches have been carried out in this field. This makes the consideration of this subject necessary (4-7).

There are different methods to detect MEs such as voluntary reporting, chart review or observation of medication process (3). In observation method, which covers the current study, the researcher observes defined medication stages to catch errors. There are large variations in the MEs ranges discover under different methods (9). Studies show that range of MES resulted from voluntary reporting is from 8.8 to 241 MES per 1000 patients-days (10-15). The range of MES by observation method were reported from 2.8 to 1500 MES/1000 patient-days (16-19). The rate for chart reviewing method is about 8.2-519 MES/1000 patient-days (20-22).

According to one systematic review, observation method is very sensitive to identify MEs (9). Flynn *et al.*, conducted a study in which they compared different methods for detecting medication errors in 36 hospitals and skilled nursing facilities (23). Flynn *et al.*, study discovered the accuracy of direct observations reported by pharmacists was more valid than self reporting incidents by other medical staffs and investigators reviewing charts (23).

In our study disguised observation method was used to detect MEs. It is mainly due to this fact that medical

team do their job precisely when they know that their action is observed by an observer. A proof to this claim may be specified by a study by Tissot *et al.*, in an internal ICU, in France, which indicates the rate of administration error in direct observation method in which nurses were aware of the process and goal of study was less than studies with disguised observational method (18). In our study nurses were unaware of goal of study.

Since there is not a standard definition and research procedures to study medication error, comparing different study result is rather difficult (9). Example for diversity of definitions is that some papers reported MEs per 1000 patient-days (9), while few studies like our study, reported MEs as opportunities for errors (9). Some studies taking into consider some stages of medication process, while others consider on all parts including (prescribing, transcribing, dispensing and administration) (9). This study shows that for 79.8% of drug doses at least one error has been occurred. From opportunities for errors point of view, out of 5785 opportunities for errors, 442 errors occur (7.6%), of those 9.8% was related to administration error, 6.8% was related to prescription error, 3.3% transcriptions and 2.3% dispensing error. As the statistics result shows, the administration errors are the highest followed by prescription, transcription and dispensing errors respectively. Studies that used direct observation showed that the range of error incidence is 3.3-72.5% (24). However studies with similar method of detecting

events with our study (observation method) which focused on entire medication process reported 172 per 645 drug administration (26.7%) (25). Krahenbuhl-melcher *et al.*, in a review of the literature about drug related problems in hospitals showed that among different stages of MEs, administration errors occur most (26). In the study by the Fahimi *et al.*, MEs were recorded over 16 randomly selected days in an intensive care unit of a teaching hospital with observation technique (5). The rate of administration and preparation error in this study was 9.4% opportunities for errors comparing with 9.8% opportunities in our study. It is of note that despite of the congruency of the result between these two studies, there are some differences between these studies. First, in the mentioned study only IV medications were evaluated however in our study administration error were evaluated for all different routes of administration (5). Second reason for the difference was that, the definition of administration error was different with our study, variables such as wrong dose, food and medicine interaction, drug omission and use of expired drug were not evaluated in Fahimi *et al* study (5).

The reasons for high prescription error occurrence in our study may be due to several factors such as: 1. there was no standard treatment guideline (STG) in the ward. 2. This ward has no clinical pharmacist to take part in the rounds. As studies show that the presence of a full time clinical pharmacist can reduce the rate of serious MEs significantly (6-7). 3. Use of hand written prescribing instead of computerized physician order entry (CPOE). Studies showed that introduction of CPOE can reduce the rate of MEs and can improve the overall patient outcome score (27).

Comparing to Kopp *et al.* study (25), in our study administration error (36.4%) occur more than prescription error, which one main reason can be that nurses prepare IV medications for administration, however in Kopp *et al.* study pharmacy involves in product preparation. In our study monitoring error was the most common prescription error which has occurred, among administration error, wrong drug preparation was on the top. Comparing to other study (5) wrong administration rate occur more than the other types of the other errors.

Regarding to classification of drugs associated with MEs in the present study, most errors occur in the antibiotics category, however one reason may be that antibiotics was prescribed more than other drug categories in this ICU. In a systematic review by Keikkas *et al.* (24) and a multinational prospective study

by Valentin *et al.* (28), it is revealed that the highest number of the errors occur about antibiotics, sedative/analgesics and cardiovascular drugs.

In the current study, among several predisposing factors, rule violations, slip and memory lapses and lack of drug knowledge were the most common reasons for error occurrence respectively. In another study, with direct observation method in ICU, lack of drug knowledge by prescribers, were most associated with medication error. In this study none of the other single proximal causes accounted for more than 14% of the total errors (25). Comparing the results of different direct observation studies regarding to the main causes contributing to errors are rather inconclusive, because the reported factors were different (24).

In this ICU 73.3% of errors lead to no harm, the result of our study was consistent with findings of other studies in that most MEs which have been occurred in ICU result in no clinically significant harm. Although the level of harm due to MEs in the studies can be underestimated, because in none of the studies length time consequences of MEs has been recorded (24).

One limitation was that the rate of errors with direct observation which have been used in the current study may be underestimated despite the superiority of this method to other detection methods. In a study performed by Flynn *et al.*, it has been shown that the rate of true errors with direct observation were 34% underestimated (23).

Conclusion: The result of this study shows that the most common MES in this ICU occur in administration and prescription stage respectively. Inappropriate monitoring of medications and wrong administration technique were most common error type. As stated above this result again emphasizes on the need of enhancing the prescription system, writing and applying the standard treatment guidelines, involvement of pharmacy department on drug preparation instead of preparation of drug admixtures by the nurses, which is now in practice. In addition to involvement of a full-time clinical pharmacist at ICU ward is necessary in order to improve the quality of care in ICU.

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