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Original Article

Medication Errors in Administration of Chemotherapeutic Agents: an Observational Study

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Abstract

Chemotherapy medication errors may lead to potentially harmful consequences while most of them could be preventable. This study aims to determine the incidence and type of drug handling and administration errors among the nurses and to identify possible contributing factors. Setting of the study was a teaching hospital affiliated to Shahid Beheshti University of Medical Sciences, Tehran, Iran. To attain the study objectives, an observational, cross-sectional study was performed in the haematology and oncology wards of the hospital. A checklist consisting of appropriate process of handling, preparation and administration of injectable chemotherapy agents was developed and used by a trained pharmacist. In addition, socio-demographic characteristics of nurses were recorded. The primary outcome was the number and type of medication errors in chemotherapy administration according to the prepared check lists. Overall, administration processes of 544 chemotherapy medications, consisting of 8322 error opportunities, were observed of which 2705 (32.5%) errors were detected. 52.8% (2926/5532), 15.5% (254/1635) and 26.5% (306/1155) of the errors were in the handling, preparation and injection stages, respectively. The top 5 drugs with the highest risk of errors were metotraxate 45.4% (20/44), fluorouracil 38.5% (439/1139), cyclophosphamide 37.1% (267/719), vincristine 34.8% (240/689) and etoposide 33.5% (125/373). Our results revealed a substantial occurrence rate of medication errors during preparation and administration of injectable chemotherapy agents, which are often made by nurses who fail to follow relevant nursing standards. This confirms that educational programs and advanced pharmaceutical care services are required for safe preparation and administration of intravenous chemotherapy agents.

*Keywords***:** Administration, Chemotherapy, Handling, Medication errors, Preparation.

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1. Introduction

Medication errors in hospital wards are never-ending problems with frequent occurrence. No single definition is available for medication error. This is a reason leading to dissimilar reports on medication error rates by various studies. The rate of medication errors are approximately 0.6-28% in patients admitted to hospitals. It is also reported that medication errors are the major causes for morbidity and mortality. In the US, for example, it has been estimated that a mortality rate of 180000 patients/year is due to medication errors.

Drug usage errors are divided into three types including medication errors, errors in the process of drug administration and healthcare professional's knowledge errors. A medication error defined as a failure in the treatment process that leads to inappropriate use of products or harm to the patients. In the US, medication errors are known as the most common cause of death in a health care system [1,2]. Medication errors can occur at any part of the medication management process. This process includes prescribing, dispensing and then administering. Prescribing error may be defined as an incorrect drug selection for a patient. Dispensing error may occur during prescription to drug delivery to the patients. Occurrence rate of 1–24 % have been reported for dispensing errors by various studies. Administration errors happen when the patients receive the drug according to a process by which nurses administer medication. According to several studies, 65-87% of medication errors occur during the prescription and administration process [3,4].

In a more comprehensive definition, Wolf classifies these errors as either acts of commission or omission which may include the followings: wrong drug; wrong route; wrong dose; wrong patient; wrong timing of drug administration; a contra-indicated drug for that patient; wrong site; wrong dosage form; wrong infusion rate; expired medication date; or prescription error. Wolf emphasizes that such errors can occur in either an intentional or unintentional manner [5]. Muller et al showed that cancer patients are highly susceptible to errors [6]. Errors can be created with any drug, however, chemotherapy drugs usually have a small therapeutic window and errors in their usage can be unsafe for the patients undergoing chemotherapy [7].

Florence et al in a study showed that oncology ward is a highly vulnerable place for drug therapy errors due to the severity of medical consequences for the patients. They demonstrated that errors in the chemotherapy ordering process are frequent [8]. In a study done by Serrano-Fabiá et al, 20.9 medication errors were detected per 1,000 patient-days.

They could intercept 16.8 medication errors per 1000 patient-days (80%), preventing them to affect any patient [9].

Nurses are the major collaborators of the administration phase of a medication usage. Physicians are responsible for drug prescribing and pharmacists are involved in the medication distribution. Normally, nurses have responsibility in administration of drugs including preparing, checking the right drugs, right patients, right time, right rout and right dose as well as administering medications, reporting adverse reactions and teaching patients about their drugs use [10]. Another focal point highlighting an important role for nurses in patient safety is the fact that they spend the greatest amount of time with hospitalized patients [10]. Decrease in the ratio of nursing staff to patients could be associated with an increased risk of medication errors such as drug administration/documentation (47%), patient supervision (20%) and undesirable outcome for patients for example major physiological change (22%) and patient/relative dissatisfaction (12%) [11,12]. Since the chemotherapy regimens are highly toxic and chemotherapy related medication errors may cause serious outcomes, then reduction in chemotherapy related medication errors can improve safety of the pharmaceutical care systems benefitting both patients and nursing staff. This will also decrease burden of disease on the health systems [13]. Bates et al found that approximately 34% of 70 administration errors were caused by nurses of which 56% were detected during ordering and transcription, while dispensing errors counted for 10% of the total medication errors [14].

According to the clinical governance standards, risk management and patient safety are important issues in hospitals, which must not be neglected, therefore, increase in awareness about medication errors in order to create a higher level of safety for patients and health care providers as well as reduction in treatment costs for patients, their families, hospitals and insurance companies are targeted by several studies [3-4,8-9,14,15-16]. Since recognition of the most common medication errors and factors related to them, is the first step to make appropriate decisions, introduce proper strategies and implement standard guidelines to reduce their occurrence, then this survey was designed and performed at the hematology and oncology wards and the relevant clinic of a teaching hospital in Iran.

2. Materials and Methods

2.1. Setting

This cross-sectional study was conducted in 70-bed inpatient haematology and medical oncology wards as well as ambulatory care clinic of the Ayatollah Taleghani Hospital, a 600-bed teaching hospital in Tehran, Iran, during August 2010 to January 2011.

2.2. Study Population

Twenty four nurses, who were responsible for administration of chemotherapy drugs in different work shifts, were included in the study. They were

Table 1. Socio-demographic characteristics of the nurses.

Nurses	**N=24**
Age, median [min - max]*	33.4 [25-53]
Women, n (%)	24 (83.33)
Years of experience, median [min - max]*	9.64 [0.7-29]
Years in the unit, median [min - max]*	5.5 [0.7-13]
Marital status [n (%), married]	16(66.6%)
Type of working contract, [n (%) permanent] **	8 (33.3%)
Second job, n (%)	0%
Professions [n (%) nurses]***	15 (62.5%)

*Data expressed as median [min-max]
**Type of contract included permanent and non-permanent employment.
***Professions included paramedic contractor and nurses.

observed closely by a trained pharmacist and medication errors were recorded.

2.3. Procedure

This study was approved by the Ethics and the Drug and Therapeutic Committee of the Ayatollah Taleghani Hospital which includes a head nurse from haematology and medical oncology wards. Preparation and administration of anti-neoplastic agents were done by nurses in the haematology and medical oncology wards, as well as outpatient clinic. Initially 26 of the most commonly used drugs in the wards and outpatient clinic were selected for observation. A pharmacist was presenting in all stages of drug administration. Nurses have been aware of the observation but unaware of its true purpose. The observer pharmacist was present in the wards 1 hour before IV drug preparation and administration. Nurses were observed during all working shifts, both evening and day shifts, however, the most administration of IV drugs was in day shifts. Therefore, most of the observations were in day shifts. Pharmacist recorded the preparation and administration of each drug in a data collection form. A checklist for each selected drug was prepared based on the manufacturer's leaflets and the reference books including hand book of injectable drugs, American health formulary services (AHFS), drug information handbook, nursing drug handbook[17-20]. Direct observation was used to detect errors, based on the method established by Barker and McConnell [21]. We tried to observe administration and preparation of IV drugs in three places with an equal rate, however since less drugs administered and prepared in outpatient clinic, less observations were made in this setting.

2.4. Measurements

The following data were collected: socio-demographic characteristics of the nurses including age, sex, work experience, university degree, marital status, and employment type (permanent *vs* temporary or non-permanent) (table 1).

Data about anti-neoplastic regimen was recorded and the checklists of preparation and administration procedures were checked and documented. Data in the checklists included type and volume of dilution fluids, reconstitution, mixing drugs, ordered dose, type of possible errors, administration technique error, usage of standard equipment for preparation of drugs (table 4).

2.5. Data Analysis

Error rates were presented as the percentage of the total number of opportunities for errors. The error rates related to each drug; error rates in usage stages of handling, preparation and administration (injection to patient); and error rates based on the sociodemographic characteristics of nurses were determined. Data analyses were performed using the Statistical Package for Social Sciences (SPSS, version 19.0) software. The Chi-square test, Pearson correlation and Spearman's rank correlation were applied for statistical analyses. P values <0.05 were considered as significance level.

3. Results and Discussion

Observation was carried out on 25 chemotherapy drugs. All of the 24 nurses working in study wards, agreed to participate in our study. Table 1 presents sociodemographic characteristics of the nurses. Overall, 544 process of handling, preparation and administration of drugs by nurses were observed, of them 146 (26.8%), 191 (35.1%) and 207 (38.1%) observations were done in outpatient unit, haematology and medical oncology wards, respectively. The total number of opportunities for errors was 8322; amongst them 2705 (32.5%) errors were identified. The error rate was higher in medical oncology unit [detected errors/error opportunities1160/3396, (34.2%)], followed by haematology [948/2814, (33.7%)] and outpatient unit [597/2112, (28.3%)]. The error rates were not significantly different between the medical oncology with hematology wards (p value = 0.70) but statistically significant differences with lower error rates were observed between outpatient unit with both oncology and haematology wards (p value $\leq$ 0.0001). A non significant relationship between age of the nurses (p value = 0.36, r = 0.22), their total experience (years) (p value = 0.30, r = 0.22), and their years of work experience in the chemotherapy units (p value = 0.54, r=0.15) with the error rates were obtained. However, there was a significant association between gender of nurses with the occurrences of errors (p value $\leq$0.0001), so that nursing errors made by men was higher compared to women. A significant association between type of the employment contract of the nurses (p value=0.001), and medication error rates was also observed, so that permanent contract nurses (error rate: 33.8%) had a higher medication error rates compared

Table 2. Error rates in study anti-neoplastic agents.

Drug	Error number	Error rate (%)	Factor correction[a]	Corrected percent (%)
Metotraxate	20	0.7	44	45.4
Fluorouracil	439	16.2	1139	38.5
Cyclophosphamide	27	9.9	719	37.1
Vincristine	240	8.9	689	34.8
Etoposide	125	4.6	373	33.5
Carboplatin	77	2.8	236	32.6
Cisplatin	105	3.9	323	325
Docetaxel	114	4.2	354	32.2
Doxorubicin	297	11	925	32.1
Ifosfamide	59	2.3	184	32.1
Cytarabine	243	9	765	31.8
Fludarabine	24	0.9	79	30.4
Vinorelbine	45	1.7	148	30.4
Gemcitabine	212	7.8	705	30.1
Oxaliplatin	148	5.5	493	30
Rituximab	53	2	184	28.8
Irinotecan	61	2.25	213	28.6
Bleomycin	27	1	100	27
Vinblastine	26	1	105	24.8
Idarubicin	41	1.5	174	23.6
Bortezomib	13	0.5	55	23.6
Paclitaxel	29	1.1	126	23
Dacarbazine	32	1.2	148	21.6
Trastuzumab	7	0.3	34	20.6
Epirubicin	1	0.1	7	14.3

a Number of observations multiplied by the number of opportunities for errors.

to fixed term contract employees (error rate: 29.8%). Interestingly, nurses with higher level of education committed more errors compared to licensed practical nurses who had a lower level of education (p value=0.001). Other sociodemographic characteristics of the nurses were not in a significant association with the error rates. The list of chemotherapy drugs that had been administered and their relevant error rate are shown in Table 2. Top 5 drugs with the highest rate of error occurrence were metotraxate (45.4%), fluorouracil (38.5%), cyclophosphamide (37.1%), vincristine (34.8%) and etoposide (33.5%) and the 5 drugs with the lowest rate were bortezomib (23.6%), paclitaxel (23%), dacarbazine (21.6%), trastuzumab (20.6%) and epirubicin (14.3%). It should be contemplated that trastuzumab and epirubicin had only 7 and 1 prescriptions, respectively. Frequency of the errors based on the stage of drug administration and sociodemographic characteristics of the nurses are presented in the table 3. Drug handling error (52.8%) were the principal type of errors observed in our study, followed by administration (injection) (26.5%) and preparation (15.5%) errors. In drug handling, some misadventures including inappropriate hand washing before drug preparation (n=281), and wrong technical method for body decontamination (n=14)were not in accordance with the guidelines at all (100%). Other common drug handling errors were: not washing hands after drug preparation and handling (n=266; 93%) and not using gloves during drug injection (n=166; 74.8%). The most frequent misadventure in the preparation process included lack of an

Table3. Error rates based on the characteristics of the nurses.

Process	Error number	Error rate (%)	Factor correction	Corrected Percent (%)
Types of contract*				
Permanent	1518	57.6	4488	33.8
Non-permanent	505	19.2	1587	31.8
Other types of employment	613	23.2	2057	29.8
Professions*				
Paramedic contractor	578	21.7	1943	29.7
Nurses	2085	78.3	6189	33.7
Gender*				
Women	2499	92.5	7808	32
Men	203	7.5	506	40.1
Marital status				
Single	405	15.4	1241	32.6
Married	2231	84.6	6891	32.4

* Values are significantly different in within group analysis ($p \leq 0.0001$)

aseptic area (n= 5; 100%), not performing allergic test before injection of drugs such as bleomycin (n=3; 100%), followed by error in keeping drug away from light (n=38; 86.4%), error in reconstitution or dilution to attain a final sterile preparation (n=35; 83.3%), mistaken infusion rate/timing (n=92; 35.2%) and incorrect dosing (n=71; 25.4%). Other drug administration errors are presented in the table 4.

In recent years, additional attention has been made towards medication errors as they lead to morbidity, mortality and more costs for patients and health care systems [22]. Errors are inevitable in any profession, and it is impossible to omit errors completely [23]. Identification of medication errors and taking appropriate actions to reduce their occurrence are major responsibility for health care systems. Jordan [24] in a commentary on 'the relationship between incidence and report of medication errors and working conditions' [25], suggests that intervention studies may help to reduce medication errors and improving patient outcomes. Our results demonstrated that injectable chemotherapy medication errors occurred repeatedly at haematology and medical oncology wards at a

frequency rate of 32.5%. This is in accordance with the upper level error rates of 0.4% to 31.9% reported in previous studies [26,27]. The high rate of medication error and drug misadventure observed in our study could be explained by the heavy workload in the study wards accelerated by a low nurse-to-patient staffing ratio. Improving the working condition of nurses and employing new educated nursing staffs could improve the safety standards and eventually reduce medication errors. Tissot et al showed that nursing workload is a contributing factor for medication administration errors [28]. In another study poor nurse-to-patient ratios, job dissatisfaction and burnout was lead to higher mortality rates [29,30]. However, the results of the Joolaee study showed that there was a significant association between nursing medication errors and working conditions [25]. We found that there is no significant difference between age of the nurses, their marital status and working experience with the rate of errors made by them. In a study by Fahimi et al, no significant relationship was also found between the rate of errors with the age of nurses, their gender, years of nursing experience and marital status [31]. However, we found that male nurses had a higher rate of errors compared to women .This could be due to the larger number of women in our study wards and also because of the fact that women have higher awareness to their responsibilities compared to men . Our finding is similar to that of Eslamian et al [32] showing that medication error was more common among the male nurses (68% men *vs* 32% women). However, results of Sozani et al [33] and Ghasemi et al [34] showed that there was no significant association between gender with medication error. In our study, permanently employed nurses had more medication errors *vs* fixed term contract employees, who are temporarily employed. Perhaps, permanent nurses has more confident on their job status, while temporary employed nurses may loss their job because of committed errors and disappointment of their employers . In this regard, there is an inconsistency between our finding with that of Fahimi et al [31] that may be due to type of the study drugs and the assessment method used in our study. Top 3 drugs with the highest rate of error occurrence were metotraxate (45.4%), fluorouracil (38.5%), cyclophosphamide (37.1%). Cyclophosphamide should be reconstituted, diluted and then shaked well before drawing up into the syringe, however, some nurses prepared it without powder being resolved completely leading to drug powder remained at the bottom of the vials. Vincristine should be kept away from light after reconstitution, nevertheless this was not performed by considerable number of the nurses. Though, appropriate hand washing before and after injectable drug handling is an essential practice [35], our results showed that nurses working in the study wards had not a suitable hand washing skill. Previous studies, reported parallel findings to our study confirming that the majority of nurses have used gloves during their practice. [36-38]

Our findings showed that the error ratio in the administration phase of medication

delivery is approximately consistent with those reported by Rink et al. [39] According to Salma et al [40], the highest error was detected in hematology-oncology wards (34%) compared to other wards. This is confirmed by our study, too. They also found that a large number of errors occurred during reconstitution or dilution (73.9%) followed by improper dose (4.6%) and wrong time (0.9%).

4. Conclusion

In conclusion, responsibility for correct handling and administration of medications is an important part of the nurses' role. In this regard, injectable chemotherapeutic agents are at the first priority due to their cytotoxic adverse effects. The present study confirms a high rate of medication errors in administration of anti-cancer chemotherapeutic drugs. Measures to reduce the number of injectable medication errors may include establishment of a clinical pharmacist driven pharmaceutical care service in the hospitals. Also, implementation of educational programs to increase the knowledge of nurses about principles of the chemotherapeutic drug-related administration, leading to certified nurses, are essential to provide a high-quality patient care services as well as nursing staff safety**.**

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