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Original Article

AN INVESTIGATION OF ERRORS: THE PREPARATION AND ADMINISTRATION OF PARENTERAL MEDICATIONS IN AN INTENSIVE CARE UNIT OF A TERTIARY TEACHING HOSPITAL IN MALAYSIA

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ABSTRACT

Objective: This study was carried out to investigate the incidence, types, and factors associated with parenteral medication preparation/administration errors. The study also investigates the concentration accuracy of prepared drug infusions and the adherence to good practices by the nurses.

Methods: This was a prospective study conducted in a general intensive care unit (GICU) of a tertiary teaching hospital in Malaysia, using an observation method. The preparation and administration of the parenteral medications by the nurses were observed, and the details were recorded using a standard checklist. The drug infusions (noradrenaline) prepared by the nurses were collected for a concentration analysis using a high-performance liquid chromatography (HPLC).

Results: This study found that 79% of the parenteral medications prepared and administered had one or more error. There were 33% doses with 2 or more errors while 6% doses contained 3 errors. The most common errors involved incorrect drug preparation (57%), followed by incorrect administration rate (33%). There was no double-checking performed in the preparation/administration of all (100%) parenteral doses. In terms of concentration accuracy, 48% of the prepared drug infusions contained errors. Failure to label syringe properly was found to result in more errors per dose ($P<0.001$).

Conclusion: Error during preparation and administration of parenteral medications is common in Malaysia's intensive care unit setting. Incorrect drug preparation and wrong administration rate were both error 'hot spots' identified in this study, and must be targeted for intervention. Some of the recommendations to improve parenteral medication safety include providing education, centralised admixture services, and interdisciplinary collaboration.

Keywords: Medication error, Nurses, Parenteral medication, Intensive care unit, Observation

INTRODUCTION

Parenteral medications remain an important part of treatment in hospitalized patient. Up to 90% of inpatients receive some form of intravenous (IV) therapy during their hospital admission [1]. However, IV medications are associated with higher error rate and risk when compared to other administration routes [1-4]. This is due to a more complex procedure are involved when preparing and administering an IV medication. Numerous studies conducted in the United Kingdom (UK) and the United States (US) have reported error rates of 48%-81% in the administration of IV medications in general and surgical wards [5-8]. Taxis (2003) reported that one-third of these errors resulted in adverse events [5], which can lead to prolonged hospital stays, and increased in health care cost [9].

Medication error has been reported to occur more readily in intensive care units (ICUs) than other wards [10]. This is due to the increased in the complexity of care, frequent needs for high-risk interventions, and the inability of the patient to communicate errors [3]. Moreover, critical care patients are more vulnerable to injuries caused by medication errors as a result of the severity and instability of their illnesses [3]. A multinational, cross-sectional study involving 113 ICUs in 27 countries was conducted to assess parenteral medication administration errors. The study investigators reported 861 errors which affected 441 patients, at a rate of 74.5 events per 100 patient days. 1% of the patients experienced permanent harm or death due to these errors [3]. However, this study was conducted using a self-report method, which may underestimate the magnitude of the problem due to under-reporting [11, 12]. The observation method has been accepted as the 'gold standard' in measuring medication administration error [11].

Another issue pertaining to parenteral medications is the concentration accuracy of drug infusions manually prepared (at the bedside) by the healthcare providers. Previous studies found that the concentration of drug infusions prepared by hand often deviates from the expected concentration, resulting in inaccurate dosing [13-16]. As compared to manual preparation, central automated admixture services by the pharmacy department had been found to produce better drug infusions quality in terms of better concentration accuracy [16]. However, most hospitals in Malaysia still rely on nurses to prepare parenteral medications manually in the ward.

In Malaysia, few medication administration studies have reported error rates of 11.4%-97.7% depending on the settings, definitions, and methods used [4, 17, 18]. However, none of these studies were conducted in the critical care setting. At the time of this study, there are no studies conducted on the concentration accuracy of manually prepared drug infusions in the local ward. Hence, this study aimed to investigate the practice of parenteral medication preparation/ administration among nurses in a GICU of a tertiary teaching hospital in Malaysia.

MATERIALS AND METHODS

Setting

This study was conducted between November 2013 and January 2014 in a GICU of a tertiary teaching hospital in Malaysia. It is a 15-bed multidisciplinary GICU, receiving mainly medical, surgical, and gynecologic cases. Each patient is assigned to one nurse at a time. Medication is prescribed using a computerized-physician-order-entry-system, and in-patient pharmacy supplies the ordered medications as prescribed. Later, nurses prepare medications in a

designated bench before administering them to the patients. Hospital dilution protocol for commonly used parenteral medications and infusion pumps were available in the ward. The GICU clinical pharmacist actively participates in the ward round, and the prescription is reviewed every weekday.

Study design

This was a prospective study using direct observation method [11].

Definition of parenteral medication administration error

Parenteral medication administration error was defined as any deviation in the administration of parenteral medications, either from a doctor's prescription, hospital protocols, or the manufacturer's instructions [11]. The errors were categorized according to The American Society of Health-System Pharmacists (ASHP), and these include: omission errors; unauthorized drug errors; incorrect drug-preparation errors; incorrect dose errors; incorrect drug administration; improper dosage form; administration of a deteriorated drug; and administration of a drug via the incorrect route, incorrect rate or at the incorrect time [19]. In addition, nurses' adherence to good practices when preparing and administering parenteral medications was recorded. Good practices were defined as the safe parenteral medication preparation/ administration practices such as aseptic technique or double-checking (refer to the standard checklist). Failure to adhere to these good practices was not considered an error.

Standard checklist

A standard checklist based on the procedures in the Manual of Clinical Nursing [2], and the World Health Organization Patient Safety Curriculum Guide [20] was developed for this study. The content of the checklist received opinions from 3 experts including a consultant anesthesiologist, a senior pharmacist (AT), and a senior nurse. Prior to the main study, a pilot study was conducted to test the checklist's content and practicality. Subsequently, the checklist was modified to improve its feasibility. Similar to other studies, this standard checklist comprised a widely used standard of practice (SOP) when preparing and administering parenteral medications [17, 21-22]. The following items were observed:

- Correct medication and dosage form were chosen
- Dose calculated/measured correctly (Good practice)
- Medication prepared correctly using the correct volume of the compatible diluent
- Syringes/drug infusion containers were labelled properly (Good practice)
- Aseptic technique followed (Good practice)
- Patient's prescription, identity (ID), and allergy status rechecked (Good practice)
- Medication administered at the correct dose, rate, route, and time
- Compatible medication administered
- Administration double-checked (Good practice)
- Documentation (Good practice)

Data collection

A convenience sample of nurses who prepared and administered parenteral medications in the GICU was observed directly by one of the researchers (SY). This was done on every weekday from 8 am to 5 pm. Parenteral medications included intravenous (bolus/infusion), intramuscular, and subcutaneous medications. Parenteral nutrition, intravenous fluids (e. g. sodium chloride 0.9%), prefilled syringes (e. g. enoxaparin injection), and other centrally prepared parenteral medications were excluded. Following the observation, SY's notes were compared with the patient's prescriptions, hospital's protocol (dilution guidelines), and the manufacturers' instructions. All discrepancies were recorded in the checklist. In addition, nurses' demographic data (such as age, gender, education level, etc.) and parenteral medication characteristics (type and class of medication) were recorded. In the event where the error is likely to cause permanent harm or death, SY intervened in a discreet manner. These errors were included in the analysis. All collected data were revised by AT, and disagreements were resolved through discussion.

Sample collection

The selected drug infusions prepared manually by the nurses in GICU were collected, and their concentrations were measured using an isocratic HPLC pump (Waters 1515, Massachusetts, US). For this purpose, IV noradrenaline infusion was chosen based on its high usage in the ward and that it requires preparation prior to use. HPLC analysis was conducted based on the work done by Xie *et al.* [23]. During the study period, nurses were asked to place all used syringes of noradrenaline infusions in a designated container. Infusion details such as the preparer's initials, final concentration, date, and time of preparation were recorded. The residual of the noradrenaline infusion in the syringe (at least 1 ml) was removed and stored in sterile containers at-80^{0}C until analysis. All specimens were diluted and assayed against standard curves of known dilution. The infusion was considered an error when the actual concentration prepared deviated by more than 10% above or below the expected concentration [24]. The formula used for calculating the % deviation is provided below.

$$\% \text{ Deviation} = \frac{\text{measured concentration} - \text{expected concentration}}{\text{expected concentration}} \text{ x } 100\%$$

Ethical approval

The study was approved by the Hospital Research Ethics Committee. The aim of the study was explained to the head nurse. Participation into the study was voluntary, and the nurse has the right to withdraw from the study at any time. Each participating nurse was given a code in order to protect their confidentiality. Informed consent was obtained from nurses who participated.

Data analysis

The error rate was calculated as followed [25]:

$$\text{Error rate} = \frac{\text{number of doses with one or more errors}}{\text{number of doses observed} + \text{number of dose omitted}} \text{ X } 100$$

All data were entered into and analyzed using the SPSS, version 22.0 (IBM Corporation, US). Chi-square test or simple logistic regression was performed on the dichotomous outcome of error occurrence to investigate which variables had an effect on the medication error individually. Independent T-test was performed to investigate the association between adherence to good practices and number of error per dose. A p-value<0.05 was considered significant.

RESULTS

Demographic data

Thirty-nine nurses from GICU were observed during the study period. table 1 shows the majority of nurses observed were female (92%), Malay race (92%), with a diploma qualification (77%).

Table 1: Nurses' characteristics (n=39)

Variables	Number of nurses (Percentage)
Gender	
Female	36 (92%)
Male	3 (8%)
Race	
Malay	36 (92%)
Indian	3 (8%)
Others	0 (0%)
Education level	
Diploma	30 (77%)
Degree	9 (23%)

The preparation and administration of 122 parenteral medication doses by 39 nurses were observed during the study period. The main types of parenteral medication administration observed were infusions (71%), followed by bolus (28%), and one subcutaneous injection (1%). Antimicrobial was the most common drug class

observed (36%), followed by an electrolyte (27%), and gastrointestinal (17%). The results are shown in table 2.

Table 2: Parenteral medication characteristics (n=122)

Variables	Number of doses (percentage)
Types of administration	
Bolus	34 (28%)
Infusion	87 (71%)
Subcutaneous	1 (1%)
Class of medication	
Analgesia/sedation	10 (8%)
Vasopressor/catecholamine	4 (3%)
Antimicrobial	44 (36%)
Diuretic	2 (2%)
Electrolytes	33 (27%)
Gastrointestinal	21 (17%)
Steroids	6 (5%)
Others	2 (2%)

Incidence and types of parenteral medication preparation/ administration errors

Table 3 shows that 96 out of 122 (79%) parenteral medication doses that were prepared and administered contain one or more error. Forty (33%) doses contained 2 or more errors, while 7 (6%) doses had 3 errors. One dose was intercepted due to incorrect dose error.

Table 3: Incidence of parenteral medication preparation/administration error

Error rate	Number of doses (percentage)
One or more error per dose	96 (79%)
Two or more errors per dose	40 (33%)
Three errors per dose	7 (6%)

As shown in table 4, the most common error observed was incorrect drug preparation (57%), followed by incorrect administration rate (35%). Ten (8%) doses were given in combination with an incompatible medication, while 7 (6%) doses were administered at the incorrect time.

Table 4: Types of parenteral medication preparation/administration error

Types of errors	Number of doses (percentage)
Incorrect medication and dosage form	0 (0%)
Incorrect drug preparation	69 (57%)
Incompatibility	10 (8%)
Incorrect dose	1 (1%)
Incorrect rate	43 (35%)
Incorrect time	7 (6%)
Incorrect route	0 (0%)

Adherence to good practices

Table 5 shows nurses did not perform a double check in the preparation/administration of all 122 parenteral doses (100%). In 15 (12%) doses, the syringes were not properly labelled. Aseptic technique was not followed in 14 doses (11%). There were 9 doses (7%) that were not rechecked for patient's prescription, identity (ID), and allergy status prior to administration.

Factors associated with the occurrence of preparation/ administration error

Using univariate analysis, no association was found between nurse characteristics (age, sex, education level, duration of clinical experience, and duration working in GICU) and the occurrence of preparation/administration error. However, types of injections ($P<0.05$) and class of medications ($P<0.001$) were found to affect significantly the occurrence of error. As shown in table 6, medication errors occurred most frequently with bolus administration (97%) with respect to the types of administration. As for the class of medication, most errors occurred in the category of gastrointestinal (95%), followed by antimicrobial drugs (86%).

Table 5: Non-adherence to good practices during preparation/administration of parenteral medication

Good practices	Number of doses (Percentage)
Prescription read, unclear prescription clarified	0 (0%)
Dose calculated/measured correctly	3¶ (2%)
Aseptic techniques	14 (11%)
Syringe labelled correctly	15 (12%)
Patient's prescription, ID, and allergy status re-checked	9 (7%)
Administration double checked	122 (100%)
Documentation	0 (0%)

¶: All non-adherences involve measuring a dose using the inappropriate syringe size (e. g. withdrawing 2 ml of medication using a 50 ml syringe).

Table 6: Types and classes of parenteral medications and rates of associated errors

Variables	Administration	No (%§) of errors
Types of administration		
Bolus	34	33 (97%)
Infusion	87	63 (72%)
Subcutaneous	1	0 (0%)
Class of medication		
Sedation and analgesia	10	7 (70%)
Vasopressor/catecholamine	4	0 (0%)
Antimicrobial	44	38 (86%)
Electrolytes	33	23 (70%)
Gastrointestinal (GI)	21	20 (95%)
Others	10	8 (80%)

§: Proportion of administration that resulted in errors.

Effect of good practice adherence on the number of error per dose

Using independent t-test, poorly labelled syringes were found to have statistically more errors per dose (1.9+0.96) as compared to syringes that were properly labelled (1.1+0.73), $t=-4.0$, $P<0.001$. Adherence to other good practices, however, did not have any effect on the number of error per dose.

Drug infusions' concentration error

A total of 40 IV noradrenaline infusion samples were collected, and their concentrations were analyzed using HPLC. Fig. 1 shows the percentage of deviation from the expected concentration in these drug infusion samples.

Concentration errors were found in 19 out of the 40 infusion samples (48%)-i.e. the concentration of infusions deviated by more than 10% above or below the expected concentration. A total of 7 samples (18%) deviated by more than 30% above or below the expected concentration, while three samples (8%) deviated by more than 50%. Nurses' characteristics (age, education level, and duration of clinical experience) did not have any effect on the concentration accuracy of the infusion prepared.

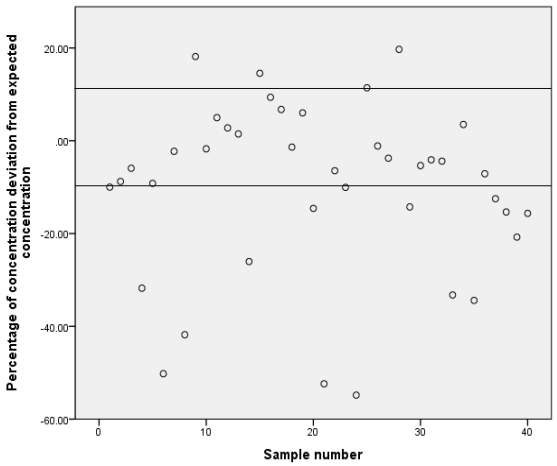

Fig. 1: Percentage of deviation from the expected concentration in 40 drug infusions (%)

DISCUSSION

Methods for detecting medication error include anonymous self-reports, incident reports, and direct observation method. The observation-based method employed in this study provides the most accurate mean of detecting medication error. [11]. In a comparative study conducted in 2 Australian hospitals, about one third of drug administration's were detected to contain error using the observation method. However, none of these errors were reported in an incident report [12]. This suggests the potential for error under-reporting using the incident report method. One concern related to the observation method is the subject being observed may change their habits if they know they are being observed, a term known as 'Hawthorn effect'. However, a study by Allen found error made by healthcare providers during medication administration were not influenced by the observation process. Hence, this concern may be unfounded [26].

In this study, almost 80% of parenteral medications were prepared and administered incorrectly in the GICU. This high error rate is comparable to a study by Westbrook (2011) and McDowell (2010), which reported error rates of 69% and 73% in the administration of IV medication respectively [22, 27]. The few studies that were conducted to address the medication administration error in the ICU, however, reported much lower error rates of 9.4%-45% [28, 29]. For example, Fahimi conducted a study in an ICU in Tehran hospital reported an error rate of 9.4% in the administration of IV medications. In their study, error rate was calculated as the percentage of error opportunities (total number of steps involved in IV medication administration multiplied by the number of doses) that resulted in an error [28]; whereas in our study, error rate was calculated as the percentage of the dose in the presence of error. Different calculation of the error rate could have resulted in the different findings. In another study that was conducted in 2 Dutch hospitals' ICU, the author reported an error rate of 45% in the administration of medication [29]. In their study, the author included the full range of administration routes (including oral route), whereas our study focuses on parenteral route alone, which have higher error rates [3, 4]. Moreover, different setting and nursing practice make it difficult to compare these study findings to ours.

We found errors were highest during the reconstitution and dilution of parenteral medications. Specifically, slightly more than half (57%) of all doses were prepared erroneously either using the incorrect diluent, the incorrect volume or were mixed insufficiently. Similarly, a systematic review conducted in various European hospitals found the reconstitution of drug and diluent contributed the most errors in the preparation and administration of IV therapy [27]. Loss of drug potency increased in toxicity, and other adverse events may occur when the incorrect diluent are used [1, 2]. In the past, lack of knowledge was identified as the main cause of IV medication errors [8]. Education intervention, including teaching session and the use of memory aid, are some of the strategies to reduce these errors. The stakeholder may also consider providing central admixture services by the pharmacy department. However, further study is required to investigate the cost-effectiveness of these services.

The second most common error in this study was the incorrect administration rate (33%), mostly involving administration of bolus drug, at a rate that exceeded 3-5 min as recommended by the manufacturers. Deliberate violation of guidelines when injecting bolus doses faster than the recommendation is a shared error in IV therapy [5, 7, 8, 21].

However, rapid administration of these potent medications can result in speed shock, syncope, shock, and cardiac arrest [1, 2]. Again, lack of information and high workload contributed significantly to incorrect rate errors [21]. Providing education program to increase nurses' awareness on the safe administrations rate, and using an infusion pump for the administration of bolus injection in order to reduce the need for nurses to be at the bedside may reduce incorrect rate error.

We observed nurses generally do not practice double-checking during preparation/administration of medications in the GICU. Although healthcare professionals are advised to practice double-checking during prescribing, dispensing, and administering medications [1, 2, 20, 27], time pressure and lack of staff causes non-adherence in this good practice [17]. Lack of double-checking either by the same person or a second person has been found to cause medication errors [20, 27]. The risk is greater in high alert medications, such as potassium chloride, which are often used in the critical care setting. At the time of the study, the double-checking system is not yet in place in the study hospital. Implementing a double-checking system into the hospital's policy, especially for high alert medications, could provide an additional safeguard. Involving a medication expert, such as a pharmacist, to witness the drug administration process may also reduce medication error.

This study found 15 doses (12%) were not labelled properly; most of them involve failure to label the syringes when there was more than one bolus injection. A study by Cousins found a significant percentage of products that were not labelled, was not used immediately, and was stored temporarily in the clinical area before administration [21]. This poses a risk because failing to label the syringe when there is more than one injection can lead to confusion, which can cause medication error. Moreover, we found that syringes that were not appropriately labelled had considerably more errors per dose. Interestingly, Wheeler *et al.* (2008) also detected syringes that were not properly labelled had significantly poorer drug preparation [13]. While failing to label a syringe properly is not a medication error by itself, we hypothesize that it is an indicator of failure to prepare and administer the drug correctly, whether due to time pressure, stress, or human weakness. Standardized stickers for labeling infusions were available in the study ward, but no stickers were provided for labeling bolus injection. A simple sticker could be provided to label the injection with the drug's name and dose.

When the content of noradrenaline infusions prepared by nurses was analysed using HPLC, almost one-half of them contained concentration errors. Three of the infusions analysed deviated by more than 50% from the anticipated concentration. While concentration errors are common occurrences in drug infusions prepared manually by healthcare providers for clinical use [13-16], these errors can lead to misinterpretation of the effective dose and wrong dosing judgment. The study hospital could consider providing automated central admixture services by the pharmacy department, or buying ready-to-administer injectable medicines to reduce such errors. Alternatively, a routine check on the accuracy of the drug infusion's concentration could be implemented as a measure of quality control. However, the cost-effectiveness of these services and new opportunity for error must be examined.

Limitations

There are limitations to our study. The observation was conducted every weekday 8 am to 5 pm only, so we were unable to examine those prepared at night or on weekends. Not every preparation and administration of parenteral medications was observed during the study period as nurses tended to reconstitute medications around

the same time, yet there was only one researcher to observe the process. We did not find any association between nurses' factors and the occurrence of error; however, some of the variances (e. g. nurses' fatigue level and the shift they work in) that have been shown to influence the occurrence of error were not measured as it was outside the scope of our study. We also did not manage to collect all the noradrenaline infusions prepared during the study period because some were discarded by nurses, who either forgot about or were unaware of the study. Despite these limitations, our study provides an insight into the medication administration practice in GICU in Malaysia and poses recommendations and future works that need to be done in order to improve parenteral medication safety. Nonetheless, our study was conducted in a GICU in Malaysia, which may have different nursing practice, and thus may not be generalizable to other countries.

CONCLUSION

There is a high error rate in the preparation and administration of parenteral medications in a Malaysia's GICU. Using the observation technique, incorrect drug preparation and wrong administration rates were both error 'hot spots' identified, and must be targeted for intervention. Some of the recommendations to improve parenteral medication safety include providing education for nurses, central admixture services by the pharmacy department, incorporating a double-checking system in hospital's policy, and interdisciplinary collaboration.

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CONFLICT OF INTERESTS

Declare none

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