Incidence of Intravenous Medication Errors in a Chinese Hospital

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ABSTRACT

Objectives: The purpose of this study was to explore intravenous (IV) medication errors in a Chinese hospital. The specific objectives were to 1) explore and measure the frequency of IV medication errors by direct observation and identify clues to their causes in Chinese hospital inpatient wards and 2) identify the clinical importance of the errors and find the potential risks in the preparation and administration processes of IV medications. Methods: A prospective study was conducted by using the direct observational method to describe IV medication errors on two general surgery patient wards in a large teaching hospital in Beijing, China. A trained observer accompanied nurses during IV preparation rounds to detect medication errors. The difference in mean error rates between total parenteral nutrition (TPN) and non-TPN medications was tested by using the Mann-Whitney U test. Results: A final total of 589 ordered IV doses plus 4 unordered IV doses as prepared and administered to the patients was observed from August 3, 2010, to August 13, 2010. The overall error rate detected on the study ward was 12.8%. The most frequent errors by category were wrong dose (5.4%), wrong time (3.7%), omission (2.7%), unordered dose (0.7%), and extra dose (0.3%). Excluding wrong time errors, the error rate was 9.1%. Non-TPN medications had significantly higher error rates than did TPN medications including wrong time errors (P = 0.0162). Conclusions: A typical inpatient in a Chinese hospital was subject to about one IV error every day. Pharmacists had a very limited role in ensuring the accuracy of IV medication preparation and administration processes. Keywords: direct observation, intravenous, high-alert medications, medication errors.

Background

The medication use system for inpatients in hospitals usually contains prescribing, transcribing, dispensing, administration, and monitoring steps. The perspective of the medication use system for health care providers was to collaboratively promote efforts to achieve optimal therapeutic goals and encourage the enhancement of highly reliable and high-quality care [1,2].

Intravenous (IV) medication preparation is a very complex process including multiple steps: the selection of correct drugs, the dissolving of powder, and the transfer of injectable fluid from the original vial or ampoule into a base solution infusion bag [3]. Medication errors may be introduced during any of these steps of this complex process. IV medications are considered to be particularly dangerous because they usually go directly into the patient's vein via infusion, with immediate onset of systemic effects, low therapeutic index of many IV medications, and the difficulty of reversing the pharmacologic effects after IV administration [4,5].

Although errors can happen at any stage of the medication use system, the ultimate outcome of the medication use system from the patient’s perspective is the rate of errors that actually reach the patient at the point of administration [6]. Many methods were used to capture medication errors, including direct observation, chart review, incident report, and so forth [7]. The direct observation method, which was developed by Barker and McConnell [8] in 1962, was confirmed to be able to detect more medication errors than did the other two methods: chart review and incident report [9]. Studies using the direct observational method found that error rates of IV medications admixed by nurses in hospitals varied largely from 26.9% to 49% in Europe [10–16]. Using the direct observation method, Flynn et al. [17] reported that the mean error rate of IV admixture compounding at five US hospital pharmacies was 9% [17].

Conflict of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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China has an overwhelming usage of IVs than do other countries. In 2009, China used 10.4 billion infusion bottles annually [18]. This number of infusions was equivalent to approximately eight infusion bottles per capita for 1.3 billion Chinese people, much higher than the estimated three infusion bottles per capita at the international level [18]. Given that life-threatening IV medication error cases have been reported recently, the study of IV medication errors in Chinese hospitals is still rare [19,20]. If the error rate of 9% was applied to the Chinese hospitals in which IV infusions were administered, about 900 million errors involving IV infusions would have occurred annually in these hospitals.

The first objective of this study was to explore and measure the frequency of IV medication errors by direct observation and identify clues to their causes in Chinese hospital inpatient wards. The second objective was to identify the clinical importance of the errors and find potential risks in existing preparation and administration processes of IV medications.

### Research Methods

#### Operational Definitions

An IV medication error was defined as any ingredient observed that was mixed in the IV bag and administered to the patients different from the interpretable physician’s orders written on the patient charts. Total opportunities for error (TOEs) were defined as the IV ingredient doses ordered by the physician and interpretable by the observer, plus unordered IV ingredient doses observed to be given to the patient. The detected medication errors were divided by the TOEs and multiplied by 100 to obtain the medication error rate.

The IV medication errors were classified into the six categories listed below:

1. An unordered drug error: A dose that was not ordered for the patient was added in the IV solution and administered to the patient.
2. An omission error: An ingredient was not mixed in the IV solution and administered to the patient.
3. A wrong dose error: An ingredient was given more than 10% volume and concentration greater or less than the correct dosage, in the judgment of the observer.
4. An extra dose error: An ingredient dose given in excess of the total number of times ordered by the physician, such as an ingredient dose injected in the IV solution and given to the patient on the basis of an expired order, after a drug has been discontinued, or after an ingredient dose has been put on hold.
5. A wrong time error: The mixed IV solution was delivered more than 60 minutes before or after the scheduled administration time.
6. A wrong route error: The mixed IV solution was administered via a different location or site on the patient’s body than was ordered.

The criterion for judging potential clinical importance was appearance in ISMP’s list of high-alert medications in 2008 [21].

#### Study Site

The research protocol was approved by the hospital site in March 2010 and by the Institutional Review Board at Auburn University in May 2010. Two general (gastrointestinal) surgery patient wards at a teaching hospital with more than 1000 beds in Beijing were offered by the hospital as a convenience sample. The patient wards with 53 beds housed 50% of cancer patients, served by 13 physicians and 18 employed nurses. Most (90%) of the prescriptions for the patients on wards were IV medications. No clinical pharmacist was currently assigned to the wards.

A new Hospital Information System (HIS), an electronic prescribing system, was installed for inpatients in the hospital in July 2010. Physicians prescribed medications both in the computerized HIS and in the patient charts (handwritten). A medical nurse sent the medication orders through the HIS to the central pharmacy in the hospital after checking the consistency of medication orders between the HIS and the patient charts. Oral medications were supplied as unit doses and IV medications were dispensed in a bulk form to the wards once a day by the central pharmacy. The medical nurses transcribed handwritten medication orders to the medication inspection sheet for each patient. IV medications, including total parenteral nutrition (TPN) medications and non-TPN medications, were prepared by medical nurses in an IV preparation room.

TPN medications, which were usually given peripherally once daily, contained multiple additives such as vitamin C injection, sodium chloride injection concentrate (10%), compound amino acid injection (15-HBC) 250 ml, and so forth in the Kabiven TM fat emulsion bag (1440 ml). The TPN doses were placed on the counter aligned with the transcribed medication inspection sheet for each patient by an auxiliary worker. The medical nurses prepared TPN doses by injecting the prescribed volume of additives (lipids, protein, electrolytes, glucose, etc.) into the Kabiven TM fat emulsion bag. The patient’s name and the bed number were written on the label using a marker pen on the Kabiven TM fat emulsion bag after the admixture process was completed.

Non-TPN medications usually contained one additive such as an antibiotic in a base solution of 5% glucose (250 ml) or 0.9% sodium chloride (100 ml). The handwritten label on the base solution bag included the name/volume of the ingredient and the administration time. No patient information was included on the label. The nurse injected the volume of the additive into the base solution and mixed them as an assembly line. The patient’s name and the bed number were handwritten on the label when the nurses administered the non-TPN medications at the patient’s bedside.

#### Data Collection Procedures

The direct observation method was used by a PhD candidate from the Department of Pharmacy Care Systems at Auburn University to detect IV medication errors. The observer was trained and certified in the direct observation method at the East Alabama Medical Center by Dr. Elizabeth Flynn in July 2008. Both preparation and administration processes were observed to detect wrong dose errors that may have occurred at the preparation process, but only medication administration errors were considered as the outcome at the end point of the medication use system.

The observer randomly picked up a nurse who prepared the IV medications and recorded the information of the admixing. When the nurse administered the IV medications to the patients, the observer accompanied the nurse as she delivered and administered the IV bags at the bedside. The observer recorded the information of the patient and the time and the label information on the IV bags administered. The observer’s notes for preparation and administration processes were combined for each patient and later compared with the physician’s orders for discrepancies.

The nurses who were 18 years or older were regularly employed for more than 1 year at the study site and regularly prepared and administered IV medications. The nurses provided their consent for observation. After the observed nurses were initially told the purpose of the study, the term “medication
“accuracy” was introduced to them for their acceptability. The participants were told that they could withdraw from the study at any time. The observed nurses were asked not to change any of their normal routines and to continue their normal working performance during the observation. Confidentiality was protected by coding the names of the nurses and the patients.

The sample was defined as the observed IV component doses that were ordered, prepared, and administered for the patients on the general surgery patient wards.

Statistical Analyses
Descriptive data of IV medication error rates including the number of errors for each error category, TOEs, and error rates were provided for each observation day. The difference in the distributions of error rates between TPN and non-TPN medications was tested by using the Mann-Whitney U test. A P-value of less than 0.05 was used to represent statistical significance. SAS software, Version 9.2 (SAS, Inc., Cary, NC), was used in statistical analysis.

Results
A flow chart of the current IV medication distribution system for inpatients on the gastrointestinal surgical patient wards is displayed in Fig. 1. The workflow chart shows that the pharmacists had a very limited role in ensuring the accuracy of IV medication preparation and administration processes.

The observations were performed in a nonjudgmental and unobtrusive way from August 3, 2010, to August 13, 2010. Day shifts from 8 AM to 3 PM were chosen for observation because of the high volume of IV administration doses. The principal investigator excluded 7 doses from the TOEs as falling outside of the operational definitions. A final total of 589 ordered doses plus 4 unordered doses as prepared and administered to the patients were observed from August 3, 2010, to August 13, 2010.

The overall IV medication error rate detected on the study wards in a Chinese hospital was 12.8% (76 errors of 593 TOEs). The range was 6.0% to 16.7%, with a 95% confidence interval of ±2.0% (see Fig. 1). Excluding wrong time errors, the error rate was 9.1%. The error types by category demonstrating the most frequent errors were wrong dose (5.4%), wrong time (3.7%), omission (2.7%), unordered dose (0.7%), and extra dose (0.3%); as a percentage of all errors, the results included wrong dose (42%), wrong time (29%), omission (21%), unordered dose (5%), and extra dose (3%) (Table 1).

The IV medications were prepared by the same group of nurses on rotation. Non-TPN medications were prepared by one nurse, whereas TPN medications were prepared by two nurses in the same IV preparation room. Non-TPN medications (60 errors out of 397 TOEs) had significantly higher error rates than did TPN medications (16 errors out of 196 TOEs) including wrong time errors (P = 0.0162) (Fig. 2). The mean error rates by category between TPN medications and non-TPN medications were compared (Table 2). Excluding wrong time errors, there was no significant difference in the distributions of error rates between TPN medications and non-TPN medications (P = 0.3271) (Table 3). Examples of TPN and non-TPN medication errors are provided in Tables 4 and 5.

Among 16 TPN dose errors, 81% of the errors (13 errors) involved ISMP’s high-alert medications, including insulin, potassium chloride for injection concentrate, and sodium chloride for injection concentrate. These errors should be taken into consideration because of their potentially significant clinical consequences. Among the errors involving high-alert medications, insulin errors occurred at the rate of 4% (7 errors out of 196 TOEs). For potassium chloride for injection concentrate and sodium chloride for injection concentrate, the error rate was 3% (5 errors out of 196 TOEs). For sodium chloride for injection concentrate, the error rate was 2% (2 errors out of 196 TOEs).

Fig. 1 – IV medication distribution system for inpatients in a Chinese hospital. IV, intravenous; TPN, total parenteral nutrition.
sodium chloride for injection concentrate, the rates were 2% (4 errors out of 196 TOEs) and 1% (2 errors out of 196 TOEs), respectively. Both potassium chloride for injection concentrate and sodium chloride for injection concentrate are important for the maintenance of the body’s fluid and electrolyte balance. The errors involving electrolyte drugs can cause electrolyte imbalance, extravasation, or heart arrest.

### Discussion

This study used the direct observation method for measuring the incidence of IV medication errors and found that the IV medication error rate was 9.1%, excluding wrong time errors. Each patient received about 10 doses per day, and each patient faced about one error every day. An observation study of errors in IV admixture compounding at five large hospital pharmacies detected an error rate of 9% (147 errors per 1679 doses), with the most common type of error being wrong dose [17].

A similar study by Taxis and Barber [15] suggested that IV drug errors can be reduced by the involvement of the clinical pharmacists as the key health professionals in ward practice, removing the nurses from the task of preparing the IV drugs, restricting the supply and stock of concentrated potassium chloride on ward, and including the central preparation of IV medications. A Council of Europe report attributed these IV errors to the lack of unit-dose injectable medications and insufficient pharmacy staffing resources [22].

A unit dose–based centralized Pharmacy Intravenous Admixture Center Service preparing TPNs was installed in this hospital 1 year after the study to improve patient safety. In the new system, a pharmacist checks the orders for the compounding session and prints out the TPN mixture labels. TPN mixture labels, which were printable and ready to stick on the infusion bag, contained patient’s and prescription information as well as

![Distribution of Wilcoxon Scores for Rate](image)

**Fig. 2** – Distribution difference of medication error rates between TPN and non-TPN medications. TPN, total parenteral nutrition.
dispensing and administration times. For example, the prescription of insulin could not be placed unless the exact dose of insulin was entered in the computer. The dosage of insulin was printed on the IV mixture labels, and no further calculation was therefore needed by nurses during the admixture procedure. Assistants filled baskets for each preparation with the needed TPN ingredients and labels. TPNs for each patient were processed as individual compounding and mixed by an individual in the compounding hood. Especially high-risk medications, narcotics, and sound-alike and look-alike medications were under centralized management in the pharmacy. Hospitals with the Pharmacy Intravenous Admixture Center Service have increased from 19% (9 of 47 hospitals) in 2009 to 27% (16 of 59 hospitals) in 2011 in the Beijing area based on survey results\[23,24\].

In this study, the range of errors of wrong dosage of insulin was 40% to 100%, with a prevalence of underdosing. The patient was at the risk for hypoglycemia when overdosing insulin, hyperglycemia when underdosing or omitting insulin, or complications due to either hypoglycemia or hyperglycemia. The Joint Commission on Accreditation of Healthcare Organizations considered insulin to be one of the top three “high-risk medications” in the inpatient setting \[21\]. Hellman \[25\] found that 33% of the medical errors that caused death within 48 hours of the error involved insulin therapy and administration in the care of a hospitalized patient.

Limitations of this study should be noted. The two patient wards were selected as a convenience sample in a large 3A level teaching hospital in Beijing, the capital of China. The Chinese hospital accreditation system starting in 1989 was reset in 2011 with a cycle of every 4 years by the Ministry of Health \[26\]. This system defines three hospital grades (3, 2, and 1, with the higher number meaning a higher level of the hospital) on the basis of infrastructure and administrative level and three within-grade levels (A, B, and Fail) on the basis of an evaluation by a committee.

<table>
<thead>
<tr>
<th>Error category</th>
<th>Mean error rate, % (SD)</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall medications</td>
<td>TPN medications</td>
<td>Non-TPN medications</td>
</tr>
<tr>
<td>Omission</td>
<td>2.3 (2.6)</td>
<td>2.3 (5.3)</td>
</tr>
<tr>
<td>Unordered dose</td>
<td>0.5 (1.1)</td>
<td>0.7 (2.3)</td>
</tr>
<tr>
<td>Wrong dose</td>
<td>5.6 (3.5)</td>
<td>3.9 (3.5)</td>
</tr>
<tr>
<td>Extra dose</td>
<td>0.3 (1.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Wrong time</td>
<td>4.1 (3.8)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

SD, standard deviation; TPN, total parenteral nutrition.

* P-values are for the comparison of distribution difference error rates between TPN and non-TPN medications.
† P < 0.01.
established by the local health bureau according to a wider range of criteria, including diagnosis information of discharged patients, hospital administrative management, patient safety, and service quality, and the criteria by the local health bureau [26,27]. The statistical data from the Ministry of Health in 2012 showed that Beijing has 550 hospitals (51 third-level hospitals, 89 second-level hospitals, and 348 first-level hospitals), which is 3% of the total hospitals in China [28]. Therefore, the generalization of the results from this hospital to other hospitals of different levels in other provinces may be limited.

Only one observer was assigned in the small IV preparation room during a busy time considering economic and space factors. Therefore, no extra training and measurement for the agreement of the operational definition was necessary. A statistical difference in error rates over the observational days was not found, meaning that the "Hawthorne Effect" (the tendency that the subjects work nervously and poorly or perform better when they are under observation in an experiment) was not found in the study.

Conclusions

The workflow chart revealed that pharmacists had a very limited role in ensuring the accuracy of IV medication preparation and administration processes, as well as in providing professional knowledge to the patients. Nurses were fully responsible for the transcription, preparation, and administration of IV medications.

During the observational period, the nurses were either unaware of the existence of the errors or they were aware without reporting because they did not think the errors were serious in nature. The findings of this study suggest that it is necessary to engage pharmacists in the IV dose preparation and administration processes.

Deficiencies in the nursing IV preparation procedure that could contribute to errors were as follows: 1) limited space when placing all TPN ingredients for each patient closely as an assembly line on the counter at one time, which may increase possibilities that one patient’s doses were mixed with those for the adjacent patient; 2) no special precautions were observed when the nurses admixed high-risk drugs; and 3) no labels containing the patient information and the component drug information were placed on the base solution bag. Such a system lacking labels seemed likely to raise the risk of errors and make them difficult to be detected in the system especially during the preparation process.

The results showed that IV medication errors were common for these inpatients in this Chinese hospital, occurring in 12.8% of the cases. Excluding wrong time errors, the error rate was 9.1%. Assuming that each patient received about 10 doses per day, such a patient was subject to about one error every day. If wrong time errors were excluded, non-TPN medications had error rates similar to those of TPN medications.

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REFERENCES


