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Medication safety in Vietnamese hospitals

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CHAPTER 5

THE EFFECT OF A CLINICAL PHARMACIST-LED TRAINING PROGRAMME ON INTRAVENOUS MEDICATION ERRORS: A CONTROLLED BEFORE AND AFTER STUDY

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ABSTRACT

Background: Little is known about interventions to reduce intravenous medication administration errors in hospitals, especially in low- and middle-income countries.

Objective: To assess the effect of a clinical pharmacist-led training programme on clinically relevant errors during intravenous medication preparation and administration in a Vietnamese hospital.

Methods: A controlled before and after study with baseline and follow-up measurements was conducted in an intensive care unit (ICU) and a post-surgical unit (PSU). The intervention comprised lectures, practical ward-based teaching sessions and protocols/guidelines, and was conducted by a clinical pharmacist and a nurse. Data on intravenous medication preparation and administration errors were collected by direct observation 12 h/day for seven consecutive days. Generalised estimating equations (GEE) were used to assess the effect of the intervention on the prevalence clinically relevant erroneous doses, corrected for confounding factors.

Results: 1204 intravenous doses were included, 516 during the baseline period (236 on ICU and 280 on PSU) and 688 during the follow-up period (407 on ICU and 281 on PSU). The prevalence of clinically relevant erroneous doses decreased significantly on the intervention ward (ICU) from 64.0% to 48.9% ($p < 0.001$) but was unchanged on the control ward (PSU) (57.9% vs. 64.1%; $p = 0.132$). GEE analysis showed that doses on the intervention ward were 2.60 (1.27–5.31) times less likely to have clinically relevant errors ($p = 0.013$).

Conclusions: The pharmacist-led training programme was effective, but the error rate remained relatively high. Further quality improvement strategies are needed, including changes to the working environment and promotion of a safety culture.

Keywords: hospital, intervention study, medication errors, patient safety

INTRODUCTION

Intravenous therapy is associated with higher rates of medication administration errors compared to orally administered medications (Shane 2009; Nguyen *et al.* 2013). In Vietnam, about three quarters of all intravenous doses were erroneous (Nguyen *et al.* 2013), which is considerably higher than error rates in other settings reported in a recent review (Keers *et al.* 2013). Most intravenous medication administration errors occur during reconstitution and injection (McDowell *et al.* 2010). Intravenous errors have been shown to be related to insufficient knowledge of practical procedures, deviations from protocols/guidelines and nurses' experience (Taxis & Barber 2003a; Taxis & Barber 2004a; Stavroudis *et al.* 2010; Westbrook *et al.* 2011). This suggests that educational interventions targeting the specific error-prone stages could be useful to improve medication safety. Such interventions have shown a reduction in medication errors in high-income countries (Ford *et al.* 2010; Chedoe *et al.* 2012; Manias *et al.* 2012). Technical interventions, such as advanced infusion pumps and bar code technology, have also been suggested as methods to help reduce medication administration errors (Duckers *et al.* 2009; Pham *et al.* 2012); however, large scale implementation of such tools will be difficult in low- and middle-income countries.

In low- and middle-income countries, patient safety is still a neglected area, with little known about medication errors. Health system infrastructures are weak and there is a poor safety culture. Inadequate training of clinical staff and lack of protocols/policy have been identified as important factors compromising patient safety (Jha *et al.* 2010; Wilson *et al.* 2012). The effect of education on medication preparation and administration errors has rarely been studied in lower-income countries. An exception is a recent study in an intensive care unit (ICU) in Chile. A considerable reduction in various types of medication errors was found after a multifaceted intervention was implemented, including the participation of a clinical pharmacist in clinical rounds, standardisation of medication use, training, and the introduction of a medication error reporting system (Romero *et al.* 2013). However, lessons learnt from high-income nations are not always applicable. In the context of limited resources, the implementation of expensive technology-based interventions is not feasible. Education, therefore, could be considered as the first practical step to improve patient safety. The aim of this study is to measure the effect of a clinical pharmacist-led training programme on clinically relevant errors during intravenous medication preparation and administration in a Vietnamese hospital.

METHODS

Setting

The study took place in a major public hospital in Vietnam. The pharmacy service in the hospital was based on ward stock supply. Commonly used medications were kept on the ward, while other medications were dispensed from the pharmacy department every morning for weekdays, and on Friday morning for the weekend. Medications prescribed by the doctors were noted on the patient's medical record and then entered into the computerised drug use record for each patient by nurses who printed out the patient's drug regimen. This print-out was used as the information source for preparing and administering drugs. Medication preparation was carried out in a separate room. Every drug administration on the ward was recorded on the nurse chart and disclosure form at the patient's bedside, which was attached to the patient's medical record on discharge. No clinical pharmacists were attached to the wards. The majority of nurses held a baccalaureate degree (2 years' training). Continuing education for healthcare professionals, including nurses, has only been introduced recently in Vietnam. Hence, nurses in the study hospital received further training infrequently (less than once a year). The study was conducted on an ICU and a unit caring for critical ill patients after surgery (a post-surgical unit, PSU). Nurses worked in shifts. On each shift, a nurse took care of three or four patients and gave about 18-20 intravenous doses. During the baseline period, no written instructions for preparing drugs were available on the wards.

Study design

This is a prospective controlled before and after study with baseline and follow-up measurements using the direct observation method (Dean & Barber 2001), conducted in two critical care units: an ICU (the intervention ward), and a PSU (the control ward).

Definition

Medication errors were defined as deviations in drug preparation and administration from the doctor's prescription, hospital policies and procedures or the manufacturer's instructions (Taxis & Barber 2004b; Chua *et al.* 2009). Medication errors were further classified into eight categories (Table 1) (Tissot *et al.* 2003; Wirtz *et al.* 2003).

The clinical relevance of each dose with one or more errors was judged by a panel of four experienced healthcare professionals (one doctor, one nurse, and two pharmacists) using a validated scale between 0 (labelled as no harm) and 10 (death). Assessors were blinded regarding ward and period. Mean scores below 3 suggested a minor outcome, scores of 3–7 a moderate outcome, and scores above 7 a severe outcome (Dean & Barber 1999). The last two outcomes were considered clinically relevant. This method has been used in similar studies (Chedoe *et al.* 2012; Taxis & Barber 2003b; Barber *et al.* 2009).

Table 1. Types of medication errors

	Type of errors	Definition
Preparation	Wrong drug	Preparation of a drug which differs from that prescribed
	Wrong dose	Preparation of a dose that is higher than, or less than, the amount prescribed ($\pm 10\%$)
	Wrong dosage form	Formulation of drug deviates from that prescribed
	Deteriorated drug	Preparation of a drug that has expired or for which the physical or chemical dosage-form integrity has been compromised
	Wrong preparation technique	Inappropriate procedure or improper technique in the preparation of a drug (compared to the manufacturer's instructions or hospital policy, including wrong diluent, wrong solvent, wrong volume, possible incompatibility)
Administration	Omission	Failure to administer an ordered dose to a patient
	Unordered drug	Administration to the patient of non-prescribed medication
	Wrong administration technique	Inappropriate procedure or improper technique in the administration of a drug (rate, incompatibility, route, dose ($\pm 10\%$) if prepared with correct dose) A rate error was identified if administration took less than 3 or more than 5 min (for a bolus dose) or 15% shorter/longer than the required infusion time (for an infusion dose). An incompatible error was determined if there was incompatibility information available in at least one of four documents including the <i>Handbook on Injectable Drugs, 15th edition</i> (Trissel 2009), <i>AHFS Drug Information 2009</i> (American Society of Health-System Pharmacists 2009), Vietnam National Drug Formulary, 2nd edition (Vietnam Ministry of Health 2009) and the manufacturer's instructions.

Intervention

Our previous study revealed that the most frequent errors were wrong administration technique and wrong preparation technique (Nguyen *et al.* 2013). An educational training programme to correct these two common errors was developed by a clinical pharmacist and the chief nurse in the study hospital. For example, wrong preparation technique was targeted through lectures, practice sessions and written guidelines by addressing reconstitution, compatibility and the correct preparation technique, such as the selection of appropriate diluents/solvents.

The intervention was carried out during 2 weeks in May 2012 in the preparation room of the intervention ward and was repeated twice to ensure the full participation of all nurses. The programme consisted of the following:

1. Classroom lectures: two 30-min teaching sessions with PowerPoint presentation covering reconstitution, compatibility, administration rate and drug preparation and administration techniques were given by the clinical pharmacist.
2. Practice-based education: one 45-min practical session covering the preparation and administration of commonly used medications and including discussion of patient cases was carried out by the chief nurse.
3. Two posters on recommended practice for safe preparation and administration and emphasising the adverse consequences of inappropriate procedures, were attached to the wall of the preparation area. Written guidelines on the preparation and administration of commonly used intravenous drugs were made available on the ward during and after the intervention period. The posters and guidelines were prepared by the clinical pharmacist and the chief nurse.

Outcome

The prevalence of doses with clinically relevant error(s) was calculated.

Sample size

The sample size was estimated using the approximate formula for normality of proportion where the effect of the intervention is controlled for a possible change in event rate over time (Agresti 1996). The level of significance was set at 0.05 and

the power was set at 0.8. The baseline clinically relevant error rate found in our previous study was about 70% (Nguyen *et al.* 2013). The estimated sample size was 177 intravenous doses per ward in each period in order to detect an absolute reduction in the error rate of at least 20% on the intervention ward.

Data collection

Medication errors were measured 2 weeks before (baseline, in April 2012) and 3 weeks after the educational programme was fully implemented (follow-up, in June 2012). Two observers were allocated to each ward (four observers in total). They collected data using direct observation of nurses (Dean & Barber 2001) for 12h each day (7:00–19:00) on seven consecutive days (Monday-Sunday) on each ward during each period. The observers were senior pharmacy students who were trained by an experienced observer for 1 week through lectures, discussions of medication errors from previous studies, and practice observations. A 1-day pilot observation was conducted on the study wards prior to the commencement of the main study to ensure all observers used the same definition of an error. All observation data were reviewed by the experienced observer. Also, the pilot study helped observers become familiar with ward routines (staff, medications, devices, schedules of drug rounds) and staff to feel comfortable with their presence in order to minimise the Hawthorne effect (Allan & Barker 1990).

The observation procedure was described previously (Chedoe *et al.* 2012). Briefly, the observers asked nurses for permission to observe, followed the nurses during drug preparation and administration, and recorded details of all intravenous doses. Nurses were not informed about the true purpose of the study to minimise any bias which might be caused by that awareness. The observers were blinded to the intervention and were asked to minimise conversation with nurses and avoid the word 'error' during the observation process. For ethical reasons, the observers intervened if they became aware of a severe error potentially affecting a patient. These errors were also included in the analysis. After each round of observation, the observers reviewed all observation notes and compared the information with the doctor's prescriptions, hospital policies and procedures, the manufacturer's instructions and available literature to detect any discrepancies.

Data analysis

The prevalence of clinically relevant errors was calculated by dividing the number of doses with clinically relevant errors by the number of opportunities for errors, which is the sum of given doses plus omitted doses (ie, prescribed but not given). Differences in the prevalence of clinically relevant errors between both periods were determined using Pearson's χ^2 statistic. CIs were calculated using standard methods (Agresti 1996).

The impact of the intervention programme on medication errors was estimated with generalised estimating equations (GEE) using an exchangeable working correlation matrix. A cumulative logit link function was applied for the ordinal variable of clinical relevance of error (ie, no error, minor error or moderate/severe error). The cluster variable was patient within ward. The analysis was controlled for drug characteristics (type of preparation, type of intravenous (IV) administration (ie, as a short IV/bolus dose or as an infusion), and ATC class (Anatomical Therapeutic Chemical) according to the ATC/WHO classification (http://www.whocc.no/atc_ddd_index)), administration time (day of the week, drug round), ward, observer on the ward and period (ie, time effect) to eliminate possible imbalances between wards and periods. The interaction term between ward and period in the model represents the intervention effect.

Data were analysed using SPSS statistical package V.20.0 (SPSS, IBM, Somers, New York, USA).

RESULTS

A total of 516 intravenous doses were included during the baseline period (236 on ICU and 280 on PSU) and 688 during the follow-up period (407 on ICU and 281 on PSU). The most frequently observed medications belonged to the blood/blood forming and anti-infective classes. The most common errors were wrong administration technique and wrong preparation technique (Table 2).

Examples of errors are given in online supplement appendix 1. On the intervention ward (ICU), the prevalence of clinically relevant errors decreased significantly from 64.0% to 48.9% ($p < 0.001$, χ^2 test). On the control ward (PSU), there was no change in the prevalence of clinically relevant errors (57.9% vs 64.1%; $p = 0.132$, χ^2 test) (Table 3).

Table 2. Prevalence as percentage (95% CI) of different error types observed during baseline and follow-up periods*

Error type	ICU (intervention ward)		PSU (control ward)	
	Baseline (n=236)	Follow-up (n=407)	Baseline (n=280)	Follow-up (n=281)
Wrong drug	0.4 (0.0 to 1.2)	0.0	0.4 (0.0 to 1.1)	0.0
Wrong dose	11.4 (7.3 to 15.4) [#]	2.2 (0.8 to 3.6) [#]	6.1 (3.3 to 8.9)	4.6 (2.2 to 7.0)
Wrong dosage form	0.0	0.0	0.0	0.0
Deteriorated drug	7.2 (3.9 to 10.5) [#]	0.7 (0.0 to 1.5) [#]	2.1 (0.4 to 3.8) [#]	0.0 [#]
Wrong preparation technique	28.4 (22.6 to 34.2) [#]	14.0 (10.6 to 17.4) [#]	14.3 (10.2 to 18.4) [#]	26.3 (21.2 to 31.4) [#]
Omission	1.3 (0.1 to 2.7)	0.2 (0.0 to 0.6)	1.4 (0.0 to 2.8)	3.9 (1.6 to 6.2)
Unordered drug	2.1 (0.3 to 3.9)	2.7 (1.1 to 4.3)	4.3 (1.9 to 6.7) [#]	0.7 (0.0 to 1.7) [#]
Wrong administration technique	44.9 (38.6 to 51.2)	46.9 (42.1 to 51.7)	61.4 (55.7 to 67.1)	54.1 (48.3 to 59.9)

*The sum of error rates exceeds the overall prevalence of errors as more than one type of error could be associated with each dose.

[#]Significant difference between baseline and follow-up (based on 95% CIs).

ICU, intensive care unit; PSU, post-surgical unit.

Table 3. Prevalence (95% CI) of clinically relevant errors

Ward	Period	Number of doses	No error	Minor error	Clinically relevant error
ICU	Baseline	236	32.6% (26.6 to 38.6)	3.4% (1.1 to 5.7) [#]	64.0% (57.9 to 70.1) [#]
	Follow-up	407	41.5% (36.7 to 46.3)	9.6% (6.7 to 12.5) [#]	48.9% (44.0 to 53.8) [#]
PSU	Baseline	280	27.1% (21.9 to 32.3)	15.0% (10.8 to 19.1)	57.9% (52.1 to 63.7)
	Follow-up	281	26.7% (21.5 to 31.9)	9.2% (5.8 to 12.6)	64.1% (58.5 to 69.7)

[#]Significant difference between baseline and follow-up (based on 95% CIs).

ICU, intensive care unit (the intervention ward); PSU, post-surgical unit (the control ward).

The GEE analysis showed that drug characteristics (type of preparation, $p < 0.001$; type of intravenous administration, $p < 0.001$; and ATC class, $p = 0.038$) were all significant, but administration time (day of the week, $p = 0.853$; drug round, $p = 0.438$), observer on the ward ($p = 0.295$), and period ($p = 0.274$) were not. Ward was significant ($p = 0.004$) and the OR for the interaction term between ward and period (ie, intervention effect) was 2.60 (1.27–5.31), indicating that the educational programme was significantly effective in reducing clinically relevant errors ($p = 0.013$).

DISCUSSION

The training programme was effective, with intravenous doses on the intervention ward being 2.6 times less likely to have clinically relevant medication errors as compared with pre-intervention/baseline. However, the overall error rate remained high, with about half of all intravenous doses having a potentially clinically relevant error. This may partly be due to the wards chosen for study, as the ICU has been reported to be an error-prone environment due to critically ill patients, heavy workload and complex clinical care (Bracco *et al.* 2001; Valentin *et al.* 2009). A study in a Chilean ICU evaluating an intervention with a similar educational component, also showed a considerable reduction in error rates. However, the results are difficult to compare in more detail because of the many differences between the two studies (eg, the Chilean researchers also included prescribing errors, did not have a control group, etc) (Romero *et al.* 2013). There is a lack of other research on intravenous medication errors in resource-restricted settings for comparison with our results.

In line with previous studies evaluating educational interventions (Ford *et al.* 2010; Chedoe *et al.* 2012; Manias *et al.* 2012) the training programme was effective. However, poor medication safety is still a big problem. Preparation errors (including wrong dose, deteriorated drug, wrong preparation technique) were successfully reduced, but administration errors were approximately similar in both periods (Table 2), although administration procedures were part of the training programme. These mistakes mainly concerned bolus doses which were injected in less than 1 min instead of 3–5 min (examples are given in online supplementary appendix 1). Such errors might be related to contextual factors, such as workload (eg, many doses had to be given in a limited time), which are not changed by education. However, they might be reduced by other measures, for example, changes in working procedures (taking more time for drug administration, using short infusions to administer some medications) (Cousins *et al.* 2005).

In addition, promoting a safety culture around medication, including drug preparation and administration, may be relevant. This could be achieved by increasing awareness of errors by emphasising the risks of inappropriate practice including fast drug administration, and introducing error reporting (Barber *et al.* 2003; Pierson *et al.* 2007; National Patient Safety Agency 2010).

Other strategies including technical interventions (implementation of electronic prescribing system, bar-code medication administration) and ready-to-use products (which are not always available for all medications) have been recommended to prevent medication errors (McDowell *et al.* 2010; Pham *et al.* 2012). However, little is known about which of these interventions are most successful in a specific setting. There is a need to balance evidence from research and experience in the local context (ie, whether the intervention is feasible and accepted by nursing/local staff) (Hughes 2008). More importantly, in the restricted-resource settings, the cost of an initiative is an important factor.

Clinical pharmacists have been shown to improve the quality of patient care, for instance by reducing medication errors and (potential) adverse drug events (Kaboli *et al.* 2006; Brown *et al.* 2008; Abbasinazari *et al.* 2012; Mueller *et al.* 2012). Our study strengthens the evidence for the relevance of clinical pharmacy in a resource-restricted setting such as Vietnam. The success of our intervention was due not only to the pharmacist, but also to the willingness and efforts of the ward staff, especially the nurses. This underlines the importance of a collaborative approach. In practice, successful implementation of quality improvement strategies needs a multidisciplinary team with strong leadership endorsed by hospital managers (Hughes 2008).

A rigorous study design (ie, a quasi-experimental design with a control group) and sophisticated data analysis were used. Potential imbalances between the two wards and two periods in drug characteristics (type of preparation, type of intravenous administration (ie, as a short IV/bolus doses or as an infusion), and ATC class) and administration time (day of the week, drug round) were taken into account in the analysis. The time effect (ie, changes over time) was controlled by the effect of period. During the post-intervention period, more patients were admitted to the ICU (intervention ward), and hence a higher number of intravenous doses was observed. Several studies suggested that a higher workload is associated with a higher error rate (Tissot *et al.* 2003; Berdot *et al.* 2012), whereas we found a lower medication error rate. We are confident that the educational intervention produced the effect found in the study setting. We therefore recommend conducting this training programme in similar settings as a first step to improving medication safety.

Our study has some limitations. Observers were blinded as to the true nature of the study, but they may have learnt from nurses on the intervention ward about

the training sessions. We included “observer” in our statistical model, but this was not significant and so we believe that this has not influenced our results. As in other observation-based studies on medication errors (Keers *et al.* 2013), information about the actual harms arising from errors was not collected. Furthermore, we have not investigated the long term effect of the training programme (ie, if the change was maintained over time). There is a risk that healthcare providers return to baseline practice, so on-going efforts are needed, for example, to keep materials (guidelines/protocols) updated (Fan *et al.* 2010). Further research examining how often the training programme should be repeated is required.

CONCLUSIONS

The pharmacist-led training programme was effective in reducing clinically relevant intravenous medication errors, but the error rate remained relatively high. Further quality improvement strategies are needed and should include other approaches such as changes in the working environment and the promotion of a safety culture.

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COMPETING INTERESTS

None.

ETHICS APPROVAL

The study was approved by the medical ethics committee, management board and ward managers of Gia Dinh Hospital in Ho Chi Minh city, Vietnam.

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