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Medication safety in Vietnamese hospitals

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CHAPTER 7

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

SUMMARY OF THE RESULTS

Patient safety in health care in low- and middle-income countries receives recently more attention, but is still a relatively neglected area with little knowledge about medication safety (Jha *et al.* 2010; Wilson *et al.* 2012). Our research addressed quality use of medications in South-East Asia by reviewing indicators assessing prescribing, dispensing and utilization of medicines. These indicators were infrequently used and the results indicated a sub-optimal quality use of medicines and raised the need of new valid, reliable and feasible indicators, especially for non-communicable diseases (Chapter 2). The extent and associated factors of medication preparation and administration errors in the specific setting of Vietnamese urban public hospitals were explored. Potentially clinically relevant errors occurred in a third of all medication preparations and administrations. Errors were likely to occur in intravenous medications, especially involving complex preparation procedures. Administration time (drug round and day of the week) was also associated with errors, but nursing experience was not (Chapter 3). In a sub-study we investigated errors involving insulin, because these carry a high risk of harm (i.e. a high-alert medication). We found that one or more errors occurred in about one-third of insulin doses. All erroneous doses were considered having potentially clinically moderate to severe outcomes (Chapter 4). Clinically relevant intravenous medication errors could be reduced by an educational training programme focusing on the most common types of errors such as wrong preparation/administration technique (Chapter 5). Despite the high level of medication problems, nurses were neutral or even positive in their perception of safety culture in their hospitals, and only few recognized stress as a factor which could affect their performance. They did have concerns about safety climate. Therefore it is not surprising that perception of safety culture was not correlated to medication errors in general. Only one item appears to be relevant, intravenous medication error rates were associated with difficulty of discussing errors (Chapter 6).

METHODOLOGY OF DETECTING AND SCORING THE SEVERITY OF MEDICATION ADMINISTRATION ERRORS

Direct observation was used to detect medication administration errors. This technique was developed about fifty years ago by Barker and McConnell (1962); since then it has been recognized as the “gold standard” (Dean & Barber 2001; Flynn *et al.* 2002) and used in various studies (Keers *et al.* 2013; Berdot *et al.* 2013). Briefly, a trained observer asked the nurse in charge for permission to observe,

followed the nurse, and noted down all details of medication preparations and administrations. The notes were compared with doctors' prescriptions, hospital policies/procedures or manufactures' instructions to detect any discrepancies which were defined as medication errors. The observation method is considered superior to other approaches for investigating medication errors such as anonymous self-reports, incident reports (including voluntary reports), the critical incident technique, chart review, as it is more sensitive in detecting errors, is independent of people's willingness to report or awareness of errors occurrence (Barker & McConnell 1962; Flynn *et al.* 2002; Barker *et al.* 2002). Observation explores people's actual behaviour rather than what they intend to do or think they do as do many other methods.

A main limitation of direct observation is the Hawthorne effect (i.e. effect of the observer on the person being observed) (Allan & Barker 1990). It has been confirmed that the person being observed would get familiar with the observer after a while and return to his/her usual behaviour (Allan & Barker 1990). In our study we tried to neutralize such effects by including a one-day observation pilot on each study ward before starting the main study. This helped the observers get familiar with ward routines (staff, medications, devices, schedules of drug rounds) and nursing staff get comfortable with someone being around (Allan & Barker 1990). We kept the study "disguised", i.e. nurses were asked for permission to observe, but were not informed about the true purposes of the study. They were told that the observer was a pharmacy student who wanted to learn more about ward-based drug preparation and administration. In this respect, it is important to emphasize that nurses' and patients' identities were anonymized and kept confidential. The observers only intervened in case of potentially serious medication errors in a non-judgmental manner. Using pharmacy students fits well with local context. The staff, especially nurses in the study hospitals were used to students (nursing, medical and pharmacy) being around. It would have been more difficult to explain the presence of hospital pharmacists or outside researchers. Also, the observers showed their willingness to learn from nursing staff about clinical/practical issues in medication preparation and administration by talking informally with nurses when they had completed the observation. This created a friendly and comfortable environment between the observer and the observed. In addition, data were collected on seven consecutive days which should further reduce the Hawthorne effect as nurses become more familiar with the observers. To finally overcome observer bias, we carefully trained the pharmacy students for one week

prior to starting the study. This ensured that observers used the same definition of an error. Moreover, all data were revised by the experienced researcher. In the light of education, observation of drug administration rounds could be integrated in the curriculum of nursing, medical, and pharmacy schools/universities to teach students practical issues of medication safety.

Another limitation of the observation approach, the limited time frame of data collection, is more difficult to overcome, because of the labour intensive nature of the observation technique. We collected data for one week on each ward, covering six wards in total. Among observation based studies this is a rather large study (Keers *et al.* 2013; Berdot *et al.* 2013). However, within such a short time frame it is unlikely to study rare events. This means that complementary study methods should be employed to study such events, for example incident reporting (see clinical implications).

Different methods have been used to study the clinical impact of errors (Keers *et al.* 2013). We used a valid and reliable method for scoring severity of medication errors developed by Dean & Barber (1999). Briefly, four healthcare professionals (one doctor, one nurse, and two pharmacists) who had at least 5 years working experience in the hospitals scored the potential clinical outcome of each medication with one or more errors (i.e. erroneous dose) using a 10-point scale between zero (*no harm*) and 10 (*death*). The mean score was calculated, a value below 3 suggested a minor outcome, of 3-7 a moderate outcome, and above 7 a severe outcome (Dean & Barber 1999). The method is quick and does not require the knowledge about actual patient's harm. The raters do not need to be trained as they are experienced healthcare professionals. This method has been used in previous studies on medication errors (Taxis & Barber 2003; Chedoe *et al.* 2012). The majority of potentially clinically relevant errors were considered as moderate and few were judged to be of minor or severe outcome. This pattern is somehow in contrast to previous studies where relatively more cases were judged to be minor (Taxis & Barber 2003; Chedoe *et al.* 2012). A possible explanation for this is that difference in culture may affect the view on (consequences of) medication errors. For example, a study validating this scoring method in German setting found that the German healthcare professionals gave lower mean scores compared to the UK ones (Taxis *et al.* 2002), implying German raters judged the cases in general as less harmful than did their UK peers. In the Asian culture, people may tend to have neutral judgments, avoid extreme opinions which may yield adverse effects on intra-group harmony and in-group solidarity (Wagner *et al.* 2013; Fujita *et al.* 2013).

IMPLICATIONS FOR FUTURE RESEARCH

Interventions to reduce medication errors

Educational interventions have shown a reduction in medication errors in high-income countries (Chedoe *et al.* 2012; Ford *et al.* 2010; Manias *et al.* 2012) and in lower-income countries as well (Romero *et al.* 2013). Our training programme focusing on the most error-prone stages (i.e. reconstitution and injection) strengthens the evidence for the impact of educational intervention on reducing clinically relevant intravenous medication errors in a resource-restricted setting (a Vietnamese hospital) (Nguyen *et al.* 2014b). This suggests that the educational programme could be employed as a first practical step to improving medication safety in similar settings. However, the long term effect of the education has not been investigated so far. There is a risk that healthcare providers return to baseline practice, so on-going efforts are needed, e.g. to keep materials (guidelines/protocols) updated (Fan *et al.* 2010). Further research examining how often the training programme has to be repeated is needed. In addition, the error rate remained high after implementation of the training programme suggests further investigations of other interventions to reduce medication errors. This should focus on errors involving high-alert medications as insulin. For instance, researchers can test the impact of employing dedicated nurses responsible for insulin preparation and administration (Walden 2010) or the effect of using additional labels for distinguishing insulin products (Dooley *et al.* 2011). The evidence-base for many of interventions to improve medication safety is weak and cost effectiveness has not been evaluated in the context of resource-restricted settings. This needs to be addressed in future research.

Safety culture

Building a culture of safety has been recommended as a crucial aspect of any high reliability organization in health care (Chassin & Loeb 2011). In the trend of growing attention to patient safety, hospitals are encouraged to measure safety culture regularly as the first step to promote patient safety (Pronovost *et al.* 2005; National Patient Safety Agency 2009), usually using staff attitude surveys (Colla *et al.* 2005; Pronovost & Sexton 2005; Halligan & Zecevic 2011). Among several available tools, the safety attitudes questionnaire (SAQ) developed by University of Texas with robust psychometric properties (Sexton & Thomas 2003; Sexton *et al.* 2006;

Jackson *et al.* 2010) is one of the most widely tested, well validated and frequently used measures (The Health Foundation 2011). It covers six domains: teamwork climate, safety climate, job satisfaction, stress recognition, perception of management, and working condition (Sexton & Thomas 2003; Sexton *et al.* 2006). The SAQ has been used in various settings to establish benchmarks, to evaluate safety improvement interventions (Colla *et al.* 2005; The Health Foundation 2011; Chaboyer *et al.* 2013; Meurling *et al.* 2013; Profit *et al.* 2012). We selected this tool for our study as it is relatively short, easy to complete and can be adapted to various contexts (The Health Foundation 2011). Furthermore, based on previous studies, it is more likely to show a link between safety culture scores and patient and staff outcomes compared to other tools (The Health Foundation 2011).

Our assessment of nurses' perception of safety culture should be considered as one of the first baseline measurements in a resource-restricted setting. We hope that our study sparks discussions of safety culture in other similar health care organizations/hospitals, and interventions/strategies/policies to promote safety culture should be designed, tested and monitored. Moreover, the fact that we did not find a correlation between medication errors and safety culture (Chapter 6) does not mean that this is not there. The relationship may be either indirect or more complex. For instance, the association between safety climate and medication errors has been shown to be moderated by the complexity of patient conditions (Hofmann & Mark 2006). Furthermore, safety culture measured by the SAQ is a broad concept encompassing other medical safety issues rather than medication errors. Nurses in our study were quite optimistic about safety culture in their hospitals in spite of the high prevalence of medication errors. So, it is understandable that perception of safety culture was not correlated to medication errors. Further theoretical work is needed to investigate which aspects of safety attitude are (if at all) related to medication errors.

IMPLICATIONS FOR CLINICAL PRACTICE

Role of the clinical pharmacist in improving medication safety in hospitals

Clinical pharmacists in hospitals have been shown to be able to reduce medication errors and (potential) adverse drug events (Kaboli *et al.* 2006; Brown *et al.* 2008; Abbasinazari *et al.* 2012; Mueller *et al.* 2012). Recent studies strengthen the evidence of the relevance of clinical pharmacy also in resource-restricted settings (Romero *et al.* 2013; Nguyen *et al.* 2014b). In Vietnam, the practice of clinical

pharmacists has just started recently and their roles in the healthcare system are not well recognized so far (Vo *et al.* 2013). The role of the pharmacist has been expanding from dispensing medications to providing services about medication management to support rational drug use and to promote patient safety (Vo *et al.* 2013). With the development of more and more complex medications (new agents, various dosage-forms and usages), it is likely that this role will continue growing to support other healthcare providers and receivers to make optimal use of available resources and to achieve expected therapeutic outcomes. Our study showed that the clinical pharmacist-led intervention was successful, but there is still room for improvement of medication safety (the error rate remained high after the intervention). Furthermore, our assessment of safety culture suggested that there should be regular discussions about medication errors among healthcare professionals. The pharmacists should implement educational activities as discussed above, but in addition initiate the following measures (Klopotowska *et al.* 2011; Klopotowska *et al.* 2010; Pierson *et al.* 2007):

- Periodic assessment (audits) of the medication safety in a quality assurance program based on observation sheets.
- Multidisciplinary ward-based discussions of medication errors (clinical case conferences).
- Implementation of a (medication) error reporting system, especially to tackle rare and serious events.

Information from all of the above initiatives could be used to develop further tailor-made interventions. However, unfortunately 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 (i.e. whether the intervention is feasible and accepted by nursing/local staff) (Hughes 2008). In practice, successful implementation of quality improvement strategies needs a multidisciplinary team (was successful in our own study) with strong leadership endorsed by hospital managers (Hughes 2008). In this respect, hospitals should consider a comprehensive approach to manage the quality of care, which put people, process and products together in order to get optimal healthcare outcomes. In other words, these efforts should lead into the implementation of a quality control group in the hospital (Chang *et al.* 2010; Wang *et al.* 2013). This group should involve relevant people with different expertise, maybe the best solution for hospitals with scarce resources is to optimize the function of Drug and Therapeutic committee which is already established in most (if not all) hospitals. A clinical/hospital pharmacist should be a member of this multidisciplinary medical team and have the lead for medication safety and shared responsibility for overall safe patient care.

Sufficient attention to/more research on non-communicable diseases in South-East Asian countries

Health and related matters in South-East Asian countries are an emerging focus for global health. The region is dealing with an increasing burden of non-communicable diseases including diabetes and a rising demand for high quality health care (Acuin *et al.* 2011; Chongsuvivatwong *et al.* 2011; Coker *et al.* 2011; Dans *et al.* 2011; Kanchanachitra *et al.* 2011). So far, attention to patient safety is insufficient due to poor health system infrastructure and inadequately trained healthcare staff (Wilson *et al.* 2012). Our systematic review revealed sub-optimal quality use of medicines in South-East Asia and the need of valid and reliable indicators focusing on non-communicable diseases (Nguyen *et al.* 2012). In addition, high prevalence of errors involving insulin therapy was observed in the hospital setting. About a third of insulin doses was used in errors with potentially moderate/severe outcome (Nguyen *et al.* 2014a). These findings stress that medication use in non-communicable diseases in the South-East Asia needs attention. A start could be to develop/adopt adequate guidelines (e.g. WHO guideline) for this area (WHO 2012; American Diabetes Association 2014). For example in Vietnam, a national or hospital treatment guideline for diabetes should be developed to promote appropriate prescribing (Beran 2008). Changes in quality of care could be monitored by using/adopting existing valid and reliable quality indicators related to diabetes mellitus and cardiovascular diseases, particularly the ones relevant to the local practice and culture to assess/monitor medicine use and quality of care (Martirosyan *et al.* 2010). As non-communicable diseases require long-term treatment and patient involvement, it is relevant to investigate patient adherence and/or to test/promote a patient education programme encouraging adherence to therapy and appropriate medicine use (Murray *et al.* 2007; Holloway & van Dijk 2011).

CONCLUSIONS

Interest in medication safety has grown remarkably since publication of the report *To Err is Human* (Stelfox *et al.* 2006). There have been numerous studies on medication errors conducted worldwide. The majority of evidence about (preventing) medication preparation and administration errors is from developed countries such as in the USA, in the UK or in the Netherlands (Keers *et al.* 2013; Berdot *et al.* 2013). In such countries, patient safety issues have been recognized a long time ago and efforts to increase medication safety such as implementation of electronic prescribing systems, barcoding, and involving clinical pharmacists at

the ward level are on-going (Duckers *et al.* 2009). Much less is known about medication errors in resource-restricted settings including Vietnam. Because of differences in local practice, resource and culture, lessons learnt from other nations are not always applicable, especially the interventions employing expensive technology-based approaches. Every country seems to need some studies on assessing the safety of medication use and tailor-made strategies to improve the situation.

Medication safety in South-East Asian countries including Vietnam remains a neglected area with a limited number of studies explicitly using quality indicators, but those few studies show a sub-optimal quality use of medicines. We found that about one-third of all medications prepared and/or administered were erroneous including high-alert medications as insulin. Our educational training programme was effective in reducing clinically relevant intravenous medication errors, especially the most common types of errors such as wrong preparation technique. Nurses perceived safety culture in general as neutral to slightly positive, but had concerns about safety climate and were rarely aware that stress may influence their performance. Medication error rates were associated with difficulty of discussing errors, but there was no correlation between safety culture domains and medication errors rates.

We hope that our results will trigger research on medication safety including non-communicable diseases and prompt managers and healthcare providers in Vietnam and similar countries in South-East Asia to review their own processes and systems to improve medication use.

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