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Medication safety in Vietnamese hospitals

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CHAPTER 1

GENERAL INTRODUCTION

BACKGROUND

Medication safety in developing countries

Medication safety is an issue worldwide (Jha *et al.* 2010; Jha *et al.* 2013). It is estimated that more than half of all medicines over the world are prescribed, dispensed or sold inappropriately (WHO 2010). In high-income countries, this has been recognized a long time ago and a lot of efforts are dedicated to improve medication safety (Institute of Medicine 1999; Stelfox *et al.* 2006). Much less is known about medication safety in low- and middle-income countries (Jha *et al.* 2010). One of the few large studies in such countries found that 2.5% to 18.4% of hospital admissions were associated with an adverse event and about 30% of those resulted in the death of the patient which was much higher than those in high-income countries. Poor health system infrastructure, inadequately trained healthcare staff, and insufficient safety culture probably contributed to this (Wilson *et al.* 2012).

Vietnam

In South-East Asia, health and related matters have recently emerged as a focus of global health (Acuin *et al.* 2011; Chongsuvivatwong *et al.* 2011; Coker *et al.* 2011; Dans *et al.* 2011; Kanchanachitra *et al.* 2011). The region is dealing with the challenge of an increase in non-communicable diseases and of a growing demand for high quality health care. However, the quality use of medicines or explicit methods to measure quality has not been addressed so far. Vietnam is a relatively small country located in the region and borders Laos, Cambodia and China (Central Intelligence Agency 2014). After the implementation of reform policy (*Đổi mới*) in late 1980's, Vietnam has had a rapid growth in economy (Giang 2011; U.S. Government 2011; United Nations Statistics Division 2014). Along with that, there were remarkable improvements in the nation's health such as an increased life expectancy and a significantly decreased child mortality rate (Giang 2011; Nguyen & Hoang 2013). However, there are still many health-related challenges including a rising burden of illness (with non-communicable diseases replacing infectious diseases as a major cause of death), an ageing population, inequities in access to healthcare services, and insufficient capacity of healthcare system (Giang 2011; U.S. Government 2011; Nguyen & Hoang 2013; WHO 2011; Nhung *et al.* 2013). There is a growing demand of better medical

care and concerns about quality and safety of healthcare services (Giang 2011; U.S. Government 2011). Ensuring affordability and quality is a national priority and much effort of managers and policy makers has been invested to support this, especially concerning rational use of medicines. Two examples: all pharmacies are asked to comply with standards of Good Pharmacy Practice and a Drug and Therapeutics committee is required in every hospital (Vietnam Ministry of Health 2011; Vietnam Ministry of Health 2013). Unfortunately, such regulations have not worked sufficiently (Nguyen *et al.* 2013). In recent years, the practice of clinical pharmacy has started, but the roles and activities of clinical pharmacists are still invisible in the health system. Improvements are needed to promote quality and safety of health care (Vietnam Ministry of Health, Department of Drug Administration 2009; Vietnam Ministry of Health 2012; Vo *et al.* 2013).

Measuring quality and safety of medicines

In order to improve quality and safety of health care, the first step should be to explore the extent of the current problems, so that strategies for improvement can be targeted to these specific problems. In the area of medicine use, regular monitoring with quality indicators has been recommended to evaluate and improve quality (Quick *et al.* 1997). Second, the wider context, underlying and associated factors of such problems have to be explored. In practice, combining different approaches is often suggested to get better insight into the current problems, and as such, increases the likelihood of success in improving quality and safety of patient care (Quick *et al.* 1997; Garrouste-Orgeas *et al.* 2012).

Indicators are explicitly defined and measurable items related to the structure, process or outcome of care (Berg *et al.* 2005; Kerr & Fleming 2007; Campbell *et al.* 2003; Mainz 2003; Majeed *et al.* 2007). In the area of quality of medicine use, indicators have been used as a tool for policy-makers and healthcare managers to assess and monitor the extent of rational medicine use, to compare differences across facilities, districts or regions, to analyse changes over time and to evaluate interventions (Quick *et al.* 1997; Majeed *et al.* 2007; Hogerzeil 1995; Laing *et al.* 2001). The first set of indicators measuring quality use of medicines and prescribing behaviour in health facilities was developed over three decades ago by the WHO in collaboration with the International Network for Rational Use of Drugs (INRUD) (Hogerzeil *et al.* 1993; WHO 1993). These indicators are widely accepted as an objective standard method to assess rational use of medicines and have been used in over 30 countries, mainly in the developing world (Laing *et al.* 2001; WHO 2004; WHO 2009). After that, indicators addressing the

pharmaceutical situation of countries including rational medicine use (WHO 2007b) and the use of medicines at household level (WHO 2007a; WHO 2011) were also published. Apart from the widely used WHO indicators, measures of quality use of medicines for specific diseases like asthma or diabetes have been developed and applied in developed countries (Martirosyan *et al.* 2010; To *et al.* 2010). As highlighted above, little is known about quality use of medicines in Vietnam as well as in South-East Asia, especially whether existing indicators are suitable for the current medical challenges.

For much of this thesis a specific area of quality indicators has been chosen, medication errors, more specifically, medication administration errors in the hospital setting (Ross *et al.* 2000; Krahenbuhl-Melcher *et al.* 2007). Medication errors may cause serious harms during hospitalization as they are associated with injury as well as additional hospital stays and costs. Further, such errors can cause fear in patients and in healthcare providers, especially nurses (Institute of Medicine 1999). Medication administration errors have been defined as deviations in preparation and administration medications from the doctor's prescriptions, the hospital policies and procedures or the manufacturer's instructions (Berdot *et al.* 2013; Keers *et al.* 2013b). Several approaches are used to study medication administration errors, among which, observation technique is considered as the "gold standard" (Barker & McConnell 1962; Barker *et al.* 2002; Flynn *et al.* 2002). There have been numerous studies on medication administration errors using observation method conducted worldwide, mainly in developed countries including the United States, the United Kingdom and the Netherlands (Berdot *et al.* 2013; Keers *et al.* 2013b). Two recent systematic reviews show median error rates between 8% and 10% (excluding time errors) (Berdot *et al.* 2013; Keers *et al.* 2013b). Two small scale studies, each including about one thousand preparations and administrations, have been carried out in a Malaysian hospital (Chua *et al.* 2010; Chua *et al.* 2009). Error rates were around 8% which is comparable to the median error rate reported recently (Keers *et al.* 2013b).

Various factors have been reported influencing medication errors such as knowledge/experience of staff and organizational culture (Keers *et al.* 2013a). Medication characteristics, for example, administration route and drug class have also been identified as error-related factors (Keers *et al.* 2013b; Chua *et al.* 2009). However, the majority of studies included only a limited number of factors using univariable analysis and/or did not take into account possible interactions between them. Also, the clinical relevance of errors was not investigated in all studies.

Many different technology-based interventions (for instance, "closed-loop systems" with bar-coded drug administration) have been suggested to reduce medication administration errors (Duckers *et al.* 2009; Pham *et al.* 2012). How-

ever, differences in local practice, resource and culture mean that lessons learnt from other nations are not always applicable. Although technology-based interventions have the potential to reduce medication errors, their implementation is not simple. New risks may occur, if the implementation is not carried out adequately. Moreover, technology-based interventions require considerable investments that are not available in many institutions in lower-income countries such as Vietnam. The benefits of clinical pharmacists in improved quality, safety and efficiency of patient care have been acknowledged a while ago, mainly in high-income countries (Kaboli *et al.* 2006). A recent study conducted in Chile reported the success of clinical pharmacist's interventions in reducing medication errors (Romero *et al.* 2013). This strengthens the evidence about the role of clinical pharmacists even in a resource-restricted setting (i.e. a lower-income country). More studies about effective interventions in similar settings are needed. As mentioned earlier, in Vietnam, the concept of clinical pharmacy has just been introduced recently and the performance of clinical pharmacist is less recognized. This suggests that clinical/hospital pharmacists should more actively participate in and share the responsibility of medical care, so that they can prove the advantages of clinical pharmacy services. One of the most feasible services which clinical pharmacists could start is enhancing quality use of medicines, for example promoting the appropriateness of medication administration, since they are known as experts in the therapeutic use of medications.

It has been widely accepted that a medication error is not only caused by human factors, but also affected by the working environment. One of the various system factors reported influencing medication errors is safety culture in an organization (Keers *et al.* 2013a). Safety culture refers to how patient safety is perceived and implemented within an organization, and the structures and processes in place to support this (The Health Foundation 2011). Establishing a culture of safety has a high priority in healthcare in developed countries (Chassin & Loeb 2011). Usually, safety culture is measured as a guide for quality improvement efforts using surveys such as the safety attitudes questionnaire (Colla *et al.* 2005; Pronovost & Sexton 2005; Halligan & Zecevic 2011). There have been studies reporting the association between safety culture and hospital morbidity, adverse events or readmission rates (Valentin *et al.* 2013; Singer *et al.* 2009; Hofmann & Mark 2006; Clarke 2006; Pronovost *et al.* 2005). Other studies have found no relationship between safety culture and patient outcomes (Rosen *et al.* 2010; Bosch *et al.* 2011). Limited evidence from low- and middle-income countries shows that there is a deficiency of safety culture and this is compromising patient safety (Jha *et al.* 2010; Wilson *et al.* 2012). Little work has been done showing the link between safety culture and medication errors (Hofmann & Mark 2006; Vogus & Sutcliffe 2007). Medication errors in these studies

were investigated using medical records (Hofmann & Mark 2006) or error reporting (Vogus & Sutcliffe 2007). These methods are known to underestimate the rate of medication administration errors due to underreporting/lack of documentation of type of errors in medical records (Flynn *et al.* 2002). More studies investigating the relationship between safety culture and medication administration error rates are needed to identify appropriate approaches to improve medication safety of this step in the process of drug use.

RATIONALE AND OBJECTIVES OF THIS DISSERTATION

This dissertation focuses on medication safety in South-East Asian countries, especially in Vietnam. Measuring safety e.g. by using indicators is a first step, but little is known about the extent of using indicators of quality use of medicines in South-East Asia. This forms the start of this thesis. The focus of the other parts of this thesis is on administration errors on hospital wards as a specific type of indicator of the quality use of medicines in the hospital setting. The extent of the problem (i.e. how many errors occur?) and the wider context (i.e. what are factors contributing to errors including the safety culture?) are studied as well as the effects of an intervention to improve medication safety. This thesis has been inspired by the wish to gain more insight into medication safety issues in Vietnamese hospitals and contribute to the development of the role of the clinical pharmacist in improving medication safety (which has been also the global aim of the Nuffic project under which this thesis has been funded). Therefore, the objectives of this thesis are:

1. To identify studies explicitly using indicators of quality use of medicines in the South-East Asian region answering the following three research questions: (i) which indicators have been used; (ii) what is known about the validity, reliability and feasibility of the existing indicators; and (iii) what are the main results based on the commonly used indicators?
2. To determine the prevalence and potential clinical outcome of medication preparation and administration errors in two Vietnamese hospitals and to identify associated factors in a multifactorial model.
3. To measure the effect of a clinical pharmacist-led training programme on clinically relevant errors in intravenous medication preparation and administration in a Vietnamese hospital.
4. To measure nurses' perception of safety culture in two public hospitals in Vietnam and to assess the association between this perception and the prevalence of intravenous medication errors.

OUTLINE OF THIS DISSERTATION

Chapter 2 systematically reviews studies explicitly using indicators of quality use of medicines in the South-East Asian region focusing on which indicators have been used and the validity, reliability and feasibility of the existing indicators. Additionally, the main results based on commonly used indicators are summarized.

Chapter 3 determines the prevalence and potential clinical outcome of medication preparation and administration errors in two urban public hospitals in Vietnam and identifies factors associated with errors.

Chapter 4 investigates the prevalence, type and potential clinical outcomes of errors in preparation and administration of insulin in two urban public Vietnamese hospitals.

Chapter 5 assesses the effect of an educational training programme on clinically relevant errors in intravenous medication preparation and administration in a Vietnamese hospital.

Chapter 6 presents the results of a survey on nurses' perception of safety culture across two public hospitals in Vietnam and an investigation of whether there is an association between safety culture and the prevalence of intravenous medication errors.

Finally, **Chapter 7** summarizes and discusses the main findings of the thesis as well as proposes implications for clinical practice and future research.

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