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Learning from Medication Errors in Healthcare – How to Make Medication Error Reporting Systems Work?

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ACADEMIC DISSERTATION

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Abstract

Medication errors are one of the most common incidents leading to adverse events in healthcare worldwide. Tackling these major problems requires the implementation of a systems approach to healthcare, stating that risks should be managed proactively by improving the healthcare system. One of the recommended key strategies for learning from medication errors and risk prone processes is the establishment of local and national medication error reporting (MER) systems in healthcare.

This study explored national and local MER systems in different countries and what makes them work in learning from medication errors. The study also explored how continuing education in medication safety could be organised for practicing healthcare professionals. The study applied both qualitative and quantitative research methods and utilized various data sources. The study was based on the theory of Human Error and the systems approach to risk management.

The study comprised of three phases. Phase I explored the existing MER systems in different countries and their development and implementation. 16 medication safety experts from different countries responded to an online-survey. A national or local MER system existed in 11 of the countries. Blaming for errors, and a lack of time, training and coordination of reporting continue to be the major barriers to reporting. Learning from errors and a non-punitive approach are essential features of a MER system. There is also a need for promoting international networking of medication safety experts and bodies for sharing information and learning from others. Several factors associated with the successful development and implementation of MER systems were also identified.

Phase II assessed the inter-rater reliability of medication error classifications in a voluntary Reporting System for Safety Incidents in Health Care Organizations (HaiPro) widely used in Finland. Also medication errors (n=32 592) reported in 2007-2009 and their contributing factors were explored. The inter-rater reliability was found acceptable ($\kappa \geq 0.41$) in 11 out of 42 (26%) variables (e.g., near miss or actual error) describing the reported medication errors. Thus, the medication errors reaching the acceptable level of inter-rater reliability could be pooled from different healthcare units for the exploration of medication errors at the level of all reporting organisations. The most frequently reported medication errors were: dispensing errors (33%, n=10 906); administration errors (24%, n=7 972); and documentation errors (17%, n=5 641). The most commonly reported contributing factor was deficiencies in communication and course of information related to patients' medications.

In Phase III educational approaches were developed for introducing medication safety for healthcare professionals as a three-day interdisciplinary course. International higher education experts in pharmacy (n=19) brainstormed four syllabi with teaching and assessment methods. Following this, a combined syllabus was developed. All four syllabi were based on constructive, problem-based learning methods and focused on understanding a systems approach in managing medication safety. Learning linked to learners' practice through assignments at the workplace appeared to be the key.

The study suggests that MER systems need to be improved in many countries together with their operational environments. Moreover, the operational environments of MER systems must support the functionality of these systems. The key factor for successful MER

systems and learning from medication errors is having a systems approach as a theoretical context in all reporting and learning processes throughout the operational environments of MER systems. The current work also suggests that constructive problem-based learning linked to learners' practice through assignments is the key when developing a course for continuing education in medication safety for healthcare professionals.

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Amen.

Espoo, April 2017

Anna-Riia Holmström

Contents

List of original publications

This thesis is based on the following original publications and a manuscript referred in the text by their Roman numerals (I-IV).

I. Holmström AR, Airaksinen M, Weiss M, Wuliji T, Chan XH & Laaksonen R: National and Local Medication Error Reporting Systems – A Survey of Practices in 16 Countries. Journal of Patient Safety 8(4):165-176, 2012.

II. Holmström AR, Laaksonen R & Airaksinen M: How to make medication error reporting systems work – Factors associated with their successful development and implementation. Health Policy 119(8):1046-1054, 2015.

III. Holmström AR, Airaksinen M & Laaksonen R: Introducing basic principles of medication safety: Development of a three-day continuing education course for healthcare professionals. Currents in Pharmacy Teaching & Learning 7(5):716-723, 2015.

IV. Holmström AR, Järvinen R, Laaksonen R, Keistinen T, Doupi P & Airaksinen M: Inter-rater Reliability of Medication Error Classification in a Voluntary Reporting System for Safety Incidents in Health Care Organizations (HaiPro) in Finland. (submitted for publication)

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Definitions of the key concepts

Adverse drug reaction
A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function (Council of Europe 2006a).

Adverse event
An incident that results in harm to a patient (e.g., the wrong unit of blood was infused and the patient died from a haemolytic reaction) (World Health Organization 2009). An adverse event is caused by medical management, in contrast to process or complication of a disease (World Health Organization 2005; Council of Europe 2006a).

Adverse drug event
A medication related adverse event resulting either because of a pharmacological reaction to a normal dose, or because of a medication error (World Health Organization 2005; Joint Commission on Accreditation of Healthcare Organizations 2006).

Blame culture
A culture in which the person is assumed to be able to perform without error (Larson & Saine 2013). Perfect performance is expected and believed to be achieved through education, professionalism, vigilance and care (Cohen 2007). Latent failures are not considered. Errors are attributed to laziness, negligence, or incompetence, resulting in blaming the person that made the error (Larson & Saine 2013).

Contributing factor
A circumstance, action or influence that is thought to have played a part in the origin or development of an incident or to increase the risk of an incident (World Health Organization 2009). Examples are human factors such as behaviour, performance or communication; system factors such as work environment; and external factors beyond the control of the organisation, such as the natural environment or legislative policy. More than one contributing factor is typically involved in a single patient safety incident.

Hazard
A circumstance, agent or action with the potential to cause harm (World Health Organization 2009). Example of hazards are unsafe practices, conduct, equipment, labels or names (World Health Organization 2005).

Human error
A failure of planned actions to achieve their desired ends, without the intervention of some unforeseeable event (Reason 1990; Larson & Saine 2013). Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care (World Health Organization 2005). Human errors can be further divided into slips, lapses, and mistakes (Reason 1990; Larson & Saine 2013).

Incident

An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient (World Health Organization 2009). Incidents arise from either unintended or intended acts, and therefore include errors, violations, patient abuse and deliberately unsafe acts that occur in healthcare. Errors are unintentional, whereas violations are usually intentional acts, though rarely malicious.

Incident reporting

Central notification and recording of incidents that led to patient harm, or could have caused harm (Woodward et al. 2010).

Medical error

An unintentional act (either of omission or commission) or one that does not achieve its intended outcome; the failure of planned action to be completed as intended (an error of execution), the use of the wrong plan to achieve an aim (an error of planning), or deviation from the process of care that may or may not cause harm to the patient (Makary & Daniel 2016). Examples of medical errors are misdiagnosis or delayed diagnosis, administration of the wrong drug to the wrong patient, or surgery on an incorrect site.

Medication error

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer (National Coordinating Council for Medication Error Reporting and Prevention 2015). Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Medication error reporting system

An electronic or paper based system that is used for systematically collecting information on medication errors, with the aim of identifying medication safety risks and thus enabling healthcare providers to improve quality of care (Hoffmann et al. 2008). A medication error reporting system can be a standalone-system in which only medication errors are reported, or as part of a wider patient safety incident reporting system where medication errors are reported among other patient safety incidents. A medication error reporting system can operate locally as an internal system in healthcare organisations or as an external or national system (e.g., reports submitted to a safety agency not affiliated with the organisation) (Cohen 2007).

Near miss (or close call)

An incident that has the potential to cause an adverse event but did not reach the patient (e.g., a medication being connected to the wrong patient's intravenous line, but the error was detected before the infusion started) (World Health Organization 2005; World Health Organization 2009).

Patient safety

Freedom for a patient from unnecessary harm or potential harm associated with healthcare (Council of the European Union 2009). Patient safety can be viewed in a practical way as the mechanisms, tools, resources and required actions to reduce and ultimately avoid unintentional harm to patients (World Health Organization 2010). These can cover any aspect of care including organisational factors, health-care personnel, the systems and environment that can contribute to a safety breach (e.g., health-care associated infections or medication errors).

Risk management

Activities or measures taken by an individual or a healthcare organisation to prevent, remedy or mitigate the occurrence or reoccurrence of a real or potential (patient) safety event (Dückers et al. 2009).

Safety

Freedom from accidental injuries and reduction of risk of unnecessary patient harm associated with healthcare (Kohn et al. 2000; World Health Organization 2009).

Safety culture

An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values, that continuously seeks to minimise patient harm which may result from the processes of care delivery (Council of Europe 2006a). Safety culture reflects the organisation's attitude toward safety, including a blame-free environment applying the systems approach and commitment of resources to improve safety (Woodward et al. 2010).

System

A set of independent elements (e.g., people, processes, equipment) that interact to achieve a common aim (European Commission 2014). In healthcare, a system can be e.g., an integrated delivery system, a centrally owned multi-hospital system, an operating room or an obstetric unit (Kohn et al. 2000).

Systems approach

An approach to safety stating that errors are mostly consequences of systematic factors, e.g., weaknesses in organisational processes (Reason 2000; Woodward et al. 2010). Building system defences to reduce and prevent errors is the main method of safety improvement in systems approach. Please see Section 3.3. of the Thesis.

Abbreviations

ADE	Adverse drug event
ADR	Adverse drug reaction
AE	Adverse event
CoE	Council of Europe
FDA	Food and Drug Administration (United States)
HaiPro	Reporting System for Safety Incidents in Health Care Organizations (Finland)
IOM	Institute of Medicine (United States)
ISMP	Institute of Safe Medication Practices (United States)
ME	Medication error
MER	Medication error reporting
MERP	ISMP Medication Errors Reporting Program (United States)
MSAH	Ministry of Social Affairs and Health (Finland)
NCC-MERP	National Coordinating Council for Medication Error Reporting and Prevention (United States)
NHS	National Health Service (United Kingdom)
NRLS	National Reporting and Learning System (United Kingdom)
ROHTO	National Centre for Pharmacotherapy Development (Finland; operated in 2003-2009)
THL	National Institute for Health and Welfare (Finland)
USP	United States Pharmacopoeia

1 Introduction

Awareness of deficiencies in patient safety has arisen internationally (Jha et al. 2010; Schreiber et al. 2016). Patient safety is considered to be a global public health issue imposing a substantial burden on the world's population. It has been estimated that one in ten hospitalised patients is harmed when receiving healthcare in industrialised countries, and half of these may be preventable (Kohn et al. 2000; Vincent et al. 2001; Vries et al. 2008). The international landmark report *To Err is Human* by the Institute of Medicine (IOM) suggested that approximately 44 000-98 000 patients die and over a million are injured as a result of adverse events in hospitals in the United States annually (Kohn et al. 2000). The subsequent studies in the United States have shown even higher incidence of medical error, ranging from 0.38 to 1.13% of admissions with a preventable lethal adverse event (Landrigan et al. 2010; Classen et al. 2011; Makary & Daniel 2016). The studies on primary care suggest approximately 2-3 incidents per 100 consultations per patient (Panesar et al. 2015). About 4% of these incidents are associated with severe harm. Epidemiological studies on adverse events, including medication errors, have not yet taken place in Finland (Järvelin 2012). If the earlier international evidence is extrapolated to Finnish healthcare and population of 5.5 million, adverse events cause annually the death of 700–1700 hospital patients in Finland (Pasternack 2006).

Medication errors are one of the most common incidents leading to adverse events in patient care (Kohn et al. 2000; Vries et al. 2008; Panesar et al. 2015). Medication errors are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of a healthcare professional, patient, or consumer (National Coordinating Council for Medication Error Reporting and Prevention 2015). Medication errors can occur during various stages of the medication use process, e.g. while prescribing, dispensing or administering a medicine (Lisby et al. 2010).

The incidence of medication errors vary between studies depending on numerous factors, such as the definition used for medication error and methods used for their detection (Lisby et al. 2010; Wittich et al. 2014; Olaniyan et al. 2015). The IOM has estimated that medication errors cause 1 out of 131 outpatient and 1 out of 854 inpatient deaths (Kohn et al. 2000). The IOM later summarised the incidence of medication errors in their report Preventing Medication Errors (2007). Other studies on medication errors have shown varying incidence rates from 8.1 to 2344 per 1000 patient-days in intensive care settings (Wilmer et al. 2010). In their recent systematic review of medication errors in primary care, Olaynian et al (2015) demonstrated that medication errors are common, with the prescribing stage being the most susceptible to medication errors.

Besides the human suffering, medication errors and other adverse events cost tens of billions of dollars for healthcare systems around the world each year (Institute of Medicine 2007). The majority of these errors are preventable and caused by system factors (e.g., problems in transferring information on patient's up to date medicines when the patient moves from one healthcare unit to another) (Vries et al. 2008; Leape 2009). Tackling these major problems requires the implementation of a systems approach to healthcare, stating that risks should be managed proactively by improving the healthcare system and its

processes rather than blaming and shaming individual healthcare professionals for committing errors (Senge 1990; Reason 2000; Spath 2011).

Although these issues have become internationally and nationally recognised, an academic research and evidence base to support improving medication safety in Finnish healthcare is currently lacking and is urgently needed (Ministry of Social Affairs and Health 2009). One of the recommended strategies to learn from medication errors and risk prone processes is the establishment of a local (e.g. hospital or unit-based) and national medication error reporting (MER) systems (Council of Europe 2006a). MER systems are typically databases where healthcare professionals are able to file reports on medication errors in their daily practice. This data can be further analysed and used for improving the detected processes producing errors in healthcare units (e.g., by introducing alert systems to iv-drug administration at hospitals). There are, however, certain limitation to error reporting systems that need to be acknowledged, such as their inability to be used for measuring safety in error rates (Pham et al. 2013). In addition to promoting the reporting of and learning from medication errors, interdisciplinary education of healthcare professionals is needed for implementing the systems approach to healthcare (World Health Organization 2011).

This study is based on the work of the Council of Europe (CoE) expert groups on medication (Council of Europe 2006a) and patient safety (Council of Europe 2006b) in 2003-2006. As an outcome of their work the expert group on medication safety published the report "Creation of a better medication safety culture in Europe: building up safe medication practices" (Council of Europe 2006a). At the national stage, this study is based on the Finnish Patient Safety Strategy 2009-2013 (an up-date of the Strategy will be released soon) (Ministry of Social Affairs and Health 2009) and the Finnish Medicines Policy 2020 which have promotion of medication safety as one of their primary goals (Ministry of Social Affairs and Health 2011). The key objective of the CoE reports (2006 a and b) and the national policy initiatives is that safety should be regarded as a system issue, managed proactively and through learning from errors. Another key objective is that patient safety incidents, including medication errors, should be reported through reporting systems, analysed and used for organisational learning from errors to avoid their reoccurrence. Furthermore, the need for reporting and learning from errors in Finnish healthcare settings has been covered by the new Healthcare Act (1326/2010, 8 §) and its Statute by the Ministry of Social Affairs and Health (341/2011).

This thesis aims to respond to these national and international needs for enhancing medication safety through the use of MER systems. The thesis consists of two parts: a literature review and an empirical section. The literature review starts with a description of national patient and medication safety work in Finland to provide a contextual framework for MER activities and healthcare system improvement in Finland (Chapter 2). Secondly, the theoretical context of the study (Chapter 3) is introduced together with a summary of MER systems as tools to improve medication safety (Chapter 4). Chapter 5 concludes the literature review by a systematic literature search of the published research in MER systems. The empirical part of the thesis investigates MER systems in different countries, how to make these systems work for learning from medication errors, and how education on medication safety could be organised for practicing healthcare professionals to improve safety (Chapters 7-11). This study is a part of a larger collection of medication safety related studies of the Clinical Pharmacy Group at the Faculty of Pharmacy, University of Helsinki.

2 Medication safety as a part of patient safety in Finland

Patient and medication safety has been actively promoted in Finland over the past 13 years. The work has been inspired by the international patient safety activities in which Finland has been actively involved. Examples of such activities are the Council of Europe expert groups on medication (Council of Europe 2006a) and patient safety (Council of Europe 2006b) in 2003-2006. Since then, the national patient safety promotion has involved several key milestones and actors in developing systems based approach to patient and medication safety in the Finnish healthcare. The active involvement of the study group members in the national patient and medication safety work has also impacted the initiation and contents of the present study.

2.1 Patient safety initiatives in Finland

The commence of national patient safety work in Finland goes back to 2005 when the Ministry of Social Affairs and Health (MSAH) established the national patient safety network (Vuorenkoski 2009). The network comprised of approximately 200 members representing healthcare professionals, healthcare providers, patients, non-governmental organisations and authorities. These national activities were preceded by local actions in some pioneering primary healthcare settings in Finland.

In 2006, the MSAH established the Patient Safety Steering Group to promote patient safety and to coordinate its development at the national level (Figure 1). One of the key targets of the Steering Group was to establish national patient safety strategy and guidelines for reporting adverse events in Finnish healthcare.

2.1.1 Strategies leading the national patient safety work

The core effort of the MSAH Patient Safety Steering Group was the development of the first National Patient Safety Strategy for 2009-2013 (Ministry of Social Affairs and Health 2009; Figure 1). The main objective of the strategy was that patient safety will be embedded in the structures and methods of operations in healthcare. The strategy outlined, e.g., that all healthcare organisations should have explicit procedures for internal reporting, monitoring and handling patient safety incidents, including medication errors (Ministry of Social Affairs and Health 2009; Vuorenkoski 2009).

The new national Patient Safety and Customer Safety Programme (2017-2020) will be released shortly. The programme is developed as a collaborative project with the MSAH and the Finnish Society for Patient Safety (Holmström et al. 2015). The new Patient and Customer Safety Programme will also include the social care settings, e.g., elderly care, and emphasises the role of a patient/customer and his or her close contacts in patient and customer safety promotion. The main aspects covered in the new Programme will be: safety culture enabling e.g., open sharing and learning from occurred adverse events in social care and healthcare settings; patient and customer safety management; statutes related to patient and customer safety, and responsibilities of different stakeholders in patient and customer safety promotion.
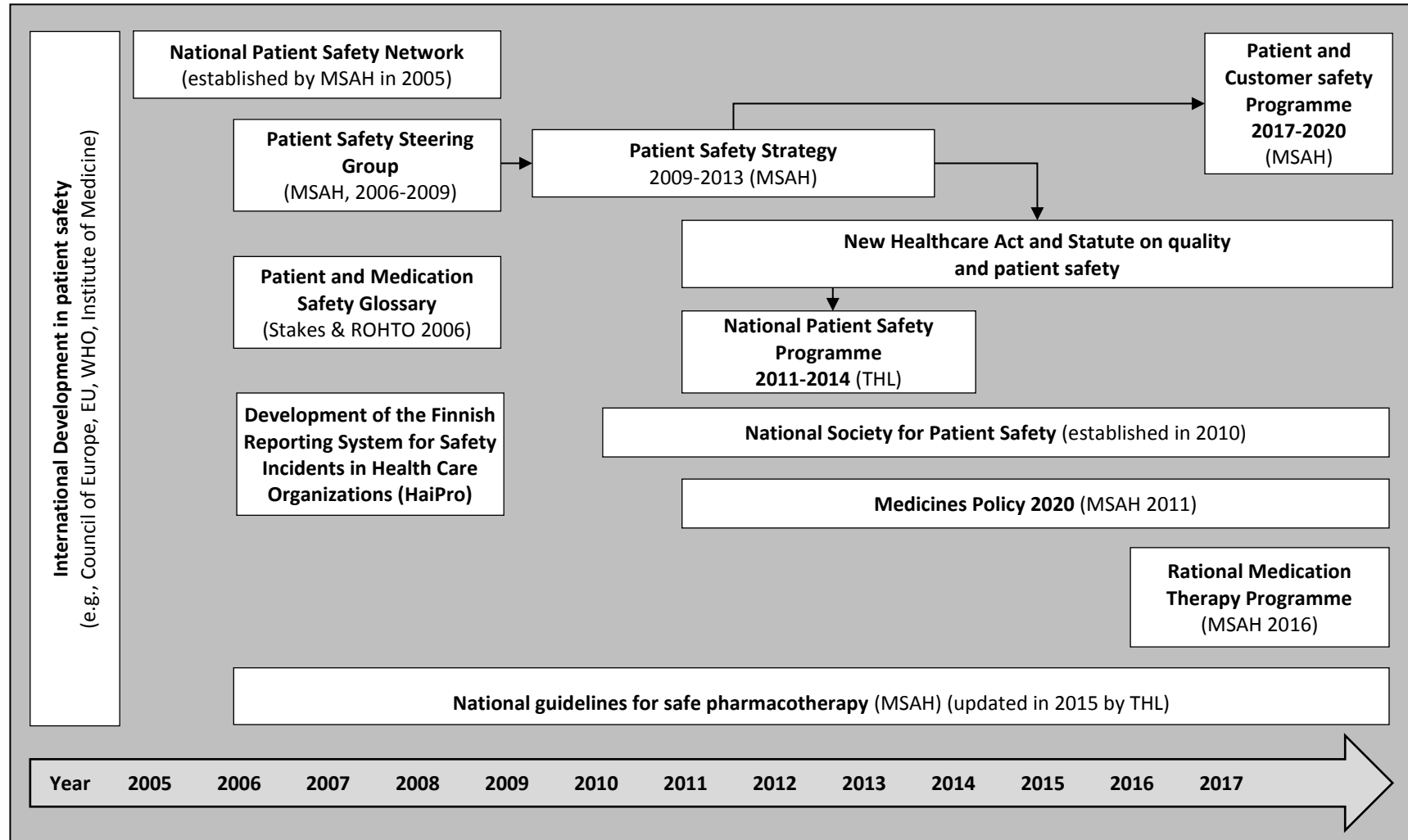
Figure 1. *Governmental and other national actions to initiate systems based patient and medication safety work in Finland. MSAH = Ministry of Social Affairs and Health; THL= National Institute for Health and Welfare; ROHTO = (former) National Centre for Pharmacotherapy Development; Stakes = (former) National Research and Development Centre for Welfare and Health.*

2.1.2 Legislation supporting patient safety

The first Patient Safety Strategy (2009-2013) served as a base for the inclusion of healthcare quality and patient safety Section as a part of the new Healthcare Act enacted in 2011 (1326/2010, 8 §) (Airaksinen et al. 2012; Figure 1). The Healthcare Act requires all Finnish healthcare institutions (hospitals and primary healthcare centres) to develop a plan for patient safety enhancement based on a systems approach. The plan is to describe the system, processes, resources and persons in charge for patient safety within the institution. A Statute by the Ministry of Social Affairs and Health (341/2011) complements the Act and gives detailed instructions on the minimum contents of a patient safety plan.

In practice, the Act and Statute have appeared to be powerful instruments: they have forced all healthcare organisations to evaluate their patient care practices and to develop a coordinated plan to make their system safer (Airaksinen et al. 2012). In many healthcare organisations this has resulted in nominating patient safety coordinators and establishing patient safety steering groups. Many organisations also use an electronic Reporting System for Safety Incidents in Health Care Organizations (HaiPro) which has been available in Finland since 2007 (Keistinen & Kinnunen 2008; Ruuhilehto et al. 2011). The HaiPro reporting system is described in more detail in Chapter 3.

2.2 Implementation of patient safety initiatives

2.2.1 National Patient Safety Programme (2011-2014)

The National Institute for Health and Welfare (THL) was mandated by the MSAH to coordinate the implementation of the patient safety initiatives, such as the first Patient Safety Strategy (2009-2013) in Finland (Airaksinen et al. 2012). For that purpose, THL launched a four-year patient safety programme in 2011 (Figure 1). The programme targeted the hospital districts, public healthcare institutions and their personnel, including directors and management staff. Collaboration for promoting implementation was facilitated through networking and joint actions between national and local stakeholders, professional organisations, hospital districts, patient safety coordinators, patient organisations, research and education institutions. The Programme consisted of several actions aimed at influencing attitudes and traditional norms within healthcare institutions.

2.2.2 The Finnish Society for Patient Safety

The Finnish Society for Patient Safety is a non-governmental organisation established in 2010 to promote patient safety and patient safety research in Finland (Holmström et al. 2015). The Society has been very actively involved in national patient and medication safety promotion. The society uses a multidisciplinary approach involving voluntary representatives from a wide range of stakeholders, including healthcare organisations and academic institutions, with a high-level of expertise in patient safety. The Society operates three sub-groups, which conduct activities in their own area of specialty. These groups are:

safe pharmacotherapy; patient safety experts acting locally in their respective healthcare organisations, and experts from organisations for patients and the disabled to give voice to patient issues in patient and medication safety promotion. The safe Pharmacotherapy group has its special focus on medication safety promotion in hospital and community settings.

The Finnish Society for Patient Safety promotes patient centeredness in its work, and has medication safety as one of its key priorities (Holmström et al. 2015). The Society also collaborates with other national stakeholders. One of its latest key initiatives involves the previously mentioned working with the MSAH to develop the national Patient and Customer Safety Programme (2017-2020). Other key activities of the Society include education for social care and healthcare professionals, promotion of research in patient and medication safety, informing patients, professionals and other stakeholders on patient safety, and publishing material for social care and healthcare organisations for promotion of patient safety in their own organisations.

2.3 Medication safety initiatives as a part of patient safety

2.3.1 Guidelines for safe medication practices

Inspired by the work of Council of Europe expert groups on medication (Council of Europe 2006a) and patient safety (Council of Europe 2006b) in 2003-2006, the former National Centre for Pharmacotherapy Development (ROHTO) established a voluntary multidisciplinary working group on medication safety in 2004. The first action taken by the group was to create a Finnish glossary of terms and concepts related to patient and medication safety from systems approach (Stakes & ROHTO 2006; Toivo & Airaksinen 2006).

At the same time, MSAH established a working group for developing guidelines for safe medication practices in public and private social- and healthcare units (Ministry of Social Affairs and Health 2006). These guidelines are the primary national medication safety tool guiding the safe medication practices in Finnish social care and healthcare. In 2015, the guidelines were updated with a stronger focus in social care settings (e.g. elderly care) and responsibilities of the patient in ensuring one's own medication safety (Finnish National Institute for Health and Welfare 2015). The key of the guidelines is that the provision of pharmacotherapy should be based on a pharmacotherapy plan developed in the unit. The plan serves as a tool for defining and managing the key aspects of the medication safety of a specific unit.

According to a follow-up study, the guidelines have led to the evaluation of practices and the establishing of a pharmacotherapy plan in Finnish social care and healthcare units (Hitonen 2013). Thus, the guidelines are fulfilling their function for clarifying responsibilities and competences in safe pharmacotherapy, and defining the minimum requirements that must be complied with in all units providing pharmacotherapy in Finland. The responsibility for drawing up, carrying out and monitoring pharmacotherapy plans is vested in the management of the social and healthcare units (Finnish National Institute for Health and Welfare 2015).

2.3.2 National Medicines Policy 2020 and other activities

Systems based patient and medication safety has been strategically highlighted during the recent years when developing the National Medicines Policy 2020 (Ministry of Social Affairs and Health 2011) and related implementation programmes, such as the medicines information strategy (Finnish Medicines Agency Fimea 2012) and a collaborative network for rational medication management for the aged people (Finnish Medicines Agency 2015a). Also several other preventive actions and tools, such as collaborative medication reviews and automated dose dispensing in hospitals and primary care, have been developed to improve medication safety in the Finnish social and healthcare system (Airaksinen et al. 2012; Leikola et al. 2012; Sinnemäki et al. 2014). Innovative electronic databases assist in medication risk assessment and are widely available throughout the healthcare in a health portal maintained by the Finnish Medical Society Duodecim (Toivo et al. 2016; Finnish Medical Society 2016). Some of the existing tools are specially designed for managing risks in the medication of the aged, such as a tool for nurses for assessing the risks of drug related problems (Dimitrow et al. 2014), the Database of Medication for the Elderly (Finnish Medicines Agency 2015b), and the SALKO and PHARAO databases to assist evaluation of medication-related risks among patients (Laine et al. 2013; Leikola et al. 2013). The Association of Finnish Pharmacists has also developed a dispensing error reporting system for detecting and learning from occurred incidents in community pharmacies.

Following the National Medicine Policy 2020, the Finnish government has initiated a national programme for promoting rational pharmacotherapy to ensure medication safety in the new Healthcare Reform taking place in 2019 (Figure 1) (Ministry of Social Affairs and Health 2017). The programme has several aims, such as promoting rational medication use by ensuring that healthcare professionals have comprehensive up-to date medication information of their patients, and promoting research related to rational medication use.

3 Theoretical context for medication error reporting and learning from medication errors

3.1 Human Error

The present study is based on the Theory of Human Error (Reason 1990; Armitage 2009). The theory states that where there is human action, errors are inevitable. Indeed, human error is one of the most remarkable contributors to accidents in risk industries, such as healthcare, with complex systems, processes and technologies (Kohn et al. 2000).

The current literature introduces two approaches to human error; the person approach and the systems approach (Senge 1990; Reason 2000). Each has its model of error causation and provides different insights into error management (Table 1). Errors are a persistent threat to patient and medication safety (Armitage 2009). Understanding the differences between these two approaches is essential for managing medication errors and other patient safety incidents in clinical practice.

Table 1. *A summary of person approach versus systems approach to human error* (Reason 2000).

Area	Approach	
	Person approach	*Systems approach*
Focus	Errors of individuals. Blaming individuals for making errors.	Errors in conditions under which individuals work. Development of strategies to prevent errors.
Premise	"Errors happen to non-competent healthcare professionals."	"Humans make mistakes and errors occur even in high quality organisations."
Errors	Arise primarily from mental processes, e.g., forgetfulness or negligence.	Consequences of systematic factors, e.g., weaknesses in organisational processes.
Countermeasures	Attempts to change human behaviour.	Attempt to change conditions under which humans work, rather than change the human behaviour.
Methods to achieve the countermeasures	Appealing to sense of fear: blaming, shaming and disciplinary actions.	Building system defences and safeguards to reduce and prevent errors.

3.2 Person approach

The traditional person approach to medication errors in healthcare has been to blame the individuals at the sharp end of the patient care, such as physicians, pharmacists and nurses (Wachter 2012; Table 1). According to the person approach, only non-competent healthcare professionals commit errors because of their forgetfulness, negligence or inattention when delivering medication care (Reason 2000). The main countermeasures comprise reducing the erroneous human behaviour, e.g., by disciplinary actions. By focusing on the individual origins of error, the person approach isolates unsafe acts from their system context. The presence of a person approach to medication error management has been one of the main

obstacles to functional medication error reporting and learning from errors in healthcare systems internationally (Weiner et al. 2008; Mahajan 2010).

3.3   Systems approach

While the person approach tends to have no insight into the underlying factors contributing to the occurrence of medication errors, the systems approach states that errors occur because of the conditions under which the individuals work (Reason 2000; Table 1). Hence, errors may be viewed as consequences of systematic failures and organisational weaknesses, for example storage of "look-alike" medications on the same shelf on a hospital ward.

The systems approach acknowledges that errors are an inevitable accompaniment of the human condition, even among the most conscientious professionals with high standards (Leape 1994). Therefore, error countermeasures in a systems approach are based on the assumption that although the human condition cannot be changed, the conditions under which humans work can be changed (Reason 2000; Table 1). When an adverse event occurs, the important issue is to ask why the event occurred, not who made the error (Cohen 2007). Creation of such an organisational culture which embraces these principles is pivotal in enabling functional medication error reporting and learning from errors in healthcare organisations (Leape 2009).

Embracing systems approach to medication safety does not imply that there would not be accountability for healthcare professionals due to poor adherence to safety practices, e.g. using the checklist when inserting central venous catheters (Wachter & Pronovost 2009). Indeed, many healthcare organisations have recognised that a unidimensional focus on creating a blame-free culture carries its own safety risks and should be tackled by balancing "no blame" with meaningful systems for accountability in cases where deliberate patient safety violations occur. However, it is notable that majority of errors are slips committed by caregivers and require system improvements.

3.4   The "Swiss cheese" model of system accidents

As the human nature cannot be changed, a central method for preventing medication errors from the systems approach is building system defences into the medication processes, such as the use of oral medication administration syringes that do not fit into iv-systems (Reason 1990; Reason 2000; Yip & Farmer 2015). However, in healthcare, the defences typically rely on individuals, such as doctors and pharmacists who are assumed not to make errors. In an ideal situation these defences would be impermeable to errors. In the real world these protective defence layers are, however, permeable to errors. This may be visualised by James Reason's Swiss cheese model of system accidents where the slices of cheese present the protective defences of the system and the holes failures (Reason 1990; Wachter 2012; Stein & Heiss 2015) (Figures 2 & 3). Holes in some slices would not cause damage, unless the holes are open in many defences concurrently. This would place the patients or possible victims in danger and enable the hazards to become losses.

The holes in the model may be caused by active failures and/or latent conditions (Reason 1990). Active failures are usually hard to foresee as they tend to be errors made by individual healthcare professionals. Latent conditions, on the contrary, may be detected before they

turn to active failures. For example, storage of two look-alike medicines on the same shelf at a hospital ward may be prevented in becoming a failure by moving one of the medicines to another shelf for storage. Understanding the role of active failures and latent conditions in medication error prevention leads to proactive risk management procedures to improve medication safety through the systems approach rather than the person approach (Reason 2000; Dückers et al. 2009). Development and implementation of functional MER systems is one of the most widely used methods to enable the organisations to identify the active failures and latent conditions in their medication processes and to build the needed defences to avoid adverse patient outcomes (Council of Europe 2006a; Cohen 2007; Cheng et al. 2011; Parmelli et al. 2012; European Commission 2014).
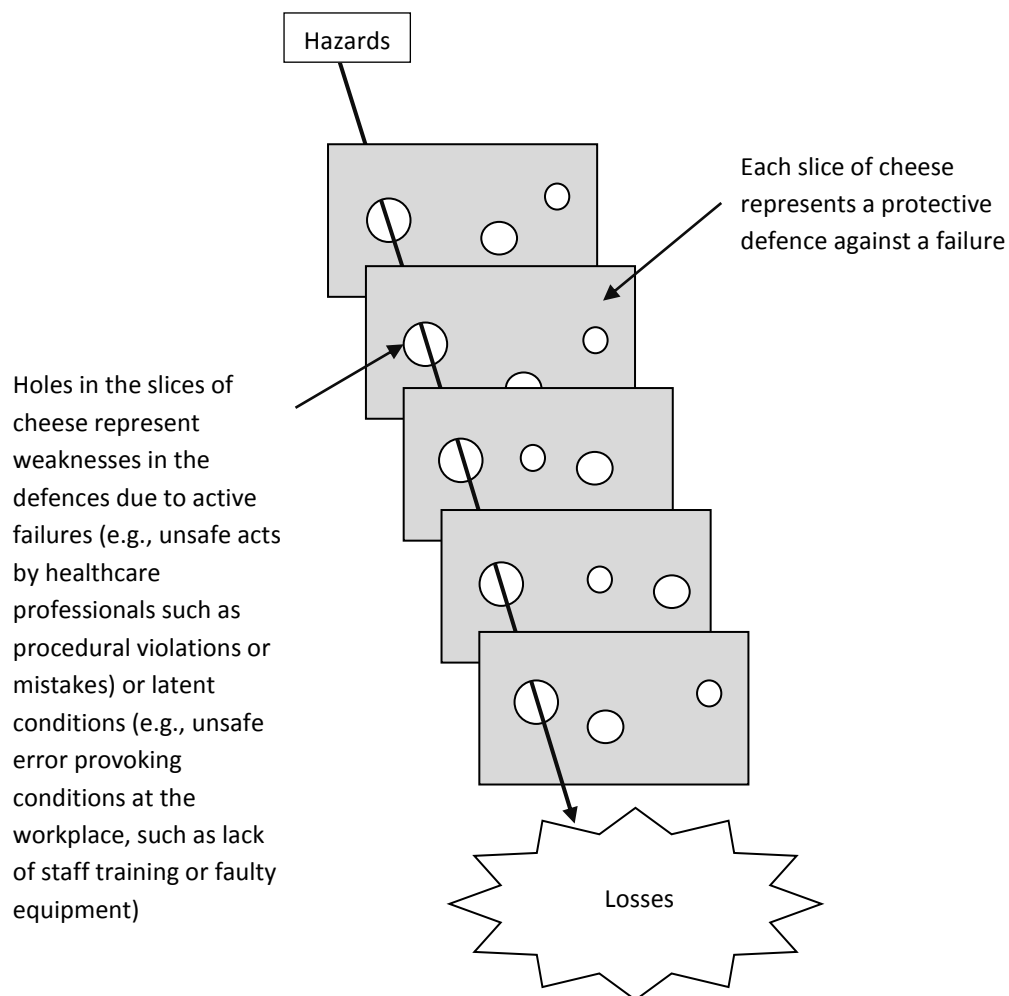
Figure 2.   *James Reason's Swiss cheese model of system accidents (Reason 2000).*

Case description:

A 86-year old female patient was admitted to a hospital due to a pulmonary embolism. Medication treatment was started immediately. According to a referral, the patient was under rheumatic treatment and was using methotrexate 5 mg on Tuesdays. The dosing was, however, transcribed to 5 mg on evenings and recorded to the patient's medication list. The patient started to recover from the pulmonary embolism. After a week of hospital admission, the patient's condition got worse. The doctors suspected for infection, but instead they diagnosed anemia and neutoropenia. This finding led to checking the medication list of the patient after 12 days of hospital stay. The healthcare staff discovered that 5 mg of methotrexate had been administered to the patient every day, although the correct dose would have been 5 mg once a week. Despite of the attempts to save the patient, the patient died to sepsis after 20 days of hospital stay.

Hazard: Medication with an unconventional dosing → Methotrexate 5 mg on Tuesdays transcribed to Methotrexate 5 mg on evenings at the emergency department.

The doctor did not check the medication after transcription due rush and long que of patients waiting for treatment.

A substituting doctor did the ward rounds on the next day. The doctor was unfamiliar with the patients. The round was long and exhausting with many patients, and the doctor did not notice the error.

The medication error was not noticed until 12 days later after the patient's condition became worse.

Resources

Competencies

Resources

Policies

Policies etc. other defences

Patient transferred to a hospital ward were there was no experience with methotrexate medication treatment.

Next day the ward doctor stated that the patient had started to recover. The ward doctor trusted the medication list "checked" by the substituting doctor, because the condition of the patient was better.

Patient dies with sepsis

Figure 3. *Application of the James Reason's Swiss cheese model (2000) of system accidents. The patient case is based on an incident occurred in Päijät-Häme central hospital in Finland (Kettunen 2007).*

4 Medication error reporting systems as a tool for promoting medication safety

4.1 History of medication error reporting systems

The development of patient safety incident reporting systems in healthcare can be traced back to the late 1970s (Elliott et al. 2014). Before that incident reporting systems had been successfully used in other safety-critical industries, such as aviation, chemicals and nuclear power (Williamson et al. 1993; Hoffmann et al. 2008). The development of the earliest MER system (USP-ISMP Medication Errors Reporting Program, please see 4.4.1) started in the United States in 1975 (Cohen 2007). Since then, many countries around the world have introduced national and local MER systems, either as stand-alone systems or as a part of wider patient safety incident reporting systems (Doupi 2009; Cheng et al. 2011; European Commission 2014).

Countries, such as the United States, the United Kingdom, Australia and Japan have been the pioneering countries providing others with lessons for MER systems development and implementation (Elliott et al. 2014). Along with the experiences of these countries, the international landmark report To Err is Human by the US Institute of Medicine (2000) has been a core incentive for countries to establish MER systems (Kohn et al. 2000). The following paragraphs present the role of MER systems in medication risk management and international recommendations on MER systems. Also MER systems by some of the pioneering countries in MER are presented together with an incident reporting system widely used in Finnish social and healthcare. Information on patient safety incident reporting systems in other European countries is presented in other sources (Council of Europe 2006a; Doupi 2009; European Commission 2014).

4.2 Role of medication error reporting systems in medication risk management

Incident reporting systems are one of the most widely used healthcare risk management tools across countries (France et al. 2004; Levtzion-Korach et al. 2009). Healthcare providers use these systems to systematically collect, aggregate and analyse medication errors and other patient safety data to learn from the failures of the healthcare system.

MER systems have several advantages in medication risk management. They have an ability to elicit contextual details about contributing factors, human errors and suggested corrective measures to promote medication safety (Williamson et al. 1993; Evans et al. 2006). Many MER systems also enable reporting of near misses and identified patient safety risk factors which have not yet caused actual errors to patients. This is important as near misses provide valuable information about the contributing factors to errors and lessons in recovery mechanisms without the consequences of actual errors (Speroni et al. 2014; Ruddy et al. 2015). Reporting of near misses is also attributable to lesser outcome bias as there is no adverse outcome in near miss reports (Williamson et al. 1993). As for the reporting of risk factors, they provide a good example of pro-active risk management instead of reactive actions to improve patient and medication safety.

If compared to other medication risk management tools, such as medical record review, MER systems are considerable low cost in relation to the amount of information obtained (O'Neil et al. 1993; Williamson et al. 1993; Beckmann et al. 2003). Some studies even suggest that when actively promoted within the clinical setting, incident reporting can capture more efficiently preventable adverse events than medical record reviews (O'Neil et al. 1993; Beckmann et al. 2003). When using a MER system to detect medication errors, the data are also obtained from many sources, reducing the effect of site-specific bias (Williamson et al. 1993).

Despite their strengths, MER systems suffer from several limitations which should be considered when deploying them in medication error risk management. Many studies have demonstrated underreporting of medication errors; only a small number of incidents are reported through voluntary incident reporting systems (e.g., Flynn et al. 2002; Sari et al. 2007; Poorolajal et al. 2015; Westbrook et al. 2015). Consequently, the major limitation of MER systems is that they cannot assess the incidence of the problem - they do not provide accurate numbers of medication error occurrences (Beckmann et al. 1996a; Shojania 2008). Other factors hindering the use of MER systems as reliable tools to measure the frequency of medication errors are the subjective nature of reports and the lack of consistency and validation of error classification in many systems (Johnson 2003; Stavropoulou et al. 2015). However, MER systems are not primarily designed to determine medication error rates (Hickner et al. 2010; Brunsveld-Reinders et al. 2016). Instead they provide a safety improvement method that uses observations of frontline healthcare staff to detect problems arising from the healthcare system, policies and procedures. MER systems can never give a complete picture of the sources of risk and patient harm (World Health Organization 2005). Therefore, it is recommended that MER systems should be used concurrently with other methods for medication safety risk management, such as chart audits, safety audits, observation of practices, and other prospective methods of analysis (World Health Organization 2005; Hoffmann et al. 2008).

The success or failure of incident reporting systems is highly dependent on leadership, organisational culture, and the reporting tool itself (France et al. 2004; Poorolajal et al. 2015; Hesselink et al. 2016). Studies which have successfully implemented MER systems have invested in intense facilitation e.g., through ward rounds or staff reminders (O'Neil et al. 1993; Beckmann et al. 2003). The role of efficient feedback for the reporting staff has been identified essential for successful reporting (Benn et al. 2009; Reznek & Barton 2014).

4.3 Recommendations on medication error reporting systems

Several international recommendations on MER systems have been published to support their development and implementation in different countries (World Health Organization 2005; Council of Europe 2006a; European Commission 2014). The Council of Europe report (2006a) represents the first international report concentrating specifically on medication error prevention and establishment of MER systems within European countries (Table 2). The WHO Draft Guidelines for Adverse Event Reporting and Learning Systems (2005) and the European Commission recommendations (2014) which take as its basis the WHO Draft Guidelines (2005), provide insights into the establishment of wider patient

safety incident reporting systems where medication errors can be reported among other patient safety incidents.

The key message of all three recommendations is that patient safety incident reporting systems should have as their main objective the improvement of patient safety through identification of errors and hazards which may require further investigation to identify underlying system causes (World Health Organization 2005; Council of Europe 2006a; European Commission 2014). The entire process of reporting incidents, their analysis and dissemination of findings and recommendations for their prevention, as well as the implementation of recommendations, should be established and communicated to all stakeholders. Incident reporting is recommended for each level of the healthcare system emphasising the need for both national and local reporting systems.

Table 2. *Recommended characteristics of a MER system by the Council of Europe (CoE) Expert Group on Safe Medication Practices* (Council of Europe 2006a).

Characteristics
➢ non-punitiveness
➢ confidentiality
➢ independence
➢ timeliness
➢ system-orientation
➢ responsiveness (e.g., provides feedback on reported errors)
MER system should
➢ encourage unrestricted reporting by all professionals working in the healthcare system
➢ be based on expert analysis of incidents
➢ offer enabling conditions for healthcare professionals to report errors (e.g., voluntarily and anonymity of reporting)
➢ provide incentives for reporting

4.4   Examples of medication error reporting systems

4.4.1 ISMP Medication Errors Reporting Program (MERP) (United States)

The Medication Errors Reporting Program (MERP) was the first national MER system established in the United States in 1975 (Cheung et al. 2011; Table 3). The system is provided by the Institute for Safe Medication Practices, which is a national non-governmental organisation devoted to medication error prevention and safe medication use (Institute for Safe Medication Practices 2015).

Focus of the MERP is on learning from reported medication errors or hazards that could lead to errors (Cohen 2007; Table 3). The purpose is to prevent the future errors through systems based solutions that can be extrapolated to all healthcare settings. After the report has been filed, an interdisciplinary team at ISMP analyses the report and determines the system based causes of errors and identifies trends. Based on the error reports the ISMP notifies the Food and Drug Administration (FDA) and drug manufacturers of needed changes in medication products to reduce the risk of serious harm from medication errors

(Cohen 2007). The MERP has remarkably contributed to medication safety nationally through several actions, such as the ISMP Early warning system (Cohen 2007). When ISMP identifies a serious hazard in the MERP database, information on the hazard is immediately disseminated by electronic nationwide alerts to healthcare providers. Also the public and media are informed about the safety issue and provided with recommendations for error reduction strategies.

4.4.2 MEDMARX (United States)

The largest adverse drug event (ADE) database in the United States, MEDMARX, was developed by the United States Pharmacopeia (USP) in 1998 (Cheng et al. 2011; Table 3). In 2008 the USP transferred the ownership of MEDMARX to a private healthcare software company, Quantros (Quantros Inc. 2008). The MEDMARX system enables its subscriber trusts, including hospitals and other healthcare providers to report medication errors, hazards and adverse drug reactions (ADRs) and to analyse the collected data (Savage et al. 2005). Reporting to MEDMARX is anonymous and standardized allowing data comparison with demographically similar facilities (Cohen 2007).

Some evaluations have been conducted on the utility of and experiences with MEDMARX, and the results have revealed a high level of satisfaction with the feasibility of the programme among the subscribers as well as barriers to reporting (Santell et al. 2003; Hicks et al. 2004; Savage et al. 2005; Coley et al. 2006; Schiff et al. 2015). About 90% of respondents in a study on healthcare staff in 550 hospitals and health systems agreed that the programme is a significant tool in providing information to prevent errors and in identifying deficiencies in medication safety (Savage et al. 2005). The MEDMARX reporting system uses the NCC-MERP index (Forrey et al. 2007) of error severity and integrates the characteristics of an effective MER system identified by Leape (Leape 2002).

Table 3. *Overview of pioneering medication error reporting (MER) systems* (Cheng et al. 2011) *and the Reporting System for Safety Incidents in Health Care Organizations, HaiPro.*

Characteristics of the MER systems								
Country	Name	Date started	Voluntary/ mandatory	Responsible organisation(s)	Aim(s) of the system	Coverage	Incident types reported	Reported information
United States (US)	Medication Errors Reporting Program (MERP)	1975	Voluntary	Institute for Safe Medication Practices (ISMP)	To provide expert analysis of the systemic causes of medication errors and to disseminate recommendations for the prevention of medication errors.	National	Actual medication errors, near misses and hazards.	Name and email of the reporter (optional); error type (e.g. prescribing, transcribing, dispensing, administering or monitoring errors); description of the error or hazard; nature of the error (actual error or near miss); patient outcome; type of setting (e.g., hospital, pharmacy, long-term care facility); causes or contributing factors; how the error or hazard was discovered; recommendations for prevention, and associated materials (photographs of products etc.).
US	MEDMARX	1998	Voluntary	Quantros, inc.	To track and identify trends in adverse drug reactions and medication errors.	National	Adverse drug reactions and medication errors.	On medication errors: severity of the error; description of the error; error type (e.g., extra dose, omission or wrong patient); causes or contributing factors; phase in which the error originated (e.g. prescribing, dispensing or administering); error location (e.g., emergency department); staff involved in the error and reporting; information on the medication involved; information on the patient; actions taken to avoid

Country	System	Year	Type	Organisation	Purpose	Scope	Incident type	Data collected
								future errors, and suggestions for system changes to prevent the error.
United Kingdom (UK)	National Reporting and Learning System (NRLS)	2003	Voluntary	National Health System (NHS) Commissioning Board Special Health Authority	To collect, collate and store data on patient safety incidents, and to provide feedback to the NHS on how this key component of healthcare can be improved, through a range of reports, alerts and other guidance.	NHS organi-sations	Patient safety incidents, including medication errors.	The service type where the incident occurred (e.g., acute, mental health or primary care); incident date, time and location; contributing factors; incident description; actions to prevent reoccurrence; patient details; degree of patient harm; actions to prevent incident affecting the patient, and effect of the incident on the patient.
Finland	Reporting System for Safety Incidents in Health Care Organizations (HaiPro)	2006	Voluntary	Awanic, ltd.	To report, analyse and learn from the occurred incidents and patient safety risks to improve patient care processes of the reporting organisations from the systems approach.	Social care and healthcare organi-sations	Safety incidents, including medication errors (HaiPro enables also reporting of occupational safety incidents).	Date, time, place (e.g. operating room) and occurrence unit of the incident; profession and unit of the person reporting; nature of the incident (actual error, near miss or violation directed to personnel); incident type (e.g. dispensing error of a medicine); description of the incident (what happened and how the incident occurred); what were the consequences for the patient and the unit; conditions at the time of the incident and other contributing factors; suggestions of how similar incidents could be avoided, and suggestions for action to prevent reoccurrence of the incident.

4.4.3   National Reporting and Learning System (NRLS) (England and Wales)

The National Reporting and Learning System (NRLS) is a central database of patient safety incident reports, including medication errors, launched in 2003 in England and Wales (Doupi 2009; Cheng et al. 2011). The system covers National Health System (NHS) organisations in England and Wales (Cheng et al. 2011) and received over four million incident reports reported by the NHS staff by the year 2016 (National Patient Safety Agency 2015). Incidents are reported and analysed locally to enable local learning and actions to improve patient safety (Doupi 2009). Afterwards, the incident reports are sent automatically to the central database where NHS organisations are also able to report directly. Since 2006, NRLS has also offered patients and their carers an opportunity to report incidents.

The NRLS uses several feedback mechanisms to inform the NHS and the public about the reported incidents (Doupi 2009). The statistics of incident data are provided to those NHS organisations that submit data regularly to the NRLS. Also quarterly data summary reports describing patterns and trends of the incidents are publicly available (National Health Service 2015). Studies have been conducted on reported medication errors to the NRLS (Cousins et al. 2012; Wahr et al. 2014) as well as on the utility of the system (Williams & Ashcroft 2009; Phipps et al. 2014).

4.4.4   The Reporting System for Safety Incidents in Health Care Organizations (HaiPro) (Finland)

In Finland, over 200 health- and social care organisations report medication errors, including near misses, in an online Reporting System for Safety Incidents in Health Care Organisations, HaiPro (Awanic Ltd 2015c). Since the establishment of the HaiPro system in 2007, over one million reports on adverse events have been filed from different social care and healthcare organisations. The development of the HaiPro reporting system and process was initiated in 2006 in collaboration between the Technical Research Centre of Finland (VTT), healthcare units and the former National Agency for Medicines (current Finnish Medicines Agency, Fimea).

The HaiPro system provides a great amount of information on the reported data, and how the organisations have learnt from their incidents and improved their processes of care. The HaiPro system is primarily targeted at internal use in healthcare units, e.g., a paediatric unit within a larger hospital organisation, and can be accessed online through the organisation's intranet. The reporting process is confidential, voluntary and anonymous. It is based on a systems approach (Reason 2000); both error reporting and data analysis are confidential and blame-free. In addition to serving as a local patient safety promotion tool, HaiPro has the potential to provide information on patient safety incidents at the level of all reporting organisations and so gives information on national medication safety promotion activities. This aspect has been explored in the current study which also describes the reporting and analysis process of the reported incidents in more detail (Manuscript for original publication III).

5 Research on medication error reporting systems

This chapter presents the current evidence on MER systems obtained from a systematic literature search. The aim of the literature search was to describe international studies conducted on functionality, development and implementation of MER systems.

5.1 Literature review

Literature searches of several online databases were conducted using the Medline Ovid, Scopus, Cinahl, Cochrane and International Pharmaceutical Abstracts (IPA). The search algorithms (Appendix 1) included combining search terms from two themes: medication errors and related terms, and reporting systems and related terms (Table 4).

Table 4. *Search terms for the systematic literature search from international scientific databases.*

Theme 1: Medication errors and related terms (n=9)	Theme 2: Reporting systems and related terms (n=4)
Medication error Medicines error Medication mishap Medication incident Adverse drug event Medication mistake Drug error Medication event Medication safety event	Reporting system Database Reporting program/programme Reporting scheme

A total of 5667 bibliographic records were identified (Figure 3). All records were entered into a bibliographic-management system Refworks, and 2350 duplicate records were removed. The records were then screened for relevance to the aims of the literature review. The search was limited to the English language. No restrictions were placed for the time of publication.
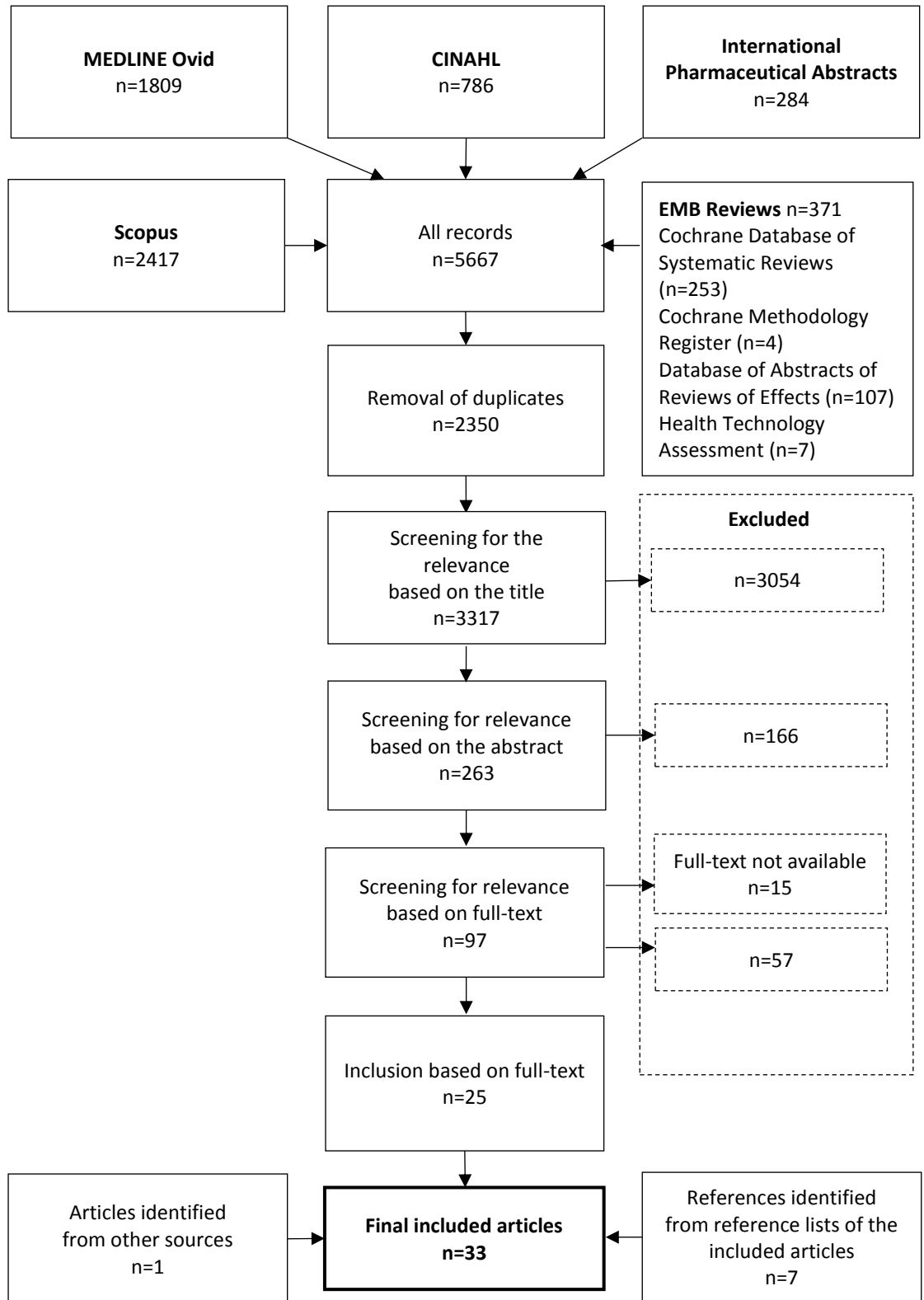
Figure 3. *Outline of the systematic literature search from international databases and other relevant sources.*

Articles exploring functionality, development and implementation of MER systems were included (Table 5). Examples of excluded topic areas were studies on pharmacovigilance reporting systems, and articles with a primary aim to explore reported medication errors instead of the functionality of the MER system (Table 5). The major challenge was to distinguish whether the studies fell into the main inclusion criteria of exploring the functionality of MER systems. Consequently, the aims and objectives of the studies were carefully reviewed when deciding on study inclusion. Also records that were not published as peer reviewed scientific articles or full-text of the article was not available via the University of Helsinki or Google, were excluded. Following the screening, 33 articles were included into the literature review (Figure 3, See Tables 6-11), and the articles are described in the following paragraphs.

Table 5. *The criteria for inclusion and exclusion of articles in the literature review on studies of medication error reporting (MER) systems.*

	Inclusion criteria	Exclusion criteria
Type of the reporting system	MER systems (either stand-alone systems or systems integrated into wider patient safety incident reporting systems).	Pharmacovigilance reporting systems. Other reporting systems not enabling MER.
Focus of the study	Explores functionality, or development and implementation of MER systems (e.g., system user satisfaction or reliability of the produced data).	Studies describing primarily the medication errors reported to the system. Studies exploring barriers or attitudes to reporting of medication errors generally instead of exploring the functionality of some certain MER system.
Outcomes	Studies using various research methods and outcome measures are included.	-
Time	No time restrictions.	-
Study design	All methods and study designs are included. Peer reviewed journal articles. Review articles.	Non-scientific publications. Articles published in professional publications or other non-scientific publications.
Other	English language. Full-text available via University of Helsinki or Google.	Full-text is not available via University of Helsinki or Google.

5.2   Overview of studies on medication error reporting systems

The identified studies (n=33) represented a blend of approaches to examine functionality, development and implementation of MER systems in different countries and healthcare domains. The studies are summarised in Tables 6-11. The characteristics of MER systems studied are described in Appendices 2 a and b.

Based on their contents, the studies were divided into six categories: (1) studies exploring the functionality of MER systems by investigating the reported medication error

data (n=6); (2) studies comparing MER systems to other methods for medication error detection and learning (n=3); (3) studies describing the development and implementation of MER systems (n=9); (4) studies on the utility of MER systems (n=11); (5) studies on MER system innovations (n=3); and (6) reviews on MER systems (n=1). Because of the overlapping findings between the studies in different categories, the synthesis of the key findings of the literature review comprised studies in all the categories instead of summarizing findings within each category separately (see 5.2.3).

Table 6. *Studies exploring the functionality of medication error reporting (MER) systems by investigating the reported medication error data (n=6). ME=medication error. Studies are presented in alphabetical order.*

Reference	Country & setting	Objectives	Design	Materials and methods	Key findings*
Armitage et al. 2010)	United Kingdom (UK), an acute hospital.	To improve reporting and learning from medication errors through investigating the contributory factors in medication errors and quality of reporting.	A two-staged study employing qualitative and quantitative methods. Data analysis informed by the Human Error theory (Reason 1990).	Quantitative and qualitative analysis of a retrospective, random sample of medication error reports (n=911) from 1999-2003. Qualitative interviews (n=40) of healthcare professionals on how the current reporting system could be improved.	The quality of reports varied greatly. 27% of reports lacked any contributory factors. The error reports focused on individuals. Communication difficulties, high workload and interruptions were the leading contributory factors in the interview data. Reporters rarely received feedback on reporting.
Haw & Cahill 2011	UK, a specialist psychiatric hospital.	To describe the first two years of operation of an electronic system for reporting MEs in psychiatry (Medi-Event system).	Descriptive analysis of MEs reported by the hospital staff between March 2008 and February 2010.	Descriptive statistics to describe the reported MEs (n=488). Expert review of the reported data: whether the reported incidents were MEs, severity ratings reported, and correct error type reported (actual error or a near miss).	Use of the Medi-Event system increased the reporting of MEs in comparison to a previously used paper based system. Staff did not always correctly classify MEs, and their severity ratings did not frequently agree with those made by the expert raters.
Evans et al. 2007	Australia, four major cities and two regional hospitals in South Australia.	To assess the effectiveness of an intervention package comprising intense education, a range of reporting options, changes in report management and enhanced feedback, in order to improve	Non-equivalent group controlled clinical trial involving medical and nursing staff working in 10 intervention and 10 control units in four major cities and two regional hospitals in South Australia.	Comparison of incident reporting rates and types of reports between baseline and study period, and control and intervention units. Interventions: education on reporting; reducing fear and burden of reporting (changes to the reporting process and forms), and improved feedback on reporting for the reporting staff.	A greater variety and number of incidents were reported by the intervention units during the study, with improved reporting by doctors from a low baseline. These findings suggest it is possible to improve reporting rates and diversify the types of incidents. However, there was considerable heterogeneity between reporting rates in different types of units.

		incident (incl. MEs) reporting rates and change the types of incidents reported.		A range of statistical tests employed for data analysis.	
Levtzion-Korach et al. 2009	United States (US), a tertiary care academic medical centre affiliated with Harvard Medical School.	To evaluate the rate, content, ease of use, reporters' profile, and the follow-up and actions resulting from reports submitted to a Web-based electronic reporting system.	A prospective cross-sectional analysis of reported incidents (incl. MEs).	Analysis of the ease of use of the system and the submitted reports (n=14 179) to a commercial Web-based reporting system at a tertiary care academic hospital for 31 months between May 2004 and November 2006. Analysis of incidents by descriptive statistics and statistical tests.	The reporting system effectively captured incidents, actions, and follow-up on reporting (e.g., change of equipment or policy, education of staff, changes in staffing levels). It was concluded that the main strengths of an electronic reporting approach are the ability to use branching logic, the ways in which it enables analysis, and the feasibility of incorporating collection of information about action and follow-up steps in the database.
Miller et al. 2006	US, the Johns Hopkins Children's Center.	To assess the accuracy and to define the epidemiology of MEs reports.	A retrospective cohort study of 581 error reports containing 1010 MEs reported between July 2001 and January 2003 at a large academic children's institution.	Evaluation of all MEs (n=1010) in error reports (n=581) reported between July 2001 and January 2003. Three clinician experts in patient safety independently reviewed all error reports classified by the reporter and recorded any corrections to the error type based on the information provided by the reporter in the free text field of the reporting form. Summary data on how often the error type was altered by the clinicians. The percentage agreement between the original classifier and the clinician was measured. Descriptive statistics of reconciled errors.	The analysis of the accuracy of error reports showed that most of the reports were accurate. Following expert review, 208 errors (21%) were deleted because they had been inappropriately coded as errors and 97 (10%) were added as they were not initially coded despite having occurred. 352 ME reports needed to have the subtype of error reclassified. The overall distribution of error type categories did not change significantly with expert review. Despite clear imperfections in the data captured, MER tools were concluded to be effective as a means of collecting reliable information on errors rapidly and in real time.

| Ricci et al. 2004 | US, paediatric cardiac intensive care unit (CICU). | To investigate the influence of two key factors, anonymity and profession (doctors versus nurses), on incident (incl. MEs) reporting by comparing two different reporting databases. | Retrospective study analysing incidents (n=211) reported via two adverse event reporting systems in a CICU. | Two adverse event reporting databases were compared: database A (DA) which is the hospital's official reporting database (non-anonymous, reports are predominantly made by nurses), and database B (DB) (anonymous and reports are submitted by a CICU consultant who collects data from daily ward rounds). Descriptive statistics to describe the incidents. | A total of 112 incidents were reported in DA, 143 in DB, and 44 in both, indicating that both databases gave an unrepresentative picture of the true frequency and severity of adverse events. Underreporting was especially notable for less severe events, including near misses. Incident reporting is heavily influenced by profession of the reporters as well as anonymity. When adverse event reporting is based predominantly on the observations of a single professional group, the data are grossly inaccurate. |

*The key findings in the Table are selected from the presented studies in relation to the focus of the systematic literature search.

Table 7. *Studies comparing medication error reporting (MER) systems to other methods for medication error detection and learning (n=3). ME=medication error. Studies are presented in alphabetical order.*

Reference	Country & setting	Objectives	Design	Materials and methods	Key findings*
Olsen et al. 2007	United Kingdom (UK), district general hospital, NHS.	To examine the value of methods for detecting and describing adverse events (AEs) (incl. MEs) in hospital practice.	Prospective data collection on the same patient cohort using incident reporting, pharmacist surveillance and patient record review as sources of information.	Data on AEs were collected on 288 patients discharged from adult acute medical and surgical units using incident reports, active surveillance of prescription charts by pharmacists and record review at time of discharge. Descriptive statistics to describe and compare the incidents detected by different methods.	No data source detected all AEs in the same patient group. Record review detected 26 AEs and 40 potential adverse events (PAEs). Incident reporting detected 11 PAEs and no AEs. Pharmacy surveillance found 10 MEs all of which were PAEs. There was little overlap in the nature of events detected by the three methods. The findings suggest that incident reporting does not provide an adequate assessment of clinical AEs and that this method needs to be supplemented with other more systematic forms of data collection.
O'Neil et al. 1993	United States (US), medical service of a university-affiliated teaching hospital, Brigham and	To assess the effectiveness of physician reporting as a method for identifying adverse events (incl. MEs), and to compare the reporting mechanism with a retrospective medical record review.	Physician reporting system using the hospital e-mail compared with a retrospective record review using a screening mechanism followed by structured, implicit physician review of the record.	Patient admissions (n=3146) to medical service during a four-month period were studied. Initial screening of patients' medical records for adverse events, followed by physician-conducted analysis of records possibly involving an adverse event. Testing the inter-rater reliability of physician reviewers by using a 10% sample of medical records. Confidential e-mail reporting of adverse events by medical staff and analysis of reports. Assessment of costs for both methods	The physician reporting system identified nearly the same number of adverse events as the record review method. The two methods identified the same patients with adverse events in only half of the cases. The physicians reporting system detected more preventable errors than the medical record review and was also less costly. The reporting system also actively integrates physicians into quality-improvement efforts which is the advantage of the system.

	Women's Hospital.			and error preventability. Statistical tests to compare the two methods.	
Sari et al. 2007	UK, a large NHS hospital in England.	To evaluate the performance of a local incident reporting system in identifying patient safety incidents.	Two stage retrospective review of patients' case notes and analysis of data submitted to the routine incident reporting system on the same patients.	A random sample of patient admissions (n=1006) during a three-month period was studied. Initial screening of patients' medical records for adverse events, followed by physician conducted analysis of records possibly involving an adverse event. Testing the inter-rater reliability of both reviews by using a 10% sample of medical records. Analysis of the data on incident reporting system for the sample admissions (n=1006) to see if the events had been reported.	The routine reporting system as implemented in the large hospital missed most patient safety incidents that were identified by case note review and detected only 5% of those incidents that resulted in patient harm. Only one third of the adverse events were detected by both methods. Findings suggest that the routine reporting system considerably underreports the scale and severity of patient safety incidents. Structured case note review may have a useful role in surveillance of routine incident reporting and associated quality improvement programmes.

*The key findings in the Table are selected from the presented studies in relation to the focus of the systematic literature search.

Table 8. *Studies describing the development and implementation of medication error reporting (MER) systems (n=8). ME=medication error. Studies are presented in alphabetical order.*

Reference	Country & setting	Objectives	Design	Materials and methods	Key findings*
Beckmann et al. 1996b	Australia, three intensive care units (ICUs).	To develop and implement an incident reporting system for MEs and other patient safety incidents.	A descriptive two-month evaluation study employing both qualitative and quantitative methods.	Healthcare staff at three ICUs participated in the study. Development of incident report form based on: - staff (n=29) group interviews (n=6) to define the key areas of the reporting form; - workplace observation by five project coordinators to observe incident occurrence, and - literature review and experiences from previous studies by the study group. Feedback questionnaire on incident reporting to assess staff attitudes and understanding of the incident reporting, research design and organisation. Response rate 88% (n=116/129). The reported incidents were described by descriptive statistics.	A positive attitude and good understanding about incident reporting was demonstrated by more than 90% of participants. Errors in communication, technique, problem recognition and charting were the contributing factors for most incidents reported (n=128). Incident reporting may be a suitable technique for improving patient safety in ICUs.
Cheung et al. 2014	The Netherlands, National MER systems in the Netherlands (Central Medication Incidents Registration, CMR-NL),	To explore to what extent alerts and newsletters about MEs issued from the MER system of one country can be relevant to other countries and to describe the characteristics of	An explorative retrospective study.	Disseminated information items (n=90) issued by national MER systems (Canada, US and UK) from June 2009 until June 2012 were collected. Items compared to CMR-NL according to the defined assessment criteria. An e-mail survey to national MER systems (Canada, US and UK) about their characteristics.	National reporting systems can benefit from sharing alerts and newsletters between countries. There is a broad range of MEs that the Dutch national reporting programme could learn from reporting systems in Canada, US and UK. From the 90 items, 88% (n=79) were relevant for Dutch healthcare.

	Canada (ISMP-Canada), United States (ISMP-US) and United Kingdom (UK) (National Reporting and Learning Service).	national MER systems.		Descriptive statistics were used for the anlysis.	For 48% (n=43) of the items the CMR-NL had received comparable or identical errors but had not disseminated any alert or newsletter about these errors. The CMR-NL had disseminated an alert or newsletter for 14 of the 90 items (16%).
Daniels et al. 2010	Canada, British Columbia Children's Hospital (an academic tertiary care facility).	To develop a web-based system, the Family Reporting System (FRS) enabling families to routinely identify adverse events (incl. MEs) and near misses.	Evaluation study using cross-sectional survey and analysis of the reported adverse events.	Face validity and usability of FRS were measured via standardized survey instruments. Utility of FRS was measured by the rate, typology, degree of harm, likelihood of recurrence, quality of information, and inter-rater agreement analysis of the reported adverse events. Descriptive statistics to describe the reported adverse events.	Approx. 18% of the reports (n=103) concerned medications. The FRS had good face validity, excellent usability, and good clinical utility. 27% of reports could not be evaluated for degree of harm due to lack of detailed information from reporter, and 34% of reports were not safety issues, indicating an inherent limitation and target for improvement in family reporting. The application of survey and human factors methodologies to the design of an electronic system is an effective means of developing an electronic adverse event reporting system for the use of families of paediatric patients.
Elliott et al. 2014	Canada, Eastern Health, a large healthcare organization in Newfoundland and Labrador, involved sites: acute care, long term care;	The sites used a paper-based reporting system pre-study. Objectives were to implement an electronic clinical safety reporting system (CSRS); to	An evaluation study using both quantitative and qualitative methods.	Measurement and comparison of the reported data for six months prior to the implementation of CSRS and six months after the implementation. A structured post-implementation user satisfaction survey to frontline clinical staff and managers (response rate 33%, n=358 out of 1079).	There are benefits in moving from a paper-based reporting of errors in healthcare to an electronic Web-based system. Several benefits were realised, e.g., increases in the number of errors reported, in errors reported within 48 hours of occurrence, in errors reported by staff other than registered nurses, in

				Pre- and post-implementation key informant interviews with senior managers (n=11). Pre- and post-implementation focus-groups to clinical staff (n=13) and managers (n=12) using the CSRS and senior managers' interviews.	near misses reported, and improved timelines between occurrence and notification by the manager. There was good user satisfaction with the tool e.g., regarding ease of use, accessibility, and consistency in performance. Frontline staff and managers supported the CSRS, and identified both benefits of the system (e.g., improved understanding on what constitutes an error and near miss) and areas for improvement (e.g., need for better feedback from reporting).
	community health in an urban setting, and an integrated services site in a rural setting.	assess the system on achieving its stated objectives (the benefits realised and disadvantages/ areas of improvement), and to identify contributions to the field of electronic clinical safety reporting.			
Jones et al. 2004	US, Critical access hospitals (CAHs) (n=6) in Nebraska.	To describe the implementation and initial findings of a voluntary MER system developed by the Nebraska centre for rural Health Research (NCRHR); to study association between hospital characteristics (e.g., availability of pharmacy support) and reported MEs between the CAH MER system and MEDMARX.	Retrospective cross-sectional study.	A voluntary MER system was developed and implemented. NCRHR analysed statistically the errors (n=800) reported in 2002-2003. Statistical tests to examine association between the CAHs and MEDMARX error data. Statistical comparison of error reports from CAHs (limited pharmacy support to reporting) and MEDMARX hospitals with 24/7 pharmacy support. Workshops (n=2) for the participating CAHs to facilitate learning from the reported errors (did not produce any research data).	Similar to MEDMARX, 99% of MEs reported by six Nebraska CAHs were not harmful, reported errors most often originated in the administration phase, and the most common error type was omission. The CAHs reported smaller proportions of near misses and errors originating in the prescribing phase than in MEDMARX. The higher likelihood of reporting errors and near misses was associated with more pharmacy support. Limited presence of pharmacists in CAHs is a barrier to implementing double checks and learning from system failures in the medication use system.
Küng et al. 2013	Switzerland, Cardiovascular Surgery	To determine: frequency and type of MEs; to assess	A cross-sectional study design to assess MEs and	MEs (n=987) were reported by nurses (n=119) using an investigator-developed	288 (29%) MERT reports indicated that there had been a ME.

	Department of the University Hospital.	the number of MEs prevented by registered nurses; to assess the consequences of MEs for patients, and to compare the number of MEs reported by a newly developed MER tool to the number reported by the hospital's critical incident reporting system (CIRS) for adverse events.	feasibility of a novel MER system.	ME self-reporting tool (MESRT) for a one month period. Data analysis employed descriptive statistics.	More MEs were reported with the MESRT (n=288) than with traditional CIRS (n=7). The finding suggests it is important to use simple reporting tools which facilitate ME reporting (see the MERST description in Appendix 2b). Nurses reported preventing 49 MEs (5%). Overall, eight MEs (2.8%) had patient consequences. The high reporting rate suggests that this new method may be a very effective approach to detect, report, and describe MEs.
Nordén-Hägg et al. 2012	Sweden, all Swedish pharmacies (approx. 880 community and 80 hospital pharmacies).	To design and evaluate a national web-based dispensing error reporting system for Swedish pharmacies, replacing the currently used paper-based system.	Descriptive cross-sectional study using both quantitative and qualitative research methods.	A working group designed the new system. The number of reports before (1999–2003) and after (2004–2005) introduction were analysed. The completeness of reports was evaluated through the study of 100 randomly selected reports from each system. Analysis was completed by statistical tests. Perceptions on introduction were collected in semi-structured interviews to the members of working group (n=4) and one assistant and subjected to descriptive analysis.	Introducing a web-based system for reporting dispensing errors had an impact on quantity of reports and their completeness. Information (e.g., seriousness of the error and outcomes to patient) was more comprehensively reported in the new system. A significant difference existed to the extent to which incidents were described as well as details provided of the medicine and the patient. Time and patience was needed to implement the changes; users initially found the web-based system difficult to handle, taking more than six months to change this perception.

Pierson et al. 2007	US, 25 nursing homes in North Carolina.	To describe the implementation and evaluation of a web-based MER system.	Evaluation study.	A total of 25 nursing homes tested the new system over a 4- month period, entering all errors (n=631) occurring at their facility during that time. Participants were also asked to complete an evaluation survey of the new system (response rate 86% of the facilities, n=20). Descriptive statistics employed for the data analysis.	It was feasible to implement a large-scale web-based MER system in long-term care facilities. Such a system can collect detailed information on the characteristics of ME. The participants felt that the system was easy to use will help them identify areas for training and improvement, improve patient safety and reduce MEs.
Tuttle 2004	US, an university affiliated teaching hospital, Strong Memorial Hospital.	Development and implementation of educational initiatives to facilitate the use of an electronic reporting system (ERS) in an academic medical centre to measure the impact on knowledge of the ERS on reporting behaviour and safety attitudes and to evaluate the accuracy of the information being reported.	Retrospective study analysing incident data (incl. MEs) reported before and after implementation of an electronic ERS, and safety culture of the study setting.	An internal ERS for safety events was implemented. A multifaceted educational program was developed to promote safety awareness and use of the ERS. The safety events reported in 2002 (n=2843) were analysed by statistical tests and compared to events (n=1542) reported by previous paper based system. A survey was administered to assess safety knowledge and attitudes of patient care personnel (response rate 10%, n=733 out of 7095).	Using of complementary educational efforts and the new electronic system were able to increase reporting significantly and to improve employees' knowledge and use of the ERS. More work is needed to involve physicians in reporting, to improve the accuracy of submitted information, and to better prioritize, organize, and streamline event analysis.

*The key findings in the Table are selected from the presented studies in relation to the focus of the systematic literature search.

Table 9. *Studies on utility of medication error reporting (MER) systems (n=10). ME= medication error. Studies are presented in alphabetical order.*

Reference	Country and setting	Objectives	Design	Materials and methods	Key findings*
Braithwaite et al. 2008	Australia, healthcare professionals.	To evaluate an electronic Incident (incl. MEs) Information Management System (IIMS) implemented system-wide by the Department of Health, New South Wales, Australia.	Cross-sectional anonymous on-line survey.	A structured questionnaire to healthcare professionals using IIMS (available for healthcare professionals on a website for one month). Acquired information: demographic information of respondents; training in and using of the system, and attitudes towards the system. Descriptive statistics and statistical tests to analyse the responses.	The majority of respondents (n=2185) had undertaken training on using IIMS and rated it highly. Most had reported incidents and maintained their previous reporting levels before IIMS implementation. Most attitudes regarding using the system and its security were favourable. There were mixed attitudes about workplace safety cultures and the value of the system. Deficiencies in quality of reporting, feedback on incident reports and lack of resources to analyse incident data were problems identified. Nurses were most, and doctors least, likely to undertake training, report incidents and express favourable attitudes towards the system.
Boyle et al. 2012	Canada, community pharmacies.	To determine how staff assessment of key quality related event (QRE) (i.e., MEs and near misses) reporting process characteristics (e.g. ease of use, time to use) and QRE learning differ in community pharmacies in which the QRE reporting process is manual	A cross-sectional survey.	Mail-based survey on pharmacy staff perceptions on a number of key areas relevant to QRE reporting (e.g., pharmacy culture). Participants: 121 respondents (response rate 49%) in pharmacies with a formal QRE reporting system. Statistical tests employed for the data analysis.	QRE reporting systems appeared to be cost effective, easy to complete and involve low risk of operations. System characteristics and learning were different in pharmacies with manual vs. computerized systems. Advantages of computerised systems were enhanced QRE reporting and analysis capabilities, integration to day-to-day practices and encouragement to staff to make continuous improvements and is not time consuming. Common QRE learning activities in pharmacies with computerized systems were effectiveness of changes made following an error; following an error, there is usually commitment to improve

					safety throughout pharmacy, and the culture is one of continuous improvement.
		versus computerized.			
Chua et al. 2003	United Kingdom (UK), four community pharmacies.	To investigate the feasibility of a self-reporting system for dispensing errors and near misses in primary care (community) pharmacies, and to identify the types of errors or near misses commonly encountered.	A feasibility study employing retrospective analysis of reported dispensing errors and qualitative focus group discussions.	The dispensing error data collection was conducted in two phases, each of 4 weeks' duration. Dispensing errors (n=39 accounting for 0,08% of 51 357 dispensed items) and near misses (n=247 accounting for 0,48%) were recorded by the pharmacy staff in a standard data collection form. A focus group discussion was held with the dispensing staff (number not reported) of participating pharmacies to identify and evaluate the feasibility of the reporting system. Descriptive statistics and statistical tests to analyse the quantitative data.	The results show that near misses occurred six times more often than actual dispensing errors, indicating the importance of final checking in pharmacies. The focus group discussion indicated that the outcome of the self-reporting scheme was more important than the incidence of errors or near misses. Participating pharmacies also agreed that the self-reporting scheme used was feasible and they would continue using the scheme although some incentives would be helpful.
Coley et al. 2006	United States (US), Pittsburgh Regional Healthcare Initiative (PRHI) hospitals in the region of Pennsylvania.	To evaluate the perceived barriers to using a region-wide MER system, MEDMARX.	A qualitative study using a series of focus groups of key informants from different types of hospitals in the study region.	A qualitative analysis of representatives (n=8) from 8 hospitals: 2 urban, 4 community, 1 long-term care, and 1 paediatric using MEDMARX. Participants were involved with at least one aspect of error reporting (i.e., data collection, report utilisation) at their institution. Information was obtained on barriers to MER and use of a regional quarterly error report.	The study identified obstacles to reporting and data sharing that must be addressed to improve patient safety across the region of Pennsylvania. Few hospitals had sufficient dedicated staff for identification, verification, and reporting of errors. Efforts to promote reporting were compromised by other demands on staff time. Information systems in most hospitals were fragmented, leading to duplication of efforts and inefficiency in reporting of errors. Healthcare staff are concerned about benchmarking by hospital administrators and reactions to increases in error reporting.

				Qualitative content analysis of the data.	Hospitals can generate internal error reports for analyses faster than they would receive the quarterly reports from MEDMARX.
Evans et al. 2006	Australia, diverse clinical settings in six Australian hospitals.	To assess awareness and use of the current incident (incl. MEs) reporting system and to identify factors inhibiting reporting of incidents in hospitals.	A cross-sectional survey.	A structured survey on knowledge and use of the current reporting system, and barriers to incident reporting. Respondents: doctors (n=186) and nurses (n=587) (response rate 73%, n=773 out of 1062). Statistical tests used for data analysis.	Most nurses and doctors (98%) were aware of the reporting system. Both doctors and nurses believe they should report most incidents, but nurses do so more frequently than doctors. To improve incident reporting, especially among doctors, clarification is needed of which incidents should be reported, the process needs to be simplified, and feedback given to reporters.
Hirose et al. 2007	Japan, Kyoto University hospital.	To explore factors associated with delays in incident (incl. MEs) reporting after adverse events and near misses.	A prospective and descriptive study exploring the reported incidents.	Incident reports (n=6880) reported by physicians and nurses in 2002-2005. Statistical analysis of the incidents and their lag time (time between occurrence and reporting).	Although physicians and nurses reported nearly equal numbers of events resulting in major injury, physicians reported far fewer minor incidents and far fewer incidents overall. Lag time was longer for physicians than nurses. Lag time for major injuries was 18% shorter than for minor injuries. Quantitative evaluation of lag time may facilitate improvements in incident reporting systems by distinguishing institutional obstacles to physician reporting from physicians' lesser willingness to report.
Kennedy & Littenberg 2004	US, community pharmacies in Vermont.	To study community pharmacists' awareness and use of the national Medication Errors Reporting Program (MERP).	Telephone survey.	A pharmacist was contacted in 98% (n=122 out of 124) of all operating community pharmacies in Vermont between June 2002 and February 2003. Pharmacists were asked about awareness and use of MERP. The telephone surveys were conducted using a standard	The majority of Vermont community pharmacists were aware of MERP. However, use was low. Pharmacists employed by independent pharmacies were more often aware of and used the MERP more than pharmacists employed by other pharmacy types (e.g., chain or supermarket) indicating that barriers to reporting to a common system such as MERP may differ depending on pharmacy type. Additionally, many non-independent community pharmacies

				script. Data were analysed by descriptive statistics and statistical tests.	reported errors to a corporate program instead of MERP. Evidence of an education deficit related to MERP and to reporting in general was identified.
Kuo et al. 2012	Taiwan, a teaching hospital in southern Taiwan.	To evaluate the use of a Web-based incident (incl. MEs) reporting system by investigating factors influencing nurses' use of the system and evaluating changes in reporting behaviour after implementation of a web-based system.	Mixed-methods design including a cross-sectional survey and a retrospective record review of incidents.	A structured questionnaire to study nurses' satisfaction with the Web-based reporting system and factors impeding their reporting willingness by four-point Likert scale answers, and recommendations for system improvements by open-ended questions (response rate 83%, n=249 out of 300). Data on nurse demographics were collected. Incidents were collected, classified, and compared between the paper-based and web-based system. Descriptive statistics and statistical tests were employed to analyse the data.	The Web-based reporting system was used more often than the paper-based system. Senior nurses were less willing to report events, nurses on internal medicine units had higher satisfaction and reporting rates than others possibly attributed to increased familiarity with the system. The lowest satisfaction was related to the time it took to file a report. The study recommends that the data entry process should be simplified and the network system improved to increase user satisfaction and reporting rates (e.g. provision of clear incident classifications).
Savage et al. 2005	US, a national electronic MER system, MEDMARX.	To evaluate the utility of the MEDMARX.	A prospective cross-sectional survey.	A survey regarding the utility of MEDMARX was developed and responded to by identified contact persons in 200 hospitals (response rate 38%, n=200 out of 525) using MEDMARX. Statistical tests and descriptive statistics were used to analyse the responses.	Implementation of the MEDMARX led to an increase in the number of reported MEs and improvements in the medication use-process. Pharmacy departments were most often reported as responsible for medication safety activities after MEDMARX implementation. Most facilities (94%) generated reports from the error database and 75% used this information to identify opportunities to improve their medication use system. Many users (66%) were satisfied with the impact of MEDMARX on improving their medication use system, and believed that MEDMARX provided a tool for root-cause analysis

					of MEs (71%) and helped to identify problems in medication use process (85%).
Williams & Ashcroft 2009	UK, an acute university teaching hospital in the North West of England.	To examine: the reliability of the severity rating scale used by the National Reporting and Learning System (NRLS) in England and Wales for MEs; and the likelihood of reporting MEs among healthcare professionals.	A descriptive cross-sectional study.	Participants (n=40, doctors, nurses, pharmacists, technicians) completed a questionnaire containing nine ME scenarios on two separate occasions; participants rated the severity of each incident using the NRLS severity rating scale and indicated the likelihood of reporting the incident via the hospital incident reporting system. Test–retest reliability of the severity ratings was also examined within and between professional groups. Statistical tests employed for the data analysis.	Pharmacists and nurses were significantly more likely to report the errors if they had witnessed them. There was a wide variation in the assignment of ME severity ratings within and between healthcare professional groups. Doctors and pharmacists reported MEs as being less severe than nurses and pharmacy technicians. Pharmacists and nurses were most likely to report and doctors the least likely to report MEs in this study. Consequently, there may be marked differences in the severity ratings for MEs reported via the NRLS between different healthcare professional groups and at different time points rated by the same individuals.
Zwart et al. 2011	The Netherlands, three general practices' (GP) out-of-hours services (OHSs).	To compare the number and nature of incident reports (incl. MEs) collected in a local incident-reporting procedure (LIRP) and the currently used centralised incident-reporting procedure (CIRP) for OHSs.	A non-equivalent controlled, quasi experimental field study.	A local incident-reporting system (intervention) was implemented in OHS1. A local committee analysed the reported incidents. In OHS2 and OHS3 serving as controls, the current centralised incident reporting system was continued, where incidents were reported to an advisory committee of the board of directors of the OHSs collaboration. Statistical tests to compare the data before and after the intervention	The study suggests that a local incident-reporting system is likely to increase the willingness to report and facilitates faster implementation of improvements. In contrast, the central system, by collating reports from many settings, seems better at addressing generic and recurring safety issues. The advantages of both approaches should be combined.

				implementation. Qualitative interviews with the managers at the study OHSs and members of CIRP and LIRP committees about their opinions on the reporting procedures.	

*The key findings in the Table are selected from the presented studies in relation to the focus of the systematic literature search.

Table 10. *Studies on medication error reporting (MER) system innovations (n=3). ME=medication error. Studies are presented in alphabetical order.*

Reference	Country & setting	Objectives	Design	Materials and methods	Key findings*
Dollarhide et al. 2008	United States (US), four university affiliated teaching hospitals.	To determine the feasibility of capturing self-reported medication events by a handheld computer-based Medication Event Reporting Tool (MERT).	Handheld computers operating the MERT software application were deployed and evaluated among study participants on the medical wards.	Participants: volunteer nurses (n=119) and physicians (n=185). Participants were encouraged to complete confidential reports on the handheld computers for medication events observed during the study period. Participants carried a handheld computer for 1-week intervals. The data was collected by the developed MERT software application (see Appendix 2b for details). Data on daily work load; work activity, stress and perceived work demands were collected by additional surveys. Statistical tests and descriptive statistics employed for data analysis.	A handheld-based reporting tool is a feasible method to record medication events in inpatient hospital care units. Handheld reporting tools may hold promise to augment existing hospital reporting systems. Over the course of 2,311 days of clinician participation, 76 medication events were reported; the median time for report completion was 231 seconds. The average event reporting rate for all participants was 0.033 reports per clinician shift. Nurses and attending physicians had the highest reporting rates.
Kennedy & Littenberg 2004	US, community pharmacies (n=7) in north-	To pilot and evaluate dictation as a novel method of reporting	A crossover study.	A reporting form was developed and implemented. Pharmacists (n=9) reported errors (n=72) by dictation	There were no differences in completeness of reports between paper and dictation.

				(n=33) and paper (n=39) methods for six weeks each. Assessment of dictation feasibility, pharmacist satisfaction with reporting, pharmacist preference for a dictation or paper reporting method (a pharmacist survey), and a content description of the prescribing errors reported were conducted.	Dictation does not appear to increase prescribing error reporting as compared with a paper method. Implementing dictation in community pharmacies proved feasible although most of the pharmacists preferred the paper method. Further investigation to explore dictation as a useful technology in community pharmacies is needed.
western Vermont.	prescribing errors in community pharmacies; to determine if dictation stimulated more prescribing error reports than a paper-based reporting method, and to assess the reporting system.				
Phipps et al. 2014	UK, National Reporting and Learning System (NRLS).	To explore the combined use of a critical incident database and work domain analysis (WDA) to understand patient safety issues in community pharmacy.	A retrospective quantitative review of incidents (incl. MEs) reported to NRLS and prospective qualitative WDA of community pharmacy.	Descriptive statistical analysis of reported incidents (n=14 709) that involved community pharmacy between April 2005 and August 2010. A WDA of community pharmacy using observational data from community pharmacies (n=5), technical documentation, and a focus group with pharmacists (n=6). Selected reports (n=30) from the NRLS were mapped onto the model generated by the WDA.	Incident reporting data can be used to identify general patterns of MEs, whereas the WDA can generate information about the contextual factors that surround a critical task (e.g., demands arising from the organisation for pharmacy staff to be both maximally efficient and thorough at the same time, creating a need to compromise between the two and therefore potentially impacting medication safety). Combining the insights from different analytical methods, such as incident reporting and WDA, improves understanding of patient safety problems.

*The key findings in the Table are selected from the presented studies in relation to the focus of the systematic literature search.

Table 11. *Reviews on medication error reporting (MER) systems (n=1). ME=medication error.*

Reference & country	Objectives	Databases	Inclusion criteria	Analysis	Key findings*
Cheng et al. 2011, China	To compare administration of incidence (incl. MEs) reporting systems for healthcare risk management in United Kingdom (UK), United States (US), Canada, Australia and Taiwan.	The official websites of the healthcare risk management agencies in the four countries and one district.	Laws, regulatory documents, research reports, reviews, and evaluation forms about healthcare risk management in the UK, US, Canada, Australia, and Taiwan (reported in another source: Sun et al. 2011).	Descriptive comparative analysis was performed on relevant documents.	142 documents were included. US had the most relevant documents (n=68). Incident reporting has expanded from MEs and hospital-acquired infections to near-misses and other patient safety incidents. Reporting systems are either government-led or legal/regulatory/non-governmental organization collaborative. Compared to four countries, the Taiwan system emphasised more the public welfare, confidentiality and information sharing.

*The key findings in the Table are selected from the presented studies in relation to the focus of the systematic literature search.

5.2.1 Study countries and settings

Most of the included studies (n=26) originated in English speaking countries, with the United States being the country with the highest rate of published studies (n=12) (Tables 6-11). The other studies were conducted in the United Kingdom (n=7), Australia (n=4), Canada (n=3), the Netherlands (n=2), China (n=1), Japan (n=1), Sweden (n=1), Switzerland (n=1) and Taiwan (n=1). One of the studies comprised of a literature review of national incident reporting systems in Australia, Canada, Taiwan, the United Kingdom and the United States (Table 11). The studies were published between 1993 and 2014, with majority of them from 2006-2010 (n=15). Hospitals were the most common settings for the studies (n=20) with community pharmacies being the second most common single site of study (n=5).

5.2.2 Study methods

The majority of the included studies were descriptive in nature. They employed quantitative and qualitative research methods. A mixed-methods approach applying both quantitative and qualitative methods within one study was also common. The relatively popular use of qualitative methods in the included studies may be explained by their usefulness for studying phenomena that are complex, contextual and influenced by the interaction between physical, psychological and social factors (Runciman 2002). Indeed, MER systems and their functionality are such a relatively new phenomenon occurring within the complex system of healthcare. A typical study design involved an analysis of reported errors and a survey or interview with the reporting healthcare professionals about the user satisfaction of the system (Beckmann et al. 1996b; Chua et al. 2003; A. G. Kennedy & Littenberg 2004; Tuttle et al. 2004; Pierson et al. 2007; Dollarhide et al. 2008; Armitage et al. 2010; Daniels et al. 2010; Elliott et al. 2014; Nordén-Hägg et al. 2012).

During the literature review, it became apparent that much of the available literature on MER systems and their functionality is of a non-experimental, descriptive type that reports case studies of locally implemented MER systems. These publications often presented the development and implementation, and the characteristics of the system without any scientific study design to explore their functionality. The same notion has been made by others studying patient safety incident reporting (Benn et al. 2009). Although being outside the scope of the present literature review, the non-experimental reports of MER systems may provide valuable insights for those seeking to establish such systems.

5.2.3 Key findings

A summary of the key findings of the literature review of studies on MER systems is presented in Table 12. Many studies reported aspects related to the effectiveness of MER systems in capturing medication error data (Table 12). Despite of imperfections in the data captured (see 5.2.4), some of these studies found MER systems to be effective as a means of collecting information on medication errors and for improving patient safety of the

reporting organisations (O'Neil et al. 1993; Beckmann et al. 1996b; Miller et al. 2006; Pierson et al. 2007; Levtzion-Korach et al. 2009; Kung et al. 2013). In contrast, some studies suggested that MER systems considerably underreport the frequency and severity of medication errors and other adverse events (Ricci et al. 2004; Olsen et al. 2007; Sari et al. 2007) suggesting that MER systems need to be supplemented with other more systematic forms of data collection (Olsen et al. 2007). However, present studies found that no data source alone detected all adverse events, including medication errors, in the same patient group (O'Neil et al. 1993; Olsen et al. 2007; Sari et al. 2007).

Table 12. *Summary of the key findings of the literature review on studies on medication error reporting (MER) systems.*

Key Findings	References
MER systems may provide an effective tool to improve medication safety, but they need to be supplemented with other data collection methods for estimating the frequency of medication errors.	O'Neil et al. 1993; Beckmann et al. 1996b; Ricci et al. 2004; Miller et al. 2006; Olsen et al. 2007; Pierson et al. 2007; Sari et al. 2007; Levtzion-Korach et al. 2009; Kung et al. 2013
Improving the quality of medication error reports represents a key target for improvement for many MER systems.	Tuttle 2004; Braithwaite et al. 2008; Williams & Ashcroft 2009; Armitage et al. 2010; Daniels et al. 2010; Haw & Cahill 2011
The users were mostly satisfied with the MER systems in their organisations with some areas needing improvement (e.g. simplifying the data entry process).	Beckmann et al. 1996b; Chua et al. 2003; Savage 2005; Pierson et al. 2007; Braithwaite et al. 2008; Daniels et al. 2010; Kuo et al. 2012; Elliott et al. 2014
Reporting of medication errors and other adverse events is influenced by the profession of the reporter with more work needed to involve physicians in reporting.	Ricci et al. 2004; Tuttle 2004; Savage 2005; Dollarhide et al. 2008; Evans et al. 2006; Hirose et al. 2007; Braithwaite et al. 2008; Williams & Ashcroft 2009; Kung et al. 2013
Measures to increase medication error reporting:	
Electronic instead of paper-based reporting.	Boyle et al. 2012; Kuo et al. 2012; Nordén-Hägg et al. 2012; Elliott et al. 2014
Staff education on reporting.	Tuttle 2004; Evans et al. 2007; Braithwaite et al. 2008
Pharmacy support for reporting.	Jones et al. 2004
Hand-held computer based reporting.	Dollarhide et al. 2008
MER systems have several advantages, such as cost-effectiveness, and as medication safety promotion tools.	O'Neil et al. 1993; Levtzion-Korach et al. 2009; Boyle et al. 2012
Lack of feedback on reporting and resources to analyse the data are barriers to effective use of MER systems.	Braithwaite et al. 2008; Armitage et al. 2010

The need for increasing the quality of the reported data in the MER systems was identified by many studies (Table 12), representing a potential key area of improvement for many MER systems. The identified problem areas that need to be targeted by actions were: varying quality of the reports, error reports focusing on individuals and lack of contributing factors in the reports (Armitage et al. 2010). Other problems were lack of information on the degree of patient harm, reporting other than safety issues (Daniels et al. 2010) and wide variation of medication error severity ratings reported by different healthcare groups (Williams & Ashcroft 2009).

An important aspect of evaluation of electronic health information systems, such as MER systems, is the end users' acceptance of the system (Elliott et al. 2014). In general, the

MER systems included in the present literature review showed a good user satisfaction (Table 12). However, there was some mixed user attitudes about the safety culture of the reporting units, the unclear value of the reporting system for the reporting staff (Braithwaite et al. 2008), the time it took to file a report and the need to simplify the data entry process (Kuo et al. 2012). One study concluded that time and patience was needed to successfully implement a new MER system in Swedish community pharmacies (Nordén-Hägg et al. 2012).

Many studies noted that MER is heavily influenced by the profession of the reporters with nurses being the professional group most likely to report (Table 12). When adverse event reporting is based predominantly on the observation of a single professional group, the data are grossly inaccurate (Ricci et al. 2004). Therefore, work is needed to involve all healthcare professionals in medication error reporting activities with special emphasis in physicians, which was found to be the profession less likely to report (Tuttle et al. 2004; Evans et al. 2006; Hirose et al. 2007; Braithwaite et al. 2008; Williams & Ashcroft 2009).

Several benefits, such as increased number of reports, were realised when moving from paper-based MER system to an electronic system (Boyle et al. 2012; Kuo et al. 2012; Nordén-Hägg et al. 2012; Elliott et al. 2014). Other interventions found to improve medication error reporting and staff knowledge of the MER system were educational efforts (Tuttle et al. 2004; Evans et al. 2007; Braithwaite et al. 2008) and pharmacy support for medication error reporting (Jones et al. 2004). A handheld-computer based reporting tool studied by Dollahide et al (2008) represented a promising innovation to augment recording medication errors instantly after their occurrence at hospital units. Phipps et al (2014) found that combining different analytical methods, such as incident reporting and work domain analysis, improves the understanding of patient safety problems in the workplace.

Several advantages of MER systems as tools to improve medication safety were identified; MER systems appeared to be cost-effective (O'Neil et al. 1993; Boyle et al. 2012), involve low risk of operations (Boyle et al. 2012) and detected more preventable errors than medical record reviews (O'Neil et al. 1993). Levtzion-Korach and colleagues (2009) concluded that the main strengths of electronic reporting are the ability to use branching logic, analysis of errors and the feasibility of incorporating the collection of information about actions and follow-up steps after the error in the database. A feasibility study for recording dispensing errors in United Kingdom primary care pharmacies found that the outcome of the reporting system was more important for the staff than the incidence of errors (Chua et al. 2003). However, others found the lack of feedback on incident reports and resources to analyse the data as barriers to overcoming effective use of MER systems (Braithwaite et al. 2008; Armitage et al. 2010).

5.2.4 Quality of the studies

The quality of the studies was not systematically evaluated in the present literature review. However, a considerable variety in the quality of reporting the studies was identified especially in relation to reporting the study methods. In some sources the description of study methods was detailed (e.g., Armitage et al. 2010). However, some sources lacked relevant information to evaluate the rigour of methods used for data collection or analysis (e.g., Beckmann et al. 1996b; Cheung et al. 2014; Elliott et al. 2014) and to make

conclusions about the quality of the study. Some of these articles comprised of distinguished descriptions about the development and evaluation of MER systems, but lacked a scientific description of the selected methods for data collection and analysis (Pierson et al. 2007; Hickner et al. 2010).

5.2.5 Limitations and future research

The described literature review is limited by the extent to which is has been able to detect all the relevant published research on functionality of MER systems. As the literature search proceeded it came apparent that some publications may have gone unidentified as the search terms did not involve terms such as "medical error", "patient safety incident" or "adverse event". Exclusion of these terms was a strategic decision at the time of the search strategy formulation as the focus was specifically in MER systems. However, MER systems are integrated to wider patient safety incident reporting systems in many countries (Doupi 2009; Cheng et al. 2011). Therefore, research on these systems may not be comprehensively found by search terms comprising medication error related terms only. However, it is believed that the present literature review represents the key publications on the area, supported by the included publications' repeated occurrence on each others' reference lists. For similar future reviews on MER systems it is still recommended to also include other patient safety related terms and to narrow to the focus of the search on studies with some certain scope (e.g., studies on the quality of data produced by MER systems).

6 Summary of the key findings of the literature (Chapters 2-5)

➢ Incident reporting systems are one of the most widely used healthcare risk management tools across countries. Healthcare providers use these systems to systematically collect, aggregate and analyse medication errors and other patient safety data to learn from the failures of healthcare system.

➢ The systems approach to medication error management is pivotal in enabling functional medication error reporting and learning from errors in healthcare organisations.

➢ Studies on MER systems' functionality, development and implementation originate mostly in English speaking countries. Studies are mainly descriptive, and use a blend of approaches to examine MER systems in different countries and healthcare domains, with hospitals being the most common study setting. However, there is a need to promote the quality of reporting of the studies on MER systems.

➢ MER systems may provide an effective and a low-cost tool to improve medication safety, but they may need to be supplemented with other data collection methods especially for estimating the frequency of medication errors.

➢ Although users of MER systems are generally satisfied with their systems, several areas of improvement exist, e.g.:

> ➢ Improving the quality of medication error reports represents a key target for improvement for many MER systems.

> ➢ Reporting of medication errors and other adverse events is influenced by the profession of the reporter with more work needed to involve physicians in reporting.

> ➢ Lack of feedback on reporting and resources to analyse the data are barriers to effective use of MER systems.

➢ Measures to increase medication error reporting include: electronic instead of paper-based reporting, staff education on reporting, pharmacy support for reporting, and hand-held computer based reporting.

7 Aims of the study

This study aimed to explore national and local medication error reporting (MER) systems in different countries and how to make them work for learning from medication errors. The study also aimed to explore how education on medication safety could be organised for practicing healthcare professionals.

The specific objectives were (number of the original publication is provided in brackets):

1. to explore the existence and characteristics of medication error reporting (MER) systems in different countries (I);
2. to explore what makes a MER system work and what are the factors associated with the successful development and implementation of MER systems (II);
3. to assess the inter-rater reliability of medication error classifications in a voluntary Reporting System for Safety Incidents in Health Care Organizations (HaiPro) (III),
4. to describe medication errors and their contributing factors reported to HaiPro in 2006-2009 (III); and
5. to develop educational approaches for introducing medication safety principles in an interdisciplinary three-day short course for continuing education of healthcare professionals (IV).

These objectives were addressed in three empirical studies of the thesis, resulting in four international peer reviewed scientific publications (Appendices I-IV).

8 Materials and methods

8.1 Study design

This was a descriptive cross-sectional study (Smith 2002). The study outline is presented in Figure 5. The study applied both qualitative and quantitative research methods and utilized various data sources (Table 13). This approach, known as mixed methods was used to achieve a comprehensive understanding of medication error reporting systems and how to make them work in different health systems (Tashakkori & Teddlie 2010).

International Perspective on MER (Phase I)

Exploring National and Local MER Systems in Different Countries (I, II)
(2007)

An international survey to explore the

- ➢ existence and characteristics of MER systems (I)
- ➢ expert perceptions of a good and effective MER system (I)
- ➢ barriers to reporting (I)
- ➢ development and implementation of MER systems (II)

National Perspective on MER (Phase II)

Exploring Medication Error Classification and Medication Errors in
a Finnish Reporting System for Safety Incidents in
Health Care Organizations, HaiPro (III)
(2012)

A database/register based study

- ➢ to assess the inter-rater reliability of classification of medication errors reported in 2007-2009

- ➢ to explore reported medication errors and their contributing factors

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Facilitating Learning in Medication Safety (Phase III)

Development of a 3-day short Course for Healthcare Professionals
in Medication Safety (IV)
(2009)

A study using a brainstorming workshop

- ➢ to develop interdisciplinary educational approaches for introducing the basic principles of medication safety for healthcare professionals

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Figure 5. *Study outline. MER = medication error reporting.*

The study comprised three phases: the first phase covered a wider international perspective on MER systems in different countries and what makes them work in learning from medication errors (Phase I, Figure 5). This phase dated back to the time when international recommendations were published on MER systems (World Health Organization 2005; Council of Europe 2006a). The contents of this phase were influenced by the knowledge on MER systems at that time and the international recommendations for their use and establishment (U 2000; Lawton & Parker 2002; Leape 2002; Anderson et al. 2006; Council of Europe 2006a). In the second phase of the study a national perspective on medication error reporting was provided by studying the reliability of medication error classification of a Reporting System for Safety Incidents in Health Care Organizations, HaiPro, widely used in Finland (Phase II).

The final phase of the study focused on the educational perspective on management of medication safety from the systems approach (Phase III). In this phase teaching and assessment methods for facilitating learning in medication safety were studied and a syllabus for a short course on the topic was developed.

The study design in Phase I was developed at the University of Helsinki. The data collection and main parts of the data analysis in the Phase I studies were conducted at the University of Bath in the United Kingdom in collaboration with the University of Helsinki. The following phases II and III were conducted at the University of Helsinki, Finland.

Table 13. *Materials and methods of the studies I-IV. MER = medication error reporting.*

Study	Methods	Material/Subjects	Analysis
I	A cross-sectional on-line survey on MER systems and practices in different countries administered in 2007. Structured and open-ended questions on multiple areas, i.e., on the characteristics and development and implementation of MER systems. Collection of statistics for describing the stage of development and quality and capacity of healthcare system in the participating countries.	Medication safety experts (n=32) identified through 120 member organisations of the International Pharmaceutical Federation in 88 countries and other professional organizations in 3 additional countries, response rate to the questionnaire 50% (16 experts out of 32). Statistics for describing the stage of development and quality and capacity of healthcare systems in the participating countries.	Quantitative analysis in the theoretical framework of the study (Chapter 3); descriptive statistics (frequencies, percentages) for the data from the structured questions in the questionnaire. T-test, chi-square, Mann Whitney U tests for the collected healthcare related statistics.
II	Same as in Study I.	Same as in Study I.	Qualitative analysis in the theoretical framework of the study (Chapter 3); qualitative content analysis for the data from the open-ended questions.
III	A study on medication errors voluntarily reported to a Reporting System for Safety Incidents in Health Care Organizations, HaiPro. Inter-rater reliability of medication error classification in HaiPro.	Medication incidents (n=32 592) reported to the HaiPro system by 36 Finnish healthcare organisations in 2007-2009; a random sample of 1% (n=288) of medication errors to test the inter-rater reliability of medication error classification.	Quantitative analysis; descriptive statistics (frequencies, percentages) for the reported medication errors. Cohen's kappa statistics for testing the reliability of the original classifications in a random sample of 1% (n=288).
IV	A brainstorming workshop during the international Life Long Learning in the Pharmacy Conference in Helsinki in 2009.	International higher education and adult learning experts in pharmacy (n=19) who brainstormed 4 syllabi in groups for a 3-day short course in medication safety for the continuing education of healthcare professionals.	Qualitative analysis in the theoretical framework of the study (Chapter 3); qualitative content analysis of the brainstormed syllabi.

8.2 Exploring national and local medication error reporting systems in different countries (I, II)

8.2.1 Subjects and setting

The study was a descriptive, cross-sectional, on-line survey targeted to national medication safety experts knowledgeable about MER systems in their countries. To identify the experts, the network of the International Pharmaceutical Federation (FIP) was used (International Pharmaceutical Federation 2015a; International Pharmaceutical Federation 2015b) An ethical approval was obtained through the University of Bath (United Kingdom) ethical review process.

In total, 120 FIP member organisations in 88 countries were asked to facilitate identifying medication safety experts in their respective countries. Additionally, 20 informants in the Council of Europe and the Nordic Patient Safety Research Network were contacted, giving a total of 140 informants in 91 contacted countries. The identified medication safety experts then received a recruitment email from the researchers in Spring 2007. The 91 countries were divided into developed and developing countries based on the United Nations' (2007) Human Development Index (HDI).

8.2.2 Questionnaire

An on-line questionnaire was developed through a multi-staged process informed by the Human Error Theory and a systems approach to patient and medication safety (Reason 1990; Reason 2000). The key content of the questionnaire was derived from the international literature on the recommended characteristics of a MER system at that time, as well as the challenges encountered in MER and recommendations for setting up MER systems (U 2000; Lawton & Parker 2002; Leape 2002; Anderson et al. 2006; Council of Europe 2006a). A detailed description of the development and piloting of the questionnaire is provided in the original publication I.

The questionnaire comprised both structured and open-ended questions. The key structured questions of the study explored: background information on individual respondents and their countries; existence and type of MER systems in the respondents' countries; characteristics of MER systems, and barriers to reporting. Through the open-ended questions we aimed to gain information on the national contexts where the national and local MER systems operated in the experts' countries or would operate if developed and implemented. We also acquired information on whether this national context, i.e., the operational environment, comprising of organisations (e.g. national authorities), systems (e.g. medical liability systems), and individuals participating in reporting (e.g., healthcare professionals) and governing reporting (e.g., policy makers) and using the information produced on medication errors, supported the functioning of MER from a systems approach. For a more comprehensive description of the questionnaire structure and contents of the questions, please see the original publications I, II and Appendix 3.

After piloting the questionnaire and questionnaire revisions, the final questionnaire was emailed to 32 identified medication safety experts in 26 countries in spring 2007. Two reminders were sent to non-respondents at two-week intervals.

8.2.3 Analysis of the quantitative data (I)

The quantitative part of the Phase I study concentrated on exploring the existence and characteristics of national and local MER systems, and described national medication safety experts' perceptions on a good and effective MER system and barriers to reporting.

The data were received in a Microsoft Excel file and entered, and analysed using an SPSS 15.0 database. All data were managed confidentially and anonymised. The quality of data entries was audited to ensure accuracy. The results were reported as frequencies (Smith 2002; Howell 2013).

8.2.4 Analysis of the qualitative data (II)

The expert narratives from 20 open-ended questions described the factors for successful development and implementation of MER systems. Conventional qualitative content analysis with an inductive approach was applied to the data (Hsieh & Shannon 2005; Elo & Kyngäs 2008). The analysis was performed in a theoretical framework of the Human error theory and systems approach (Reason 1990; Reason 2000). The data from all open-ended questions was combined to obtain a comprehensive understanding about the issues under exploration. Some of the quantitative data was used to support the interpretation of the qualitative data.

The analysis was performed in Microsoft Word by the first author (ARH). All data were managed confidentially and anonymized. The credibility of the coding was checked by another researcher (RL) to ensure analytical rigour. The study group reflected the findings of the analysis in relation to the theoretical framework to encapsulate the key findings. In 2010, the data was reanalysed to confirm the accuracy of the coding. Consequently, some codes, themes and clusters were subjected to minor changes. For the contents of the open-ended questions, please see Section 8.2.2. Based on the findings, a model to assist in the development and implementation of MER systems was constructed and presented in the form of a diagram (see Figure 9).

8.3 Exploring medication error classification and medication errors in a Finnish Reporting System for Safety Incidents in Health Care Organizations (HaiPro) (III)

8.3.1 Medication error data

This study comprised 32 592 medication errors within the pool of all patient safety incidents (n=64 405) reported by healthcare organisations (n=36) using HaiPro during the pilot phase of the system in 2007-2009. More information on the reporting HaiPro organisation is provided in the manuscript III submitted for publication.

The HaiPro reporting process utilises an online data collection form in which structured and narrative information on a patient safety incident are reported by a healthcare professional (Appendix 4) (Awanic Ltd 2015a; Awanic Ltd 2015b). After the incident has been reported a local data classifier, usually a hospital unit nurse, classifies the narrative information by using a separate structured data classification form (Appendix 4).

The approval for using the data for research was sought from the reporting organisations by the HaiPro Steering Committee which then granted permission for the use of the medication error data for the present study. An ethical approval was obtained through the ethical review process of the Vaasa Hospital District, Finland.

8.3.2 Analysis of the data

The original data of reported patient safety incidents (n=64 405) were stored in the databases of the reporting organisations (n=36). With their permission the data on these databases were pooled to form a single Excel-database. For the analysis the data was transferred to PASW 18.0. statistical software.

The stages of the data handling and analysis are shown in Figures 6 & 7. The narrative parts of the medication error reports (Awanic Ltd 2015a) had been classified by different data classifiers in their respective organisations using HaiPro. The inter-rater reliability of the medication error classifications was evaluated to indicate which elements of the narrative information could be pooled to form a larger data set for analysing medication errors at the level of all reporting organisations. For this purpose, a random sample of 1% (n=302) of errors was drawn from the data on medication errors (n=32 592) by using the PASW 18.0 software (Figure 6). After removing errors not related to medications (n=14), an independent researcher (RJ) re-classified the narrative parts of the medication error reports, the nature of the error and the error type (n=288) (Figure 7).

The re-classification process of the narratives in the random sample (n=288) was two-staged (Figure 7); in the first stage the classification system used by the researcher (RJ) was standardised by using another independent researcher (ARH). For this purpose, a systematic random sample of every third error (n=96) was drawn from the random sample (n=288) and was re-classified by the two researchers (RJ and ARH) (Figure 7). Following this, the inter-rater reliability of agreement between the researchers was measured using the PASW 18.0. statistical software. The researchers and the original data classifiers used the same classification form comprising 96 variables with different values (e.g. variable "nature of the error" had values: 1=near miss, 2=actual error); each of the values was a yes/no selection in the classification process. Before classifying the systematic random sample of medication errors (n=96), the researchers reviewed the classification instructions provided to the original data classifiers. Some additional instructions and standard principles for the classification process were made for the study researchers to complete the original instructions.
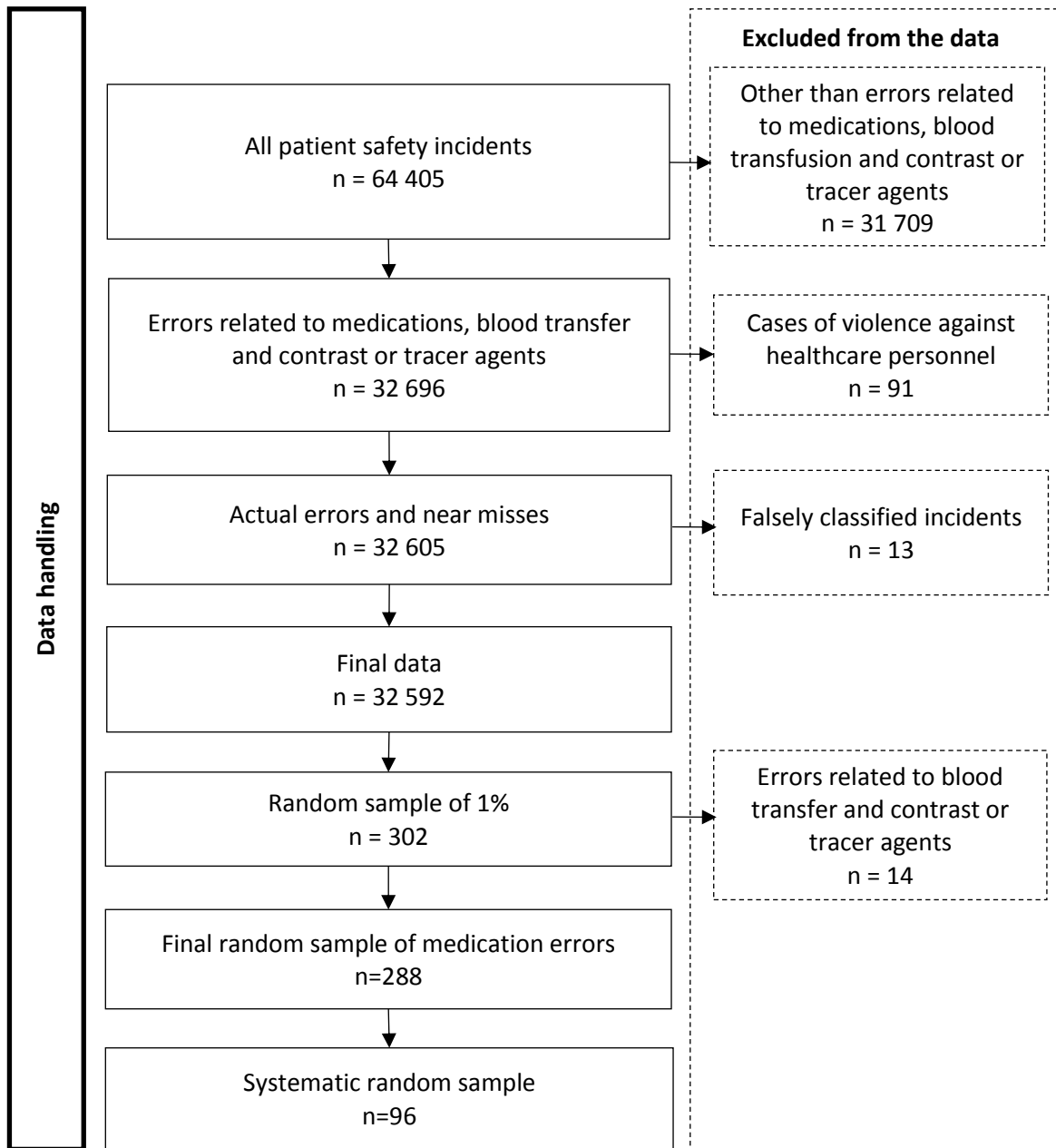
Figure 6. *The phases related to handling of the data from the HaiPro Incident Reporting System.*

In the second stage of the re-classification process, the first researcher (RJ) independently classified the remaining medication error narratives (n=192) in the random sample (n=288) (Figure 7). Following this, classifications made by the first researcher (RJ) were compared to the classifications of the original data classifiers to test the reliability of the data on medication errors (n= 32 592).

The inter-rater reliability was measured using Cohen's kappa (κ) to describe the degree of conformity between the two researchers (RJ and ARH), as well as between the study researcher (RJ) and the original data classifiers (Howell 2013). Cohen's kappa is the most commonly used statistic for categorical items to measure the agreement between two reviewers in studies of patient safety incidents (Kunac et al. 2006; Howell 2013). In the present study, the degree of agreement was considered acceptable when resulting in kappa values of 0.41 or above (Fleiss et al. 2003; Gisev et al. 2013). Interpretation of the kappa-values is presented in the Table 14.

Table 14. *Interpretation of Cohen's kappa (Gisev et al. 2013).*

Value of kappa	Level of agreement
<0.00	Poor agreement or less than agreement by chance
0.00–0.20	Slight agreement
0.21–0.40	Fair agreement
0.41–0.60	Moderate agreement
0.61–0.80	Substantial agreement
0.81–1.00	Almost perfect agreement
1.00	Complete agreement

The kappa values for some of the variables in the systematic random sample of 96 medication errors were low (see Table 17 at page 76; κ I) when calculating inter-rater reliability between the study researchers (Figure 7). Consequently, the classification instructions were revised to better standardise the classification process. Following this, both researchers independently reviewed their own classifications by using the revised classification instructions (Figure 7).

The analyses were performed through the use of Microsoft Excel and PASW 18.0. statistical software. Descriptive statistics were used for describing the reported medication errors. The variables with a high enough agreement rate ($\kappa \geq 0.41$) were described at the level of the entire data (n=32 592) (Smith 2002; Howell 2013). The variables with $\kappa < 0.41$ were described at the level of the random sample (n=288) based on classifications made by the study researcher (RJ).

Analysis

Standardising the classification system used by the researchers

- ➤ Re-classification of a systematic random sample of medication errors (n=96) drawn from the random sample of errors (1%, n=288 out of 32 592) by two researchers (RJ & ARH).
- ➤ Assessing the inter-rater reliability of agreement on classifications by Cohen's kappa (κ)→ indicating the reliability of the classification system used by the researchers by interpreting the κ value.

Some κ values found low (κ<0.41) → Need for improving the reliability of the classification system used by the researchers

- ➤ Revising classification guidelines for the researchers (RJ & ARH) and reviewing their own classifications by both researchers.
- ➤ Re-assessing the inter-rater reliability of agreement on classifications of the systematic random sample of medication errors (n=96) by Cohen's kappa.

Measuring agreement between the researcher and the original data classifiers

- ➤ Classifying the rest of the random sample of medication errors (1%, n=288 out of 32 592) by the independent researcher (RJ).
- ➤ Assessing the inter-rater reliability of agreement on classifications by Cohen's kappa.
- ➤ Interpreting the reliability of the original classifications and the validity of the data.

Describing the medication errors by descriptive statistics

- ➤ Describing the medication errors that had an acceptable level of agreement (κ≥0.41) at the level of all medication error data (n= 32 592).
- ➤ Describing the medication errors that had a low level of agreement (κ<0.41) at the level of the random sample of medication errors (1%, n=288 out of 32 592) based on classifications by the researcher (RJ).

Figure 7. *The process of assessment of inter-rater reliability of classifications in a random sample of medication errors (1%, n=288 out of 32 592) reported to HaiPro, and exploring the reported medication errors at the level of all reported medication errors (n=32 592) and a random sample of medication errors (n=288).*

8.4 Development of a 3-day short course for healthcare professionals in medication safety (IV)

8.4.1 Setting and participants

A brainstorming workshop was used to consult international higher education and adult learning experts in pharmacy in order to develop a syllabus for a 3-day interdisciplinary course in medication safety. The workshop was conducted during the International Life Long Learning in Pharmacy Conference in 2009 in Helsinki, Finland. Overall, 124 participants participated in the conference from Africa (n=11), Australasia (n=15), Europe (n=73), and North America (n=25).

8.4.2 Data collection

During the workshop, participants were asked to brainstorm a syllabus comprising teaching and assessment methods for a three-day interdisciplinary course in medication safety in four groups. To support brainstorming, sample contents for such a course were provided in the form of a leaflet (Appendix 5) based on one of the leading handbooks in the field (Cohen 2007). The brainstorming was facilitated by the researchers (ARH and RL). The data were collected in the form of proposals for teaching and assessment methods by each group (n=4).

8.4.3 Qualitative analysis of the data

After the workshop the data was transferred to a Word-document for a conventional qualitative content analysis to explore their contents by the first researcher (ARH) (Hsieh & Shannon 2005). The credibility of the coding was checked by another researcher (RJ) (Pope et al. 2000).

Finally, the identified teaching and assessment methods, and the core contents of the course suggested in the four syllabi, and sample contents of the course (Appendix 6) were synthetized by the researchers (ARH, RL and MA) to form a combined syllabus (Appendix 6). The synthesis was based on the teaching and assessment methods occurring most frequently in the plans, i.e., the agreement between the groups. The current literature, as well as innovativeness and applicability of the methods from the medication safety education perspective were also considered when forming the combined syllabus.

9 Results

This chapter describes the key findings of the original publications I-IV. The key findings are also summarized in Figure 13.

9.1 Exploring national and local medication error reporting systems in different countries (I, II)

Contact details for 32 medication safety experts in 26 countries were received from the informants in the FIP and other sources (8.2.1). Overall, 16 experts representing different countries in Africa (n=3), Australasia (n=3), Europe (n=9) and North-America (n=1) responded to the questionnaire, giving a response rate of 50% (Table 15). For other demographics of the respondents, please see the original publication I.

Table 15. *Existence and type of medication error reporting (MER) systems in the participating countries (n=16).*

MER system	Country
National system	
Stand-alone MER system	Canada* Japan* Sweden*
MER system integrated in an adverse event reporting system	Norway* Zambia†
Local system	
Within a community setting	Australia*
In community and hospital setting	Czech Republic*
A shared system between several hospitals	Finland*
Within a hospital setting	Hungary*
Setting not known	Austria* Rwanda†
No system	
	Ghana† India* Kosovo* Latvia* Serbia*

*Developed country; †Developing country according to the United Nations Human Development Index (HDI) (United Nations 2007).

9.1.1 Existence and characteristics (I)

At the time of the study in 2007, a MER system existed in 11 countries: nine in developed and two in developing countries (Table 15). The respondents provided further information on five national and three local MER systems (Table 16). The most common characteristic of a MER system was the confidentiality of reported information (n/N=6/8) (Table 16).

National MER systems were commonly provided and maintained by one national organization (4/5); they were an integral part of a patient safety reporting system (4/5); provided confidentiality of reported information (4/5); and allowed all healthcare professionals to report errors (4/5). All three of the local systems were reported to be easy to use, available electronically, allowed reporting both of potential and of actual errors, and provided feedback on the error analysis results to those involved in reporting.

9.1.2 Characteristics of a good and effective medication error reporting system and barriers to reporting (I)

Common perceived characteristics of a good and effective MER system were: the MER system should provide an opportunity for evaluating the causes of errors (n/N=9/16); have a non-punitive approach to reporting (8/16); provide feedback of error analysis results to those involved in reporting (8/16), and be easy to use (8/16). The most commonly perceived barrier to reporting was fear of consequences (13/16). Other common barriers were a culture of blame (8/16), a lack of training needed for reporting (8/16), a lack of time for reporting (8/16), and a lack of organisational leadership and support (7/16).

Table 16. *Characteristics of the national and local medication error reporting (MER) systems in participating countries providing further information on their MER system (n/N=8/16) (structured questions with alternatives given were used). The characteristics are presented in descending order.*

Characteristic	Type of MER system							
	National system					Local system		
	Canada	Japan	Norway	Sweden	Zambia	Australia	Czech Republic	Finland
Provides confidentiality of reported information	x	x		x	x	x		x
Provides feedback of results of error analysis for those involved in reporting	x	x		x		x	x	x
Provided and maintained by one national organization	x	x	x	x		x		
An integral part of a patient safety reporting system		x	x	x	x			x
Allows all healthcare professionals to report errors	x		x	x	x			x
Paper based			x	x	x	x	x	
Provides opportunity for error data analysis	x	x		x		x	x	
Provides an opportunity for evaluating causes of errors (e.g. root cause analysis)	x	x		x		x	x	
Available in electronically	x	x				x	x	x
Includes reporting of both potential and actual errors	x		x			x	x	x
Reporting of errors is mandatory		x	x	x		x		
Reporting of errors is voluntary	x				x		x	x
Uses a non-punitive approach to reporting	x	x				x		x
Provides a choice of reporting anonymously	x	x					x	x
Produces recommendations and guidelines for improving medication safety	x			x		x	x	
Easy to use	x					x	x	x
Quick to use	x						x	x
An independent reporting system dedicated for medication error reporting	x	x				x		
Provides patients/consumers an opportunity to report errors	x				x			

9.2 Factors influencing successful development and implementation of medication error reporting systems (II)

The qualitative analysis of received responses to the open-ended questions of the questionnaire by the 16 experts revealed several factors that were perceived to influence successful development and implementation of MER systems (Figure 8). These factors were related to the national context of MER systems, i.e., their operational environment, and are presented as steps towards development and implementation of MER systems in the Figure 9. Moreover, the operational environments of the MER systems were identified as inadequate to support functional MER in the experts' countries.

All experts (n=16)

- Information on the national context of MER systems in experts' countries
  - Legislation and regulations related to patient and medication safety, MER and HCPs' practice
  - Roles of different authorities in MER; quality and safety of healthcare, and patient and medication safety

Experts in countries with a national or local MER system (n=11)

- Application for collected data on medication errors
- Changes or improvements made to the MER system following the implementation

Experts in countries with no current MER system (n=5)

- Plans and actions to develop national or local MER systems
- Awareness of the need to pay attention in medication safety issues
- The needed organisational support to develop and implement national MER system
- The needed organisational or cultural changes to enable MER
- Capacity of the country to develop and implement a MER system

Main outcomes

Awareness of deficiencies in medication safety

Political will

International and governmental support

Adequate resources

Factors for successful development and implementation of MER systems

Safety culture

Systems approach

An organisation or centre for MER

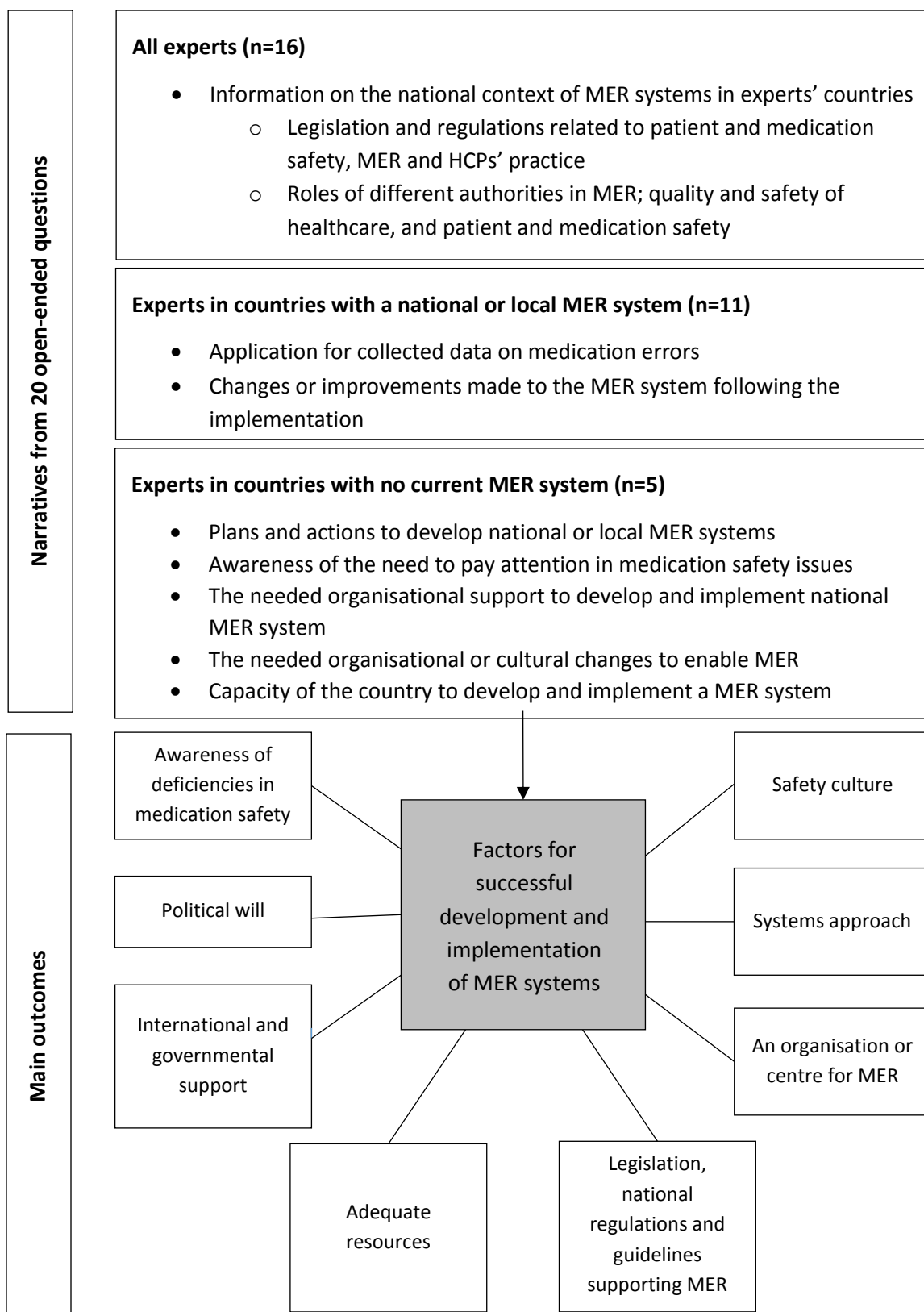Legislation, national regulations and guidelines supporting MER

Figure 8. *Proposed factors for successful development and implementation of medication error reporting (MER) systems (based on qualitative analysis of responses from 16 medication safety experts).*

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9.2.1 Summary of the factors

General awareness of deficiencies in medication safety was lacking in some of the countries, influencing the perceived necessity of MER systems. Consequently, creating such awareness among healthcare professionals, decision makers and the public was recommended as a preliminary mission to initiate the development and implementation process of a MER system (Figures 7 & 8). Engaging policy makers was proposed as key to gaining political will for these actions.

The lack of financial and human resources hampered the development and implementation of MER systems in some countries. Therefore, strong expectations for governmental and international support and collaboration in these actions were expressed by the experts (Figures 7 & 8).

The need to establish a national organisation or centre for MER was emphasised by the experts (Figures 7 & 8). Such an organisation was needed to create leadership and coordination in reporting, and for the utilisation of the reported data in order to promote a medication safety and systems approach to error prevention. While in general the findings were found applicable to both national and local MER systems, establishment of a national organisation or centre for MER was thought especially crucial for national systems.

The existence of a safety culture for those involved in error reporting was reported by the experts to be essential in developing and implementing functional MER systems (Figures 7 & 8), and was seen to be affected mainly by the legislation and regulations on adverse events. A need to reform the current legislation on dealing with adverse events towards a non-punitive approach appeared to be essential for an operational environment that supports MER.

The experts perceived learning from reported medication errors as the most valuable outcome of MER systems (Figures 7 & 8). The experts emphasised exploring the mechanisms and causes of errors from a systems approach with less focus on solely quantitative approaches on counting errors. A climate fostering learning from medication errors was perceived to promote change in the culture and enable reporting (Figures 7 & 8). Please see the original publication II for a more detailed description of the experts' proposals for the factors for successful development and implementation of MER systems.
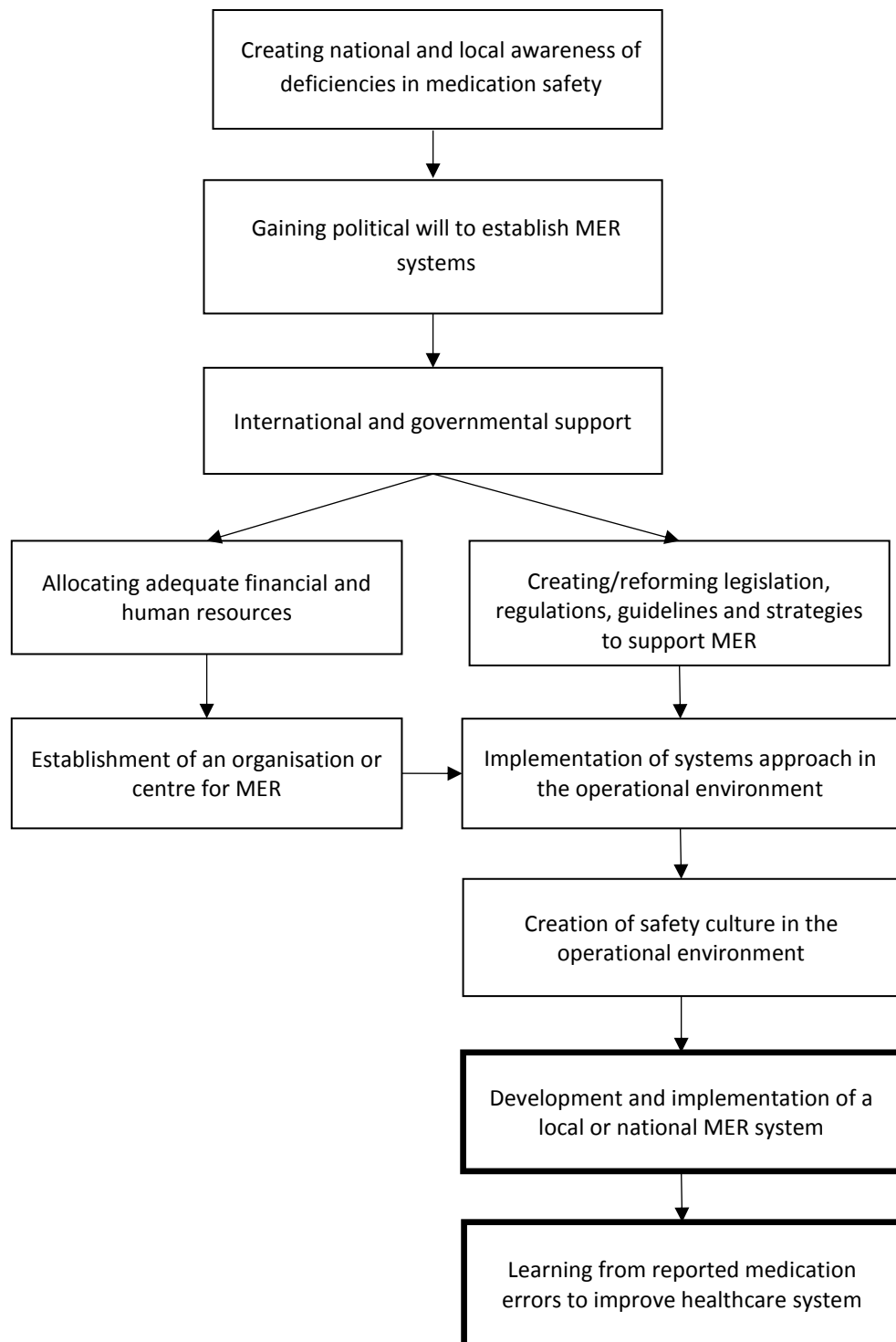
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┌─────────────────────────────────┐
│  Creating national and local    │
│  awareness of deficiencies in   │
│  medication safety              │
└─────────────────────────────────┘
                 │
                 ▼
┌─────────────────────────────────┐
│  Gaining political will to      │
│  establish MER systems          │
└─────────────────────────────────┘
                 │
                 ▼
┌─────────────────────────────────┐
│  International and governmental  │
│  support                         │
└─────────────────────────────────┘
        │                   │
        ▼                   ▼
┌──────────────────┐  ┌─────────────────────────┐
│ Allocating       │  │ Creating/reforming      │
│ adequate         │  │ legislation,            │
│ financial and    │  │ regulations, guidelines │
│ human resources  │  │ and strategies to       │
│                  │  │ support MER             │
└──────────────────┘  └─────────────────────────┘
        │                   │
        ▼                   ▼
┌──────────────────┐  ┌─────────────────────────┐
│ Establishment    │→ │ Implementation of       │
│ of an            │  │ systems approach in     │
│ organisation or  │  │ the operational         │
│ centre for MER   │  │ environment             │
└──────────────────┘  └─────────────────────────┘
                           │
                           ▼
                      ┌─────────────────────────┐
                      │ Creation of safety      │
                      │ culture in the          │
                      │ operational environment │
                      └─────────────────────────┘
                           │
                           ▼
                      ┌─────────────────────────┐
                      │ Development and         │
                      │ implementation of a     │
                      │ local or national MER   │
                      │ system                  │
                      └─────────────────────────┘
                           │
                           ▼
                      ┌─────────────────────────┐
                      │ Learning from reported  │
                      │ medication errors to    │
                      │ improve healthcare      │
                      │ system                  │
                      └─────────────────────────┘
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Figure 9. *The steps towards development and implementation of medication error reporting (MER) systems and learning from errors (based on qualitative analysis of responses from 16 medication safety experts).*

9.3   Inter-rater reliability of medication error classification in HaiPro (III)

The agreement rate between the two researchers (RJ and ARH) was acceptable (κ≥0.41) for 40 out of 41 variables for which the kappa value was possible to be calculated in the random sample of medication errors (n=288) (for the variable "prolonged care of the patient", the kappa was not able to be calculated as only one of the researcher used the classification, see Table 17).

Table 17 *Inter-rater reliability of medication error classifications in the random sample of medication errors (n=288) for which the kappa (κ) was able to be calculated.* Acceptable agreement rates (κ≥0.41) are in bold. Each classification is a yes/no selection in the used classification system.*

Classification	Agreement between two independent researchers κ (95% CI) n=96	Agreement between the researcher and the original data classifiers κ (95% CI) n=x*
Nature and type of the medication error		
Nature of the error (near miss or actual error)	**0.81 (0.71 to 0.92)**	**0.83 (0.76 to 0.90)** n=242
Type of the error known	**0.49 (-0.12 to 1.10)**	0.21 (0.06 to 0.35) n=288
Type of the error	**0.81 (0.72 to 0.91)**	**0.63 (0.56 to 0.69)** n=284
Type of dispensing error (at the unit) known	**0.86 (0.76 to 0.97)**	**0.67 (0.58 to 0.75)** n=288
Type of the dispensing error	**0.82 (0.70 to 0.93)**	**0.67 (0.58 to 0.74)** n=280
Type of administration error known	**0.85 (0.74 to 0.97)**	**0.67 (0.56 to 0.77)** n=287
Type of the administration error	**0.83 (0.72 to 0.94)**	**0.57 (0.47 to 0.68)** n=286
Type of medication documentation error known	**0.85 (0.74 to 0.97)**	**0.65 (0.54 to 0.76)** n=280
Type of the medication documentation error	**0.85 (0.74 to 0.96)**	**0.59 (0.49 to 0.69)** n=288
Type of storage error known	**0.66 (0,04 to 1.28)**	**0.57 (0.125 to 1.00)** n=288
Type of the storage error (e.g. wrong storage conditions)	**0.66 (0,04 to 1.28)**	**0.66 (0.22 to 1.10)** n=287
Type of prescription error known	**0.66 (0.22 to 1.10)**	**0.65 (0.43 to 0.88)** n=288
Outcome for the patient		
Outcome for the patient known	**0.66 (0.50 to 0.82)**	0.08 (-0.02 to 0.17) n=288
Patient harmed	**0.68 (0.56 to 0.81)**	0.21 (0.13 to 0.29) n=288

Severity of the outcome to the patient	0.36 (0.17 to 0.56)	0.18 (0.08 to 0.29) n=286
Outcome for the hospital unit		
Outcome for the unit known	**0.59 (0.43 to 0.75)**	0.06 (-0.03 to 0.15) n=288
The error caused harm to the unit	**0.60 (0.46 to 0.73)**	0.10 (0.03 to 0.19) n=288
Image harm to the unit	**0.54 (0.37 to 0.70)**	0.07 (-0.01 to 0.14) n=288
Material loss	**0.52 (0.36 to 0.69)**	0.07 (-0.02 to 0.15) n=288
Extra financial costs	**0.53 (0.36 to 0.70)**	0.07 (-0.02 to 0.16) n=288
Additional work or minor care for the patient	**0.56 (0.43 to 0.70)**	0.08 (0.00 to 0.15) n=288
Prolonged care for the patient	e^{**}	0.08 (-0.01 to 0.17) n=288)
Long-term care for the patient	**0.51 (0.34 to 0.68)**	0.07 (-0.02 to 0.16) n=288
Personnel harmed	**0.53 (0.36 to 0.70)**	0.07 (-0.02 to 0.16) n=288
Other individuals harmed	**0.53 (0.36 to 0.70)**	0.07 (-0.02 to 0.16) n=288
Management of the error situation		
Management of the error known	**0.83 (0.72 to 0.94)**	0.14 (0.05 to 0.24) n=288
Error managed by those involved in the situation	**0.83 (0.72 to 0.94)**	0.13 (0.04 to 0.23) n=288
Extra personnel called out	**0.83 (0.72 to 0.94)**	0.13 (0.05 to 0.22) n=288
Immediate actions		
Immediate actions known	**0.79 (0.66 to 0.91)**	0.15 (0.05 to 0.25) n=288
Actions taken to correct the error	**0.76 (0.65 to 0.87)**	0.24 (0.16 to 0.47) n=288
Patient observed and/or informed	**0.75 (0.63 to 0.87)**	0.22 (0.13 to 0.30) n=288
Actions taken to mitigate the effects of and additional harm caused by the error	**0.60 (0.46 to 0.74)**	0.16 (0.08 to 0.24) n=288
Working conditions and other contributing factors		
Conditions and other contributing factors known	**0.79 (0.67 to 0.91)**	0.22 (0.11 to 0.43) n=288
Communication and flow of information	**0.72 (0.60 to 0.84)**	0.21 (0.15 to 0.30) n=288
Working patterns	**0.68 (0.56 to 0.80)**	0.15 (0.06 to 0.24) n=288

Work environment and tools, resources	**0.77 (0.66 to 0.88)**	0.22 (0.13 to 0.32) n=288
Patient and his/her carer	**0.74 (0.62 to 0.86)**	0.23 (0.13 to 0.33) n=288
Education and orientation, competence of personnel	**0.76 (0.63 to 0.88)**	0.23 (0.13 to 0.33) n=288
Medicines	**0.75 (0.63 to 0.87)**	0.20 (0.09 to 0.30) n=288
Team or group work	**0.74 (0.61 to 0.87)**	0.19 (0.08 to 0.30) n=288
Devices or instruments	**0.80 (0.68 to 0.92)**	0.20 (0.09 to 0.31) n=288
Organisation and leadership	**0.79 (0.67 to 0.91)**	0.21 (0.09 to 0.32) n=288

* Some classifications which prevented the calculation of the kappa were removed as only one of the reviewers had used some specific value related to the classification, resulting in a varying number (n) of classifications
**Calculation not possible as only one of the reviewers has used the classification

Between the researcher (RJ) and the original data classifiers the acceptable rate of agreement was achieved for 11 out of 42 (26%) variables. Thus, these variables were classified in such a consistency by the classifiers in different reporting healthcare organisations that they could be analysed descriptively in the whole data set (n=32 592). These 11 variables were related to: the nature of the error; the type of the error; medication documentation errors; dispensing errors; administration errors, and storage errors. However, for storage errors confidence intervals resulted in poor values. Figure 10 shows the types of the reported medication errors.

The degree of conformity between the study researcher (RJ) and the original classifiers did not reach the agreed acceptable level for the majority of the variables on medication errors (Table 17). The researchers were also able to identify more circumstances and contributing factors in the medication error narratives than the original data classifiers had classified. A more comprehensive description of the results is provided in the manuscript III submitted for publication.
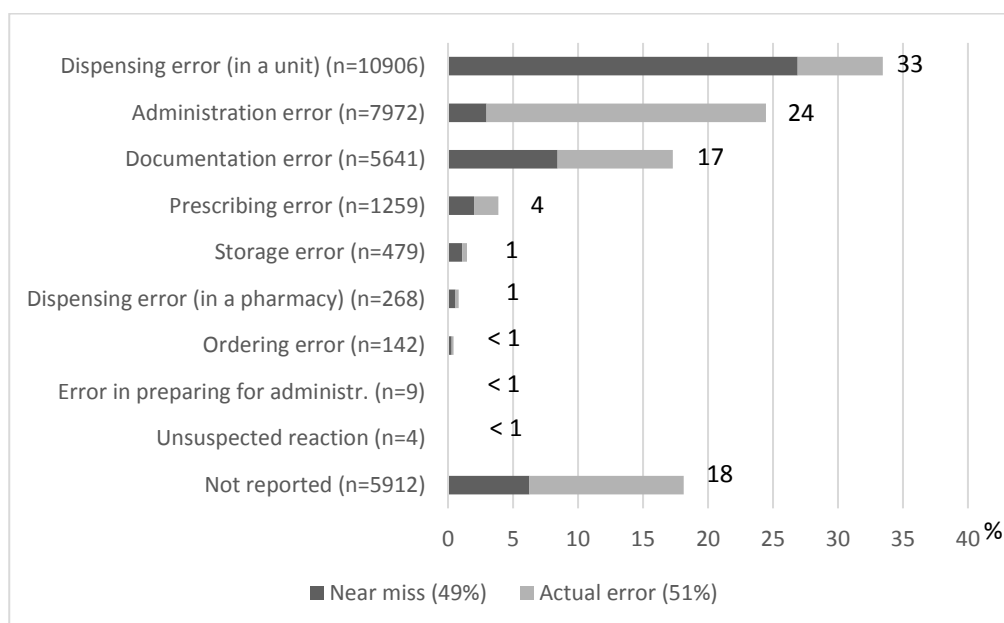
Figure 10. *The reported medication errors as percentages in the data set (n=32 592) from the different healthcare organisations (n=36) using the Reporting System for Safety Incidents in Health Care Organizations, HaiPro, between 2007-2009 in Finland.*

9.4 Development of a 3-day short course for healthcare professionals in medication safety (IV)

Nineteen higher education and adult learning experts from Africa (n=2), Europe (n=16) and North America (n=1) participated in the workshop. All the developed syllabi (n=4) for a three-day interdisciplinary course in medication safety applied a constructive, problem-based learning approach.

The teaching and assessment methods ranged from the pre-course to post-course period (Figures 11 & 12; Table 18) and involved sharing the learning of the course participants with their colleagues at the workplace in addition to peer support of the course participants (Figure 12). The syllabi comprised methods for developing personal learning objectives and reflection (Figure 11), methods for facilitating interactive learning (Table 18) and learning at the workplace (Figure 12). While the management of medication safety from the systems approach represented the core content of the course in the syllabi, the workshop participants also identified other aspects in medication safety to be covered (Table18).

9.4.1 Personal learning objectives and reflection

The workshop participants suggested that the course should begin with self-reflection on the learner's personal learning needs (Figure 11) in order to identify the learner's pre-course skills in medication safety and to set goals for competency following the course. The self-reflection would then be followed by development of personal learning objectives to guide and assess learning during and after the course.
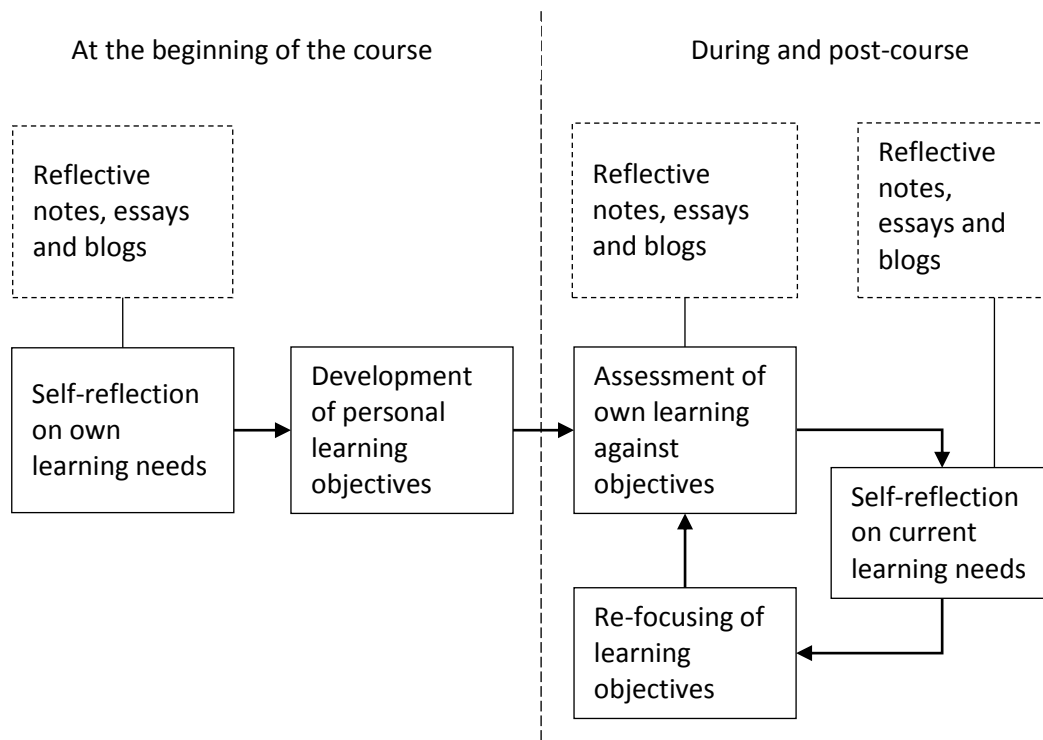
At the beginning of the course | During and post-course

Reflective notes, essays and blogs

Reflective notes, essays and blogs

Reflective notes, essays and blogs

Self-reflection on own learning needs → Development of personal learning objectives → Assessment of own learning against objectives

Self-reflection on current learning needs

Re-focusing of learning objectives

Figure 11.   *Outline of the learning process for a three-day interdisciplinary course in medication safety and the role of self-reflection in developing personal learning objectives and re-focusing them throughout the course, including the pre- and post-course phases.*

9.4.2 Methods for facilitating interactive learning in medication safety

All the four groups based the three training days on interactive learning and proposed a variety of methods (Table 18). The goal was to assist the learners in creating a knowledge base on medication safety and to support their reflective learning at the workplace between the training days and after the course. Also some self-directed learning methods, such as reading, were suggested to support forming the knowledge base on medication safety.

Table 18. *A summary of the methods for facilitating interactive learning during the three training days of an interdisciplinary course in medication safety, including proposed stages of the course when to apply the methods and the purpose of their use.*

Method	Stage of the course when applied	Purpose for using the method
Pre-reading	Before the first training day; discussion on the contents of the reading material on the first training day.	To demonstrate, and familiarize the learners with the topic, and to share and deepen the learning experiences with the peer learners.
Audio-visual recordings	Before the first training day; discussion on the contents of the videos on the first training day (suggested contents for the videos: management of medication errors and aviation accidents).	To demonstrate, and familiarize the learners with the topic; to demonstrate how high risk industries have used a systems approach to successfully learn from errors, and to share and deepen the learning experiences with the peer learners.
Case studies	As orientation pre-course assignments before the first training day (Figure 12); the analysis of the incidents with the peers on the first training day.	To identify a medication error or a near miss occurring at the learner's own workplace, and to practice analysis of medication-related incidents.
	On the second training day (short case studies).	To assess and reflect learning.
	Between the training days at the learners' workplaces and in a web-based learning environment *(Figure 12).*	To guide learning between the training days.
Real life examples	On the first training day (e.g., inviting a healthcare professional who has made an error to share his/her experiences, or other examples of unfortunate incidents, their root causes and management).	To demonstrate the needs for and importance of medication safety promotion in healthcare organisations; to motivate the learners and stimulate their interest towards the topic; to demonstrate the role of human error in medication incidents, and to assist the learners in gaining an understanding of the differences between the person and systems approaches to managing medication safety.
Networking of the learners (facilitated or self-directed)	On the first training day.	For learners to get to know each other; to promote interaction between professions, and to create good group dynamics and a positive atmosphere for learning.
	On the last training day	To foster collaboration and experience sharing after the course.
Experience sharing	At multiple stages of the course.	To share the learners' work based experiences and knowledge on medication safety and the existing good practices for promoting medication safety.
Group discussions	At multiple stages of the course in varying group size and discussion platform (e.g., face-to-face training days, or a web-based learning	E.g., to create deeper understanding of complex issues, such as how to make medication processes safer in healthcare organizations.

	environment between the training days and post-course).	
Role plays	On the first and second training days *(suggested scenarios: a healthcare professional and a patient or a healthcare team).*	To foster development of essential skills in medication safety, and to assess, and provide feedback on, the learners' team performance and interaction.
Interactive presentations	By the learners on the second and third training days (e.g., based on self-directed reading material supporting the learners learning process and reflection of the material with colleagues at the workplace between the training days).	To assess and reflect learning, and to give feedback for the learners about their own learning.

9.4.3 Learning at the workplace

The workshop participants proposed course assignments integrated in the learners' daily work. This was suggested to create competence in applying knowledge in practice (Figure 12). Involvement of the learner's colleagues in working on the assignments was suggested for knowledge sharing at the workplace.

Three different workplace-based learning processes were suggested by the workshop participants (Figure 12). Web-based tools (e.g., Moodle) were proposed for learners' communication between the training days and maintaining the created networks after the course. One group suggested that the learners attended the three training days one month apart, allowing time for processing the learning experiences and working on the assignments at the workplace.
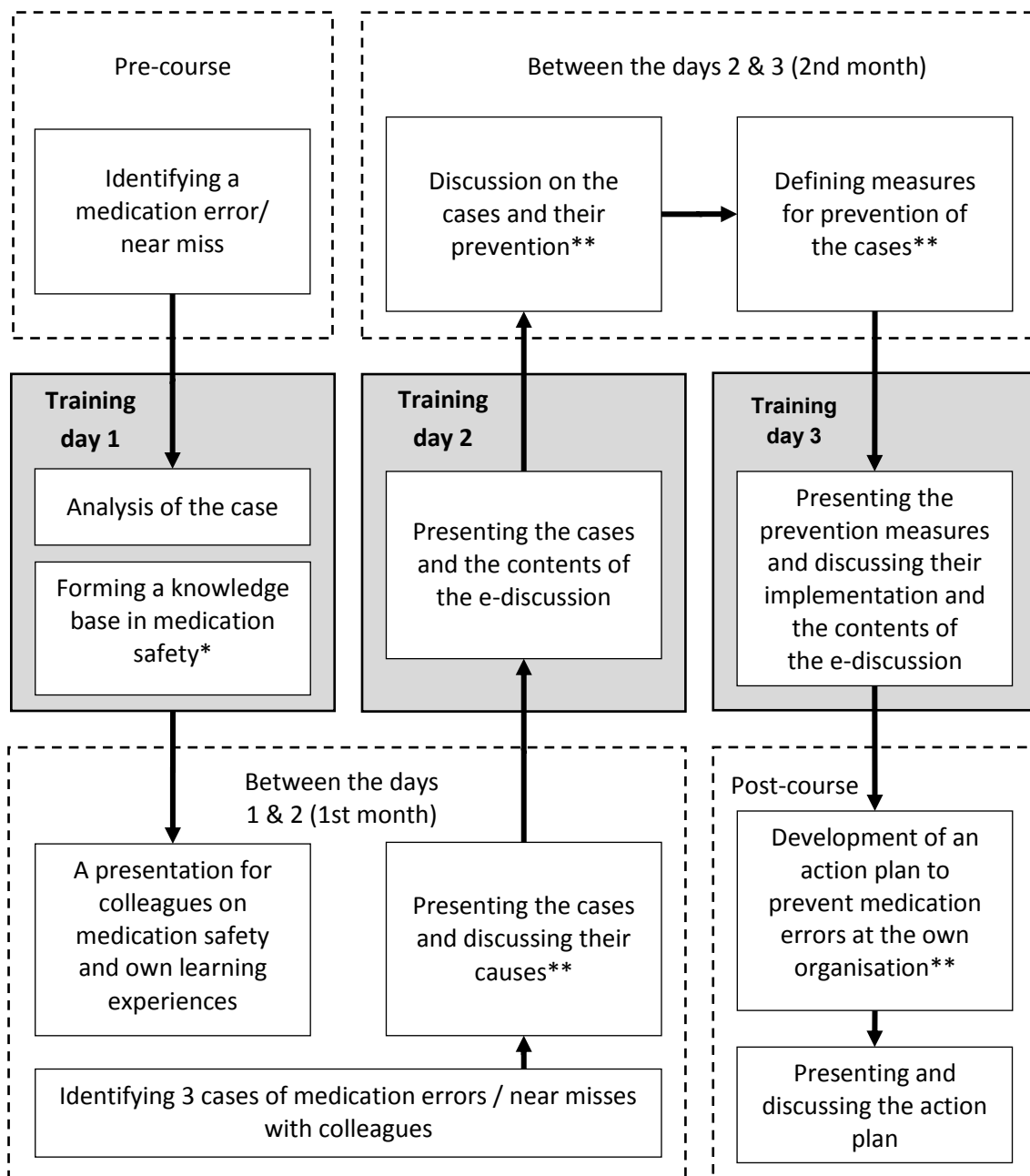
*Also during the other training days.

**In interdisciplinary small groups in a web-based learning environment.

Figure 12. *Integration of learning at the workplace in a 3-day interdisciplinary course in medication safety. The activities cover the pre- and post-course phases, and learning between the training days.*

9.4.4 Core contents of the course

The workshop participants proposed management of medication safety using the systems approach as the key content of the course. They prioritised it from the leaflet on the sample content of the course (Appendix 5) and prioritised it in their syllabi. A more detailed description of the key contents of the course is provided in the original publication IV.

9.4.5 The combined syllabus

The combined syllabus of a three-day interdisciplinary course in medication safety (Appendix 6) resulted in a combination of methods facilitating interactive learning and workplace-based learning with personal learning objectives and reflection to assess and guide learning. The combined syllabus provides options for pedagogic methods to be applied, e.g. depending on the resources allocated for the course and the learners' learning needs.

9.5 Key findings of the study

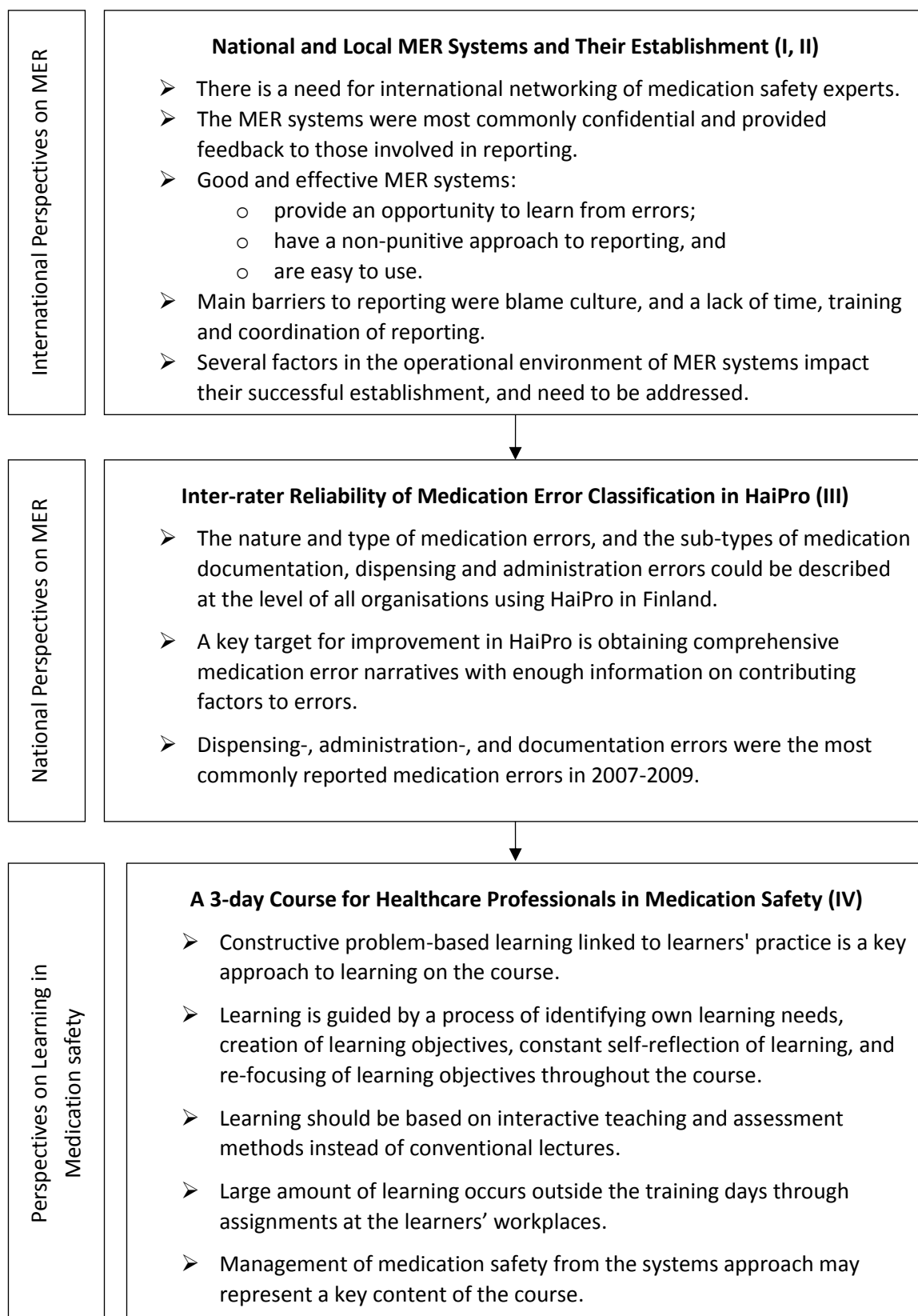Summary of the key findings are presented in Figure 13.

International Perspectives on MER

National and Local MER Systems and Their Establishment (I, II)

➢ There is a need for international networking of medication safety experts.

➢ The MER systems were most commonly confidential and provided feedback to those involved in reporting.

➢ Good and effective MER systems:
  o provide an opportunity to learn from errors;
  o have a non-punitive approach to reporting, and
  o are easy to use.

➢ Main barriers to reporting were blame culture, and a lack of time, training and coordination of reporting.

➢ Several factors in the operational environment of MER systems impact their successful establishment, and need to be addressed.

National Perspectives on MER

Inter-rater Reliability of Medication Error Classification in HaiPro (III)

➢ The nature and type of medication errors, and the sub-types of medication documentation, dispensing and administration errors could be described at the level of all organisations using HaiPro in Finland.

➢ A key target for improvement in HaiPro is obtaining comprehensive medication error narratives with enough information on contributing factors to errors.

➢ Dispensing-, administration-, and documentation errors were the most commonly reported medication errors in 2007-2009.

Perspectives on Learning in Medication safety

A 3-day Course for Healthcare Professionals in Medication Safety (IV)

➢ Constructive problem-based learning linked to learners' practice is a key approach to learning on the course.

➢ Learning is guided by a process of identifying own learning needs, creation of learning objectives, constant self-reflection of learning, and re-focusing of learning objectives throughout the course.

➢ Learning should be based on interactive teaching and assessment methods instead of conventional lectures.

➢ Large amount of learning occurs outside the training days through assignments at the learners' workplaces.

➢ Management of medication safety from the systems approach may represent a key content of the course.

Figure 13. *Summary of the key findings of the study. MER = medication error reporting*

10 Discussion

This study focused on exploring national and local MER systems in different countries and the factors which make them work for learning from medication errors in healthcare. The study also explored how education on medication safety could be organised for practicing healthcare professionals. The work consisted of two parts: a literature review and the empirical part. In this chapter 1) the key findings from the original publications (I-IV) are summarised and compared with the previous literature; and 2) the methodological aspects of the research are discussed.

Although MER systems have been widely studied in different healthcare settings internationally, several targets for improvement, such as need to improve the quality of medication error reports, still exist in relation to the functionality of MER systems (please see Chapters 4 and 5). The current study adds to the existing knowledge by outlining the factors that enable successful development, implementation and use of MER systems as medication safety risk management tools in healthcare. To our knowledge no previous research has studied these factors in such extent in such many countries with different stage of development. The current study also sought for a perspective to the wider operational environments of MER systems and how these operational environments (incl. e.g., state regulatory systems) support functionality of MER systems. Hence, the study differs from the existing literature which has primarily focused on describing the functionality of individual MER systems in their own organisations (e.g., Haw & Cahill 2011; Elliott et al. 2014).

This study also provides information on the inter-rater reliability of medication error classifications in a Finnish Reporting System for Safety Incidents in Health Care Organizations, HaiPro, during its pilot phase in 2007-2009. The quality of the reported data in a MER systems is a timely issue both in Finland and internationally as many countries are developing and implementing new systems, or improving their existing systems. Effective learning from medication errors requires reliable reporting (Williams & Ashcroft 2009). The reported information on medication errors should inform medication safety development activities in healthcare organisations (European Commission 2014). Therefore, the accuracy and completeness of the reported information needs to be ensured in MER systems (Armitage et al. 2010). In this part of the study, medication errors and their contributing factors reported to the HaiPro were explored. These findings provide an overview of medication errors reported in Finland in comparison to findings from other international studies (e.g., James et al. 2009; Cousins et al. 2012).

Creating competence in medication safety among healthcare professionals is a current issue for healthcare systems internationally (World Health Organization 2011). The present study introduces one solution for how medication safety education could be provided for practicing HCPs in a format that is easy for a learner to adopt. As not many studies exist on continuing education of HCPs in medication safety, the current work provides a practical tool for introducing the basic principles of medication safety as a three-day continuing education course for HCPs. The key findings of the thesis will be discussed in the following sections.

10.1 National and local medication error reporting systems in different countries (I)

The current study was based on the international recommendations for developing MER systems and sharing experiences with existing systems (Kohn et al. 2000; World Health Organization 2005; Council of Europe 2006a; European Commission 2014). In our study, 16 medication safety experts in different countries provided information on their local and national MER systems. Our findings support the previous literature suggesting the fear of consequences to be a major barrier to reporting medication errors (e.g., Evans 2006; Hartnell et al. 2012). Our findings also indicate that the blame culture is resilient despite efforts to change it, and would need to be targeted by more effective actions.

The study suggests interesting differences between national and local MER systems. National systems seem to require a national focal point: an organisation that will provide and maintain the MER system. Indeed, the WHO has emphasized the supporting role of national agencies in effective error reporting by healthcare organisations (World Health Organization 2005). National MER systems also appeared likely to be integrated in patient safety reporting systems and allowed all healthcare professionals to report. On the contrary, local systems seemed to have focused more on learning from errors and providing feedback to those involved in reporting than the national systems. Indeed, the differing characteristics of national and local schemes are central in terms of their utility and promoting learning from errors (Zwart et al. 2011). While the local systems may facilitate faster implementation of safety improvements and more effective feedback (Benn et al. 2009; Armitage et al. 2010), the central schemes, by collating reports from many settings, seem better at addressing generic and recurring safety issues (Zwart et al. 2011).

Access to medication safety experts knowledgeable about the MER systems in their representative countries proved challenging despite using the wide FIP network, contacts in the Council of Europe and the Nordic Patient Safety Research Network in search of such experts. These difficulties may arise from a lack of medication safety experts' "visibility" among the contacted organisations and a possible lack of national and international coordination of patient and medication safety affairs as is recommended (Council of Europe 2006a). If this is the case, then there is a need for more effective national and international networking of medication safety experts. This would be especially crucial for those countries which do not necessarily have much experience in promoting medication safety, such as many developing countries. Such a network is essential for facilitating effective sharing of experiences on safe medication practices. For similar future studies it is recommended to use also other sources of medication safety experts, such as the International Medication Safety Network (IMSN) (International Medication Safety Network 2016).

10.2 Factors associated with successful development and implementation of medication error reporting systems (II)

This study outlines the factors associated with successful development and implementation of MER systems. The study suggests that the lack of focus in operational environments may explain why many current MER systems are dysfunctional (Mahajan 2010). In many of the countries of the experts' who participated in the study, the environment did not support MER systems or appeared "not ready" for their development and implementation. This was the case even in countries where a MER system already existed. This represents a key finding as even the most technically sophisticated systems will not work if the context does not support their use. The greatest gaps between the current situation and the needs for improvement were in the legislation and leadership structures related to MER.

10.2.1 The culture of the operational environment is the corner stone

Our findings strengthen the position of safety culture as the key for a functional reporting system and are in line with the findings of previous studies (Kohn et al. 2000; Snijders et al. 2009; Halligan & Zecevic 2011). According to our study, implementing safety culture should not be limited to the organisations involved in reporting but should extend to other parts of the operational environment, such as medical liability systems or federal regulations guiding reporting practices. In the experts' countries, there also appeared to be a perceived lack of a systems approach as a theoretical foundation in organisational and national medication error prevention strategies and activities. To support safety culture and MER, the strategies and activities should express the systems approach as recommended for reporting organisations (World Health Organization 2005; Council of Europe 2006a; Weiner et al. 2008; Ministry of Social Affairs and Health 2009). Moreover, the systems approach should become the theoretical foundation on which the structures of the operational environment are built, employing the same principles for the reporting system and its context.

10.2.2 Raising awareness of deficiencies in medication safety

The experts called for action to draw attention to the need for safety improvements at local and national levels when developing MER systems. Although deficiencies in medication safety are well recognised by international academic research (Pham et al. 2012), the gap between what has been scientifically shown and its implementation in practice still remains a challenge. Indeed, the experts' emphasis on the need to raise awareness of deficiencies in medication safety related to the identified low overall perception of medication safety by healthcare professionals, policy makers and the public (Fajardo-Dolci et al. 2010). Awareness creation may require targeted actions, such as the national and local surveys suggested by the experts, on the current state of medication safety to provide information on how best to develop a MER system. Carefully planned public information campaigns (Limb 2012) aimed at patients and healthcare professionals may represent an additional strategy. Public campaigns may also provide the means to attract the attention of stakeholders in the government, policy makers, professional organisation leaders and

regulatory bodies. For instance, in Finland, such a national programme operated in 2011-2014 to support healthcare organisations in the promotion of patient and medication safety (Airaksinen et al. 2012).

10.2.3 Need for political will to introduce medication error reporting systems

The study indicates a need for stronger political will in the form of, e.g., policies or legislation on introducing viable MER systems. Despite the extensive evidence of the incidence of medication errors and the need for functional reporting schemes, incident reporting still needs to be addressed with more explicit plans of action in national health policies (Noble et al. 2011). Indeed, national and local medication safety strategies should support the establishment of MER systems (World Health Organization 2005). This might enable the creation of more politically recognised MER systems to advance health policy concerning medication safety and raise national or local commitment to safety improvements.

10.2.4 National coordination and leadership on medication error reporting

The need for an authority or organisation to coordinate reporting and provide a link between the actors in the operational environment appeared to be a prerequisite for the successful implementation of a MER system. This may be even more crucial for national systems as discussed before (please see 10.1.). While some sophisticated national coordination and leadership structures existed in some countries, in other countries such structures were lacking or poorly organised.

Healthcare quality organisations seemed to exist in many countries; however, their support and contribution to incident reporting was not what the experts called for. These experiences indicate a strong need to establish the current structures of these organisations, their areas of responsibility and their capacity to coordinate reporting.

10.2.5 Legislation as a driving force of non-punitive reporting

According to our findings, dysfunctional medical liability systems, also criticised previously (Kohn et al. 2000; Cohen 2007), continue to represent a challenge for the operational environments of MER systems. Overall, legislation did not seem to support the feasible use of MER systems in the experts' countries. Many experts reported that medication errors are considered criminal acts followed by disciplinary or legal action depending on the seriousness of the incident. To enable the implementation of MER systems and their use, a reform of legislation in all these regards remains a target for improving the operational environments.

10.2.6 Need for adequate resources to introduce medication error reporting systems

Many experts in countries without a MER system claimed that a lack of adequate resources prevented the development and implementation of a system. The requirements for establishing MER systems are documented by the WHO (2005). If resources are scarce, alternative methods for identifying problem areas in medication safety may need to be considered. The suggested small-scale local pilot systems may be a cost-effective way to explore the resources and to strengthen local safety culture. It should be noted that implementing a reporting system without adequate resources for analysis of and feedback on reported data will not support learning (Benn et al. 2009; European Commission 2014).

10.2.7 Learning as the objective of the operational environment

In the present study, learning from the reported medication errors was seen as the foundation of MER systems. However, the translation of lessons into action was perceived not only as the objective of a reporting system but the objective of the entire operational environment involving those drawing up policy and practice guidelines. The need for a comprehensive feedback system was strongly expressed, and has also been described in previous research and recommendations (Lawton & Parker 2002; World Health Organization 2005; Council of Europe 2006a; Benn et al. 2009; Kiekkas 2011; European Commission 2014).

Healthcare professionals' lack of competence in medication safety and reporting was often reported by the experts. Indeed, only few errors are reported by the current MER systems, perhaps due to differing views about medication errors, risks and reporting by different professionals and professional groups (Dixon-Woods 2010). Healthcare staff may not be fully aware of what should be reported and how (Hartnell et al. 2012). Some experts also felt that a lack of motivation hindered reporting, and education in medication safety has an essential role in tackling the described cultural and motivational challenges. Thus, interdisciplinary education may represent an important intervention in creating good practices in medication safety and reporting (World Health Organization 2011).

10.3 Inter-rater reliability of medication error classification in HaiPro (III)

HaiPro is a unique reporting system and a comprehensive tool for healthcare organisations to improve their patient safety and medication processes (Keistinen & Kinnunen 2008; Ruuhilehto et al. 2011). This study indicates that information on the nature and type of medication errors, and the sub-types of medication documentation, dispensing and administration could be pooled from different healthcare units for their exploration at the level of all healthcare organisations using HaiPro.

Many variables, e.g., outcomes of medication errors to a patient and hospital organisation, had low inter-rater reliability between the researcher and the original data classifier. The study indicates the need to improve the quality and conformity of medication error reports and their classification. The need for improving the quality of medication error reports has also been confirmed by other studies (Tuttle 2004; Braithwaite et al. 2008; Williams & Ashcroft 2009; Armitage et al. 2010; Daniels et al. 2010; Haw & Cahill 2011).

It was found out in this study that especially reporting and classification of error circumstances and contributing factors need to be improved to provide more detailed system-based information for medication safety promotion activities in the reporting healthcare organisations. In this task, obtaining comprehensive narratives on reported medication errors is key; many narratives in the current data did not have enough information to enable complete classification of the error or to identify contributing factors.

These findings call for educational actions to ensure that all healthcare personnel understand why reporting of errors is necessary and what information needs to be reported to identify unsafe medication processes and to plan safety improvements. Similar findings have been reported for other incident reporting systems with a large number of reporting fields left empty, resulting in the loss of necessary information (Doupi 2009; Armitage et al. 2010).

According to this study, the data classifiers could benefit from additional guidance or training especially concerning the classification of medication error circumstances and contributing factors. Classification of these variables did not reach an acceptable level of conformity between the researcher and the original data classifiers. The researchers were also able to identify and classify more circumstances and contributing factors from the same narratives than the original data classifiers. This may reflect the researchers' more comprehensive understanding about systems approach as a theoretical framework for error prevention and, therefore, enable them to explore the contributing factors in the medication error narratives in more detail. Furthermore, understanding the systems approach enables the identification of the possible contributing factors in the healthcare organisation as a system instead of solely focusing on individual personnel members, e.g., their lack of competence (Waterson 2009). Consequently, it must be ensured that the reporting personnel and the data classifiers have sufficient understanding of the systems approach, in order to provide the needed information for healthcare organisations to plan system based actions for medication error prevention. These findings may also contribute to underuse of the HaiPro system and possibly similar systems in other countries in detecting circumstances and contributing factors to incidents (Cousins et al. 2012).

The achieved conformity of classifications between the two study researchers indicates that it is possible to classify the medication errors in a uniform way by developing and using a detailed standard guideline for classifications and by basing the classification on systems approach (Reason 1990; Reason 2000).

10.4 Medication errors in the data of HaiPro (III)

Our findings support the need for improving the dispensing, administration and medication documentation stages of the medication process in hospitals (James et al. 2009; Cousins et al. 2012). In approximately a quarter of the reported errors the medication was "not documented", "not dispensed" or "not administered" to a patient. These all represent an error of omission, increasing the risk of the patient being left without the prescribed medication (Cohen 2007). Consequently, our findings show the need to decrease this type of risk which has been identified as the most common medication process-related risk in healthcare organisations (Lisby et al. 2005). These notions, however, represent only an

illustrative touching on some of the key findings from the reported medication errors to HaiPro in years 2007-2009.

10.5 Development of a 3-day short course for healthcare professionals in medication safety (IV)

The goal of the current work was to develop a syllabus for a compact three-day interdisciplinary course in medication safety for HCPs. Regardless of the short duration of the planned course, all the expert groups based their syllabi on non-didactic teaching and assessment methods. No conventional lectures were included in any of the syllabi. Instead, the chosen methods activated the learners to acquire core skills in ensuring medication safety through constructive, problem-based learning. With this learner-centred approach, better learning outcomes and changes in professional practice are more likely to occur if compared to three days of lectures alone (Cantillon & Jones 1999; Davis et al. 1999). This represents a key finding as the majority of the current methods in continuing education of HCPs, are based on lectures and traditional behaviouristic, instructor-centred approaches (Leach & Fletcher 2008).

The reflective assignments before, during and after the course expand the course far beyond what could be reached by three days of contact learning alone. This is a key finding as a multiplicity of learning takes place outside the training days, providing the course with more content. From the practitioner's perspective as a learner this gives an opportunity to deepen the learning without attending too many contact learning sessions. Continuing education of HCPs has also been criticized for not being sufficiently based on learner's needs (Davis et al. 1995; Davis et al. 1999; Mazmanian et al. 2002; Murad & Varkey 2008). In this study, founding the learning process on learner's personal learning needs was the basis for the learning. This has been suggested to increase motivation and course satisfaction of participating HCPs (Grant 2002).

Learning in continuing education should be relevant to the daily practice of HCPs (Leach & Fletcher 2008). In the present syllabi, learning was very practice focused and hands-on. The course work to be conducted at the learner's workplace was the key for bringing into practice the learner's knowledge and experiences acquired during the training days. Moreover, involving the learner's colleagues in the course work provides possibilities for the whole unit or organisation to participate in learning. Especially the support by management is vital in creating and sustaining practice changes (Dennison 2007). The support by work community and management may represent the key enabling factors for a successful course in terms of actual changes in the medication safety practices at the workplaces of the learners, and therefore, should be carefully considered when developing such a course.

The management of medication safety through a systems approach was found to be the most important content of the course. Indeed, adopting systems based thinking is essential to being able to analyse medication errors and create system safeguards (Aboumatar et al. 2012): the central role of systems approach in medication safety promotion has not changed during the past years and needs to be educated for practicing HCPs (World Health Organization 2011). More information on the application of the findings are presented in the original publication III.

10.6 Methodological considerations

10.6.1 Exploring national and local MER systems in different countries and establishment of MER systems (I, II)

The low number of participating countries limits the generalizability of the findings (Smith 2002). The response rate may have been influenced by the small number of countries which actually have a MER system. This may also explain why the developed countries were dominating the sample. Nevertheless, many of those who did respond provided detailed information on MER systems. Conversely, pioneering countries in MER systems, such as the United States and the United Kingdom, were missing from the data. Given these features of the realised sample, the current study's findings were consistent with what is reported in the published literature on MER systems in the United Kingdom and the United States (Kohn et al. 2000; Doupi 2009; Noble et al. 2011). This consistency suggests that the experiences and lessons learnt from MER may be transferable to other countries.

In relation to exploring the factors associated with successful development and implementation of MER systems (the original publication II), a qualitative content analysis was applied to explore the expert narratives obtained from open-ended questions. The chosen research method placed some restrictions on interpreting the data as probing questions could not be presented to explore further aspects raised by the experts (Hsieh & Shannon 2005). However, the experts were able to provide detailed narrative information on the research questions. Similar issues were presented by experts from different countries, indicating that the issues related to MER systems may be universal to some extent. Thus, the findings presented by the study can be valuable at the international level. However, there may be other factors affecting development and implementation of MER systems which our study did not explore.

The studies I and II were conducted some years ago, representing a potential limitation. However, we described problems in wide societal structures supporting healthcare quality and safety and provided solutions to these challenges: improvements in these structures tend to progress slowly. Therefore, we consider the information presented still valuable for healthcare planners, regulators and providers in high and low income countries planning to develop and implement a MER system, or willing to improve their current systems.

10.6.2 Assessing the inter-rater reliability of medication error classification in HaiPro (III)

In this study, the inter-rater reliability of medication error classification was assessed by re-classifying a random sample of medication errors from the data set on medication errors reported to the HaiPro system. The random sample of incidents included only a few less reported medication error types (e.g., errors in prescribing and preparing medications for administration), so influencing on the validity of the reliability testing. Hence, it was not possible to calculate the kappa-value for these error types. Additional research is needed to draw final conclusions about the quality of medication error classifications in HaiPro.

The data set was not drawn from all healthcare organisations in Finland; only a part of healthcare organisations participated in the HaiPro pilot programme in 2006-2009 with the majority of them being special healthcare units. However, our study provides preliminary results of the reliability of the medication error classifications in the HaiPro and recommendations for designing and improving similar systems in other countries.

The methods employed in this study proved to be rather time-consuming. Plenty of standardisation was required between the researchers to gain the required level of conformity when classifying the medication errors. Thus, trained data classifiers familiar with the operational environments of the reporting hospital units are recommended to be used in future studies instead of researchers who may tend to be "neutral" or "academic" in relation to the actual everyday practice in healthcare where the errors occur, and are classified.

10.6.3 Development of a 3-day short course for healthcare professionals in medication safety (IV)

The workshop used for data collection of the study was relatively short. Despite this potential limitation, the workshop participants were able to suggest a large amount of varying teaching and assessment methods in the given time. According to these experiences, the applied brainstorming approach can be used when new innovative ways of learning are developed.

The workshop participants represented international expertise in higher education and adult learning in pharmacy; although they were not specially experts in medication safety. However, the methods suggested by the participants were identified as suitable for education in medication safety. This and the similarities between the developed syllabi indicate that the findings could be adopted by different educational institutions in different countries.

The syllabus has not yet been piloted and evaluated for its impact on improving medication safety, and therefore, represents a vision for such a course. The implementation of the course will be the next step. However, the syllabus contains a variety of tried-and-tested active learning methodologies that have the potential to drive a successful continuing education course; e.g., the current evidence suggests that interactive learning in continuing education can change professional practice and achieve large and sustainable improvements in knowledge and skills (Davis et al. 1999; Sanci et al. 2000; Dennison 2007). Our findings are also consistent with the literature suggesting experiential learning as the most effective method to teach and assess competence in patient and medication safety (World Health Organization 2011; Varkey et al. 2009). While not many studies exist on continuing education of HCPs in medication safety, the existing evidence with undergraduates indicate that it is possible to influence safety knowledge, skills and systems thinking by short courses in patient safety (Halbach & Sullivan 2005; Madigosky et al. 2006; Moskowitz et al. 2007; Patey et al. 2007; Thompson et al. 2008; Aboumatar et al. 2012). Therefore, it is reasonable to assume that the presented syllabus has potential to produce positive learning outcomes and to reduce the risk for patient harm caused by medication errors. There may also be need to developing additional details about the content of the course, such as the role of information technology and clinical decision support systems in medication safety (Radley et al. 2013; Marasinghe 2015).

Since the syllabus has not yet been tested, the course organizers should be aware of the potential barriers to successful implementation of the course. Despite their pedagogical strengths, the relatively time-consuming out-of-class activities may limit feasibility of participation for practitioners. Additionally, guaranteeing interdisciplinary participation should be addressed with special plans on how to recruit course participants from different healthcare professions.

10.7 Further research

Further research will be needed to confirm whether local MER systems better serve as learning tools for the reporting organisation, than do the more massive national systems. For the development of future policies, it is important to have evidence on which of these MER approaches is more cost-effective, especially considering the resources of the developing countries. So far, the international trend has been directed towards national reporting systems (Kohn et al. 2000; Council of Europe 2006a; European Commission 2014). However, both schemes have their strengths (Zwart et al. 2011). Combining the advantages of both schemes should be examined. Having a safety culture embedded in healthcare systems is a prerequisite for using an MER systems for learning purposes in host organisations as well as in national levels. Systematic efforts are still needed for the implementation of a safety culture in practice. It would be useful also to conduct a follow-up study to evaluate progress in these aspects in different countries.

For the purpose of developing and implementing MER systems, as well as for improving the existing systems, a follow-up study would be needed to explore the current stage of development, and trends and experiences in the use of these systems in different countries. Especially studies exploring how information produced by MER systems has been used for improving medication processes from the systems approach would be imperative. More information is also needed on other possible factors affecting successful development and implementation of MER systems which our study did not explore. When designing these studies, special consideration should be placed on the proper sources for information and how to best reach these sources. These sources could include e.g., the previously mentioned International Medication Safety Network (International Medication Safety Network 2016). Based on the experiences from this study, qualitative data would be recommended to supplement quantitative research to ensure the depth of the acquired information.

Learning from medication errors requires reliable reporting (Williams & Ashcroft 2009). Therefore, it is recommended to conduct similar evaluations, as described in our study (manuscript for original publication III), on other patient and medication safety incident reporting systems as a part of quality assurance of the produced data. Data reliability testing is crucial, especially for systems collecting reports from different healthcare organisations, to avoid biases in data interpretation and misleading findings informing patient safety improvement actions. Data reliability testing and standard guidelines for incident classification might also benefit the local reporting in healthcare organisations, especially when multiple data classifiers exist. For future studies, some additional methods, such as consensus panels for those classifying the incidents (Van Doormaal et al. 2008), is recommended to be included to complete the reliability testing. Observational studies may also be needed to determine the actual occurrence of medication errors and near misses, and

their contributing factors (Flynn et al. 2002; Montesi & Lechi 2009). As the free text narratives of error reports are highly informative in regards, e.g., contributing factors to errors, further research is also needed to determine whether filing incomplete reports is primarily a competence issue of reporting healthcare professionals or the result of a lack of time or motivation for reporting.

As this study focused on developing a three-day short course for healthcare professionals in medication safety, the syllabus of the course has not yet been evaluated for its impact on improving medication safety. This represents a target for future research. The existing literature on patient safety education provides examples for such evaluation methods (Thompson et al. 2008; Aboumatar et al. 2012).

11 Conclusions

In order to provide a functional tool for medication safety promotion, MER systems need to be improved in many countries together with their operational environments. Moreover, the operational environments of MER systems must support functionality of these systems. The key factor for successful MER systems and learning from medication errors is having a systems approach as a theoretical context in all reporting and learning processes throughout the operational environments of MER systems.

Regardless of the differing quality and capacity of the healthcare systems of countries, as well as their stage of development, the obstacles and enabling factors for successful establishment and functioning of MER systems seem to be quite similar. This supports the transferability of the experiences between countries and healthcare settings in establishment of functional MER systems. The following more detailed conclusions can be drawn based on this study:

➢ There is a need for promoting international networking of medication safety experts and bodies for sharing information and learning from others to develop, implement and improve MER systems in different countries.

➢ Blame culture, a lack of time, training and coordination of reporting continue to be the major barriers to reporting. Learning from errors and having a non-punitive approach to reporting represent the most critical features of a functional MER system.

➢ Several factors at the national and local levels impact on the functionality of MER systems and should be considered in relation to their development and implementation. A lack of resources may inhibit establishing MER systems in some countries, representing a target for international collaboration. The safety culture should be extended to all parts of the operational environment to facilitate openness on, and learning from, medication errors.

➢ Consistency of classification and the quality of narratives are central areas of improvement for the Finnish Reporting System for Safety Incidents in Health Care Organizations, HaiPro, as well as reporting and classification of contributing factors to provide high quality information on medication errors. Improving the quality of MER reports represents also a key target for improvement for many MER systems in other countries.

➢ At least the nature of a medication error; the type of the error; medication documentation errors; dispensing errors, and administration errors can be pooled from different healthcare units for exploration of medication errors at the level of all organisations using HaiPro in Finland. Additional research is needed to draw final conclusions about the quality of medication error data produced by HaiPro. Moreover, reporting of contributing factors to medication errors and the quality of

narratives in medication error reports are central, and need to be improved in HaiPro for better medication safety promotion.

➢ The current work suggests that constructive problem-based learning linked to learners' practice through assignments is key when developing a continuing education course on medication safety for healthcare professionals. A large amount of learning occurs outside the training days through assignments at the learners' workplaces. However, commitment of the learners and their work communities to the course are needed to create and sustain improvements in medication safety as a potential outcome of the course.

12 References

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Appendices

Appendix 1: Literature search strategy for using international search databases.

Ovid MEDLINE in Process & Other Non-Indexed Citations (October 09, 2015)
EMB Reviews – Cochrane Database of Systematic Reviews 2005 to August 2015
EMB Reviews – Cochrane Methodology Register 3rd Quarter 2012
EMB Reviews – Database of Abstracts of Reviews of Effects 2nd Quarter 2015
EMB Reviews – Health Technology assessment 3rd Quarter 2015

1. exp Medication Errors or (medication* adj3 error*).mp.
2. (medicines adj3 error*).mp.
3. (medication* adj3 mishap*).mp.
4. (medication* adj3 incident*).mp.
5. (adverse drug adj3 event*).mp.
6. (medication* adj3 mistake*).mp.
7. (drug* adj3 error*).mp.
8. (medication* adj3 event*).mp.
9. (medication safety adj3 event*).mp.
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. (reporting adj3 system*).mp.
12. database*.mp.
13. (reporting adj3 program*).mp.
14. (reporting adj3 scheme*).mp.
15. 11 or 12 or 13 or 14
16. 10 and 15
18. limit 16 to English language

SCOPUS

(((TITLE-ABS-KEY (medication* W/3 error*)) OR (TITLE-ABS-KEY (medicines W/3 error*)) OR (TITLE-ABS-KEY (medication* W/3 mishap*)) OR (TITLE-ABS-KEY (medication* W/3 incident*)) OR (TITLE-ABS-KEY ("adverse drug" W/3 event*)) OR (TITLE-ABS-KEY (medication* W/3 mistake*)) OR (TITLE-ABS-KEY (drug* W/3 error*)) OR (TITLE-ABS-KEY (medication* W/3 event*))) OR (TITLE-ABS-KEY ("medication safety" W/3 event*))) AND ((TITLE-ABS-KEY (reporting W/3 system*)) OR (TITLE-ABS-KEY (database*)) OR (TITLE-ABS-KEY (reporting W/3 program*)) OR (TITLE-ABS-KEY (reporting W/3 scheme*))) AND (LIMIT-TO (LANGUAGE , "English"))

CINAHL
International Pharmaceutical Abstracts (IPA)

(((MH Medication Errors)) OR (medication* N3 error*) OR (medicines N3 error*) OR (medication* N3 mishap*) OR (medication* N3 incident*) OR (adverse drug N3 event*) OR (medication* N3 mistake*) OR (drug* N3 error*) OR (medication* N3 event*) OR (medication safety N3 event*)) AND ((reporting N3 system*) OR database* OR (reporting N3 program*) OR (reporting N3 scheme*))

Appendix 2a: Description of the national medication error reporting (MER) systems (n=6) included in the literature review (Chapter 5). ME=medication error.

Reference, reporting system & country	Description of the reporting system
Cheung et al (2014); Medication Incidents Registration (CMR), Netherlands. (description of the CMR is based on Cheung et al. 2011).	*Information reported into the system*: Date of the incident and the organisation identification number; patient information (gender and year of birth); open description about the medication incident; risk of recurrence; educational potential of the incident for other healthcare providers, and perceived need for a national alert. The structured questions with drop down menus concern the type of the medication incident, the underlying causes and the harm for the patient.
	Other information on the reporting system: A nationwide voluntary CMR was developed in 2006 and is maintained by a national CMR organisation. The system consists of a website, a database, a web-based reporting form, an application to import generated error reports to other reporting systems (incl. a real-time interface), an application to generate an overview of reported medication incidents (incl. trend analyses), and a national warning system for healthcare providers (alerts and newsletters by email, which are also available through the website). Types of organisations able to report: community pharmacies, hospitals, mental healthcare organisations and primary healthcare organisations who all are able to report either directly through the website reporting form, upload internally reported medication error reports of the organisation to CMR, or through the organisations' internal reporting systems which have a direct interface to the CMR. The data is analysed by the CMR team who then generates the feedback to the system users. CMR users are able to analyse their own reports and compare them with all the reported incidents within the sector (e.g., hospital or community pharmacies)
Cheung et al (2014); Canadian Medication Incident Reporting and Prevention System (CMIRPS), Canada. (description of the CMIRPS is based on Cheng et al. 2011 and	*Information reported into the system*: Date and time of the incident; open description of the incident; medication process stages involved (e.g., prescribing or dispensing); type of the incident (e.g. incorrect medication); discovering healthcare professional and place of occurrence (e.g., community pharmacy); severity outcome of the incident; error intervention; involved medication (strength, administration number, manufacturer, lot number, a potentially involved confusing drug name, label or packaging); additional picture material on the incident; follow-up actions conducted; recommendations for prevention; system improvement strategies implemented; patient information; reporter information, and contributing factors.

Institute for Safe Medication Practices Canada 2015).	*Other information on the reporting system:* A voluntary and confidential web-based medication incident reporting system started in 2002. The system is maintained by the Institute for Safe Medication Practices (ISMP Canada), Health Canada, Canadian Patient Safety Institute (CPSI) and Canadian Institute for Health Information (CHIH). Aims of the system are to coordinate the capture, analysis and dissemination of information on medication incidents, and to enhance the safety of the medication use system for Canadians. Expert review, analysis and trend identification are conducted based on the data. Feedback is provided through recommendations for risk mitigation activities which are made available via safety bulletins and alerts to stakeholders, such as the reporting healthcare organisations.
Kennedy et al (2004) and Cheung et al (2014); ISMP Medication Error Reporting Program (MERP), United States.	See Table 3
Nordén-Hägg et al (2012); Swedish Dispensing Error Reporting System, Sweden.	*Information reported into the system*: Description of the event (free-text field); details of the medicine involved (name, strength, free-text field), gender and age of patient (drop-down menus); information on type and cause of error (tick-boxes and drop-down menus), and outcome to the patient (free-text field).
	Other information on the reporting system: A mandatory, electronic web-based system established in 2002 for reporting dispensing errors in Swedish pharmacies. No training provided for the reporting staff as the system is designed to be self-explanatory with written instructions available.
Phipps et al (2014) and Williams et al (2009); National Reporting and Learning system (NRLS), United Kingdom.	See Table 3
Savage et al (2005), Coley et al (2006) and Cheung et al (2014); national electronic MER system, Medmarx, United States.	See Table 3

Appendix 2b: Description of local medication error reporting (MER) systems included in the literature review (Chapter 5). The MER system descriptions are based on the information provided in the research papers and for those systems (n=20) for which the information was available. ME=medication error.

Reference, reporting system, country & setting	Description of the reporting system
Armitage et al (2010); Patient safety incident reporting system.	***Information reported into the system:*** Incident reporting form consists of three free text boxes: "incident circumstances", "underlying causes" and "action to prevent recurrence". The reported information is the same for all incidents, including MEs.
United Kingdom (UK), an acute hospital, reports submitted to the Trust Risk Management Department.	***Other information on the reporting system:*** MEs are reported as a part of other patient safety incidents. Paper based system (at the time of the study) introduced in 2000. Severity of the incident outcome and likelihood of recurrence graded by the Central Risk Management Department. Causation of and action taken based on the incident are documented into the reporting system by the unit manager.
Beckmann et al (1996); Intensive care unit (ICU) incident reporting system.	***Information reported into the system:*** An open description of the incident and suggestions for measures to prevent future incidents. Structured part of the form comprised information on: patient; patient outcome; staff involved in the incident; when and where the incident occurred; factors contributing to the incident (human and system factors), and factors limiting the effect of incident (e.g., re-checking the patient).
Australia, three intensive care units (ICUs).	***Other information on the reporting system:*** Paper-based reporting system (at the time of the study) for staff members for reporting patient safety incidents, including MEs, in ICUs. The follow-up of the incident completed by the local coordinator to the incident reporting form. The local coordinator reviewed the reports regularly and discussed local patient safety concerns at regular staff review sessions. After reviewing the incident and follow-up information was added to the form by the local coordinator, prior to forwarding the information to the national coordinator who then analysed the aggregate data by descriptive statistics to show the types and frequencies of errors.
Chua et al (2003); Dispensing error reporting system.	***Information reported into the system:*** Date and time of the error; whether the error was an actual error or near miss; type of the error; description of the error; the information of the person who made the error, and description of training or organisational changes introduced as a result of the error identified.
UK, Four community pharmacies.	***Other information on the reporting system:*** A paper-based reporting system used by community pharmacy staff to report dispensing errors, including near misses.

Daniels et al (2010); Family Reporting System (FRS). Canada, British Columbia Children's Hospital (an academic tertiary care facility).	***Information reported into the system:*** The respondents choose the occurred incident from a category of six incidents: medication problems; miscommunication between staff; complication of care; equipment problem; other concerns, and miscommunication between the family and staff. After selecting the category, follow up questions are provided as a series of drop-down lists and pop-up boxes with structured and open-ended questions about the incident.
	Other information on the reporting system: MEs are reported as a part of other patient safety incidents. Electronic system integrated into a web-based patient safety learning system (Datix Corporation, London, UK) deployed for provider-based reporting in the hospital. Design of FRS is based on systems perspective of adverse events and near misses. Reporters are able to include identifying information for contact for further information about the incident and for the recruitment of a parent liaison committee to represent families during hospital efforts to prevent future adverse events.
Dollarhide et al (2006); Medication Error Reporting Tool (MERT), a customized software application. United States (US), four university affiliated teaching hospitals.	***Information reported into the system:*** Reporter information; event date and time; location; type; severity; stage of the medication process, and contributing factors.
	Other information on the reporting system: Used via handheld computers. Designed to be consistent with the standard reporting systems used by participating institutions of the study to facilitate interpretation and classification of data. A forced-choice, menu-driven response format that directed respondents to provide detailed descriptions on MEs was used. Time for completing the report recorded and medication formularies specific to each hospital were constructed on the reporting tool. Collected data transferred each week to a central server database.
Elliott et al (2014); Clinical safety reporting system (CSRS). Canada, Eastern Health (a large healthcare organisation in Newfoundland and Labrador).	***Information reported into the system:*** The name of the patient; patient record number; diagnosis; location of the incident; type of occurrence; time of occurrence; impact on patient; notification information; assessment information; physician assessment, and follow-up actions required. Incidents reported: falls; safety/security issues for patients; MEs; treatment and procedural mishaps, and medical equipment malfunctions.

	Other information on the reporting system: Incident report is completed by an individual involved in or witnessing an error, and forwarded to a manager. The manager forwards the communication to the appropriate levels of authority and ensures follow-up action. The organisation can customize some parts of the CSRS (e.g. drop-down menus) and terminology used in the incidence reporting. Enables timely notification of the managers, improved communications between the different personnel involved, trending, and tracking of incidents.
Haw et al (2010); Medication event reporting system. UK, a specialist psychiatric hospital.	Information reported into the system: Event date; time and location; whether the event is a near miss, a ME or an adverse drug event; the type of incident (e.g. wrong drug, extra dose, missing signature); severity rating; name(s) of the drug(s) involved; a description of the incident including whether any action was needed as a result of the error, and any contributory factors and recommendations for preventing similar incidents.
	Other information on the reporting system: An internal reporting system for medication events (MEs, near misses and adverse drug reactions). Reporting form accessible via patients' individual records in the Hospital intranet. Reporting form is designed to be easy to complete and consists of a number of drop-down menus as well as free text boxes with the aim of producing a standardized data set. After reporting a Head Pharmacist, the Registered Manager and the Clinical Services Manager of the Hospital are notified by email. For more serious incidents or where repeated minor errors are made by the same individual the Senior Nurse Manager carries out a detailed investigation of the event(s) and formulates an action plan. A senior pharmacist collates the Medication Event forms each month and reports the findings to the organisation's Medication Management Group. The staff receives feedback on reporting in the form of e-newsletters and training days on reporting.
Hirose et al (2007); KUH Incident reporting system. Japan, Kyoto University hospital.	Information reported into the system: The reported information: occurrence date; reception date by the PSD; clinical department; ward and unit of the reporter, and severity of the injury.
	Other information on the reporting system: MEs are reported as a part of a wider patient safety incident reporting system. The reporting process is voluntary, confidential and non-punitive. The professional witnessing the incident submits a report to a Patient Safety Division (PSD) at the hospital. Reports received primarily by fax (at the time of the study). PSD staff screen the reports and classify them by standardised guidelines.

	More incident details are requested from the reporters, if needed. The reporting system contributes to patient safety especially by learning from near misses with heightened potential for harm and serious accidents.
Jones et al (2004); MER system US, Critical access hospitals (CAHs) (n=6) in Nebraska.	***Information reported into the system*:** Severity and harm of error (based on the NCC MERP Index: Snyder et al. 2007); causes and contributing factors; additional interventions, and actions to avoid future errors.
	Other information on the reporting system: A voluntary system for reporting MEs only. Developed by Nebraska Center for Rural Health Research (NCRHR) in collaboration with the participating CAHs. Statistical analyses on reported errors performed by NCRHR. Education to the reporting staff and workshops to facilitate learning from errors.
Kennedy et al (2004); Prescribing error reporting system. US, Community pharmacies (n=7) in north-western Vermont.	***Information reported into the system*:** The reporting form involves structured text with minimal free text about the error.
	Other information on the reporting system: A voluntary MER system for reporting prescribing errors in community pharmacies. Opportunities for dictation by a cassette recorder or reporting by a paper-based reporting form. A verbal description of the event was required when reporting by dictation. Dictation instructions were provided for the reporting pharmacists.
Kuo et al (2012); Web-based incident reporting system. Taiwan, a teaching hospital in southern Taiwan.	***Information on the reporting system:*** A Web-based reporting tool for reporting patient safety incidents, including MEs, by nurses. Developed by the nursing department of the hospital with the assistance of the information systems department. Nurses were required to take a 2-hour training on patient safety and were educated about the incident reporting system. Incidents were required to be reported within 24-hours of occurrence by an electronic reporting form. After being reported, the report was sent to nurse manager for verification and subsequently to the nurse superintendent. The system sent e-mails automatically to the nurse administrators (nurse manager and superintendent) to remind about a new report.
Küng et al (2013); Medication error self-reporting tool (MESRT).	***Information reported into the system*:** The reporting form collects data on ME frequency and type (e.g., ordering, transcribing and preparing errors); information whether the incident was a near miss and the nurse who prevented the error, and patient consequences attributable to MEs.

Switzerland, Cardiovascular Surgery Department of the University Hospital in Bern.	***Other information on the reporting system:*** A voluntary and anonymous system for reporting MEs only instead of addressing all adverse events occurring. A pocket size leaflet with 50 sheets were provided for participants for reporting occurred MEs right away after occurrence (or if there were none, this information was documented on the leaflet at the end of the nurse's shift). Nurses were provided with instructions for reporting MEs.
Levtzion-Korach et al (2009); Risk Monitor Pro. US, a tertiary care academic medical centre affiliated with Harvard Medical School.	***Information reported into the system:*** The incident reporting form includes sections divided into reporter's and manager's parts. The reporter provides: general information on the incident, personal information; incident details including level of harm to the patient; clinical findings; equipment involved, and other notification.
	Other information on the reporting system: An electronic, confidential reporting tool enabling reporting of patient safety incidents by the hospital personnel. Patient safety officers, risk managers, and subject matter experts review the incident reports and determine which incidents (e.g., sentinel events, near misses that carry a significant risk of injury and systemic issues) require further investigation such as root cause analysis and proactive assessment for some events to just asking caregivers some additional questions regarding the incident. Trends identification is carried out from the reports. Summary reports of the data are generated monthly for use by management. All reporters receive feedback and a safety newsletter on actions taken after reports. Feedback is sent monthly to reporters, nursing and department managers and the senior leadership. The manager reviews the report (within 72 hours), identifies, and assigns at least one contributing factor from a drop down list, outcome of action taken, likelihood rating, level of risk, and root cause. The management level can be alerted to a report and can review it immediately after the incident has been reported.
Miller et al (2006); MER system US, the Johns Hopkins Children's Center.	***Information reported into the system:*** Structured information of the error type (prescribing, dispensing, administering or medication administration record error); free text description of the event; outcome scale of the event (0-4, with 0=event did not reach patient and 4=event reached patient and life threatening or serious morbidity or death occurred), and indication whether the incident was a near miss.
	Other information on the reporting system: A voluntary online system for reporting MEs at a children's institution in place from July 2001 to July 2004 (from 2004 the system has included reporting of all types of adverse events). Developed internally at the Johns Hopkins Children's Center and was accessible via all public workstation computers. All providers (e.g., nurse, pharmacist, physician, therapist) were able to file reports.
Olsen et al (2007); Adverse event reporting system.	***Information on the reporting system:*** A paper-based (at least at the time of the study) reporting system for adverse events, including MEs. Confidential and non-anonymous system.

UK, district general hospital, NHS.	The reporting form contained mandatory data fields and space for free text about the incident.
	No additional incentives or encouragements to enhance reporting (at least at the time of the study).
O'Neil et al (1993); Adverse event reporting system. US, Birgham and Women's Hospital.	***Information on the reporting system:*** Confidential e-mail reporting system for physicians for reporting adverse events in patient care. Enabled also paper based reporting of events. Enabled uploading case-patient summaries and other relevant elements for the event analysis as a part of the report. Physicians reminded every week about the opportunity for reporting events. Rapid reporting of the incidents within 24 hours of occurrence and analysis of the incidents within 48 hours of occurrence.
Pierson et al (2007); MER system. US, 25 nursing homes in North Carolina.	***Information reported into the system:*** Information reported in the structured reporting form: level of harm to the patient; patient information; date, shift, and number of time the error was repeated; type of the error (e.g., overdose, wrong medication or wrong patient); phase of medication care process where error first occurred; personnel involved in the error; medical effects of the error on the patient (e.g., respiratory distress, headache or excessive side effects); causes of the error (e.g. medication name confusion or poor communication), and medication involved in the error.
	Other information on the reporting system: A confidential MER system for long-term care setting in North Carolina. The data are reviewed in internal medication management advisory committees in the settings using the system. The committee also recommends changes to improve the safety of medication care. The web-based MER system was designed to be able to be used with minimal training; the user is guided step by step to enter correct information needed (e.g., if the error is overdose, the system prompts for both intended dose and dose administered). The system uses a drug identification tool that enables users to quickly search and select the medication involved in the error, including drug strength, route and dosage form. The system provides on-demand summary reports as feedback and quality improvement material of the reported information for the reporting nursing homes. Users can create and print summaries of all errors entered, categorize them by time period, patient impact, type of the error and other relevant variables.

Ricci et al (2004); Two different adverse event reporting databases. US, paediatric cardiac intensive care unit (CICU).	***Information on the reporting systems:*** Reports submitted to two different databases, which collect information from the same cardiac intensive care unit (CICU). ME reported as a part of other adverse events. Both databases classify adverse events into incident type (drug errors, ventilation, cannula/indwelling lines, chest drains, blood transfusion, equipment, operational) and severity (0=no, 1=minor, 2=major, 3=life threatening consequences). **Database A (DA)** ➤ Non-anonymous, hospital's official adverse event reporting system; ➤ Predominantly used by nurses, only occasionally by doctors; ➤ Incident forms filled in immediately after an adverse event is detected, and ➤ Forms submitted to the hospital's Risk Management Team for analysis, and result of the analyses are summarized in quarterly reports describing the frequency and severity of adverse events per ward/department. **Database B (DB)** ➤ Anonymous, and all reports are filled in at the end of the morning ward round by a consultant intensivist (a doctor); ➤ Data collection is based on the consultant's direct experience of adverse event or on information provided by members of the CICU team (other consultants, junior doctors, nurses etc.), and ➤ No detailed analysis of the information entered in the database was carried out at the time of the study.
Tuttle et al (2004); Electronic Reporting System (ERS). US, an university affiliated teaching hospital, Strong Memorial Hospital.	***Information reported into the system:*** Data collection form collects structured information by drop-down menus on: demographic/background information for each event; event classification; event subtype; level of impact, and contributing factors. Additional details can to be given on falls, medication, transfusion and medical device related events. An optional open text field available for event description. For type two users additional fields are available for additional event information and follow up actions taken or planned.
	Other information on the reporting system: Voluntary and confidential (non-anonymous) electronic reporting system for adverse events, including MEs, in patients and visitors. Implemented throughout all clinical care areas (e.g., inpatient, outpatient, same day surgical areas), all staff able to report. Levels one (reporting healthcare staff) and two (accountable managers/quality assurance liaisons) user types. Type two users have additional access to the database functions of event notification, editing, follow up and closure, data enquires and analysis. Employs four major event classifications: falls, medication, adverse clinical events and administrative.
Zwart et al (2011); Two patient safety incident reporting systems.	***Information on the reporting systems:*** **Local incident reporting procedure (LIRP)** (used by OHS 1 in the study)

Netherlands, three general practices' (GP) out-of-hours services (OHSs).	➢ Reported information on the incident: narrative about what happened; date, time and place of the incident; involved individuals, and harm for the patient; ➢ All healthcare professionals report all incidents in patient care by a paper based form in out-of-hours services; ➢ A local, trained and multidisciplinary incident reporting procedure committee (physicians, nurses and professionals working on the OHS location of the incident) screened and analysed the incident reports. Incidents selected for analysis by first assigning a risk score (0 to 4) based on an estimate of potential harm and frequency of occurrence. Incidents with a risk score of 2 or higher were analysed based on PRISMA (Prevention and Recovery Information System for Monitoring Analysis) and root cause analysis techniques; ➢ The incident reporting procedure committee was responsible for feedback to reporters and to the organisation, as well as for development of improvement measures when appropriate, and ➢ Processing of the incident reports in feedback loop: 2-3 weeks. **Central incident reporting procedure (CIRP)** (used by OHS 2 and 3 in the study) ➢ Electronic system in which incident reports are sent by email to an advisory committee of the boards of directors of the GP OHSs collaboration who then analyses the reports and provides feedback to reporting organisations, and ➢ Processing or the incident reports in feedback loop: 8-12 weeks.

Appendix 3: The final questionnaire on medication error reporting systems conducted in the study phase I.

QUESTIONNAIRE ON MEDICATION ERROR REPORTING SYSTEMS

This questionnaire comprises three sections. Please answer all the relevant questions in section 1, and thereafter follow the instructions that will lead you to either section 2 or 3.

 Please answer the questions by ticking the relevant boxes, or by writing your answers in the relevant answer fields as appropriate.

For clarity, the following definitions of medication safety and medication errors are used in this study (Council of Europe 2005).

Medication Safety : freedom from accidental injury during the course of medication use; activities to avoid, prevent, or correct adverse drug events which may result from the use of medications.

Adverse Event : an unintended injury caused by medical management rather than by a disease process

Medication Error : any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Adverse Drug Reaction: a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in the main for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

Reference:

Council of Europe: Committee of Experts on Management of Safety and Quality in Healthcare (SP-SQS) Expert Group on Safe Medication Practices. Glossary of terms related to patient and medication safety, 2005

SECTION 1

Background information on respondent countries

This section will provide us with some background information on your organisation and country to help us classify your answers.

Q 1.1   Organisation name:

Organisation country:

Q 1.2 Please provide us with your contact details in case we need to contact you later for further information.

        Name:

        Email:

        Work telephone number:

        Work address:

Q 1.3 Please tick all options that apply of the following alternatives to describe your organisation.

☐ Government (e.g. Ministry of Health)   ☐ Regulatory body (e.g. National Agency for Medicines)

☐ Professional body (e.g. National Medical Association)

☐ Hospital setting   ☐ Community setting

☐ Another organisation. *Please specify*

Legislation and regulations

Q 1.4 In your country, does a national authority for

a) **patient safety** exist?

☐ Yes

☐ No *(Please go to Q 1.4 b)*

☐ Do not know

If yes,

Please provide the name of the authority

What is their area of responsibility in patient safety issues?

b) **medication safety** exist?

☐ Yes

☐ No *(Please go to Q 1.5)*

☐ Do not know

If yes,

Please provide the name of the authority

What is their area of responsibility in medication safety issues?

If you answered yes in both Q 1.4 a) and b),

Are the national authorities for patient safety and medication safety integrated?

☐ Yes   ☐ No

Q.1.5 In your country, does an authority for **medication error reporting** exist?

☐ Yes   ☐ No *(Please go to Q 1.6)*   ☐ Do not know

If yes,

a) Please provide the name of the authority

b) What is their area of responsibility in medication error reporting issues?

Q 1.6 In your country, do national authorities and/or systems exist that govern and regulate the quality of healthcare services, for example standards of care?

☐ Yes   ☐ No *(Please go to Q 1.7)*   ☐ Do not know

If yes,

a) Please provide the name of the authorities and/or systems

b) What is their area of responsibility in patient and medication safety issues, if any?

Q 1.7 In your country, do national legislation and/or regulations exist regarding healthcare professionals' practice (e.g. maintaining professional competence)?

☐ Yes   ☐ No   ☐ Do not know

If yes, please specify

Q 1.8 In your country, are healthcare professionals required to register with an authority before they are allowed to practise their profession? *Please tick all options that apply.*

☐ Yes, a requirement for doctors   ☐ Yes, a requirement for nurses

☐ Yes, a requirement for pharmacists   ☐ Yes, a requirement for other professionals

Please, specify

Q 1.9 In your country, do national legislation and/or regulations exist regarding

a) Adverse events

☐ Yes   ☐ No   ☐ Do not know

b) Medication errors

☐ Yes   ☐ No   ☐ Do not know

c) Adverse drug reactions

☐ Yes   ☐ No   ☐ Do not know

Q 1.10 In your country, would these or other legislations encourage the healthcare professionals to report medication errors? Please describe in detail.

Q 1.11 What type of actions may be taken within the legislative framework of your country when a healthcare professional is reported to have made a medication error (e.g. prescribing, transcribing, dispensing or administration error), if any?

Q 1.12 Are these actions different for different healthcare professionals (doctors, nurses, pharmacists)?

☐ Yes   ☐ No   ☐ Do not know

If yes, please specify

Characteristics and existence of medication error reporting systems

Q 2.13 Please provide us your comments or ideas how to best develop and implement a medication error reporting system.

Q 1.14 Please provide us information on which characteristics describe a good and effective **medication error reporting system (MERS)** in your opinion. *Please choose the top five (5) options that apply.*

☐ Reporting of errors through the MERS is voluntary	☐ The MERS provides a choice of reporting anonymously
☐ Reporting of errors through the MERS is mandatory	☐ The MERS allows all healthcare professionals to report errors
☐ The MERS is easy to use	☐ The MERS is quick to use
☐ The MERS is an integral part of a patient safety reporting system	☐ The MERS is an independent reporting system dedicated to medication error reporting
☐ The MERS uses a non-punitive approach to reporting	☐ The MERS is available in electronic form
	☐ The MERS is paper based
☐ The MERS provides confidentiality of reported information	☐ The MERS provides an opportunity for error data analysis
☐ The MERS provides patients/consumers an opportunity to report errors	☐ The MERS includes reporting of both potential and actual errors
☐ The MERS is provided and maintained by one national organisation	☐ The MERS produces recommendations and guidelines for improving the medication safety
☐ The MERS provides feedback of results of error analysis for those involved in reporting	☐ The MERS provides an opportunity for evaluating causes of errors (e.g. root cause analysis)

Q 1.15 Which of following, if any, could be regarded as barriers to reporting medication errors in your opinion?

Please choose top five (5) options that apply.

☐ Non-anonymous reporting	☐ Fear of consequences
☐ Lack of time for reporting	☐ Lack of healthcare staff
☐ Lack of financial resources	☐ Lack of training in medication error reporting for healthcare professionals
☐ Perceived to be bureaucratic	☐ Concern that no beneficial action will follow
☐ Lack of understanding why it is needed	
☐ Lack of relevant guidelines and policies on medication error reporting	☐ Lack of organisational leadership and support
☐ Culture of blame *(blaming the individuals e.g. doctors, nurses and pharmacists for making errors instead of the system)*	☐ Lack of legal protection for individual healthcare professionals who have made an error

☐ Other barriers. *Please, specify*

Q 1.16 In your country does an **adverse drug reaction reporting system** (i.e. pharmacovigilance system) exist?

☐ Yes   ☐ No   ☐ Do not know

Q 1.17 In your country, does a national **medication error reporting system** exist?

☐ Yes, it is a stand alone system *(Go to Section 2)*

☐ Yes, it is integrated in an Adverse Event Reporting system *(Go to Section 2)*

☐ Yes, it is integrated in an Adverse Drug Reaction reporting system *(Go to Section 2)*

☐ Yes, it is integrated in another system. *Please, specify*   *(Go to Section 2)*

☐ No *(Please go to Q 1.18)*

Q 1.18 Are you aware of any local **medication error reporting systems** in any hospitals or other healthcare settings in your country?

☐ Yes, they are widespread

☐ Yes, there are a few

☐ No, there are none *(Please go to Section 3)*

If yes, where does the most developed medication error reporting system exist? *(If you are aware of several systems in different settings, please consider the one you are most familiar with)*

☐ Within a hospital setting   ☐ A shared system within several hospitals

☐ Within a community setting ☐ Within another setting. *Please specify*

Please go to Section 2.

SECTION 2

Countries which have a national system or local systems for reporting medication errors

This section helps us to learn more about your medication error reporting system.

Please note: If both a national system and local systems exist in your country, please consider the national system when answering the questions.

Q 2.1 Please specify which medication error reporting system you are going to give information on.

☐ National system   ☐ Local system

Q 2.2 When was the reporting system implemented? *Please choose the most appropriate alternative from drop down menu by clicking the question mark.*   ?

Q 2.3 a) Which organisation **established** the medication error reporting system? *Please provide the name of the organisation for us.*

b) Which organisation **maintains** the medication error reporting system?

c) Which organisation **collects** the medication error reports?

d) Which organisation **analyses** the medication error reports?

e) Which organisation **provides feedback** on the analysed data for healthcare professionals?

Q 2.4 For what purpose is the reporting system used? *Please, tick all options that apply.*

☐ Reporting medication errors   ☐ Reporting other patient safety adverse events

☐ Reporting adverse drug reactions   ☐ Other purpose. *Please specify*

Q 2.5 Please respond to the following statement by clicking the question mark below and choosing the appropriate alternative from drop down menu.

In my opinion the number of errors reported through the current medication error system is a realistic representation of the actual number of errors made.   ?

Q 2.6 Please indicate which features are included within the **medication error reporting system (MERS)**?

Please choose all options that apply.

☐ Reporting of errors through the MERS is voluntary	☐ The MERS provides a choice of reporting anonymously
☐ Reporting of errors through the MERS is mandatory	☐ The MERS allows all healthcare professionals to report errors
☐ The MERS is easy to use	☐ The MERS is quick to use
☐ The MERS is an integral part of a patient safety reporting system	☐ The MERS is an independent reporting system dedicated for medication error reporting
☐ The MERS uses a non-punitive approach to reporting	☐ The MERS is available in electronic form
	☐ The MERS is paper based
☐ The MERS provides confidentiality of reported information	☐ The MERS provides an opportunity for error data analysis
☐ The MERS provides patients/consumers an opportunity to report errors	☐ The MERS includes reporting of both potential and actual errors
☐ The MERS is provided and maintained by one national organisation	☐ The MERS produces recommendations and guidelines for improving the medication safety
☐ The MERS provides feedback of results of error analysis for those involved in reporting	☐ The MERS provides an opportunity for evaluating causes of errors (e.g. root cause analysis)

Q 2.7 If the medication error reporting system is non-anonymous, which personal details have to be reported on the person who made the error?

Q 2.8 a) The severity of medication errors may vary. In this system, which potential or actual medication errors are **mandatory** to report? *Please tick all options that apply.*

☐ Near miss
(an error that was about to happen but was detected before any harm was caused to patient)
☐ Mild
(an error requiring further observation or minor treatment of the patient, and/or causes a minimal harm to patient)
☐ Moderate
(an error causing significant but not permanent harm to patient)
☐ Severe
(an error resulting to permanent harm to patient, for example organ damage)
☐ Fatal
(an error resulting in the death of the patient)
☐ Another type. *Please specify*

Q2.8 b) The severity of medication errors may vary. In this system, which potential or actual medication errors are **voluntary** to report? *Please, tick all options that apply.*

☐ Near miss
(an error that was about to happen but was detected before any harm was caused to patient)

☐ Mild
(an error requiring further observation or minor treatment of the patient, and/or causes a minimal harm to patient)

☐ Moderate
(an error causing significant but not permanent harm to patient)

☐ Severe
(an error resulting to permanent harm to patient, for example organ damage)

☐ Fatal
(an error resulting in the death of the patient)

☐ Another type. *Please specify*

Q 2.9 Please provide us information on the different types of potential and actual medication errors that are reported through the system by ticking **one** of the following boxes for each type of error. The alternatives are *very likely* **to be reported;** *likely* **to be reported;** *not likely* **to be reported;** *not at all likely* **to be reported;** *not applicable*.

Please, choose the alternative **not applicable** if some types of medication errors are *not* advised to be reported.

	Very likely to be reported	Likely to be reported	Not likely to be reported	Not at all likely to be reported	Not applicable
Near Miss	☐	☐	☐	☐	☐
Mild	☐	☐	☐	☐	☐
Moderate	☐	☐	☐	☐	☐
Severe	☐	☐	☐	☐	☐
Fatal	☐	☐	☐	☐	☐
Another type.	☐	☐	☐	☐	☐

Please specify

Q 2.10 Medication errors can occur in any step of medication process. Which medication errors types are reported through the system? *Please tick all options that apply.*

☐ Prescribing errors *(occurring during the prescribing stage of a medicine)*

☐ Transcribing errors *(occurring during the transcription of a name of the medicine provided by a doctor to a prescription by a nurse or pharmacist)*

☐ Dispensing errors *(a deviation from a prescription or a medication order made by a pharmacist, or any deviation from references or guidelines affecting dispensing procedures)*

☐ Administration errors *(occurs in the administration stage of medication when medication is given to a patient by a nurse, patient themselves or a caregiver)*

☐ Errors related to poor communication between healthcare professionals and patients

☐ Other errors. *Please specify*

Q 2.11 Which of the following could report medication errors? *Please tick all options that apply.*

☐ Doctors

☐ Pharmacists

☐ Nurses

☐ Patients

☐ Others. *Please specify*

Q 2.12 In which settings are healthcare professionals able to report medication errors? *Please tick all options that apply.*

☐ In hospital settings

☐ In intensive care units in hospitals

☐ In community primary healthcare settings

☐ Nursing homes

☐ In community pharmacies

☐ In other settings. *Please specify*

Q 2.13 Please provide us with information on how often you think the following report medication errors by ticking **one** of the following boxes for **each**. The alternatives are *very often*; *often*; *sometimes*; *never* and *not applicable*. If some do *not* take part in reporting, please choose the alternative **not applicable**.

	Very often	Often	Sometimes	Never	Not applicable
Doctors	☐	☐	☐	☐	☐
Nurses	☐	☐	☐	☐	☐
Pharmacists	☐	☐	☐	☐	☐
Patients	☐	☐	☐	☐	☐
Other professionals	☐	☐	☐	☐	☐

Please specify

Q 2.14 Which applications are there for the data collected through the medication error reporting system?

Please tick all the alternatives that apply, and describe in more detail.

☐ Development of training programmes on patient and medication safety issues.

☐ Development of guidelines or standardised operating procedures for patient care.

☐ Development or use of system failure (e.g. in patient care) evaluation tools (e.g. root cause analysis).

☐ Any other purposes?

Please describe in more detail here

Q 2.15 Following the implementation of the medication error reporting system, have any changes or improvements been made to the medication error reporting system?

☐ Yes   ☐ No

If yes, please describe these changes in more detail

Thank you for your contribution to this study!

SECTION 3

Countries which do not have a medication error reporting system

Q 3.1 Have there been **any plans** for developing a medication error reporting system

a) Nationally?

☐ Yes   ☐ No   ☐ Do not know

If yes, please describe in more detail

b) Locally in

☐ Hospital setting(s)?   ☐ Community setting(s)?

☐ Another setting. *Please specify*   ☐ Do not know

Please describe the local plans in more detail

Q 3.2 Has **any action** been taken to develop a medication error reporting system

a) Nationally?

☐ Yes   ☐ No   ☐ Do not know

If yes, describe in more detail

b) Locally? *Please tick all options that apply.*

☐ Within hospital setting

☐ Shared activities within several hospitals

☐ Within community setting

☐ Within another setting. *Please specify.*

☐ Do not know

Please describe these local actions in more detail

Q 3.3 In your country, is there awareness of the need for paying attention to medication safety issues? *Please tick all options that apply.*

☐ Nationally

☐ Locally (e.g. in any hospital)

☐ Do not know

If yes, please describe

Q 3.4 What kind of organisational support should be available to develop and implement a national medication error reporting system?

Q 3.5 What kind of organisational or cultural changes (e.g. attitude changes), if any, may be needed to enable medication error reporting?

Q 3.6 Please comment on the capacity of your country to develop and implement a medication error reporting system.

Thank you for your contribution to this study!

Appendix 4: Information on the patient safety incidents collected by the Reporting System for Safety Incidents in Health Care Organizations, HaiPro, in the Pilot Phase of the system in 2007-2009 (1).

Information provided by the healthcare professional reporting the incident
Reported through structured drop-down menus in the electronic HaiPro reporting form (2)
Date incident occurred
Unit of the healthcare professional reporting the incident
Unit were the incident occurred
Profession of the person reporting the incident
Date and time of the incident
Place of occurrence (e.g. operating room)
Nature of the incident (actual error, near miss or violation directed to personnel)
Incident type (e.g. dispensing error of a medicine)
Reported as open narratives in the HaiPro reporting form (2)
Description of the incident • What happened and how the incident occurred • What were the consequences for the patient and the unit • Conditions at the time of the incident and other contributing factors • Views of the reporting person on how similar incidents could be avoided in the future
Suggestions for action to prevent reoccurrence of the incident
Information classified by the data classifier (based on reported narratives) by a structured electronic data classification form
Defined type of the incident (e.g. a wrong medicine dispensed to a patient)
Consequences for the patient and the unit
Management of the incident situation
Instant actions in the incident situation
Conditions at the time of the incident and other contributing factors (e.g. lack of information on the medicines the patient is using)
Information reported by the data classifier as an open narrative in the HaiPro system
Actions to prevent the reoccurrence of the incident suggested by the reporter, or explanation of why actions are not needed
Description of how the suggested actions were executed

1. Ministry of Social Affairs and Health. Introduction of a reporting system for dangerous situations in healthcare. [Abstract in English]. Reports of the Ministry of Social Affairs and Health 2008:16.
2. Awanic Ltd. HaiPro – Patient safety incident report: http://83.150.87.4/haipro/20/lomake.asp?kieli=ENG. Accessed [215 Sep 2].

Appendix 5: The sample contents of the course provided for the workshop participants to support the brainstorming of teaching and assessment methods for a three-day interdisciplinary course in medication safety.

INTERDISCIPLINARY APPROACH TO MEDICATION SAFETY

A three-day short course for healthcare professionals

Aims:

At the end of this course, the learner will be able to:

- describe medication safety from the systems approach, and its role in patient safety

- identify causes of medication errors and to develop actions to prevent medication errors

- use skills of different healthcare professionals to promote medication safety

Description:

Training is provided for a group of 20 healthcare professionals involved in medication process of patients (e.g. pharmacists, practitioners and nurses). This is a three-day-short course involving different teaching and assessment methods.

Contents [1]:

Day 1. Understanding the causes of medication errors (7h)   - Introduction to patient and medication safety (2h)   - Causes of medication errors (e.g. hectic working environment, too heavy workload, "sound alike" and "look alike" medicines) (3h)   - Analysis of medication errors (what happened and why?) (2h)
Day 2. Prevention of medication errors (7h)   - Prevention of medication errors (prescribing, dispensing, administration and counselling errors) (3h)   - High alert medications – Safeguarding against errors (2h)   - Role of patient in preventing medication errors (2h)
Day 3. Safe medication process as a target of interdisciplinary co-operation (7h)   - Preventive collaborative actions (e.g. medication review)   - Medication reconciliation

[1] Based on: Cohen M. Medication Errors. 2nd edition. Washington, D.C.: American Pharmacists Association; 2007.

Appendix 6: The combined syllabus for a three-day course titled "Interdisciplinary Approach to Medication Safety". HCP = Healthcare professional.

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Interdisciplinary Approach to Medication Safety

AIMS:

At the end of this course, the learner will be able to:

- describe medication safety from the systems approach, and its role in patient safety
- identify causes of medication errors and to develop actions to prevent medication errors
- use skills of different healthcare professionals to promote medication safety

DESCRIPTION:

Training is provided for a group of 20 healthcare professionals involved in medication process of patients (e.g. pharmacists, practitioners and nurses). The course is based on three interactive training days and learning at the workplace. The time between the training days is one month. The course comprises three training days (á 7h) and out-of-class work (approx. 30 hours). The facilitators/teachers of the course are recommended to be experts in medication safety and change management.

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PRE-COURSE

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- Pre-reading material in medication safety (see examples at the end of the syllabus)
- Audio-visual recordings (e.g. videos of aviation accidents and management of medication errors)
- Identification of a medication error/near miss occurred at the learner's workplace [1]

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TRAINING DAY 1

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Theme: Understanding medication safety and the causes of medication errors (7h)

- The learners network and get to know each other
- Group discussion on
  - what is medication safety and the role of systems approach in it
  - learners' own experiences in medication safety
- Group-reflection on pre-course assignments
- Self-reflection on own learning needs (notes, essays and blogs) *(see examples for reflection prompts in the end of the syllabus)*
- Development of personal learning objectives *(see examples in the end of the syllabus)*
- Real-life examples
  - inviting a HCP who has made an error to share his/her experiences, **or**
  - other examples of unfortunate accusations of malpractice
- Analysis of
  - the cases of medication errors and their causes in the pre-course videos, **or**
  - the identified cases of medication errors/near misses at the learners' workplaces and the causes of the incidents

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LEARNING AT THE WORKPLACE BETWEEN TRAINING DAYS 1 & 2 (1st month)

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- A presentation for colleagues on medication safety and own learning experiences
- Searching for reading material to support own learning process, and reflecting the material with the colleagues at the workplace
- Identifying new cases of medication errors/near misses with the assistance of colleagues at the workplace [1]
- Presenting the cases and discussing their causes in interdisciplinary small groups of course participants [2]

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TRAINING DAY 2

Theme: Safe medication practices and prevention of medication errors (7h)
 	
• Feedback on learning at the workplace between the training days 1 & 2:
  o presenting the identified cases of medication errors/near misses;
  o presenting the contents of e-discussion; and
  o presenting the findings from reading material and reflection with the colleagues
• Experience sharing on safe medication practices at own workplace
• Role play (patient-HCP **or** healthcare team)

LEARNING AT WORK BETWEEN TRAINING DAYS 2 & 3 (2nd month)
• Discussion on the identified cases of medication errors/near misses and their prevention [2] • Defining measures for prevention of the cases [2]
TRAINING DAY 3

Theme: Safe medication process as a target of interdisciplinary collaboration and reflecting learning (7h)
 	
• Feedback on learning at the workplace between the training days 2 & 3:
  o Presenting the contents of e-discussion
  o Presenting the prevention measures of identified medication errors/near misses and discussing the implementation of the prevention measures [3]
• Reflection of learning
  o Self-assessment of learning against own objectives and course aims
  o Self-reflection on current learning needs
  o Re-focusing of learning objectives
  o Self-reflection on changes in own attitudes towards medication safety and in behavior at the workplace
  o Group reflection
• Learners form networking groups for post-course communication

POST-COURSE

• Development of an action plan to prevent medication errors at own organisation
  o learners use the networks created on the third training day, and in the interdisciplinary small groups used for web-based learning between the training days
• Presenting and discussing the action plan at the workplace
• Reflection of learning
  o Assessment of own learning against objectives
  o Self-reflection on current learning needs
  o Re-focusing of learning objectives

EXAMPLES [4]

• Examples of pre-reading material for the course:
  o Cohen M. Medication Errors. 2nd ed. Washington, D.C.: American Pharmacists Association; 2007.
  o Institute for Safe Medication Practices: Medication Safety Tools and Resources. Available at: https://www.ismp.org/ (Accessed October 6, 2014)
  o World Health Organization. The WHO Patient Safety Curriculum Guide: Multi-professional

Edition. 2011.

- Example prompts for learners to reflect on their learning needs:
    - What would you like to learn about contributing factors to medication errors?
    - What skills to promote medication safety at your workplace would you like to master after the course?
    - In what way would you like to improve as a team worker?
- Examples of learning objectives for the course (some based on the WHO Patient Safety Curriculum Guide) [5]

At the end of the course I will be able to:

- Identify the potential contributing factors of medication errors at my workplace
- Identify the mechanisms that could minimize medication errors at my workplace, e.g. medication reconciliation or checklists, and to develop them as a customized tools to promote medication safety at my workplace
- Describe the principles of good communication with other HCPs and patients

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[1] The learners can be encouraged to especially identify cases of high-alert medications (References:

Institute for Safe Medication Practices. ISMP's List of High-Alert Medications for Acute Care Settings. 2012. http://www.ismp.org/tools/highalertmedications.pdf. Accessed April 20, 2015.

Institute for Safe Medication Practices. ISMP's List of High-Alert Medications in Community/Ambulatory Healthcare. 2011. https://www.ismp.org/communityRx/tools/highAlert-community.pdf. Accessed April 20, 2015.

[2] In inter-disciplinary small groups in a web-based learning environment

[3] Also other measures/tools for medication safety promotion, such as medication review or medication reconciliation, can be included in the discussion

[4] Provided by the researchers to assist in the course planning and implementation

[5] Reference: World Health Organization. The WHO Patient Safety Curriculum Guide: Multi-professional Edition. 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501958_eng.pdf?ua=1. Accessed April 20, 2015.