Introduction, overall aims, and thesis outline

INTRODUCTION

What we know

Medication safety is worldwide a concern. This includes errors in prescribing drugs, administering a wrong dose or strength of a drug to patients, errors in identifying patients, confusion of look-alike and sound-alike drugs, wrong routes of administration, misuse of equipment as infusion pumps, errors in calculating the right dose of a drug, and miscommunication about medication amongst healthcare workers. Medication errors are a frequent and daily reality and arise during every single stage in the process of prescribing, compounding, dispensing, preparation, and administration of medication. Medication errors may not only cause harm to patients, but they could also be a tragedy for healthcare professionals and may potentially lead to higher costs in healthcare [1,2]. In hospitals about 5-10% of all medication orders result in errors [3-7].

Medication administration errors form an important subcategory of medication errors. Administration of prescribed drugs is the final step in the medication process, and, because there are few possibilities to detect and prevent errors in this step, administration errors may directly affect the patient. The prevalence of medication administration errors in hospitals is approximately 19% [8-10] of 'total opportunities for error' (in the process of medication administration in hospitals more than one error in one administration to one patient can occur). Research from the United Kingdom (UK) showed that 0.6%-21% of the medication administration errors that reach the patient, cause patient harm [11]. Bearing all this in mind, prevention of medication errors is important in healthcare.

Interventions aimed to enhance medication safety

Several interventions have been developed to prevent medication errors. In hospitals; training and re-training, process changes such as the introduction of 'do-not-disturb' jackets to be used by nurses in charge of medication administration, introduction of double-checking, and technology-based interventions such as 'smart-infusion-pumps,' automated dispensing machines, computerized physician order entry systems, and use of bar-code-assisted medication administration were realized, and the effects of them in preventing medication errors analyzed [12-25].

Information technology-based interventions to enhance medication safety

Of all these medication safety interventions, technology-based tools are thought to be most promising to improve medication safety in different ways [26-29]. Information technology (IT) has the potential to contribute to standardization, transparency, proper documentation and structure of a process. IT-based tools like computer order entry can prevent errors in written or verbal prescription orders [30,31].

Computerized Physician Order Entry (CPOE) systems are characterized by physicians entering and sending treatment instructions – including medication – via a computer application instead of verbal orders, orders by paper or fax machine. CPOE has several potential benefits: reducing errors, improving patient safety and improving the efficiency of care. In before-after research carried out by Bates et al. a significant reduction in all types of medication errors was found [32]. Both healthcare professionals and healthcare authorities consider the use of CPOE as an essential element in the safe use of medication in hospitals [33,34].

Bar-Code-assisted Medication Administration (BCMA) is an IT-system that uses bar-codes to prevent errors in the distribution and administration of drugs to hospital inpatients by electronically identifying both patients and medication. The goal of BCMA is to make sure that patients are receiving the correct medication at the correct time in the correct dose by electronically validating and documenting medication in the patient's record. The information encoded in bar-codes allows for the comparison of the medication being administered with what was ordered for the patient. BCMA based systems have been shown to reduce different types of medication errors in different patient care areas [35-37].

Information technology-based interventions, the downside

Notwithstanding all the advantages, shortly after the implementation and use of IT-based interventions such as CPOE and BCMA in healthcare, studies reported the sometimes wrong or ineffective use of these systems in hospitals and also new errors were described [38-49]. These early IT-based systems were error-prone and not always correctly designed or implemented in hospitals, not used as instructed or required, or did not fit the daily workflow of end-users [38]. Schiff et al. [50] analyzed 1.04 million medication errors reported in the United States of America (USA) during the years 2003-2010. More than 64.000 of them were CPOE related. These IT-related medication errors included missing or erroneous computer-label output, wrong dose or strength of the medication, problems with the wrong quantity of drugs, scheduling problems, delays in medication processing or administration due to confusing orders and wrong drug identity or wrong patient identity. Reasons for these errors were found in miscommunication between healthcare workers, miscommunication between multiple IT-based systems within the same hospital, inexperience or lack of training in using the CPOE system, failure to follow protocols, typing and juxtaposition errors, and ignoring or over-riding computer alerts and confusion related to or arising from comments fields produced by the IT-system. In a review Young et al. [51] reported mixed results regarding medication errors while using a BCMA system, with three studies demonstrating a significant reduction in the incidence of medication administration errors after implementation of the barcode technology and one study demonstrating a significant increase of medication administration errors after implementation of this

IT-based intervention. The majority of the errors in that study were wrong dose and wrong time errors when administering drugs to patients. Reasons for these errors were found in human and system factors such as insufficient training and nurses performing work-arounds.

Workarounds ('informal temporary practices for handling exceptions to normal workflow' [52]) can be the source of errors in IT-based systems. Both Niazkhani et al. and Koppel et al. [53,54] describe the occurrence and also the hazards of workarounds in using IT-based interventions in healthcare. Niazkhani describes various workarounds to overcome sub-optimal usability of a CPOE and specific organizational factors. Koppel documented 15 types of workarounds associated with BCMA systems, such as affixing patients' identification barcoded wristbands to computer carts and carrying several patients' pre-scanned medication on carts. More than 31 causes of these workarounds were documented, for example, malfunctioning scanners, unreadable or missing patient wristbands, medication without a barcode, failing batteries of the IT-system and uncertain and unstable wireless connectivity in the hospital.

By not taking into account the correct and intended use of IT-based interventions; hospitals are at risk of missing out on the expected benefits on medication safety [55-58]. Wrong or ineffective use of IT-based interventions could induce new and unintentional IT-based incidents, potentially resulting in medication errors.

Incidents induced by IT-based interventions aimed to enhance medication safety

It is crucial to gain a better insight into the nature of IT-related incidents caused by these new interventions. Nature, causes, and consequences of IT-related incidents are still insufficiently studied. Potential reasons may relate to hardware failures or the human-to-machine interaction, resulting in the wrong or no computer output, wrong interpretation of computer output, or user-software related items such as juxtaposition errors. Also, miscommunication between different IT-systems in use within the same hospital or not performing system required actions or user input by end-users as was reported in recent research [59,60] can result in misinterpretation of data potentially resulting in medication errors.

A classification system of errors, caused by the use of IT-based systems in healthcare can help us to understand their origin and consequences. Magrabi et al. [61,62] developed such a system, based on a voluntary incident reporting database across one Australian state and IT manufacturer incidents reported to the United States Food and Drug Administration (FDA) [63]. In the Netherlands, a nationwide reporting system (Central Medication incidents Registration (CMR)) collects voluntary reports of medication-related incidents.

Data-mining this CMR database for IT-related medication errors could give the opportunity to analyze the nature, causes, and consequences of reported medication errors using the classification of Magrabi et al. [62].

This information can be used to develop approaches to avoid IT-based incidents, e.g., by developing a better user interface or more and better operational hardware and making these systems less error-prone for user input. Besides that, this information helps healthcare workers to become aware of potential risks in handling IT-based interventions designed to enhance medication safety, in their daily practice.

Factors related to the successful implementation of IT-based interventions

Adoption of IT-based interventions such as CPOE or BCMA by end-users is a significant cause of concern [50,64-76], as is their satisfaction with the IT-based intervention. Lack of adoption or end-user satisfaction could be a threat to the successful use of these interventions [77]. IT-based systems can only realize their full potential if they are used as intended, fitting the workflow of the end-users.

Hospital organizations are not always able to accomplish significant process changes, such as the implementation of a CPOE or BCMA system in a short period. In many cases, there is insufficient organizational learning capacity in hospitals, lack of leadership and vision among stakeholders or support for workflow-changes by end-users [78]. So, it is assumed that successful use of IT-based interventions is more than overcoming technology barriers only [79,80]. Factors beyond technology, e.g., support and user satisfaction, are important as well.

The wrong or ineffective use of IT-based interventions in hospitals might be caused by poor software implementation or usage of the implemented software, not taking into account the end-users' role and their daily workflow. This phenomenon could lead to a lack of system-support or dissatisfaction possibly leading to system misuse and leading to unintended IT-related incidents [50,64]. Adjustment of implemented IT-based interventions frequently happens retrospectively, after users have reported errors. Thus, the retrospective analysis of errors aids in improving IT-based interventions, but has the disadvantage of being carried out after the incident has occurred with all its consequences.

In contrast, risk analysis before the implementation of an IT-based intervention identifies which aspect of the intervention may fail and which impact that failure may have on medication safety [81,82]. The prospective Failure Mode and Effects Analysis (FMEA) [83] is believed to be a useful tool in identifying risks in the IT-based intervention as CPOE.

Both prospective as retrospective risk analysis may improve the implementation of this IT-based intervention and possibly end-user satisfaction. Hence it is possible that a risk analysis will contribute to the safer use of IT-based interventions.

Working around the system in using IT-based interventions

The wrong use of IT-based interventions could be based on workflow barriers or technology failures such as failing hardware, drained batteries, poor IT-functionality or social and personal shortcomings such as insufficient user-training, inadequate and unknown user-protocols or protocol awareness. These blockades or obstacles can lead to informal user-practices known as workarounds [52,84] in which users seek an opportunity to complete their task regardless of the barriers [85-90]. A workaround is a (temporary) method for achieving a task when an instructed, a usual or a planned method is blocked or not working well. In the field of information technology, a workaround is often used to deal with hardware, programming, design or communication problems. The implications of workarounds in the daily use of IT-based interventions on medication safety are unknown, but several researchers assume safety incidents due to workarounds [91-93].

Moreover, risk factors associated with the occurrence of workarounds are mostly unknown. A variety of risk factors can potentially play a role. For example the nurse's education and experience, the type or route of the medication and the workload of nurses. In a review, Debono et al. [94] found both individual and collective workarounds performed by healthcare workers in hospitals and a variety of possible risk factors, related to the organization work-process, patient, individual healthcare worker or social/professional factors.

AIMS OF THIS THESIS

The studies combined in this thesis aim to increase our understanding of the use of IT-based interventions in healthcare to prevent medication errors.

Thesis outline

Chapter 2 gives an overview of measures to increase the safety of medication administration in hospitals, with a focus on IT-based interventions.

Chapter 3 describes a study aimed to identify the nature and consequences of IT-related incidents resulting in medication errors reported to the nationwide Dutch reporting system CMR.

Chapter 4 describes a study into the association of performing prospective and retrospective risk analysis during the implementation of CPOE, with end-user satisfaction.

In chapter 5 we describe a multicenter prospective study protocol intended to explore the association of workarounds with medication administration errors and to determine the frequency and type of workarounds and medication administration errors. The study also aimed to explore the potential risk factors for workarounds in the barcode-assisted medication administration (BCMA) process.

In chapter 6 we present our findings on the association of workarounds with medication administration errors using BCMA to administer drugs to hospital inpatients, and the frequency and types of workarounds and medication errors.

In chapter 7 we report the outcomes of the study on potential risk factors associated with workarounds in the BCMA process in hospitals.

This thesis ends with chapter 8 in which the main findings of our studies are summarized and discussed in detail. Theoretical and practical suggestions and possible interventions are pointed out. Recommendations for future research are put forward.

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