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Medication Errors and Safety in Hospital Care

A process-oriented human factors approach to investigate safety barriers and interventions

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“We cannot change the human condition,

but we can change the conditions under which humans work.”

(James Reason, 2000)

Acknowledgments

Danke – Merci – Thank you – Gracias

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1. Introduction

Background

Numerous studies have shown significant problems in medication safety as one of the main risks to patient safety in hospitals in the past decades (D. W. Bates, Cullen, Laird, & et al., 1995; Hicks, Cousins, & Williams, 2004; Kohn et al., 2000). Leape et al. stated that on average a patient in hospital is exposed to at least one medication error per day (Leape et al., 1991). Understanding the incidence, type and preventability of medication errors is necessary for continuous improvement of medication safety (Lisby, Nielsen, & Mainz, 2005). Without a systematic analysis of error chains, it is difficult to assess the effectiveness of implemented safety barriers and to establish preventive interventions. In order to establish and verify preventive and practical interventions breaking error chains, profound analyses of reported medication errors at organizational, group and individual levels are essential (Pape, 2003). The aim of medication incident analyses is to identify frequent error types and failing safety barriers as early as possible in the medication use process to prevent them from propagating and ultimately reaching patients.

Research on the distribution of medication errors indicate incidence of errors in all steps of the medication use process. Until recently, the analyses of medication errors have predominantly focused on isolated process steps, particularly on medication administration (Aspden, Wolcott, Bootman, & Cronenwett, 2006; Hughes & Ortiz, 2005; Taylor, 2007). This isolated view does not reflect the system complexity of error occurrence and propagation. A holistic view of safety barriers takes the entire medication use process into account and reflects the interdependencies between all process stages. While the concept of error chains has been used previously in incident analyses, it has not yet been applied systematically in medication management. Surprisingly, researchers have started only very recently to use similar approaches (Carayon et al., 2014; Samaranayake, Cheung, Chui, & Cheung, 2013).

Purpose and aim

The thesis aimed to introduce a novel process-oriented approach of medication error chains to medication incident analysis. The major benefit and contribution of the error chain model is to gain important insights into complementing existing knowledge on errors, system weaknesses and safety barriers along the entire medication use process. This opens

up new perspectives for detecting and stopping errors by targeted interventions before reaching the patient. This novel method closes existing research gaps by – for the first time – systematically applying a holistic, process-oriented approach to analyze errors across all stages of the medication use process and to implement and evaluate targeted safety barriers and interventions based on these results.

The thesis applied this method to three settings that have been investigated in three separate research studies. **Study A** systematically applies the process-oriented approach of medication error chains to medication incident analysis with the aim to identify (a) frequency of medication errors, (b) frequent medication error chains, (c) errors in the various stages, (d) contributing factors and (e) targeted safety barriers for stopping medication error chains. Based on this study results, **study B** evaluates the effect of optimizing the work environment by separate medication rooms as one specific intervention and safety barrier to improve medication safety during the critical task of medication preparation. One aim was to reduce interruptions as an important contributing factor to medication errors and critical link within error chains. Finally, **Study C** uses staff training and the implementation of safety vests as a simpler and inexpensive combined intervention to reduce interruptions during medication preparation. An overview of all study aims, research questions, hypothesis and settings is given in figure 1.

Thesis structure

The following chapters cover all three studies in more detail. In order to position the thesis aim Chapter 2 introduces relevant definitions (Chapter 2.1) and theoretical foundations, including human factors (Chapter 2.2) and medication safety (Chapter 2.3) covering errors in the medication use-process (Chapter 2.3.1), medication error chains (Chapter 2.3.2), interruptions as one important contributing factor to medication errors (Chapter 2.3.3) and safety barriers to reduce interruptions (Chapter 2.3.4). *Chapter 3 examines the present thesis including an overview (Chapter 3.1) of the three scientific studies (Studies A, B and C). The three research studies are key elements to contribute to the overall purpose of this thesis. Chapter 3.2 links and integrates the three studies under the medication error chain view.* Chapter 4 provides a general discussion with limitations, practical and theoretical implications and an outlook for future research. Finally, Chapter 5 presents the three original study articles.

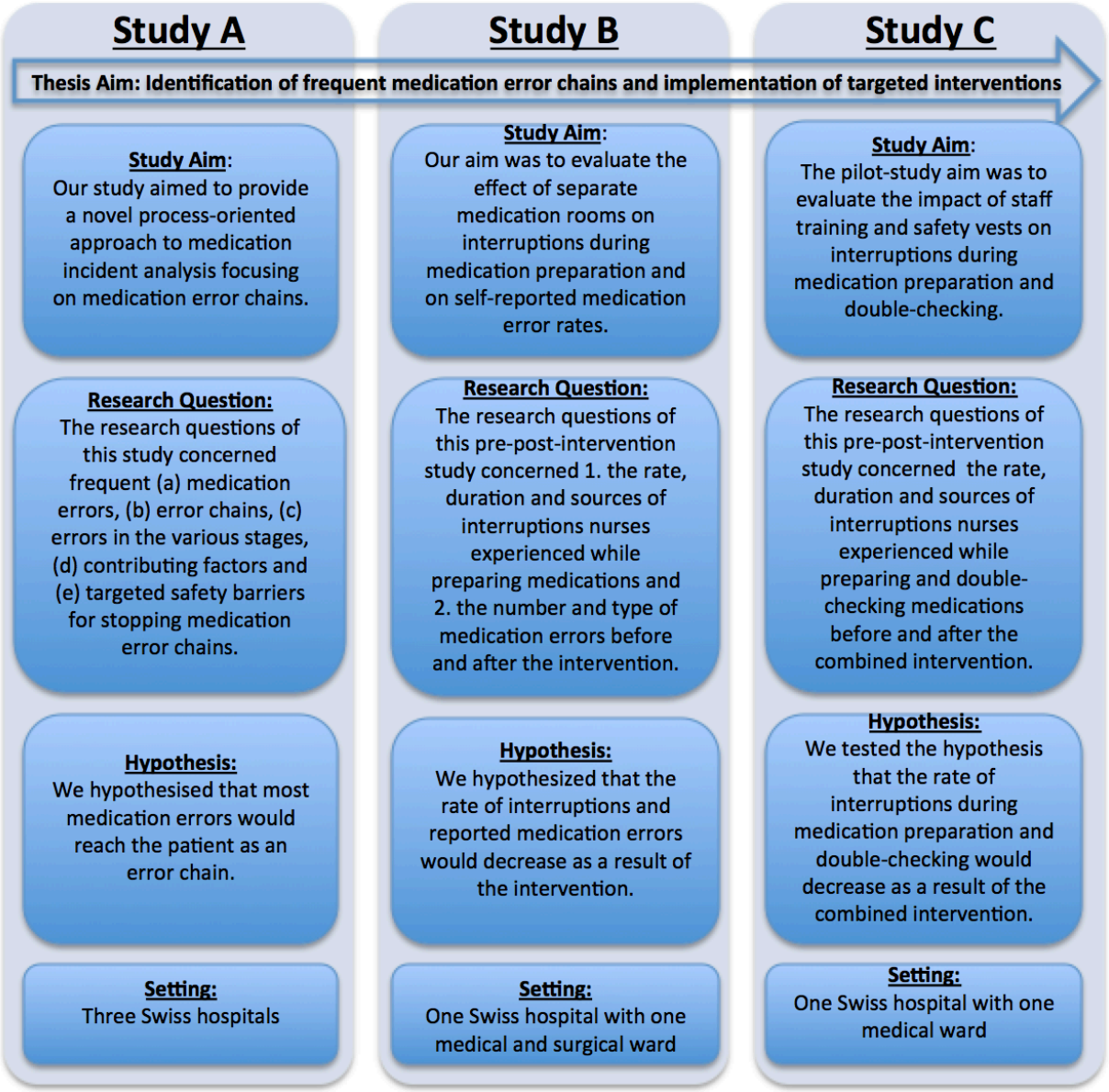

Figure 1: Overview of thesis studies A, B and C

2. Theoretical framework of human factors and medication safety

Clarifying fundamental concepts and definitions of human factors and medication safety is remarkably difficult, but very important for a common understanding. The current use in literature is sometimes inconsistent, unclear and overlapping. Therefore, the entire chapter is an attempt to present coherent definitions in order to facilitate the consistent application of the term and concepts within the thesis. The section introduces the taxonomic foundations and central terms used throughout this thesis: human factors, human errors, medication safety, medication use process, medication errors, medication error chains and interruptions as one important contributing factor to medication errors. The following subsections state precise descriptions integrating the various definitions that come into play when addressing human factors, medication safety and errors within healthcare systems. The final subsection summarizes the transfer of the theoretical framework and background to the thesis and its applications within the three research studies. The author does not claim that the presented definitions and concepts are a "gold standard" but are based on the idea that a minimum consensus on the terms and concepts from previous literature is achieved and consistently applied within the thesis.

Annotation: In the following, underlining the relevant phrases, sentences or paragraphs in the text and figures, highlights the key points for the theoretical foundation of this thesis.

2.1 Human factors approach: theoretical background and basic concepts

Since the Institute of Medicine (IOM) (Kohn et al., 2000) report "To err is human" was published, human factors in healthcare and preventable adverse patient outcomes, especially medication errors, have received enormous public and scientific attention (Vincent, 2012). A human factors approach is used to understand where and why systems or processes break down based on human errors. Studying human factors can contribute to the design of safer systems and processes, for example, simplifying and standardizing processes, building in redundancy, improving communications within teams,

Human factors studies focus on human beings and how they interact with products, devices, procedures, workspaces, and the work environments (Sanders & McCormick, 1993). Human factors research considers human strengths and limitations to the design of interactive systems of people, equipment, and their environment to ensure their effectiveness, safety and ease of use (Chapanis, Garner, & Morgan, 1949).

or redesigning the work environment (Kohn et al., 2000). The report "To Err is Human: Building a Safer Health System" underlined the role of human errors in patient and medication safety (Kohn et al., 2000). Human factors literature in healthcare has been particularly inspired by the work of Rasmussen (Rasmussen, 1983), Reason (1997) and Vincent (Vincent, Taylor-Adams, & Stanhope, 1998). All approaches contribute to the theoretical framework of this thesis.

The following conceptual frameworks cover models and theories of human factors, human errors and organizational accidents. Different approaches and theories to patient safety and medication safety have been proposed in the literature. The thesis is based and focuses particularly on theories of Reason and his "Swiss cheese model". Reason has proposed a fundamental concept of human factors research and theory in healthcare to the present day. The "Swiss cheese model" has been applied and translated into the novel error chain model for medication safety (introduced in Chapter 2.3). The error chain model is the underlying framework for all three scientific studies in this thesis.

2.1.1 Error context and management: person and system approach

Error management can help to detect, minimize, reduce or prevent errors. There are two well-known ways to view and manage human errors and to improve medication safety: the person approach and the system approach (Reason, 1990, 2000).

Human error has been defined "as a failure of a planned action or a sequence of mental or physical actions to be completed as intended, or the use of a wrong plan to achieve an outcome" (Reason, 1990).

The **person approach** concentrates on unsafe acts of humans at the sharp end causing errors. It considers the individual's behavior as unsafe and ascribes it to forgetfulness, inattention, low motivation, etc. The 'person' approach concentrates on modifying human behaviors to reduce errors (e.g. to reduce inattention and improve individual's awareness and recognition of 'error traps') and it does not consider conditions or problems that are inherent in the work environment, systems and processes and contribute to human errors (Reason, 2000).

The **system approach** concentrates on the conditions under which humans work and tries to identify factors in the workplace, organizational processes or systems that contribute to errors and to build defenses to prevent errors (e.g. better design of systems, minimize staff interruptions, add redundancies 'double checks'). The assumption is that humans are

fallible and "to err is human". Averting errors and improving patient safety need a systems approach to adapt the conditions that contribute to errors involving various aims: the person, the team, the task, the workplace, and the institution as a whole. *When an error occurs, there is a breakdown in the defenses, barriers and safeguards. The important issue is how and why the defenses failed and did not prevent errors from occurring, which is displayed in the "Swiss cheese model" (Reason, 2000).*

2.1.2 The "Swiss cheese model" of system accidents

Reason argued that errors should be understood in relation to the context in which humans work and not in isolation. Contributing factors further back in the causal chain can create conditions in which errors or accidents occur. This places operators (e.g., physician, nurses, pharmacists etc.) at the sharp end of a process with direct contact to the patient, e.g. a nurse administering a wrong drug to a patient. In the patient safety community, the *"Swiss cheese model" or "organizational accident model"* of Reason (Reason, 1990, 1997) is one of the most well known system model. *This model is displayed in figure 2 and explains the alignment of hazards (or 'holes') that contribute to frontline human errors or accidents close to the patient. Defenses, barriers, and safeguards have a central role in this approach.* Healthcare systems have numerous defensive layers (e.g. alarms, physical barriers, etc.) and their function is to protect potential errors or accidents from hazards. Many defensive layer are weak like "slices of Swiss cheese", having several holes. The occurrence of weak holes in any one "slice" does not generally cause a negative outcome. Normally, a preventable adverse event (or patient injury) only arises, when inadequate barriers or defenses (holes) in many layers temporarily line up to permit a trajectory of accident opportunity and fall short in intercepting active failures. (Reason, 2000). Reason described the holes in the defenses occur for two reasons: active failures (i.e., outcome mainly from systems factors, causing immediate events and include operators of complex systems) and latent conditions (i.e., factors that are inherent in the system). Approximately all adverse events comprise a combination of both factors, which can be detected by incident analyses (Reason, 1990).

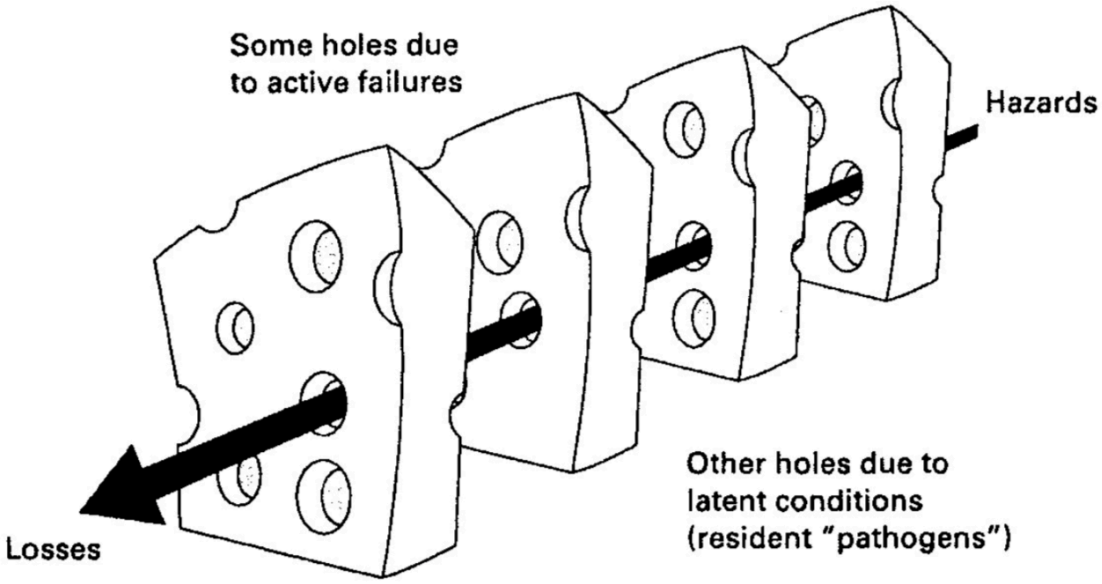

Figure 2: "Swiss cheese model" of system accidents (Reason, 2000)

2.1.3 Types of error

Active failures are unsafe acts caused by individuals who are in direct interaction with the patient or system and having immediate effects at "the sharp end" (e.g., administering the wrong medicine). Active failures tend to be the final outcome of a sequence of events ending in an error and are directly involved in an accident. They can take a variety of forms: **slips, lapses, mistakes, and violations** (Reason, 1991)**.**

Slips are associated with attentional failures and refer to doing the right action, but doing it incorrectly (e.g., picking up the wrong drug). **Lapses** are failures of memory and lack of actions that did not arise as planned (e.g. forgetting to give a drug because someone/something caused an interruption). ***Slips and lapses*** *often occur when functioning on "auto-pilot" and affect the short-term memory, which is used for attention and awareness (Reason, 1991).* For example, interruptions can cause staff to lose attention at a critical time that can certainly result in an error. **Mistakes** are errors of knowledge or planning (e.g., because of lack of medication information, choosing the wrong drug for a patient). **Violations** occur when rules of correct behavior are consciously ignored (e.g., not checking patient identification before medication administration). Principally, interruptions, communication problems, time pressure, and noise are tasks of the external environment, whereas, the risk for slips and mistakes is a function of the internal environment. When

inherent human influences and external pressures combine, errors are more likely to occur (Reason, 1991). For this reason it is central to consider both.

Further, Rasmussen (Rasmussen, 1983) and Reason (Reason, 1990) classified human errors in three categories and described the mechanism of cognitive functioning as ***skill-based*** *(attention and memory failures like slips and lapses, including omitted tasks),* **rule-based** (misinterpretation or misuse of relevant data or applying the wrong rule), and **knowledge-based** (errors made due to lack of knowledge or experience with a particular process or situation). Working conditions that cause interruptions and divert attention often trigger a skill-based error. For example, carrying out the right action on the wrong object, such as nursing staff change the infusion rate on the wrong medication when numerous drugs are being infused simultaneously. Mistakes are knowledge- or rule-based errors. A considered plan is followed, but the plan is wrong to reach the required aim. A mistake is a knowledge-based error when there is a lack in knowledge or misinterpretation of a problem. For example, knowledge-based errors can happen when a nurse is floated to a unit with patients who have conditions that are unfamiliar to the nurse. (Rasmussen, 1983; Reason, 1990)

Latent conditions may lie inactive within the system for several years as contributing factors leading to active failures such as mistakes, violations and lapses (Reason, 2000). Often, latent factors are hidden until they combine with other factors and an active failure appears that leads to an adverse event. Latent conditions occur from decisions at the "blunt end" made by managers, designers and others. Latent conditions contribute to errors by error provoking working conditions (e.g., lack of staff, inadequate equipment, fatigue, and inexperience) and they can create long-lasting holes or weaknesses in the defenses (e.g., poor design, incorrect installation, poorly structured organizations, untrustworthy alarms, and construction deficiencies). Examples of latent factors are drugs that are packed similarly and sound alike. All systems contain defenses, but if for some reasons they fail, an adverse event occurs. *Therefore, it is important to identify and remove proactively latent conditions before an adverse event occurs.* (Reason, 2000)

2.1.4 Expanded human factors framework for analyzing critical incidents

Analyzing critical incidents provides an understanding of the conditions that produced an error, where systems broke down, why errors occurred, and contributing factors (Kohn et al., 2000).

Vincent and colleagues (Vincent et al., 1998) have expanded the organizational accident model based on the research by Reason (Reason, 1990, 1997). This framework defines seven categories of system factors that influence healthcare professionals in their daily work and the contributions to errors: (1) institutional context, (2) organizational and management factors, (3) work environment, (4) team factors, (5) individual (staff) factors, (6) task factors, and (7) patient characteristics (Vincent et al., 1998). According to Vincent's model (Vincent et al., 1998), adverse events occur as a consequence of latent failures (i.e. management decision, organizational processes) that cause conditions of work (i.e. workload, supervision, communication, equipment, knowledge/skill), which in turn produce active failures. Barriers or defenses may prevent the active failures to turn into adverse events. On the other hand, these conditions generate problems for care delivery and may lead to unsafe acts (i.e., errors and violations), which may then produce an incident if the defenses and barriers are not appropriate (Vincent et al., 1998).

Henriksen and colleagues (Henriksen, Dayton, Keyes, Carayon, & Hughes, 2008) have adapted the model of Reason and Vincent by categorizing human factors influencing patient and medication safety as follows: *(1) characteristics of individuals (e.g., skill, education, experience, training, knowledge, inattention and fatigue levels), (2) nature of clinical work (e.g., need for attention, interruptions, time pressures, workload), (3) design of physical environment (e.g., designing rooms to reduce interruptions during medication preparation),* human-system-interfaces (e.g., not accessible or up to date drug information) and organizational/social/environmental (e.g. communication), (4) management (e.g., patient load and safety culture) and (5) external environment (e.g., regulations for safe medication practices, public awareness of patient and medication safety) (Henriksen et al., 2008). Figure 3 shows this framework and the important contributing factors that should be attended to gain a better understanding of the nature of preventable errors.

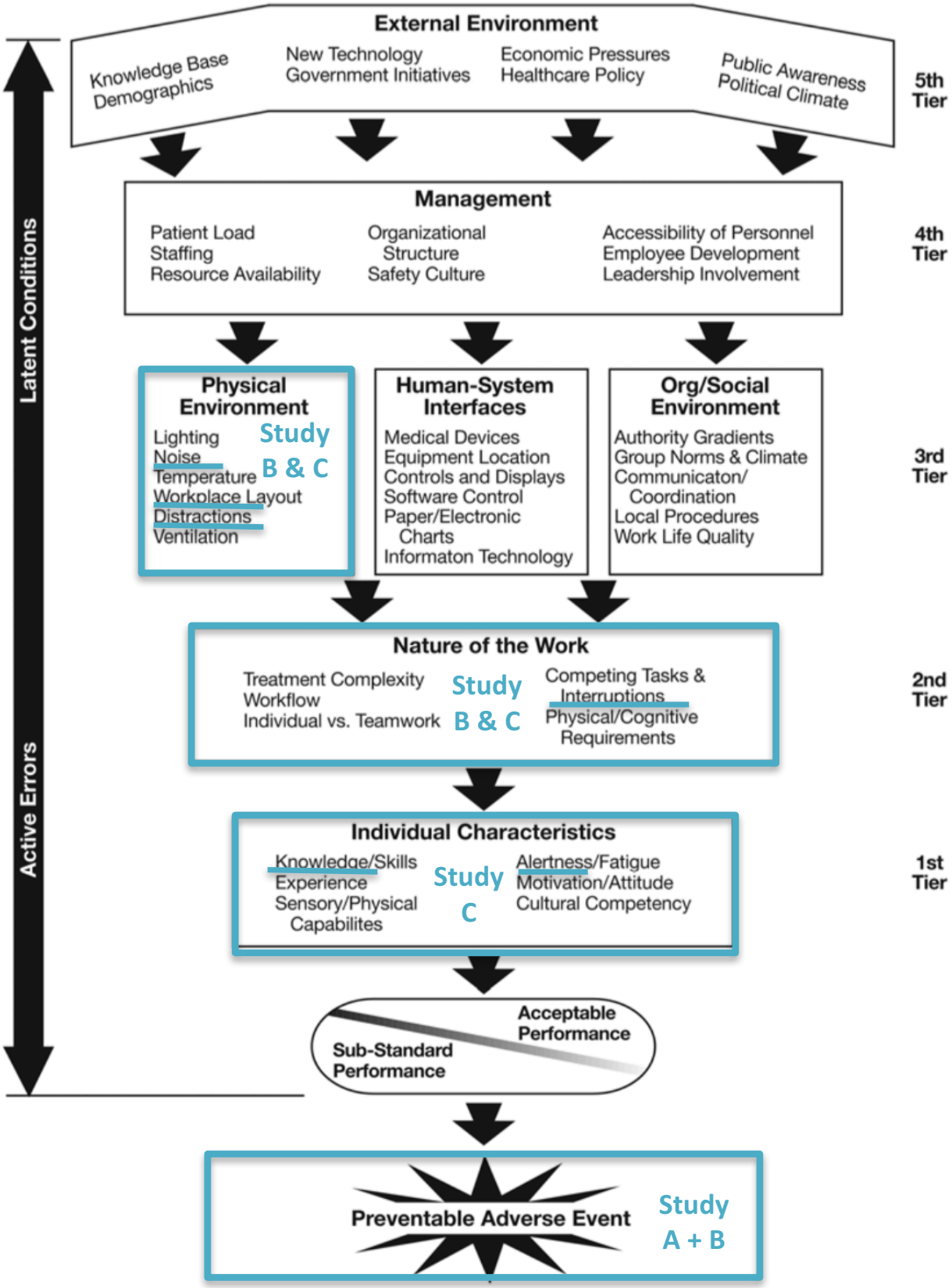

Figure 3: Contributing Factors to Adverse Events in Health Care (Henriksen et al., 2008)

Furthermore, the World Alliance for Patient Safety developed *an international classification and conceptual framework for categorization and analyzing patient safety incidents* as an extension of the human error and organizational accidents approach (Organization & Organization, 2009; Runciman et al., 2009; Sherman et al., 2009). This international classification and framework standardized the patient safety terminology. *Patient safety incidents are at the central part of this framework and can be categorized for example into medication/IV fluids*, clinical administration and procedure, healthcare-associated infection etc. (Runciman, et al., 2009). The conceptual framework displays that contributing factors can lead to incidents and such incidents can be detected or mitigated (i.e. preventing patient harm) (Organization & Organization, 2009; Runciman et al., 2009; Sherman et al., 2009). An overview of the conceptual framework is displayed in figure 4 and an overview of the medication error framework and contributing staff factors in figure 5 and 6 (Organization & Organization, 2009).

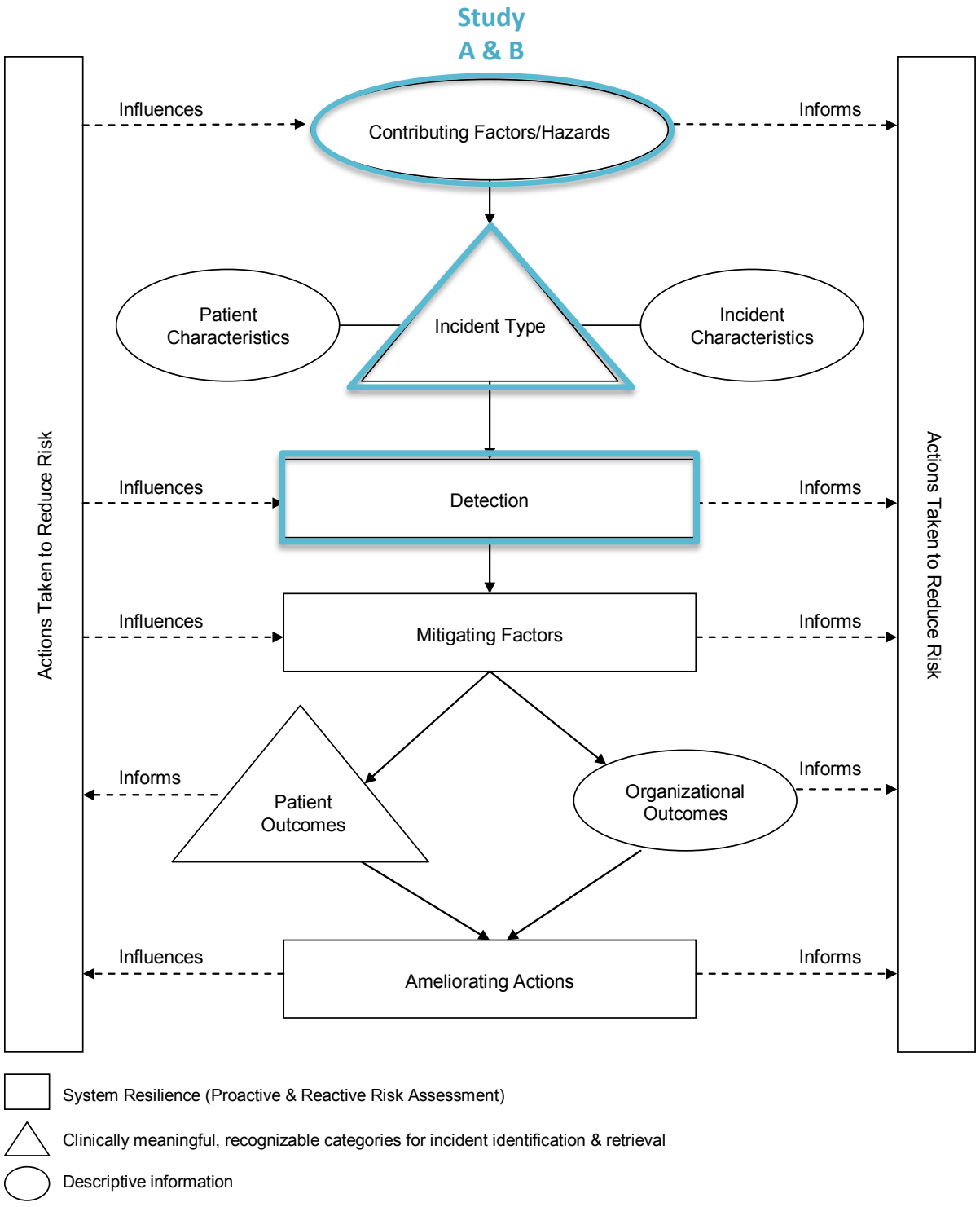

Figure 4: The Conceptual Framework for the International Classification for Patient Safety (Organization & Organization, 2009)

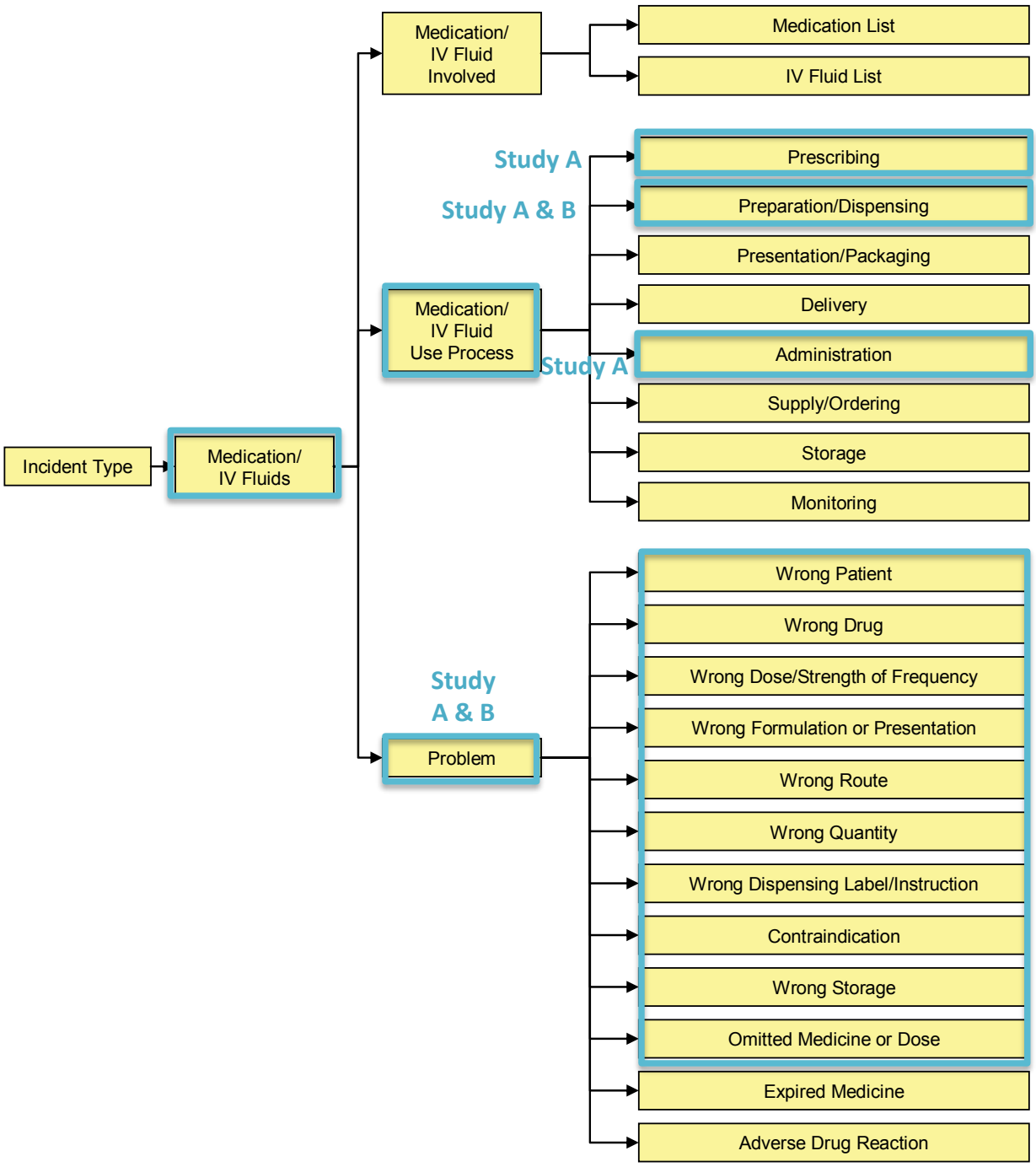

Figure 5: Medication Error Framework of the International Classification for Patient Safety (Organization & Organization, 2009)

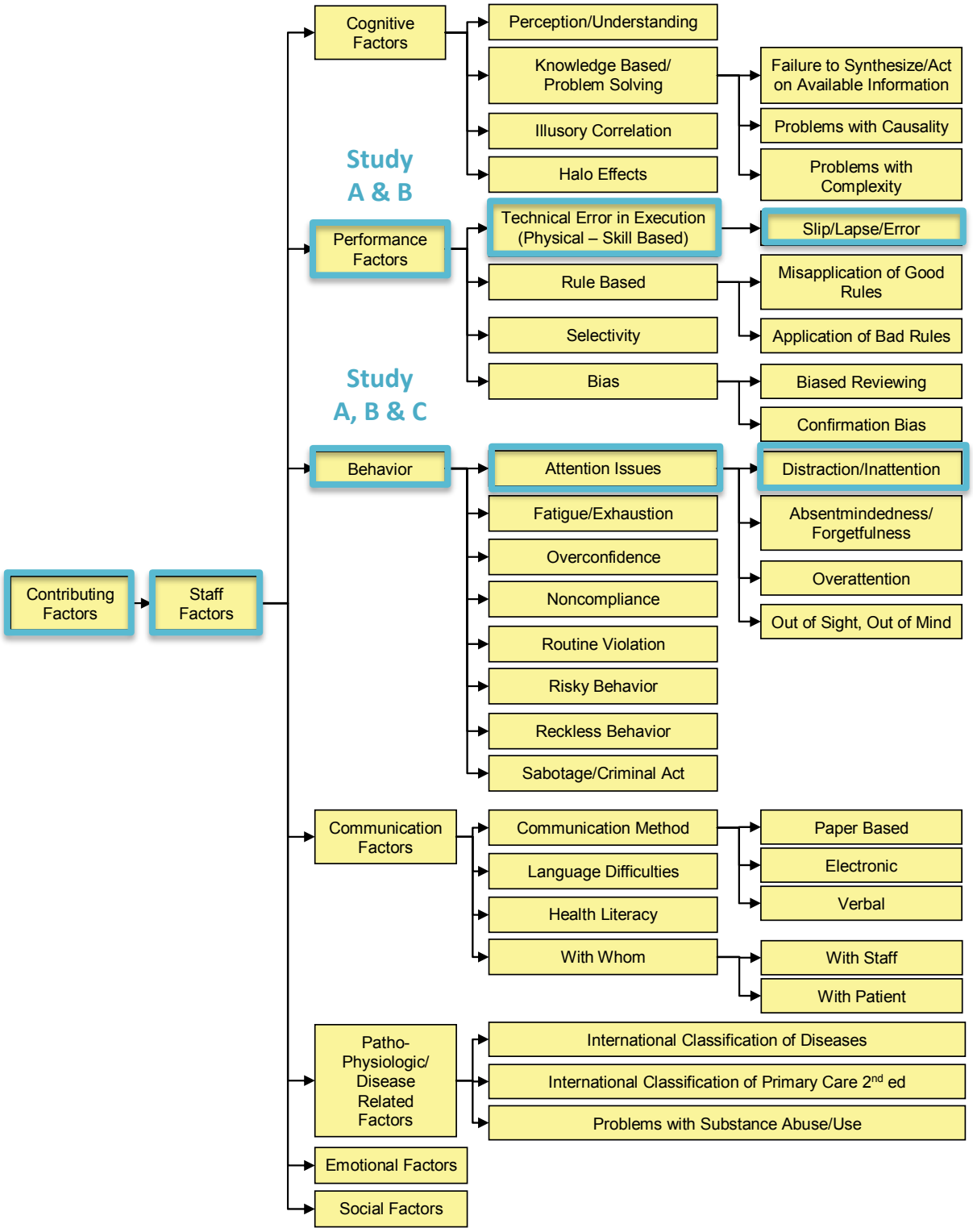

Figure 6: Contributing staff factors of the International Classification for Patient Safety (Organization & Organization, 2009)

2.2 Application of the human factors framework: understanding medication errors and improving medication safety

Research of human factors, based on industrial engineering and psychology, has only recently been applied to health care, especially to medication safety (Kohn et al., 2000). Medication safety is dependent upon systems, processes and human factors, which can differ across health care settings and countries. Sharp-end, frontline human errors occur close to the delivery of medications (Kennedy, 2004). Basic psychological limitations should be considered for those involved in the task. *These include a person's ability to focus in the face of interruptions,* conversation and noise, while preparing or administering medications safely. Studying medication errors in the hospital setting is important for several reasons: they are one of the most common types of error and occur frequently in hospitals, substantial numbers of individuals are affected, and they can result in a substantial increase of health care costs (Kohn et al., 2000). *Preventing medication errors from reaching the patient means designing health care systems and processes safer. Limited research exists addressing human factors and work redesign to reduce medication errors and contributing factors. Most published studies recognize causes and measures to reduce medication errors, but few have provided practical interventions* (Pape, 2003).

Patient safety is defined from the patient's perspective as freedom from accidental injury (Kohn, Corrigan, & Donaldson, 2000). Therefore, **medication safety** can be described as the avoidance and prevention of adverse outcomes, errors or injuries caused during the medication use-process by medications.

How health care systems and processes could be analyzed and designed safer is addressed in the following subsections. Therefore the chapters translated and mapped the theoretical framework of human factors to understand medication errors and to improve medication safety in hospital settings. For building safe hospital environments, the thesis first describes the mechanisms of errors in the medication use process. These mechanisms have led to the novel concept of medication error chains analyzing interruptions as contributing factors and establishing effective interventions and safety barriers.

2.2.1 Errors in the medication use process

The medication use process is complex and a high-risk procedure, involving multiple steps and a variety of personnel. Therefore, this process is particularly vulnerable to errors if attention is diverted. As a result, medication errors are common in hospitals and can occur at any point of basically five stages of the medication use process: prescribing, transcription, preparation, administration and monitoring (figure 7) (Hughes & Ortiz, 2005). This thesis focused on the process steps prescribing, transcription, preparation, and administration. In outpatient settings monitoring problems may dominate and are therefore not covered in the thesis.

The medication use process involves multiple steps, i.e. prescription, transcription, preparation inclusive double-checking, administration and monitoring. The process of the provision of a new drug to the delivery to the patient includes approximately 50-100 steps (Wachter, 2012).

A medication error is defined as „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" (NCCMERP).

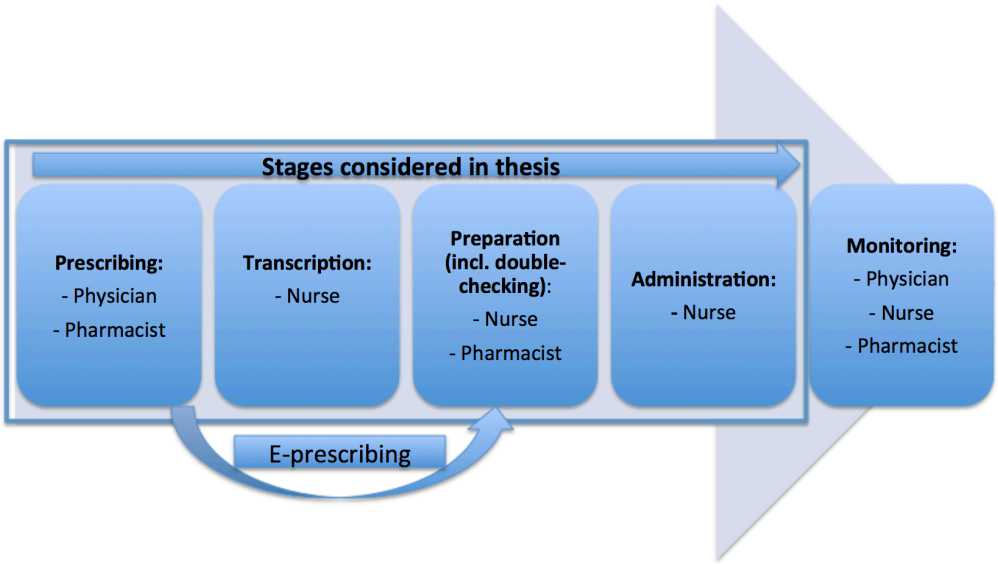

Figure 7: Medication use process

Medication errors may or may not reach the patient; and while some medication errors have serious consequences, others change a patient's outcome but without resulting in any harm (Hughes & Ortiz, 2005). Medication errors are potentially preventable. Thus, an in-depth investigation of these errors is necessary for continuous improvement of medication safety, regardless of whether an injury occurred or the potential for injury was present (NCCMERP). Consequently, each of the steps in the process needs improvement and further

study (Aspden et al., 2006). Most medication errors cause no patient harm or remain undetected by healthcare staff (Bates, 1996). Medication errors rates vary, depending on the applied detection method. The most common types of reported medications errors are wrong dose, omitted medicine and wrong time (Hicks et al., 2004; Leape et al., 1995; Leape et al., 1991).

Of the displayed stages of the medication use process, **prescribing** most often initiates an error chain resulting in a patient receiving a wrong dose or wrong drug. In this stage, for example, a wrong drug, dose, or route can be prescribed by a physician in some cases with support by a pharmacist (figure 7); this includes drugs to which a patient has known allergies (Dean, Schachter, Vincent, & Barber, 2002). Examples of error types in this stage include unclear, unreadable and/or incomplete prescriptions, orders for contraindicated or wrong medications, and inappropriate doses (Hughes & Blegen, 2008).

In many hospitals, particularly in Germany and Switzerland, medication prescriptions are transcribed. Nurses are mainly involved in **transcribing** medications (figure 7). *Thus, they can have an important role in intercepting and preventing prescribing errors before propagating trough the medication use process.* Examples of errors that can be initiated at the transcribing stage include errors to transcribe the order, e.g. wrong drug, wrong dose and wrong route or omission of a medication (Hughes & Blegen, 2008).

Commonly, nurses are the last link at the sharp end of the medication use process, performing final safety checks intended to identify and intercept medication errors before reaching the patient. This includes **preparing** inclusive verifying or double-checking **and administering** the right medication to the right patient, at the right time, with the right dosage, frequency, route, and technique, with no omissions by nurses or pharmacists (figure 7) (S. Flanders & A. P. Clark, 2010). Research on medication preparation and administration reported errors mostly in the form of wrong time, wrong rate, or wrong dose (Hughes & Blegen, 2008).

Overall, the fundamental environmental conditions encouraging safe medication practices include the right to (a) complete and clearly written prescriptions that specify the medication, dose, route, and frequency; (b) have the correct drug route and dose dispensed from nurses or pharmacies; (c) have access to drug and patient information; (d) have guidelines on safe medication use; (e) administer medications safely and to identify problems early and (f) stop, think and be vigilant when administering medications (Colleran Cook, 1999) (Hughes & Blegen, 2008).

2.2.2 Medication error chains

Medication errors are rarely the result of one, single isolated human error. More commonly, multiple errors and contributing factors during the medication use process occur, resulting in in a network of faults and failures, called *an error chain. Frequent contributing factors are workplace design, interruptions, inadequate training and incomplete information* (T. M. Pape et al., 2005). Several error-producing conditions have been identified to affect performance during the medication use process, for example over-stimulation can affect attention, knowledge, concentration, and skill performance (Moray, 1994). Due to errors in multiple steps of the medication use process, many studies recommend a systems approach to reduce medication errors (Clifton-Koeppel, 2008).

The novel concept of medication error chains highlights the fact that many errors are the result of a sequence of events, the contributing factors of which may be tightly coupled, all contributing to the final outcome. The basic idea behind using the error chain concept is to identify a critical link in the error chain and remove it so that the error chain is broken, and thus, no incident should occur (AHRQ; Huckels-Baumgart & Manser, 2014). According to this model, fatal errors usually occur when several safety barriers fail (Reason, 1995, 2000). Safety barriers are often vulnerable, but in most cases a succession of barriers ensures that an error is caught before a negative outcome occurs (Mahajan, 2010; Reason, 1995, 2000).

Reason`s "Swiss Cheese Model" is well suited to discuss medication error chains that are similar to Reason`s error trajectory (Badke-Schaub, Hofinger, & Lauche, 2008). Each slice of cheese represents a defense, barrier or safeguard against medication errors. Medication errors and deficiencies are results of unsafe practices by humans that work in a hospital (e.g. omission of a double-check of a prepared drug by a nurse), *while latent conditions (e.g. interruptions)* are reflecting defective system structures. When a medication error passes through one defense, perhaps it will stop in another defense (e.g. medication process step) or it will propagate through the process, resulting in an increasing risk of a medication error reaching the patient. In the case of well-designed healthcare systems the medication error would rarely be able to pass through existing defenses (Karavasiliadou & Athanasakis, 2014).

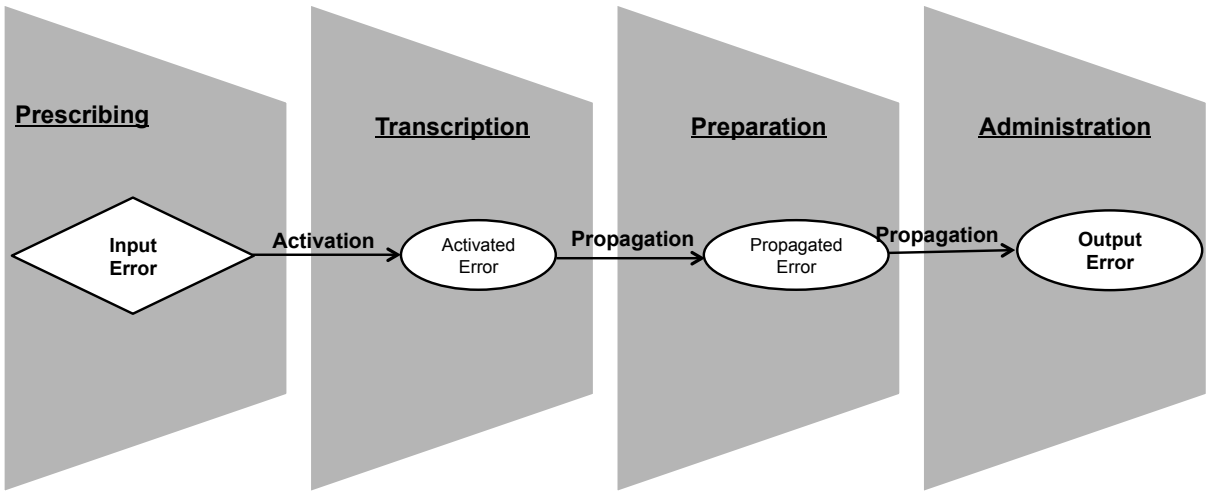

Figure 8: Simplified illustration the concept of error chains spanning across the stages of the hospital medication use process

The general idea of the process-oriented medication error chain approach, which was newly developed in this thesis, is illustrated in figure 8. This novel error chain model suggests that input errors (e.g. an illegible handwritten prescription) can be activated and transformed into output errors (e.g. wrong prepared or administered dose or drug) through contributing factors (e.g. inattention, interruptions), working conditions (e.g. space, noise) and missing or ineffective safety barriers (e.g. undisturbed workspace for drug preparation). One example in this concept is an illegible handwritten prescription by a physician as an input error. The error is activated when a nurse transcribes this prescription with a wrong dose without re-checking with the physician. The wrong dose may propagate through the further medication use process and be prepared by another nurse without recognition of the pre-existing error and administered to the patient. While in figure 8 an error chain spans across all stages of the medication use process, it is important to note that error chains can be triggered and stopped at any stage by adequate safety barriers (Huckels-Baumgart & Manser, 2014).

Although the idea of error chains has been used previously in incident analyses, it has not been applied systematically using a process-oriented approach for analyzing reported medication errors before this thesis. Until recently, the analyses of medication errors have predominantly focused on isolated process steps, especially on medication administration (Aspden et al., 2006; Hughes & Ortiz, 2005; Taylor, 2007). *Studying medication error chains helps to identify weaknesses in safety barriers and to point out where exactly in the medication use process safety barriers are missing, not effective or require improvement.*

Improving the effectiveness of existing safety barriers and establishing new ones will help to interrupt error chains before affecting a patient and, thus, improve patient safety.

Frequent contributing factors to medications errors are interruptions in the preparation stage of the medication use process. Using the concept of error chains, *interruptions during medication preparation may be viewed as one important critical link between preparation activities and errors because they can interfere with the primary task as well as with safety checks and may thus increase inattention and medication errors* (Li, Magrabi, & Coiera, 2012; Page, 2004; Reason, 1990). If this link is removed the error chain is broken and an incident averted. This lead to a more detailed outline of interruptions and their dynamics in the next subsection.

2.2.3 Interruptions as a major contributing factor to medication errors

Interruptions of healthcare staff are common (Weigl, Muller, Vincent, Angerer, & Sevdalis, 2012). *Interruptions are particularly relevant to patient safety when occurring during high-risk procedures in the hospital such as the medication use process because staff attention is diverted from concentrated tasks, increasing the risk of medication errors* (Grundgeiger & Sanderson, 2009; Palese, Sartor, Costaperaria, & Bresadola, 2009). Several studies indicated that interruptions are an important contributing factor to medication errors (Armutlu, Foley, Surette, Belzile, & McCusker, 2008; A. D. Biron, Loiselle, & Lavoie-Tremblay, 2009; Fry & Dacey, 2007; Hickam et al., 2003; Karavasiliadou & Athanasakis, 2014; Mayo & Duncan, 2004; Tang, Sheu, Yu, Wei, & Chen, 2007) and medication error rates increase with interruption frequency (J. I. Westbrook et al., 2010). These findings are also consistent with psychological studies that display a variety of negative outcomes associated

Interruptions are defined as "a break in the performance of a human activity initiated by a source internal or external to the recipient, with occurrence situated within the context of a setting or a location" (Brixey et al., 2007). Interruptions are situations in which a nurse ceases the medication preparation or checking in order to attend to an external stimulus (J. I. Westbrook, Woods, Rob, Dunsmuir, & Day, 2010). An interruption can be initiated by the nurse him/herself (self-initiated), by another individual or by the work environment (e.g. alarms). In the context of medication preparation a common source of interruptions is communication; often concerning information irrelevant to the primary task (e.g. a (non-)verbal cue from another individual prompting the nurse to give a (non-)verbal response (Grundgeiger & Sanderson, 2009; Smeulers, Hoekstra, van Dijk, Overkamp, & Vermeulen, 2013) or the nurse initiating a conversation with another person). While other studies distinguish between "interruptions" and "distractions" to describe causes and precursors of errors (Relihan, O'Brien, O'Hara, & Silke, 2010; Sanderson & Grundgeiger, 2015), in this thesis the term "interruption" (including self-initiated interruptions) is used as comprising both.

with interruptions, like frequent errors, forgetting or taking longer to complete tasks (Johanna I Westbrook, 2014). *Experimental studies indicate that interruptions produce negative impacts on memory by requiring individuals to switch attention from one task to another* (A. D. Biron et al., 2009). These studies also display that interruptions can activate cognitive failures, including lapses in attention, memory or perception (Johanna I Westbrook et al., 2010).

Particularly in a hospital setting, nurses are vulnerable to a multitude of interruptions that affect situation awareness, working memory, concentration and therefore the ability to focus during critical tasks of the medication use process. *Interruptions include anything that draws nurses away, diverts, or disturbs their attention* (Pape, 2003; T. M. Pape et al., 2005). Interruptions stop the main activity performed by nurses (e.g. medication preparation), who then begin a secondary and unplanned task, leaving the primary task to be continued later (Brixey et al., 2007). When nurses are interrupted during the medication use process, they need to remember at which step they paused when restarting the task. Consequently, omission errors are likely to happen because nurses may believe they were at a different step in the medication process than they were. Research indicates omission errors linked to prospective memory failures can explain the relationship between interruptions and human errors (Craig, Clanton, & Demeter, 2013; Grundgeiger & Sanderson, 2009). Even if nurses' attention is not immediately redirected to an interruption, an initiating event automatically capturing attention will distract, causing an interruption from the current task, at least briefly. Also alarms and short phone calls, which do not necessarily require a lengthy shift to a new task will often be noted as an interruption (Boehm-Davis & Remington, 2009).

Nurses commonly prepare and administer medications. Thus, they have the major responsibility as the last link in the medication use process, performing final safety checks intended to identify and intercept medication errors before reaching the patient. This includes preparing and administering the right medication to the right patient, at the right time, with the right documentation, frequency, dose, route, and with no omissions (Sonya Flanders & Angela P Clark, 2010). Skill-based performance is mostly automatic and is found in routine actions, like medication preparation and administration. These routine actions require attentional checks to ensure correct task completion. Interruptions during skill-based

performance may interfere with these required attentional checks and can lead to slips and lapses (Reason, 1990).

The previous arguments make it clear, that unnecessary interruptions should be reduced in the medication use process. Although interruptions may occur at any stage of this process (Vincent, Barber, Franklin, & Burnett, 2009), *medication preparation is especially prone to interruptions* because it is the last stage and opportunity before medication administration and for an error to be intercepted before reaching the patient. Thus, it has very few safeguards against errors. *Reducing interruptions during medication preparation appears to be an effective strategy to improve patient safety and decrease the risk of medication errors. The preparation phase requires nurses' full attention* because several critical cognitive processes are involved, such as reading the medical prescription, verifying the name of the drug and patient, searching for the medications in the right dose and form, and confirming if the selected medications matches with the prescription (Tomietto, Sartor, Mazzocoli, & Palese, 2012).

Interruptions during the medication use process have been studied across various hospital settings particularly with a focus on medication administration (Raban & Westbrook, 2014; Relihan et al., 2010). While its known that interruptions and errors both are common during medication preparation, we found only four studies (Anthony et al., 2010, Tomietto et al., 2012, Biron et al., 2009b, Duruk et al., 2016) specifically investigating interruptions during medication preparation. No study considered their relationship to medication errors. *Thus, the existing evidence for interventions effectively reducing interruptions*(Colligan, Guerlain, Steck, & Hoke, 2012; Freeman, McKee, Lee-Lehner, & Pesenecker, 2013; Julie Kliger, Singer, Hoffman, & O'Neil, 2012) *has not yet been linked to a reduction of errors during medication preparation. Therefore, there is a need to develop interventions and safety barriers that can reduce interruptions and errors during medication preparation.*

2.2.4 Safety barriers

Studies on contributing factors, like interruptions, help to understand the underlying causes of medication errors. Such studies are urgently needed to assist in the development of effective safety barriers *(Vincent et al., 1998). The first step is to become aware of when interruptions happen, the types that commonly occur, and the effects they have on medication*

errors (Clifton-Koeppel, 2008). Consequently, it becomes important to implement safety barriers that eliminate interruptions as latent conditions and increase patient safety (A. D. Biron et al., 2009; Grundgeiger & Sanderson, 2009). Effective safety barriers present opportunities to interrupt medication error chains and prevent errors from reaching the patient. Patient safety experts have turned to other high-risk industries such as airline or nuclear power to achieve a deeper understanding of interventions to improve safety, including the reduction of interruptions. For example, the airline industry acknowledged the relationship of interruptions, unnecessary conversations during critical processes, and pilot errors with the "sterile cockpit" regulation (Clifton-Koeppel, 2008).

Training staff to work effectively and safely have achieved important improvements of human performance in aviation. In addition staff training costs comparably little, whereas increasingly advanced equipment and technology alone do not help and simply relocate human factors problems (Reason, 1995). Many intervention strategies to reduce interruptions require a change in clinician's behavior so that unnecessary or non-urgent communications are avoided or delayed during medication preparation. *Educating clinical staff about the impact of interruption on patient safety provides reasons and principles for changing behavior and safety awareness* (T. M. Pape et al., 2005). Staff training is widely recognized as an effective strategy to reduce interruptions during medication administration (J. Kliger, 2010; Pape, 2003; T. M. Pape et al., 2005; Relihan et al., 2010).

The redesign of workspaces might offer an alternative or additional, sustainable solution to avoid interruptions during medication preparation. Designing work environment with attention to human factors means attending to the effect of interruptions, and their relationship to alertness. Safe design, for example, can avoid reliance on memory (Kohn et al., 2000). *Creating a separate room reduces the occurrence of interruptions* during medication administration (Bennett, Harper-Femson, Tone, & Rajmohamed, 2006; Tomietto et al., 2012) and intuitively appears to be also an effective intervention to improve safety during medication preparation. Another approach is to provide clearly marked 'No Interruption Zones' or physical barriers to clinical staff to clarify that they are entering a zone of higher risk task, and that interruption is not permitted or limited to urgent communication. This idea is based on the concept of a sterile cockpit in aviation (Clifton-Koeppel, 2008; Hohenhaus & Powell, 2008; O'Shea, 1999).

In addition, the wearing of 'Do Not Disturb' vests by the nurse reminds the team not to interrupt. This safety barrier is considered effective in preventing interruptions during medication administration (Pape, 2003; T. M. Pape et al., 2005; Relihan et al., 2010) and consequently, it could be also effective during medication preparation. Other interventions to reduce interruptions include removing phones and placing visible "Do Not Disturb" signs to support as reminders to avoid interruptions (Pape, 2003; T. M. Pape et al., 2005; Relihan et al., 2010).

Remarkably, most of the mentioned safety barriers and interventions were designed to reduce interruptions during medication administration, with limited evaluation of the impact on medication error rates. *There is only weak evidence regarding the effectiveness of such interventions in reducing interruptions and medication errors during medication preparation. Medication preparation is one important step, where most of the medication errors can be caused, for example the preparation of a wrong dose, wrong drug, a drug for a wrong patient and wrong route. Consequently, there is a strong requirement to develop interventions during medication preparation to reduce interruptions as one important contributing factor to medication errors.*

2.3 Conclusion and transfer for the thesis

Different models of human errors and organizational accidents are important in highlighting

(1) different **types of errors** (Rasmussen, 1983; Reason, 1990),

(2) the importance of **contributing factors** (Organization & Organization, 2009; Runciman et al., 2009; Vincent et al., 1998), and

(3) the implementation of effective safety barriers respectively **interventions** to reduce errors.

These models and frameworks are important to examine complex patient care processes, like the medication use process, with various interactions that can lead to patient safety incidents. Preventable patient errors can occur without adequate safety barriers or defenses, which could intercept frontline human errors (Reason, 1995). In summary, the key aspects and novel approaches of the thesis that we have used and adapted for analyzing medication errors and improving medication safety in the hospital setting are based on the following key components of the previously discussed theoretical frameworks:

- The **"Swiss cheese model"** or "organizational accident model" of Reason (Reason, 1990, 1997) was the foundation for the medication error chain model, applied in **study A** of this thesis. When a medication error occurs, there is a breakdown in the defenses, barriers and safeguards. The important issue is how and why the defenses failed and did not prevent errors from occurring, which is displayed in our medication error chain concept. In our novel process-oriented concept we used the terms "input and output errors", which is similar to "active failures", and "contributing factors" comparable with "latent conditions". The results of **study A** were used in **study B and C** to implement targeted interventions to intercept frequent contributing factors to medication error chains (figure 9).
- The following aspects of **Henriksen and colleagues** (Henriksen et al., 2008) were considered in the three studies: (1) preventable adverse events (reported medication errors in **study A and B**), (2) characteristics of individuals (staff training about the impact of interruption on medication safety to reduce interruptions in **Study C**), (3) nature of clinical work (inattention and interruptions in **Study B and C**), (4) design of the physical environment (implementing separate medication

rooms in **Study B** and 'Do Not Disturb' safety vests in **Study C** to reduce interruptions during medication preparation) (figure 9).

- For the critical incident analysis of the reported medication errors the international classification and **conceptual framework for categorization and analyzing patient safety incidents** (Organization & Organization, 2009; Runciman et al., 2009; Sherman et al., 2009) was used in **study A and B** (figure 9).
- Medication errors are rarely the result of one, single isolated human error. More commonly, multiple errors and contributing factors during the medication use process occur, resulting in an error chain (Huckels-Baumgart & Manser, 2014).
- Interruptions may be viewed as one important critical link between preparation activities and errors because they can interfere with the primary task as well as with safety checks and may thus increase inattention and medication errors (Li et al., 2012; Page, 2004; Reason, 1990). Interruptions include anything that draws nurses away, diverts, or disturbs their attention. Reducing interruptions during medication preparation appears to be an effective strategy to improve patient safety and decrease the risk of medication errors. Therefore, the focus in **study C and B** was to become aware of when interruptions happen, the types that commonly occur, and the reduction of **interruptions as a main attentional problem** and necessary condition for skill-based errors (attention and memory failures like slips and lapses, including omitted tasks) by safety barriers during medication preparation. Slips and lapses often occur when functioning on "auto-pilot", like the preparation of medications, and affect the short-term memory, which is used for attention and awareness (Reason, 1990).
- The theoretical background showed that there is only weak evidence regarding medication error chains and the effectiveness of interventions reducing interruptions during medication preparation as an important contributing factor to medication errors. Most published studies recognize only single process steps, causes and measures to reduce medication errors, but few have provided a process-oriented approach and practical interventions especially during medication preparation (Pape, 2003). This research gap was addressed in this thesis by **study A, B and C**.

	Applied Framework Figure 2: Swiss cheese model (Reason, 1990, 1997)	Applied Framework Figure 3: Contributing Factors to Adverse Events in Health Care (Henriksen et al., 2008)	Applied Framework Figure 4 & 5: Conceptual Framework for the International Classification for Patient Safety (Organization & Organization, 2009)	Applied Framework Figure 6: Contributing staff factors of the International Classification for Patient Safety (Organization & Organization, 2009)
Study A:	Basis for the medication error chain model analysis in study A and the implementation of targeted interventions in study B and C	Categorization and analysis of **preventable adverse events** (reported medication errors with focus on error chains)	Consideration for the analysis and identification of frequent medication errors and contributing factors (inattention/interruptions)	Identified performance factors (reported medication errors) and staff behavior (attention issues: distraction=interruptions/ inattention)
Study B:		Consideration of: - **Nature of the work** with focus on interruptions - **Physical environment** with focus on noise, workplace layout and distractions by the implementation of separate medication rooms		Focus on frequent staff contributing factors of medication errors identified in study A: performance factors (reported medication errors) and staff behavior (attention issues: distraction=interruptions/ inattention)
Study C:		Consideration of: - **Individual characteristics** with focus on knowledge and alertness by using staff training to reduce interruptions - **Nature of the work** with focus on reducing interruptions - **Physical environment** with focus on noise, workplace layout and distractions by the implementation of safety vests	--------	Focus on frequent staff contributing factors of medication errors identified in study A: staff behavior (attention issues: distraction=interruptions/ inattention)

Figure 9: Overview of applied frameworks in the three thesis studies

3. The studies of this thesis

The aim of this thesis is to address existing research gaps on medication error chains on the basis of critical incident reports and to contribute to a deeper understanding of medication errors, system weakness, safety barriers and targeted interventions during the medication use process, especially with focus on medication preparation, to detect and stop medication errors before reaching the patient. Medication preparation is one important process step, where many of the medication errors can be caused, for example the preparation of a wrong dose, wrong drug, a drug for a wrong patient and wrong route. The weak evidence in the literature clarified, that there is a strong need to develop and evaluate interventions during medication preparation to reduce interruptions as one important contributing factor to medication errors.

Reasons premise is that "we cannot change the human condition, we can change the conditions under which humans work" (Reason, 2000). Overall, this is the foundation and basic idea for this thesis and the three displayed **studies A, B and C**.

3.1 Summary of thesis studies

3.1.1 Study A

Identifying Medication Error Chains From Critical Incident Reports: A New Analytic Approach

Authors: Saskia Huckels-Baumgart & Tanja Manser (published 2014)

The first study A aimed to provide a novel process-oriented approach to medication incident analysis focusing on medication error chains. Previous research into the distribution of medication errors usually focused on isolated stages within the medication use process.

Study A was conducted across a 900-bed teaching hospital in Switzerland. All reported 1,591 medication errors 2009–2012 were categorized using the Medication Error Index NCC MERP and the WHO Classification for Patient Safety Methodology (Organization & Organization, 2009). In order to identify medication error chains, each reported medication incident was allocated to the relevant stage of the hospital medication use process.

The results displayed that only 25.8% of the reported medication errors were detected before they propagated through the medication use process. The majority of medication errors (74.2%) formed an error chain encompassing two or more stages. Most of the medication errors in our study reached the patient, propagated across more than one stage and potential safety barrier along the medication use process. The most frequent error chain comprised preparation up to and including medication administration (45.2%). "Non-consideration of documentation/ prescribing" during the drug preparation was the most frequent contributor for "wrong dose" during the administration of medication. As contributing factors "inattention," "work condition," and "lack of training" were most frequently reported by the staff. In order to prevent medication errors clinicians frequently proposed "improvement of training," "good communication," and "situational awareness."

Study A showed that medication error chains provide important insights for detecting and stopping medication errors before they reach the patient. Existing and new safety barriers need to be extended to interrupt error chains and to improve patient safety. The results of study A formed the basis for the displayed interventions in studies B and C.

3.1.2 Study B

Separate medication preparation rooms reduce interruptions and medication errors in the hospital setting: a prospective observational study

Authors: Saskia Huckels-Baumgart, André Baumgart, Ute Buschmann, Guido Schüpfer & Tanja Manser (published 2016)

In study A, only few medication errors were prevented before reaching the patient. The most frequent error chain comprised preparation up to and including medication administration and one of the most named contributing factors were "inattention" and "working conditions". These results point at necessary improvements of safety barriers at the critical stage of medication preparation to interrupt error chains before medication administration and reaching the patient. One intervention to improve "situational attention" and to reduce errors and interruptions during medication preparation is to optimize the work environment (e.g., space, noise) by establishing an undisturbed separate medication room. This intervention was implemented and evaluated in Study B.

The aim of study B was to evaluate the effect of separate medication rooms on interruptions during medication preparation and on self-reported medication error rates. Interruptions and errors during the medication process are common, but published literature shows no evidence supporting whether separate medication rooms are an effective single intervention in reducing interruptions and errors during medication preparation in hospitals.

Study B performed a pre- and post-intervention study using direct structured observation of nurses during medication preparation and daily structured medication error self-reporting of nurses by questionnaires in two wards at a major teaching hospital in Switzerland.

In study B a volunteer sample of 42 nurses was observed preparing 1498 medications for 366 patients over 17 hours pre- and post-intervention on both wards. During 122 days nurses completed 694 reporting sheets containing 208 medication errors. After the introduction of the separate medication room the mean interruption rate decreased significantly from 51.8 to 30 interruptions per hour ($p<0.01$) and the interruption-free preparation time increased significantly from 1.4 to 2.5 minutes ($p<0.05$). Overall, the mean medication error rate per day was also significantly reduced after implementation of the

separate medication room from 1.3 to 0.9 errors per day ($p<0.05$). Most medication errors were detected during medication preparation and double-checking. Therefore, most of the reported medication errors were recognized and prevented before medication administration and reaching the patient.

Study B indicated the positive effect of a hospital-based intervention: after the introduction of the separate medication room, the interruption and medication error rates decreased significantly. The results of study B highlighted the importance of mitigating interruptions during medication preparation to reduce errors and to incease the likelyhood of error detection at this step. Therefore, the implementation of safety barriers by redesigning workspaces, are important.

3.1.3 Study C

A combined intervention to reduce interruptions during medication preparation and double-checking: a pilot-study evaluating the impact of staff training and safety vests

Autors: Saskia Huckels-Baumgart, Milena Gauch, Tanja Manser, Christoph R. Meier & Carla Meyer-Massetti (under review 2016)

Another intervention to improve "situational attention" and "working conditions" is to reduce interruptions during medication preparation by implementing clinical staff training regarding contributing factors to medication errors and possible safety barriers on the one hand and safety vests with the sign "Do not disturb" on the other hand. This combined intervention were implemented and evaluated in Study C.

The aim of study C was to evaluate the impact of staff training and safety vests on interruptions during medication preparation and double-checking. We tested the hypothesis that the rate of interruptions during medication preparation and double-checking would decrease as a result of the introduction of staff training and safety vests labeled "Do not disturb".

Study C performed a pre- and post-intervention pilot-study used direct structured observation of nurses during medication preparation and double-checking in a medical ward at a major teaching hospital.

The interruption rate during medication preparation was reduced from 36.8 to 28.3 interruptions per hour and during double-checking from 27.5 to 15 interruptions per hour with the help of staff training and the introduction of safety vests. Most interruptions occurred due to conversations and were initiated mostly by the nurses themselves.

Study C showed that interruptions during the preparation and double-checking of medications in the inpatient setting can be reduced by the combined intervention such as staff training and safety vests.

3.2 Integrating and linking thesis studies under the medication error chain view

All three studies can be integrated into the model of medication error chains considering different aspects of this concept (figure 10). Error chains highlight the fact that errors are the result of a sequence of events, the contributing factors of which may be tightly coupled, all contributing to the final outcome. The basic idea behind using the error chain concept is to identify critical links in the error chain and remove it so that the error chain is broken, and thus, no incident should occur. While in figure 8 an error chain spans across all stages of the medication use process, it is important to note that error chains can be triggered and stopped at any stage.

Study A systematically applies the novel process-oriented approach of medication error chains to medication incident analysis with the aim to identify (a) frequency of medication errors, (b) error chains, (c) errors in the various stages, (d) contributing factors and (e) targeted safety barriers for stopping medication error chains. The results of **study A** displayed that input errors (especially a wrong prepared dose) can be frequently transformed into output errors (a wrong administered dose) through contributing factors (especially inattention respectively interruptions as a main attentional problem), working conditions (e.g. space, noise) and missing or ineffective safety barriers (e.g. undisturbed workspace for drug preparation). **Study A** showed that the majority of errors occurring during medication preparation were not intercepted prior to medication administration and reached the patient due to a sequence of events forming an error chain. Inattention was the most frequent contributing factor to medication errors reported by the staff (Huckels-Baumgart & Manser, 2014). One recommendation of **study A** was that the effectiveness of established or newly implemented safety barriers (e.g. undisturbed workspace for drug preparation) should be evaluated systematically using observations and focused reporting by staff. Possible interventions to reduce "inattention" by optimizing the working environment (e.g. space, noise) are to establish undisturbed workspaces for drug preparation or to use "Do Not Disturb" safety vests.

Based on this study results, these recommended targeted safety barriers were implemented and their effect were evaluated in **study B** (optimizing the work environment by separate medication rooms separate medication rooms) and **study C** (staff training and the implementation of "Do Not Disturb" safety vests as a more simple and inexpensive combined intervention) to reduce interruptions as a main attentional problem during the

critical task of medication preparation (figure 10). Using the concept of error chains, interruptions during medication preparation, commonly performed by nurses, may be viewed as one important critical link between preparation activities and errors. Interruptions can interfere with the primary task as well as with safety checks and may thus increase inattention and medication errors (Li et al., 2012; Page, 2004; Reason, 1990).

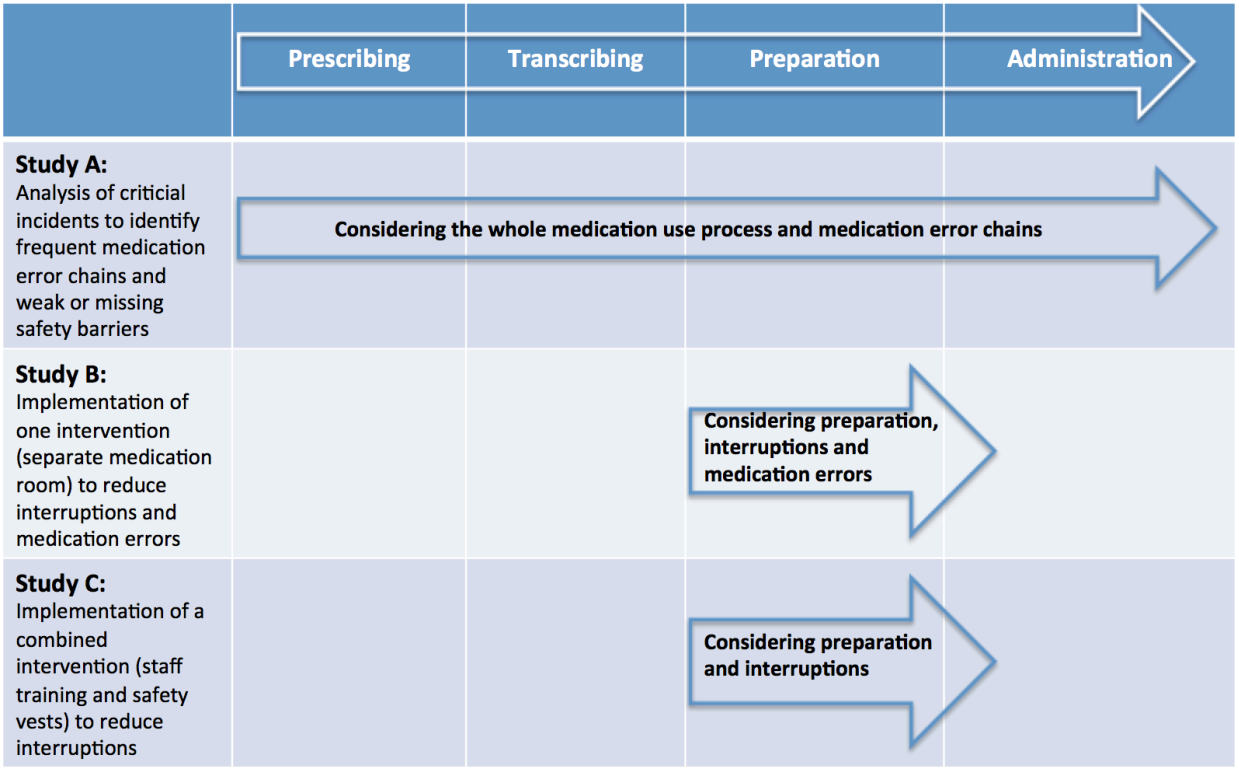

Figure 10: Integrating and linking thesis studies under the medication error chain view

3.3 Author's contribution to thesis articles

Table 1 lists Ph.D. candidate's contribution to study A-C.

Paper	Publication Status	Ph.D. candidate's contribution
Study A		
Huckels-Baumgart & Manser	Published in Journal of Clinical Pharmacology (2014)	Substantial contribution to • conception & design, • data acquisition and collection, • analysis and interpretation, • draft and revision of the manuscript
Study B		
Huckels-Baumgart, Baumgart, Buschmann, Schüpfer & Manser	Published ahead-of- print in Journal of Patient Safety (2016)	Substantial contribution to • conception & design, • data acquisition and collection, • analysis and interpretation, • draft and revision of the manuscript
Study C		
Huckels-Baumgart, Gauch, Manser, Meier & Carla Meyer-Massetti	Under Review in Journal of Nursing Management (2016)	Substantial contribution to • conception & design, • data acquisition and collection, • analysis and interpretation, • draft and revision of the manuscript

Table 1: Overview of author's contributions to thesis articles

4. Discussion and synthesis

4.1 Contribution to theory and practice

The thesis provided new evidence on human factors and medication safety research. The three studies aimed to contribute to a deeper understanding of medication error chains and investigating the effectiveness of practical interventions. In particular, the studies explored the reduction of interruptions during the critical task of medication preparation as one important contributing factor to medication errors.

The medication error chain concept provided a novel, innovative framework developed in this thesis. The existing theoretical foundations revealed only weak evidence regarding medication error chains and the effectiveness of interventions reducing interruptions during medication preparation. Existing research into the distribution of medication errors indicates incidence of errors in all stages of the medication use process, but predominantly focuses on isolated process steps (Aspden et al., 2006; Hicks et al., 2004; Hughes & Ortiz, 2005; Lisby et al., 2005; Taylor, 2007). This isolated view does not reflect the complexity of error occurrence along the entire medication use process and neglects the interdependencies between these stages. Most published studies recognize only single process steps, causes and measures to reduce medication errors, but only few have provided a process-oriented approach and interventions during medication preparation. Taking the dynamics of medication errors into account, these existing research gaps were addressed in this thesis by **study A, B and C** covering practical interventions that influence error chains surrounding medication preparation.

Study A systematically applies a novel process-oriented approach of medication error chains to medication incident analysis with the aim to identify (a) frequency of medication errors, (b) error chains, (c) errors in the various stages, (d) contributing factors and (e) targeted safety barriers for stopping medication error chains.

While the concept of error chains has been used previously in incident analyses, it has not been applied systematically in medication management before this thesis. Surprisingly, researchers have only very recently started to use similar approaches (Carayon et al., 2014; Samaranayake et al., 2013). While no study explicitly referring to the error chain concept could be found, two recent analyses of medication incidents applied similar approaches.

One study (Samaranayake et al., 2013) compared intercepted and non-intercepted (34.1%) medication errors along the medication use process using Reason's "Swiss Cheese Model" (Reason, 1995, 2000) as an analytic framework. This framework provides a useful foundation for targeted prevention strategies. A second study (Carayon et al., 2014; Samaranayake et al., 2013) analyzed medication incidents in two intensive care units using a combination of incident reports and chart reviews.

Study A indicated that the majority of errors occurring during medication preparation were not intercepted prior to medication administration and reached the patient due to a sequence of events forming an error chain. "Inattention", "work condition" and "lack of training" were the most frequently reported contributing factors to medication errors. In order to prevent medication errors clinicians frequently proposed "improvement of training" and "situational awareness". The study results strongly suggest a need for the implementation of targeted interventions respectively safety barriers to reduce interruptions as a main attentional problem during medication preparation.

Although interruptions may occur at any stage of the medication use process (Vincent et al., 2009), medication preparation is especially prone to interruptions because it is the last stage and opportunity intercepting errors before medication administration and reaching the patient. A high frequency of medication errors occurs during medication preparation (Huckels-Baumgart & Manser, 2014). For example, wrong dose, wrong drug, a drug for a wrong patient and wrong route are major preparation errors. Nurses commonly prepare and administer medications and they have the major responsibility as the last link in the medication use process. In nursing driven health services like Switzerland, nurses perform final safety checks intended to identify and intercept medication errors before reaching the patient. Thus, the preparation phase has very few safeguards against errors and requires nurses' full attention.

Interruptions during the medication use process have been studied across various hospital settings particularly with a focus on medication administration (Raban & Westbrook, 2014; Relihan et al., 2010). While its known that interruptions and errors both are common during medication preparation, we found only four studies (Anthony et al., 2010; Biron et al., 2009; Duruk, Zencir, & Eşer, 2016; Tomietto et al., 2012) specifically investigating interruptions during medication preparation. No study considered their relationship to medication errors. Thus, the existing evidence for interventions effectively reducing

interruptions (Colligan et al., 2012; Freeman et al., 2013; Julie Kliger et al., 2012) has not yet been linked to a reduction of errors during medication preparation. Preventing medication errors from reaching the patient means designing health care systems and processes safer. Limited research exists addressing human factors and work redesign to reduce medication errors and contributing factors. Most published studies recognize causes and measures to reduce medication errors, but few have provided practical interventions (Pape, 2003). Therefore, the thesis addressed the need to develop interventions and safety barriers during medication preparation to reduce interruptions as one important contributing factor to medication errors.

Based on the results of **study A** and the existing research gaps, **study B** evaluates the effect of optimizing the work environment by separate medication rooms as one targeted intervention and safety barrier to improve medication safety during medication preparation. The aim was to reduce interruptions during the critical task of medication preparation and thus the potential to cause medication errors. Finally, **Study C** uses staff training and the implementation of "Do Not Disturb" safety vests as a more simple and inexpensive combined intervention to reduce interruptions. The focus of **study B and C** was to become aware of (1) when interruptions happen, (2) what types commonly occur, and (3) how to reduce interruptions as a main attentional problem during medication preparation. Henriksen and colleagues (Henriksen et al., 2008) considered similar aspects related to the studies: (1) preventable adverse events (reported medication errors in **study A and B**), (2) characteristics of individuals (staff training about the impact of interruption on medication safety to reduce interruptions in **Study C**), (3) nature of clinical work (inattention and interruptions in **Study B and C**), (4) design of the physical environment (implementing separate medication rooms in **Study B** and 'Do Not Disturb' safety vests in **Study C** to reduce interruptions during medication preparation). **Study B and C** showed that interruptions during medication preparation and in **study B** also medication errors could be successfully reduced by a re-design of the work environment and staff training as an important part of human factors research.

However, not all interruptions are preventable and lead to errors. Interruptions might also have positive effects on patient safety, for example alarms in emergency cases. Despite any interventions and safety barriers implemented, interruptions will likely remain a part of clinical work, due to its very nature (Grundgeiger & Sanderson, 2009) and a complete

interruption of medication error chains could not be achieved. In consequence interruptions during medication preparation will probably never be eliminated completely in daily hospital practice.

Therefore, it is important that hospitals have a wider range of safety barriers in place. For example, further well-established safety barriers in medication management are the "four eyes principle or double-check" (i.e. a cross-check of a prepared medication by two clinicians) and the "six rights" (i.e. checking every medication for right medication, right patient, right time, right documentation, right route and right dosage) (Hughes & Blegen, 2008). The strict application of the "double-checks" and "six rights" are important safety barriers after medication preparation and before administration. When performed carelessly, without thought and attention, the importance and effectiveness of these safety checks get lost (Clifton-Koeppel, 2008). When completed correctly (attentively, completely, independently, and uniformly) and in a manner in which safety is the goal, these checks can be effective in detecting and reducing medication errors. Correctly, safely and attentively performed double-checks can catch approximately 95% of all errors and should be applied as an added safety-net for patients (ISMP, 2013).

Overall, the three studies in this thesis include a theoretical and practical approach based on human factors frameworks and the medication error chain concept. This thesis has given an important contribution to existing human factors and medication research as well as the practical implementation of safety barriers within hospitals. By evaluating targeted interventions to improve the work environment and redesign of medication preparation areas the thesis proposed means that ensure effectiveness, safety and ease of use.

4.2 Limitations

Despite its strengths and novelties, several limitations need to be taken into account when interpreting the results of this thesis.

First, the three studies of this thesis were performed in one academic teaching hospital across three hospital sites in one country (Switzerland). Therefore, the findings may not be generalizable to other settings. For example, the system of care, ward layout, medication process and staffing patterns may be different across units, hospitals and countries.

Second, different formats of data collection such as chart review, observation and incident reporting or respectively self-reporting will lead to different findings. As shown by several investigators, a self-reporting method carries the risk of reporting biases and underreporting (Hughes & Blegen, 2008). Self-reported incident reports are recognized as under-representing actual errors (Evans et al., 2006; Lawton & Parker, 2002). In the hospital setting, multiple studies have demonstrated that errors often go unreported with only 5% of significant errors being reported (Leape et al., 1995). Moreover, in study B we received a much higher number of medication error reports through the focused action on structured daily reporting of medication errors than through the hospital wide critical incident reporting system. This approach captures medication errors that have been detected and corrected and thus would not be captured by chart review. Although medication errors can be detected by chart reviews, this is also a subjective and resource intensive method because errors are often not clearly documented and a relationship based on given drugs needs to be interpreted by the reviewers. Further, participant behavior during observation is subject to the Hawthorne effect that is behavior changes due to the act of being observed. The observation duration should be extended and of equal lengths pre- and post-intervention in future studies, which is a resource intensive method.

Third, we considered the process steps prescribing, transcription, preparation and administration in study A and focused on the process step medication preparation in study B and C. In outpatient settings monitoring problems may dominate. Thus, there may be a lack of generalizability to other healthcare settings.

Fourth, in study A “inattention” was the most frequent contributing factor to medication errors reported by staff. We considered “interruptions” as a main attentional problem in

study B and C, but we have not explicitly measured, whether “inattention” was also improved and “attention” has increased generally by reducing interruptions.

A further limitation is the linearity of the error chain model in study A: An error does not always lead directly to the next error, but "local trigger" and "unusual conditions" meet with errors. Thus, it is also possible to speak of a collection of safety barriers, where errors can slip through the holes.

Additionally, the outcome of study B and C was not equal because medication errors could not be measured in study C. In study C it was tested if a reduction of interruptions could be achieved as well with a less expensive intervention. Future studies should consider both outcomes “interruptions” and “medication errors”.

Finally, this thesis addressed a subset of existing research gaps identified in the literature and focused on the most relevant gaps in the given hospital setting; however, it could not consider all of them.

4.3 Conclusion and outlook

This thesis makes a valuable contribution to the field of research on human factors and medication safety and addressed existing research gaps identified in the literature. Whereas study A highlights the importance of identifying medication error chains in general, Studies B and C focus more specifically on targeted interventions to reduce interruptions as a main attentional problem and contributing factor to medication errors during medication preparation.

The benefit of the novel process-oriented approach to medication error analysis in study A is to gain important insights concerning medication error chains and the effectiveness of safety barriers along the entire medication use process. The identification of medication error chains complements existing knowledge on medication errors and system weakness. This thesis opens up new perspectives for detecting and stopping medication errors before they reach the patient. Thus, the medication error chain concept forms a novel and solid basis for future research and more sophisticated or complex evaluations based on this process-oriented analysis.

Further, studies should follow to increase knowledge around error chains and to implement comprehensive safety barriers to improve medication safety. The feasibility of the novel process-oriented analytic approach in study A has been illustrated in this thesis using medication incident reports in a hospital. In the future, this concept can also be used for other healthcare settings and patient safety "hot-spots". Additional data sources such as chart reviews or observations could provide further insights into error chains and underlying event rates. In study A, only few medication errors were prevented before reaching the patient. This points towards necessary improvements of safety barriers at each stage - especially in early stages - of the medication use process to interrupt error chains. While hospitals usually have implemented a range of safety barriers, without a systematic analysis of error chains it is difficult to assess their effectiveness and to establish preventive measures breaking these error chains as early as possible.

Nurses are mostly involved in medication preparation, double-checking and administration of drugs. They provide a fundamental function in nursing driven systems in detecting and preventing errors that occurred in the prescribing, transcribing, and preparation stages. The studies of this thesis clarified that nurses' work environment is characterized by

frequent interruptions as a main attentional problem that are initiated mostly by colleagues. Although interruptions are commonplace and have been identified as a major contributor to medication administration errors previously, little evidence existed to reduce interruptions during medication preparation before this thesis. Study B and C addressed this research gaps and indicated positive effects of different hospital-based interventions: separate medication rooms, staff training and the wearing of safety vests with the note "Do Not Disturb" could reduce interruptions during medication preparation and improve medication safety.

The results of this thesis highlight the importance of incorporating patient safety at an early architectural design stage. While measures to minimize interruptions such as separate medication rooms and safety vests contribute to an improved work environment for medication preparation, nurses also need to feel empowered to speak up to discourage unwanted interruptions and conversation while preparing medications. These attempts will be more successful if adequately supported by work design. For this reason, architectural changes are recommended as they present an even stronger defense against interruptions. Additionally, an improved work layout with direct access to medical records could eliminate specific, unnecessary interruptions. Even though electronic medication logistics are being introduced widely in hospitals and wards and may seemingly make those interventions unnecessary, they will still be required in practice for medication preparation on short notice or in case of emergency. Future research is needed to better understand why interruptions occur and to implement effective interventions to reduce interruptions. The study design of this thesis could be expanded to determine if the interventions will be effective in other types of process-steps, units and hospitals. Overall, in addition to technical interventions, clinical staff has to be trained regarding error chains, suitable safety barriers and on how errors and unnecessary interruptions can be reduced successfully by increasing staff awareness and the implementation of physical barriers.

This thesis ends in accordance to James Reason, whose following quote accurately illustrates the motivation of this thesis and emphasizes the importance of investing in human factors and (medication) safety for all those involved in hospitals and healthcare system: “We cannot change the human condition, but we can change the conditions under which humans work.”

5. Thesis Articles

The three studies (Study A-C) are presented as self-contained articles including their own structure and references. Language, formatting and citation style is based on the journal in which the article was published or to which it was submitted. All references from Chapter 1-4 are listed at the end of this thesis.

5.1 Study A: Identifying Medication Error Chains From Critical Incident Reports: A New Analytic Approach

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Identifying Medication Error Chains From Critical Incident Reports: A New Analytic Approach

Saskia Huckels-Baumgart, MSc[1] and Tanja Manser, PhD[2]

Abstract

Research into the distribution of medication errors usually focuses on isolated stages within the medication use process. Our study aimed to provide a novel process-oriented approach to medication incident analysis focusing on *medication error chains*. Our study was conducted across a 900-bed teaching hospital in Switzerland. All reported 1,591 medication errors 2009–2012 were categorized using the Medication Error Index NCC MERP and the WHO Classification for Patient Safety Methodology. In order to identify medication error chains, each reported medication incident was allocated to the relevant stage of the hospital medication use process. Only 25.8% of the reported medication errors were detected before they propagated through the medication use process. The majority of medication errors (74.2%) formed an error chain encompassing two or more stages. The most frequent error chain comprised preparation up to and including medication administration (45.2%). "Non-consideration of documentation/ prescribing" during the drug preparation was the most frequent contributor for "wrong dose" during the administration of medication. Medication error chains provide important insights for detecting and stopping medication errors before they reach the patient. Existing and new safety barriers need to be extended to interrupt error chains and to improve patient safety.

Keywords

medication error chains, medication error, medication use process, incident analysis

Numerous studies have shown significant problems in medication safety as one of the main threats to patient safety in hospitals.[1–6] Understanding the incidence, type and preventability of medication errors is crucial to improving the safety of healthcare delivery.[2]

A medication error is defined as "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."[7] Medication errors can occur at any point of the well-established five stages of the medication use process: prescribing, transcribing, preparation, administering, and monitoring. Furthermore, medication errors may or may not reach the patient; and while some medication errors have serious consequences, others change a patient's outcome but this change does not result in any harm.[8]

Medication errors are—by definition—potentially preventable. Thus, an in-depth investigation of these errors is necessary for continuous improvement of medication safety, regardless of whether an injury actually occurred or the potential for injury was present.[7] The aim of medication incident analyses is to identify frequent error types as early as possible in the medication use process to prevent them from propagating and ultimately reaching patients.

Research into the distribution of medication errors across the different stages of the medication use process found that, in hospitals, medication errors were common at the stages prescribing, transcription, preparation and administration, thus highlighting their relevance along the entire medication use process.[2,4,8–10]

While these findings indicate incidence of medication errors in all stages, research predominantly focuses on isolated process steps. This isolated view does not reflect the system complexity of error occurrence and failing safety barriers along the entire medication use process and neglects the interdependencies between these stages. In order to gain a deeper understanding of medication errors, safety wholes and barriers throughout the entire medication use process we applied a novel approach to medication error analysis that focuses on *medication error chains*.

The concept of error chains highlights the fact that many errors are the result of a sequence of events, the contributing factors of which may be tightly coupled, all

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contributing to the final outcome. The basic idea behind using the error chain concept is to identify a critical link in the error chain and remove it so that the error chain is broken, and thus, no incident should occur.[11] Hospitals usually have a whole range of safety barriers in place. For example, well-established safety barriers in medication management are the "four eyes principle" (ie, a cross-check of a prepared medication by two clinicians) and the "six rights" (ie, checking every medication for right medication, right patient, right time, right documentation, right route, and right dosage).[7,12]

Safety barriers are often vulnerable, but in most cases a succession of barriers ensures that an error is caught before a negative outcome occurs.[13–15] Studying medication error chains helps to identify weaknesses in safety barriers and to pinpoint where exactly in the medication use process safety barriers are missing, not effective or require improvement. Improving the effectiveness of existing safety barriers and establishing new ones will help to interrupt error chains before affecting a patient and, thus, improve patient safety.

The general idea of error chains in the hospital medication use process is illustrated in Figure 1. An example for an input error is an illegible handwritten prescription by a physician. The error is activated when this prescription is transcribed by a nurse with a wrong dose without double-checking with the physician. The wrong dose may propagate as through the further medication use process and be prepared by another nurse without recognition of the preexisting error. This error chain may result in the output error of the wrong dose being administered to the patient. While this example of an error chain spans across all stages of the medication use process, it is important to note that error chain can be triggered and stopped at any stage. Effective safety barriers present opportunities to interrupt error chains and prevent the error from reaching the patient. One safety barrier helping to interrupt the error chain in our example during the prescription and transcription stages might be an electronic order entry system. The strict application of important safety practices such as "four eye principle" and "six rights" could act as safety barriers after the preparation and before administration.

While the concept of error chains has been used previously in incident analyses, it has not yet been applied systematically in medication management. Surprisingly, researchers have started only very recently to use similar approaches.[16,17] We believe that the identification of medication error chains provides important insights complementing existing knowledge on medication errors, system weakness, effectiveness of safety barriers and opens up new perspectives for detecting and stopping medication errors before reaching the patient.

This study aimed to address these research gaps by systematically applying a process-oriented approach to medication incident analysis. We aimed to identify frequent medication error chains including a classification of error types. We also explored contributing factors and possible safety barriers for interrupting error chains along the medication use process.

Method

The study was conducted in a 900-bed teaching hospital in Switzerland with 6,000 employees across three hospital sites which all share a critical incident reporting system (CIRS) that had been introduced as part of a quality improvement project in 2006.

Nurses, physicians, pharmacists, and other healthcare professionals from all departments can report critical incidents anonymously. The blank CIRS template used at the three study sites is attached in supplemental Table S1. We analyzed all 3,557 incidents reported across the three hospital sites from 2009 to 2012.

Data Analysis

Using a Microsoft Excel export of the reports from the hospital-wide CIRS, incident data were coded in several steps applying established coding systems.[18,19] All

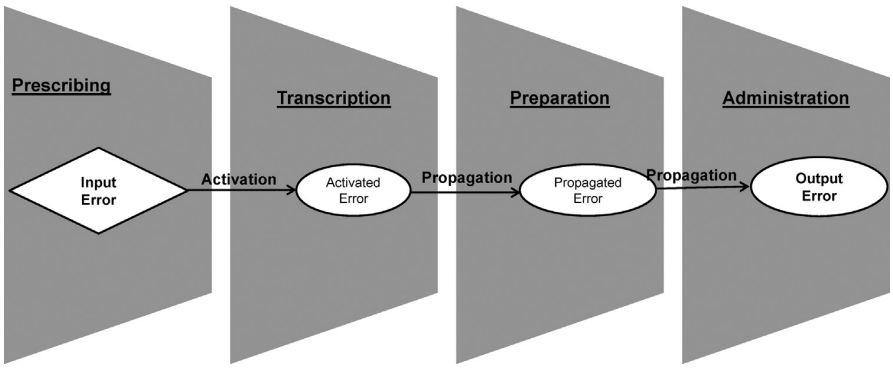

Figure 1. Simplified illustration the concept of error chains spanning across the stages of the hospital medication use process.

reported medication errors we analyzed contained de-identified information, so ethics approval and consent were not required. In a first step, all 3,557 incident reports in this database were analyzed and grouped according to the World Health Organization (WHO) Classification for Patient Safety Methodology.[18] In a second step, all 1,591 reports coded as medication errors in the previous step were categorized using (a) the Medication Error Index and (b) the WHO Categories for medication errors. Each incident was then allocated to all relevant stages of the mediation use process. Finally, within the allocated stages all applicable medication error types according to the WHO Classification were assigned.

Categorization Using the Medication Error Index. All 1,591 medication errors were categorized using the Medication Error Index established by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). NCC MERP classifies errors according to the severity of the outcome and if it reached the patient or not. Category A includes error-causing circumstances and category B covers recognized and prevented errors. Categories C–D incorporate errors that reached the patient. In category C an error occurred but did not cause patient harm whilst category D required an intervention/monitoring. In Categories E–I medication errors result in patient harm or death.[19] Because the CIRS we based our analysis is not intended to collect reports that include patient harm or death for which a separate reporting procedure exists in all participating hospitals, the severity of medication errors included in our study cover categories A–D.

Categorization Using the WHO Classification for Patient Safety Methodology. The 1,591 medication errors were each categorized into medication error types according to the WHO classification (wrong patient, wrong drug, wrong dose, wrong quantity, omitted medicine or dose) with one reported medication error potentially including several errors at different stages.

Allocation to Stages of the Medication Use Process and Identification of Medication Error Chains. To identify error chains, each reported medication incident was allocated to the relevant stages of the hospital medication use process: prescribing, transcription, preparation, and administering. A medication error may extend over several stages before it is averted. In these error chains, events can be detected and intercepted or they remain undetected through all stages. For every incident report we recorded in which stage(s) what kind of error type occurred. Afterwards, frequent medication error chains with their input and output errors were identified. "Input errors" were defined as errors triggering a medication error chain, while "output errors" marked the endpoint and characterized a potential adverse outcome. In the next step we added two error types not contained in the WHO classification (ie, "wrong time" and "non-consideration of documentation/prescribing"). Furthermore, the contributing factors reported by the staff in the incident reports were assigned to the medication error chains concerned.

Review Process

Two reviewers (quality manager and intensive care nurse) independently categorized all medication incidents according to the coding steps described above and thereafter all codings were discussed, to reach a consensus. Using the categorization Medication Error Index (NCC MERP) there was an initial agreement between rates of 98.5% (1,567 reports) and for the categorization WHO Classification for Patient Safety Methodology the initial agreement was 95.8% (1,524 reports). In the allocation to the stages of the medication use process the initial agreement was 86.4% (1,375 reports). After discussing all disagreements in the research team, consensus was reached for all cases. Therefore, no reports were excluded.

Prior to coding, the two reviewers were trained in incident report classification. Training manuals provided definitions of medication error types, process steps and the NCC MERP Index as well as examples of medication error reports. Training was followed by pilot coding of actual CIRS data. Reviewers received feedback concerning accuracy and inter-reviewer agreement.

Statistical Analysis

Descriptive statistics were used to examine the characteristics of the reported medication errors. For the statistical analysis of reported medication error categories and main types of medication errors we used the Pearson's Chi-squared test of independence. The independence of the reported error categories and main types of medication errors were examined using Chi-square statistics comparing the years 2009–2012. Category counts smaller than 5 were not included in the statistical analyses. All statistical analyses were performed in R (Version 2.15.3).

Results

Frequency of Medication Errors Reaching the Patients

Table 1 provides an overview of the reported medication errors assigned to the NCC MERP Medication Error Category Index for each year of the study period and in total. A total of 3,557 incidents were reported 2009–2012 including 1,591 (44.7%) medication incidents. 15.7% of medication incidents were recognized and averted before reaching the patient (ie, categories A and B). 84.3% of the reported medication errors reached the patient (categories C–D). A further 75.5% fell into category C and 8.8% in category D. No errors were recorded in categories E–I because the CIRS we based our analysis on does not include patient harm or death. Overall, annual frequencies

Table 1. Frequencies and Percentages of Incidents Per NCC MERP Medication Error Category Index

Medication Error Category Index	2009 (n = 375)		2010 (n = 385)		2011 (n = 341)		2012 (n = 490)		Total (n = 1,591)		χ^2
	n	%	n	%	n	%	n	%	n	%	
A = Circumstance or events that had capacity to cause error	0	0.0	2	0.5	0	0.0	2	0.4	4	0.3	n.a.
B = Error did not reach patient	67	17.9	37	9.6	33	9.7	109	22.2	245	15.4	60.15*
C = Error reached patient but caused no harm	282	75.2	298	77.4	287	84.2	334	68.2	1,202	75.6	5.50
D = Error reached patient and required monitoring to confirm no harm or intervention to preclude harm	26	6.9	48	12.5	21	6.2	45	9.2	140	8.8	15.60*

χ^2-value = statistic for the comparison of differences between years. n.a., not applicable. Categories E–H = Error, harm or I = Error, death are not part of our critical incident reporting dataset. Category A was excluded from analysis due to minor relevance and data values smaller 5. *$P < 0.05$

of reported medication errors (ie, categories B, C, and D) differed significantly by year (Chi-square 49.137, $P < .05$).

Most Frequent Types of Medication Errors

Table 2 provides an overview of the main medication error types based on the WHO Classification for Patient Safety Methodology. The most frequent types of medication errors were "wrong frequency of dose/strength" (27.5%), "omitted medicine or dose" (17%) and "wrong drug" (13.3%). There was no significant difference in the types of medication errors captured from 2009 to 2012 (Chi-square 30.76, $P = .078$) (Table 2).

Medication Error Chains and Single-Stage Medication Errors

Allocation of all data from 2009 to 2012 to the four stages of the hospital medication use process showed that a single report might include errors at multiple stages. Therefore, the number of medication errors across stages exceeded the number of medication incidents reported during the study period.

Using the total number of the reported medication errors (n = 1,591) as the denominator for calculating percentages, our analysis showed that only 410 (25.8%) of the reported medication errors were successfully detected before propagating through the medication use process (ie, single stage error; gray arrows in Figure 2).

The majority of medication errors (74.2%) formed an error chain comprising two or more stages. Most error chains were triggered during medication preparation with 50.3% and during prescription with 26.1%. Output errors as endpoints occurred most frequently in the administration stage (82.5%). Detailed information on the distribution of medication error chains and single error stages broken down for the three hospital sites and each year from 2009 to 2012 is presented in supplemental Table S2.

Overall, we identified six different error chains in the medication use process. Error chains and single stage medication errors are summarized in Figure 3. For all error chains we identified different input errors triggering the error chain and the same input error could result in different output errors.

Table 2. Main Types of Medication Errors From 2009 to 2012 Per WHO Classification

Main Types of Medication Errors	2009 (n = 375)		2010 (n = 385)		2011 (n = 341)		2012 (n = 490)		Total (n = 1,591)		χ^2
	n	%	n	%	n	%	n	%	n	%	
Wrong dose/strength of frequency	94	25.1	113	29.4	108	31.7	123	25.1	438	27.5	3.99
Omitted medicine or dose	76	20.3	47	12.2	60	17.6	87	17.8	270	16.9	13.76*
Wrong quantity	62	16.5	62	16.1	39	11.4	70	14.3	233	14.6	9.22*
Wrong drug	56	14.9	47	12.2	55	16.1	53	10.8	211	13.3	0.92
Wrong formulation or presentation	33	8.8	37	9.6	29	8.5	60	12.2	159	10	14.56*
Wrong patient	27	7.2	33	8.6	22	6.5	41	8.4	123	7.7	6.53
Contraindication	11	2.9	20	5.2	11	3.2	24	4.9	66	4.2	7.82
Wrong route	10	2.7	9	2.3	8	2.4	14	2.9	41	2.6	2.02
Wrong storage	1	0.3	5	1.3	6	1.8	7	1.4	19	1.2	n.a.
Wrong dispensing label/instruction	3	0.8	8	2.1	2	0.6	5	1.0	18	1.1	n.a.
Adverse drug reaction	0	0	3	0.8	1	0.3	5	1.0	9	0.6	n.a.
Expired medicine	2	0.5	1	0.3	0	0.0	1	0.2	4	0.3	n.a.

χ^2-value = statistic for the comparison of differences between years. n.a., not applied. The last four rows were excluded from analysis due to data values smaller 5. *$P < 0.05$

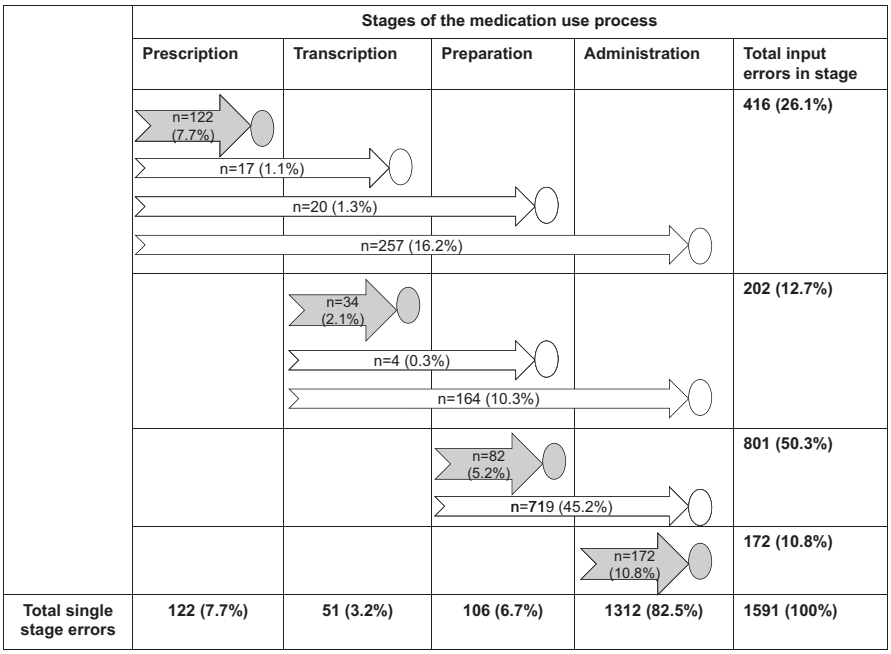

Figure 2. Medication error chains and input and output errors across stages of the medication use process.

The three most frequent error chains were: preparing up to and including medication administration (45.2%), prescribing up to and including medication administration (16.2%) and transcription up to and including medication administration (10.3%).

Prescribing to Administration. The input error "wrong formulation" during prescribing propagated most frequently until administration. This resulted in "wrong quantity" (39.7%) or "wrong dose" (28.4%) during transcription and remained undetected until the administration.

Transcription to Administration. The transcription of a "wrong quantity" remained undetected until administration 54.9%. In 40.8% "wrong formulation" during transcription spread to "wrong dose" during preparation and remained undetected until administration.

Preparation to Administration. In 54% of reports the preparation of a "wrong quantity" remained undetected until administration. "Non-consideration of documentation/prescribing" during preparation was the most frequent contributor for "wrong dose" [14.7%] during administration.

Successfully Interrupted Error Chains

Most successfully intercepted medication errors were contained to a single stage; that is, 82 cases (10.2%) of 801 errors occurring during preparation were captured before propagating further. Concerning error chains starting during prescription (n = 416), 17 (4.1%) were successfully interrupted during transcription and another 18 (4.3%) before administration. At the different stages the following safety barriers were successful: double check by a second person, application of the "six rights" and "four eyes principle" as well as confirming a prescription with another clinician and involving patients as vigilant partners.

Contributing Factors and Proposals for the Prevention of Medication Errors

As shown in Table 3, staff reported "inattention" and "work conditions" as contributing factors for medication errors most frequently. The most frequent proposals for preventing medication errors were "improved training", "good communication," and "situational awareness."

Discussion

Errors in medication management and their frequency have been widely studied, but until recently without consideration of medication error chains. Our study identified frequent medication error chains including a classification of error types. Further, we explored contributing factors and possible improvements to safety barriers for interrupting error chains along the medication use process.

Our findings indicate a need for improvement in safety barriers in all stages of the medication use process. Most of the medication errors in our study reached the patient, propagated across more than one stage and potential safety barrier along the medication use process.

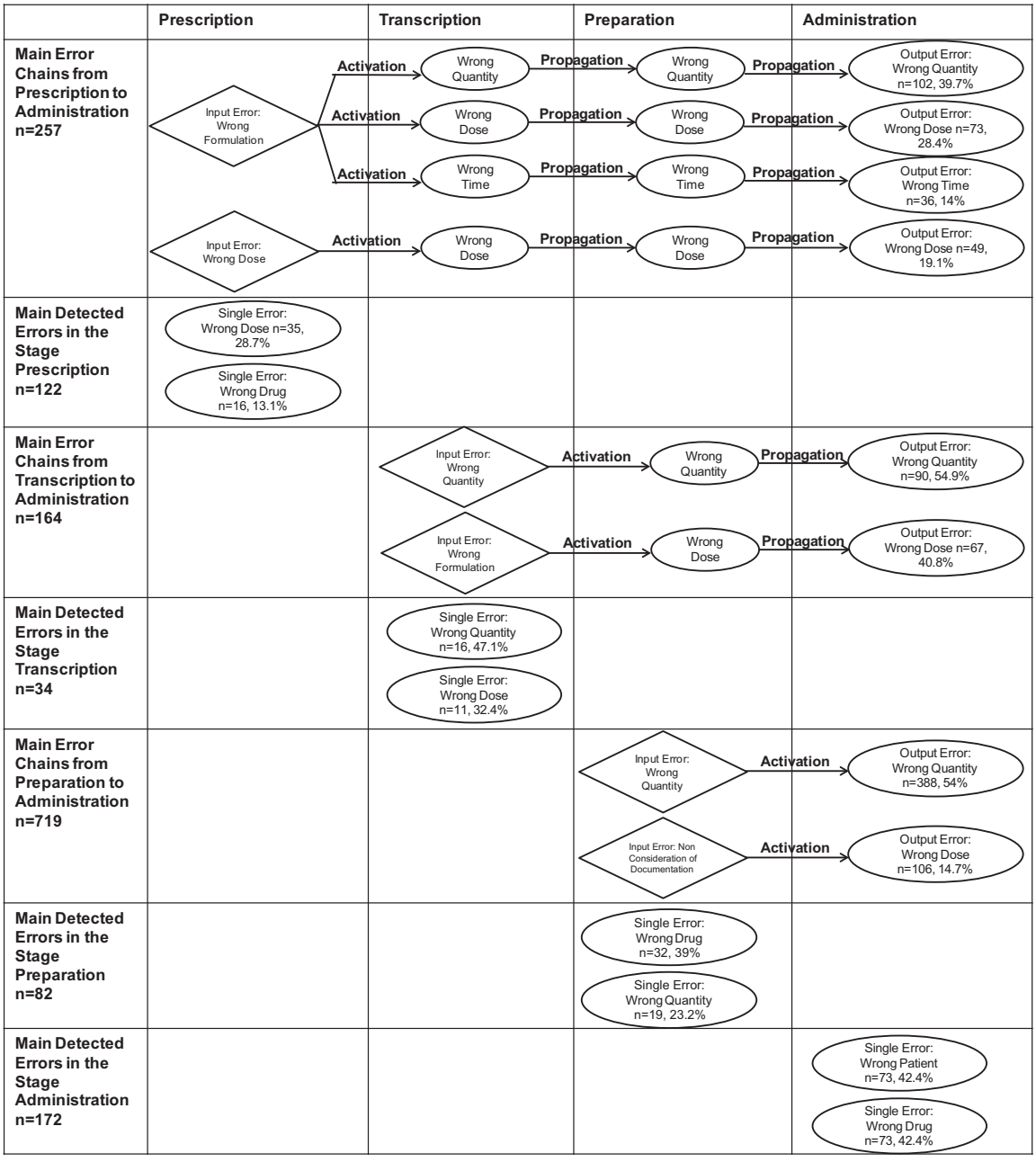

Figure 3. Main input and output errors in the medication error chains and detected errors in the single stages.

Medication Error Chains and Reason's "Swiss Cheese Model"

While we were unable to find any study explicitly referring to the error chain concept, two recent analyses of medication incidents applied similar approaches. One study[17] compared intercepted and non-intercepted (34.1%) medication errors along the medication use process using Reason's "Swiss Cheese Model"[13,14] as an analytic framework and provides useful for targeted prevention strategies. A second study[16,17] analyzed medication incidents in two intensive care units (ICU) using a combination of incident reports and chart reviews. The identified medication errors were categorized into single, grouped and sequential errors, with the final group resembling the medication error chains that were the focus of our study.

Table 3. Contributing Factors of Medication Errors and Proposals for Medication Error Prevention

Leading Causes of Error	Total Reports (n = 1,591)	
	n	%
Contributing factors of medication errors		
Inattention	962	60.5
Work conditions (heavy workload, time pressure, staff shortages, team composition)	500	31.4
Lack of training (skills)	282	17.7
Work environment (space, noise)	92	5.8
Communication problem (team, patient)	146	9.2
Recommendations for medication error prevention		
Improved training (appropriate experience, better preparation, correct algorithms)	1,122	70.5
Good communication	836	2.5
Situational attention	758	47.6
Improved work conditions (additional staff)	121	7.6

Note: In the CIRS it was possible to report more than one contributing factor and proposal for prevention, therefore the total numbers exceeded those of the reported medication errors. Total numbers of reported medication errors were used as the denominator for calculating percentages.

In line with our results, both studies found medication errors related to prescribing and administration to be most frequent. Differences between the three studies, such as the higher frequency of error chains in our study may be due to the different study settings (ICU vs. hospital-wide/ pharmacists involved in medication preparation or not), the database (incident reports vs. chart review) and the primary research goals leading to the identification of error chains. While these differences will require further exploration in future studies, it is important to highlight the valuable insights that the shift from focusing on isolated stages in the medication use process to a workflow-oriented analysis has generated in all three studies.

Reason's well-established "Swiss Cheese Model" is well suited to discuss medication error chains that are similar to Reason's error trajectory.[20] According to this model, fatal errors usually occur when several safety barriers fail.[13–15] This was also the case for most medication incidents in our sample that actually reached the patient. Moreover, our study identified a number of latent conditions that may negatively influence medication safety (eg, heavy workload, inadequately trained personnel, stressful environment, poor communication).[21]

Types and Frequency of Medication Errors

In our study the most common error types were wrong dose/strength of frequency (27.5%), wrong quantity (16.9%), omitted medicine or dose (14.6%) and wrong drug (13.3%). Although 16.9% of all medication errors in our study were related to omitted medicine or dose, and thus seemingly less serious, the potential impact of such occurrences should not be underestimated. The majority of medication errors (74.2%) propagated as an error chain through two or more stages. The main input errors were most frequent during medication preparation (50.3%) and during prescription (26.1%). Output errors as endpoint and adverse outcome occurred most often in the administration stage with a total of 1,312 (82.5%).

The frequency of medication errors we found is in line with several other studies.[1–6] However, results from different studies are difficult to compare because of differing definitions and methods of detecting errors. Thus, reported error rates in medication administration vary greatly depending on factors such as the inclusion or exclusion of different routes of administration as well as timing errors.[9]

One study found that error frequency fell from 56% to 34% when excluding timing errors.[22] Most errors in other studies occurred during the administration of the medication use process. Nearly one quarter of the errors involved incorrect dose of a medication. Three quarters of the errors were influenced by distractions.[2,4–6,9,10,22,23] Common reasons for medication errors include for example handwritten prescriptions that are difficult to read, selection of incorrect strength/dosage, medication names that sound alike and medicine administered to the wrong patient.[9] Other studies show that omission and wrong dosage errors were also found to be commonly occurring medication errors.[2,4–6,9,10,22,23] Another, review of medication errors observed in critical care settings found similar results,[24] as did a review of prescribing errors in hospitals, which found that dosage errors were most commonly reported in the majority of studies. Wrong time, administration rate, and preparation errors were among the most common medication error subcategories observed with regard to intravenous administration.[24]

Contributing Factors and Practical Implications for Incident Interception and Analysis

In our study "inattention," "work condition," and "lack of training" were the contributing factors most frequently reported. In order to prevent medication errors clinicians

frequently proposed "improvement of training," "good communication," and "situational awareness."

Despite existing safety barriers concerning medication preparation and administration a complete interruption of medication error chains could not be achieved. The introduction of a computerized physician order entry system might help to further reduce "wrong or unclear formulation" as well as communication and knowledge-based errors during the prescription.[24] Thus, this intervention can be seen as a critical safety barrier helping to interrupt medication error chains at the stage of the prescription.

To interrupt medication error chains at the stages prescription and administration and to mitigate the contributing factor "lack of training," the introduction of ward pharmacy services is a possible solution. Clinical pharmacists can support physicians to intercept prescribing errors and can provide pharmacotherapeutic information to nursing staff.[25,26]

Two commonly used practices that can act as a safety barrier at the medication administration stage are the "four eyes principle" and the "six rights."[12] These practices may also help to counteract "inattention" that was mentioned frequently as a contributing factor in our study. Similarly, bar code assisted medication administration can improve "situational attention" and interrupt medication error chains at the administration stage through the indication of misidentification (ie, patient, medication). This intervention has also been reported to reduce the number of wrong-time omission and wrong dose errors[24] and is thus relevant to many medication incident reports in our study.

Another intervention to reduce "inattention" by optimizing the working environment (eg, space, noise) is to establish an undisturbed workspace for drug preparation[27] or to use interruption vests (eg, "Do not interrupt medication round in progress").[28] These interventions may help to improve "situational attention" and will facilitate other safety practices such as the "four eye principle" during the drug preparation. In our sample, these interventions might impact on the most frequently reported medication errors at this stage (ie, wrong medication for the wrong patient, wrong dose and omitted medicine).

Another important strategy to reduce medication error chains, lack of training and communication problems is the continuous staff training and education surrounding the most frequent errors and contributing factors.[11] Many opportunities for improvement and prevention exist when clinicians and healthcare facilities are willing to share information about medication errors and error chains. In particular, effective safety barriers should be emphasized and communicated regularly together with the successfully interrupted error chain and contributing factors such as "inattention" (interruptions) and working conditions (space, noise). Further, the effectiveness of established or newly implemented safety barriers (eg, undisturbed workspace for drug preparation) should be evaluated systematically using observations and focused reporting by staff. Based on our data, it seems that more effective safety barriers are required especially in early stages of the medication use process. However, due to a potential underreporting of successfully interrupted error chains other methods (eg, observations) and additional control variables should be considered. For example, a study of Dollarhide et al exploring associations between medication events and real-time performance-shaping factors showed that physicians reporting greater patient caseloads, greater perceived workload, and more emotional stress were found to be substantially more likely to report medication events.[29] Further, reliable and valid databases can provide valuable information, such as the description, types and contributing factors of medication error chains, the factors that contributed to the error chains, and the patient outcome. These databases can be used for further research studies and/or the development of policies and procedures. Properly identifying and reporting medication errors and error chains allow for opportunities to learn from these reports, improve team communication, staff training and to create system level interventions that interrupt error chains to reduce patient vulnerability.[30]

Further, improving communication with patients will empower them to take a more active role in their own medication safety. If patients are well informed about their own medications, they are able to identify a wrong drug or dose before this is being dispensed or administered to them. A few medication error reports in our reporting system described these facts, where patients identified a medication error on time and stopped error chains before the wrong drug or dose was administered.

Although these interventions may reduce the incidence of certain types of medication errors, as well as interrupting error chains before they reach the patient, further research could consider a multifaceted approach to error rate reduction.

CIRS analysis in medication management contains valuable information that can help to identify (a) frequency of medication errors, (b) error chains, (c) errors in the various stages, (d) contributing factors, and (e) strategies for interrupting error chains. The benefit of our novel process-oriented approach to medication error analysis is to gain important insights concerning medication error chains and the effectiveness of safety barriers along the entire medication use process. This opens up new perspectives for detecting and stopping medication errors before they reach the patient. Thus, more sophisticated evaluations based on our process-oriented incident analysis should follow to increase knowledge around error chains and to implement comprehensive measures to improve medication safety.

Limitations

Our study has several limitations. Firstly, different formats of data collection such as chart review or incident reporting will lead to different findings. As shown by several investigators, a self-reporting method carries the risk of reporting biases and underreporting.[12] The use of external observers might be considered ideal, but this method is resource intensive and introduces the bias of staff behaving differently while under observation (Hawthorne effect). Because we used facilitated reporting by a structured questionnaire for the occurrence of medication errors over an extended period of time, we minimized these biases. However, more general cognitive and reporting biases may have contributed to limited information on successfully interrupted error chains in our study. Errors that do not reach the patient may be less likely to be noticed and considered relevant enough by clinicians to be reported via any system. Thus, a more comprehensive analysis of successful interruption of error chains might require a different approach to data collection. Secondly, we focused on the process steps prescribing, transcription, preparation, and administration in our study. In outpatient settings monitoring problems may dominate. Thus, there may be a lack of generalizability to other healthcare settings. A further limitation is the linearity of the error chain model: An error does not always lead directly to the next error, but "local trigger" and "unusual conditions" meet with errors. Thus, it is also possible to speak of a network of safety barriers, where errors can slip through the holes. Lastly, it must be mentioned that the chosen error categories were developed and validated by North American hospitals; for the purpose of this study, the method has been followed for three Swiss hospitals. In order to confirm the results achieved and draw conclusions, it would be necessary to test and validate it on a larger scale.

Conclusion

Research into the distribution of medication errors indicates incidence of errors in all stages of the medication use process, but predominantly focuses on isolated process steps. This isolated view does not reflect the complexity of error occurrence along the entire medication use process and neglects the interdependencies between these stages. Our results highlight the importance of identifying medication error chains. The feasibility of this novel analytic approach has been illustrated here using incident reports. In the future additional data sources such as chart reviews or observations will have to be included to allow for further insights into error chains and underlying event rates.

In our study, only few medication errors were prevented before reaching the patient. This points at necessary improvements of safety barriers at each stage of the medication use process to interrupt error chains. In addition to technical interventions, clinical staff has to be trained regarding error chains and possible safety barriers. Staff awareness will be enhanced by internal publication of error chains, training on medication error chains and suitable strategies on how error chains can be identified and intercepted.

While hospitals usually have implemented a range of safety barriers but without a systematic analysis of error chains it is difficult to assess their effectiveness and to establish preventive measures breaking these error chains as early as possible. We believe that the identification of medication error chains complements existing knowledge on medication errors, system weakness and opens up new perspectives for detecting and stopping medication errors before they reach the patient.

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S1 (Supplemental Table 1): Blank CIRS template used at the three study sites

Definition	A critical incident is an unintended or preventable event that might endanger the patient, but will not cause harm. In case of doubt, please report.
Information about the event	• Hospital (pull-down menu) • Reporting circle (pull-down menu) • Description of the event (free text) • Possible measures to prevent a similar incident in the future (free text) • Assessment of severity (select): (I) minor, no action required (II) medium, treatment / intervention required (III) serious, serious or life-threatening consequences might have occurred • Time incident occurred (pull-down menu)
Event categorization	Please select: • Medication • Mobilization • Storage • Equipment failure • Incorrect operation of equipment • Material failure • Incorrect use of material • Information process (for example, rapport) • Guidelines • Misjudgment • Other: (free text)
What were the reasons for the incident (contributing factors)?	Please select: Human factors: • Misjudgment • Inattention • Confusion • Insufficient expertise / skill • Heavy workload • Private problem • Lack of training • Not aware of guidelines • Illness • Other: (free text) Organization / communication: • Communication issues - patient • Communication issues - relatives • Communication issues - team • Lack of supervision • Staff shortages • Unfavorable staff composition (for example, too few

	personnel) • Unclear / missing regulation / procedure / documentation • Other organizational problems: (free text) Infrastructure / environment: • Limited space • Noise • Time pressure because of vital danger to the patient • Time pressure for organizational reasons • Other infrastructure / environment problems: (free text) Technical problems: • Equipment failure • Equipment not available • Lack of technical knowledge • Other technical issues: (free text) Other contributing factors: • Drug side effect • Allergy • Wrong patient • Other issues: (free text)
What led to the correction or what has been done?	Personal factors: • Adequate knowledge • Experience • Correct algorithms Team factors: • Good communication / team building • Good communication with patients • Good communication with relatives • Good communication within the team itself System factors: • Additional monitoring or material • Additional staff • Other: (free text) Proposal for prevention: • No proposal • Additional material • Additional training • Improve preparation • Improve communication • Additional staff • Improve situational awareness • Other: (free text)

S2 (Supplemental Table 2): Medication Error Chains and single error stages for each year from 2009 to 2012 and for the three hospital sites

	2009			2010			2011			2012			Total
Medication Error Chains	**Hospital1 n (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	**Hospital1 No. (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	**Hospital1 No. (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	**Hospital1 No. (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	
Prescribing to Administration	38 (11.8%)	5 (15.6%)	5 (23.8%)	49 (16.2%)	12 (29.3%)	15 (34.9%)	42 (15.7%)	5 (16.7%)	13 (30.2%)	58 (15%)	3 (7.7%)	12 (19.1%)	257 (16.2%)
Prescribing to Transcription	5 (1.6%)	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (2.3%)	1 (2.6%)	0 (0.0%)	17 (1.1%)
Prescribing to Preparation	0 (0.0%)	1 (3.1%)	1 (4.8%)	3 (1.0%)	1 (2.4%)	0 (0.0%)	4 (1.5%)	0 (0.0%)	1 (2.3%)	6 (1.6%)	0 (0.0%)	3 (4.8%)	20 (1.3%)
Transcription to Preparation	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)	0 (0.0%)	0 (0.0%)	4 (0.3%)
Transcription to Administration	35 (10.9%)	3 (9.4%)	2 (9.5%)	35 (11.6%)	8 (19.5%)	5 (11.6%)	26 (9.7%)	3 (10%)	4 (9.3%)	33 (8.5%)	6 (15.4%)	4 (6.4%)	164 (10.3%)
Preparation to Administration	151 (46.9%)	15 (46.9%)	8 (38.1%)	140 (46.5%)	14 (34.2%)	14 (32.6%)	142 (53%)	14 (46.7%)	19 (44.2%)	160 (41.2%)	14 (35.9%)	28 (44.4%)	719 (45.2%)
Single Error Stages	**Hospital1 n (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	**Hospital1 No. (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	**Hospital1 No. (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	**Hospital1 No. (%)**	**Hospital2 No. (%)**	**Hospital3 No. (%)**	
Prescribing	25 (7.8%)	5 (15.6%)	1 (4.8%)	10 (3.3%)	0 (0.0%)	3 (7%)	12 (4.5%)	6 (2%)	2 (4.7%)	48 (12.4%)	3 (7.7%)	7 (11.1%)	122 (7.7%)
Transcription	14 (4.3%)	0 (0.0%)	1 (4.8%)	5 (1.7%)	2 (4.9%)	0 (0.0%)	4 (1.5%)	0 (0.0%)	2 (4.7%)	6 (1.6%)	0 (0.0%)	0 (0.0%)	34 (2.1%)
Preparation	13 (4.0%)	1 (3.1%)	2 (9.5%)	22 (7.3%)	0 (0.0%)	1 (2.3%)	17 (6.3%)	1 (3.3%)	1 (2.3%)	22 (5.7%)	2 (5.1%)	0 (0.0%)	82 (5.2%)
Administration	41 (12.7%)	2 (6.3%)	1 (4.8%)	33 (11%)	4 (9.8%)	5 (11.6%)	21 (7.8%)	1 (3.3%)	1 (2.3%)	44 (11.3%)	10 (25.6%)	9 (14.3%)	172 (10.8%)
Total reports	322 (100%)	32 (100%)	21 (100%)	301 (100%)	41 (100%)	43 (100%)	268 (100%)	30 (100%)	43 (100%)	388 (100%)	39 (100%)	63 (100%)	1591 (100%)

5.2 Study B: Separate medication preparation rooms reduce interruptions and medication errors in the hospital setting: a prospective observational study

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ABSTRACT

Background: Interruptions and errors during the medication process are common, but published literature shows no evidence supporting whether separate medication rooms are an effective single intervention in reducing interruptions and errors during medication preparation in hospitals. We tested the hypothesis that the rate of interruptions and reported medication errors would decrease as a result of the introduction of separate medication rooms.

Aim: Our aim was to evaluate the effect of separate medication rooms on interruptions during medication preparation and on self-reported medication error rates.

Methods: We performed a pre- and post-intervention study using direct structured observation of nurses during medication preparation and daily structured medication error self-reporting of nurses by questionnaires in two wards at a major teaching hospital in Switzerland.

Results: A volunteer sample of 42 nurses was observed preparing 1498 medications for 366 patients over 17 hours pre- and post-intervention on both wards. During 122 days nurses completed 694 reporting sheets containing 208 medication errors. After the introduction of the separate medication room the mean interruption rate decreased significantly from 51.8 to 30 interruptions per hour ($p<0.01$) and the interruption-free preparation time increased significantly from 1.4 to 2.5 minutes ($p<0.05$). Overall, the mean medication error rate per day was also significantly reduced after implementation of the separate medication room from 1.3 to 0.9 errors per day ($p<0.05$).

Conclusions: The present study showed the positive effect of a hospital-based intervention: after the introduction of the separate medication room, the interruption and medication error rates decreased significantly.

Interruptions of healthcare staff are common[1] and particularly relevant to patient safety when occurring during high-risk procedures such as the medication process known to be susceptible to errors. Interruptions during the medication process have been studied across various hospital settings with a focus on medication administration.[2-9] A review of Biron et. al reported a rate of 6.7 interruptions per hour during medication administration.[10] Similarly, an observational study in surgical wards reported one interruption for every 3.2 drugs given during nurses' medication rounds.[11] The main sources of these interruptions reported in the literature are co-workers including nursing colleagues.[2,10,12-14]

The medication process is a routine but complex activity, involving multiple steps (i.e. prescription, transcription, preparation, double-checking, administration and monitoring) and a variety of personnel.[15] Therefore, this process is particularly vulnerable to errors if attention is diverted. Interruptions have repeatedly been identified as a key contributory factor to medication errors.[10,11,17-31] Westbrook and colleagues found that medication error severity increased with interruption frequency.[32] Although interruptions may occur at any stage of the medication process,[33] medication preparation is especially prone to interruptions because it is the last stage before medication administration to the patient and it has very few safeguards against errors.[28] One study showed that the majority of errors occurring during medication preparation were not intercepted prior to medication administration and reached the patient due to a sequence of events forming an error chain.[28] Using the concept of error chains, interruptions during medication preparation may be viewed as a critical link between preparation activities and errors because they can interfere with the primary task as well as with safety checks and may thus increase

medication errors.[34-36] If this link is removed the error chain is broken and an incident averted.[28]

While its known that interruptions and errors both are common during medication preparation, we found only three studies[4,37,38] specifically investigating interruptions during medication preparation and no study considered their relationship to errors. Thus, the existing evidence for interventions effectively reducing interruptions[4,37-41] has not yet been linked to a reduction of errors during medication preparation.

Many intervention strategies to reduce interruptions require a change in clinician behavior such as minimizing unnecessary conversation or waiting for co-workers to complete their task before addressing them. The redesign of workspaces might offer an alternative, potentially more sustainable solution (e.g. implementing "No Interruption Zones" or physical barriers).[26,37,39,42,43] The introduction of separate medication rooms intuitively appears to be an effective intervention to improve safety during medication preparation. One multi-intervention study that included the introduction of a dedicated room for medication preparation as one of three components of their intervention strategy found positive effects.[4] However, we found no evidence that separate rooms for medication preparation as a single intervention effectively reduce interruptions and errors.

Our study aimed to explore the effect of separate medication rooms to improve medication safety during the critical task of medication preparation when implemented as a single intervention. The research questions of this pre-post-intervention study set in a surgical and a medical ward concerned 1. the rate, duration and sources of interruptions nurses experienced while preparing medications and 2. the number and type of medication errors before and after the intervention. We hypothesized that the rate of interruptions and reported medication errors would decrease as a result of the intervention.

Setting and intervention

The study was undertaken in a medical and a surgical ward of a 900-bed teaching hospital in Switzerland. Each ward had 18-beds organized in 11 patient rooms and supported by 46 nurses in a three-shift system. Between 3 to 4 fully qualified nurses were responsible for the patient care per shift. The two wards selected for this study moved to newly designed facilities that were equipped with a separate medication room for each ward in which oral and intravenous medications were stored, prepared and double-checked (compared to a freely accessible medication preparation area at the nursing station in the old infrastructure). Information necessary for medication preparation was paper based. On both wards one nurse was responsible for preparing all patient medications for the day. The prepared medications were then double-checked by a second nurse and administered to their assigned patients.

Definitions

Interruptions are defined as "a break in the performance of a human activity initiated by a source internal or external to the recipient, with occurrence situated within the context of a setting or a location".[44] Interruptions are situations in which a nurse ceases the medication preparation or checking in order to attend to an external stimulus.[32] An interruption can be initiated by the nurse him/herself (self-initiated), by another individual or by the work environment (e.g. alarms). In the context of medication preparation a common source of interruptions is communication; often concerning information irrelevant to the primary task (e.g. a (non-)verbal cue from another individual prompting the nurse to give a (non-)verbal response[8,37,45] or the nurse initiating a conversation with another person). While other studies distinguish between "interruptions" and "distractions" to describe causes and

precursors of errors,[5,9] we use the term "interruption" (including self-initiated interruptions) as comprising both.

Study design and sample

Our pre- and post-intervention mixed-methods study used direct structured observation of nurses during medication preparation by an external observer and structured daily medication error self-reporting by nurses. We use the term pre-intervention for medication preparation in the old facilities without a separate medication room and post-intervention accordingly for medication preparation in the new facilities with separate medication rooms. Exclusion criteria were nurses in training, new employees and nurses not routinely working in the study units.

According to research ethics guidelines in Switzerland this study was exempt from formal ethics approval because patient observation was not included in this study (Federal Act on Research involving Human Beings (Human Research Act, HRA). Participation in the study was voluntary and verbal consent was sought from each nurse prior to each observation period.

Data collection procedure

Data were collected in two phases. Pre-intervention data was collected from April through May 2012. Approximately one week before data collection commenced, all nursing staff was informed by the quality manager that observations of medication preparation would take place and that they were required to fill in structured reporting forms for medication errors at the end of each shift during the study period. To minimize observation and reporting biases, nurses were informed about the study aim but not about the exact outcome measures (i.e. reducing interruptions and medication errors).

Three months after both wards had moved into the new facilities with separate medication rooms and staff had become accustomed to the new work area post-intervention data were collected from September through October 2012 using the same methods and instruments as during pre-intervention data collection. Once data collection was complete, nurses were debriefed on the study purpose and informed about the findings.

Observation of interruptions. A paper-based observation protocol was developed to record interruptions during nurses' medication preparation. We used a modified version of the validated Medication Administration Distraction Observation Sheet (MADOS)[46] to collect the frequency of each of 12 sources of interruption experienced during the medication round (see supplemental table S1). Observations were carried out pre- and post-intervention during the main medication preparation and when additional medications were prepared or checked by other nurses. Four peak times of medication preparation were identified by the nurse manager of both units (i.e. 8AM-10AM, 10.30AM-12.30AM, 1PM-3PM and 3PM-5PM on weekdays); night shifts and weekends were excluded. Observation lasted for 2 hours or until all medications were prepared. A medication preparation cycle and thus observations started when the nurse began the medication preparation for all patients on the ward. The medication cycle ended when the nurse completed the medication preparation. To minimize the intrusiveness of observations, observers were positioned close but slightly to the side of the medication preparation area.

Two observers (out of a pool of trained observers with two hospital pharmacists, one nurse and one quality manager) independently and simultaneously observed medication preparation of each nurse. Each time an interruption occurred, they recorded it and also noted the source of the interruption in the structured observation sheet. After each medication preparation session interobserver agreement was achieved by comparing and

discussing observed interruptions, their duration and causes. Discussions between the observers resolved potential disagreements.

Medication error reporting. At the end of each shift during the study period participating nurses were requested to anonymously fill in a structured paper-based reporting form based on the hospital's electronic critical incident reporting form and the WHO Classification for Patient Safety[47] (see supplemental table S2). The form asked whether a medication preparation error had occurred during their shift and if so, which type of error, which factors had contributed to the error and at which step of the medication process it was detected. Completed reporting sheets were collected in a locked post-box on each ward.

Data analysis

Data were analyzed using STATAv.12.1. We used descriptive statistics to indicate the observed rate of interruptions during medication preparation and the reported medication error rate. Rates were calculated in line with previous publications, i.e. mean interruption per hour and medication errors per day.[5,10] For example, the mean interruptions per hour were calculated for each observed medication preparation activity by dividing the observed interruptions per medication preparation cycle by the duration of preparation time in minutes multiplied by 60. Medication errors per day are given as the sum of all reported errors of nurses from the returned reporting sheets. Frequency, percentage and position indexes [mean, standard deviation (SD)] were calculated accordingly. Independent sample two-sided t-tests were conducted to compare the number and duration of interruptions and the number of reported medication errors per day between the pre- and post-intervention period for the overall data set and for each ward. Differences were considered (highly) statistically significant where the p-value was <0.05 (<0.01). One self-reporting form

containing one reported error had to be excluded from data analysis because no information was given on the type of error, the cause and the process step. All other returned self-reporting forms contained at least type of error and either cause or process step. Effect size and statistical power were assessed via post-hoc power analysis with *G*Power Version 3.1.9.2.*[48] For the comparison of reported sources of interruptions and medication error categories (type of error, cause and process step) pre- and post-intervention we only report descriptive statistics due to small sample size in subcategories of medication errors.

RESULTS

Total observation time was 17 hours (1036 minutes) during 72 medication preparation cycles on 9 weekdays pre- and 9 weekdays post-intervention (Table 1). A volunteer sample of 42 nurses (one male nurse) was observed preparing 1498 medications for 366 patients pre- and post-intervention on both wards. Nursing experience varied between 1 and more than 20 years (mean 8.6 years, SD=7.1). The same nurses were included in the pre- and post-intervention group. During pre-intervention data collection a total of 311 patients were treated on the study wards (107 patients on the surgical ward, 204 patients on the medical ward) and 319 patients (148 patients on the surgical ward, 171 patients on the medical ward) during post-intervention data collection.

Rates and duration of interruptions

A 2-tailed independent t-test revealed statistically significant differences in several categories between interruptions before and after implementation of the separate medication room. Table 1 provides an overview of the interruption rates pre- and post-intervention separated by type of ward. The mean interruption rate decreased significantly from 51.8 to 30 interruptions per hour ($p<0.01$). To determine whether this decrease was

statistically significant we used the number of interruptions per hour to correct for differences in the number of medication processes that occurred in the 9 days before and the 9 days after the intervention due to variation in patient load. The mean duration of interruptions was 33 seconds (range 15 seconds to 24 minutes). Comparing pre- and post-intervention, the interruption-free preparation time increased significantly from 1.4 to 2.5 minutes ($p<0.05$) (Table 1). For the interruptions per hour (per medication cycle) the effect size was 0.68. The power to detect an effect of this size in the two settings was determined to be 0.80 with a critical $t(70) = 1.99$.

-Insert Table 1 about here-

	Surgical ward			Medical ward			Both wards			Total
	Pre	Post	p value	Pre	Post	p value	Pre	Post	p value	
Total observed aspects										
Total numbers of interruptions	160	54		284	109		444	163		607
Total duration of preparation time in minutes	273	139		391	233		664	372		1036
Total duration of interruption time in minutes	59	40		159	61		218	101		319
Total numbers of prepared medications	483	248		421	346		904	594		1498
Total numbers of observed nurses	10	8		15	9		25	17		42
Total numbers of included patients for medication preparation	92	39		157	78		249	117		366
Total numbers of observations (medication preparations)	13	9		31	19		44	28		72
Interruption rates										
Mean interruptions per hour	42.24 (16.79)	18.22 (28.25)	0.017 *	55.87 (36.11)	35.54 (23.32)	0.017 *	51.84 (34.23)	29.97 (22.67)	0.002 **	43.34 (31.94)
Mean interruptions per nurse	16.00 (18.95)	6.75 (8.96)	0.097	18.93 (35.66)	12.11 (15.39)	0.262	17.76 (29.64)	9.59 (12.70)	0.115	14.45 (24.37)
Mean interruptions per nurse per hour	54.91 (32.34)	20.50 (25.80)	0.012 *	115.46 (81.80)	75.03 (47.54)	0,070	91.24 (73.00)	49.37 (47.00)	0.014 *	74.29 (65.92)
Mean interruptions per drug	2.33 (4.07)	0.30 (0.17)	0.045 *	2.76 (3.43)	1.42 (1.79)	0.039 *	2.63 (3.58)	1.07 (1.58)	0.007 **	2.02 (3.05)
Mean interruptions per drug per hour	15.21 (28.55)	0.94 (1.34)	0.048 *	32.22 (40.03)	14.00 (14.21)	0.013 *	27.2 (5.66)	9.80 (13.19)	0.003 **	20.43 (31.49)
Mean duration										
Mean duration of interruptions in minutes	0.36 (0.20)	0.80 (0.74)	0.059	0.52 (0.36)	0.61 (0.77)	0.324	0.47 (0.33)	0.67 (0.76)	0.102	0.55 (0.54)
Mean duration of preparation in minutes	21.0 (18.8)	15.4 (10.3)	0.193	12.6 (16.9)	12.3 (10.8)	0.465	15.1 (17.7)	13.3 (10.6)	0.295	14.4 (15.3)
Mean preparation time without an interruption in minutes	2.00 (1.05)	3.04 (3.13)	0.181	1.21 (0.70)	2.25 (1.74)	0.010 *	1.44 (0.89)	2.51 (2.25)	0.012 *	1.86 (1.63)

* p < .05, ** p < .01

\+ t-test, unequal variances

Table 1: Observed interruption rates and duration pre- and post-intervention

Sources of interruptions

Table 2 shows a breakdown of observed interruptions into different sources for both wards and overall when comparing pre- to post-intervention data. Because the number of

medication preparation processes observed after the intervention was lower due to fewer patients on the wards the frequencies given here should be interpreted with caution. However, the proportion of all observed interruptions for which these sources were relevant shows that pre-intervention the most frequent source of interruptions in both wards were interruptions by colleagues (n=209, 47.1%), especially staff interruptions by nurses (n=162, 36.5%), and self-initiated interruptions (n=127, 28.6%) (Table 2). Although, there was a decrease after the intervention these remained the most frequent sources of interruptions.

-Insert Table 2 about here-

	Surgical ward				**Medical ward**				**Total**			
	Pre		**Post**		**Pre**		**Post**		**Pre**		**Post**	
Sources of interruptions	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.
Nurses	35.6%	57	24.1%	13	37.0%	105	48.6%	53	36.5%	162	40.5%	66
Physicians	2.5%	4	0.0%	0	9.2%	26	0.0%	0	6.8%	30	0.0%	0
Other personnel	2.5%	4	3.7%	2	4.6%	13	0.0%	0	3.8%	17	1.2%	2
Total interruptions by colleagues	**40.6%**	**65**	**27.8%**	**15**	**50.7%**	**144**	**48.6%**	**53**	**47.1%**	**209**	**41.7%**	**68**
Response to conversation or noise	24.4%	39	5.6%	3	21.5%	61	30.3%	33	22.5%	100	22.1%	36
Leaves the room	5.0%	8	20.4%	11	6.7%	19	5.5%	6	6.1%	27	10.4%	17
Total self-initiated interruptions	**29.4%**	**47**	**25.9%**	**14**	**28.2%**	**80**	**35.8%**	**39**	**28.6%**	**127**	**32.5%**	**53**
Alarm	0.0%	0	0.0%	0	0.4%	1	1.8%	2	0.2%	1	1.2%	2
Phone call	5.0%	8	9.3%	5	12.3%	35	5.5%	6	9.7%	43	6.7%	11
Total interruptions by technology	**5.0%**	**8**	**9.3%**	**5**	**12.7%**	**36**	**7.3%**	**8**	**9.9%**	**44**	**8.0%**	**13**
Patients	0.0%	0	0.0%	0	0.4%	1	0.0%	0	0.2%	1	0.0%	0
Families/visitors	0.0%	0	0.0%	0	0.4%	1	0.0%	0	0.2%	1	0.0%	0
Total interruptions by other people	**0.0%**	**0**	**0.0%**	**0**	**0.7%**	**2**	**0.0%**	**0**	**0.5%**	**2**	**0.0%**	**0**
Missing Information, e.g. patient records	10.6%	17	20.4%	11	2.8%	8	3.7%	4	5.6%	25	9.2%	15
Missing medication	14.4%	23	13.0%	7	4.6%	13	4.6%	5	8.1%	36	7.4%	12
Unclear or unreadable prescription	0.0%	0	3.7%	2	0.7%	2	0.0%	0	0.5%	2	1.2%	2
Total interruptions by other disabilities / delays	**25.0%**	**40**	**37.0%**	**20**	**8.1%**	**23**	**8.3%**	**9**	**14.2%**	**63**	**17.8%**	**29**
Total	**100.0 %**	**160**	**100.0 %**	**54**	**100.0 %**	**284**	**100.0 %**	**109**	**100.0 %**	**444**	**100.0 %**	**163**

Table 2: Observed sources of interruptions per total observed interruptions

Self-reported medication errors

During 122 days (61 days pre- and 61 days post-intervention in both wards) nurses completed 694 reporting sheets containing 208 medication errors. The mean medication error rate per day was significantly reduced after implementation of the separate medication room from 1.3 to 0.9 errors per day ($p<0.05$). For the medical ward the error rate decreased significantly from 1.4 to 0.9 errors per day ($p<0.05$) whereas the decrease in the surgical ward was not statistically significant (Table 3). The self-reported errors per day resulted in an effect size of 0.27. The power to detect a significant difference was calculated to be 0.69 ($t(242) = 1.65$).

-Insert table 3 about here-

Total numbers of reported medication errors	**Surgical ward**			**Medical ward**			**Total**		
	Pre	**Post**		**Pre**	**Post**		**Pre**	**Post**	
Number of completed reporting sheets	85	178		281	148		366	326	
Total number of reported medication errors	32	45		84	47		116	92	
Mean medication error rate per day (study period)	**Pre**	**Post**	**p value**	**Pre**	**Post**	**p value**	**Pre**	**Post**	**p value**
Mean medication error rate per day	1.1 (1.4)	0.9 (1.1)	0.221	1.4 (1.7)	0.9 (1.36)	**0.046 ***	1.3 (1.6)	0.9 (1.3)	**0.022 ***

* p < .05, ** p < .01

+ t-test, unequal variances

Table 3: Total numbers and mean medication error rate per day

Pre- and post-intervention, the most frequently reported type of errors was “wrong dose”. Overall, this error type decreased after the implementation of the separate medication room. Staff of both wards reported “inattention” most frequently as contributing factor for medication errors pre- and post-intervention. Most medication errors were detected during medication preparation and double-checking. Therefore, most of the reported medication errors were recognized and prevented before medication administration and reaching the patient (Table 4).

-Insert table 4 about here-

	Surgical ward				Medical ward				Total			
	Pre		Post		Pre		Post		Pre		Post	
Type of reported medication errors	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.
Wrong dose	18.8%	6	4.4%	2	23.8%	20	38.3%	18	22.4%	26	21.7%	20
Omitted medicine or dose	15.6%	5	22.2%	10	6.0%	5	6.4%	3	8.6%	10	14.1%	13
Wrong time	3.1%	1	15.6%	7	9.5%	8	14.9%	7	7.8%	9	15.2%	14
Incorrect documentation (incl. transmission error)	15.6%	5	4.4%	2	13.1%	11	6.4%	3	13.8%	16	5.4%	5
Wrong drug	9.4%	3	2.2%	1	13.1%	11	8.5%	4	12.1%	14	5.4%	5
Wrong quantity (e.g. double delivery)	9.4%	3	8.9%	4	7.1%	6	8.5%	4	7.8%	9	8.7%	8
Other	25.0%	8	31.1%	14	22.6%	19	10.6%	5	23.3%	27	20.7%	19
Wrong route	0.0%	0	4.4%	2	1.2%	1	2.1%	1	0.9%	1	3.3%	3
Wrong patient	3.1%	1	6.7%	3	3.6%	3	4.3%	2	3.4%	4	5.4%	5
Contributing factors reported												
Not specified	0.0%	0	62.2%	28	13.1%	11	14.9%	7	9.5%	11	38.0%	35
Inattention	18.8%	6	22.2%	10	34.5%	29	17.0%	8	30.2%	35	19.6%	18
Miscommunication during prescription	3.1%	1	0.0%	0	9.5%	8	8.5%	4	7.8%	9	4.3%	4
Interruption	12.5%	4	6.7%	3	6.0%	5	8.5%	4	7.8%	9	7.6%	7
Workload	28.1%	9	2.2%	1	8.3%	7	10.6%	5	13.8%	16	6.5%	6
Other	21.9%	7	6.7%	3	25.0%	21	34.0%	16	24.1%	28	20.7%	19
Noise	6.3%	2	0.0%	0	1.2%	1	2.1%	1	2.6%	3	1.1%	1
Problem of medication name, labeling, packaging	0.0%	0	0.0%	0	1.2%	1	4.3%	2	0.9%	1	2.2%	2
Shortage of staff	9.4%	3	0.0%	0	1.2%	1	0.0%	0	3.4%	4	0.0%	0
Process step of medication error detection												
During preparation	40.6%	13	55.6%	25	53.6%	45	34.0%	16	50.0%	58	44.6%	41
During double check (4-eyes principle)	28.1%	9	6.7%	3	26.2%	22	34.0%	16	26.7%	31	20.7%	19
After administration	9.4%	3	11.1%	5	7.1%	6	14.9%	7	7.8%	9	13.0%	12
During administration	9.4%	3	11.1%	5	3.6%	3	8.5%	4	5.2%	6	9.8%	9
After preparation	3.1%	1	4.4%	2	0.0%	0	2.1%	1	0.9%	1	3.3%	3
Not specified	9.4%	3	11.1%	5	9.5%	8	6.4%	3	9.5%	11	8.7%	8
Total number of reported medication errors	**100.0 %**	**32**	**100.0 %**	**45**	**100.0 %**	**84**	**100.0 %**	**47**	**100.0 %**	**116**	**100.0 %**	**92**

Note: Data sorted by frequency of reports per category across both wards.

Table 4: Reported medication errors, contributing factors and process step of detection

DISCUSSION

This intervention study introducing separate medication rooms showed a significant decrease in the frequency of interruptions and in medication error rates during the critical task of medication preparation.

Our study made two important contributions focusing on the infrequently studied stage of medication preparation: First, it showed that the mean interruption rate decreased significantly from 51.8 to 30 interruptions per hour after the implementation of the separate medication room. Our results revealed a mean duration of 33 seconds per interruption. Both results are in line with studies on medication administration that report an average of 42 interruptions per hour[49] and a mean duration of 45 seconds.[50] Overall our findings show that interruptions during medication preparation are frequent, most interruptions are of short duration and therefore nurses act within a work environment with a high potential for interruptions. Regarding clinical specialty, our study showed that nurses faced more interruptions in medical than in surgical wards. Again, this finding is supported by a similar study on medication administration.[45] The results revealed the relative contribution of different sources of interruptions. Nurse colleagues were the most frequent source of interruptions, which is consistent with previous research.[5,46,51,52] Nurses interrupted each other while preparing medication mostly to discuss personal matters. To minimize this kind of interruption, it is important to increase staff awareness of 'interruptive communication practices' during critical medication preparation tasks.

Second, the mean medication error rate per day was significantly reduced overall in the post-intervention setting. Pre- and post-intervention the most frequently reported errors were "wrong dose" and the most frequently contributing factor "inattention", which is in line with findings by Westbrook et al.[32] Most medication errors were detected during

medication preparation and double-checks which was also shown in another study based on incident reports.[28] This highlights the importance of mitigating interruptions during medication preparation to reduce errors and to incease the likelyhood of error detection at this step. Therefore, the implementation of defenses, for example by redesigning workspaces, is needed.

Practical implications

In many hospital wards medication preparation areas are designed as open workspaces shared by staff involved in a variety of tasks. Our study showed that frequent interruptions are a major disadvantage of this workspace design and that separate medication rooms reduce interruptions and self-reported medication errors. Although it may be difficult to integrate separate medication rooms in existing ward structures, ward redesign and hospital construction projects should consider possibilities for separate medication areas or rooms. The present results show the relevance to incorporate patient safety considerations at an early architectural design stage, especially until other medication safety measures such as electronic unit dose systems will be implemented for automatic medication preparation. The implementation of separate medication rooms is only one option reducing interruptions. One important complementary intervention is awareness trainings on the negative impact of interruptions on patient safety and on strategies to effectively manage and reduce interruptions.[4,5,10,46,51,53] Increasing the nurses' awareness of these issues might help to lower self-initiated interruptions, conversations and phone calls.[7,43,45] A simple but effective approach is that colleagues should acknowledge the cognitive demands of safe medication preparation and minimize interruptions whenever possible.[53] Further, interruptions can be reduced by implementing 'No Interruption Zones' in medication preparation areas, where interruption is not permitted or limited to urgent

communication or safety barriers such as colored safety vests with the note "do not disturb".[26,37,51] However, wearing the vests requires an appropriate understanding of the staff and accompanying training. These alternatives should be considered especially if the implementation of separate medication rooms is not feasible due to structural conditions or high construction costs.

Despite all these interventions interruptions during medication preparation will probably never be eliminated completely in daily hospital practice. Therefore, as our study showed, double-checking medication after preparation is essential to prevent medication errors from reaching the patient. Correctly performed double-checks can catch approximately 95% of all errors.[54] Although staff may feel this practice is “unnecessary” and takes additional time under the condition of staffing shortages and increased workload, verification tasks are grounded in a human factors approach and should be applied in daily practice as an added safety-net for patients.[43]

Future research is needed to better understand why interruptions occur and to implement effective interventions to reduce interruptions. This study design could be expanded to determine if the intervention will be effective in other types of units and hospitals. Even though electronic medication logistics are being introduced widely in hospitals and wards and may seemingly make separate medication rooms unnecessary, they will still be required in practice for medication preparation on short notice or in case of emergency.

Limitations

First, the study was performed on surgical and medical units of one academic hospital and therefore the findings may not be generalizable to other settings. For example, the system of care, ward layout, medication process and staffing patterns may be different across units, hospitals and countries. Nevertheless, our study aimed to reduce factors contributing to

errors reaching the patient during the critical task of preparation in the medication process. Second, participant behavior during observation is subject to the Hawthorne effect that is behavior changes due to the act of being observed. However, observations took place over an extended period of time with the aim of diminishing observer biases and as described in the methods section, nurses were not informed about the study measures and should therefore not have an influence on the study results. Third, self-reported incident reports are recognized as under-representing actual errors.[55,56] In the hospital setting, multiple studies have demonstrated that errors often go unreported with only 5% of significant errors being reported.[57] Moreover, in our study we received a much higher number of medication error reports through the focused action on structured daily reporting of medication errors than through the hospital wide critical incident reporting system. This approach captures medication errors that have been detected and corrected and thus would not be captured by chart review. Although medication errors can be detected by chart reviews, this is also a subjective and resource intensive method because errors are often not clearly documented and a relationship based on given drugs needs to be interpreted by the reviewers. Thus, we believe, that focused self-reports as a new approach bring a benefit and identify actual errors.

CONCLUSIONS

In summary, nurses' work environment is characterized by frequent work interruptions that are initiated mostly by colleagues. Although interruptions are commonplace and have been identified as a major contributor to medication administration errors previously, there is little evidence to reduce interruptions during medication preparation. This study shows a positive effect of a hospital-based intervention: after the introduction of separate medication rooms, the interruption and medication error rates decreased significantly. While measures to minimize interruptions such as separate medication rooms, 'No Interruption Zones' and safety vests contribute to an improved work environment for medication preparation, nurses also need to feel empowered to speak up for themselves to discourage unwanted interruptions and conversation while preparing medications. These attempts will be more successful if adequately supported by work design. The implementation of separate medication rooms is just one example of an effective intervention. However, our results highlight the importance of incorporating patient safety at an early architectural design stage.

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Medication Preparation Interruption Observation Sheet

Ward: Date: Observation-Duration:

Shift: Nurse function: ID:

Categories	Sources of interruptions	Duration of interruptions	Number of observed interruptions	Comments
Interruptions by colleagues	Nurses			
	Physicians			
	Other personnel			
Interruptions by other people	Patients			
	Families/visitors			
Interruptions by technology	Phone call			
	Alarm			
Self-initiated interruptions	Response to conversation or noise			
	Leaves the room			
Interruptions by other disabilities / delays	Missing Information, e.g. patient records			
	Unclear or unreadable prescription			
	Missing medication			
Total observed interruptions	during the preparation process			
Total number of	prepared drugs per patient			
	of included patient charts			

Appendix A: Medication Preparation Interruption Observation Sheet

Reporting form medication error Ward: Date: Shift: Nurse function:

Did you notice any medication preparation errors during your shift today? **Number:**

☐ Yes ☐ No

If yes, which type of medication error and how many errors did you notice? **Number:**

- ☐ Wrong dose
- ☐ Wrong drug
- ☐ Wrong patient
- ☐ Wrong quantity (e.g. double delivery)
- ☐ Omitted medicine or dose
- ☐ Wrong time
- ☐ Incorrect documentation (incl. transmission error)
- ☐ Wrong route
- ☐ Other:

What were contributing factors for the medication error? **Number:**

- ☐ Inattention
- ☐ Noise
- ☐ Interruption
- ☐ Workload
- ☐ Shortage of staff
- ☐ Miscommunication during prescription
- ☐ Problem of medication name, labeling, packaging
- ☐ Other:

When did you notice the medication error? **Number:**

- ☐ During preparation
- ☐ After preparation
- ☐ During double check (4-eyes principle)
- ☐ During administration
- ☐ After administration

Appendix B: Reporting form medication error

5.3 Study C: The impact of staff training and safety vests on interruptions during medication preparation and double-checking

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ABSTRACT

AIM

The aim was to evaluate the impact of staff training and safety vests as a combined intervention on interruptions during medication preparation and double-checking.

BACKGROUND

Interruptions and errors during the medication process are common and an important problem for patient safety in the hospital setting.

METHODS

We performed a pre- and post-intervention pilot-study using direct structured observation of 26 nurses preparing and double-checking 431 medication doses (225 pre-intervention and 206 post-intervention) for 36 patients (21 pre-intervention and 15 post-intervention).

RESULTS

The interruption rate during medication preparation was reduced from 36.8 to 28.3 interruptions per hour and during double-checking from 27.5 to 15 interruptions per hour with the help of staff training and the introduction of safety vests.

CONCLUSION

This study showed that the frequency of interruptions decreased during the critical tasks of medication preparation and double-checking after the introduction of staff training and safety vests.

IMPLICATIONS FOR NURSING MANAGEMENT

Unnecessary interruptions can be reduced successfully by increasing staff awareness of 'interruptive communication practices' and the implementation of physical barriers. This is the first pilot-study specifically evaluated staff training and safety vests regarding the reduction of interruptions during medication preparation and double-checking.

The medication process in the inpatient setting is highly complex, involving multiple sub-processes (i.e. prescription, transcription, preparation, administration and monitoring) and staff from a variety of disciplines (Wachter, 2012). The process of providing newly prescribed drugs to the patient at bedside includes approximately 50-100 steps. Therefore, this process is particularly vulnerable to errors (Hughes and Blegen, 2008).

Several studies indicated that interruptions are a significant risk factor for medication errors (Armitage and Knapman, 2003, Fry and Dacey, 2007, Mayo and Duncan, 2004, Palese et al., 2009, Tang et al., 2007, Biron et al., 2009c, Stratton et al., 2004, Armutlu et al., 2008, Karavasiliadou and Athanasakis, 2014, Hickam et al., 2003, Santell et al., 2003, Prakash et al., 2014, Flanders and Clark, 2010, Huckels-Baumgart and Manser, 2014, Ashcroft et al., 2005, Samaranayake et al., 2013, Hughes and Blegen, 2008), and that medication error rates increase with interruption frequency (Westbrook et al., 2010). Consequently, interruptions should be avoided.

In this pilot-study we defined interruptions as "a break in the performance of a human activity initiated by a source internal or external to the recipient, with occurrence situated within the context of a setting or a location" (Brixey et al., 2007). Interruptions are circumstances in which a nurse stops preparing or checking medication in order to pay attention to an external stimulus (Westbrook et al., 2010). An interruption can be generated by the nurse him/herself (self-initiated), by another individual, or by the work environment (e.g. alarms). Communication is a common source of interruptions; it often involves information that is irrelevant to the primary task, such as a (non-)verbal cue from another individual prompting the nurse to give a (non-)verbal response (Smeulers et al., 2013, Anthony et al., 2010, Grundgeiger and Sanderson, 2009), or the nurse initiating a

conversation with another person. Whereas other studies differentiated between "interruptions" and "distractions" to define causes and precursors of errors (Relihan et al., 2010, Sanderson and Grundgeiger, 2015), we use the term "interruption" (including self-initiated interruptions) for both.

Although interruptions may occur at any stage of the medication process (Vincent et al., 2009), the main focus should be on interruptions during medication preparation and double-checking of prepared medications, because these are the last stages in the medication process before administration, with few safeguards against errors reaching the patient (Huckels-Baumgart and Manser, 2014). Most studies considering interruptions during the medication process concentrate on medication administration (Raban and Westbrook, 2014, Prakash et al., 2014, Biron et al., 2009c, Biron et al., 2009a). We found only four studies (Anthony et al., 2010, Tomietto et al., 2012, Biron et al., 2009b, Duruk et al., 2016) specifically investigating interruptions during medication preparation. While staff training and safety vests labelled "Do not disturb" are widely recommended interventions to reduce interruptions during medication administration (Pape, 2003, Pape et al., 2005a, Kliger, 2010, Relihan et al., 2010), there is no evidence of their effectiveness during medication preparation. This is the first pilot-study specifically evaluated the combined interventions of staff training and safety vests regarding the reduction of interruptions during medication preparation and double-checking. The combined intervention might offer solutions to increase awareness of colleagues to prevent interruptions and to change clinician behaviour, such as minimizing unnecessary conversation or waiting for co-workers to complete their task, far less expensive than the frequently proposed redesign of workspaces (e.g. implementing separate medication rooms) (Anthony et al., 2010, Prakash et al., 2014, O'Shea, 1999, Clifton-Koeppel, 2008, Colligan et al., 2012). Many interventions are not effective without staff training. Educating nurses about the impact of interruptions

is necessary to change behaviour and increasing safety awareness (Pape et al., 2005a). It thus provides an important addition to the implementation of safety vests.

The aim of this pilot-study was to close the research gap by evaluating the potential of staff training and safety vests as a combined intervention to reduce interruptions during medication preparation and double-checking. We hypothesised that the rate of interruptions experienced by nurses while preparing and double-checking medications would decrease as a result of the combined intervention. We also explored the impact of the combined intervention on the duration and the sources of interruptions.

METHODS

Setting

The pilot-study was undertaken on a medical ward with a focus on oncology and palliative care in a 900-bed teaching hospital. The ward had 20-beds allotted to 12 patient rooms and was staffed by a total of 28 nurses rotating through four shifts. Between four to five fully qualified nurses per shift were responsible for patient care. The ward was equipped with a freely accessible medication preparation area in the nursing station where drugs were stored and prepared (no utilization of unit dose systems). Multi-dose dispensers were used for medication preparation pre- and post-intervention. Information necessary for medication preparation was paper based. One nurse was responsible for preparing all patient medication for the day. The prepared medication was than double-checked by a second nurse and administered to the assigned patients. Infusions were prepared as needed during the day.

Pilot-study design and sample

Our pre- and post-intervention pilot-study used direct structured observation of nurses during medication preparation and double-checking by an external observer. Exclusion criteria for personnel were nurses in training, new employees and nurses not routinely working on the study ward ('floaters'). Participation in the study was voluntary, and verbal consent was sought from each nurse prior to each observation period.

Ethics

According to research ethics guidelines in Switzerland this pilot-study was exempt from formal ethics approval because no direct patient observation was executed (Federal Act on Research involving Human Beings (Human Research Act)).

Combined interventions

Staff training (first intervention step = post-intervention 1). At the beginning of April, seven weeks after pre-intervention observations, all nursing staff was trained as the first step of the combined intervention. The aim of staff training as a first intervention step was to raise nurses' awareness of interruptions and of their risk during the preparation and double-checking of medication. A lecture with ward-specific findings on interruptions during pre-intervention observations, literature-based facts and potential improvement measures was created for this training intervention. Additionally, an information leaflet with literature-based facts and study results was compiled and distributed in order to make new nurses aware of interruptions.

Safety vest (second intervention step = post-intervention 2). At the end of April, two weeks after staff training was completed and interruptions were observed, safety vests were introduced as a second intervention step of the combined intervention to highlight staff occupied with critical tasks. All nurses had to wear the safety vest while preparing and

double-checking all medication during the observed drug rounds. The nursing staff could choose between yellow, red and pink safety vests. The back of all safety vests was labelled "Do Not Disturb".

Data collection procedure

Pre-intervention data was collected without prior staff training and safety vests during 12 medication preparation and double-checking cycles in February. Post-intervention data was collected during 17 medication preparation and double-checking cycles after the introduction of staff training (post-intervention step 1) and safety vests (post-intervention step 2) as a combined intervention at the beginning and end of April.

Observation of interruptions. We developed a paper-based observation protocol based on the validated Medication Administration Distraction Observation Sheet (MADOS) (Pape, 2003) to record the frequency of each of 14 possible sources of interruptions pre- and post-intervention (see appendix A). Observations were carried out by one pharmacy student during medication preparation and checking on weekdays; night shifts and weekends were excluded. Observation lasted until all medication was prepared or double-checked during the observed medication cycle. A medication preparation cycle - and thus the observation- - started when a nurse began the medication preparation or double-checking process, and ended when the nurse completed medication preparation or double-checking. Each time an interruption occurred, the observer categorized the interruption source and recorded it, including the duration on the structured observation sheet. To minimize the intrusiveness of observations, the observer was positioned close by but slightly peripheral to the medication preparation area.

Data analysis

Data were analysed using Excel®. We used descriptive statistics to indicate the observed rate and differences of interruptions during medication preparation and double-checking pre- and post-intervention. For the comparison of reported sources of interruptions pre- and post-intervention and for the calculation of interruption duration, descriptive statistics were used as well. Statistical significance was not calculated due to small sample size.

RESULTS

Total observation time was 9 hours (524 minutes), carried out during 6 medication preparation cycles (2 pre-intervention and 4 post-intervention), and during 23 double-checking cycles (10 pre-intervention and 13 post-intervention). The observed time of medication preparation was 264 minutes (168 minutes pre-intervention and 96 minutes post-intervention) and of double-checking 260 minutes (142 minutes pre-intervention and 118 minutes post-intervention). We observed a sample of 26 nurses (12 pre-intervention and 14 post-intervention) preparing and double-checking 431 medication doses (225 pre-intervention and 206 post-intervention) for 36 patients (21 pre-intervention and 15 post-intervention).

Rates and sources of interruptions during medication preparation

The rates and sources of interruptions pre- and post-intervention are shown in Table 1. The mean interruption rates decreased from 36.8 pre-intervention to 32.1 interruptions per hour during medication preparation post-intervention 1, and to 28.3 interruptions per hour post-intervention 2. Overall, the combined intervention decreased interruptions by 23.1% (Table 1).

Pre-intervention, nearly half of all interruptions (49% [51/103]; 18.2 interruptions per hour) were caused by nursing colleagues, followed by self-initiated interruptions (27% [28/103]; 10.0 interruptions per hour).

Post-intervention 1 interruptions were most often self-initiated (32% [7/22]; 10.2 interruptions per hour), followed by interruptions caused by physicians (23% [5/22]; 7.3 interruptions per hour) and by missing patient records (23% [5/22]; 7.3 interruptions per hour). Post-intervention 2, the majority of interruptions were missing patient records (34.6% [9/26]; 9.8 interruptions per hour), self-initiated interruptions (30.8% [8/26]; 8.7 interruptions per hour) and interruptions caused by nursing staff (26.9% [7/26]; 7.6 interruptions per hour) (Table 1).

-Insert Table 1 about here-

Medication preparation	**Pre-Intervention**	**Post-Intervention step 1: after staff training**		**Post-Intervention step 2: after the introduction of safety vests**		
Sources of interruptions	**Interruptions per hour n=103 Observation duration= 1h 24 min.**	**Interruptions per hour n=22 Observation duration= 41 min.**	**Difference of interruptions compared to Pre-Intervention [%]**	**Interruptions per hour n=26 Observation duration= 55 min.**	**Difference of interruptions compared to Pre-Intervention [%]**	**Difference of interruptions compared to Post-Intervention 1: staff training [%]**
Total interruptions by colleagues	**20.0**	**10.2**	**-49.0**	**7.6**	**-62.0**	**-25.5**
▪ Nurses	18.2	2.9	-84.1	7.6	-58.3	+162.1
▪ Physicians	0.7	7.3	+928.2	0.0	-100.0	-100.0
▪ Other personnel	1.1	0.0	-100.0	0.0	-100.0	0.0
Total self-initiated interruptions	**10.0**	**10.2**	**+2.0**	**8.7**	**-13.0**	**-14.7**
Total interruptions by technology	**2.9**	**4.4**	**+53.8**	**2.2**	**-23.1**	**-50.0**
▪ Phone call	0.4	0.0	-100.0	1.1	+205.6	-
▪ Alarm	2.5	4.4	+76.0	1.1	-56.0	-75.0
Total interruptions by other disturbance / delays	**3.9**	**7.3**	**+85.3**	**9.8**	**+148.7**	**+34.2**
▪ Noise	0.4	0.0	-100.0	0.0	-100.0	0.0
▪ Missing medication	1.4	0.0	-100.0	0.0	-100.0	0.0
▪ Missing patient records	1.8	7.3	+307.8	9.8	+447.5	+34.2
▪ Other	0.4	0.0	-100.0	0.0	-100.0	0.0
Total	**36.8**	**32.1**	**-12.7**	**28.3**	**-23.1**	**-11.8**

Table 1: Observed sources of interruptions pre- and post-intervention during medication preparation

Rates and sources of interruptions during double-checking

The rates and sources of interruptions during double-checking pre- and post-intervention are displayed in Table 2. The mean interruption rates decreased from 27.5 pre-intervention to 16.4 interruptions per hour post-intervention 1, and to 15 interruptions per hour post-intervention 2 (Table 2). Overall, 45.4% of interruptions were reduced by the combined intervention. Pre- and post-intervention, the most frequent sources of interruptions during double-checking were interruptions by colleagues, especially staff interruptions by nurses, self-initiated interruptions, and missing patient records. Pre-intervention, a large number of interruptions were caused by nursing colleagues (43% [28/65]; 11.8 interruptions per hour), followed by self-initiated interruptions (28% [18/65]; 7.6 interruptions per hour) and missing patient records (5.9 interruptions per hour). Post-intervention 1 most interruptions were self-initiated (50% [9/18]; 8.2 interruptions per hour) and caused by nursing colleagues (27.8% [5/18]; 4.5 interruptions per hour). Post-intervention 2 most of the interruptions were generated by nurses (46% [6/13]; 6.9 interruptions per hour), followed by missing patient records (23% [3/13]; 3.5 interruptions per hour) and self-initiated interruptions (15% [2/13]; 2.3 interruptions per hour) (Table 2).

-Insert Table 2 about here-

Double-Checking	**Pre-Intervention**	**Post-Intervention step 1: after staff training**		**Post-Intervention step 2: after the introduction of safety vests**		
Sources of interruptions	**Interruptions per hour n=65 Observation duration= 2h 22 min.**	**Interruptions per hour n=18 Observation duration= 1h 6 min.**	**Difference of interruptions compared to Pre-Intervention [%]**	**Interruptions per hour n=13 Observation duration= 52 min.**	**Difference of interruptions compared to Pre-Intervention [%]**	**Difference of interruptions compared to Post-Intervention 1: staff training [%]**
Total interruptions by colleagues	**13.5**	**6.4**	**-52.9**	**8.1**	**-40.3**	**+26.9**
▪ Nurses	11.8	4.5	-61.6	6.9	-41.5	+52.3
▪ Physicians	1.7	1.8	+7.6	1.2	-31.7	-36.5
▪ Other personnel	0.0	0.0	0.0	0.0	0.0	0.0
Total self-initiated interruptions	**7.6**	**8.2**	**+7.6**	**2.3**	**-69.7**	**-71.8**
Total interruptions by technology	**0.4**	**0.0**	**-100.0**	**1.2**	**+173.1**	**-**
▪ Phone call	0.0	0.0	0.0	1.2	0.0	-
▪ Alarm	0.4	0.0	-100.0	0.0	-100.0	0.0
Total interruptions by other disturbance / delays	**5.9**	**1.8**	**-69.3**	**3.5**	**-41.5**	**+90.4**
▪ Noise	0.8	0.0	-100.0	0.0	-100.0	0.0
▪ Missing medication	1.3	0.0	-100.0	0.0	-100.0	0.0
▪ Missing patient records	2.5	0.9	-64.1	3.5	+36.5	+280.8
▪ Other	1.3	0.9	-28.3	0.0	-100.0	-100.0
Total	**27.5**	**16.4**	**-40.4**	**15.0**	**-45.4**	**-8.3**

Table 2: Observed sources of interruptions pre- and post-intervention during double-checking

Duration of interruptions

Overall, most of the interruptions during medication preparation and double-checking were of short duration and lasted a maximum of 10 seconds pre- and post-intervention (Figure 1). Pre-intervention, only a few interruptions lasted 2 minutes or longer. Those interruptions were eliminated post-intervention 2. In addition, the number of interruptions with a duration of 1 minute or longer decreased during medication preparation and double-checking post-intervention 2. The number of interruptions with a short duration of a maximum of 10 seconds increased during medication preparation and double-checking post-intervention 2 (Figure 1). The time for medication preparation and double-checking has generally decreased by 52% from 84 minutes for 225 doses (22 sec/dose, 4 min/patient) to 41 minutes for 206 doses (12 sec/dose, 2.7 min/patient) after the combined intervention.

-Insert figure 1 about here-

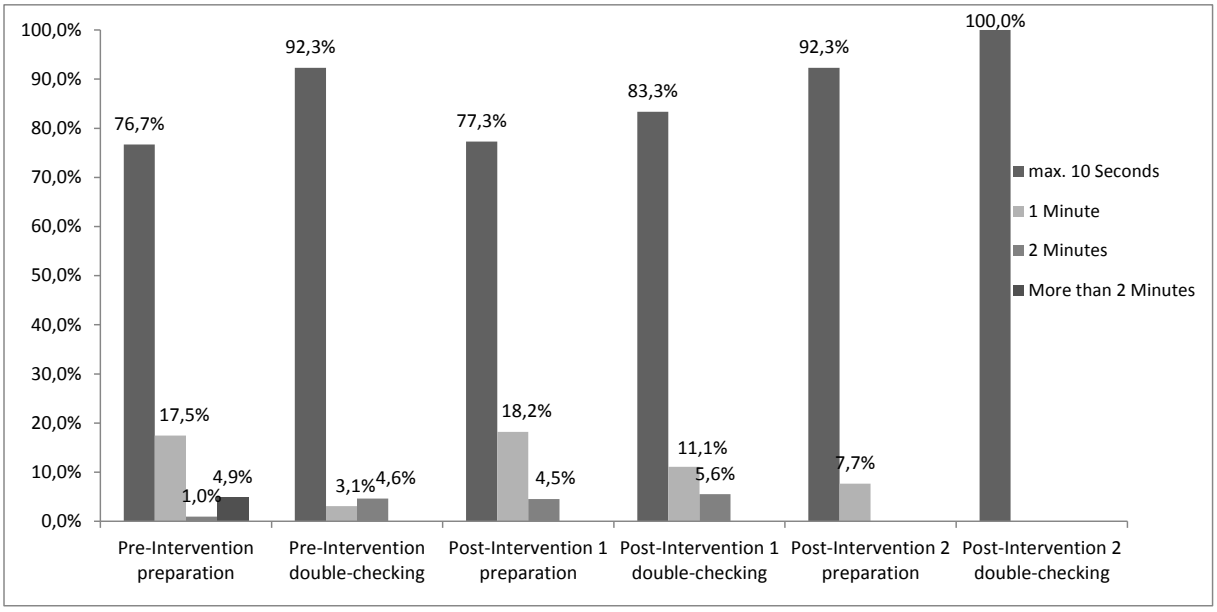

Figure 1: Duration of interruptions pre- and post-intervention

DISCUSSION

This pilot-study showed that the frequency of interruptions decreased during the critical tasks of medication preparation and double-checking after the introduction of staff training and safety vests as a combined intervention. The interruption rate during medication preparation was reduced from 36.8 to 28.3 interruptions per hour, and during double-checking from 27.5 to 15 interruptions per hour. Overall, this was a reduction of interruptions of 23.1% during medication preparation and of 45.4% during double-checking. Pre- and post-intervention during medication preparation and double-checking interruptions by colleagues, especially staff interruptions by nurses, self-initiated interruptions, and missing patient records were the most frequent sources. While all kinds of interruptions were recorded in this pilot-study, not all sources were directly addressed by the combined intervention (e.g. missing patient record, missing medications, and noise). Especially interruptions by staff, self-initiated interruptions and responding to alarms or phone calls were addressed by the combined intervention. One reason for the increase of staff interruptions by nurses post-intervention 2 in comparison to post-intervention 1 could be that staff training was more accepted by the nurses than wearing a coloured safety vest during medication preparation and double-checking; the resistance against the safety vests was rather high. However, the effect of staff training can decrease over time, and safety vests can serve as an important, continuous and visible reminder for the team not to interrupt. The increase of interruptions by physicians post-intervention 1 was probably based on the fact that they were not included in staff training and, thus, not instructed that nurses should not be interrupted during the critical task of medication preparation and double-checking. Post-intervention 2 interruptions by physicians were reduced, possibly associated with the fact that nurses did wear safety vests. Missing patient records as another frequent interruption source was not affected by the combined intervention.

However, as this is a system-related problem, which cannot be easily resolved without the implementation of electronic patient records, the lack of effect was expected. If the handling of paper-based patient records is excluded from the analysis, it is evident that the combined intervention had a positive effect on the reduction of interruptions during medication preparation and double-checking. Overall, it is an important finding that deepens our understanding of the medication use process and interruption sources to identify safety gaps. Most interruptions were of short duration and lasted a maximum of 10 seconds pre- and post-intervention. Interruptions lasting longer than 2 minutes were reduced completely post-intervention, and contributed to a reduced overall preparation time by 52%. We found no evidence that long interruptions are worse than short interruptions, but experimental studies suggested that every interruption produces negative impact on memory by requiring individuals to switch attention from one task to another. They can trigger cognitive failures, including lapses in attention, memory or perception (Biron et al., 2009c). Overall our findings show that interruptions during the critical process steps of medication preparation and double-checking are frequent and that nurses work in an environment with a high potential for interruptions. Our results are in line with studies on medication preparation (Duruk et al., 2016) and medication administration reporting an average of 42 interruptions per hour (Woloshynowych et al., 2007) and a mean interruption duration of 45 seconds (Spencer et al., 2004). In previous research, nursing colleagues were also the most frequent source of interruptions (Duruk et al., 2016), and the second most interruptions were self-initiated (Pape et al., 2005b, Kreckler et al., 2008, Pape, 2003, Relihan et al., 2010). Several studies, mainly based on self-reports, surveys or retrospective analyses, have shown that interruptions can cause medication errors (Armitage and Knapman, 2003, Fry and Dacey, 2007, Mayo and Duncan, 2004, Palese et al., 2009, Tang et al., 2007, Biron et al., 2009c, Stratton et al., 2004, Armutlu et al., 2008,

Karavasiliadou and Athanasakis, 2014, Hickam et al., 2003, Santell et al., 2003, Prakash et al., 2014, Flanders and Clark, 2010, Huckels-Baumgart and Manser, 2014, Ashcroft et al., 2005, Samaranayake et al., 2013, Hughes and Blegen, 2008). Westbrook et al. found that one interruption increases the risk of medication error by 12.1%. Without interruptions, the estimated risk of a medication error is 2.3%. This risk doubles to 4.7% if four interruptions occur (Westbrook et al., 2010). Therefore, it is important to minimise unnecessary interruptions and subsequent medication errors potentially reaching patients by increasing staff awareness of 'interruptive communication practices' and the implementation of physical barriers.

Practical implications

On many hospital wards medication preparation areas are designed as open workspaces shared by staff involved in a variety of tasks. Our pilot-study showed that frequent interruptions especially by colleagues are a major disadvantage of this workspace design and that staff training and safety vests can reduce interruptions. However, wearing the vests requires an appropriate understanding of the staff, and accompanying awareness training on the negative impact of interruptions on patient safety and on strategies to effectively manage and reduce interruptions (Tomietto et al., 2012, Pape, 2003, Pape et al., 2005b, Kliger, 2010, Relihan et al., 2010, Biron et al., 2009c). Increasing nurses' awareness of these issues may help to lower self-initiated interruptions, conversations, interruptions by colleagues and phone calls (Hohenhaus and Powell, 2008, Clifton-Koeppel, 2008, Smeulers et al., 2013). A simple but effective approach is that colleagues should acknowledge the cognitive demands of safe medication preparation and minimize interruptions whenever possible (Kliger, 2010). These interventions require little infrastructure and additional costs. Furthermore, interruptions can be reduced by

implementing separate medication rooms or 'No Interruption Zones', where interruption is not permitted or limited to urgent communication (Anthony et al., 2010, Prakash et al., 2014, Pape et al., 2005b). The availability of electronic medical records during medication preparation and double-checking is also crucial to decrease such interruptions. Interruptions during medication preparation and double-checking will probably never be eliminated completely in daily hospital practice. Correctly, safely and attentively performed double-checks can catch approximately 95% of all errors and should be applied as an added safety-net for patients (ISMP, 2013).

Limitations

First, the pilot-study was performed on a single medical ward of one hospital and therefore the findings may not be generalizable to other units, hospitals and countries. Secondly, we observed only a small medication preparation and double-checking sample, thus not addressing all sources of interruptions. Third, the combined intervention was introduced and observed during a short period of time. Thus, it is unclear how long the effect of staff training and safety vests persisted. In addition, the positive effect of the safety vest cannot be considered independently of the training conducted previously. Furthermore, participant behaviour during observation is subject to the Hawthorne effect and staff might have behaved differently when not being observed.

Future research is needed to implement effective interventions to reduce interruptions during medication preparation and double-checking. This pilot-study design could be expanded to determine if the interventions will be effective in other types of settings and evaluate their long-term impact.

In summary, interruptions of nursing staff during the preparation and double-checking of medications are frequent, especially those who are initiated by colleagues. Interruptions represent a high risk to patient safety and consequently they should be reduced. This is the first pilot-study specifically evaluated staff training and safety vests regarding the reduction of interruptions during medication preparation and double-checking. The study showed a positive effect of this combined hospital-based intervention: the combination of staff training and the wearing of safety vests with the label "Do Not Disturb" could reduce interruptions during medication preparation and double-checking, especially interruptions initiated by colleagues. While the combined intervention contributed to an improved work environment for medication preparation, nurses also need to feel empowered to speak up to discourage unwanted interruptions and conversations while preparing and double-checking medications. Additionally, these attempts will be more successful if adequately supported by work environment design. For this reason, architectural changes, for example separate medication rooms, are recommended as they present an even stronger defence against interruptions. Also, an improved work layout with direct access to medical records could eliminate these specific, unnecessary interruptions. Furthermore, for all kind of interventions an accompanying reorganization process is important. Our results highlight the relevance of considering patient safety during medication preparation and double-checking, especially until other medication safety measures such as electronic unit dose systems have been implemented for automatic medication preparation. Overall, unnecessary interruptions can be reduced successfully by increasing staff awareness of ‘interruptive communication practices’ and the implementation of physical barriers.

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Medication Preparation Interruption Observation Sheet

Ward: Date: Observation-Duration:

Shift: Nurse function: ID:

Categories	Sources of interruptions	Duration of interruptions	Number of observed interruptions	Comments
Interruptions by colleagues	**Nurses**			
	Physicians			
	Other personnel			
Interruptions by other people	**Patients**			
	Families/visitors			
Interruptions by technology	**Phone call**			
	Alarm			
Self-initiated interruptions	**Response to conversation or noise**			
	Leaves the room			
Interruptions by other disabilities / delays	**Missing Information, e.g. patient records**			
	Unclear or unreadable prescription			
	Missing medication			
Total observed interruptions	**during the preparation process**			
Total number of	**prepared drugs per patient**			
	of included patient charts			

Supplementary File A: Medication Preparation Interruption Observation Sheet

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7. Curriculum Vitae

PERSONAL

Saskia Huckels-Baumgart

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EDUCATION

10/2012 - present	PhD student (part time), Department of Psychology; University of Fribourg/Switzerland
04/2005 - 08/2009	Study of Health Care Management; University of Cologne
	Degree: Diploma in Health Care Management

PROFESSIONAL EXPERIENCE

02/2016 - present	Project manager; Quality Management & Patient Safety;
	University Hospital Zürich
08/2014 – 12/2016	Researcher; Institute for Patient Safety;
	University Hospital Bonn
07/2011 - 08/2014	Quality Manager with focus on Patient Safety;
	Department of Quality and Risk Management;
	Luzerner Kantonsspital, Lucerne/Switzerland
11/2009 - 07/2011	Trainee (funded by the Robert Bosch Stiftung);
	Department of Quality and Change Management;
	Robert Bosch Krankenhaus GmbH; Stuttgart

QUALIFICATION

AWARDS

2015	Wilfried-Lorenz health services research award for the article: "Identifying medication error chains from Critical Incident Report - a new analytic approach" published 2014 in Journal of Clinical Pharmacology together with Prof. Dr. Tanja Manser

PUBLICATIONS

ARTICLES & PAPERS

Huckels-Baumgart, S.; Baumgart, A.; Buschmann, U.; Schüpfer G.; Manser, T. (2016): Separate Medication Preparation Rooms Reduce Interruptions and Medication Errors in the Hospital Setting: A Prospective Observational Study. Journal of Patient Safety.

Manser, T., Berning, D. & Huckels-Baumgart, S. (2016). Checklisten & Co: Instrumente zur Förderung der Patienten-sicherheit in der Chirurgie. Allgemein- und Viszeralchirurgie up2date.

Huckels-Baumgart, S. & Manser, T. (2014). Identifying medication error chains from critical incident reports - a new analytic approach. Journal of Clinical Pharmacology, 54(10), 1188-1197.

POSTERS

Huckels-Baumgart, S., Berning, D. et. al.„Medication Reconciliation in the high 5s-project: results of the German hospitals“. ISQUA Conference, 4.-7.10.2015, Qatar (präsentiert durch Daniel Berning).

Huckels-Baumgart, S., Manser, T.: Separate medication preparation rooms reduce interruptions and medication errors: an intervention study in two wards. BSAS Conference, 09.-10.10.2015, Bonn.

Huckels-Baumgart, S. et. al. „Medication Reconciliation im High 5s-Projekt: Zwischenergebnisse der deutschen Krankenhäuser“. 10. Jubiläum des Aktionsbündnisses Patientensicherheit, 16.-17.04.2015, Berlin.

Huckels-Baumgart, S. et. al. „Medication Reconciliation in the high 5s-project: interim results of the German hospitals“. PASQ Conference, 12.12.2014, Helmond.

Huckels-Baumgart, S., Dr. Ute Buschmann et. al. „Medication Errors - analysis of critical incident reports and the perception of physicians and nurses in a teaching hospital“, COME Conference, 03/2013, Ascona.

Huckels-Baumgart, S., Dr. Ute Buschmann et. al. „Analysis of critical incident reports in an academic teaching hospital – error categorisation of medication events“,ISQua, 10/2012, Genf.

Huckels-Baumgart, S., Dr. André Baumgart et. al. „Medikamentenfehler in der Anästhesie: systematische Analyse der Inzidenz in Notfall- und Routinebetrieb auf Basis von Berichten aus CIRS - AINS“,DAC, 05/2012, Dresden.

Huckels-Baumgart, S., Dr. Ute Buschmann et. al. „OP-Sicherheitschecklisten zur Verbesserung der Patientensicherheit - eine Bilanz 2 Jahre nach Einführung“, Patientensicherheit in Aktion, 04/2012, Berlin.

Huckels-Baumgart, S., Dr. Ute Buschmann et. al. „Fehlerketten im Medikamentenmanagement – Fehlerarten, Ursachen und mögliche Sicherheitsbarrieren“, Huckels et. al., Kongress Patientensicherheit, 11/2011, Bern.

ORAL PRESENTATIONS

Huckels-Baumgart, S. (2016). Pre-Conference Workshop Medication Reconciliation, APS Jahrestagung, 14.-15.04.2016, Berlin.

Huckels-Baumgart, S. (2016). “Fehlerketten als neuer Anlayseansatz”, APS Jahrestagung, 14.-15.04.2016, Berlin.

Huckels-Baumgart, S. (2016). “Fokussiertes Reporting”, APS Jahrestagung, 14.-15.04.2016, Berlin.

Huckels-Baumgart, S. (2015). „Fehler nutzen – aus kritischen Ereignissen lernen“. AGRBM Fortbildung „Fehlermanagement im ART-Labor“, 31.10.2015, Aachen.

Huckels-Baumgart, S. (2015). „Identifying medication error chains from critical incident reports: A new analytic approach“. Deutscher Kongress für Versorgungsforschung im Rahmen der Wilfried-Lorenz-Verorgungsforschungspreisverleihung“, 07.-09.10.205, Berlin.

Huckels-Baumgart, S. (2015). „CIRS Workshop: Richtig melden: Darauf kommt es an!“. CIRS Gipfel NRW 2015, 30.09.2015, Uniklinik Düsseldorf.

Huckels-Baumgart, S. (2015). High 5s-Projekt – Medication Reconciliation Evaluation, High 5s Abschlussveranstaltung. 01.-02.06.2015, Bundesärztekammer Berlin.

Huckels-Baumgart, S. (2013). „Klinisches Risikomanagement in der Praxis – CIRS und Medikationssicherheit am LUKS“, Qualitätszirkel, Psychiatrische Klinik Zugersee.

Huckels-Baumgart, S. (2012). „Medikationssicherheit am LUKS“, Risikomanagement AG SQMH, Waidspital Zürich.

Ehrenwörtliche Erklärung

Ich erkläre ehrenwörtlich, dass ich meine Dissertation selbständig und ohne unzulässige fremde Hilfe verfasst habe und sie noch keiner anderen Fakultät vorgelegt habe.

Saskia Huckels-Baumgart

Luzern, 08.08.2016