HIGH-RELIABILITY IN HEALTHCARE: NURSE-REPORTED PATIENT SAFETY CLIMATE AND ITS RELATIONSHIP WITH PATIENT OUTCOMES IN SWISS ACUTE CARE HOSPITALS

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LIST OF ABBREVIATIONS

ACM	Accident Causation Model
AE(s)	Adverse event(s)
AHRQ	Agency for Healthcare Research and Quality
BERNCA	Basel Extent of Rationing in Nursing Car
CIRRNET	Critical Incident Reporting and Reacting NETwork
CIRS	Critial Incident Reporting System
CVI	Content Validity Index
DRGs	Diagnoses Related Groups
EU	European Union
HFMEA™	Healthcare Failure Mode and Effect Analysis
HSOPSC	Hospital Survey on Patient Safety Culture
I-CVI	Item Content Validity Index
ICD	International Classification of Disease
IHOS	International Hospital Outcome Study
IOM	Institute of Medicine
MSI	Modified Stanford Patient Safety Culture Survey Instrument
PARiHS	Promoting Action on Research Implementation in Health Services
PDCA	Plan-Do-Check-Act
PDSA	Plan-Do-Study-Act
PES-NWI	Practice Environment Scale from the Nurse Work Index
PSC	Patient Safety Climate
PSCHO	Patient Safety Culture in Healthcare Organizations Survey
PSIs	Patient Safety Indicators
RICH	Rationing in Nursing Care in Switzerland
RN(s)	Registered Nurse(s)
RN4CAST	Nurse Forecasting: Human Resources Planning in Nursing
S-CVI/Ave	Scale Content Validity Index/Average Method
SAQ	Safety Attitudes Questionnaire
SEIPS	System Engineering Initiative for Patient Safety
SOS	Safety Organizing Scale
WHO	World Health Organisation

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Conducting research, publishing articles and completing this dissertation, I have sometimes imagined myself as the protagonist of a superhero film. According to the conventions of the genre, a more or less ordinary person who can fly, spin webs, or buy bat-themed gadgets (i.e., not typically a PhD student) is intrinsically motivated to combat injustice (though not typically in the healthcare system) and to protect the public. He works alone and generally incognito to resolve diverse and apparently insoluble problems.

In my version, like Superman, Spiderman or Batman, I have battled seemingly insurmountable forces. However, my adversaries are not, for the most part, evil scientists or manic sociopaths, but medication errors, nosocomial infections, patient falls, uncooperative publishers and recalcitrant reviewers. And there is another more important difference. I have never worked alone: from the beginning of this adventure I have always been part of a super team. Therefore, I wish to dedicate this section to all the "superheroes" who have contributed to the preparation and realization of this dissertation project.

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Hanna Burkhalter, Monika Kirsch and Dr. Lut Berben for their support and generosity in sharing their experiences, ideas and insights with me during lunch hours, coffee breaks and “beer support” meetings. Over the last three years we have become not only esteemed colleagues, but also good friends. It is difficult to express in words how grateful I am for our friendship, which has filled this adventure not only with professional experience but also with interpersonal relationships.

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PREFACE

This dissertation project was imbedded as a sub-study in the multicentre cross-sectional Swiss RN4CAST study (Nurse Forecasting: Human Resources Planning in Nursing), using nurse and patient survey data. As part of the RN4CAST consortium, which consisted of 12 European countries, the University of Basel's Institute of Nursing Science conducted the Swiss arm of the international RN4CAST study. Funded by the EU 7th Framework (EU Project number: 223468), this was led by the Centre for Health Services and Nursing Research, Katholieke Universiteit Leuven (Belgium) and co-led by the Center for Health Outcomes and Policy Research at the University of Pennsylvania (USA). The RN4CAST built upon the International Hospital Outcomes Study (IHOS), an internationally recognized study on the organization of nursing care in hospitals [1]. Led by Prof. Linda Aiken of the Center for Health Outcomes and Policy Research at the University of Pennsylvania, the IHOS study revealed associations between nurse-related organizational variables, such as the quality of the nurse work environment, nursing staff deployment (number and qualification), negative nurse outcomes (e.g., burnout, job dissatisfaction) and adverse patient outcomes (e.g., mortality, failure-to-rescue) [2-4].

As one of the largest nurse workforce studies ever conducted worldwide, the RN4CAST study aimed to enrich and refine traditional nurse workforce forecasting models by considering how features of the work environment impact outcomes for both nurses (e.g., retention, burnout) and patients (e.g., mortality, patient satisfaction). Using a cross-sectional design, it was conducted between 2009 and 2011. Via nurse and patient surveys, as well as hospital administrative and patient discharge data, the RN4CAST teams assembled and analysed data on a set of nurse-related organizational factors including the nurse work environment, nurse staffing and educational level, and outcomes for nurses (e.g., job satisfaction, burnout) and patients (e.g., patient satisfaction). The resulting data enable the simulation of scenarios to illustrate how changes to organizational factors might improve nurse workforce planning and help ensure a nurse workforce that is adequate for future care requirements [5].

To enable comparability of data across countries, the international RN4CAST study protocol standardized all necessary data collection procedures and survey instruments. For example, every version of the international nurse questionnaire focused on important nurse-related organizational variables such as the nurse work environment, nurse staffing and educational level, job satisfaction and burnout. However, this questionnaire only partially covered elements of safety climate, which is considered a separate organizational factor regarding patient safety and quality of care [6]. As the study protocol allowed each country a degree of flexibility (e.g., to consider country-specific characteristics of the healthcare system and the nursing workforce), based on our research interests in the field of patient safety and quality, as included in the research portfolio of the University of Basel's Institute of Nursing Science, the Swiss RN4CAST team decided to make use of this flexibility. We extended the nurse questionnaire by integrating the Safety Organizing Scale, which reflects elements of the patient safety climate. The translation, validity and reliability testing of this measure not only enabled this dissertation project, but added value to the Swiss RN4CAST study, as it allowed us to illuminate this important issue on a national level for the first time.

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SUMMARY

Healthcare is a high-risk industry. Worldwide, healthcare systems struggle daily to keep patients safe and protect them from harm. Still, every day, countless errors occur. Most are minor and pass unnoticed; however, a significant proportion result in adverse events such as pressure ulcers, patient falls, or healthcare-associated infections, with consequences for patients ranging from discomfort to mortality [6-10]. Today, a close focus on patient safety, i.e., "the continuous identification, analysis and management of patient-related risks and incidents in order to make patient care safer and to minimize harm to patients" [11, p. 9], is a key component of high-quality care [12, 13]. Conversely, as in other high-risk industries, such as aviation or nuclear power, adverse events should be viewed not as failures of individual healthcare professionals but as symptoms of system vulnerability [14-16]. And, as experience in those industries has shown, the majority of "human error" in healthcare originates not with poorly performing individuals, such as nurses, physicians, or other providers, but with faulty systems / processes such as stressful environments, heavy workloads or inadequate communication [17, 18].

To overcome such systemic defects, a growing number of international experts agree that a well-developed "culture of safety" is fundamental to understanding patient safety mechanisms and preventing adverse events [13, 19]. Other high-risk industries regularly evaluate and improve their safety cultures via workforce surveys designed to assess and monitor safety climate (i.e., the perceived safety culture of a particular group at a particular time) [20]. Since the 1999 publication of *To Err is Human* [21], safety culture and climate have attracted increasing interest in healthcare, leading to major advances in patient safety climate research, particularly regarding instrument development and psychometric evaluation [22-24]. To date, though, few studies have investigated the relationship between patient safety climate, adverse event incidence and patient outcomes [24-29].

Overall, this dissertation's aim is to describe the results of 4 studies designed first to test nurse-reported patient safety climates in Swiss acute-care hospitals, then to analyze for relationships with possible contributing factors (e.g., characteristics of Swiss acute care hospitals) and consequences (e.g., patient outcomes). Three of these studies used survey data originally collected for the Swiss RN4CAST (Nurse Forecasting: Human Resources Planning in Nursing) study, including data from 1,633 nurses and 997 patients on 132 general medical, surgical and mixed medical/surgical units in 35 Swiss acute care hospitals.

The dissertation is organized in **7 chapters**:

Chapter 1 introduces the problematic issue of patient safety and adverse events, as well as of human contributions to error. Emphasis is placed on the importance of understanding human factors, including organizational safety-related behaviors / perceptions, i.e., organizational safety culture / climate, regarding understanding and minimizing human errors and their underlying system defects. An overview is provided of the state of safety climate research in healthcare, and the conceptual framework of this dissertation project is presented. In the final part of the introduction, gaps in the scientific literature are summarized, along with this dissertation's contribution to narrowing those gaps. **Chapter 2** describes the aims of this dissertation, including the translation and first psychometric testing of the German, French and Italian versions of the Safety Organizing Scale. Findings addressed in four component studies are reported (**Chapter 3** to **Chapter 6**).

Chapter 3 presents the results of a German study describing the translation process according to the adapted Brislin translation model for cross-cultural research [30]. In addition, based on content validity rating and calculations of content validity indices at the item and scale levels, the content validity testing results for the German version of the Safety Organizing Scale (SOS) are described.

Chapter 4 presents our initial evidence regarding the validity and reliability of the German-, French- and Italian-language versions of the SOS. For each translation, psychometric evaluation revealed evidence based on content (scale-content validity index > 0.89), response patterns (e.g., average of missing values across all items = 0.80%), internal structure (e.g., comparative fit indices > 0.90, root mean square error of approximation < 0.08) and reliability (Cronbach's alpha > 0.79). We differentiated the SOS regarding one related concept (implicit rationing of nursing care). At the individual level, higher SOS scores correlated with supportive leadership and fewer nurse-reported medication errors, but not with nurse-reported patient falls. The results suggest that the SOS offers a valuable measurement of engagement in safety practices that might influence patient outcomes, including adverse events. Further analysis using more reliable outcome measures (e.g., mortality rates) will be necessary to confirm concurrent validity.

Chapter 5 reports on our study describing nurse reports of patient safety climate and nurses' engagement in safety behaviors in Swiss acute care hospitals, exploring relationships between unit type, hospital type, language region, and nurse-reported patient safety climate. Of the 120 units included in the analysis, only on 33 (27.5%) did at least 60% of the nurses rate their patient safety climates positively. The majority of participating nurses (51.2-63.4%, n=1,564) reported that they were "consistently engaged" in only three of the nine measured patient safety behaviors. Our multilevel regression analyses revealed both significant inter-unit and inter-hospital variability. Of our three variables of interest (hospital type, unit type and language region) only language region was consistently related to nurse-reported patient safety climate. Nurses in the German-speaking region rated their patient safety climates more positively than those in the French- and Italian-speaking language regions. This study's findings suggest a need to improve individual and team skills related to proactively and preemptively discussing and analyzing possible unexpected events, detecting and learning from errors, and thinking critically about everyday work activities/processes.

Chapter 6 presents the results of our explorative study of the associations between nurse-reported patient safety climate, nurse-related organizational variables and selected patient outcomes. In none of our regression models was patient safety climate a significant predictor for medication errors, patient falls, pressure ulcers, bloodstream infections, urinary tract infection, pneumonia, or patient satisfaction. However, from the nurse-related organizational variables, implicit rationing of nursing care emerged as a robust predictor for patient outcomes. After controlling for major organizational variables and hierarchical data structure, higher levels of implicit rationing of nursing care resulted in a significant decrease in the odds of patient satisfaction (OR = 0.276, 95%CI = 0.113 to 0.675) and a significant increase in the odds of nurse reported medication errors (OR = 2.513, 95%CI = 1.118 to 5.653), bloodstream infections (OR = 3.011, 95%CI = 1.429 to 6.347), and pneumonia (OR = 2.672, 95%CI = 1.117 to 6.395). Overall, our findings did not confirm our hypotheses that PSC is related to improved patient outcomes. Given the current state of research on patient safety climate, then, the direct impact of PSC improvements on patient outcomes in general medical / surgical acute-care settings should not be overestimated. As a structural component of the work environment, PSC might influence the care process (by calling attention to rationing of nursing care) and thus have only an indirect effect on patient outcomes. Testing this possibility will require further analyses.

Finally, in **Chapter 7,** major findings of the individual studies are synthesized and discussed, and methodological strengths and limitations of this dissertation are discussed. Furthermore, implications for further research and clinical practice are suggested. The findings of this dissertation add to the existing literature the first evidence regarding validity and reliability of the German, French and Italian versions of, the Safety Organizing Scale, a patient safety climate measurement instrument. Our findings did not confirm the underlying theoretical assumption that higher safety climate levels are related to improved patient safety and quality. Although these findings suggest the need to im-

prove of patient safety climate on general medical, surgical and mixed medical/surgical units in Swiss hospitals, it remains unclear whether improving nurses' engagement in safety behaviors will lead to improved patient safety outcomes (e.g., reduced occurrence of adverse events). This dissertation will contribute to the further development of safety culture and climate theory and raises methodological issues that will require consideration in future studies.

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CHAPTER 1

INTRODUCTION

1. INTRODUCTION

Modern healthcare systems combine human interactions, processes and technologies to serve ever-greater target populations. However, one principle has remained constant throughout medical history: healthcare has always involved a risk that the cure can become worse than the disease. In 1999, in a striking report titled "To Err is Human", the American Institute of Medicine (IOM) presented evidence that modern healthcare was seriously flawed in terms of patient safety. In the USA, hospital-based errors were reported as the eighth leading cause of death, ahead of breast cancer, AIDS and motor vehicle accidents [1].

Patient safety is defined as "the continuous identification, analysis and management of patient-related risks and incidents in order to make patient care safer and to minimize harm to patients" [2, p. 9]. In simpler terms, patient safety means protecting patients from harm. Today, alongside other key quality principles such as effectiveness, efficiency, accessibility, patient-centeredness and equitability,[3] safety is recognized as the "emotional heart" of healthcare[4, p. ix]; and unless it is safe, we cannot consider it to be of high quality [5]. Unfortunately, the available evidence suggests not only that patient safety is difficult to improve, but that the risk of harmful errors in health care may even increase in the future. As new devices, equipment, procedures, and drugs increase the complexity of care delivery, they also increase the likelihood of error and harm [6], i.e., it is becoming increasingly difficult for healthcare professionals to contribute to the reliability and resilience of their healthcare organizations. For example, at the interface between patients and their healthcare systems, nurses play a major role in patient protection. As the largest group of healthcare professionals, they act as a round-the-clock human "surveillance system" [7]. However, their daily duties often involve systems / processes and conditions that hinder their ability to prevent, detect or correct errors [1].

Over the last twelve years, patient safety has become a major area of public discussion and debate [8]. Societies' acceptance and awareness of this challenge has increased on healthcare's micro- (clinicians and patients), meso- (healthcare organizations), and macro- (policy maker) levels, fostering widespread determination to overcome safety and quality problems [4]. Besides the USA's Institute of Medicine, other major international and national policy institutions, such as the World Health Organization [9], the International Council of Nurses [10], the Institute for Healthcare Im-

provement [11] and the National Patient Safety Agency [12] have all placed patient safety and quality at the top of their agendas, launching numerous quality improvement and research initiatives. Efforts to improve the quality and safety of healthcare have included approaches such as redesigning professional education, reengineering systems of care according to practice guidelines, increasing competition among organizations, publicly reporting quality data, implementing performance-based rewards or sanctions, and applying continuous quality improvement or total quality management tools from other industries [6]. Consequently, over the same period, awareness of patient safety issues – disseminated in articles, books, reports, websites and other media – has increased significantly [13, 14].

However, the question remains open as to whether these efforts and investments have also increased our ability to improve patient safety. We have certainly – often painfully – learned that keeping patients safe is much more difficult than it sounds. Despite their many improvements, healthcare systems are still struggling to create "cultures" hardy enough to achieve and sustain high levels of safety and quality performance over time [6]. One point is certain: there will be no quick or simple solutions. Patient safety is a multifactorial problem in view of cultural, technical, clinical and psychological issues within healthcare systems and their care-providing institutions [4]. Minimizing the likelihood of errors during care processes will demand the full commitment of all healthcare disciplines and actors in a broad range of activities at every social, professional, and institutional level [15]. More than 10 years after the IOM's report we have to recognize that patient safety is not a destination [16] but a journey, and one which has just begun. In this sense, this dissertation offers one course of many in the direction of increased healthcare reliability.

1.1 Adverse events – The magnitude of a problem in healthcare

Every day countless errors occur in every healthcare institution. Fortunately, only a small proportion of those errors, whether they occur during clinical procedures or result from clinical decisions, result in adverse events, i.e., lead to patient harm. An adverse event (AE) is "an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition of the patient" [17, p. 4]. "Medical intervention includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. AEs may be preventable or non-preventable" [18, p. 8]. The Institute of Medicine's definition of an AE focuses only on medical injuries, i.e., AEs that occur secondarily to errors in medical management. The WHO [18] definition of an AE is somewhat more inclusive: the outcome of a vulnerable system where all healthcare disciplines – including nurses – influence the quality of care and patient safety. Indeed, an increasing body of evidence consistently supports the relationship between nursing care and patient safety outcomes, including pressure ulcers, healthcare-associated infections, length of stay, and even 30-day mortality [19-23, 24].

According to international studies, between 2.9% and 16.6% of hospitalized patients are affected by AEs such as surgical (peri- and post-operative) complications, medication errors, healthcare-associated infections, and injuries including patient falls [4, 25-29]. Up to 33% of these adverse events occur due to negligence and over one-third lead to temporary (34%) or permanent disability (6-9%). Between 3% and 20.8% of patients experiencing AEs die: their risk of in-hospital death is seven times higher than that of patients without treatment-related complications. Between 36.9% and 70% of all AEs are considered preventable [26, 27, 29-31].

In addition to the personal suffering and costs the patients must bear, AEs result in additional healthcare system costs. Considering that one AE typically increases the affected patient's length of stay by 3.6 - 8.5 days (range 0-70 days) [29-31], the repercussions are discernable even at the level of national economies [30-32]. One Australian study estimated that the total annual cost of AEs in that country was 460,311 million Australian dollars, representing 15.7% of the total expenditure on direct hospital costs, or 18.6% of the total national inpatient hospital budget. Adjusting for age and co-morbidities, the average AE added $6,826 to the cost of hospitalization [32]. The direct costs of nurse-sensitive AEs (for which nurses are responsible) were estimated at between $1,029 and $1,160 [24].

Apart from direct medical and legal costs, AEs burden patients' human costs including pain, psychological trauma, loss of trust in the healthcare system, loss of independence, impaired functionality and loss of productivity [1, 33]. Still another class of damage remains largely unnoticed: the human costs to the involved healthcare professionals. As the "second victims" of AEs, they are often affected by loss of confidence and satisfaction, depression, stress, frustration, shame and guilt [34, 35]. Indeed, it has recently been noted that, considering the non-tangible consequences to patients, healthcare professionals and societies, the problem of AEs is likely much greater than previously thought [36].

Part of the problem of dealing with AEs is that they often go unreported. Less expensive approaches to AE detection include the Patient Safety Indicators, developed by the Agency for Healthcare Research and Quality, which use automated review of discharge codes (ICD-9 or ICD-10 codes) or Critical Incident Reports. However, as both methods are affected by underreporting by healthcare professionals, its credibility is limited for public reporting and organizational performance comparisons [37]. Previous studies, e.g., the Harvard Medical Practice Study [38] used a two-stage process (trained nursing staff, physicians) for screening records for AEs. However, many of these case note review studies used non-standard definitions, settings, methods of data collection and classification [8, 39]. One promising approach is the Institute for Healthcare Improvement's Global Trigger Tool, refined by the Harvard Medical Practice Study [38]. This consists of an extensive and systematic chart review by two or three professionals (e.g., nurses and pharmacists) for a trigger word or condition for an AE, such as intra-op or post-op death. Any notation of a trigger leads to further investigation into whether an AE occurred and, if so, its severity [37, 40]. A recent study using the Global Trigger Tool revealed that AEs

in hospitals might be up to ten times more common than previously reported, as earlier methods missed all but the most serious incidents (up to 90%). With a sensitivity of 94.5% and a specificity of 100%, the Global Trigger Tool detected AEs in one-third (33.2%) of hospital admissions. In spite of the high number of patients affected, though, this study confirmed that medication errors, surgical complications and healthcare-associated infections were the most common types of AEs [36].

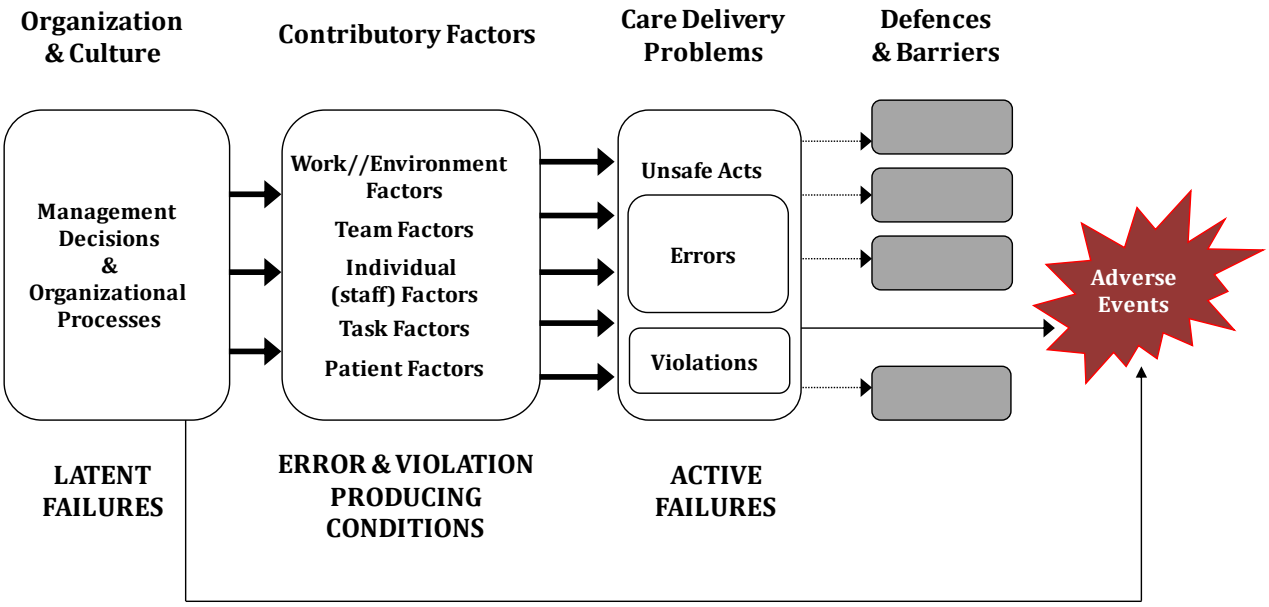
1.2 Understanding adverse events: The human contribution

Donald Berwick, outgoing Administrator of the USA's Centers for Medicare and Medicaid Services and former President of the Institute for Healthcare Improvement, observed that "*each system achieves exactly the results it was designed to get".* Due to the high numbers of AEs, the famous IOM report [17] compared conditions in healthcare with those of high-risk industries, such as aviation. One of the report's main conclusions is that, as in other high-risk industries, the majority of medical errors in healthcare are not the result of poorly performing individuals, such as nurses, physicians, or other providers. More commonly, human errors are caused by faulty systems, whose processes depend on unreliable components of human performance, such as memory or vigilance, and thus provide conditions that lead people to make mistakes or fail to prevent them. Examples include heavy workloads, inadequate expertise, stressful environments or inadequate communication [1].

Although not the IOM's primary objective in producing *To Err is Human,* that report paid close attention to principles of system thinking and human factors, i.e., the strengths and limitations of „human beings and how they interact with products, devices, procedures, work spaces, and the environments encountered at work and in daily living" [41, p. 1]. This means that the tasks that healthcare professionals perform, the technology they use, the environment in which they work, and the organizational decisions that impact their work activities may or may not be a good fit for their strengths and limitations. When system factors and the sensory, behavioural, and cognitive characteristics of healthcare professionals are poorly matched, human errors and sub-optimal patient outcomes are more likely to occur [41]. However, the term „human error" is still negatively associated with lack of attention, reckless behaviour, individual failure or the allocation of blame. Thus, besides recognizing human errors rather as a consequence than a cause, understanding organizational behaviours and system errors is fundamental to reducing the incidence of AEs and improving patient safety [9].

To understand the reasons behind a human error, it is necessary to look back to organizational "error and violation producing conditions" that may have contributed to it, including relevant decisions made by management and others [1, 4]. Several sociotechnical models on interrelated system factors are described in the literature [41], many of which provide models illustrating how organizational system factors can lead to human errors and adverse events. For example, Charles Vincent et al. have adapted James Reason's Accident Causation Model (ACM) for use in healthcare. The adapted ACM [42] provides an excellent overview of the dynamic multifactorial flow leading to an accident (Figure 1).

Figure 1: Adapted Vincent Accident Causation Model [4]



The process leading to an AE begins with "latent failures" in decision-making and organisational processes at the hospital management level (e.g., strategy, planning, scheduling, forecasting), which affect factors at the unit level, such as the work environment or the team, leading to an accumulation of „error and violation producing conditions". Vulnerabilities inherent to these organizational factors increase the likelihood that health care professionals, including nurses, will make or fail to prevent mistakes. If defences and barriers at the end of this causal pathway fail, e.g., patients are not engaged as vigilant partners [43], human errors can result in AEs.

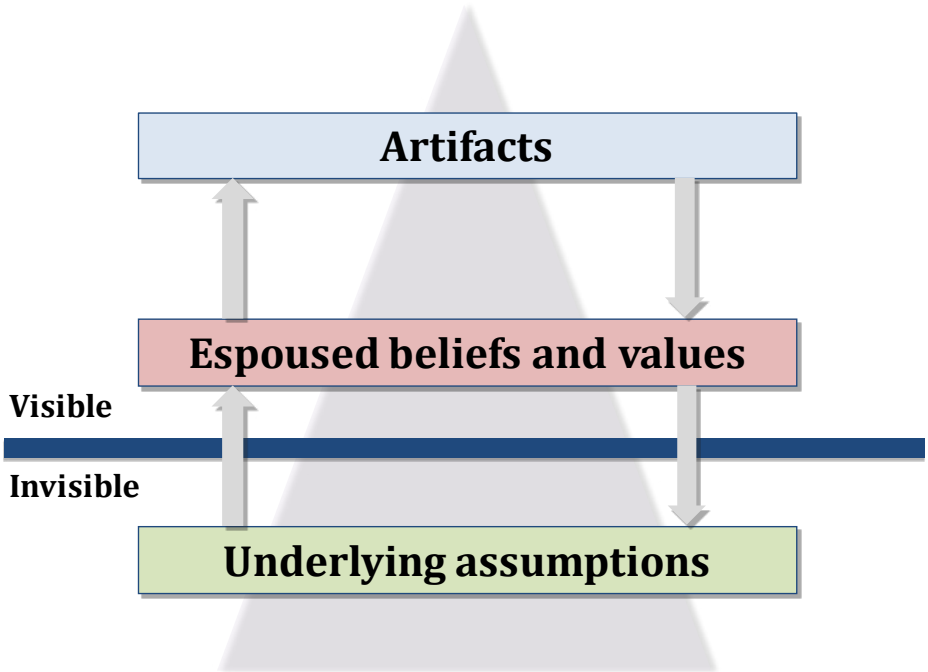
1.3 Promoting patient safety through a "culture of safety"

In the search for ways to reduce the incidence of AEs and to improve overall safety and quality, an increasing body of evidence suggests that the most effective solutions focus on care delivery system defects that give rise to errors [44-46]. Internationally, experts recommend that every healthcare organization develop a "culture of safety" to overcome such system defects [4, 42].

Safety culture is a component of organizational culture [47], which is, in turn, imbedded in healthcare culture and ultimately in national culture [48]. Yet, while the concept of „culture“ has long interested anthropologists, sociologists, psychologists and political scientists, [49] there is little consensus, either across or within disciplines, as to what the term denotes [50]. For instance, from an anthropological perspective culture can be defined as “the system of shared beliefs, values, customs, behaviors, and artifacts that the members of society use to cope with their world and with one another, and that are transmitted from generation to generation through learning” [51].

Edgar H. Schein, one of the founders of the field of modern organizational psychology, was the first to use this definition of “culture“ and to employ it to denote subsystems of societal organizations. According to his model, “organizational culture“ is consisting of three layers: (1) “*Artifacts*” are visible components, such as architecture and other physical surroundings; (2) “*Espoused beliefs and values*“ are those attitudes championed within an organization; and (3) “*Underlying assumptions*“ are often unconscious determinants of an organization’s attitudes (see Figure 2). These assumptions are fundamental to any culture, as they have often become so implicit that individuals are unaware of their influence. Another characteristic of Schein’s model is that the closer we focus on underlying assumptions, the less visible / observable the organizational culture will be [52].

Figure 2: Schein’s organizational culture model [52]



In the context of organizational culture, the term "safety culture" was first coined in 1986 in the nuclear industry following the Chernobyl disaster. From there, it was adopted in other high-risk fields, notably the petrochemical and aviation industries [53]. The IOM's publication of *To Err is Human* sparked a similar demand within healthcare systems for a patient safety culture [1].

However, more than a decade later, there is still not consensus on the conceptualization, definition and operationalization of safety culture, as the combination of a positively-connoted concept (*safety*) with one that is neutrally connoted (*culture*) makes it a challenging endeavor for researchers [49]. The theoretical background of patient safety culture research lies mostly in industries more traditionally regarded as high-risk. For instance, the five most frequently cited theories in healthcare studies are (1) high-reliability organization theory, (2) the cultural maturity model, (3) Donabedian's quality of care model (and its adaptations [54, 55], (4) organizational theory and (5) system theory, of which only Donabedian's model on structure, process and outcome focuses primarily on healthcare [56].

Recently, another safety culture feature of "high-reliability organizations" (as a subset of high-risk industries) is attracting interest. Research has revealed that a key aspect of their safety culture, facilitating the maintenance of excellent performance, is "collective mindfulness", i.e., a shared motivation to discover and correct errors before they result in negative outcomes [57]. In broad terms, high-reliability organizations encourage their workers to take note of any unexpected development, then to halt or contain it [6, 57]. Successfully implemented systems share 5 conditions: First, employees are *preoccupied with failure,* regarding any small lapse as a possible precursor of a major event. Second, they *resist oversimplification*, as they welcome diversity and scepticism to create a more complete picture of the complex, unstable and unpredictable world. Third, employees have well-developed situational awareness, noticing anomalies during operations and making continuous adjustments (i.e., *sensitivity to operations*). Fourth, they are *committed to resilience*, i.e., keeping errors small and improving work environments to maintain system stability. Fifth, high-reliability organizations promote front-line decision making by the people with the most expertise (i.e., *deference to expertise*). By applying specific behaviors related to these five principles, front-line employees are able to stay mindful and perform work safely even in hazardous environments [6, 57].

Despite differing theoretical underpinnings and numerous definitions of safety culture, it is generally agreed that safety culture is a subset of organizational culture, which refers to the members of an organization's shared attitudes, values, norms and beliefs regarding risk and safety [53, 58, 59]. For example, recent studies have shown that organizational culture and patient safety culture are positively related. More specifically, more developed levels of patient safety culture emerged in hospitals with organizational cultures emphasizing group orientation [47] and reduced hierarchy [47, 60]. One key factor of organization-wide safety culture is senior leadership accountability. En-

gaged leaders can drive safety culture via strategies and structures that guide safety processes and outcomes. Conversely, a lack of leadership can seriously hinder the development of a patient safety culture [59]. Other properties of a patient safety culture described in the literature are teamwork, open communication founded on trust, organizational learning, non-punitive, blame-free approaches to AE reporting and analyses, evidence-based, patient-centered care, and a shared belief in the importance of safety [56, 59].

Another term often confused with patient safety culture is "safety climate". Although culture and climate are used inconsistently in the related literature and the concept of safety climate is closely related to safety culture, the two terms apply to different concepts [61]. First, culture and climate can be differentiated based on Schein's framework, which describes three levels of organizational culture, each of which includes its own level of safety culture. The concept of safety climate, on the other hand, applies chiefly to the level of espoused beliefs and values, observable and measurable attitudes concerning safety. Basic assumptions, the core of an organization's safety culture, are difficult to measure and need not relate directly to safety [53]. In fact, Sexton et al. [62] suggest that "safety climate" is the appropriate term for the most measurable group-level perceptions and attitudes acting on an overall safety culture. Therefore safety climate can be considered as the surface features of safety culture [63].

Safety climate and safety culture can also be distinguished based on their underlying research paradigms (respectively positivism versus constructivism). As culture research is rooted in sociology and anthropology, it uses mainly qualitative research methods, such as interviews or focus groups, to focus on personal, subjective expressions of culture and the dynamic processes of creating and shaping it. However, climate research, with roots in social and organizational psychology, focuses more on collective indicators of organizational / safety conditions, mainly in terms of sets of dimensions, and mainly through surveys. Measuring the safety climate in healthcare can help to depict the underlying safety culture of a work unit or a whole organization. As such quantitative measurement applies only to a particular place at a particular time, it is subject to short-term fluctuations [64]. To assess such a complex social construct, the best methodological approach might be to combine quantitative (deductive) and qualitative (inductive) research methods. Mixed-method research exploits the strengths of both approaches and may help to develop an overall view of an organizational safety culture by depicting all three layers of Schein's model (i.e., artifacts, espoused beliefs and values and underlying assumptions).

1.4 State of research: What do we know about patient safety climate?

To depict the state of a healthcare organization's patient safety climate, the most popular strategy is to survey healthcare professionals concerning their perceptions and attitudes on patient safety issues. Therefore, the majority of research on patient safety climate involves administering questionnaires either developed or adapted for healthcare needs. In 2005 and 2006, two systematic reviews identified 9 [65] and 12 [66] instruments designed to assess the patient safety climate, all developed after the publication of *To Err is Human*.

However, differing theoretical backgrounds and conceptual definitions have led to numerous ways of defining and measuring patient safety climate [65, 66]. According to Ginsburg et al. [67] patient safety climate is sometimes conceptualized very broadly, including more distant subdimensions such as job satisfaction [62] or staffing [68]. The most frequent dimensions of the instruments used in healthcare organizations include clinicians' perceptions of patient safety related to management/supervisors, safety systems, risk perception, job demands, reporting and speaking up, safety attitudes/behaviors, communication/feedback, teamwork, personnel resources (e.g., stress), and other organizational factors [66]. In both reviews the authors concluded that few of the instruments in use had undergone adequate psychometric testing, as several were at early stages of development [65, 66].

Since 2006, although the number of instruments developed to measure patient safety climate has grown [69], evidence of their validity and reliability remains scant [67, 70, 71]. According to Halligan and Zecevic (2011), [56] based on validity and reliability, the top four questionnaires are (1) the Agency for Healthcare Research and Quality (AHRQ)'s Hospital Survey on Patient Safety Culture (HSOPSC) [68]; (2) the Safety Attitudes Questionnaire (SAQ) [62]; (3) the Patient Safety Culture in Healthcare Organizations Survey (PSCHO) [72]; and (4) the Modified Stanford Patient Safety Culture Survey Instrument (MSI) [67]. Despite differences in their theoretical underpinnings and conceptualizations, these four questionnaires cover similar dimensions and topics, e.g., teamwork, psychological safety (fear of blame and shame), learning, and perception / support of management (see Table 1). To date, only two of these instruments, the AHRQ HSOPSC and the SAQ have been translated into languages other than English and used globally in healthcare settings. Important characteristics of these questionnaires, including their theoretical underpinnings and conceptualization (dimensions) are summarized in Table 1.

Another promising new tool is the Safety Organizing Scale (SOS) [73] (see Table 1). Developed by Vogus & Sutcliffe, the SOS is based on high-reliability organizational theory, reflecting the organizational characteristic of "collective mindfulness" [73, p. 47]. Its nine items use 7-point Likert scales (1=not at all; 7=to a very great extent) to assess the extent to which registered nurses and their colleagues are engaged in safety behaviors and practices on their unit [73]. The SOS is supported by strong psychometric properties. Confirmatory factor analyses have confirmed the instrument's uni-dimensional conceptualization, as well as its discriminant validity regarding employee commitment and trust in manager. Significant between-unit variability, intra-class correlations and within-group agreement indicate that the SOS reflects safety climate at the unit level, justifying data aggregation. Testing criterion validity has revealed significant positive relationships between units with higher patient safety climate levels and two theorized antecedents: higher trust in manager and higher staffing levels. In addition, multilevel regression analyses have revealed that units with higher patient safety climate levels had lower numbers of reported medication errors and patient falls over a subsequent 6-month period [73].

Table 1: Overview on the most often used patient safety climate questionnaires with sound psychometric properties: summary of characteristics (based on Colla et al. [65] and Halligan and Zecevic [56])

Characteristics		Name of survey				
		PSCHO	SAQ	AHRQ HSOPSC	MSI	SOS
1)	**Developing authors**	Singer et al. [72]	Sexton et al. [62]	Sorra and Nieva [74]	Ginsburg et al. [67]	Vogus & Sutcliffe [73]
2)	**Year of publication**	2006	2006	2004	2009	2007
3)	**Country**	USA	USA	USA	CA	USA
4)	**Theoretical Underpinnings**	High-reliability organizations theory	Vincent's framework for analyzing risk and safety and Donabedian's conceptual model for assessing quality	Donabedian's conceptual model for assessing quality	Adaptation of the PSCHO	High-reliability organization theory
5)	**Number of Items**	38	60	42	38	9
6)	**Type of Likert scale**	5-point	5-point	5-point	5-point	7-point
7)	**Number of Dimensions**	9	6	12	5	1
8)	**Dimensions covered**	Senior managers' engagement, Organizational resources for patient safety, Overall level of emphasis on patient safety, Unit norms for patient safety, Unit recognition and support for safety efforts, Fear of shame, Fear of blame, Learning, Provision of unsafe care	Teamwork Climate, Safety Climate, Perceptions of Management, Job Satisfaction, Working Conditions, Stress Recognition	Teamwork within units, Organizational learning, Supervisor/manager expectations and actions promoting patient safety, Hospital management support for safety, Communication openness, Error feedback and communication, Staffing, Non-punitive response to error, Teamwork across units, Hospital handoffs and transitions, Overall perceptions of safety, Frequency of event reporting	Organization leadership for safety, Unit leadership for safety, Perceived state of safety, Shame and repercussions of reporting, Safety learning behaviors	Interrelated behavioral safety processes of "collective mindfulness"
9)	**Psychometric evidence based on**					
a)	Content	No	Yes	Yes	No	Yes
b)	Internal structure	Yes	Yes	Yes [70, 71]	Yes	Yes
c)	Relationships with other variables	Yes	Yes [75]	No	No	Yes [76]
d)	Reliability	Yes [77, 78]	Yes	Yes	Yes	Yes
10)	**Published translated and cross-culturally adapted language versions**	No	Belgium (Dutch) [79], Sweden [80], Spain [81], Taiwan [82], Norway [83], Germany [84], Cyprus [85], Ireland [86]	Switzerland (German) [87], Lebanon [88], Taiwan [89], Netherlands [90], Norway [91], Belgium [92], United Kingdom [93], France [94], Japan [95], Italy [96], Saudi Arabia [97], Turkey [98]	No	No

Legend of tool abbreviations: PSCHO = Patient Safety Culture in Healthcare Organizations Survey, SAQ = Safety Attitudes Questionnaire, AHRQ HSOPSC = Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture, MSI = Modified Stanford PSC Survey Instrument, SOS = Safety Organizing Scale.

Descriptive-explorative studies using these measurement tools detected variations in the patient safety climate by work area, discipline and management level. The results demonstrated that the employee-perceived safety climate varied between and within hospitals [99]. Personnel in more critical wards (e.g., emergency departments) perceived lower safety climate levels than in other hospital wards; nurses had an overall lower perception of safety climate than other disciplines (e.g., physicians); and front-line workers perceived lower safety climate levels than management [100-102]. Overall, the results of these studies suggest that activities to improve safety climate should focus on the level of the unit rather than those of the individual or hospital, [103] and should be tailored to the target respondent's clinical area and discipline [100, 101].

The basic assumption underlying the concept of safety culture in healthcare organizations, and thus of improvement activities, is that a higher safety climate rating reflects a higher level of patient safety. Units and hospitals with high safety climate levels give patient safety a high priority vis-à-vis the provision of daily care [56]. To date, though, few studies have examined the relationship between safety climate and patient outcomes, including AEs, and fewer still have reported statistically significant associations. Singer et al. [78] and Mardon et al. [104] investigated the relationship between safety climate and patient safety on selected AHRQ Patient Safety Indicators (PSIs) in acute hospital settings, with results linking the hospital safety climate to indicators of patient safety. Hospitals with better safety climates overall had a lower relative incidence of PSIs. Using data from 67 US hospital sample, Hansen et al. found a relationship between higher hospital safety climate and lower incidence rates of patient readmission [77] and Vogus and Sutcliffe [73], using the self-developed Safety Organizing Scale found statistically negative relationships between unit safety climate and incident reports on medication errors and patient falls in the subsequent 6-month period.

Although the evidence supporting the theoretical assumption of causal relationships between patient safety climate and patient outcomes is still far from convincing, an increasing number of intervention studies are focussing on improving overall safety climate in clinical areas to improve patient safety and patient outcomes. Halligan et al. [56] reviewed 21 studies reporting on the impact of safety climate improvement activities. Using quality improvement cycles (e.g., Plan-Do-Check-Act), they aimed (1) to describe the institutional safety climate in unit and hospital samples, identifying problematic areas, (2) to implement safety-enhancing interventions, such as bundled behavioral interventions targeting the problematic areas, then (3) to evaluate quality improvements by reassessing the safety climate [105, 106]. One reviewed study, by a research group from John Hopkins Hospital, investigated the impact of a „comprehensive unit-based safety program“ on the safety climates of two intensive care units. Their program consisted of six components: (1) assessing safety climate; (2) providing safety science education; (3) identifying safety concerns; (4) establishing senior leadership partnerships with units; (5) learning from one safety defect per month; and (6) reassessing the safety climate. One year after implementation of this program they observed reduced incidences of medication errors, a shorter average length of stay, and, surprisingly, lower nursing staff turnover [46].

1.5 Patient safety and quality of nursing care framework

Despite a range of theories underlying the concept of safety climate, e.g., high-reliability organization theory, [57] and initial evidence linking safety climate to safety performance [78, 104], no comprehensive theoretical model yet specifies the relationship between safety climate, organizational factors and patient safety [53]. In addition, it is not yet clear *how* safety climate reduces the occurrence of AEs [73].

For this dissertation project, in the absence of such a theoretical model, we developed a conceptual framework to guide our empirical examination by combining three existing conceptual frameworks: (1) Vincent's adapted Accident Causation Model (ACM) for healthcare organizations, [4, 107] (2) the System Engineering Initiative for Patient Safety (SEIPS) model, [54] and (3) the Rationing of Nursing Care in Switzerland (RICH) model [108, 109].

As described above in chapter 1.2, Vincent's adapted ACM [4, 107] provides an overview on the dynamic multifactor flow through an accidental event in healthcare, as well as the accident sequences and the contributing human factors. The ACM's focus is primarily on describing the causal flow leading to accidents and AEs, considering the hierarchical pathway from management level to the workplace and individual levels, and describing possible contributing factors at the workplace level. Thus, it provides a conceptual basis for analyzing AEs. Using it, Taylor-Adams and Vincent developed the "London protocol", a step-by-step guide for system analysis of clinical incidents [110]. Few other researchers have used ACM-based frameworks, as its focus on the etiology of negative patient outcomes provides no guidance for system redesign or patient safety improvement [111,]. One notable exception was a prospective study by Dean et al. [112], who applied it to analyze and classify hospital physicians' prescription errors. They found that the most frequent contributory factors related to the work environment (staffing and workload) and to individual staff profiles (inadequate skills and knowledge and physical health) [112]. Although the ACM is the best-known model of accident and AE causality, it neither describes nor discusses the care process. For this reason, we combined it with the SEIPS and RICH models.

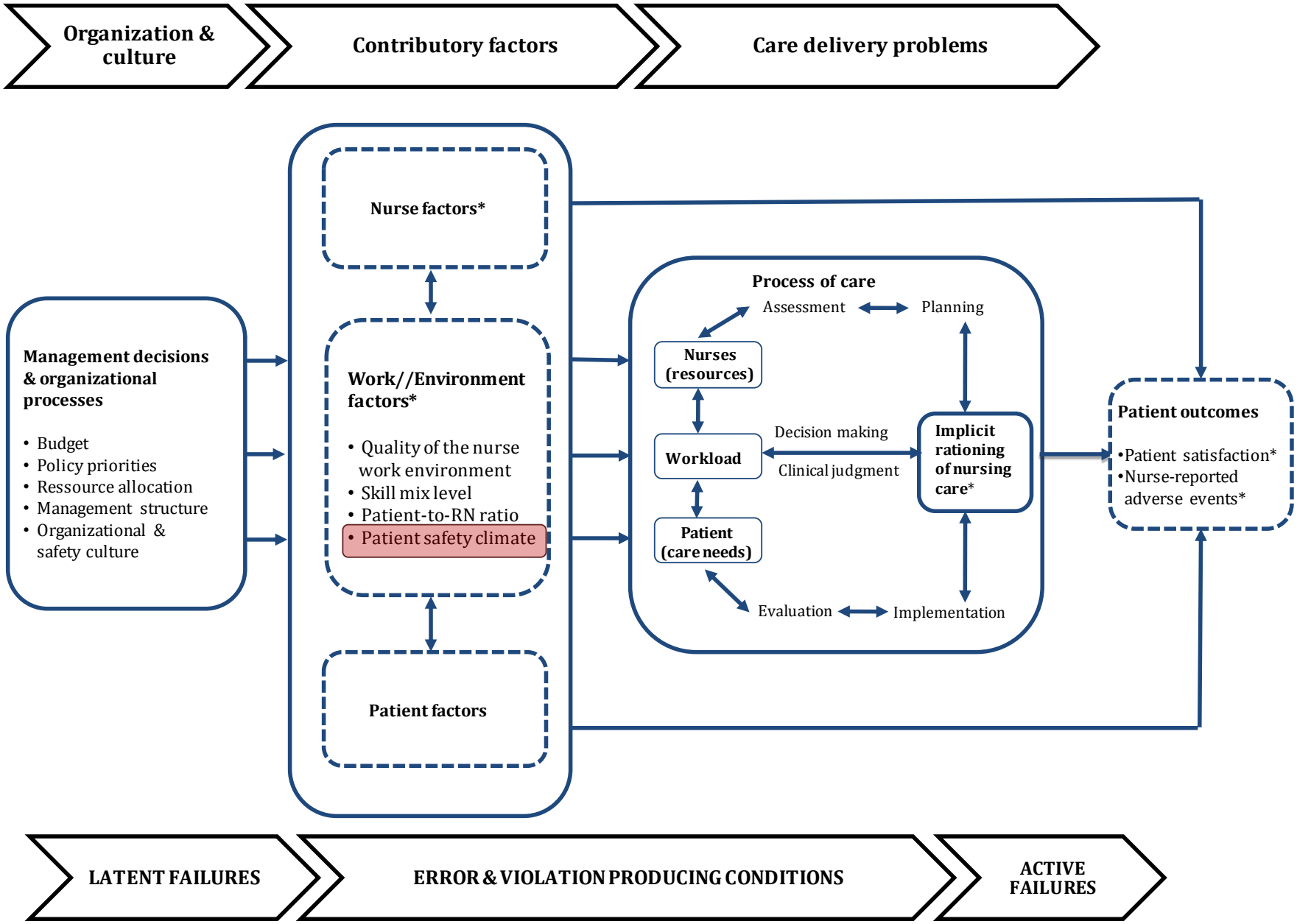
The SEIPS model is anchored in human factor science and builds upon Donabedian's quality model [111,] to provide a framework for understanding the structures, processes and outcomes of healthcare organizations such as hospitals [54]. The SEIPS model describes the system components and their relationships / interactions, as well as their impact on patient, employee and organizational outcomes. It also complements Donabedian's model with (1) employee/organizational outcomes (e.g., job satisfaction, burnout), (2) possible relationships between patient outcomes and employee/organizational outcomes, (3) other non-care processes (e.g., information flow), and (4) a more comprehensive description of organizational structure (i.e., "work system"). The SEIPS model facili-

tates both the assessment of patient safety and the design of safer healthcare systems. Carayon used it successfully in a system engineering intervention aimed at improving patient safety in outpatient surgery centers [113].

As this dissertation focuses on patient safety and nursing care-related quality, we also used the RICH model, [108, 109] an extension of the International Hospital Outcomes Study model developed by Aiken et al. [114]. To date, the RICH model, which measured implicit rationing of nursing care, i.e. "the withholding of or failure to carry out necessary nursing measures for patients due to a lack of nursing resources (staffing, skill mix, time)" [109, p. 417] describes the nursing care process in considerable detail.

In nursing, the care process starts with the assessment of patients' care needs. Next, based on scientific evidence, professional expertise and patient preferences, appropriate nursing measures are chosen, planned and implemented to achieve defined patient outcomes. In the last step of the process, the effectiveness of the care planned and delivered is evaluated [115]. As a result of structural factors (e.g., inadequate staffing or skill mix levels) at the workplace level, however, imbalances between nursing resources and patient care needs can lead to excessive workloads. In such cases, nurses have to set priorities and make decisions about withholding patient care judged necessary to reach desired outcomes or protect patients from AEs [109, 115]. The RICH study indicated a close relationship between implicit rationing of nursing care and patient outcomes: even low rationing levels correlated with reduced patient satisfaction, nurse-reported medication errors, patient falls, nosocomial infections, pressure ulcers and critical incidents [108, 116].

Figure 3: **Patient safety and quality of nursing care model**



* Variables measured in the RN4CAST study

In our patient safety and quality of nursing care model (Figure 3) the process leading to patient outcomes, including AEs, begins with „latent failures“ in decision-making and organizational processes by the hospital or nurse management (e.g., strategy, planning, scheduling, forecasting). The consequences of these activities can directly increase or decrease the likelihood of AEs. In addition, “latent failures” by the hospital management also affect organizational factors at the workplace (e.g., medical/surgical units), such as work environment, team, individual, patient and task factors. For instance, an increasing amount of international evidence demonstrates that nurse-related organizational factors at the workplace level, such as the work environment [7, 117-119], nurse staffing levels [20, 21, 120-122], skill mix / educational levels [118, 123, 124], and nursing leadership [22] are related to patient outcomes. In the absence of a patient safety climate model or framework that adequately depicts its relationship with patient outcomes [53], we treated patient safety climate as a feature of clinical units' local work environment. At the unit level, „error & violation producing conditions“ in these organizational factors (e.g., inadequate staffing/ skill mix levels), can lead to problems in the care delivery process. Such vulnerabilities in organizational factors lead health care professionals, including nurses, to make or fail to prevent errors, which can, in turn, result in AEs and negative patient outcomes. The concept of implicit rationing of nursing care might illuminate such problems in the process of nursing care.

1.6 Identified research gaps and dissertation rationales

In summary, the following gaps in the scientific literature on “patient safety climate” guided the development and implementation of this dissertation project.

First, few studies have investigated the relationship between the patient safety climate and patient outcomes, such as AEs. According to Colla et al. [65], more research is necessary to understand such relationships. Units and clinical areas in hospitals with positive safety climates may have a strong and proactive commitment to patient safety. Likewise, a more positive unit-level safety climate may correlate with lower incidences of AEs and improved patient outcomes [58]. However reasonable or obvious these associations may appear, though, confirming their existence will require research.

Second, as described in subchapter 1.4, several instruments are available to measure the patient safety climate in a broad way [65]. The most frequently used – the Hospital Survey on Patient Safety Culture (HSOPSC) [68] and the Safety Attitudes Questionnaire (SAQ) [62] – include multiple sub-dimensions and high numbers of items (HSOPSC: 42; SAQ: 30-60), both of which characteristics impede confirmation of their internal structure after cross-cultural translation [83, 87]. Variations in internal structure might also impair cross-national comparison and benchmarking. In addition, these

questionnaires' length might make them impractical for the regular monitoring of patient safety climate in clinical practice, resulting in low response rates and missing data [125].

Third, even less research has been conducted on patient safety climate in Switzerland than in other similarly developed areas. Most related studies have focused on instrument development, but few of the developed instruments have been translated into German, Italian or French languages and adapted to Switzerland's specific cross-cultural context of Switzerland. In the absence of a safety climate measure available for all three Swiss languages, to date there has been no national overview of patient safety climate in Swiss healthcare institutions.

Given the knowledge gaps remaining to be filled, the following rationales apply for this dissertation.

First, systematic investigation is necessary to confirm the underlying assumption regarding safety climate research that link exists between nurse-reported patient safety climate and patient outcomes in acute care hospitals. Empirical evidence on the relationship between patient safety climate and patient outcomes is critical to the validity of measures reflecting on the patient safety climate, and will be necessary to justify activities and initiatives that aim to improve overall patient safety and quality by improving the patient safety climate.

Second, although several instruments measure healthcare patient safety climate somewhat extensively [65], it is our understanding that patient safety climate is characterized by the strong engagement of clinicians in safety behaviors [73], which may be directly related to patient outcomes. As the short and concise Safety Organizing Scale captures nine nurse safety behaviors, reflecting the "collective mindfulness" integral to a climate of safety, it might be a valuable tool for measuring and monitoring patient safety and quality of care.

Third, although the original English version of the SOS has strong psychometric properties, it has not yet been tested in a cross-cultural setting. Therefore, it is expected that using it to study patient safety climate will increase our understanding of healthcare professionals' behaviors regarding patient safety [73] and help identify problematic issues within the cultural context of Swiss healthcare organizations.

Thus, the proposed dissertation and the included research studies will contribute in several ways to the international scientific literature, as well as expanding the existing knowledge of patient safety climate in Swiss healthcare facilities.

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CHAPTER 2

STUDY AIMS

Given the identified gaps in the literature regarding patient safety climate, this research project includes the following aims:

- To translate the Safety Organizing Scale into German, Italian and French, to adapt the translated versions to the Swiss cultural context and to test their content validity (**Chapter 3**)
- To examine the psychometric properties of the German, Italian and French versions of the Safety Organizing Scale (**Chapter 4**)
- To describe the nurse-reported patient safety climate and nurses' engagement in specific safety behaviors of general medical, surgical and mixed medical-surgical units in a national hospital sample (**Chapter 5**)
- To explore the association between the nurse-reported patient safety climate and characteristics of Swiss acute care hospitals (type of unit, type of hospital and language regions) (**Chapter 5**)
- To explore the relationship between the nurse-reported patient safety climate and selected patient outcomes (**Chapter 6**)

CHAPTER 3

PROVIDING EVIDENCE BASED ON CONTENT THROUGH THE USE OF THE *CONTENT VALIDITY INDEX* ON A SAFETY CLIMATE IN HOSPITAL MEASURE

[DIE BESTIMMUNG DER INHALTSVALIDITÄT ANHAND DES *CONTENT VALIDITY INDEX* AM BEISPIEL EINES INSTRUMENTS ZUR ERFASSUNG DES SICHERHEITSKLIMAS IM KRANKENHAUS]

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3.1 Zusammenfassung

Der *Content Validity Index* (CVI) ist eine quantitative Methode zur Bestimmung der Inhaltsvalidität beispielsweise eines Fragebogens und wird in pflegewissenschaftlichen Untersuchungen im deutschsprachigen Raum bislang kaum eingesetzt. Der vorliegende Beitrag beschreibt die Methode des CVI, dessen praktische Anwendung und die Ergebnisse im Rahmen der Inhaltsvalidierung der „*Safety Organizing Scale*" (SOS), eines Instruments zur Erfassung des Sicherheitsklimas im Krankenhaus. Die US-amerikanische SOS wurde in einem Übersetzungs- und Rückübersetzungsprozess in die deutsche Sprache (Schweizer Kontext) übersetzt (SOS-CH) und von einem deutschen Forscherteam an den bundesdeutschen Kontext angepasst (SOS-DE). In der Schweiz bewerteten 12 und in Deutschland 13 Experten (Pflegefachpersonen und Ärzte/Ärztinnnen) für beide Versionen die Relevanz der neun Items in Bezug auf das Konzept „Sicherheitsklima". Für die SOS-CH bzw. SOS-DE reichten die I-CVI Werte von 0,67 bis 1,00 bzw. von 0,85 bis 1,00. Für die gesamte Skala der SOS-CH bzw. SOS-DE ergab sich ein S-CVI/Ave Wert von 0,91. Die Untersuchungsergebnisse belegen eine gute Inhaltsvalidität für beide SOS-Versionen. Für beide SOS Versionen sind der Nachweis von Konstrukt- (Konvergenz- und Diskriminanz-), Kriteriumsvalidität und Reliabilität noch zu erbringen. Die Bestimmung der Inhaltsvalidität mittels CVI-Verfahrens stellt eine transparente, nachvollziehbare und ressourcensparende Methode dar. Als kritische Erfolgsfaktoren für die Bestimmung des CVI müssen u.a. die sorgfältige transkulturelle Adaptation der einzelnen Items berücksichtigt werden.

Summary

The Content Validity Index (CVI) is a quantitative method to provide information on content validity. However, its use is rarely reported in the nursing literature within German-speaking countries. This paper aims to report on the method and practical use of the CVI, as well as the results on content validity testing of the "Safety Organizing Scale" (SOS), an instrument to capture patient safety climate in hospitals. Using a forward-backward translation process, the SOS was translated first from a Swiss research group into German language (Swiss context, SOS-CH) and adapted afterwards from a German research group to the German context (SOS-DE). In Switzerland and Germany two expert groups (nurses and physicians) rated the relevance of the nine items in terms of the underlying concept of "safety climate". For the SOS-CH and SOS-DE the I-CVI values ranged from 0.67 to 1.00 and from 0.85 to 1.00, respectively. For the overall scale the S-CVI/Ave for the SOS-CH and the SOS-DE was 0.91. These results demonstrate good content validity for both SOS versions. Further psychometric properties on both SOS versions, such as construct validity (convergent and discriminant), criterion validity and reliability need to be established. Determining the content validity according to the CVI procedure presented in this paper is a clear, understandable and resource-saving method.

3.2 Einleitung

In den letzten Jahren wurde deutlich, dass die Gesundheitsversorgung der Bevölkerung in vielen Belangen einer „Hochrisikoindustrie“ gleicht wie beispielsweise die Luftfahrt, jedoch bedeutend mehr Geschädigte zu verzeichnen hat. Studien zufolge sind zwischen 3% und 17% der Patienten im Rahmen von Krankenhausaufenthalten von so genannten unerwünschten Ereignissen (engl. adverse events, critical incidents) betroffen wie z.B. Medikamentenfehlern, Dekubitalulzera oder nosokomialen Infektionen [1-8]. Diese unerwünschten Ereignisse sind weniger Ausdruck einer zugrunde liegenden Krankheit des Patienten oder Ergebnis individuellen Versagens von Fachleuten, sondern hängen primär mit den Prozessen und Rahmenbedingungen der medizinisch-pflegerischen Leistungserbringung zusammen [9]. Laut Weltgesundheitsorganisation [9] ist die „Patientensicherheit“ ein wesentliches Kennzeichen einer qualitativ hochstehenden Gesundheitsversorgung und ist definiert als „Freiheit von unbeabsichtigten Schäden, die sich im Lauf der medizinischen Versorgung ereignen können“ [10]. Da nach aktuellem Wissenstand bei der Entstehung der meisten Fehler bzw. unerwünschten Ereignisse, unzureichende Systeme und Abläufe eine größere Rolle als individuelles Versagen spielen [11], kann Patientensicherheit nur im Kontext einer umfassenden, systembezogenen Betrachtung von medizinischen und pflegerischen Prozessen, Interaktionen mit den Patienten sowie zwischen den beteiligten Fachleuten verstanden werden.

Eine entscheidende Rolle bei der Gewährleistung der Patientensicherheit spielt dabei die „Sicherheitskultur“ beispielsweise eines Krankenhauses resp. deren Subkulturen auf den einzelnen Abteilungen. Die Sicherheitskultur ist eine Eigenschaft der gesamten Organisation, die sich im kollektiven Verhalten ihrer Mitarbeiter widerspiegelt. Sicherheitskultur wird definiert als „der gemeinsame Wissens-, Werte- und Symbolvorrat einer Organisation, der ihre Kapazität erhöht, die Sicherheit zu fördern“ [12] und umfasst Elemente und Eigenschaften wie Leadership, Kommunikation, Teamwork, Evidenzbasierte Praxis, Patientenzentriertheit, Fairness & Offenheit, sowie Lernbereitschaft [13]. Die Entwicklung einer Sicherheitskultur wird Experten zufolge als ein systemischer und proaktiver Verfahrensansatz verstanden, welcher zur Verhinderung von Fehlern und unerwünschten Ereignissen beiträgt [14, 15]. Die Erfassung der Sicherheitskultur spielt eine wichtige Rolle, um potentielle Fehlerquellen in Systemen, Abläufen und Verhaltensweisen der gesamten Organisation und deren Abteilungen zu identifizieren [16]. Das Konzept der „Sicherheitskultur“ hat seinen Ursprung in der Hochrisikoindustrie und wurde in den letzten Jahren verstärkt auf die Gesundheitsversorgung übertragen. So wurden in den USA Fragebögen, wie z. B. der „Hospital Survey on Patient Safety Culture [17, 18], der „Safety Attitudes Questionnaire“ [19] oder die „Safety Organizing Scale“ [20] entwickelt, mit denen das „Sicherheitsklima“, d. h. beobachtbare bzw. von Mitarbeitern bekundete Meinungen, Werte und Verhaltensweisen bezüglich Patientensicherheit, durch Fragebögen erfass- und messbar gemacht wurden [21-23].

Während das Thema „Patientensicherheit“ auch im deutschsprachigen Raum Europas in den letzten Jahren an Bedeutung gewonnen hat, erfährt die Erfassung des Sicherheitsklimas in den verschiedenen Gesundheitseinrichtungen bislang relativ wenig Beachtung. Ein Grund dafür ist sicher auch die Tatsache, dass im deutschsprachigen Raum kaum valide und reliable Instrumente zur Messung des Sicherheitsklimas vorliegen [24, 25]. Die sorgfältige Übersetzung beispielsweise englischsprachiger Instrumente für den transkulturellen Einsatz, sowie die Testung der psychometrischen Eigenschaften der übersetzten Versionen erfordern zeitliche, finanzielle und personelle Ressourcen. Messinstrumente für schriftliche Befragungen und quantitative Interviews bilden stets ein zu Grunde liegendes Konzept bzw. Konstrukt, wie z. B. das Sicherheitsklima ab. Reliabilität (Testgüte/-stabilität) und Validität (Testgenauigkeit) stellen wichtige Kriterien für die Eigenschaften eines Messinstrumentes dar, welche sowohl bei der Entwicklung eines Instruments, als auch bei dessen Übersetzung in einen anderen Kulturraum sichergestellt werden müssen [26]. Die Inhaltsvalidität ist dabei das Ausmaß, mit dem der Inhalt eines Instruments das zugrunde liegende Konzept bzw. Konstrukt widerspiegelt [27]. Sie stellt einen wichtigen Gradmesser für die Testgenauigkeit eines Instruments dar und ist gleichzeitig ein wichtiger Schritt bei der vollständigen Überprüfung der psychometrischen Eigenschaften von Messinstrumenten, wie beispielsweise Konstrukt- (Konvergenz- und Diskriminanz-), Kriteriumsvalidität und Reliabilität (interne Konsistenz).

Die Inhaltsvalidität (*Content Validity*) kann auf unterschiedliche Weise ermittelt werden und sollte ein hohes Ausmaß an Objektivität gewährleisten. Zumeist wird sie als *Face Validity* bestimmt, indem Experten eine augenscheinliche inhaltliche Gültigkeit des Instrumentes bestätigen. Die gängigsten und am häufigsten angewandten Methoden für die *Face Validity* sind Gruppensitzungen mit Experten oder Delphi Verfahren. Letzteres erfasst die Expertenmeinung mittels schriftlicher Befragung bis zur Bildung eines Gruppenkonsenses [26]. Während Gruppensitzungen mit Experten oder das Delphi-Verfahren „qualitative“ Verfahren zur Bestimmung der Inhaltsvalidität darstellen, bietet der *Content Validity Index (CVI)* einen quantitativen Ansatz. Der CVI beinhaltet ebenfalls einen „Expertenkonsens“ zur Relevanz des Messinstruments in Bezug auf das zugrunde liegende Konzept/Konstrukt. Der Berechnung des CVI geht eine quantitative Bewertung der Inhalte des Messinstruments (*Content Validity Rating*) durch eine Gruppe von Experten voraus [28-30]. Zu neu entwickelten bzw. übersetzten Fragebögen oder anderen Messinstrumenten im Rahmen von pflegewissenschaftlichen Untersuchungen wird im deutschsprachigen Raum die CVI-Methode zur Überprüfung der Inhaltsvalidität im Vergleich zu den *Face Validity* Verfahren, kaum eingesetzt.

Das Ziel des vorliegenden Beitrages ist die Darstellung und kritische Würdigung des *Content Validity Index,* dessen praktische Anwendung und der Ergebnisse im Rahmen der Inhaltsvalidierung der „Safety Organizing Scale“, eines übersetzten Instruments zur Erfassung des Sicherheitsklimas im Krankenhaus.

3.3 Methode und Material

3.3.1 Safety Organizing Scale

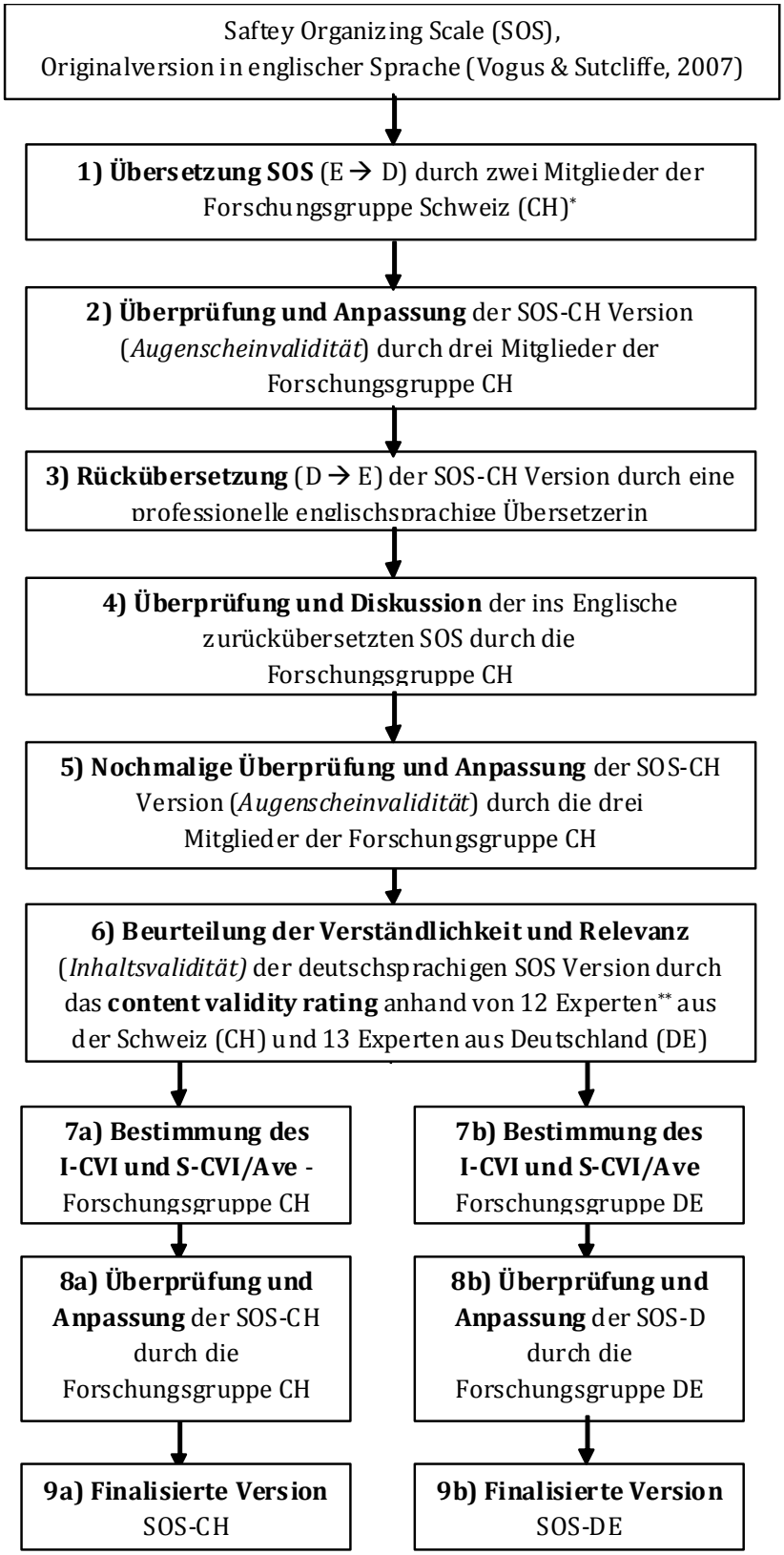
Die Safety Organizing Scale (SOS) wurde von [20] entwickelt. Das theoretische Grundgerüst bilden Fallstudien zum Sicherheitsverhalten in Organisationen der Hochrisikoindustrie („high-reliability organizations“) und des Gesundheitswesens. Das dem Fragebogen zugrunde liegende Konzept bildet das Sicherheitsklima ab. Es wurde von den Autoren als „sichtbares Lebenszeichen“ einer kollektiven Sorgfalt bzw. Achtsamkeit durch die Umsetzung von sicherheitsrelevanten Maßnahmen definiert. Das Gesundheitspersonal, wie z. B. Ärzte/Ärztinnen oder Pflegefachpersonen bewerten dabei in welchem Ausmaß Verhaltensweisen und Maßnahmen zur Gewährleistung der Patientensicherheit auf Abteilungsebene eingehalten resp. umgesetzt werden auf einer 7-stufigen Likert-Skala [von „überhaupt nicht“ (1) bis „in sehr großem Ausmaß“ (7)]. Die psychometrische Testung der englischsprachigen SOS ergab hervorragende Testeigenschaften. Die konfirmatorische Faktorenanalyse bestätigte die Eindimensionalität der SOS (Konstruktvalidität). Die Überprüfung der Diskriminanzvalidität ergab einen signifikanten Unterschied von zwei ähnlichen Konzepten (Engagement in der Organisation und Vertrauen in das Management). Signifikante negative Zusammenhänge mit Medikamentenfehlern (B = -0,678, $p < 0,001$) und Patientenstürzen (B = -0,629, $p < 0,001$) legen die Kriteriumsvalidität nahe. Cronbach’s alpha für die SOS betrug 0,88 [20]. Das solide theoretische Grundgerüst, der kurze und prägnante Inhalt, sowie die hervorragenden psychometrischen Eigenschaften waren der Grund, der SOS den Vorzug vor anderen vorhandenen Fragebögen zur Erfassung des Sicherheitsklimas zu geben.

3.3.2 Methodisches Vorgehen

3.3.2.1 Übersetzung der SOS

Die SOS wurde im Frühjahr 2009 von einem Schweizer Forscherteam in einem mehrstufigen Verfahren in die deutsche Sprache übersetzt (Abbildung 1). Das gesamte Übersetzungsverfahren folgte dem Übersetzungs- und Rückübersetzungsprozess (*forward-backward translation)* gemäß adaptierten Brislin Protokoll [31]. Damit lag erstmals eine in die deutsche Sprache (Schweizer Kontext) übersetzte Version der SOS (SOS-CH) mit etablierter Augenscheinvalidität vor. Auf Basis dieser übersetzten Version wurde das Instrument von zwei Autorinnen für den bundesdeutschen Kontext angepasst. Hierfür wurden beispielsweise die Begriffe „Übergaberapport“ in „Übergabe“ und „Spital“ in „Krankenhaus“ geändert (Abbildung 2).

Abbildung 1: Übersetzungs- und Validierungsprozess der deutschsprachigen SOS



* Das Forscherteam Schweiz setzte sich aus vier Mitgliedern des Instituts für Pflegewissenschaft der Universität Basel zusammen. Drei davon sind deutschsprachig mit sehr guten Englisch-Sprachkenntnissen und ein Mitglied hat Englisch (USA) als Muttersprache.

** Die Expertengruppen setzten sich aus je 10 bzw.11 diplomierten/examinierten Pflegefachpersonen sowie je zwei Ärztinnen/Ärzten zusammen.

Abbildung 2: Sicherheitsorganisationsskala für die deutschsprachige Schweiz (SOS-CH) und Deutschland (SOS-DE)

Bitte schätzen Sie bei den folgenden Aussagen das Ausmaß ein, mit welchem Sie und die diplomierten Pflegefachpersonen, mit denen sie primär zusammenarbeiten, die aufgelisteten Verhaltens- und Vorgehensweisen umsetzen. Mit Arbeitsort ist die Abteilung gemeint, in der sie gegenwärtig tätig sind (z.B. chirurgische Station A2)

Die Kernfrage lautet also: **"In welchem Ausmass charakterisieren die folgenden Aussagen ihren Arbeitsort, in dem Sie gegenwärtig tätig sind?"**

1=überhaupt nicht, 2=in sehr geringem Ausmaß, 3=in geringem Ausmaß, 4=in eher geringem Ausmaß, 5=in eher großem Ausmaß, 6=in großem Ausmaß, 7=in sehr großem Ausmaß

Item-Nr.	Version	Wortlaut der Items
1.	CH	Wir haben ein klares Bild von den Begabungen und Fähigkeiten/Fertigkeiten (Fachkompetenzen) unserer einzelnen Teammitglieder.
	DE	
2.	CH	Wir sprechen miteinander über Fehler und wie wir aus ihnen lernen können.
	DE	
3.	CH	Wir sprechen miteinander über unsere fachlichen Kenntnisse und Fähigkeiten und wissen daher, wer in dieser Abteilung über wichtiges, spezialisiertes Fachwissen und Erfahrung verfügt.
	DE	Wir tauschen uns über unsere fachlichen Kenntnisse und Fähigkeiten aus und wissen daher, wer in dieser Abteilung über besonderes Fachwissen und Erfahrung verfügt.
4.	CH	Wir diskutieren für unsere Routinetätigkeiten auch alternative Vorgehensweisen.
	DE	Wir diskutieren in Bezug auf unsere Routinetätigkeiten auch alternative Vorgehensweisen.
5.	CH	Beim Übergaberapport an die nächstfolgende dipl. Pflegefachperson wird üblicherweise besprochen, worauf zu achten ist.
	DE	Bei der Übergabe an die nachfolgende Pflegende wird üblicherweise besprochen, worauf zu achten ist.
6.	CH	Beim Versuch ein Problem zu lösen, nutzen wir die vorhandenen fachlichen Kompetenzen unserer Teammitglieder.
	DE	Bei dem Versuch, ein Problem zu lösen, nutzen wir die vorhandenen fachlichen Kompetenzen unserer Teammitglieder.
7.	CH	Wir nehmen uns Zeit, um Tätigkeiten zu identifizieren, die nicht „schiefgehen" dürfen.
	DE	Wir nehmen uns Zeit, um Tätigkeiten zu identifizieren, die auf keinen Fall scheitern dürfen.
8.	CH	Wenn Fehler passiert sind, besprechen wir, wie wir diese hätten verhindern können.
	DE	
9.	CH	Wenn bei einem Patienten eine kritische Situation auftritt, versuchen wir diese durch die Nutzung unserer fachlichen Kompetenzen rasch zu lösen.
	DE	

CAVE: Sollte eine Verwendung des Fragebogens angestrebt werden, kontaktieren Sie bitte den federführenden Autor.

3.3.2.2 Methodik der Inhaltsvalidierung

Auf Basis der internationalen Literatur [28-30] wurde für die Bestimmung des CVI der beiden deutschsprachigen SOS-Versionen ein definierter Ablauf in vier Schritten gewählt.

Schritt 1: Stichprobe - „Expertenbefragung"

Die Expertengruppe für das Content Validity Rating soll Personen umfassen, die mit dem Konstrukt (Thema) vertraut sind, um die inhaltliche Güte bewerten zu können [29]. Die Beurteilung eines Messinstruments kann bei Experten, denen das Konstrukt nicht bekannt ist, zu Fehlinterpretationen führen. Darüber hinaus sollte die Expertengruppe am besten zwischen 8 und 12 Personen umfassen, damit ein gewisses Mass an Variabilität (Nicht-Übereinstimmung der Experten) zwar erfasst wird, sich aber nicht unverhältnismässig negativ (wie bei kleinen Stichproben) auf die Inhaltsvalidität der Items auswirken kann [29]. Da die SOS auch die interdisziplinäre Zusammenarbeit zwischen Pflegefachpersonen und Ärzten und Ärztinnen bei der Umsetzung sicherheitsrelevanter Maßnahmen berücksichtigt, eignet sie sich für die Befragung beide Berufsgruppen. Folglich wurden sowohl Ärzte/Ärztinnen als auch Pflegefachpersonen als potentielle Experten-Zielgruppen (user groups) erachtet.

In der Schweiz und in Deutschland wurden dazu zwei Gelegenheitsstichproben mit 12 bzw. 13 Experten (10 bzw. 11 Pflegepersonen, je 2 Mediziner) rekrutiert. Die Zusammenstellung der Stichprobe in der Schweiz erfolgte durch eine Pflegeexpertin und Qualitätsbeauftragte. Dabei wurden interessierte Pflegefachpersonen und Ärzte/Ärztinnen von medizinischen und chirurgischen Abteilungen eines städtischen Krankenhauses der Notfall- und erweiterten Grundversorgung ausgewählt. In Deutschland wurde die Expertengruppe durch eine Qualitätsbeauftragte in einem Krankenhaus der Spitzenversorgung ausgewählt, wobei Mitarbeiter in ausgewiesenen Positionen des Qualitätsmanagements eingeschlossen wurden.

Schritt 2: „Expertenbefragung" (Content Validity Rating)

Die Experten erhielten ein Dossier, das sich aus einem Informationsblatt, einem Fragebogen und (in der Schweiz) einem Rückantwortkuvert zusammensetzte. Anhand des Informationsblattes wurden die Experten über den genauen Inhalt und den Ablauf der Befragung informiert. Für das Content Validity Rating wurde ein eigener Fragebogen vorbereitet, indem jedem SOS-Item eine Frage nach seiner Verständlichkeit und Relevanz hinzugefügt wurde. Anhand einer 4-stufigen Likert-Skala (1=gar nicht, 2=wenig, 3=ziemlich, 4=sehr) schätzten die Experten dann die inhaltliche Relevanz der einzelnen Items der deutschsprachigen SOS ein. Ein zusätzliches „freies" Feld nach jedem Item ermöglichte es den Experten zusätzliche Kommentare abzugeben. Abbildung 2 illustriert anhand eines einzelnen Items, wie die SOS (CH und DE) für das Content Validity Rating vorbereitet wurde.

In der Schweiz erhielten die Experten die Unterlagen via interne Krankenhauspost und sandten den ausgefüllten Fragebogen per Rückantwortkuvert via Pflegexpertin an das Forscherteam zurück. In Deutschland wurden die Fragebögen von der Qualitätsbeauftragten im Krankenhaus den Adressaten persönlich überreicht und binnen zwei Wochen wieder eingesammelt.

Abbildung 3: Fragen zur Beurteilung der Relevanz einer SOS Aussage (Item 2).

Wir sprechen miteinander über Fehler und wie wir aus ihnen lernen können.
Diese Aussage ist klar und verständlich formuliert: ❑ ja ❑ nein
Für wie relevant erachten Sie diese Aussage? ❑ gar nicht ❑ ein wenig ❑ ziemlich ❑ sehr
Kommentar:

Schritt 3: Berechnung des I-CVI und S-CVI/Ave

Die Daten der ausgefüllten Fragebögen wurden in Microsoft Office Excel 2007 eingegeben. Fehlende Werte wurden dabei als „nicht relevante" Aussagen der Experten berücksichtigt.

Für die statistische Berechnung des CVI erfolgt zu Beginn eine Dichotomisierung der Antwortkategorien in „nicht relevant (gar nicht = 1 und wenig = 2)" und „relevant (ziemlich = 3 und sehr = 4)" [29, 30]. Für jedes einzelne dichotomisierte Item wird der prozentuelle Anteil der Experten berechnet, welche das Item als relevant erachtet haben. Dieser prozentuale Wert für jedes einzelne Item wird als CVI auf Item-Ebene (I-CVI) bezeichnet. Die I-CVI können Werte von 0 bis 1 einnehmen, wobei 0 eine völlige Übereinstimmung der Experten als „nicht relevant" und 1 eine völlige Übereinstimmung als „relevant" bedeuten. Ab einem I-CVI von 0,78 kann einem Item eine gute Inhaltsvalidität bescheinigt werden [29, 30].

Die statistische Problematik der Auswertung der einfachen Übereinstimmung (prozentuales Ausmaß) wird in der wissenschaftlichen Literatur kritisch diskutiert [29, 30]. Zumeist wird die Berechnung einer zufallskorrigierten Übereinstimmung mittels Cohen's Kappa empfohlen. Allerdings ist diese Berechnungsmethode aufwändig und für die inhaltliche Diskussion kaum hilfreich [29, 30], weshalb von der Verwendung der Kappa-Statistik in der hier vorliegenden Untersuchung abgesehen wurde.

Bei der Auswertung des CVI für das gesamte Instrument wurde die *Scale Content Validity Index/Average Method* (S-CVI/Ave) gewählt. Bei der S-CVI/Ave Methode werden alle I-CVI Werte addiert und durch die Anzahl der Items dividiert. Ein S-CVI/Ave Wert $\geq$0,90 wird als gute Inhaltsvalidität interpretiert [29, 30].

Schritt 4: Diskussion der Ergebnisse und Anpassung der Items

Auf Basis der Ergebnisse des *Content Validity Ratings* wurden SOS-Items mit einem I-CVI <1.00 in den Forscherteams diskutiert und gegebenenfalls Anpassungen der Items vorgenommen. In der Schweiz wurden die schriftlichen Kommentare der Experten im Forscherteam intern besprochen, während in Deutschland, ebenfalls anhand der schriftlichen Kommentare zu den einzelnen Items, eine Gruppendiskussion mit den befragten Experten durchgeführt wurde.

3.3.3 Ergebnisse

Die Mitglieder der beiden, an der SOS Inhaltsvalidierung beteiligten Expertengruppen waren in einem städtischen 500 Betten Krankenhaus der Notfall- und erweiterten Grundversorgung (Schweiz) resp. in einem 900 Betten Krankenhaus der Spitzenversorgung (Deutschland) tätig. Alle 25 Experten, welche zur Teilnahme am *Content Validity Rating* eingeladen wurden, füllten den Fragebogen aus (Rücklauf = 100%). Das mittlere Alter der Schweizer Experten lag bei 39,2 Jahren, die mittlere Berufserfahrung betrug 14,6 Jahre (siehe Tabelle 1). Die Mitglieder der deutschen Expertengruppe wiesen ein mittleres Alter von 41,2 Jahren auf und verfügten über eine mittlere Berufserfahrung von 17,8 Jahren. Die Angaben der Deutschen Experten beziehen sich dabei auf elf der insgesamt 13 Experten, da für zwei Pflegefachpersonen die soziodemographischen Angaben fehlen (Tabelle 1).

Tabelle 1: Soziodemographische Merkmale der Expertengruppen.

Merkmale	Schweiz (n=12)	Deutschland (n=11)*
Fachbereiche		
Innere Medizin	5	n. e.†
Chirurgie	7	n. e.†
Beruflicher Status		
Pflegefachperson‡	10	9
Arzt/Ärztin§	2	2
Alter in Jahren		
Mittelwert (SD)	39,2 (11,8)	41,2 (8,4)
Median (Min.- Max.)	35 (27-61)	45 (25-52)
Berufserfahrung in Jahren		
Mittelwert (SD)	14,6 (11,5)	17,8 (8,6)
Median (Min.-Max.)	12 (1-32)	21 (3-31)

* Die Angaben von zwei Pflegefachpersonen fehlen.
† n. e. = nicht erhoben.
‡ Pflegefachpersonen mit einer mindestens dreijährigen Ausbildung mit Diplomabschluss.
§ Assistenzärztinnen/-ärzte (Ärztinnen/Ärzte im Abteilungsdienst).

3.3.3.1 Content Validity Index

Die einzelnen Items der SOS-CH und SOS-DE wurden von den beiden Expertengruppen als relevant für ein Sicherheitsklima im Krankenhaus erachtet, wie die Beurteilungswerte in Tabelle 2 und Tabelle 3 zeigen.

Für die SOS-CH reichten die I-CVI von 0,67 (Item 4) bis zu 1,00, wobei drei Items (2, 3 und 8) von allen Experten übereinstimmend als „relevant" erachtet wurden (Tabelle 2). Für die gesamte Skala der SOS-CH ergab sich ein S-CVI/Ave von 0,91 (Tabelle 2).

Die I-CVI für die SOS-DE ergaben für die Items 3, 6 und 7 den tiefsten Wert von 0,85. Zwei Items (1und 2) wurden von allen Experten übereinstimmend als relevant erachtet (Tabelle 3). Daraus ergab sich für die gesamte SOS-DE ein S-CVI/Ave von 0,91.

Tabelle 2: Validierungsmatrix der SOS-CH

Item \ Experte	1	2	3	4	5	6	7	8	9	10	11	12	I-CVI
1	1	0	1	1	1	1	1	0	1	1	1	1	0,83
2	1	1	1	1	1	1	1	1	1	1	1	1	1,00
3	1	1	1	1	1	1	1	1	1	1	1	1	1,00
4	0	0	1	1	1	1	1	0	1	1	0	1	0,67
5	1	1	0	1	1	1	1	1	1	1	1	1	0,92
6	1	0	1	1	1	1	1	1	1	1	1	1	0,92
7	1	1	0	1	1	1	1	0	1	1	1	1	0,83
8	1	1	1	1	1	1	1	1	1	1	1	1	1,00
9	1	1	0	1	1	1	1	1	1	1	1	1	0,92
											S-CVI		0,91

0 = Item wurde als „gar nicht relevant" oder als „etwas relevant" beurteilt.
1 = Item wurde als „ziemlich relevant" oder als „sehr relevant" beurteilt.

Tabelle 3: Validierungsmatrix der SOS-DE.

Experte / Item	1	2	3	4	5	6	7	8	9	10	11	12	13	I-CVI
1	1	1	1	1	1	1	1	1	1	1	1	1	1	**1,00**
2	1	1	1	1	1	1	1	1	1	1	1	1	1	**1,00**
3	1	1	1	0	1	0	1	1	1	1	1	1	1	**0,85**
4	0	1	1	1	1	1	1	1	1	1	1	1	1	**0,92**
5	1	1	1	1	1	1	1	1	1	0	1	1	1	**0,92**
6	1	0	1	1	1	1	1	0	1	1	1	1	1	**0,85**
7	0	1	1	0	1	1	1	1	1	1	1	1	1	**0,85**
8	1	1	0	1	1	1	1	1	1	1	1	1	1	**0,92**
9	1	1	1	1	1	0	1	1	1	1	1	1	1	**0,92**
											S-CVI AVE			**0,91**

0 = Item wurde als „gar nicht relevant“ oder als „etwas relevant“ beurteilt.
1 = Item wurde als „ziemlich relevant“ oder als „sehr relevant“ beurteilt.

Auf Basis der quantitativen Ergebnisse des *Content Validity Ratings* und der „qualitativen“ schriftlichen Kommentare wurden im Folgenden sprachliche Anpassungen einzelner Items diskutiert bzw. vorgenommen. So wurde vom Schweizer Forscherteam, beispielsweise bei Item 1 „Wir haben ein klares Bild von den Begabungen und Fähigkeiten/Fertigkeiten (Fachkompetenzen) unserer einzelnen Teammitglieder“ der Expertenkommentar, dieses Item mit „…und setzen diese entsprechend ein“ zu ergänzen, nicht aufgenommen. Diese eigentlich plausible Ergänzung hätte die Aussage von Item 1 jedoch mit einer Aktivitätskomponente erweitert, die die Bedeutung der originalen Item-Aussage deutlich und das Antwortverhalten von Befragten in anzunehmender Weise verändert hätte. Bei Item 5 „Beim Übergaberapport an die nächstfolgende Pflegende wird üblicherweise besprochen, worauf zu achten ist“ wurde der Begriff „üblicherweise“ durch eine Expertin als verbesserungswürdig deklariert. Das Forscherteam diskutierte andere Begriffe, fand aber keine überzeugende Alternative und hat die Aussage deshalb so belassen.

In der SOS-DE wurde vom deutschen Forscherteam für Item 3 die Formulierung „Wir sprechen miteinander“ in „Wir tauschen uns aus“ und für Item 7 die Formulierung „nicht schiefgehen dürfen“ in „auf keinen Fall scheitern dürfen“ geändert.

3.3.4 Diskussion

Für die Bestimmung der Inhaltsvalidität der SOS wurde mit der Ermittlung des CVI ein transparentes und ressourcensparendes Verfahren detailliert und nachvollziehbar vorgestellt. Wenngleich sich beispielsweise Gruppensitzungen mit Experten und Expertinnen oder Delphi Verfahren zur Bestimmung der Inhaltsvalidität als *Face Validity* eignen, können diese Verfahren aufgrund ihres Forschungsansatzes nur ein begrenztes Maß an Objektivität gewährleisten. Deshalb sollte auf die alleinige Verwendung solch „qualitativer" Verfahren verzichtet werden [26]. Unter den verschiedenen wissenschaftlichen Methoden zur Bestimmung der Inhaltsvalidität von neu konstruierten bzw. in einen anderen Kulturraum übersetzten/angepassten Messinstrumenten ist der CVI der bislang einzige „quantitative" Maßstab für die Inhaltsvalidität. Die Bestimmung der Inhaltsvalidität anhand des CVI bietet einen objektiven Maßstab für die inhaltliche Güte und sollte der *Face Validity* vorgezogen werden [26]. Wie in dieser Untersuchung erfolgt, kann jedoch im Sinne eines Mixed-Method-Ansatzes die Bestimmung der Face Validity durch Gruppensitzungen mit Experten der Bestimmung des CVI vorausgehen.

Die S-CVI/Ave Werte für die SOS-CH und SOS-DE bestätigten eine gute Inhaltsvalidität für die gesamte Skala. Allerdings muss der S-CVI/Ave als alleiniger Indikator der Inhaltsvalidität kritisch betrachtet werden, da sich trotz eines hohen durchschnittlichen S-CVI/Ave Wertes für das gesamte Instrument, hinter einzelnen Items niedrige I-CVI Werte verbergen können. Eine differenzierte Betrachtung aller I-CVI Werte ist deshalb für die Beurteilung der Inhaltsvalidität angezeigt. Während in der SOS-DE nach dem *Content Validity Rating* alle neun Items höhere Werte als den empfohlenen Grenzwert von 0,78 aufwiesen [29], lag für die Schweizer Version der SOS ein Item unter diesem Grenzwert (Item 4). Dies kann darauf hinweisen, dass Item 4 „Wir diskutieren für unsere Routinetätigkeiten auch alternative Vorgehensweisen" von den Experten als vergleichsweise wenig bedeutsam im Kontext „Patientensicherheit" bewertet wurde, da diese sicherheitsrelevante Maßnahme in der klinischen Praxis bislang kaum umgesetzt wird.

Wie im Methodenteil dargestellt, bestand das Vorgehen zur Ermittlung der Inhaltsvalidität anhand des CVI in einer prozesshaften Abfolge von vier Schritten. [29] empfehlen grundsätzlich die Analyse der Inhaltsvalidität (Schritt 3) zuerst ausschließlich auf Item-Ebene (I-CVI) durchzuführen und alle Items, deren I-CVI-Wert kleiner gleich 0,78 sind, einer Revision zu unterziehen. Nach Anpassung des Messinstruments (Schritt 4) sollte ein zweites *Content Validity Rating* erfolgen. Die Expertengruppe kann dabei bei der zweiten Expertenbefragung kleiner gewählt werden, d. h. Experten, die alle Items als sehr relevant einschätzen, müssen nicht erneut befragt werden. Diese Empfehlung erweitert die hier dargestellten vier Prozessschritte um zwei weitere Schritte (zweite Expertenbefragung, zweite Berechnung von I-CVI und S-CVI/Ave). [29] zufolge kann allerdings auf die Gruppendiskussion und Anpassung der Items (Schritt 4) und das zweite *Content Validity Rating* verzichtet werden, falls ein Instrument bereits nach der ersten Befragung I-CVI Werte >0,78 aufweist. Dies wäre in

dieser Untersuchung für die SOS-DE der Fall gewesen. Trotzdem wurde vom deutschen Forscherteam für die SOS-DE nach erfolgter Gruppendiskussion und Anpassung der Items eine zweite Expertenbefragung mit 10 Experten durchgeführt, wodurch der S-CVI/Ave Wert von 0,91 bestätigt wurde. Für die SOS-CH wurden die Items, insbesondere Item 4, im Forscherteam auf Basis der Kommentare der Expertenbefragung diskutiert. Allerdings wurde auf eine zweite Expertenbefragung verzichtet, da der I-CVI Wert lediglich für ein Item unter dem empfohlenen Grenzwert lag und das Instrument für eine Studie benötigt wurde.

Als kritische Erfolgsfaktoren für die Inhaltsvalidität eines übersetzten Messinstrumentes und die Bestimmung des CVI können anhand der Erfahrungen in dieser Untersuchung (1) die Übersetzung des Instruments, (2) die transkulturelle Anpassung der Items und (3) die Auswahl der Teilnehmer am *Content Valdity Rating* festgehalten werden. Die Übersetzung der SOS wurde vom Schweizer Forscherteam durch einen rigorosen Übersetzungs- und Rückübersetzungsprozess auf Basis eines internationalen Protokolls vorgenommen. Bei der Übersetzung und Anpassung der Items galt es sicherzustellen, dass der Inhalt und die Bedeutung der Items zwar in einen transkulturellen Kontext gesetzt werden, gleichzeitig aber die ursprüngliche Bedeutung erhalten blieb [32]. Dies wurde vom Schweizer Forscherteam u.a. durch die Überprüfung der Augenscheinvalidität während und nach dem Übersetzungsprozess gewährleistet. Als wichtige Informationsquelle für die sprachlichen Anpassungen und Verfeinerungen des Instruments haben sich die Kommentare, welche neben der Beurteilung der Relevanz von den Experten zu den Items ergänzt wurden, bewährt.

Die sorgfältige Auswahl der Teilnehmer an der Expertenbefragung, welche die Relevanz der einzelnen Items in Bezug auf das zu Grunde liegende Konzept/Konstrukt bewerten, spielt eine entscheidende Rolle. Derzeit sind keine methodische Vorgehensweise bzw. explizite Kriterien für die Expertenauswahl in der Literatur beschrieben. Als einziges Kriterium wird von [29] erwähnt, dass die Teilnehmer an der Expertenbefragung mit dem zu bewertenden Konstrukt vertraut sein sollen. Die Auswahl für die berichteten Erhebungen erfolgte jeweils durch eine Person in einem Krankenhaus, welche vom jeweiligen Forscherteam beauftragt wurde, Experten für das *Content Validity Rating* auszuwählen. Diese Strategie könnte zu einer Auswahl interessierter und hoch motivierter Experten und zu einer Überschätzung der Inhaltsvalidität geführt haben. Die Auswahl der Experten (Gelegenheitsstichprobe) muss als limitierender Faktor gesehen werden.

3.3.5 Schlussfolgerungen

Die Bestimmung der Inhaltsvalidität anhand des CVI stellt einen quantitativen Indikator und ein transparentes, nachvollziehbares und ressourcensparendes Verfahren dar. Auf Basis der internationalen Literatur wurde ein mindestens vier Prozessschritte umfassender Ablauf definiert. Bei niedrigen I-CVI nach der Expertenbefragung müssen nach erfolgter Diskussion und Anpassung der Items zwei weitere Schritte, eine erneute Expertenbefragung (*Schritt 5*) und eine erneute Bestimmung der CVI für die einzelnen Items (I-CVI) und die gesamte Skala (S-CVI/Ave) (*Schritt 6*), in Betracht gezogen werden. Als kritische Erfolgsfaktoren für die Bestimmung des CVI von übersetzten Messinstrumenten / Fragebögen können anhand dieser Untersuchung die Übersetzung nach internationalen Standards, die sorgfältige transkulturelle Adaptation der einzelnen Items, sowie die Auswahl der Teilnehmer am Content Validity Rating genannt werden.

Anhand der S-CVI/Ave Werte können der SOS-CH und der SOS-DE je eine gute inhaltliche Validität zugesprochen werden. Die Instrumente können im deutschsprachigen Raum in Studien zur Erfassung des Sicherheitsklimas eingesetzt werden, um die weiteren psychometrischen Eigenschaften der beiden SOS Versionen zu testen. In der europäischen RN4CAST Studie [33] wurde das Instrument kürzlich in der Schweiz benutzt. Bei entsprechendem Nachweis der Konstruktvalidität (Konvergenz- und Diskriminanzvalidität), Kriteriumsvalidität und Reliabilität kann die SOS in der Praxis beispielsweise zum Monitoring des Sicherheitsklimas im Krankenhaus verwendet werden.

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CHAPTER 4

VALIDITY AND RELIABILITY ON THREE EUROPEAN LANGUAGE VERSIONS OF THE SAFETY ORGANIZING SCALE

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4.1 Abstract

Background: The Safety Organizing Scale (SOS) offers a reliable snapshot of nurses' engagement in unit-level safety behaviours in hospitals. As no comparable questionnaire exists in German, French and Italian, we explored the psychometric properties of SOS translations into each of those languages.

Design and Methods*:* The psychometric properties of the 9-item SOS were tested according to American Educational Research Association guidelines.

Subjects and Setting*:* Between October 2009 and June 2010, 1633 registered medical and/or surgical nurses in 35 Swiss hospitals completed translated SOS questionnaires.

Results*:* For each translation, psychometric evaluation revealed evidence based on content (scale-content validity index > 0.89), response patterns (e.g., average of missing values across all items = 0.80%), internal structure (e.g., comparative fit indices > 0.90, root mean square error of approximation < 0.08) and reliability (Cronbach's alpha > 0.79). We differentiated the scale regarding one related concept (implicit rationing of nursing care). Higher SOS scores correlated with supportive leadership and lower nurse-reported medication errors, but not with nurse-reported patient falls.

Conclusions*:* The SOS offers a valuable measurement of engagement in safety practices that might influence patient outcomes. Initial evidence regarding the validity and reliability of the translated versions supports their use in German, French and Italian. Concurrent validity will require confirmation via further analysis using more reliable outcome measures (e.g., mortality rates). The translated versions' predictive validity needs to be established in prospective studies.

4.2 Introduction

As a fundamental determinant of quality in healthcare organizations, safety culture must be considered in assessing incidences of adverse events and negative outcomes [1-4]. High-risk industries such as aviation successfully use safety culture questionnaires to identify potential improvements and correct faulty processes [5, 6]. In European healthcare, however, as no valid, reliable instrument is available to measure safety culture, it is not yet possible to do the same in terms of patient safety [7]. This study is a step toward bridging that gap by translating and testing a measure of safety behaviour in all three languages of Switzerland.

4.2.1 Safety culture and high reliability

In the past years it has become obvious that quality and patient safety are major challenges for healthcare [8-10]. According to patient safety experts, developing a "safety culture" is a foundation for overcoming current safety and quality problems in healthcare [11-13]. Numerous conceptual definitions exist for safety culture, most of which originated in high-risk industries [5, 14]. For instance, safety culture within healthcare organizations can be defined as a "subset of organizational culture which relates specifically to the values and beliefs concerning patient safety" [15, p. 312], depending of the prevailing sub-cultures of its single units [16]. However, a "lived safety culture" must be visible as reflected by observable safety behaviours [17].

Despite many improvements, healthcare is still struggling in creating a culture that sustains high levels of safety and quality performance over time [18]. Research on "high-reliability organizations" revealed that a key feature of their safety culture that facilitates the maintenance of excellent performances is "collective mindfulness" [19]. To stay mindful despite hazardous environments frontline employees consider constantly five principles: tracking small failures, resisting oversimplification, remaining sensitive to operations, maintaining capabilities for resilience and taking advantage of shifting locations of expertise [18, 19]. Studying „collective mindfulness" in healthcare could help to better understand healthcare professionals' behaviours underlying a patient safety culture [17] and might be a fruitful pathway leading to maintainance of safety performance over time [18].

4.2.2 Measuring the reliability of healthcare organizations

The Safety Organizing Scale (SOS) [17], developed by Vogus & Sutcliffe, corresponds to such interrelated behavioural safety processes of "collective mindfulness" [17, p. 47]. The SOS is a unidimensional instrument backed by high-reliability organisational theory. The nine items (see Table 2) assess the extent RNs and their colleagues engage in safety behaviours and practices on their unit. Previous evidence supports the SOS's strong psychometric properties [17].

As no validated safety culture questionnaire existed in German, French and Italian, the SOS's psychometric excellence and uni-dimensional structure made it a strong candidate for cross-cultural testing. In addition, replication of studies under new conditions increases external generalizability of findings and the validity of the underlying theory [20]; if results on the SOS could be confirmed in a different cultural context, the underlying theory of high-reliability organizations in healthcare and the measurement of it by the SOS would be supported. To measure safety culture across a national sample of Swiss hospitals, we translated the SOS into German, French and Italian, then used the translated versions within the framework of the Swiss RN4CAST study (Nurse Forecasting: Human Resources Planning in Nursing). We surveyed registered nurses, as they represent the largest subgroup of healthcare professionals in hospitals and play a major role in guaranteeing patient safety [21-23].

This study aims to explore the psychometric properties of the German, Italian and French versions of the SOS by translating the instrument and assessing its reliability and validity in new settings.

4.3 Methods

4.3.1 Design

This is a sub-study of the Swiss RN4CAST study, a multicentre cross-sectional study within the EU Seventh Framework (EU Project number: 223468).

4.3.2 Setting and sample

RNs working on medical, surgical and mixed medical-surgical wards of Swiss acute-care hospitals were surveyed. Hospitals were sampled according to a quota sample method based on language region and hospital type (university, cantonal and regional hospitals with ≥ 60 beds and ≥ 50 RNs). For university and cantonal hospitals random samples of 2 to 6 eligible wards were selected; for smaller regional hospitals, all eligible wards were included to survey at least 50 RNs per hospital. All RNs active on the selected units were invited to participate.

4.3.3 Cross-cultural translation of the SOS

To adapt the SOS in a culturally relevant and comprehensible form while maintaining its original meaning and intent [24], we translated the SOS according to the adapted Brislin model [25] – an iterative process involving forward-backward translation and expert group discussion. The 7-point Likert response scale was retained. Following back-translation, our expert group identified no inconsistencies in any item's meaning or wording.

4.3.4 Validity and reliability testing

Our general research question was whether German, French and Italian versions of the SOS would reveal psychometric properties similar to those of the original. Therefore, our validation strategy was based on that of Vogus & Sutcliffe [17]. Following American Educational Research Association guidelines, [26] hypotheses and research questions were developed specific to test the three translations' validity and reliability (Table 1).

Evidence based on content was examined regarding **research question 1** (Table 1). After translating, we asked experienced RNs whether the SOS reflected a relevant content domain. For each language version 10 experienced RNs were asked to rate the extent to which the SOS reflected nurses' safety behaviours. We established content validity by calculating the consensus estimates of the ratings of item scale relevance (content validity index of individual items and overall scale) [27].

Evidence based on response processes (**research question 2 & 3**, Table 1) was compiled through assessment of distribution and skewing of the data, missing responses, multiple crosses for each item and overall scale, and acceptability (number of respondents omitting no items).

The internal consistency of the measurements and the precision of test results were tested via **research question 4** (Table 1) by calculating Cronbach's Alpha. Further, to test whether the translated versions of the SOS reliably reflect a unit level construct– making aggregation of data appropriate – we computed five measures. Using F-statistic from a one-way variance analysis we calculated between-group variance. We applied two types of intraclass correlations, to calculate the proportion of variance explainable by unit membership (intraclass correlation 1) and the reliability of unit means (intraclass correlation 2). Both measures describe how strongly responses from RNs' in the same unit resemble each other. [17]. We also calculated design effects to account for within-group sample size, which could have inflated intraclass correlations. The degree to which responses of individuals within a group are interchangeable was calculated with the within-group agreement [17].

To provide evidence based on internal structure we aimed to confirm the uni-dimensional structure of the original (English) SOS [17] (**Hypothesis 1,** Table 1). To test whether our model would fit the data, we conducted confirmatory factor analysis.

We assessed discriminant and concurrent validity to provide evidence of the relationships of the SOS with other variables. Both RNs engagement in safety behaviours and implicit rationing of nursing care might be visible features of a safety culture and are therefore related to each other. Yet, implicit rationing of nursing care served as a comparison concept to explore whether the SOS is discriminant from this important factor determining patient safety and quality of care [28] (**Hypothesis 2,** Table 1). Vogus & Sutcliffe provide initial evidence that better leadership abilities of nurse managers and adequate staffing levels are associated with better safety culture, and fewer adverse events such as medication errors and patient falls [17, 29]. To provide concurrent validity for the translated versions of the SOS we assessed these relationships in the Swiss cross-cultural setting (**Hypotheses 3 – 5,** see Table 1). Five variables were used for discriminant and concurrent validity testing: Implicit rationing of nursing care, leadership abilities, staffing level, medication errors and patient falls.

Implicit rationing of nursing care, i.e. "the withholding of or failure to carry out necessary nursing measures for patients due to a lack of nursing resources (staffing, skill mix, time)" was measured with the 32-item, uni-dimensional *Basel Extent of Rationing of Nursing Care (BERNCA)* instrument [28], which asks how often in their last 7 working days nurses have been unable to carry out any of 32 listed necessary nursing tasks. Evidence is supporting the BERNCA's validity and reliability [28]. Cronbach's alphas for the German-, French- and Italian language versions were 0.94, confirming the internal consistency of this construct.

To assess leadership abilities we used the "*Nurse Manager Ability, Leadership, and Support*" subscale of the *Practice Environments Scale* [30], which asks nurses whether specific leadership elements are present at their workplace. Psychometric strength of the PES was reported in previous studies [30, 31]. Cronbach's alphas for the German- and Italian-versions were 0.76, for the French-version, 0.80.

The staffing level and adverse outcomes were measured with RN self report of the *nurse-to-patient ratio* on the last shift, and the frequency of *medication errors* and *patient falls* on their units over the last year. These three variables matched single items from the instrument battery of the RN4CAST nurse questionnaire. All instruments and items (except the SOS) used in the Swiss RN4CAST study had been used in previous studies [32, 33].

4.3.5 Data collection and data management

Data collection took place between October 12, 2009 and June 30, 2010. For each participating hospital a pre-identified contact person (e.g., nursing expert, chief nursing officers) supported us in planning and conducting the data collection. If response rates were below 70% after 2 weeks of data collection, reminders were sent. Completed questionnaires were scanned and data were subjected to quality control procedures.

4.3.6 Statistical analysis

The statistical analyses corresponding to our research questions and hypotheses are listed in Table 1. To evaluate the SOS's internal structure we performed confirmatory factor analysis using MPlus (version 6.1, 2010, Muthen & Muthen).

Descriptive, correlation, reliability and variance analyses were performed using IBM SPSS Statistics (version 18.0.2; SPSS Inc., Chicago, IL); regression analysis was performed with STATA (version 11/SE; StataCorp LP), while ICCs, design effects and within-group agreement were calculated with Microsoft Office Excel 2011®. All hypotheses were subjected to two-sided testing, whereby the level of significance was set at $P < 0.05$.

4.3.7 Ethical considerations

Surveyed RN consented to participate in the study by voluntarily completing and returning the questionnaires. The study was approved by ethics committees representing all involved cantons.

Table 1: Research questions and hypotheses of this validation study

Evidence on validity and relaibility	Research questions (R) and hypothesis (H)	Developed research questions and hyphothesis	Statistical analyses	Desirable results for decision making
Evidence based on content	R1	Are the 9 items relevant and appropriate in terms of safety culture in the Swiss healthcare setting?	Calculation of the Content Validity Indices for individual items (I-CVI) and scale-level content validity index S-CVI/Ave	I-CVI of more than 0.78 and S-CVI/Ave of more than 0.90 indicate excellent content validity [27]
Evidence based on response processes	R2	How many missing values appear in the SOS?	Descriptive statistics (frequencies, medians, interquartile ranges, means, standard deviations, variances, graphs, and cross-tabulations)	- Floor effects [>50% indicating 1 (not at all) or 2 (to a very limited extent)] - Ceiling effects [>50% indicating 6 (to a great extent) and 7 (to a very great extent)].
	R3	Are there distribution abnormalities in the different items of the SOS?		
Internal consistency	R4 (Reliability)	Is the SOS instrument internally consistent and does it reflect on a unit-level construct?	- Calculations of Intraclass correlations, within-group-agreement and design effects based on results of one-way ANOVA with the Safety Organizing score as the dependent variable and hospital units as independent variable - Calculation of Cronbach's alpha.	- Significant between-group variance using F-statistic (P<0.05) - Intraclass correlation 1 between 0.05 and 0.30 and Intraclass correlation 2 above 0.70 [17]. - Design effects should be ≥ 2 to demonstrate the nesting of the data [38]. - Within-group agreement values should be 0.70 or greater [17]. - Cronbach's alpha ≥ 0.70 indicate factor consistency [39]
Evidence based on internal structure	H1	The translated German, Italian and French versions of the SOS have an unidimensional structure	Confirmatory Factor Analysis	-Non-significant chi-square values -Comparative fit index > 0.90 - Weighted root mean square residual < 0.90 - Upper confidence interval of the root mean square error of approximation < 1.00 - P of close fit > 0.05 [36]
Evidence based on relationship with other variables	H2 (Discriminant validity)	Safety culture is not strongly correlated with implicit rationing of nursing care (BERNCA).	Spearman's correlation	Less than a strong correlation (r_s < .40)
	H3 (Concurrent validity)	There is a positive relationship between leadership abilities of the ward nurses (measured with the PES) and safety culture (measured with the SOS)	Multilevel linear regression analysis	Significant positive regression coefficient between leadership abilities and the SOS (P<0.05) after adjusting for hierarchical data structure
	H4 (Concurrent validity)	There is a negative relationship between nurse-to-patient ratio and safety culture.	Multilevel linear regression analysis	Significant negative regression coefficient between leadership abilities and the SOS (P<0.05) after adjusting for hierarchical data structure
	H5 (Concurrent validity)	There is a negative relationship between safety cimate and nurse-reported medication errors and patient falls	Multilevel logistic regression analysis	Significant odds for lower frequent nurse reports for medication errors and patient falls (odds ratios < 1.00, P<0.05) after adjusting for hierarchical data structure

4.4 Results

Questionnaires were completed and returned by 1633 RNs (overall response rate = 72%: German = 73%; French = 74%; Italian = 69%). Of these, 1630 (German = 1074; French = 401; Italian = 155) were eligible for statistical analyses (3 questionnaires were excluded from analysis as they could not be assigned to a unit). Characteristics of the participant sample are presented in Table 2.

Table 2: Characteristics of the participating hospitals and registered nurses

Hospitals	Total Switzerland (N=35)	German Speaking region (n=20)	French speaking region (n=11)	Italian speaking region (n=4)
Hospital type– n				
University hospital	4	2	2	-
Cantonal hospital	15	8	5	2
Regional hospital	16	10	4	2
Hospital size (Acute care beds) – n				
Large (> 500)	6	4	2	-
Intermediate (200 – 500)	12	6	4	2
Small (< 200)	17	10	5	2
No. units – n				
Medical	62	32	22	8
Surgical	59	36	17	6
Mixed medical/surgical	11	11	-	-
Unit size (beds) – Median (IQR)	21 (8)	20 (9)	20 (8)	22 (5)
Patients per registered nurse – Median (IQR)	7 (5)	7 (5)	7 (7)	8 (2)
Registered nurses	**(N=1630)**	**(n=1074)**	**(n=401)**	**(n=155)**
Female - %	91.7	94.0	89.1	82.1
Age (in years) - %				
20-30	41.7	42.9	39.7	37.8
31-40	27.9	26.1	30.8	33.6
41-50	20.5	20.7	20.8	18.2
>51	9.9	10.3	8.7	10.5
Nurse training in Switzerland - %	78.0	84.0	63.0	72.0
Employment - %				
>90%	48.5	47.5	12.8	9.0
51-90%	32.6	29.9	37.6	38.2
10-50%	18.9	22.6	49.6	52.8
Professional experience (in years) – Median (IQR)				
as a nurse	8 (15)	8 (16)	7 (13)	8 (14)
in this hospital	5 (10)	5 (10)	5 (10)	6 (10)

IQR indicates Interquartile range

The content validity ratings for the three language versions of the SOS revealed the relevance both of the individual items and of the overall SOS scale. Content validity indices for individual items for the German version ranged from 0.6 (items 4) to 1.0 (items 2, 3 and 8); for the French version from 0.7 (item 7) to 1.0 (items 2, 6 and 8); and for the Italian version from 0.7 (items 3 and 7) to 1.0 (items 2, 6 and 8). Scale-level content validity index was 0.91 for the German and the French versions and 0.89 for the Italian version.

Frequencies of missing values were low, ranging from 0.4% to 1.9% (average = 0.8%). In all, 1564 RNs (95.8%) submitted questionnaires with no missing values. For confirmatory factor analysis, then, we used only data from complete questionnaires.

Mean item values on the 7-point scale ranged from 4.62 (standard deviation = 1.27; item 4) to 5.62 (standard deviation = 1.07; item 5). The mean for the entire scale (SOS score) was 5.11 (standard deviation = 0.91) and the median score was 5.22 (25th-75th quartile = 4.56, 5.22, 5.78). All nine items and the SOS score were slightly left-skewed and minor ceiling effects could be observed in items 5, 6 and 9.

The alpha coefficients for this one-dimensional construct were 0.90 (German), 0.92 (French) and 0.79 (Italian), indicating scale reliability. The reliability of the SOS as an aggregate unit measure was shown by the significant ANOVA, within group agreement, intraclass correlation 1, and design effects. The intraclass correlation 2 scores were slightly below recommended levels for the French and Italian versions (see Table 3).

Table 3: Measures to determine the effect of data nesting of the Safety Organizing Scale within hospital units

Measures	German version (n=1038)	French version (n=385)	Italian version (n=141)
F-statistics	F(85,952)=4.19***	F(35,349)=2.48***	F(13,127)=2.48**
Within-group-agreement	0.96	0.93	0.94
Intraclass correlation (ICC) (1)	0.19	0.11	0.11
Intraclass correlation (ICC) (2)	0.76	0.59	0.59
Design effect	3.09	2.21	2.21

*P<0.05, **P<0.01, ***P<0.001

For each language version confirmatory factor analyses described the closest possible data fit. As Table 4 shows, items had highly significant factor loadings for all three versions. For the German and French versions our model demonstrated excellent fit across all fit-indices; for the Italian version we failed only to demonstrate an acceptable root mean square error of approximation (Table 4). In summary, these results provide evidence of the one-dimensional structure of all three translated versions of the SOS and justify the aggregation of the nine individual items to a single SOS score.

Table 4: **Standardized factor loadings, standard errors and fit-indices of the confirmatory factor analysis for the three language versions of the Safety Organizing Scale**

Items of the SOS	German version (n=1038)		French version (n=385)		Italian version (n=141)	
	Factor loadings	Standard Error	Factor loadings	Standard Error	Factor loadings	Standard Error
1. We have a good "map" of each other's talents and skills	0.708***	0.018	0.760***	0.026	0.402***	0.068
2. We talk about mistakes and ways to learn from them	0.823***	0.014	0.814***	0.021	0.783***	0.042
3. We discuss our unique skills with each other so we know who on the unit has relevant specialized skills and knowledge	0.828***	0.012	0.859***	0.016	0.762***	0.044
4. We discuss alternatives as to how to go about our normal work activities	0.760***	0.014	0.879***	0.016	0.826***	0.036
5. When giving report to an oncoming nurse, we usually discuss what to look out for	0.616***	0.023	0.746***	0.028	0.369***	0.075
6. When attempting to resolve a problem, we take advantage of the unique skills of our colleagues	0.804***	0.013	0.771***	0.021	0.665***	0.051
7. We spend time identifying activities we do not want to go wrong	0.630***	0.021	0.653***	0.029	0.742***	0.038
8. When errors happen, we discuss how we could have prevented them	0.736***	0.019	0.799***	0.021	0.843***	0.040
9. When a patient crisis occurs, we rapidly pool our collective expertise to attempt to resolve it	0.611***	0.022	0.708***	0.027	0.489***	0.060
Chi square	50.710***		26.003*		24.811*	
Degrees of freedom	13		13		13	
Comparative Fit Index	0.997		0.998		0.993	
Root Mean Square Error of Approximation (90%Confidence Interval)	0.053 (0.038,0.069)		0.051 (0.021,0.079)		0.080 (0.028,0.128)	
P of Close Fit	0.352		0.437		0.139	
Weighted Root Mean Square Residual	0.462		0.319		0.375	

*$P<0.05$, **$P<0.01$, ***$P<0.001$

To show concurrent validity, correlation analysis between the SOS and the BERNCA revealed a weak but statistically significant negative relationship for all three translations (German $r_s = -0.24$ $p < 0.01$; French $r_s = -0.24$, $p < 0.01$; Italian $r_s = -0.28$, $p < 0.01$). These results distinguish safety culture, as measured with the SOS, from implicit rationing of nursing care.

As reported in Table 5, concurrent validity was examined via several regression models. The first shows the association of nurse-reported leadership and patient-to-RN ratios on the SOS Score. For all three translations leadership was positively related to the SOS, whereas no significant relationships were found between the patient-to-RN ratios and the SOS (Table 5). Model 2 shows that higher SOS scores were associated with lower nurse-reported medication errors for all three translations (German: odds ratio = 0.941,; French: odds ratio = 0.959,; Italian: odds ratio = 0.878,), whereas in model 3 no SOS score was significantly related to patient falls in any language version (Table 5).

Table 5: **Multilevel regression analysis results for relationship of the Safety Organizing Scale with other variables (concurrent validity)**

Language versions	Variables	SOS (Model 1)		Medication Errors (Model 2)		Patient Falls (Model 3)	
		Coefficient (*P*)	95% CI	Coefficient (*P*)	95% CI	Coefficient (*P*)	95% CI
German version (n=1038)	**Safety Organizing Score**	-	-	-0.060 (<0.001)	-0.092 to -0.028	-0.013 (0.279)	-0.036 to 0.010
	Leadership	0.612 (<0.001)	0.524 to 0.700	-0.016 (0.604)	-0.064 to 0.031	0.007 (0.684)	-0.027 to 0.042
	Patient-to-RN ratio	-0.006 (0.142)	-0.014 to 0.002	0.001 (0.336)	-0.002 to 0.006	0.001 (0.362)	-0.001 to 0.004
	Intercept (86 units)	2.977 (0.001)	2.488 to 3.466	0.545 (<0.001)	0.281 to 0.809	0.079 (0.414)	-0.111 to 0.270
French version (n=385)	**Safety Organizing Score**	-	-	-0.042 (0.031)	-0.081 to -0.004	-0.017 (0.340)	-0.051 to 0.018
	Leadership	0.603 (<0.001)	0.443 to 0.762	-0.013 (0.682)	-0.075 to 0.049	-0.035 (0.224)	-0.091 to 0.021
	Patient-to-RN ratio	0.003 (0.773)	-0.016 to 0.022	0.007 (0.048)	0.00007 to 0.014	0.002 (0.490)	-0.004 to 0.009
	Intercept (36 units)	2.415 (0.001)	1.502 to 3.328	0.517 (0.004)	0.166 to 0.867	0.432 (0.007)	0.119 to 0.744
Italian version (n=141)	**Safety Organizing Score**	-	-	-0.130 (0.017)	-0.236 to -0.023	-0.092 (0.086)	-0.196 to 0.013
	Leadership	0.434 (<0.001	0.201 to 0.667	0.026 (0.703)	-0.108 to 0.160	-0.013 (0.847)	-0.143 to 0.117
	Patient-to-RN ratio	0.008 (0.663)	-0.029 to 0.046	0.005 (0.650)	-0.016 to 0.026	0.001 (0.895)	-0.021 to 0.024
	Intercept (14 units)	4.483 (0.001)	3.126 to 5.839	0.211 (0.640)	-0.673 to 1.095	0.601 (0.189)	-0.296 to 1.498

Multilevel linear (Model 1) and logistitc (Model 2 and 3) regression analysis were performed with STATA 11 with unit-level random effects. Including the random effects accounts for the hierarchical structure of the data (RNs nested within units).

Coefficient in model 1 refers to the unstandardized regression coefficients (B), in model 2 and 3 to logit coefficients.

All models were adjusted for sociodemographic characteristics of RNs (age, education, employment grade, professional experience).

RN indicates registered nurses, *P* = P-value, CI, confidence interval

4.5 Discussion

This study provides evidence supporting the validity and reliability of all three translated versions of the SOS, which we tested in the cultural context of the Swiss healthcare system, pursuing procedures conforming to rigorous international standards [26].

The SOS measures healthcare professionals' engagement in crucial safety behaviours at the unit level, reflecting the safety culture of healthcare organizations. Most instruments measuring the patient safety culture are based on multi-dimensional conceptualizations [1, 34], but capture few patient safety behaviours. In our understanding, safety culture is characterized by visible features of a safety culture [35], such as safety behaviours of professionals that directly influence patient outcomes. The SOS's quick diagnostic sampling of crucial patient safety behaviours reflecting on "collective mindfulness" makes it a valuable tool for monitoring the reliability of healthcare organizations.

Overall, our results indicate similar psychometric properties to those for the original SOS. *Evidence based on content* confirmed our accurate and rigorous translation process. This might have resulted in a low proportion of missing values and indicated the instrument's practicability and acceptability (*evidence based on response processes*). The observed slightly positive data skewing and ceiling effects for three out of nine items give little reason for concern (e.g. systematic measurement error), because all 9 items still reflected variability across units. However, the SOS's responsiveness to change needs to be explored in future safety and quality improvement research.

The structure of the tool as uni-dimensional was supported for all versions. Item loadings on one factor were strong for all three versions. The one weak value was for the Italian SOS version; we failed to demonstrate adequate root mean square error of approximation. The root mean square error of approximation depends on the sample size, represented in the denominator of its equation [36]. Although only a few parameters required estimation, the sample size for the Italian version was likely not sufficient for an adequate estimation of this fit index and its confidence interval. Future studies should re-confirm the internal structure of the Italian version with a larger sample size.

While we confirmed the hypothesis that supportive leadership was positively related with the SOS (H3), we found no association between the patient-to-RN ratio and the SOS (H4). The recall of the workload of each RN for the last shift might not be accurate and there was little variability in the data across the hospitals, making it difficult to show a relationship with the SOS. In contrast to Vogus & Sutcliffe [17] SOS scores were inversely associated with nurse-reported medication errors, but showed no relationship with nurse-reported patient falls. We assume that the SOS might be less sensitive to this type of adverse events, as there are many patient-related risk factors triggering patient falls [37], which are difficult to be influenced by RNs general safety behaviours. Our initial inconsistent findings on the relationship between the translated versions of the SOS and patient outcomes require confirmation via fur-

ther analysis using more reliable outcome measures (e.g., mortality rates), as our nurse-reported patient outcomes may be subject to bias (recall bias) and therefore less sensitive to other variables, such as the SOS [3]. The RN4CAST study used a cross-sectional design, which does not allow deriving causal inferences between the SOS and patient outcomes. Predictive validity of the translated versions of the SOS for patient safety outcomes need to be established in future prospective studies. One further limitation of this study is that in terms of the psychometric properties of the measures used to provide evidence based on relationships with other variables were only evaluated concerning their internal consistency.

4.6 Conclusions

In summary, the SOS is a valuable tool to measure RNs' engagement in safety behaviours and processes with possible direct relationships to patient outcomes. Initial evidence on the validity and reliability of the translated SOS versions support their use in German-, French- and Italian-speaking healthcare settings. In clinical practice it can be used to describe and monitor both the extent of healthcare professionals' engagement in the tested behaviours / processes and the prevailing "collective mindfulness" at unit-level. As the individual items entail information on changeable behaviours / processes, the SOS allows unit and hospital leaders to plan, implement and evaluate interventions to improve the safety culture [14].

With further validity testing of the German, French and Italian SOS versions, this measure can be used in outcome research to explain its interaction with other known outcome influencing factors, such as rationing of nursing care or the nurse practice environment. This would augment our knowledge of the most significant factors of clinical practice related to patient safety and quality of care.

4.7 Funding /Potential competing interests

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CHAPTER 5

NURSE-REPORTED PATIENT SAFETY CLIMATE IN SWISS ACUTE CARE HOSPITALS – A DESCRIPTIVE-EXPLORATIVE SUBSTUDY OF THE SWISS RN4CAST STUDY

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5.1 Summary

Questions under study*:* Measuring the patient safety climate in healthcare organization can help to identify problematic issues in order improve patient safety. We aimed (1) to describe the nurse-reported engagement in safety behaviors, (2) the prevailing nurse-reported patient safety climate of general medical, surgical and mixed medical-surgical units in Swiss acute-care hospitals and (3) to explore differences between hospital type, unit type and language regions.

Methods*:* This substudy utilized data from the nurse survey (N=1,633) of the multicentre-cross sectional RN4CAST study. Patient safety climate was measured with the 9-item Safety Organizing Scale (SOS) which captured registered nurses' engagement in safety behaviors and practices at the unit level.

Results*:* A total of 35 Swiss hospitals participated in the study. Of the 120 eligible units included in the analysis, only on 33 units (27.5%) did at least 60% of the nurses report a positive patient safety climate. A majority of nurses (51.2-63.4%, n=1564) reported that they were "consistently engaged" in only three of the nine measured patient safety behaviors. Our multilevel regression analyses revealed both significant between-unit and between-hospital variability. From our three variables of interest (hospital type, unit type and language regions) only language regions was consistently related to nurse-reported patient safety climate. Nurses in the German-speaking region reported more positive patient safety climate than nurses in the French- and Italian-speaking language regions.

Conclusions*:* The findings of this study suggest a need to improve the patient safety climate on many units in Swiss hospitals. Leaders in hospitals should strengthen the patient safety climate at unit level by implementing methods, such as root cause analysis or patient safety leadership walk rounds to improve individual and team skills and redesigning work processes. The impact of these efforts should be measured by periodically assessing the patient safety climate with the SOS.

5.2 Introduction

Today's hospital based healthcare is highly complex and despite high quality standards adverse events (AEs) occur every day. Internationally, between 2.9% and 16.6% of hospitalized patients are affected by AE such as surgical (peri- and postoperative) complications, medication errors, healthcare-associated infections or patient falls [1-6]. Healthcare is often delivered in a high risk and dynamic environment, involving a vast array of technology and many individual decisions and judgments by healthcare professionals. Most AEs do not result from individual recklessness [7], but from faulty systems/processes that provide conditions that lead people to make mistakes or fail to prevent them [8].

According to international experts, the development of a so-called "culture of safety" within healthcare organisations appears to be a systemic and fruitful approach to better understand patient safety mechanisms and protect patients from harm due to AEs [9, 10]. Patient safety culture is defined as a „subset of organizational culture, which relates specifically to the values and beliefs concerning patient safety within healthcare organizations" [11, p. 312]. In high-risk industries such as aviation or nuclear power a common approach to evaluate and improve the safety culture is the use of workforce surveys designed to assess and monitor the safety climate (i.e., the perceived safety culture of a particular place at a particular time) [12].

Measuring the patient safety climate (PSC) in healthcare organizations provides insight into the safety of healthcare environments [10]. Such results, in turn, can help to identify problematic areas/issues and lead to the development of adequate counter measures [13-16]. Recent studies investigated the PSC within hospitals and its various clinical areas. The results demonstrated that employees' perceptions of the PSC varied between and within hospitals [17]. Personnel in specialized areas, where patients may be at higher risk for AE, such as emergency departments, perceived lower PSC than those in other hospital wards. Nurses had an overall lower perception of the PSC than other disciplines (e.g. physicians) and frontline workers perceived a lower PSC than management [18-20]. Studies have identified problematic PSC issues in intensive care units [21-23] and operating rooms [24-27], such as poor communication and teamwork [25].

Despite an increasing interest on studying the PSC in healthcare organizations over the past years, most of research on this topic was carried out in the US and few studies have been conducted in European healthcare systems [15, 28, 29], including Switzerland [30]. In addition, although the perception of PSC has been found to differ between various healthcare professionals, little attention has been given to describing nurses' perceptions of the PSC in depth, which is important considering their key role in delivering patient care and protecting patients from harm [31]. For the first time in Switzerland, we aimed (1) to describe the nurse-reported PSC on general medical, surgical and mixed medical-surgical units in a national hospital sample, (2) to describe nurses' engagement in specific

safety behaviors, and (3) to explore the association between the nurse-reported PSC and characteristics of Swiss acute care hospitals. We hypothesized that there would be differences in nurse-reported PSC based on (a) hospital type (university/cantonal hospital versus regional hospitals), (b) unit type (medical versus surgical units) and (c) language regions (German- versus French- / Italian-speaking).

5.3 Methods

5.3.1 Design

For this substudy, we utilized nurse survey data from the multicentre-cross sectional Swiss-RN4CAST (Nurse Forecasting: Human Resources Planning in Nursing). The Swiss RN4CAST is part of the 12 European country RN4CAST study funded by the EU 7th Framework (EU Project number: 223468). Using a cross-sectional design the RN4CAST assessed a number of variables, such as the nurse work environment, nurse staffing and educational level, nurse (e.g. job satisfaction, burnout) and patient outcomes (e.g. patient satisfaction, risk-adjusted in-hospital mortality) through nurse and patient surveys as well as administrative hospital and patient discharge data. The main aim of the RN4CAST study was to enrich and refine traditional nurse forecasting models with factors that take into account how features of the work environment impact on nurse retention, burnout and patient satisfaction. Thus, allows simulating scenarios to illustrate how changes of different nurse-related organizational factors impact future nursing workforce needs [32].

5.3.2 Sample

The sample of this substudy included registered nurses (RNs) working on medical, surgical and mixed medical-surgical units within Swiss acute care hospitals. The sampling method of the Swiss RN4CAST study was a multi stage sampling approach. In the 1st step we selected acute-care hospitals using quota sampling. For step 1 we obtained a list of all acute-care hospitals (n=150) from the Swiss Federal Office of Public Health for the year 2005. Hospitals were eligible to participate, if they had at least 60 acute care beds and employed at least 50 RNs. We aimed to include a total of at least 30 hospitals and one hospital for each language region and canton. From a total of 150 acute-care hospitals 88 hospitals (62 German-, 19 French- and 7 Italian-speaking hospitals) met our eligibility criteria. Based on the number of hospitals per language regions and per cantons (ranging from 1 to 14 hospitals), 41 hospitals were selected and invited for study participation based on research group consensus. From those 41 hospitals, hospital directors and chief nursing officers from 35 hospitals (85%) agreed to participate and gave their written consent for study participation, anonymous benchmarking and dissemination of the study results.

In the 2nd step, a total sample of 132 units from the 35 study hospitals was included: 62 general medical, 59 general surgical units and 11 mixed medical-surgical wards (German-speaking region only). Within the participating university and cantonal hospitals units were randomly selected (n=76 units) whereas in regional hospitals all medical/surgical wards (n=56 units) had to be included to achieve the planned RNs sample size per hospital. In the 3rd step, within selected units all registered nurses (except those on sick leave, maternity leave or those who were on vacation) were invited to complete the questionnaires.

5.3.3 Measures

PSC was measured with the Safety Organizing Scale (SOS) [33, see items on Table 2]. The SOS measures the extent to which RNs and their colleagues engage in patient safety behaviors and practices on their unit. Its theoretical background lies in the high-risk industry and it was adapted for healthcare organizations to reflect crucial safety behavioral processes (e.g. preoccupation with failures) [33]. The SOS is a one-dimensional instrument, consisting of nine items each assessed by a 7-point Likert scale (1=not at all, 2=to a very limited extent, 3=to a limited extent, 4=to a moderate extent, 5=to a considerable extent 6=to a great extent and 7=to a very great extent). The SOS score, the average of the single nine items, gives information on the prevailing PSC. The original English version of the SOS has excellent psychometric properties, such as a high internal reliability (Cronbach's alpha = 0.88), convergent validity (e.g. comparative fit index = 0.964, root mean square error of approximation = 0.055, $p < 0.001$ for all factor loadings) and criterion validity (medication error: B = -0.678, $p < 0.001$ and patient falls: B = -0.629, $p < 0.001$) [33].

The SOS was translated into German, French and Italian following a forward-backward translation procedure according to the adapted Brislin's model [34]. Psychometric evaluation according to the guidelines of the American Educational Research Association (AERA) [35] revealed evidence based on content (S-CVI > 0.89), response patterns (e.g. average of missing values across all item = 0.80%), internal structure (e.g. comparative fit indices > 0.90, root mean square error of approximation < 0.08) and reliability (Cronbach's alpha > 0.79) for all three language-versions. Intraclass correlations and within-group agreement demonstrated that the SOS is meaningful at the unit level, which justified aggregation of the individual SOS score at unit level.

The predictor variables, hospital type (university and cantonal=1, regional=2), unit type (surgical=1, medical =2, medical-surgical=3) and language region (German-speaking=1, French- and Italian-speaking=2) were all categorical variables. As these three variables were inclusion criteria for the national hospital sample, data were retrieved prior and during the sampling strategy from the Swiss Federal Statistic Office (hospital types) and from the hospitals' chief nursing officers (unit types). According to the Swiss Federal Statistic Office, university and cantonal hospitals in Switzerland are

characterized by a higher number of medical specialties, with complex structures and processes and they provide healthcare services for a higher number of patients and a higher proportion of seriously ill patients than regional hospitals [36].

Socio-demographics and professional characteristics on the participating RN included age (in years), education/training in Switzerland (0=no, 1=yes), employment level (10-100%), professional experience as a RN (in years) and professional experience in the hospital where they were currently working (in years) and were collected with a subscale of the nurse questionnaire which has been used in previous outcome studies [37, 38].

5.3.4 Data collection and data management

Data collection took place from October 12, 2009 to June 30, 2010. For each participating hospital a predefined contact person (e.g., ward nurses, clinical nurse specialists or chief nursing officers) supported us in the planning and data collection. All required documents, including the nurse survey questionnaire and additional information about the study were prepared at the Institute of Nursing Science (University of Basel) and sent to the contact persons in each participating hospital. They distributed the questionnaires to all eligible RNs on the selected units. The questionnaires were distributed with prepaid, addressed envelopes that allowed RNs to send the completed questionnaires to the research team. Response rates were calculated for each unit, based on the number of questionnaires that were sent out by the research team and sent back by RNs. Units with response rates <70% after two weeks were reminded by the contact person to complete the questionnaires and if necessary again four weeks after distribution of the questionnaires in order to improve the response rate. Completed questionnaires were scanned and data underwent quality control (e.g. 10% of entered questionnaires were randomly selected and checked for data entry errors).

5.3.5 Statistical methods

To describe the RN and hospital samples and to detect data anomalies (e.g. outliers, extreme values, and missing values) descriptive analyses such as frequencies, means, standard deviations, medians, interquartile ranges, cross-tabulations and graphs were performed. As the missing value rate per item was very low (<1.9%), for descriptive and inferential analyses only SOS questionnaires with complete data were included.

First to describe the nurse-reported PSC on the hospital units, the SOS total score was calculated as the average of the scores on the nine items. Then the proportion of RNs who reported a posi-

tive PSC (SOS score ≥ 6, „to a great extent“) for their unit was calculated. In this study, units were considered to have a positive PSC if at least 60% of RNs reported an average SOS score ≥ 6 (consistent with engaging in the measured behaviors to a great or very great extent). Units were only included in these analyses if at least 50% of their eligible RNs completed the survey.

Second, to describe RNs' perceptions that they and colleagues on their unit are engaged in each of the nine safety behaviors measured by the SOS, we collapsed the 7-point Likert scale to a 3-point Likert scale as follows: not at all (1) and to a very limited (2) and limited (3) extent were recoded as not engaged; to a moderate (4) and considerable (5) extent were recoded as not consistently engaged; and to a great (6) and very great (7) extent were recoded as consistently engaged. We then calculated the number and proportion of RNs who reported that they and colleagues were not engaged, not consistently engaged and consistently engaged in each of the behaviors.

Third, to test our two-sided hypothesis we used regression analyses with the SOS score as dependent variable and language region, hospital size and unit type as independent dichotomous variables (model 1) and adjusted for RN socio-demographics and professional characteristics as possible confounding variables (model 2). We adjusted for the hierarchical data structure (nurses nested within units and units nested within hospital), utilizing multilevel linear modelling with units and hospitals as random effects (model 3). We excluded mixed medical-surgical units from the regression analysis, as they were only present in the German-speaking hospitals and data from RN working on these units was not comparable to those working on either medical or surgical.

The level of significance was set at $p < 0.05$. Descriptive analyses were completed using IBM SPSS Statistics (version 18.0.2; SPSS Inc., Chicago, IL) and Microsoft Office Excel 2011®; for regression analyses we used STATA (version 11.2/SE; StataCorp LP).

5.3.6 Ethical aspects

The study was approved from all 13 responsible ethical committees of the respective Cantons. RNs were surveyed voluntarily and they gave their consent to participate in the study by filling out and sending back the questionnaires. Measures were taken to protect the identity of the nurses and to guarantee the confidentiality of collected data (e.g. pre-coded questionnaires, prepared addressed envelopes, and questionnaires stored under lock and key).

5.4 Results

5.4.1 Hospitals and nurses

In total, 35 hospitals from the three language-regions of Switzerland participated in the RN4CAST study. The hospitals included 4 university, 15 cantonal and 16 regional hospitals varying in size from <200 to >500 acute care beds. Most of the participating hospitals were regional hospitals with less than 200 acute-care beds.

A total of 1'633 RNs from 132 medical, surgical and mixed medical-surgical units completed the questionnaires, corresponding to an overall response rate of 72%. Response rates at the unit level ranged between 40% and 100%. The majority (91.7%) of RN's was female, 41.7% were between 20 to 30 years old and almost half of the respondents (48.5%) were employed in fulltime positions (working >90%). Their median years of "professional experience as a nurse" and the "professional experience as a nurse in the given hospital" were 8 years and 5 years, respectively. Two thirds of the respondents (65.9%) were German-speaking. The proportion of RN working on medical units (48.4%) was slightly higher than the proportion on surgical units (44.8%) (Table 1).

Table 1: Characteristics of the participating hospitals and RN

Hospital characteristics		RN4CAST hospital sample(N=35)	Swiss acute-care hospital population* (N=150)
		n (%)	n (%)
Hospitals per language region			
German-speaking		20 (57.0)	105 (70.0)
French-speaking		11 (31.5)	34 (22.7)
Italian-speaking		4 (11.5)	11 (7.3)
Hospital type			
University hospital		4 (11.0)	5 (3.3)
Cantonal hospital		15 (43.0)	23 (15.4)
Regional hospital		16 (46.0)	122 (81.3)
Hospital size			
Large (> 500 acute-care beds)		6 (17.0)	9 (7.6)**
Medium (200 – 500 acute-care beds)		11 (31.0)	29 (24.4)**
Small (< 200 acute-care beds)		18 (52.0)	81 (68.0)**
RN characterstics (N=1633)	**Median (IQR)**	**n (%)**	
Female		**1466 (91.7)**	
Age in years			
20-30		652 (41.7)	
31-40		437 (27.9)	
41-50		321 (20.5)	
>50		155 (9.9)	

Table 1 continued		
Nursing education in Switzerland		**1275 (78)**
Employment		
>90%		766 (48.5)
51-90%		515 (32.6)
10-50%		299 (18.9)
Professional experience in years,		
as a nurse	8 (15)	
in this hospital	5 (10)	
RN per language region		
German-speaking		1074 (65.9)
French-speaking		401 (24.6)
Italian-speaking		155 (9.5)
RN per unit type		
Surgical units		731 (44.8)
Medical units		789 (48.4)
Mixed medical/surgical units (only German-speaking region)		110 (6.7)
Number of RN per unit	**12 (5)**	

* Characteristics on the Swiss acute-care hospital population (without psychiatric and rehabilitations clinics) were retrieved from the annual hospital statistics 2005 of the Swiss Federal Office of Public Health (http://www.bag.admin.ch/)

** Data available only on 109 of 150 acute-care hospitals

5.4.2 Nurse-reported patient safety climate in Swiss hospitals

Most respondents (1'564 of 1633 RNs; 95.77%) filled out the SOS without omitting items. Overall their perceptions of the extent to which their unit engagement in the listed patient safety behaviors ranged between a moderate (4) to considerable extent (5) for item 4 „We discuss alternatives as to how to go about our normal work activities" [mean=4.62 (95% CI: 4.56 -4.69)] and to a considerable (5) and great extent (6) for item 5 „When giving report to an oncoming nurse, we usually discuss what to look out for" [5.62 (95% CI: 5.57 to 5.68)]. The average SOS score on the nine items was 5.11 (95% CI: 5.07-5.16) suggesting that on average RNs perceived that the measured behaviors were practiced to a considerable extent on their unit (Table 2).

Table 2: Mean, 95% confidence interval (CI), standard deviation (SD), median and interquartile range (IQR), for the single nine items and the SOS score (n=1564)

Items of the SOS [33]	Mean (95% CI) ± SD	Median (IQR)
1. We have a good "map" of each other's talents and skills	5.23 (5.17 to 5.28) ± 1.073	5 (1)
2. We talk about mistakes and ways to learn from them	4.92 (4.86 to 4.98) ± 1.251	5 (2)
3. We discuss our unique skills with each other so we know who on the unit has relevant specialized skills and knowledge	5.13 (5.07 to 5.19) ± 1.237	5 (2)
4. We discuss alternatives as to how to go about our normal work activities	4.62 (4.56 to 4.69) ± 1.270	5 (2)
5. When giving report to an oncoming nurse, we usually discuss what to look out for	5.62 (5.57 to 5.68) ± 1.071	6 (1)
6. When attempting to resolve a problem, we take advantage of the unique skills of our colleagues	5.30 (5.25 to 5.36) ± 1.154	6 (1)
7. We spend time identifying activities we do not want to go wrong	4.71 (4.64 to 4.77) ± 1.330	5 (2)
8. When errors happen, we discuss how we could have prevented them	4.91 (4.84 to 4.97) ± 1.305	5 (2)
9. When a patient crisis occurs, we rapidly pool our collective expertise to attempt to resolve it	5.58 (5.53 to 5.64) ± 1.060	6 (1)
SOS score	5.11 (5.07 to 5.16) ± 0.913	5 (1)

In order to compare the PSC on the participating medical, surgical and mixed medical-surgical units we computed the proportion of RNs on each unit reporting a positive PSC (defined as a mean SOS score ≥ 6). From a total of 132 units, 120 units had a response rate > 50% and were eligible for this analysis. The proportion of RNs per unit that reported a positive PSC ranged from 0% to 92.31% (mean = 43.84%, 95% CI: 39.67% to 48.01%). The RN-reported PSC was positive on only 33 out of 120 units (27.5%). For three units (2.5%) no RN reported a positive PSC (Figure 1).

Figure 1: **Unit's patient safety climate (n=120)**

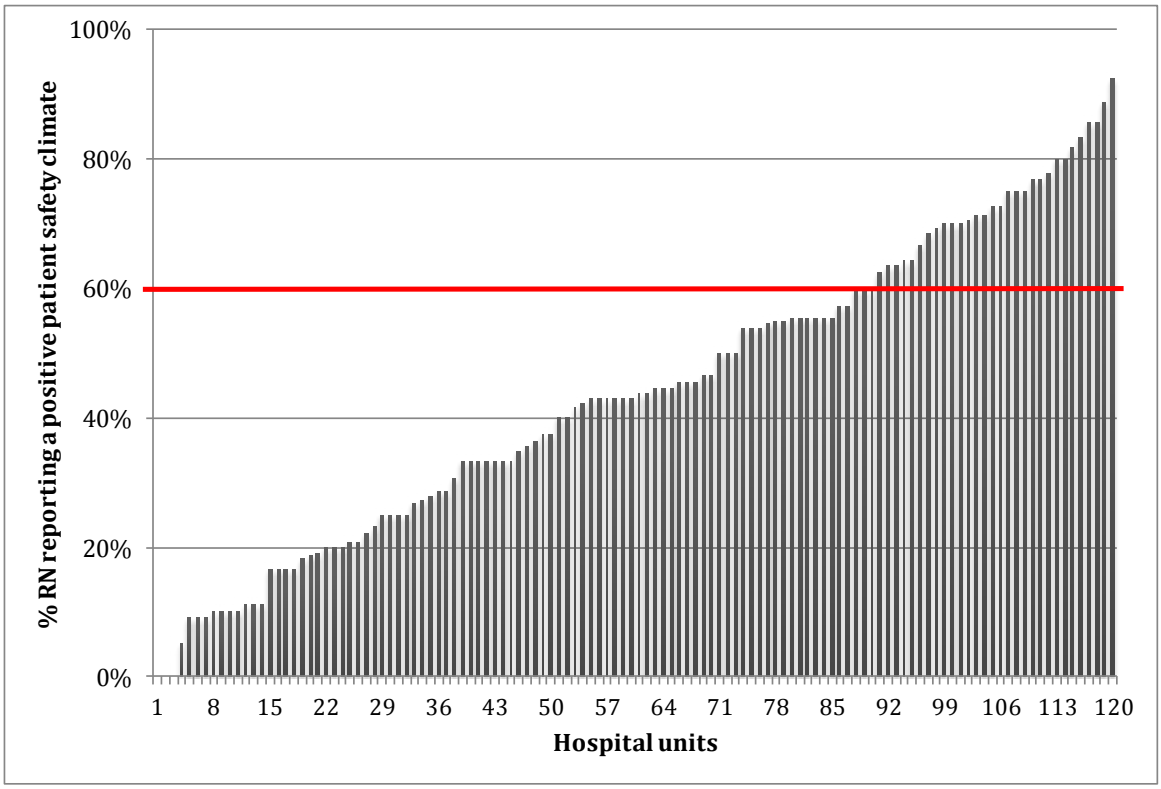
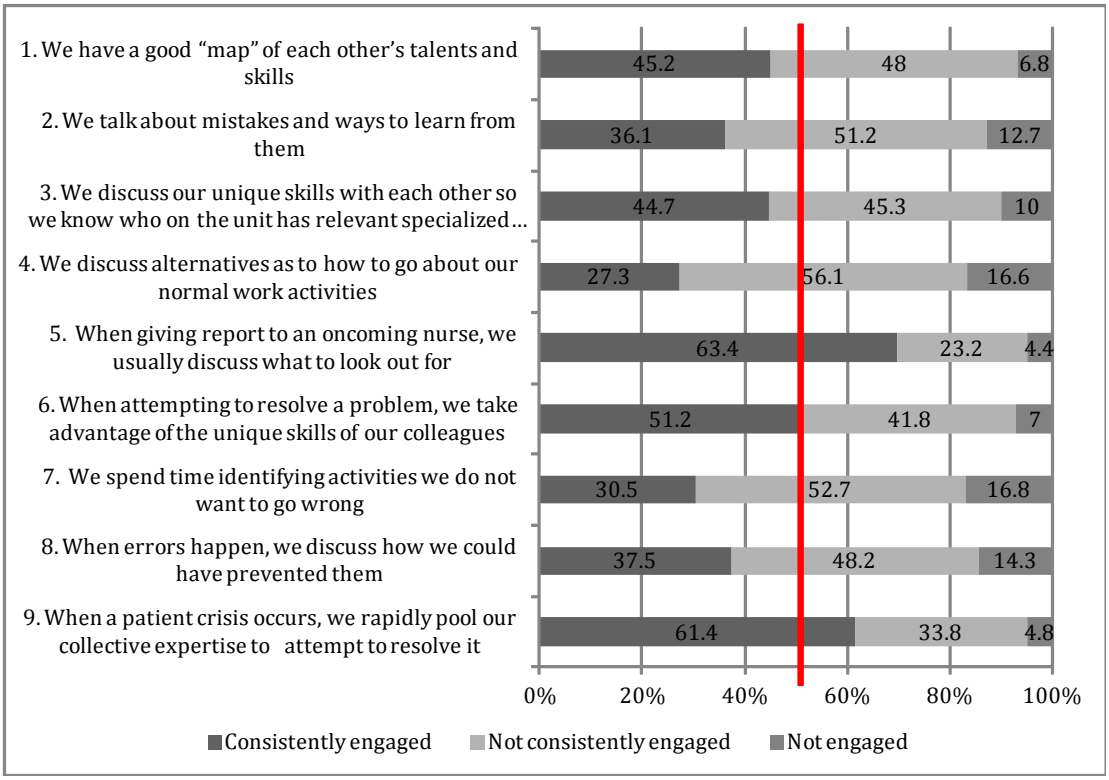


Figure 2 displays the proportion of RNs who reported that they and colleagues were not engaged, not consistently engaged and consistently engaged in each of the PSC behaviors based on the collapsed SOS categories. The behaviors that the highest proportion of the participants (63.4% and 61.4% respectively) reported that they and colleagues didonsistently were "When giving report to an oncoming nurse, we usually discuss what to look out for" (Item 5) and "When a patient crisis occurs, we rapidly pool our collective expertise to attempt to resolve it" (Item 9). The behavior that the fewest reported engaging consistently was " "We discuss alternatives as to how to go about our normal work activities" (Item 4; 27.3% of participants).

Figure 2. **Frequencies (%) of the single items comparing RN's engagement ("Consitently engaged" = answer categories 6-7, "Not consistently engaged" = answer categories 4-5, "Not engaged" = answer categories 1-3) in safety behaviors (n=1564)**



5.4.3 Differences between nurse-reported PSC

Data from 1456 RNs were included in regression analysis. In the two naive regression models the unit type and language regions were significantly associated with the nurse-reported PSC with (1) RNs working on medical units expressing higher PSC than RNs working on surgical units and (2) RNs from the French- and Italian-speaking language regions reporting lower PSC than RNs from the German-speaking language region (Table 3). For our third variable of interest, hospital type, RNs working in regional hospitals reported higher PSC than those in university and cantonal hospitals, but results were only borderline statistically significant (see Table 3).

Adjusting also for the hierarchical data structure, considering units and hospitals as random effects (regression model 3) we found both significant between-unit variability (Variance = 0.100, SE = 0.024, 95% CI: 0.062 to 0.699) and significant between-hospital variability (Variance = 0.040, SE = 0.022, 95% CI: 0.014 to 0.118). In this fully adjusted model only language regions remained a significant predictor for nurse-reported PSC. When we included socio-demographic and professional characteristics as potential confounding variables (Model 2 and 3), we observed a significant negative relationship between RNs' total years of experience in the participating hospital and PSC, but we did not find significant relationships for age, educational level, employment level or professional experience in the hospital where RNs were currently working and PSC (Table 3).

Table 3: **Association between the nurse-reported PSC and characteristics of Swiss acute care hospitals (n=1456)**

Variables	Model 1 (naive, unadjusted)		Model 2 (naive, adjusted)		Model 3 (multilevel, adjusted)	
	Coefficient (p)	95% CI	Coefficient (p)	95% CI	Coefficient (p)	95% CI
Hospital type*	0.093 (0.059)	-0.004 to 0.189	0.091 (0.065)	-0.006 to 0.187	0.125 (0.230)	-0.079 to 0.329
Unit type#	0.104 (0.025)	0.013 to 0.195	0.101 (0.030)	0.009 to 0.193	0.070 (0.346)	-0.076 to 0.217
Language region+	-0.434 (<0.001)	-0.526 to -0.342	-0.436 (<0.001)	-0.529 to -0.343	-0.428 (<0.001)	-0.630 to -0.227
RN age - in years			0.001 (0.552)	-0.001 to 0.003	0.0001 (0.947)	-0.002 to 0.002
RN education°			-0.001 (0.597)	-0.170 to 0.068	-0.002 (0.507)	-0.006 to 0.003
Employment level - %			-0.0003 (0.575)	-0.001 to 0.002	0.0003 (0.676)	-0.001 to 0.002
RN professional experience (total) - in years			-0.003 (0.017)	-0.010 to -0.001	-0.003 (0.029)	-0.005 to -0.0003
RN professional experience (hospital currently working) -in years			0.002 (0.150)	-0.001 to 0.005	0.002 (0.163)	-0.001 to 0.005
Constant	5.441 (<0.001)	5.210 to 5.671	5.409 (<0.001)	5.152 to 5.666	5.433 (<0.001)	4.952 to 5.915

* Hospital type: university and cantonal hospitals versus regional hospitals

\# Unit type: surgical units versus medical units

\+ Language region: German-speaking region versus French- and Italian-speaking region

° RN education: education in Switzerland versus education outside Switzerland

5.5 Discussion

This is the first study to describe the nurse-reported PSC in a representative national sample of Swiss acute care hospitals. We observed variability in the extent to which RNs reported that they and colleagues engage in the individual safety behaviors measured and the PSC climate across units and hospitals. The three items that the RNs reported they and colleagues consistently engaged in reflected safety behaviors such as nurses' shift reports and the use of one another's skills and expertise in critical situations and in resolving problems in patient care. As more than half of the participating RNs reported that personnel of their units consistently engaged in these activities (SOS score ≥ 6, consistent with "to a great extent"), it may be that these are implicit safety behaviors that are seen as part of their daily business in preventing/protecting patients from harm. Furthermore, results on the use of one another's skills and expertise in critical situations and in resolving problems (items six and nine) suggest good interprofessional relationship and communication among RNs and physicians, an essential feature for high levels of patient safety and quality of care [39].

However, in our sample a high proportion of RNs reported that they and colleagues did not or did not consistently engage in six out of the nine behaviors. Those items reflect important patient safety behaviors such as proactive and preemptive analysis and discussions of possible unexpected events, capabilities to detect and learn from errors and critical thinking about normal, everyday work activities/processes. Learning from errors and near misses is crucial for patient safety and over the last several years many European countries, including Switzerland have invested in patient safety measures, methods and instruments. For example, Critical Incident Reporting Systems (CIRS) have been implemented in healthcare systems [40-43]. However, for the benefits of such well-meant systems to be realized, healthcare professionals must be willing to report and share errors [44], which is known to be problematic. For example in one study, RNs reported only half of the medication errors that occurred [45]. Despite a blame-free and non-punitive environment [45] the functioning and success of CIRS might depend also on healthcare professionals individual capabilities and skills in detecting, reporting, analyzing and learning from errors. To strengthen these individual skills and to increase willingness to report and share errors on systemic levels, creating a "positive" PSC at unit level by implementation of appropriate activities, such as root cause analysis is necessary [46].

In addition to processes responding to the occurrence of errors, proactive analyses of unexpected events and critical analysis of existing work activities/processes are important to avoid errors. The results of our study suggest that these behaviors are not yet "implicit behaviors" to the same extent as other safety behaviors measured with the SOS. Activities addressing these proactive behaviors that have been reported in the scientific literature include tools such as patient safety

leadership walking rounds [47], safety briefings [48] and Healthcare Failure Mode and Effect Analysis (HFMEA™) [49]. Such prospective methods, aiming to stimulate safety awareness of healthcare professionals and to identify and prevent process problems before they occur, may not yet be extensively implemented in Swiss acute care hospitals.

The fact that the majority of RNs reported that they and colleagues did not consistently engage in six out of the nine SOS safety behaviors was also reflected in a low proportion of units with an overall positive PSC. Given that previous research has shown that units and hospitals with a lower PSC have higher rates of AEs, such as medication errors and patient falls [33, 50, 51], these findings should encourage Swiss hospitals to improve their PSC.

Our hypothesis, that there would be differences in nurse-reported PSC based on (a) hospital type, (b) unit type and (c) language regions, was only partially supported, as in our multilevel model only language region significant related to variability in the nurse-reported PSC. The higher nurse-reported PSC in the German-speaking region could be related to the implementation of several initiatives on patient safety over the past years, such as the "Critical Incident Reporting and Reacting NETwork (CIRRNET)" within 24 hospitals [52], initiated by the Swiss patient safety foundation first in the German-speaking language region of Switzerland. Recently, CIRRNET and other important initiatives (e.g. "Error & Risk Analysis) are being expanded to the Italian- and French-speaking regions or initiated at a national level [52] and may contribute to an improvement in PSC at the unit level. In our naïve regression models we found that (1) RNs on surgical units reported lower PSC than nurses on medical units and (2) RN working in regional hospitals expressed higher perceptions of their unit's PSC than RNs working in cantonal and university hospitals. These results might indicate that higher complexity of structures (university and cantonal hospitals) and a high number of interfaces in the care processes (e.g. peri- and post-operative care) might negatively impact the PSC, as it is more difficult for health care professionals, such as RNs, to guarantee patient safety in such environments. However, after statistical adjustment for the nested data structure, these relationships were no longer significant. These results indicate that the PSC variability between units and between hospitals is in general higher than the variability between medical or surgical units and between university / cantonal or regional hospitals.

5.5.1 Limitations of the study

Even though this study allowed us to develop a picture on nurse-reported PSC in the acute care setting, there are some limitations/precautions to consider. The RN4CAST study used a cross-sectional study design, which doesn't allow the assessment of causal relationships between study variables. Since we have not used randomized sampling techniques in all stages of our sampling process this increases the risk for a bias. External validity is restricted to general medical, surgical and

mixed medical-surgical units in Swiss acute care hospitals. Since we only included acute-care hospitals with 60 or more beds to achieve a sample size of at least 50 RNs per hospital, regional hospitals were relatively underrepresented in contrast to the total hospital population.

The SOS gives important information on crucial patient safety behaviors and processes at the unit level, but other aspects of PSC such as management support for patient safety engagement or a blame free environment [11, 30] are not measured with the SOS. Therefore, the SOS may not present a complete picture of the PSC. As the RN4CAST study included only RNs, the PSC perceptions of other healthcare professionals, e.g. physicians were not captured.

5.6 Conclusions

The results of this study provide initial insights on RNs' perceptions of the extent to which they and colleagues engage in patient safety behaviors and the prevailing PSC on general medical, surgical and mixed medical-surgical units in a national sample of Swiss acute care hospitals. Despite the increasing awareness of patient safety in Switzerland over the last years, our findings show variability in RNs' perceptions of safety behaviors, as well as significant variability in the prevailing PSC between units, hospitals and language regions and indicate the potential for improvement. Hospital leaders at various levels should strengthen the PSC at the unit level and support/foster healthcare professionals' engagement in safety behaviors by implementing safety methods such as root cause analysis, patient safety leadership walk rounds or safety briefings and de-briefings. This could, in turn, improve individual and team skills and awareness concerning discussions on errors, proactive and critical analyses of possible unexpected events and work processes, improve adherence with CIRS and, most importantly, result in better patient safety outcomes. The regular measurement of PSC with the SOS allows evaluation of the impact of implementing such activities and provides a means for ongoing monitoring of the prevailing PSC within hospitals. Linking the PSC with other structural and process indicators (e.g. staffing level, skill mix, leadership abilities, implicit rationing of nursing care) could lead to a better understanding of the complex relationships that impact the quality of patient care.

5.7 Funding / Potential competing interests

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CHAPTER 6

THE ASSOCIATION OF PATIENT SAFETY CLIMATE AND NURSE-RELATED ORGANIZATIONAL VARIABLES WITH PATIENT OUTCOMES IN SWISS ACUTE CARE HOSPITALS - A CROSS-SECTIONAL SURVEY

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6.1 Abstract

Background*:* Patient safety climate (PSC) is an important work environment factor determining patient safety and quality of care in healthcare organizations. Few studies have investigated the relationship between PSC and patient outcomes, considering possible confounding effects of other organizational features of the hospital work environment.

Objective*:* The purpose of this study was to explore the relationship between PSC and patient outcomes in Swiss acute care hospitals, adjusting for major organizational variables.

Methods*:* This is a sub-study of the Swiss arm of the multicentre-cross sectional RN4CAST (Nurse Forecasting: Human Resources Planning in Nursing) study. We utilized data from 1,630 registered nurses (RNs) working in 132 surgical, medical and mixed surgical-medical units within 35 Swiss acute care hospitals. PSC was measured with the 9-item Safety Organizing Scale, which captured RNs' engagement in patient safety behaviors and practices. Other organizational variables measured with established instruments included the quality of the nurse practice environment, implicit rationing of nursing care, nurse staffing, and skill mix levels. We performed multilevel multivariate logistic regression to explore relationships between seven patient outcomes (nurse-reported medication errors, pressure ulcers, patient falls, urinary tract infection, bloodstream infection, pneumonia; and patient satisfaction) and PSC.

Results*:* In none of our regression models was PSC a significant predictor for any of the seven patient outcomes. From our nurse-related organizational variables, the most robust predictor was implicit rationing of nursing care. After controlling for major organizational variables and hierarchical data structure, higher levels of implicit rationing of nursing care resulted in significant decrease in the odds of patient satisfaction (OR = 0.276, 95%CI = 0.113 to 0.675) and significant increase in the odds of nurse reported medication errors (OR = 2.513, 95%CI = 1.118 to 5.653), bloodstream infections (OR = 3.011, 95%CI = 1.429 to 6.347), and pneumonia (OR = 2.672, 95%CI = 1.117 to 6.395).

Conclusions*:* We failed to confirm our hypotheses that PSC is related to improved patient outcomes, which we need to re-test with more reliable outcome measures, such as 30-day patient mortality. Given the current state of research on PSC, the direct impact of PSC improvements on patient outcomes in general acute-care settings should not overestimated. Based on our findings, general medical / surgical units should monitor the rationing of nursing care levels which may help to detect imbalances in the "work system", such as inadequate nurse staffing or skill mix levels to meet patients' needs.

6.1.1 What is already known about the topic?

- Patient safety climate emerges as important system factor in healthcare organizations.
- Few studies have examined the relationship between patient safety climate and patient outcomes.
- Of these, only one study has adjusted for major organizational factors, such as staffing and educational levels.

6.1.2 What this paper adds?

- Patient safety climate was not significantly related with any of our seven patient outcomes.
- Rationing of nursing care was shown to be the most consistent predictor, significantly related to four out of seven patient outcomes in line with previous research.
- Observed suppression effect might indicate a mediating role for rationing of nursing care between factors of the work environment and patient outcomes.

6.2 Introduction

6.2.1 Problem statement

Today's patient care in healthcare organizations is anything but safe, as between 2.9% and 16.6% of hospitalized patients are affected by adverse events such as medication errors, healthcare-associated infections, or patient falls. More than one-third of adverse events lead to temporary (34%) or permanent disability (6% - 9%) and between 3% and 20.8% of the patients experiencing an adverse event die [1-4]. As 37% to 70% of all adverse events are considered preventable [3, 5, 6], harmful impacts on patients, such as psychological trauma, impaired functionality or loss of trust in the healthcare system as well as socio-economic costs, could be avoided [6-8].

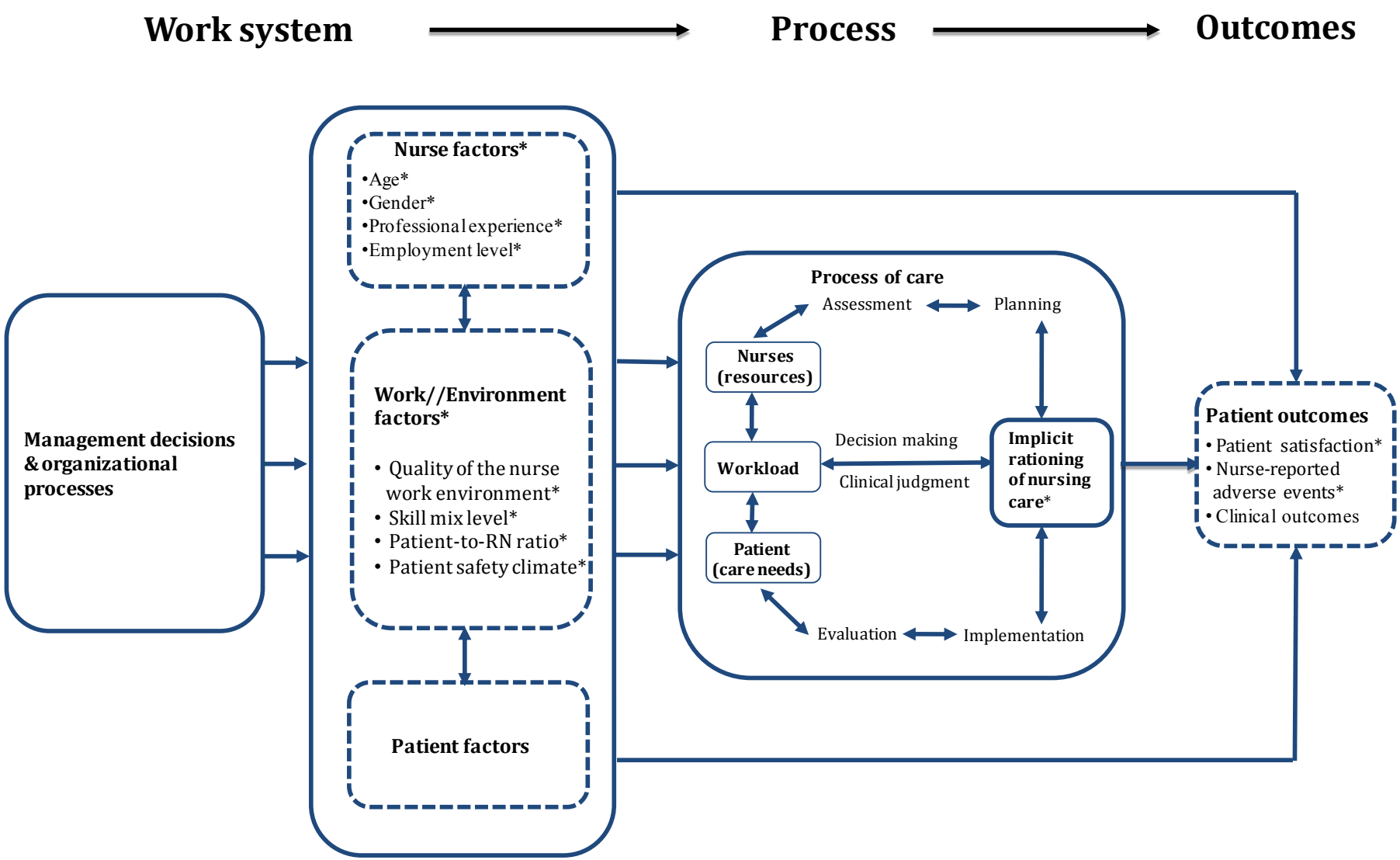
Achieving a high level of safety through patient harm prevention is an essential step in improving the quality of care [9]. In order to improve patient safety, it is necessary to identify "error and violation producing conditions" within healthcare organizations [7, 10]. High numbers of adverse events are related with organizational factors [11], such as heavy workloads, inadequate expertise, stressful environments, or poor communication. Thus, understanding organizational behavior is foundational to reduce the incidence of adverse events and improve patient safety [12].

6.2.2 Conceptual framework

The conceptual framework for this study (see Figure 1) describes how organizational features are related to patient outcomes and builds on the System Engineering Initiative for Patient Safety model [13] and the Rationing of nursing care in Switzerland model [14, 15], adapted from the International Hospital Outcomes Study model [16]. Within hospital organizations, management decisions and organizational processes at the hospital level affect the local workplaces, respectively the unit level. For instance, structural components of medical and surgical units, such as the work environment, and characteristics of healthcare professionals (e.g. educational level, professional experience) and patients (e.g. acuity level) play a critical role in providing high quality of care including patient safety, and patients' satisfaction with care. Individual nurse factors are also interrelated with the work environment, as e.g. the educational level and the professional experience impact the quality of the nurse work environment, such as the professional collaboration with physicians. In addition, vulnerabilities or imbalances in the work system (hospital level and unit level) can affect the process of care which may lead healthcare professionals, including nurses, to make mistakes or fail to prevent them, resulting in adverse events. Implicit rationing of nursing care, which is „the withholding of or failure to carry out necessary nursing measures for patients" [15, p. 417] might indicate problematic conditions in the process of nursing care.

An increasing amount of international evidence supports our framework, demonstrating that patient outcomes are related to nurse-related organizational factors concerning the work environment [17-20], nurse staffing levels [21-26], skill mix / educational levels [18, 27, 28], nursing leadership [29] and processes (e.g. implicit rationing of nursing care) [14, 30] .

Figure 1: **Conceptual Framework**



*Variables measured in this study

6.2.3 Patient safety culture/climate

Recently, another organizational feature determining patient safety and quality of care in healthcare organizations, the so-called "safety culture" has received increased attention in research and practice [7, 31, 32]. Safety culture is defined as "the subset of organizational culture, relating specifically to the attitudes, values, norms and beliefs towards patient safety" [33,p. 312].

Measuring the patient safety climate (PSC), which is the visible feature of a safety culture, such as strong engagement in safety behaviors [34, 35], might give information on the underlying safety culture [36-39]. In the absence of a satisfying model or framework of PSC that describes its relationship with patient outcomes and other organizational variables [40], we considered PSC as an organizational feature of hospital units' work environment (see Figure 1). One underlying assumption of the PSC concept is that units or hospitals with high PSC levels have improved patient outcomes, as patient safety is given high priority and is a guiding factor in daily care [41]. For instance, recent studies revealed that units and hospitals with higher levels of PSC had lower patient readmission rates [42], lower incidence of a composite score of 12 unweighted, risk-adjusted patient safety indicators [43], and fewer reported critical incidents on medication errors and patient falls [44].

6.2.4 Literature gap

While an increasing number of studies have consistently linked patient outcomes to work systems factors, evidence is still far from convincing that higher levels of PSC are associated with improved patient outcomes [45, 46]. The overlap between the two research movements - nurse work environment and PSC - makes it necessary to combine both, to control for possible confounding effects between organizational factors and patient outcomes and to increase internal validity of inferences made about such relationships. For example, only one study [44] examined the relationship between PSC and patient outcomes controlling also for several important nurse-related organizational factors, such as staffing or educational levels. In addition, a better understanding of which organizational factors are related with patient outcomes would be beneficial for facilitating the development of benchmarking among and within hospitals and fostering initiatives for safety improvements [43].

6.2.5 Study aim

The purpose of this study was to explore the relationship between PSC and selected patient outcomes in Swiss acute care hospitals, adjusting for major organizational variables, including rationing of nursing care and quality of the nurse practice environment. We hypothesized that higher levels of PSC would be associated with less frequent nurse-reported adverse events (medication errors, patient falls, pressure ulcers and healthcare-associated infections) and higher patient satisfaction.

6.3 Methods

6.3.1 Design

For this substudy we utilized Swiss data from the nurse and patient survey of the multicentre-cross sectional RN4CAST (Nurse Forecasting: Human Resources Planning in Nursing) study, financed within the EU Seventh Framework Programme (EU Project number: 223468).

6.3.2 Sample

Registered nurses (RNs) and patients on medical, surgical and mixed medical-surgical units of acute care hospitals in Switzerland were surveyed between October 12, 2009 and June 30, 2010. A quota sample of 35 Swiss acute care hospitals was selected. First, from a total of 150 acute-care hospitals in Switzerland, 88 hospitals met our eligibility criteria, i.e. more than 60 acute care beds and employed more than 50 RNs. Second, for study participation 41 hospitals (27%) were selected based on geographic location (three language regions and Swiss cantons) and hospital type according to the classification of the Swiss Federal Statistic Office (university hospitals, centre care hospitals, and primary care hospitals) and invited to participate. Third, from those 41 hospitals, hospital management from 35 hospitals (85%) gave their written consent for study participation.

As the goal was to include at least 50 RNs from each hospital, for university and centre care hospitals a random sample of general medical and surgical units or mixed medical-surgical wards (German-speaking region only) was selected. In primary care hospitals all medical/surgical wards had to be included to achieve the planned sample size. Within selected units all RNs (N = 2,280), except those on sick leave, maternity leave, or vacation were invited to complete the questionnaires.

Overall, 1,459 patients were approached on the same selected hospital units if they could understand and read German, French or Italian, and if their physical and mental conditions were judged from the responsible RNs as adequate for participation. Since we included a national sample of Swiss hospitals and nurses from all three national language regions, all original English questionnaire items were forward-backward translated into German, French and Italian using a modified Brislin protocol [47].

6.3.3 Variables and measures

6.3.3.1 Organizational variables (analyzed at unit level)

Our primary interest, PSC, was measured with the Safety Organizing Scale (SOS), which reflects the extent to which RNs and their colleagues engage in patient safety behaviors and practices on the unit level such as "We talk about mistakes and ways to learn from them"; "We discuss alternatives as to how to go about our normal work activities"; or "When a patient crisis occurs, we rapidly pool our collective expertise to attempt to resolve it" [44]. The SOS is a one-dimensional instrument, consisting of nine items each assessed by a 7-point Likert scale [not at all (1), to a very limited extent (2), to a limited extent (3), to a moderate extent (4), to a considerable extent (5), to a great extent (6) or to a very great extent (7)]. The SOS score, the average of the single nine items, gives information on the prevailing PSC.

The theoretical foundation, concise content, one-dimensional structure and excellent psychometric properties, such as convergent validity and reliability of the SOS [44] convinced us to translate and use this instrument in the Swiss cross-cultural setting. Psychometric evaluation of the German, French and Italian versions confirmed its validity and reliability. For instance, content validity rating revealed almost excellent content validity (e.g. Scale Content Validity Index > 0.89); confirmatory factor analyses confirmed the one-dimensional structure (e.g. comparative fit indices > 0.90, root mean square error of approximation < 0.08) and calculation of alpha coefficients revealed internal consistency and reliability (Cronbach's alpha > 0.79) for all three language versions.

The following organizational factors have been found in previous studies to be associated with patient outcomes and were considered as secondary predictor variables: the quality of the nurse practice environment, implicit rationing of nursing care, nurse staffing level and skill mix. The *quality of the nurse practice environment* was measured with a revised version of Lake's Practice Environment Scale of the Nursing Work Index (PES-NWI) [48]. It consisted of 32 items addressing five dimensions: (i) Nurse Participation in Hospital Affairs (8 Items); (ii) Nursing Foundations for Quality of Care (9 Items); (iii) Nurse Manager Ability, Leadership, and Support of Nurses (4 Items); (iv) Staffing and Resource Adequacy (4 Items) and (v) Collegial Nurse–Physician Relations (7 Items). Using a 4-point Likert-type scale (from „strongly disagree" to „strongly agree"), nurses were asked whether specific elements were present in their workplace. Exploratory factor analysis (Principal Axis Factoring using Kaiser's criterion and Varimax rotation) resulted in the same five factor solution as the original version [48]. However, due to collinearity between three nurse practice environment subscales („nurse manager ability, leadership and support of nurses", „nurse foundation for quality of care" and „the nurse participation in hospital affairs") we calculated the quality of the nurse practice environment as the mean of the 5 subscale scores [48, 49]. Cronbach's alpha for the entire scale was 0.93, indicating internal consistency of the revised PES-NWI.

Implicit rationing of nursing care was measured using the revised version of the Basel Extent of Rationing of Nursing Care (BERNCA-R) instrument developed and validated within the Rationing of Nursing Care in Switzerland study [15]. With 32 items, the BERNCA-R asks nurses how frequently they were unable to perform basic nursing tasks in the past 7 working days due to inadequate time, nurse staffing level and/or skill mix. Respondents rated each item on a 5-point Likert-type scale [task was not required (0), never (1), rarely (2), sometimes (3) and often (4)]. Exploratory factor analysis (Principal Axis Factoring) revealed one strong factor, indicating one-dimensionality of the measure. Cronbach's alpha for the BERNCA-R was 0.94. To calculate the average level of implicit rationing of nursing care on the unit, the scores for each nurse per unit were averaged over all 32 items.

Nurse staffing level was calculated as the ratio between the total number of patients and the total number of RNs in the unit during their most recent shift (patient-to-RNs ratio). *Skill mix* was computed as the percentage of non-registered nurses on the total number of nurses during their most recent shift. Both variables were calculated using single items from the RN4CAST study nurse questionnaires [50].

6.3.3.2 Outcome variables (analyzed at individual level)

We measured six types of nurse-reported adverse events, all of them considered to be sensitive to nursing care: (i) medication administration errors, (ii) pressure ulcers (stage ≥ II), (iii) patient falls (with injury) and three types of healthcare-associated infections: (iv) urinary tract infections, (v) bloodstream infection (catheter-related) and (vi) pneumonia. No data registries on nurse-sensitive indicators, such as the *National Database of Nursing Quality Indicators®*, are available for hospitals in Switzerland. Therefore, for this sub-study we considered nurse reports as appropriate estimates of adverse events, as also used in previous outcome research in Switzerland study or internationally study [14-16]. Thus nurses reported the perceived incidence of adverse events over the past year on a 7-point Likert-type scale ranging from never (0) to daily (6). Because ordinal scales were used and the data were skewed, nurse responses were dichotomized for our analyses as follows: “never”, “a few times a year or less,” or “once a month or less” were recoded as “irregularly” (= 0); and “a few times a month”, “once a week,” “a few times per week,” or “daily” were recoded as a “regularly“ (= 1).

Patient satisfaction was assessed with the Hospital Consumer Assessment of Healthcare Providers and Systems [51]. This instrument covers specific domains of patient experiences of their hospital care, such as communication with physicians and nurses, communication about medication or adequacy of planning for discharge. From the two single items, reflecting on the overall rating of patient satisfaction with their hospital care, we used the question about whether patients would recommend this hospital to their family and friends (possible responses: definitely yes, probably yes, probably no, and definitely no). According to previous studies [52] and data

distribution we dichotomized responses on the 4-point Likert scale as follows: definitely no (1), probably no (2) and probably yes (3) were recoded as probably or not (= 0); and definitely yes (4) was kept (= 1).

6.3.3.3 Possible confounding variables

Socio-demographics and professional characteristics of the participating RN's, such as *gender* (0 = male, 1 = female), *age* (in years), *employment level* (10% - 100%) and *professional experience in the hospital where they were currently working* (in years) were considered as possible confounder variables. These variables were assessed using single items from the RN4CAST nurse questionnaire. Patient socio-demographic characteristics included *self-reported health status* (5-point Likert scale: from poor to excellent) and *educational level* (5-point Likert scale: from no degree to university degree). In the development and evaluation of the Hospital Consumer Assessment of Healthcare Providers and Systems questionnaire these two patient characteristics influenced patients' perception of care [51].

Characteristics on the participating hospitals and units, which we considered also as possible confounding variables included: *hospital type* (university hospitals = 1, centre care hospitals = 2, primary care hospitals = 3), *unit type* (surgical = 1, medical = 2, medical-surgical = 3) and *language region* (German-speaking = 1, French-speaking = 2 and Italian-speaking = 3).

6.3.4 Data collection and data management

For each participating hospital a predefined contact person (e.g., ward nurses, clinical nurse specialists or chief nursing officers) supported us in the planning of and data collection. The data collection packages, including information about the study, questionnaires and pre-stamped envelopes were prepared at the Institute of Nursing Science (University of Basel) and sent to the contact persons in each participating hospital. On the defined day, these contact persons distributed the questionnaires to the RNs and patients who met inclusion criteria on the selected units. One hospital refused to participate in the patient survey but gave no reason why. Pre-stamped envelopes allowed RNs and patients to return the completed questionnaires directly to the research team. The questionnaires were coded to identify hospitals and units, but it was not possible to identify individuals who completed the questionnaire. Completed nurse and patient questionnaires were scanned and data were subjected to quality control procedures (e.g. random review of 10% of the questionnaires for data entry errors).

6.3.5 Statistical methods

We used descriptive statistics including frequencies, cross-tabulations, and graphs to uncover any data anomalies, such as missing values, outliers or extreme values and to describe the nurse and hospital sample, as well as the variables under study to determine their levels of measurement and data distributions. In our understanding patient safety climate, rationing of nursing care, quality of the nurse practice environment, patient-to-nurse staffing ratio and skill mix are reflecting rather organizational properties of nursing units rather than individual RNs characteristics. Therefore, to test whether our measures reflect unit level constructs– making aggregation of data appropriate – we computed five measures: between-group variance, within-group-agreement, intraclass correlations (1) and (2), and design effects [44, 53, 54].

To test our hypothesis, we built logistic regression models for each of the seven patient outcome variables. Our explanatory variables were PSC, rationing of nursing care, quality of the nurse practice environment, patient-to-RN ratios and skill mix (all at unit level). First, we computed bivariate regression models for each patient outcome and organizational variable. Second, we performed multivariate regression analyses for each patient outcome by including all organizational variables and adjusting also for nurse/patient, unit, hospital and regional characteristics. As the data were naturally clustered (nurses and patients within units and hospitals) we used multilevel modeling and included units (Level-2) and hospitals (Level-3) as random intercepts in bivariate and multivariate models.

The level of significance was set at $P < 0.05$. All analyses were performed using IBM SPSS Statistics (version 19.0.1; IBM Inc., Armonk, NY, USA) and STATA 11.2 (StataCorp LP, College Station, TX, USA).

6.3.6 Ethical aspects

Positive approval for the RN4CAST study was obtained from all 13 ethical committees of the respective Swiss Cantons. Completing the nurse and patient questionnaire was voluntary. Data that could be used to identify nurses or patients were not recorded on the questionnaire or entered into the database.

6.4 Results

6.4.1 Participants

A total of 35 hospitals from the three language-regions, including all Swiss hospital types and varying by hospital size participated in the RN4CAST study. More than half of the included hospitals (n = 19) were part of a hospital group and had less than 200 acute care beds (18 hospitals). Nearly all hospitals (n = 34) were in public ownership. We obtained data on 132 units from these hospitals. Further characteristics on the hospital sample are presented in Table 1.

Data were retrieved from 1,633 RN and 997 patients, which was an overall response rate of 72% and 69%, respectively. Most (1,630) nurse questionnaires were eligible for statistical analyses (three questionnaires were excluded from analysis as they could not be assigned to a unit and/or a hospital). For RNs, the majority (91.7%) were female, 41.7% were between the age of 20 to 30 years, and more than half (51.5%) were working part-time (less than 90%). The medians for "professional experience as a nurse" and the "professional experience as a nurse in this hospital" were 8 years and 5 years, respectively. Concerning the two socio-demographic characteristics of the patient survey, the highest proportion were patients reporting a "good" health status (41.0%); 44.7% had completed vocational education and training.

We observed statistically significant differences between the three hospital types for some RNs' and patients' characteristics (see Table 2). University hospitals had a higher proportion of male nurses (12.7%) and of nurses working full-time (55.4%). Patients that were hospitalized in university hospitals had a higher educational level (42.1% reported higher school or university degree) than patients in centre care and primary care hospitals.

Table 1: Characteristics of the participating hospitals

Hospital characteristics	Hospitals (N = 35)
Hospitals per language region – % (n)	
German-speaking (DE-CH)	57.0 (20)
French-speaking (FR-CH)	31.5 (11)
Italian-speaking (IT-CH)	11.5 (4)
Hospital is part of a hospital group – % (n)	
Yes	54.3 (19)
No	45.7 (16)
Public ownership - % (n)	97.1 (34)
Hospital run for profit - % (n)	8.6 (3)
Hospital type – % (n)	
University hospitals	11.5 (4)
Centre care hospitals	42.8 (15)
Primary care hospitals	45.7 (16)
Services provided - % (n)	
Emergency	100 (35)
ICU	85.7 (30)
Open Heart Surgery	22.8 (8)
Organ Transplant Surgery	14.3 (5)
Hospital size (Acute care beds) – % (n)	
Large (> 500)	17.1 (6)
Intermediate (200 – 500)	31.5 (11)
Small (< 200)	51.4 (18)

Table 2: Characteristics of the participating nurses and patients

Nurse characterstics	Total (*N* = 1630)	University hospitals (n = 211)	Centre care hospitals (n = 806)	Primary care hospitals (n = 613)	P-values*
Female - %	**91.7**	**87.3**	**91.4**	**93.5**	**0.02**
Age (in years) - %					
20-30	41.7	42.1	40.5	43.1	0.68
31-40	27.9	26.4	28.7	27.5	
41-50	20.5	23.9	20.8	19.0	
>50	9.9	7.6	10.0	10.5	
Nurse training in Switzerland - %	**77.9**	**74.5**	**77.8**	**79.4**	**0.35**
Employment - %					
>90%	48.5	55.4	49.7	44.6	**<0.001**
51-90%	32.6	34.7	28.9	36.7	
10-50%	18.9	9.9	21.4	18.8	
Professional experience (in years) – Median (IQR)					
as a nurse	8 (15)	6.5 (9)	8 (10)	8 (14)	0.17
in this hospital	5 (10)	5 (13)	5 (10)	5 (10)	0.99
Patient characteristics	**Total (*N* = 997)**	**University hospitals (n = 132)**	**Centre care hositals (n = 486)**	**Primary care hospitals (n = 379)**	**P-values***
State of health - %					
Poor	9.2	11.6	7.6	10.4	0.39
Fair	30.8	32.2	29.6	31.7	
Good	41.0	40.5	44.8	36.3	
Very Good	16.3	14.0	15.4	18.3	
Excellent	2.8	1.7	2.6	3.4	
Educational level - %					
No education	2.4	0.8	2.1	3.5	**0.01**
Obligatory school	21.0	18.5	22.9	19.5	
Vocational education and training	44.7	38.7	42.8	49.5	
Higher School	22.7	26.1	22.0	22.4	
University	9.2	16.0	10.3	5.1	

*Chi-square statistics or Median-Test

6.4.2 Organizational factors

Results on between-group variance, intraclass correlations, within-group agreement and design effects for our organizational variables justified aggregation of individual nurse survey data at the unit level and are summarized in Table 3b. The mean level of PSC at the unit was 5.11 on the 7-point scale (Min: 3.82, Max: 6.16) indicating that the RNs reported to be engaged slightly above a considerable extent (5.00) in patient safety behaviors and practices with colleagues on their unit (Table 3). The mean level of implicit rationing of nursing care (M = 1.69; Min: 0.82, Max: 2.56) indicated that RNs were never (1) to rarely (2) unable to perform specific nursing tasks in the last seven days (Table 3). Results on the averaged five dimensions of the 4-point practice environment scale indicated neither strong

agreement nor disagreement (M = 2.86, Min: 2.28, Max: 3.47). The average patient-to-RN ratio over the last 24 hours (morning, afternoon and night shifts) was eight patients (Min: 3.44, Max: 15.85) and the average skill mix indicated that on the last recent shift 36% (Min: 13.57, Max: 58.89) of the total nursing staff were non-registered nurses (Table 3). Correlation analyses revealed a strong positive relationship (r = 0.69, p < 0.01) between the PSC and the quality of the nurse practice environment and a moderate negative relationship (r = -0.40, p < 0.01) between the PSC and rationing of nursing care (Table 3a). We also observed a strong negative relationship between unit scores on rationing of nursing care and the unit practice environment (r = -0.63, p < 0.01).

Table 3a: Measures to determine the effect of data nesting of organizational variables within hospital units

Variables	F-statistics [a]	Rwg(j) [b]	ICC(1) [c]	ICC(2) [c]	Design effects [e]
Patient safety climate	F(131,1493)=4.51***	0.97	0.21	0.77	3.52
Implicit rationing of nursing care	F(131,1496)=5.22***	0.80	0.25	0.80	4.00
Nurse practice environment	F(131,1497)=7.17***	0.72	0.32	0.86	4.84
Patient-to-RN ratio	F(131,1475)=2.08***	-	0.08	0.52	1.96
Skill mix	F(131,1425)=3.01***	-	0.13	0.67	2.56

Rwg (j) indicates within-group-agreement; ICC, Intraclass correlation;

Interpretation of measures and findings:

[a] Beetween-unit variance: F-statistic from a one-way variance analysis (ANOVA) should yield a significant result, $P<0.05$.

[d] Degree to which responses of individuals within a group are interchangeable (values should be 0.70 or greater) [44]

[c] Describe how strongly RNs' responses in the same unit resemble each other: ICC (1) should have values between 0.05 and 0.30; ICC(2) above 0.70 is considered acceptable.

[d] Design effects account for within-group sample size, which could have inflated ICCs (values should be ≥ 2 to demonstrate the nesting of the data) [53]

*$P<0.05$, **$P<0.01$, ***$P<0.001$

Table 3b: Descriptive statistics and correlations of the organizational variables at unit level (N = 132 units)

Variables	Descriptive Statistics		Correlation matrix				
	Mean (SD)	Median (Min – Max)	Safety climate	Implicit rationing	Nurse practice environment	Patient-to-RN ratio	Skill mix
Patient safety climate	5.11 (0.49)	5.18 (3.82 – 6.16)	1.00				
Implicit rationing of nursing care	1.69 (0.32)	1.67 (0.82 – 2.56)	-0.40*	1.00			
Nurse practice environment	2.86 (0.27)	2.87 (2.28 – 3.47)	0.69*	-0.63*	1.00		
Patient-to-RN ratio	7.88 (2.03)	7.65 (3.44 – 15.85)	-0.04	0.14	-0.25*	1.00	
Skill mix	36.31 (9.38)	35.37 (13.57 – 58.89)	0.23*	0.10	0.12	0.18*	1.00

*P-value < 0.01

6.4.3 Patient outcomes

Of the 997 patients, 761 (76.3%) were satisfied with their hospitalization and would definitely recommend the hospital to their family and friends. The proportion of RNs, who reported that adverse events occurred "regularly" on their unit (few times a month or more frequent) ranged from 5% (pressure ulcers) to 25.5% (urinary tract infections). These proportions were 16.2% for bloodstream infection, 16.0% for medication errors, 10.9% for pneumonia and 9.6% for patient falls. The majority of the RNs reported that these six types of adverse events occurred "irregularly, i.e. once a month or few times a year (Table 4).

Table 4: Nurse reported adverse events on their unit in the last year (*N*=1630)

Variables	"Inregularly"– n (%)			"Regularly"– n (%)			
	Never	A few times a year or less	Once a month or less	A few times a month	Once a week	A few times a week	Every day
Medication administration error	110 (6.8)	849 (52.8)	391 (24.3)	188 (11.7)	42 (2.6)	22 (1.4)	5 (0.3)
Pressure ulcer (stage 2 or higher)	298 (18.5)	991 (61.6)	240 (14.9)	66 (4.1)	8 (0.5)	5 (0.3)	2 (0.1)
Patient falls	127 (7.9)	910 (56.5)	421 (26.1)	130 (8.1)	14 (0.9)	8 (0.5)	2 (0.1)
Healthcare-associated infections							
Urinary Tract Infection	73 (4.6)	634 (39.6)	485 (30.3)	322 (20.1)	62 (3.9)	23 (1.4)	1 (0.1)
Bloodstream infection (catheter-related)	268 (16.8)	721 (45.2)	348 (21.8)	196 (12.3)	47 (2.9)	13 (0.8)	2 (0.1)
Pneumonia	178 (11.2)	844 (52.9)	399 (25.0)	136 (8.5)	23 (1.4)	11 (0.7)	4 (0.3)

6.4.4 Effect of PSC and organizational factors on patient outcomes

In none of our bivariate and multivariate regression models units' was PSC a significant predictor for any of the seven selected patient outcomes (Table 5). Also higher patient-to-RN ratios were not associated with patient outcomes. The most robust predictor in all models was implicit rationing of nursing care. In our full-adjusted models higher levels of rationing of nursing care were significantly related with higher frequency of nurse-reported adverse events and lower frequency of satisfied patients. Specifically, a one-point unit increase in rationing of nursing care scores was associated with a 72% increase in the odds of patients not or probably not recommending the hospital to family and friends, and up to more than doubled increase in the odds of RNs reporting medication errors, bloodstream infections and pneumonia occurring „regularly" over the past year (Table 5).

Before controlling for other major variables, the quality of the nurse practice environment was a significant predictor for nurse-reported pressure ulcer. However, after controlling for PSC, rationing of nursing care, patient-to-RN ratios and skill mix levels, higher quality of the nurse practice environment was no longer significantly related to better patient outcome (Table 5). Higher skill mix levels were significantly related with patient falls in the bivariate, but not in the multivariate models. However, we observed a significant relationship between skill mix levels and pneumonia in both bivariate and multivariate models. A one-point unit increase in units' skill mix levels was associated with a nearly 3% increase in the odds of RNs reporting pneumonia occurring "regularly" over the past year.

We observed a suppression effect in the patient satisfaction model for the quality of the nurse practice environment (see Table 5), when we entered rationing of nursing care in the multivariate (adjusted) models. In this specific case the quality of the nurse practice environment had no significant effect in the bivariate model, but became significantly associated with patient satisfaction in the (adjusted) multivariate model.

Table 5: Relationship between organizational variables and seven patient outcomes

Variables	Unadjusted (bivariate) models		Adjusted (multivariate) models*	
	Odds ratios (*P*-value)	95% CI	Odds ratio (*P*-value)	95% CI
Patient satisfaction				
Recommendation of the hospital (*N*=829) ^				
Patient safety climate	1.005 (0.982)	0.667-1.514	1.026 (0.923)	0.608-1.733
Rationing of Nursing Care	0.465 (0.017)	0.248-0.871	0.276 (0.005)	0.113-0.675
Quality of the nurse practice environment	0.759 (0.483)	0.350-1.642	0.234 (0.022)	0.068-0.812
Patient-to-RN ratio	0.939 (0.195)	0.854-1.032	0.896 (0.066)	0.797-1.007
Skill mix level	0.998 (0.834)	0.979-1.017	1.004 (0.691)	0.983-1.027
Nurse-reported adverse events				
Medication administration error (*N*=1,501) #				
Patient safety climate	0.860 (0.428)	0.592-1.249	0.963 (0.891)	0.564-1.644
Rationing of Nursing Care	2.012 (0.013)	1.158-3.505	2.513 (0.026)	1.118-5.653
Quality of the nurse practice environment	0.605 (0.150)	0.305-1.199	0.885 (0.838)	0.273-2.866
Patient-to-RN ratio	1.004 (0.936)	0.918-1.097	0.948 (0.320)	0.854-1.053
Skill mix level	1.007 (0.487)	0.987-1.026	0.995 (0.683)	0.973-1.018
Pressure ulcer (stage 2 or higher) (*N*=1,503) #				
Patient safety climate	0.641 (0.185)	0.332-1.238	1.491 (0.296)	0.705-3.154
Rationing of Nursing Care	7.394 (<0.001)	2.922-18.715	3.436 (0.052)	0.988-11.948
Quality of the nurse practice environment	0.132 (0.001)	0.039-0.452	0.203 (0.086)	0.033-1.252
Patient-to-RN ratio	0.938 (0.456)	0.793-1.109	0.852 (0.073)	0.716-1.015
Skill mix level	0.982 (0.265)	0.952-1.014	0.994 (0.700)	0.962-1.026
Patient falls (*N*=1,505) #				
Patient safety climate	0.890 (0.660)	0.531-1.494	0.880 (0.661)	0.498-1.557
Rationing of Nursing Care	3.846 (<0.001)	1.824-8.111	1.934 (0.138)	0.809-4.624
Quality of the nurse practice environment	0.518 (0.173)	0.201-1.335	1.781 (0.384)	0.486-6.524
Patient-to-RN ratio	1.119 (0.061)	0.995-1.259	1.107 (0.074)	0.990-1.238
Skill mix level	1.037 (0.005)	1.011-1.064	1.011 (0.343)	0.988-1.035

Table 5 continued				
Urinary Tract Infection (*N*=1,495) #				
Patient safety climate	0.874 (0.458)	0.614-1.246	0.921 (0.761)	0.541-1.567
Rationing of Nursing Care	1.431 (0.201)	0.827-2.476	1.270 (0.555)	0.574-2.813
Quality of the nurse practice environment	0.544 (0.060)	0.288-1.025	0.532 (0.290)	0.165-1.711
Patient-to-RN ratio	1.051 (0.251)	0.966-1.143	0.972 (0.587)	0.878-1.076
Skill mix level	1.010 (0.293)	0.992-1.028	1.014 (0.186)	0.993-1.036
Bloodstream infection (catheter-related) (*N*=1,489) #				
Patient safety climate	1.471 (0.107)	0.920-2.351	1.067 (0.816)	0.618-1.842
Rationing of Nursing Care	1.097 (0.808)	0.521-2.309	3.011 (0.004)	1.429-6.347
Quality of the nurse practice environment	1.641 (0.262)	0.690-3.907)	1.502 (0.492)	0.471-4.791
Patient-to-RN ratio	0.997 (0.947)	0.902-1.102	1.502 (0.525)	0.881-1.066
Skill mix level	1.018 (0.122)	0.995-1.040	1.003 (0.776)	0.982-1.024
Pneumonia (*N*=1,490) #				
Patient safety climate	0.976 (0.917)	0.624-1.528	1.091 (0.773)	0.603-1.975
Rationing of Nursing Care	2.996 (0.001)	1.533-5.858	2.672 (0.027	1.117-6.395
Quality of the nurse practice environment	0.469 (0.062)	0.212-1.038	0.533 (0.354)	0.141-2.015
Patient-to-RN ratio	1.039 (0.484)	0.934-1.154	0.956 (0.460)	0.850-1.077
Skill mix level	1.035 (0.003)	1.012-1.059	1.026 (0.033)	1.002-1.051

Multilevel (bivariate and multivariate) logistic regression analysis were performed with STATA 11.2 (maximum likelihood estimates using 8-point adaptive quadrature with "xtmelogit" command) with unit-level and hospital-level random effects, accounting for the hierarchical structure of the data (RNs nested within units within hospitals).

* Adjustments were made for socio-demographic characteristics of RNs (gender, age, employment level, professional experience), respectively patients (actual health status, educational level) and characteristitcs of the unit (medical, surgical, mixed medical-surgical) and hospitals (university, centre care and primary care hospitals) and language region (German-, French- and Italian-speaking).

^ Patient recommendation of the hospital (0=„probably or not" vs. 1=„definitely yes"); Variation from the total patient sample (*N* =997) is due to missing data.

Nurse reported adverse events (0="unregularly" vs. 1="regularly"); Variations from the total nurse sample (*N*=1,630) are due to missing data.

CI, confidence intervall, *N*, the number of registered nurses, respectively patients.

6.5 Discussion

To our knowledge, this is the first study to explore associations between PSC and selected patient outcomes and controlling for major organizational variables, patient, nurse, and hospital-related covariates, as well as using appropriate statistical methods to analyze the hierarchical data structure. Using data from a national representative Swiss hospital sample we failed to confirm our hypothesis, as variations in units' PSC levels were not significantly related with any of the seven patient outcomes studied.

Although the relationship between safety climate and improved patient safety and quality is increasingly emphasized by healthcare policy and regulators, evidence on this association is still limited [42]. Previous studies revealed that lower PSC levels were associated with overall higher rates of adverse events, such as AHRQ's Patient Safety Indicators [43, 45] or higher numbers of reported medication errors [44, 55]. However, the same number of studies found no statistical significant relationship [56-58].

One possible reason for our findings on PSC could be related to the one-dimensional conceptualization of our measure. The SOS reflects the level of engagement of RNs and their colleagues in safety behaviors, such as discussing errors and ways to learning from them, as well as how to avoid the risk of reoccurrence [44]. From a theoretical perspective, such safety behaviors represent the core of the interrelated triangle of an organization's structures, culture, and processes and are assumed to be directly related to safety outcomes [59]. However, recent research has shown that dimensions on unit and hospital aspects of PSC, such as organizational resources, support and recognition for safety efforts are less related with adverse events, than dimensions on interpersonal aspects such as fear of blame and shame [43]. Unfortunately, the SOS only partially covers such individual psychological features of a so-called "Just culture", which refers to an environment where individuals can question existing practices, express concerns, and admit mistakes without suffering punishment [60]. However, beside a general measure of PSC such as the SOS, future research studies investigating the relationship between PSC and patient outcomes have to include such psychological interpersonal dimensions as important determinants of patient safety and quality of care.

Although we included a representative national sample of Swiss acute-care hospitals, we investigated only RNs and patients from general medical, surgical and mixed medical-surgical units, which limits the generalizability of findings particularly to these settings. It is known from previous research that in more complex and dynamic settings, such as intensive care units, emergency departments or operating rooms patients, where patients might be at higher risk for adverse events, the PSC is perceived lower by healthcare professionals than those in other hospital wards [61]. Several studies investigated critical care units and revealed significant relationship between higher PSC levels and improved patient outcomes [62-64]. Therefore, we argue that PSC might be a more important determinant for patient safety and quality in more complex acute care settings than in general medical / surgical settings.

All outcomes in this study except patient satisfaction were assessed through nurse reports, which represent only a rough estimate of patient adverse events and might be subject to bias [61]. However, another study of the validation of nurse-reported patient falls against hospital records revealed significant concordance [65], suggesting that RNs are well-positioned to observe critical issues in terms of patient safety and quality. Such findings might justify the use of nurse-reported outcome data in research studies, if more valid and reliable data using established detection methods (e.g. Global Trigger Tool) is lacking [66, 67]. It is a limitation of our study that we were not able to validate the nurse reports on adverse events. Nevertheless, we tested the stability of our study findings with several sensitivity analyses, such as using other cut-off values for the dichotomization of the nurse-reported adverse events („once a week") and patient satisfaction („probably yes"), which led to similar regression results and identical patterns of conclusions. Additional studies are needed to confirm our results with more valid and reliable outcome data, such as patient outcomes from discharge data (e.g. 30-day patient mortality).

Most of the evidence on the association between PSC and patient outcomes used observational study designs [42-45]. Also the RN4CAST study, similar to previous nursing outcome studies, such as the Rationing of Nursing Care in Switzerland study [14, 15] and the International Hospital Outcomes Study [14-16] used a cross-sectional design, which does not allow deriving causal inferences in view of relationships between variables. Therefore, a critical step in future research on the PSC concept is to demonstrate the causal pathway from higher safety climate scores to improved clinical outcomes, as well as sustainability of high PSC levels and high levels of safety and quality over time. In addition, although we used a representative Swiss hospital sample, the number of Swiss hospitals and units was relatively small compared to other studies testing similar hypotheses [42, 43].. As some of these studies found only small to moderate effect sizes [45, 55], our study was probably underpowered to demonstrate similiar significant effects.

From our set of nurse-related organizational variables analyses revealed that implicit rationing of nursing care was the most consistent factor associated with four out of seven selected patient outcomes. These results confirm previous research findings that rationing of nursing care is a strong independent predictor of patient outcomes [14]. The consistent association of rationing of nursing care can be explained by the fact that within the care process the withholding of or failure to carry out specific nursing tasks occurs directly at the nurse-patient interface [15] and its proximity to the process of care, while other factors of the „work system“ are more distant. Thus, for the patient outcomes measured in this study and in general acute-care settings, rationing of nursing care might play a more important role than the engagement in general safety behaviors measured with the SOS. We demonstrated that even low levels of rationing of nursing care (between very rarely and rarely) are more likely to be associated with negative patient outcomes.

Higher nurse ratings of the quality of nurse work environment were not a statistically significant predictor in our models adjusting for PSC and other organizational variables. Sensitivity analyses, e.g. by categorizing the quality of the nurse work environment into favourable, mixed and unfavourable work environments [49] revealed similar results and identical patterns of conclusion. Prior research suggests that higher-quality practice environments in hospitals are associated with superior patient outcomes [18, 19, 68]. However, evidence is much more consistent in showing significant practice environment association on nurse outcomes, such as job satisfaction, intention-to-leave, and burnout [17, 69, 70] than on specific adverse events. While recent studies revealed that lower nurse staffing ratios are related to poorer patient outcomes [21, 22], in this study patient-to-RN ratios failed to predict any of the selected patient outcomes studied. Similar results on these three organizational factors have already been observed in the RICH Nursing study [14] and might indicate that in our RN4CAST data there was not enough variability or our measures on nurse staffing and skill mix levels (nurse responses) were not sufficiently refined to show significant effects.

Finally, referring to our conceptual model (Figure 1), work environment factors within work systems, such as the PSC, the quality of the nurse practice environment, patient-to-RN ratio and skill mix level represent structural components. Thus, low to moderate variability in structural components might not result in strong direct effects on patient outcomes. Rather, structural components within work systems might have indirect effects on patient outcomes by influencing components of the process of care, such as rationing of nursing care, which occur directly at the nurse-patient interface. The suppressor effect we observed in one of our regression models might indicate a mediating role of the rationing of nursing care. This assumption, which needs to be further investigated, would give an additional explanation for our non-significant findings on hospital units' PSC and the strong effect of rationing of nursing care on patient outcomes. To develop an in-depth understanding of hypothesized mechanisms (direct and indirect effects) and the mediating role of rationing of nursing care more sophisticated statistical methods, such as structural equation modeling, should be taken into consideration. For instance, a first step towards such understanding would be the identification of relevant antecedents of implicit rationing of nursing care.

Transferring this assumption to patient safety improvement efforts made to improve work environment factors, such as the PSC, might not necessarily and immediately results in direct improvements on patient outcomes. It is assumed that improving the PSC at the unit level might help to create a hospital safety culture by changing attitudes, values, norms, and beliefs towards patient safety. For instance, one recent study revealed that a teamwork and communication intervention within a one-year period resulted in safety cultural adjustments in hospital units [71]. But if and how PSC improvements impact patient outcomes or the process of care by enabling healthcare professionals, such as RNs, to make correct clinical decisions and to prioritize tasks to guarantee patient safety and quality of care needs further investigation in intervention studies.

6.6 Conclusions

To date, few studies have investigated the relationship of PSC with patient outcomes and its relationship with other organizational variables. Similar to previous studies our findings did not confirm the assumption that units with higher PSC levels might have improved patient outcomes. Measuring and monitoring the PSC in healthcare organizations allows hospital and nurse leaders to detect vulnerabilities and to implement and evaluate improvement interventions to strengthen the PSC. However, at the current stage of research on PSC the impact of the PSC improvements on patient outcomes in general medical / surgical acute-care settings should not overestimated. Results of our study might help to further develop theory in this area of outcomes research, suggesting that in a general medical / surgical setting PSC as a structural component of the work environment might rather influence the process of care (rationing of nursing care) and thus have only an indirect effect on patient outcomes. Additional studies are needed (1) to confirm our findings with more valid and

reliable outcome data, such as patient outcomes from discharge data (e.g. 30-day patient mortality) and (2) to test relationships between PSC and antecedents (e.g. organizational climate), mediators (e.g. rationing of nursing care), as well as with other established constructs and patient outcomes.

Hospital and nurse leaders in general acute-care setting should monitor the level of rationing of nursing care as on units with even small rationing levels, it's more likely that patients might experience a negative outcome. Thus, benchmarking within and between hospitals could help to identify units and hospitals at high-risk for the occurrence of adverse events. Such data would enable nursing administrators to use implicit rationing of nursing care as a „thermometer" concerning patient safety and quality of care and could help also to detect imbalances in the "work system", such as inadequate staffing or skill mix levels to meet patients' needs.

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CHAPTER 7

SYNTHESIS AND DISCUSSION

* Variables measured in the RN4CAST study

7. SYNTHESIS AND DISCUSSION

In this final chapter the results of the four studies of this dissertation are synthesized and key findings are discussed from a perspective that goes beyond the discussions of the individual manuscripts (**Chapter 3** to **6**). Furthermore, methodological strengths and limitations of the dissertation are described. The last sections of this chapter suggest implications for research and practice.

Our intentions to narrow the observed knowledge gaps concerning patient safety climate were achieved as follows. We translated and adapted one patient safety climate assessment instrument – the Safety Organizing Scale [1] – into German, French and Italian according to an accepted international cross-cultural translational model [2]. For each language version we carried out an expert rating and provided evidence based on content by calculating the content validity indices. The results suggested that both individual items and the overall scale reflect the underlying theoretical concept. Using the translated versions of the Safety Organizing Scale in the framework of the cross-sectional Swiss RN4CAST (Nurse Forecasting: Human Resources Planning in Nursing) study, we then surveyed registered nurses working on general medical, surgical and mixed medical/surgical care units across a nationally representative sample of 35 Swiss hospitals on their units' prevailing patient safety climates.

Using the RN4CAST nurse survey data, we conducted a series of three sub-studies. First, following American Educational Research Association guidelines, we tested the psychometric properties of the three translations of the Safety Organizing Scale [3]. For each translation, psychometric evaluation revealed evidence based on internal structure, response patterns and reliability, as well as initial evidence on relationships with other variables. Second, we carried out a sub-study with three purposes: (1) to describe nurse-reported engagement in safety behaviors, (2) to explore the prevailing nurse-reported patient safety climates of general medical, surgical and mixed medical-surgical units in Swiss acute-care hospitals, and (3) to explore differences correlating to hospital type, unit type and language region.

This study revealed a need to improve the patient safety climates of many units in Swiss hospitals. More precisely, patient safety behaviors such as proactive, preemptive analysis and discussions of possible unexpected events, capabilities to detect and learn from errors, and habits involving critical thinking about every-day work activities/processes should be reinforced. We also explored the association between patient safety climate and selected patient outcomes, adjusting for major nurse-related organizational variables. The results did not confirm our hypotheses: in none of our regression models was the unit patient safety climate a significant predictor of nurse-reported medication errors, pressure ulcers, patient falls, urinary tract infection, bloodstream infection, pneumonia, or patient satisfaction.

7.1 Discussion of key findings

7.1.1 Theoretical background, conceptualization and measurement of patient safety culture / climate

The selection of the Safety Organizing Scale to measure the patient safety climate was based on the following criteria: (1) strong psychometric properties, (2) feasibility in terms of translation and cross-cultural adaptation, (3) practicability, and (4) consideration of additional survey burden regarding integrating the instrument in the RN4CAST nurse questionnaire on nurse-related organizational factors such as nurse work environment, nurse staffing and educational level and nurse outcomes (e.g., job satisfaction, burnout). In light of the empirical findings described in **Chapter 6**, along with international evidence on the ambiguous relationship between safety climate and patient safety / quality [1, 4-9], critical reflections on theory will be necessary regarding conceptualization and measurement of patient safety culture and climate using the Safety Organizing Scale.

The concepts of "safety culture" and "safety climate" originate in high-risk industries [10, 11]. In fields such as nuclear power and aviation, studies have linked safety culture/climate to safety performance (e.g., participation and compliance regarding safety-enhancing behavior), as well as to incidences of occupational accidents and injuries [12]. Since the publication of the report *To Err is Human* in 1999 [13], interest in healthcare safety culture and climate has grown rapidly. Twelve years later, research on these concepts is in transition from childhood to adolescence. For several instruments, including the Safety Organizing Scale, construct validity has been established [1, 14, 15]. However, the components, causes and consequences of safety culture and climate, as well as the distinctions between culture and climate, still need much greater exploration [16].

One reason for the prevailing ambiguity and inconsistency regarding the components, causes and consequences of safety culture and climate lies in the background of the two concepts, as no strong theoretical and conceptual underpinning has yet been applied to either. None of the existing instruments used to measure patient safety climate are built upon healthcare safety culture theory, i.e., generated through qualitative research methods, such as grounded theory or case studies in healthcare organizations. Instead, researchers have most commonly followed social psychological or organizational psychological traditions and adapted existing quantitative instruments for healthcare. However, the theoretical bases of the original instruments were designed to explain relationships between safety culture/climate in settings far-removed from healthcare [16]. Examples include high-reliability theory [17], human factors framework [18] or human resource management [16]. Likewise, the most prominent questionnaires, the Agency for Healthcare Research and Quality (AHRQ)'s Hospital Survey on Patient Safety Culture [19] and the Safety Attitudes Questionnaire [15], were operationalized based on literature reviews, with item development guided by existing survey instruments from various industries. For the widely used Patient Safety Culture in Healthcare Organiza-

tions Survey (PSCHO), for example, no exact theoretical background is available [20], suggesting that the many healthcare researchers who have used it underestimate the importance of the epistemologies and theoretical roots underlying the development of their instruments [21].

The background of the Safety Organizing Scale lies in high-reliability theory [1]. Examining case studies in high-risk organizations, Weick and Sutcliffe [17] discovered five key principles of their cultures of safety: (1) preoccupation with failure, (2) reluctance to simplify or accept simple solutions, (3) sensitivity to "sharp end" operations, i.e., those involving immediate risks, (4) capability for resilience when a sudden or unexpected failure occurs, and (5) deference to expertise (rather than hierarchy or title), with the flexibility to access that expertise [22]. These principles of „collective mindfulness“ guided the conceptualization and development of the 9-item Safety Organizing Scale for healthcare organizations. In **Chapter 3** and **Chapter 4** we provided evidence based on content validity for the German-, French- and Italian-language versions of the SOS. Without strong theoretical underpinnings in the safety culture and climate of healthcare organizations, though, it remains unclear whether applying the principles of collective mindfulness to healthcare contexts will result in reliability improvements analogous to those in other industries. Given the scarcity of patient safety culture and climate theories in healthcare, then, it is possible that the experts who rated the content validity of the Safety Organizing Scale overestimated the importance of the safety behaviors in view of the underlying concept.

The lack of either a solid theoretical grounding or a conceptual framework continue to impede clear definitions of patient safety culture/climate. To date, some agreement exists between researchers that patient safety culture is part of an organizational culture, i.e., „ management and staff values, beliefs, and norms about what is important in a health care organization, how organization members are expected to behave, what attitudes and actions are appropriate and inappropriate, and what processes and procedures are rewarded and punished with regard to patient safety“ [14, p. 1]. Although this definition of safety culture builds upon Schein's definition of an organizational culture [23], it remains incomplete, as it mainly reflects only the 2nd layer of Schein's model (see Figure 1): "*Espoused beliefs and values*“ (i.e., observable and measurable attitudes and behaviors concerning safety). Two important layers concerning patient safety culture are omitted: "*artifacts*" (i.e., tangible components, such as architecture, physical surroundings or IT infrastructure) and "*underlying assumptions*“ (i.e., unconscious, determinants of safety attitudes and behaviors). According to some authors, "espoused beliefs and values" represent the patient safety climate, the observable "snapshot" of and proxy measure for the prevailing patient safety culture [10]. This incomplete conceptual definition of patient safety culture might also be one reason that the terms safety culture and safety climate are often used interchangeable and are difficult to distinguish. As the divisions between the three layers of Schein's organizational model are fluid, there are obviously areas of convergence between culture and climate, and the contrast may prove more apparent than real [24]. Nevertheless,

we support separating patient safety culture and climate based on Schein's organizational culture model and thus the levels measurements target. We also advocate refining definitions of patient safety culture to emphasize "*artifacts*" and "*underlying assumptions*" as strongly as "*espoused beliefs and values*". Considering underlying assumptions seems to be particularly important, since these are thought to explain safety attitudes and behaviors [23, 25].

Despite a lack of clear healthcare-based theory regarding safety culture and climate, some agreement exists between researchers that both concepts are multidimensional [26, 27]. As described in **Chapter 1**, the four most widely used questionnaires (SAQ, PSCHO, HSOPSC and Modified Stanford Patient Safety Culture Instrument, see Table 1, p. 22-23) all cover multiple dimensions and topics, with teamwork, psychological safety (fear of blame and shame), learning, or perception / support of management covered by all four. A recent qualitative meta-synthesis proposed a very broad multidimensional conceptualization of patient safety climate, identifying the following components: leadership, teamwork, evidence-based practice, communication, learning, "just" (i.e., trust, freedom from blame), and patient-centeredness [28]. Additional evidence will be necessary to determine whether all these features actually influence the patient safety climate or whether such a conceptualization represents a global perspective on organizational factors related to patient safety and quality of care. Based on the existing evidence, attitudes and behaviors related to "*organizational learning*", i.e., reporting, discussing and learning from errors, and "*psychological safety*", i.e., questioning existing practices, expressing concerns, and admitting mistakes without suffering punishment, are likely the two core components of a patient safety climate. In recent studies, published while this dissertation was underway, these features have been related to adverse events and patient outcomes, [5, 29]. Other dimensions, such as leadership, teamwork or communication, clearly represent important organizational factors, but might not reflect the patient safety climate per se. The 9-item Safety Organizing Scale reflects on mindful safety behaviors, such as discussing errors, ways to learn from them, and ways of reducing the risk of reoccurrence. Unfortunately, it only partially reflects on behaviors related to psychological safety (i.e., no fear of blame and shame) [1]. Although we provided initial evidence regarding the validity and reliability of the German-, French- and Italian-language versions of the one-dimensional Safety Organizing Scale (see **Chapter 4**), the SOS items might not capture "psychological safety" as fully as other instruments, e.g., the Safety Attitudes Questionnaire. Based on existing evidence, further quantitative research on patient safety climate should focus on attitudes and behaviors related to both "organizational learning" and "psychological safety", e.g., those covered by the safety climate subscale of the Safety Attitudes Questionnaire subscale [15].

7.1.2 Patient safety climate and the process of nursing care

Our findings raise theoretical questions on the underlying assumption of *how* the patient safety climate, e.g., the engagement of nurses in the safety behaviors measured by the Safety Organizing Scale,

protects patients from harm and contributes to safety and quality. To date, no comprehensive framework has explored (1) how a healthcare organization's patient safety climate is embedded in its practices and system structures, (2) how a patient safety climate emerges and through which mechanisms it can be modified, and (3) how a patient safety climate is related to clinical patient outcomes and quality of care [10].

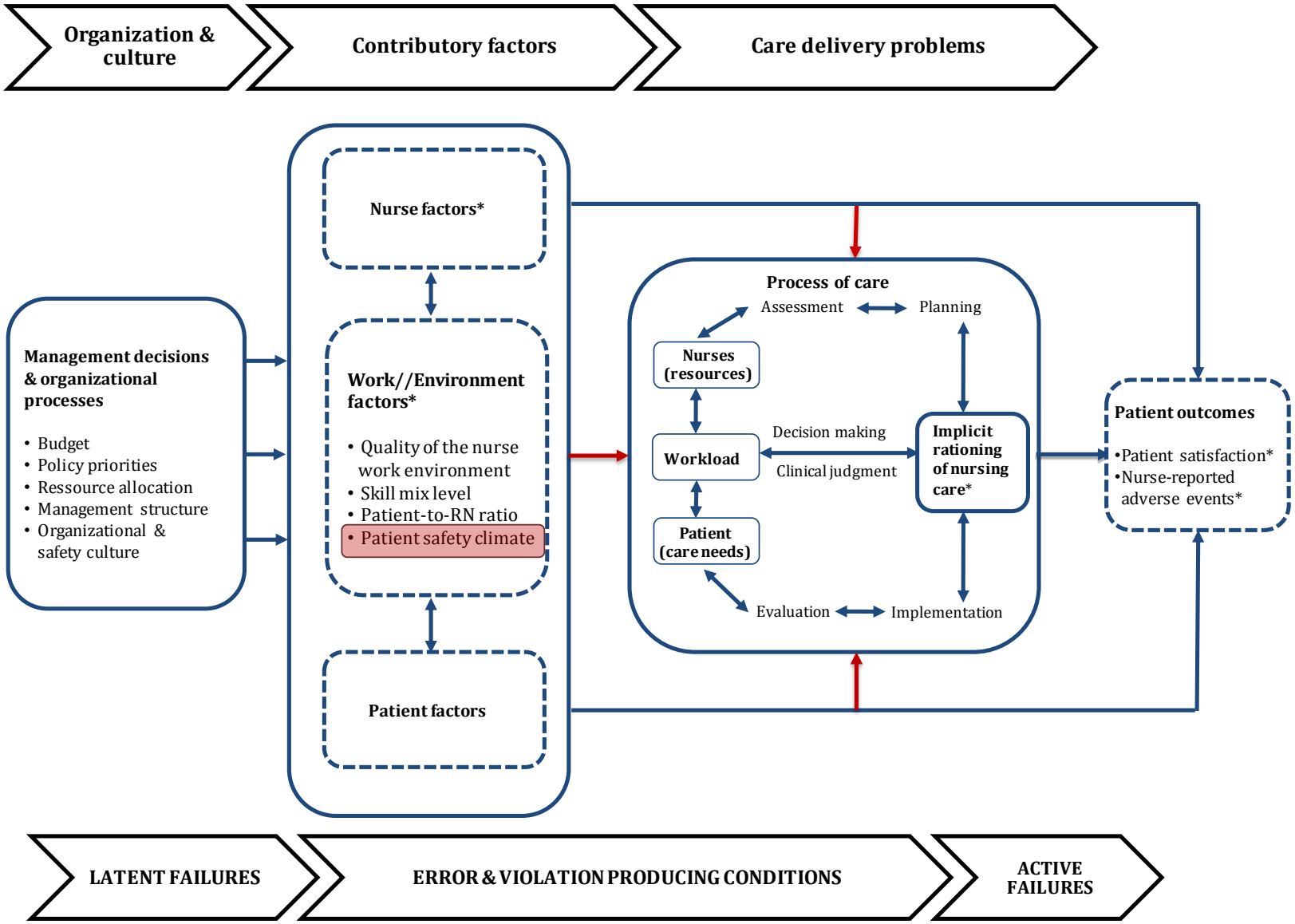
As described in **Chapter 1**, due to the current scarcity of safety culture theory and evidence, we used a framework of patient safety and quality of nursing care based on (1) Vincent's adapted Accident Causation Model (ACM) for healthcare organizations [30, 31], (2) the System Engineering Initiative for Patient Safety (SEIPS) model [32], and (3) the Rationing of Nursing Care in Switzerland (RICH) model [33, 34] (see Figure 3, p. 22). In our framework we acknowledged the potential relationships between patient safety climate, other nurse-related organizational factors, and patient safety and quality. We considered patient safety climate a structural feature in the work environment of hospital units, directly linked to patient safety and quality of care. While our results did not support our hypothesized direct relationship between patient safety climate and patient outcomes, our final study (Chapter 6) confirmed previous results on the importance of implicit rationing of nursing care [33]. This system factor appears to very close to the interface between patients and nursing care; our results confirm its proximity to patient outcomes.

The RICH model [34], one of the underlying models for the framework of this dissertation, describes the process of care more comprehensively than any other patient safety or quality of care model [30, 32, 35]. In nursing, the care process includes the assessment, planning, implementation and evaluation of nursing measures to achieve desired patient outcomes [36]. The number and priority of nursing tasks provided are based on the nurses' assessment of patients' care needs, desired outcomes, the effectiveness of the care delivered during the nursing process, empirical evidence, professional expertise and patient preferences [37]. However, when the workload is too high and nursing resources too scarce (e.g., inadequate staffing / skill mix levels) to provide all patients with all care judged necessary to reach all desired outcomes or protect the patients from adverse events, nurses have to set priorities. Where a gap exists between planned and deliverable nursing measures, implicit rationing of nursing care reflects this process of clinical judgment and decision making [34, 37].

For an image of patient safety climates, we used the Safety Organizing Scale to assess general safety attitudes and behaviors thought to be important in protecting patients from harm. For example, reporting, discussing and learning from errors are considered important behaviors to improve system functioning and patient safety [38-40]. However, such practices offer only a limited reflection of specific safety behaviors in the process of nursing care and generally occur away from direct patient contact. Patient safety behaviors such as nurses' adherence to hand hygiene guidelines might play a more important role for clinical patient outcomes, as they happen at the nurse-to-patient interface. Therefore, it

may be that the patient safety climate has a more indirect mediating effect on patient outcomes, by influencing nurses' behaviors in the process of care and thus, e.g., how they set priorities about the care to be delivered, their clinical judgment and decision making or how strictly they comply with evidence-based practice guidelines. Based on this theoretical proposition, on units with higher patient safety climate ratings, nurses might be expected to place higher than average priority on protective measures such as surveillance (e.g., monitoring of patients), prevention (e.g., adequate hand hygiene) and prophylaxis (e.g., mobilization, changing a patient's position), i.e., implicit rationing levels for these nursing tasks would be significantly less likely than average. Such an assumption requires further exploration, and could improve our knowledge on how nurse-reported patient safety climates influence nurse-sensitive outcomes, including adverse events. To test this proposition, our patient safety and quality of care framework needs to be adapted. We propose that patient safety climate has a direct influence on care-related processes, including implicit rationing of nursing care, but only an indirect effect on nurse-sensitive patient outcomes (see Figure 4).

Figure 4: **Adapted patient safety and quality of nursing care model**



* Variables measured in the RN4CAST study

7.1.3 Patient safety climate and quality improvement

As in other high-risk organizations, effective healthcare safety management demands attention to human factors, i.e., healthcare professionals' work environments and working conditions [41]. By focusing on human factors that influence reliability, healthcare organizations can identify and capture potential errors before they precipitate adverse events [42]. As described above, numerous theoretical and conceptual lessons remain to be learned about safety culture and climate in healthcare. Nevertheless, international experts and agencies, including the Agency for Healthcare Research and Quality (AHRQ) [43], increasingly emphasize the use of culture surveys and patient safety climate questionnaires [18, 31] as a promising approach to gain insights into the safety of healthcare environments. Although evidence is still limited, within the patient safety and quality improvement movement, monitoring and taking steps to improve the safety culture is increasingly treated as "good practice".

In **Chapter 5** we described the findings of our descriptive-explorative sub-study on nurse-reported patient safety climates in Swiss acute-care hospitals. The relevant data were collected using the Safety Organizing Scale. This revealed that 3 safety behaviors considered important in high-risk organizations [17] were reported by nurses as less "implicit" in their daily practice than others: detecting and learning from errors; critical thinking about normal, everyday work activities/processes; and proactive and pre-emptive analysis and discussions of possible unexpected events. As our findings showed no direct association between the nurse-reported patient safety climate and patient outcomes (reported in **Chapter 6)**, additional research is needed to understand whether / how these behaviors are related to patient outcomes before recommending interventions focused on improving them. These behaviors may have an important indirect impact on care-related processes, e.g., decisions regarding the rationing of nursing care. Such potential relationships need to be explored in future studies. One additional theoretical proposition, based on organizational learning theory [44, 45], is that reinforcing safety behaviors might improve nurses' awareness and acceptance of patient safety and quality issues, thereby contributing to patient safety and quality at an organizational level.

Following the publication of *To Err is Human*, healthcare organizations sought to emulate high-reliability organizations in industries such as aviation or nuclear power [46]. Many implemented safety strategies and quality improvement tools to enhance their capabilities regarding „organisational learning" [45]. Unfortunately, most of these were based on anecdotal evidence, with no theoretical or scientific evidence to support them. The basic premise of organizational learning is that employees are encouraged to "…continually expand their capacity to create the results they truly desire, where new and expansive patterns of thinking are nurtured, where collective aspiration is set free, and where people are continually learning to see the whole together" [44, p. 3]. For example, over the last decade, many healthcare organizations in European countries, including Switzerland, have implemented Critical Incident Reporting Systems (CIRS) to enhance organizational learning [47] and increase hospitals' resilience [1, 17, 48]. Risks

and errors reported to CIRS offer learning opportunities that strengthen organizational structures and processes in order to improve safety performance of clinicians and other healthcare workers [49-52]. Unfortunately, these anonymous reporting systems often suffer from underreporting by nurses and other healthcare professionals [53-55], raising questions as to how much this well-meant system can realistically contribute to organizational learning and thus to patient safety and quality.

While healthcare organizations have often addressed technical issues related to CIRS implementation, they have often neglected adaptive work. One important issue to consider before implementing patient safety and quality improvement strategies involves adaptations and changes in healthcare teams [56-58]. According to the PARiHS framework (Promoting Action on Research Implementation in Health Services), for example, successful implementation (SI) depends on the interrelations between three key elements: evidence (E), context (C) and facilitation (F) [SI = f (E, C, F)] [59]. Thus, providing healthcare professionals, including nurses, with capabilities and skills in detecting, reporting, analyzing and learning from errors might be an important facilitating factor regarding improved error reporting, which has to be considered for hospital-level system changes such as the implementation of CIRS [56-58]. The learning skills of individual healthcare professionals and teams can be strengthened trough team-based learning activities addressing *reactive learning*, e.g., learning from defects [60] and system analysis of clinical incidents [61], as well as *proactive learning*, e.g., Leadership Walk-Rounds [62] or Healthcare Failure Mode and Effect Analysis (HFMEA™) [63]. Apart from providing a blame-free environment, reducing reporter burden and closing communication gaps [53], proactive and reactive learning activities at unit level could increase safety awareness of individual nurses and teams, as well as the willingness of individuals and teams to share errors and risks on an organizational level, and, in turn, to contribute to organization-wide learning through CIRS.

7.2 Strengths and limitations of methods

Using cross-sectional nurse and patient survey data from Switzerland, this dissertation was imbedded in the multicentre Swiss arm of the international RN4CAST study – the largest nursing outcome study conducted to date. Overall, integration in a parent study offered several notable advantages in terms of project management, effective use of personal and financial resources, and the development of leadership and advanced research skills. However, despite these personal advantages, the methodological strengths and limitations of such a dissertation project depend on the methods used in the parent study. Therefore, the strengths and limitations of this dissertation project have to be viewed in light of its relationship to the RN4CAST study [64].

RN4CAST used a cross-sectional study design and observational research methods. Using such a study design provides only a "snapshot" of the organizational behavior at a particular point in time. Therefore, as it records no chronological relationships, no cause and effect relationships can be confirmed [65]. Although the development of this dissertation's aims and hypotheses were guided by a conceptual framework, the results of correlation and regression analyses, such as the relationships between patient safety climate and other nurse-related organizational variables or patient outcomes, do not allow causal interpretation.

Adding to the record of well-performed nursing outcome studies in Switzerland, such as the Rationing of Nursing Care in Switzerland study [33, 34, 66], the RN4CAST study collected data on important nurse-related organizational factors relating to patient safety from a nationwide Swiss hospital sample. The sampling method of the Swiss RN4CAST study was a multi-stage approach, using a combination of quota sampling (acute-care hospitals) and randomized sampling (medical, surgical and mixed medical / surgical units) procedures. Our quota sample of acute-care hospitals included 35 hospitals from all three of Switzerland's language regions (German-, French- and Italian-speaking) and all hospital types (University, Cantonal, and Regional), allowing us to compare findings on a national level. However, based on the international RN4CAST study protocol, in order to achieve a sample size of at least 50 RNs per hospital, we only included units from acute-care hospitals with 60 or more beds [64]. Due to these inclusion criteria, regional hospitals were underrepresented in relation to their portion the total hospital population, which increases the risk for a selection bias. We did not use randomized sampling techniques in all stages of our sampling process, although stratified random sampling techniques for the selection of hospitals might have been more appropriate for our purposes. In addition, external validity is restricted to general medical, surgical and mixed medical-surgical units in Swiss acute care hospitals. Although, these units represent the largest proportion of units in acute-care facilities [67], study findings cannot be transferred to intensive care units, emergency departments, operation rooms, long-term care facilities or primary care settings.

The large overall sample size of nurses (N=1,633) and patients (N=997) was a strength, as it ensured statistical power, i.e., a strong chance of detecting a statistically significant results [65]. The overall high response rates for nurses and patients (72% and 69% respectively) provided us with robust datasets on important nurse-related organizational features, including patient safety climate. High response rates avoid nonresponse bias and ensure accuracy of survey data [65]; at the level of interest, e.g., the unit or hospital level, response rates of at least 60% are necessary to be considered a representative sample [68], which is necessary to justify aggregation of individual responses at the organizational level [69]. Although response rates were not above 60% for all hospital units, we received at least five responses for every unit, which ensured variability within units. Within the framework of the RN4CAST study we only investigated

nurses. If we consider the patient safety climate as the shared perceptions and behaviors of all healthcare professionals, nurse reports alone do not provide a full picture of patient safety climate.

Finally, to test for relationships between patient safety climate and adverse event incidents, we used nurse reports on adverse events (medication errors, patient falls, pressure ulcers, bloodstream infection, urinary tract infection and pneumonia) as outcome indicators. As nurses were asked to report how often they had observed adverse events over the last year, difficulties in recalling past events might have contributed to bias, affecting the reliability and validity of our outcome measures. When the dissertation project was planned, we considered requesting data from SwissNOSO, a major Swiss organization registering infection rates on three nurse-sensitive healthcare-associated infections (bloodstream infection, urinary tract infection and pneumonia). However, in the planning phase we learned that such data had only been collected on a national level between 1996 and 2004 [70]. In addition, no national data registries exist in Switzerland for our other nurse-sensitive adverse events (medication errors, patient falls and pressure ulcers). Prior to beginning data collection, we surveyed nursing directors from our 35-hospital sample to determine whether comparable data on our selected outcome variables were available at the hospital level. A small number responded that their hospitals had data available on our outcomes of interest. For example, for healthcare-associated infections, data collected according to SwissNOSO's guidelines was only available for nine of the 35 participating hospitals. As previous studies, including the International Hospital Outcome Study [35, 71] and the Rationing of Nursing Care in Switzerland Study [33, 34, 66], had used nurse reports on adverse events, for this dissertation project this data source was considered appropriate to form preliminary insights on possible relationships with patient safety climates. In addition, results from a study validating nurse-reported patient falls against hospital records revealed significant concordance regarding one-year reports [72] which supported our strategy. Nevertheless, nurse reports represent only a rough estimate of patient adverse events. It is a major limitation of this dissertation project that we were not able to validate the nurse reports.

7.3 Implications for future research

Although this dissertation project is completed, further analyses using the collected data are necessary to deepen our knowledge of the relationships between nurse-reported patient safety climate, major organizational variables, and patient safety and quality. The results of these analyses will provide important insights in view of planning subsequent studies.

The associations between patient safety climate and major organizational variables in Swiss acute-care hospitals should be re-tested using risk-adjustment models and more reliable outcome measures, preferably patient discharge data from the Swiss Federal Statistic Office, including 30-day

mortality, failure-to-rescue and readmission rates. Such analyses would add to evidence on the validity of the translated Safety Organizing Scale by providing stronger evidence based on relationships with other variables (concurrent validity). Second, we need to expand our knowledge both of how patient safety climate is related to other system factors such as implicit rationing of nursing care, and of how these factors affect patient safety and quality. To date, studies on patient safety climate or other organizational variables have sometimes looked too narrowly at their relationship with patient outcomes. Most, including this dissertation project, have thus far tested only for direct associations, most commonly using regression analyses [1, 5, 7-9]. Testing relationships between patient safety climate and other well-established constructs, such as antecedents (e.g., organizational climate), moderators and mediators [73], will push the science forward. As an example, the conceptual model of this study might provide guidance for testing indirect effects between structural-related factors, e.g., patient safety climate, process-related factors, e.g., implicit rationing of nursing care, and patient outcomes. Testing indirect effects would require more sophisticated analyses, such as Structural Equation Modeling [74].

Regarding our translated German-, French- and Italian-language versions of the Safety Organizing Scale, it will be important to evaluate the importance of the five principles of „collective mindfulness“ for Swiss healthcare organizations in greater depth using qualitative methods, such as interviews and focus groups with patient safety experts and front-line healthcare professionals. To date, no studies have been conducted on patient safety culture using an ethnographic methodological approach [21]. Since cultural anthropologists specialize in cultural variations, it might also be worthwhile to involve one or more to obtain an “emic” (insider) perspective, e.g., on the cross-cultural meaning of patient safety culture and “collective mindfulness” in Swiss hospital settings. In addition, mixed method studies could be used to identify “positive deviants”, i.e., hospitals and units that received high patient safety climate ratings on the Safety Organizing Scale (quantitative study part). Once identified, interviews with hospital and nurse leaders (qualitative study part) from those hospitals/units could help to identify management and leadership activities that promote the development of a culture of safety. In addition, it might be interesting to understand how an organization’s basic assumptions are related to the attitudes and behaviors of its employees.

Taking an international perspective, much stronger safety culture and climate theory is needed to improve our understanding of the nature of these two concepts in the healthcare setting and to develop an integrative framework on how safety culture, patient safety and quality of care are related. Qualitative studies are needed to bring new insights to this research topic and to develop stronger theoretical bases for the concepts of both safety culture and safety climate in healthcare. Although disagreement remains as to the definition of patient safety culture and whether it is a multidimensional construct [28], its causes, components (e.g., conceptual definition and operationalization) and consequences, as well as the distinction between safety culture and climate, have all been adequately

explored [10]. Expert consensus, using international expert panels, could be an approach to discuss such issues and to develop common understandings on key issues relevant to these concepts. However, defining culture is known to be tricky: creating a widely accepted definition will be challenging for safety culture researchers. It might is questionable as to whether disambiguating the "fuzzy" concept of safety culture will be possible [10]. However, a critical step in the research on patient safety climate will be to provide compelling evidence of the relationship between patient safety climate and patient outcomes, including evidence of the predictive validity of patient safety climate instruments. Such evidence is required to justify efforts to monitor patient safety climate as a "safety performance indicator" within healthcare organizations. The coming years will likely reveal whether the development of patient safety climate measurement has been a landmark or just another stop on an ongoing journey toward high reliability healthcare organization [75].

Although the numbers of safety and quality improvement activities in healthcare have grown, limited empirical evidence exists regarding their effects on patient safety and quality [68]. Examples of such activities include team-based learning activities addressing *reactive learning*, e.g., learning from defects [60], system analysis of clinical incidents [61] and *proactive learning*, e.g., Leadership Walk-Rounds [62], and Healthcare Failure Mode and Effect Analysis (HFMEA™) [63], all of which growing numbers healthcare organizations are implementing. Cluster-randomized controlled studies could be a way to test the effectiveness of such learning-based interventions on healthcare professionals' safety awareness, organizational and professional commitment, the process of care (e.g., implicit rationing of nursing care, compliance with best practice guidelines) and patient outcomes under rigorous conditions. Another methodological approach, strongly emphasized by the Institute of Medicine, is to employ comparative-effectiveness studies, i.e., primary research studies comparing the outcomes of one intervention to those of another or others [76]. This study design would allow researchers to compare the effects of two or more interventions [40, 77], such as Leadership WalkRounds and learning from defects, on patient safety improvements. However, it will be a key factor to develop any safety and quality interventions, e.g., enhancement of organizational learning, on solid theoretical frameworks, such as organizational learning and organizational behavior theory.

Finally, patient safety research is an applied science: a balance is necessary between research and quality improvement [68]. Less rigorous quality improvement studies are valuable as they apply research to practice and employ a less top-down approach, adapting, changing and building team capacities and resilience at the micro level [68]. Therefore, evidence-based interventions, such as the comprehensive unit-based safety programme [77], aimed at improving patient safety climate, could be tested in cross-cultural settings under non-experimental conditions. Such quality improvement strategies would allow to us to explore how and under which conditions such improvement interventions work in specific healthcare and organizational contexts. Using plan-do-study-act (PDSA) cycles,

for example, could be a fruitful strategy to combine quality improvements and research. Healthcare organizations would benefit strongly from the use of bottom-up research methods, combining adaptive strategies (culture change) with technical work (scientific evaluation) [68, 78].

7.4 Implications for practice

Increasing public awareness of safety problems (e.g., adverse events reported in social media) and new reimbursement systems for healthcare services (e.g., SwissDRGs in Switzerland) are currently subjecting hospitals to even more pressure to assure that patients are protected from harm due to treatment and care. Creating a "culture of safety" demands a broad range of activities, such as changing and strengthening existing safety behaviors while implementing evidence-based methods and tools [75] on both unit and hospital levels [68, 77]. Although methods and tools will help, it is human factors that define a safety culture: leadership, communication, teamwork, and staff empowerment [22], focusing on group orientation [79] and reducing hierarchy [79, 80]. Senior leadership accountability is a key factor for supporting an organization-wide safety culture. Engaged hospital and unit leaders can drive cultural improvements by designing strategies and building structures that guide safety processes and outcomes [28, 81].

On the path to high reliability, hospital leaders need to develop and implement comprehensive and systematic frameworks that guide patient safety measurement and evaluation of improvements [68, 77]. Such frameworks require a measurement approach that balances (1) evaluating progress in clinical patient outcomes, (2) translating evidence into practice, (3) measuring and improving culture, (4) identifying and mitigating hazards, and (5) evaluating the association between organizational characteristics and outcomes [68, 75, 82]. Although the complex phenomena of "safety culture" have not yet been sufficiently explored [83], measuring and improving culture is strongly emphasized by many governmental bodies and agencies, including the Agency for Healthcare Research and Quality (AHRQ) [43], and has already become part of safety and quality management in healthcare organizations. Based on the existing literature, the use of multi-dimensional instruments, e.g., the Agency for Healthcare Research and Quality (AHRQ)'s Hospital Survey on Patient Safety Culture [19] and the Safety Attitudes Questionnaire [15], might be preferable. Compared to our measurement instrument, the Safety Organizing Scale, these tools provide more comprehensive insights regarding patient safety and quality of care topics, including "organizational learning" and "psychological safety" in healthcare environments. However, measuring and improving safety culture can never replace the measurement and monitoring of clinical patient outcomes, e.g., risk-adjusted mortality rates or central line–associated bloodstream infections.

The decision of hospital leaders to survey employees, including nurses, on their organizations' patient safety climates can be considered a patient safety intervention [77]. Through such sur-

veys, hospital leaders demonstrate that patient safety and quality of care are high priorities, and that they are willing to learn proactively from the insights and perspectives of their staff. This offers an opportunity to align employees' views on patient safety issues, leading to increased safety awareness, organizational commitment [84] and maturity throughout the organization [85, 86]. Hospital-wide measurements and regular monitoring allow benchmarking between units and longitudinal comparisons. Such data can provide information to aid the hospital management in terms of strategic planning and decision-making. However, while comprehensive measurement of patient safety climate is important, it is not sufficient for quality improvement. In order to increase patient safety awareness and exploit learning opportunities, hospital units and teams need constant feedback on their performance. To build and develop systems focussed on care quality and patient safety hospitals will first have to engage healthcare professionals, including nurses, in deciding that change is necessary, then empower teams to identify adapt the relevant processes and behaviors [87].

In terms of patient safety and quality, the "music is playing at the micro-level" i.e., on hospital units [88, 89], i.e., activities for sustaining improvements in view of patient safety and quality, as well as cultural improvements, need to be tailored to the unit level [90]. Evidence clearly indicates that because nurses work at the interface of patients and healthcare, acting as a human surveillance system [71], they also play a major role in protecting patients from harm [91, 92]. It is likely that the abilities to detect and learn from errors, to proactively and preemptively analyze and discuss possible unexpected events, and to think critically about normal, everyday work activities/processes have significant influences on the care-related processes (e.g., implicit rationing of nursing care), and are therefore important goals for high-reliability healthcare organizations [17]. According to organizational learning theory [44], strengthening reactive and proactive learning of nurses should also improve their awareness of patient safety and quality [93], their system-oriented thinking, and their motivation to develop and use evidence-based practice [94]. Although our results demonstrate no direct link between nurse-reported patient safety climate levels and patient outcomes, hospitals should consider the implementation of learning-based activities, such as learning from system defects [60], system analysis of clinical incidents [61], Leadership Walk-Rounds [62] and Healthcare Failure Mode and Effect Analysis (HFMEA™) [63] to enhance organizational learning.

In their report in 2010 titled *The Future of Nursing,* the Institute of Medicine strongly emphasized the possibility that involving nurses as full partners in healthcare delivery would improve patient safety and quality [95]. Within interdisciplinary teams assembled for this purpose, nurses could perform leadership roles by devising and implementing quality improvement projects, tracking improvement, and making necessary adjustments to realize established goals. In comprehensive, unit-based patient safety programs [40, 77] nurses already play key roles, functioning as „safety champions" on their units, working as patient safety office staff, trained to debrief interdisciplinary teams, or

guiding learning-based activities to discuss patient safety and quality improvement strategies. However, to become fully engaged partners in the field of patient safety and quality, nurses require high-level preparation (e.g., at the Master's level or through continuous education), as well as in-depth skills in leadership, communication and teamwork, project and change management, translational and action research [96-98].

7.5 Conclusions

Although modern healthcare has delivered inestimable benefits to humanity, it has not yet achieved the same reliability as other high-risk industries such as nuclear power or aviation. Adverse events, such as medication errors, patient falls, pressure ulcers and healthcare-associated infections due to medical treatment and nursing care, commonly cause harm to patients. As in other high-risk organizations, developing a safety culture in healthcare requires a systemic and proactive approach to overcoming defects in its structures, processes and outcomes. Surveying healthcare professionals on observable and measurable safety attitudes and behaviors that reflect their patient safety climate can help to identify problematic system conditions in terms of human factors related to patient safety and quality of care. To the existing literature on the subject, this dissertation adds the first evidence on the validity and reliability of the German, French and Italian versions of the Safety Organizing Scale, a patient safety climate measure. Our results did not confirm the underlying theoretical assumption that higher safety climate levels are related to improved patient safety and quality. Although our findings suggest the need to improve the patient safety climates of many general medical, surgical and mixed medical/surgical units in Swiss hospitals, it remains unclear whether improving nurses' engagement in safety behaviors will result in improvement of patient safety outcomes (e.g., reduced incidence of adverse events). In contributing to the further development of safety culture and climate theory, this dissertation raises methodological issues that will need to be considered for future studies.

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2010-: The International Society for Quality in Health Care (iSQua)

FUNDED RESEARCH

Schwendimann, R., Zuniga, F., Jaccard, H., Widmer, M., Schubert, M., **Ausserhofer, D.**, Desmedt, M., Engberg, S., De Geest S. Swiss Nursing Homes Human Resources Planning (SHURP), Main study. Grant: 100,000 CHF, Stiftung Pflegewissenschaft Schweiz (Nursing Science Foundation Switzerland), Basel, Switzerland. Role: Co-Investigator. Time period: September 2011 – August 2013.

Schwendimann, R., Schubert, M., **Ausserhofer, D.**, Desmedt, M., De Geest S. *RN4CAST (Nurse Forecasting: Human Resource Planning in Nursing), Swiss study arm*. Federal Office of Public Health, Switzerland. Direct costs: 80,000 CHF. Role: Co-Investigator. Time period: 2009–2011.

Zuniga F, Jaccard H, Widmer M, Schubert M, **Ausserhofer D**, Desmedt M, De Geest S, Schwendimann R. *Swiss Nursing Homes Human Ressources Planning - SHURP*. Bundesamt für Statistik (BFS). Direct costs: 50,000 CHF Role: Consultant. Time period: 2010-2011.

PUBLICATIONS

PEER REVIEWED JOURNALS

2012 **Ausserhofer, D.**, Schubert, M., Engberg, S., Blegen, M., De Geest, S., Schwendimann, R. Nurse-reported patient safety climate in Swiss acute care hospitals – A descriptive-explorative substudy of the RN4CAST study. *Swiss Medical Weekly, 142*, 0. doi: 10.4414/smw.2012.13501.

2010 **Mantovan**, F., **Ausserhofer, D.**, Huber, M., Innerhofer, E., Götsch, I., Ploner, E., Them, C. (2010): Care management for informal caregivers – A pilot study to improve caregiver's burden. *Pflegewissenschaft 10*(07): 1-8.

2009 Mantovan, F., **Ausserhofer, D.**, Schulc, E., Them, C. (2009): Interventions and their effects on informal caregivers of people with dementia: a systematic literature review. *Pflege 23*(4): 223-239.

Mantovan, F., **Ausserhofer, D.**, Baumgartner, V. (2009): An explorative study on the handling of preoperative soberness in Italian and Austrian hospitals. *Pflegewissenschaft 10*(1): 29-33.

Ausserhofer, D., Mantovan, F., Them, C., Innerhofer, E., Götsch, I., Ploner, E. (2009): Informal caregivers of elderly people in South Tyrol. *Pflegezeitschrift 62*(11): p. 678-682.

Ausserhofer, D., Mantovan, F., Pirhofer, R., Huber, M., Them, C. (2009): The burden of parents caring for their children and adolescents with severe disabilities in South Tyrol. *Pflege 22*: 184-192.

2008 **Ausserhofer, D.**, Fritz, E., Them, C. (2008): *Care of Non-tunneled Central Venous* Catheters: – Literature search on Disinfectants, Dressing and Intervals between Dressing changes*. Pflegezeitschrift 61*(8): 457-463.

OTHER JOURNALS

2010 **Ausserhofer, D.**, Schubert, M., & Schwendimann, R. (2010). [Risk lies in failing systems]. *Krankenpflege. Soins Infirmiers, 103*(9), 34-35.

PRESENTATIONS

INTERNATIONAL

2011 **Ausserhofer, D.**, Schubert, M., Blegen, M., De Geest, S., & Schwendimann, R. (2011, November 29-30). *Patient safety climate and healthcare-associated infections.* Oral presentation at the international congress „patient safety – avanti!" of the patient safety foundation, Basel, Switzerland.

Ausserhofer, D., **Schubert, M.**, Blegen, M., **De Geest, S.**, & **Schwendimann, R.** (2011, November 29-30). *Patient safety climate and healthcare-associated infections.* Poster presentation at the international congress of the Swiss patient safety foundation „patient safety – avanti!" , Basel, Switzerland.

Ausserhofer, D., **Schubert, M.**, **Engberg, S.**, Blegen, M., **De Geest, S.**, & **Schwendimann, R.** (2011, November 29-30). *Nurse reported patient safety climate in Swiss hospitals.* Poster presentation at the international congress of the Swiss patient safety foundation „patient safety – avanti!", Basel, Switzerland.

NATIONAL

2010 **Ausserhofer D., &** Swiss RN4CAST Team. (2010, October 22). *RN4CAST Switzerland – First results of the nationwide nurse survey.* Oral presentation at the annual conference of the Swiss Nurse Directors Association (SVPL), Bern, Switzerland.

REGIONAL

2011 **Ausserhofer, D.**, & Swiss RN4CAST Team. (2011, March 24). RN4CAST (Nurse Forecasting: Human Resources Planning in Nursing) – Erste Ergebnisse der landesweiten Befragung von Pflegefachpersonen. Oral presentation at the Meeting of the Nurse Directors of the Canton Graubünden, Jenaz, Switzerland.

2010 **Ausserhofer, D.** (2010, November 9). *Strategien zu Prävention nosokomialer Infektionen*. Oral presentation at Kolloquium INS-Universitätsspital Basel, Basel, Switzerland.

Ausserhofer, D. (2010, April 30). *Patient safety and quality: Is it worthwile to invest in nursing care?* Congress of the nursing management in the hospitals of Sanitas and Zimmerberg, Horgen, Switzerland.

TEACHING ACTIVITIES

2012	Patient safety and quality of care course. Lectures for Master students of the Institute of Nursing Science, University of Basel, Switzerland
2012	Research methods II course. Lectures for Bachelor students of the Institute of Nursing Science, University of Basel, Switzerland
2010 – 2011	Research methods I course. Lectures for Bachelor students of the Institute of Nursing Science, University of Basel, Switzerland
2009 – 2011	Scientific writing course. Lectures for Bachelor students of the Institute of Nursing Science, University of Basel, Switzerland